Wheat Flour Fortification: Current Knowledge And Practical Applications

SUMMARY REPORT

Cuernavaca, Mexico
1-3 December, 2004

Photograph by Alejandro Chicheri courtesy of WFP
Wheat Flour Fortification:
Current Knowledge and Practical Applications

December 1-3, 2004
Cuernavaca, Mexico

SUMMARY REPORT OF AN INTERNATIONAL TECHNICAL WORKSHOP

Flour Fortification Initiative
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Annex 1: Workshop Agenda

Annex 2: Workshop Participant List
ACKNOWLEDGEMENTS

The following people advised and assisted in the development of the workshop: Jack Bagriansky (Consultant), Robert Baldwin (CDC), Erick Boy (MI), Gary Brittenham (Columbia University), Hector Cori (DSM), Omar Dary (MOST), Wilma Freire (PAHO), Gary Gleason (INF), Jessica Gleason (INF), Jeff Gwirtz (IAOM), Eva Hertrampf (INTA, Chile), Roby Hill (FFI), Christopher Howson, (MOD), Richard Hurrell (Swiss Federal Institute of Technology), Quentin Johnson (MI), Vinod Kapoor (Kapoor Mills), Sean Lynch (Eastern Virginia Medical School), Glen Maberly (FFI), Nune Mangasaryan (UNICEF), Venkatesh Mannar (MI), Joe Mulinare (CDC), Ibrahim Parvanta (CDC), Peter Ranum (MI), Katie Tripp (CDC), Rick Trowbridge (CDC), Anna Verster (GAIN/WHO), Annie Wesley (MI).

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### Acronyms

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<th>Acronym</th>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>FFI</td>
<td>Flour Fortification Initiative</td>
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<td>Food and Chemical Codex</td>
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<td>GAIN</td>
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<td>International Association of Operative Millers</td>
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<td>NGOs</td>
<td>Non-Governmental Organizations</td>
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<td>PAHO</td>
<td>Pan American Health Organization</td>
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<td>RBV</td>
<td>Relative Biological Value</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
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Executive Summary

Background
An international technical workshop on wheat flour fortification with iron and folic acid was convened in Cuernavaca, Mexico in December, 2004 at the National Institute of Public Health of Mexico (INSP), with support from the U.S. Centers for Disease Control and Prevention (CDC), Micronutrient Initiative (MI), March of Dimes (MOD), and the Global Alliance for Improved Nutrition (GAIN). A group of over 50 technical experts from public health agencies, research institutions, vitamin and mineral pre-mix manufacturing and milling industries, and development agencies participated in the workshop. The workshop participants acknowledged the public health benefits of fortification of flour with other micronutrients, but did not discuss this, as the focus of the meeting was on iron and folic acid only.

The workshop objectives were to review the latest scientific and technical information in regard to the fortification of wheat flour with iron and folic acid, to identify technical and practical barriers that may impede the implementation of fortification, and to provide practical recommendations in regard to how those barriers may be overcome. Six discussion papers (www.sph.emory.edu/wheatflour/CKPAFF/Discussionpapers.html), prepared by selected specialists, served as background information for the workshop.

Iron Fortification
The workshop concluded that wheat flour fortification with iron compounds with an adequate relative biological value (RBV) can make a significant contribution to reducing the prevalence of iron deficiency. The goal of fortification of wheat flour with iron is to prevent iron deficiency rather than simply restore flour to the original nutritional content of wheat.

Iron compounds should be selected to maximize the bio-available iron delivered to the population at the lowest cost, without adversely affecting the organoleptic and storage properties of flour and flour products.

**Low Extraction Flour:** The preferred iron sources for low extraction wheat flours (< 0.8% ash) are small particle size, dried ferrous sulfate and small particle size ferrous fumarate.
In populations consuming more than 200 g/day of wheat flour, the addition of 30 ppm iron from dried ferrous sulfate or fumarate is recommended.
In populations consuming less than 200 g/day of wheat flour the addition of 45 ppm iron from ferrous sulfate or ferrous fumarate is recommended.
If it is not possible to fortify flour with either ferrous sulphate or fumarate at the levels suggested above, due to cost or other factors, flour should be fortified with electrolytic iron or other iron fortificants with a RBV of at least 50% of dried ferrous sulfate. The level of these iron sources added to flour should be twice that used for ferrous sulfate.
Sodium iron EDTA (NaFeEDTA) at 30 ppm is the preferred fortificant for low extraction flours where there is no fermentation process in food preparation (i.e. in the preparation of unleavened breads such as chapatti).

**High Extraction Flour:** NaFeEDTA is the preferred fortificant for high extraction flours (>0.8% ash) and in populations where the overall diet is of low iron bioavailability. In these environments, the addition of up to 30ppm of iron from NaFeEDTA is recommended as long as there are no adverse effects on organoleptic properties.

Fortification of wheat flour with appropriate levels of iron is safe. It causes little risk of adverse consequences even in the very small proportion of individuals with clinical disorders relating to iron absorption and storage. Iron fortification programs should be monitored as recommended in the WHO/CDC consultation.

Specific recommendations for research included the development of a standardized screening method for assessing the bio-availability of iron fortificants and the design of inexpensive, robust and flexible methods for use in regulatory oversight at the flour mill. Additional recommendations included further evaluation of the potential bio-availability and compatibility of iron compounds with flour and flour products and further assessment of technologies for iron absorption enhancement (encapsulation, micronization, dephytanization). Also suggested was the implementation of additional studies of the biological impact of ongoing national interventions and compilation of a comprehensive data base on iron fortification. The development of regional recommendations for iron fortification was also proposed.

**Folic Acid Fortification**

Folic acid has been shown to be effective in the prevention of 50 - 70% of neural tube defect cases. Additional benefits include the correction of folic acid deficiency anemia, decreased homocysteine levels, and possibly a reduced risk of other birth defects, strokes, heart disease and cancer. There have been no reports of folic acid fortification masking anemia in vitamin B12 deficiency.

All fortified wheat flour should include synthetic folic acid at a level between 1.4 and 2.8 ppm based on flour consumption patterns of the population. Populations consuming folic acid fortified flour should be monitored, using both coverage and biological indicators. If possible, the incidence of neural tube defects should also be monitored.

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2 Recommendations for the use of folic acid to reduce the number of cases of spina bifida and other neural tube defects. MMWR 1992;41 (No. RR-14).
Recommendations for research included defining optimal biochemical indicators to assess population folate status and to develop appropriate field measures for those assessments. The development of a reliable and cost effective test for monitoring folic acid levels in nutrient premix, and flour and flour products was also recommended.

**Cost Considerations in Flour Fortification**

The cost of fortification is extremely small in relation to the cost of flour and flour products. However, the incremental cost of flour fortification may be perceived by millers as significant when the market environment does not enable them to recover the cost from their customers due to unfair competition, a lack of consumer demand for fortified products and/or government controls that prevent price increases in flour or flour products.

In situations when the incremental cost of fortification cannot be sustained by millers or passed directly to the consumer, governments may assist by assuring consistent enforcement of fortification regulations, subsidization, or tax exemptions. Other steps to be considered include bulk purchasing of premix for distribution to millers and the purchase of premix on a regional basis, when fortification standards are sufficiently compatible.

**Quality Control and Assurance**

Assurance of the quality of nutrient premix is a key factor for the successful implementation of fortification. Barriers that can limit the ability of millers to obtain premix of assured quality at the best price include the proliferation of producers and traders with limited technical capacity, lack of a uniform system for quality assurance and lack of clear regulatory guidance. Strategies recommended to address these issues include, the development of national premix standards and specifications, utilization of a “Code of Practice” for premix manufacturers, accreditation of premix suppliers, and training and capacity building for public monitoring and food control agencies, as well as new premix manufacturers.

**Conclusion**

The workshop concluded that the addition of iron and folic acid to wheat flour is a feasible, affordable, and effective strategy to reduce the prevalence of these important micronutrient deficiencies. Flour fortification should be an integral part of a comprehensive strategy of vitamin and mineral deficiency prevention and control.

Fortification of wheat flour with appropriate levels of iron and folic acid is safe and the cost of fortification is extremely small in relation to the cost of flour and flour products. The workshop identified a variety of quality control issues potentially limiting the implementation of flour fortification and recommended strategies to address them. Priorities for research and monitoring were also identified.
Background

The fortification of wheat flour with iron and folic acid is an important strategy that will help to improve the nutritional status of people globally. Currently, wheat flour fortification strategies are being implemented in more than 60 countries across the world. Still, there has been limited, demonstrated impact on reduction of iron deficiency and anemia due to the inadequacies in the types and amounts of iron fortificant added, inadequate quality assurance and control mechanisms and lack of enforcement of regulations. The impact of folic acid fortification of wheat flour has been demonstrated in Canada, Chile and the United States. However, much more needs to be done to promote fortification of wheat flour with folic acid globally.

With the growth of scientific evidence demonstrating the importance of assuring adequate iron and folic acid nutrition, there is an urgent need to develop consensus and provide concrete recommendations that can guide industry and governments in implementing successful wheat flour fortification programs. One essential aspect of flour fortification that needs particular consideration is the determination of the type and amount of iron compounds to be added to wheat flour. The bioavailability, compatibility, cost and sensory/organoleptic qualities of these compounds need to be carefully defined, and recommendations on appropriate use must be disseminated broadly to industry and governments.

As part of the global initiative to advance knowledge and practice of wheat flour fortification, an international technical workshop on wheat flour fortification with iron and folic acid was convened at the National Institute of Public Health of Mexico (INSP) in Cuernavaca, Mexico in December, 2004, with support from the U.S. Centers for Disease Control and Prevention (CDC), Micronutrient Initiative (MI), March of Dimes (MOD), and the Global Alliance for Improved Nutrition (GAIN). A group of over 50 technical experts from public health agencies, research institutions, vitamin and mineral pre-mix manufacturing and milling industries, and development agencies (see list of participants in the annex 2) participated in the workshop. Six discussion papers (www.sph.emory.edu/wheatflour/CKPAFF/Discussionpapers.html), prepared by selected specialists, served as background information for the workshop.

The workshop participants acknowledged the public health benefits of fortification of flour with other micronutrients, but did not discuss this, as the focus of the meeting was on iron and folic acid only.

The objectives of the 3 day workshop were to (1) review and summarize knowledge about the efficacy and effectiveness of current iron and folic acid fortification practices with wheat flour; (2) assess new research findings and technical developments that hold promise for improving the efficacy and effectiveness of wheat flour fortification in the future; (3) review technical and cost barriers to implementing iron and folic acid fortification and identify strategies for overcoming these barriers; and (4) provide clear,
practical and economically feasible recommendations that can be implemented with current knowledge and technology.

**Workshop Recommendations**

The workshop agenda included a series of presentations based on specially prepared background documents prepared by selected experts/specialists, followed by discussion periods. At the end of each day workgroups were convened to consider the main issues presented and provide specific recommendations. One workgroup focused on developing recommendations on technical issues related to iron and folic acid fortification. A second workgroup developed recommendations relating to issues of cost and quality control. A summary of the workshop recommendations is presented below:

**Iron Fortification**

The consensus of the workshop was that wheat flour fortification with iron can be a valuable tool to lower the prevalence of iron deficiency. It is recommended that wheat flour fortification be an integral part of a comprehensive strategy of iron deficiency prevention and control. Other interventions include vitamin and mineral supplementation, improved access to a varied diet, promotion of adequate breast feeding and use of fortified complementary foods for infants and other public health measures implemented throughout the life span.

**EFFECTIVENESS OF WHEAT FLOUR FORTIFICATION**

Fortification of wheat flour is a feasible, affordable, and effective strategy to reduce the prevalence of iron deficiency.

There is strong evidence that fortification of wheat flour with ferrous sulfate in Chile has contributed significantly to the reduction of iron deficiency in that country.

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3 The background documents may be accessed separately at http://www.sph.emory.edu/wheatflour/Main.htm.

4 This workshop considered only iron and folic acid fortification. However, the importance of fortification with other micronutrients such as B vitamins, vitamin A zinc and other micronutrients is recognized.
There is anecdotal and circumstantial evidence to indicate that iron fortification of wheat flour has contributed to reducing iron deficiency in industrialized countries. The experience of iron fortification in Sweden is a good example.

Recent observations related to the fortification of other food items such as condiments and salt demonstrate that fortification can be a highly effective strategy for reducing the prevalence of iron deficiency, provided that the dose is sufficient and the bioavailability is adequate.

**SELECTION OF IRON FORTIFICANT**

Wheat flour fortification with iron fortificants with an adequate relative biological value (RBV), according to the approaches recommended below, can contribute significantly to reducing the prevalence of iron deficiency.

Iron compounds should be selected to maximize bio-available iron delivered to the population at the lowest cost without adversely affecting the organoleptic and storage properties of flour and flour products.

It may be useful to define region-specific recommendations for iron fortification for populations. These recommendations should be based on estimates (if possible using currently available data) of population iron status; dietary intake of bio-available iron; factors in the diet influencing iron absorption; requirements of at-risk groups; flour intake and RBV of the iron compound.

**Fortification of Low Extraction Wheat Flour**

- **Ferrous Fumarate and Ferrous Sulphate**
  
  Where flours typically undergo a fermentation process in food preparation, the preferred iron sources for low extraction wheat flours (< 0.8% ash) are small particle size, dried, ferrous sulfate and small particle size ferrous fumarate.

  In populations consuming more than 200 g/day of wheat flour, the addition of 30 ppm iron from dried ferrous sulfate or fumarate is recommended.

  In populations consuming less than 200 g/day of wheat flour the addition of 45 ppm iron from ferrous sulfate or ferrous fumarate is recommended.

- **Electrolytic Iron**
  
  If it is not possible to fortify flour with ferrous sulphate or fumarate, flour should be fortified with electrolytic iron, or other iron products with a RBV of at least 50% of dried ferrous sulfate, as demonstrated in rat assays.
- The level of these iron sources added to flour should be twice that used for ferrous sulfate.

✓ Other Iron Fortificants

- Sodium iron EDTA (NaFeEDTA) is the preferred fortificant for low extraction flours where there is no fermentation process in food preparation.

- Small particle size (2.5 micron) ferric pyrophosphate is a promising iron compound proven in rat assays to offer at least 50% of the RBV of ferrous sulfate.

Fortification of High Extraction Wheat Flour

Sodium iron EDTA is the preferred fortificant for high extraction flours (> 0.8% ash) and in populations where the over-all diet is of low bioavailability, providing there is not excessive loss of this soluble iron salt in cooking water that is discarded, as in the preparation of fresh noodles.

In populations consuming more than 200 g/day of wheat flour 30 ppm iron from NaFeEDTA is recommended, provided that there are no adverse effects on organoleptic properties. In populations consuming less than 200g per day of high extraction flour the benefits of consuming flour fortified with NaFeEDTA are currently un-documented. However, as indicated on page 14, fortification of high extraction flour with folic acid is recommended and if economically feasible the addition of NaFeEDTA at 30 ppm should also be considered.

QUALITY ASSURANCE

Quality assurance of iron fortificants is essential and should include:

Certification by micronutrient premix suppliers specifying the type, source and manufacturing process of all iron fortificants for all commercial, regulatory and research applications.

The inclusion of RBV estimates for iron sources in the food and chemical codex (FCC), and other compilations of ingredient specifications.

SAFETY OF IRON FORTIFICATION

Fortification of wheat flour with appropriate levels of iron is safe. It causes little, if any risk of adverse consequences, even in the very small proportion of people with clinical disorders relating to iron absorption and storage.
For individuals with iron overloading disorders, the increased rate of iron accumulation
due to the consumption of iron-fortified flour is small, and poses little additional risk for
individuals with clinical disorders such thalessemia major or hemachromatosis.

Evidence of dose related, immune-mediated effects of iron on increasing the risk of
clinical malaria has been restricted to oral supplementation in children at doses greater
than 2 mg iron per kilogram of bodyweight per day, or the use of parenteral iron. These
doses from supplements are significantly higher than those delivered by fortification,
even in populations with very high flour consumption. There have been no reported
adverse consequences of iron fortification in these circumstances.

Despite the lack of evidence for any increase in risk, indicators of iron status, and the
occurrence of unwanted health effects potentially related to iron status should be
monitored.

**ASSESSMENT AND MONITORING**

The implementation of iron fortification programs should be guided by ensuring
the quality of fortified flour and flour products, and tracking the iron status of
populations that regularly consume the fortified products.

- Measurement of the reduction in prevalence of iron deficiency is the best
  indicator to gauge the success of iron fortification programs. The measurement of
  anemia alone is not considered sufficient.

- Hemoglobin and serum ferritin should be used to monitor the biological impact of
  flour fortification, as recommended in the WHO/CDC technical consultation in
  2004:

- An acute phase protein (e.g. C-reactive protein or alpha-1-glycoprotein) should
  also be assessed to help adjust the distribution of serum ferritin data to account
  for potential false-negative results due to elevations in serum ferritin of
  individuals suffering from inflammatory conditions (especially if there is evidence
  that the prevalence of infectious disease has increased in the target population
  since the initiation of the flour fortification program).

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5 Assessing the iron status of populations: report of a joint World Health Organization/Centers for Disease Control and Prevention
RESEARCH

Further research is needed to identify and define optimal approaches for iron fortification of wheat flour. Specific research objectives include:

Development of small particle size (<75 microns) encapsulated ferrous sulfate, and encapsulated ferrous fumarate. The current commercial compounds have an RBV of 100 in rats, and have been shown to prevent fat oxidation in stored cereal products. However, the particle size of existing commercially produced encapsulated products is greater than 600 microns and they would be removed during final sifting in most large scale mills.

Development of a standardized screening method for establishing and monitoring relative bioavailability of iron fortificants.

Further evaluation of the potential bioavailability and compatibility of iron compounds with flour and flour products including:

Feasibility and efficacy of new fortificants such as very small particle size (micronized) ferric pyrophosphate;

Consumer acceptability of NaFeEDTA in high phytate flours, and in low phytate flours in low bioavailability diets⁶;

Establishment of upper limits for the addition of all iron compounds to different flours without adversely affecting the quality and acceptance of flour and flour products. This is especially important for ferrous sulfate, which is the least expensive source of bioavailable iron and therefore more accessible to lower income countries.

Evaluation of the potential for combining two or more iron compounds within a single premix to achieve improved bioavailability while retaining acceptable sensory quality.

Evaluation of the impact on iron fortificants of premixes containing multiple micronutrient in various food matrices.

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⁶ Research has shown the NaFeEDTA offers no increased absorption over soluble iron salts in high bioavailability meals.
Assessment of the feasibility, effectiveness and acceptability of technologies for iron absorption enhancement including, encapsulation, micronization, de-phytanization and other options.

Design of inexpensive, robust and flexible methods at the flour mill to monitor the homogeneity, variability, and other quality parameters of fortified flour.

Compilation of a comprehensive data base, and a critical review of all studies relating to bioavailability, efficacy, and effectiveness of fortified flour and flour products in reducing the prevalence of iron deficiency and anemia. The review should assess the adequacy of the studies in regard to the following:

- Adequate specification of the iron compounds used in fortification;
- Assurance that the fortified products contained adequate levels and bio-available forms of the iron fortificants;
- Appropriate statistical analysis of biological indicators and other outcome measures.

Implementation of additional studies of the biological impact of ongoing national interventions.

All published research on iron bioavailability and efficacy should specify the type, source and properties of the iron compounds used.

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**Folic Acid Fortification**

All low and high extraction fortified wheat flour should include synthetic folic acid at a level between 1.4 and 2.8 ppm based on flour consumption patterns of the population.

Folic acid has been shown to be effective in the prevention of 50-70% of neural tube defect (NTD) cases.

Additional benefits of folic acid fortification also include the correction of folic acid deficiency anemia and decreased homocysteine levels. Increased folic acid intake may also reduce the risk of other birth defects, and the incidence of stroke, heart disease, and some cancers.

There have been no cases documenting folic acid fortification masking anemia in vitamin B12 deficiency.

Monitoring should include:

Process indicators reflecting the level of implementation of folic acid fortification (i.e. the actual folic acid levels reaching consumers through fortified wheat flour and its products).
The incidence of NTDs should be monitored, as much as possible, to serve as a basis for modifying the levels of folic acid in flour.

Develop a system for recording potential cases of folic acid masking of vitamin $B_{12}$ deficiency.

**RESEARCH**

There is a need for further research to identify optimal approaches for folic acid fortification of wheat flour. Specific objectives may include the following:

Develop a science base for the assessment and monitoring of folate status in populations.

Identify the optimal biochemical indicators and develop appropriate field measures to assess population folate status.

Develop a reliable and cost effective test for assessing folic acid levels in fortificant premix, flour, and flour products for monitoring the operational success of the fortification program.

Expand the rationale for folic acid fortification beyond NTD prevention including:

Conduct further research on the effects of folic acid in reducing the risk of other congenital malformations and cardiovascular diseases.

Conduct research on the prevalence of $B_{12}$ deficiencies and the health outcomes connected with $B_{12}$ fortification.

Identify outcome and biological indicators including serum and red cell folates and mortality from cardiovascular disease.

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**The Cost of Flour Fortification**

The cost of fortification is extremely small in relation to the cost of flour or flour products. For this reason the incremental cost of flour fortification, in itself, should not present an obstacle to implementing fortification provided that the benefits are widely communicated and understood, and the cost of fortification is fairly and inexpensively passed on to the consumer.

Based on 70 years of commercial experience in industrialized countries, flour fortification is best sustained when financed directly by the consumer via a slight increase in retail price.
When fortification is mandatory and public investments are made in effective food control and transparent enforcement of regulations, the slight increase in cost can be successfully passed on to the consumer.

**COST ISSUES RELATED TO WHEAT FLOUR FORTIFICATION**

Under certain circumstances, the incremental cost of fortification may be perceived by flour millers as significant, and present an obstacle during the initiation and early phases of flour fortification programs. The initial responsibility and financial risk associated with fortification may be perceived as unfairly falling on the production sector when:

The market environment does not enable flour millers to recoup the cost of fortification from their customers due to:

- Unfair competition and a lack of a “level playing field” where all companies compete on an equal basis. Unfair competition may result from an inconsistent enforcement of regulations.
- Lack of awareness of the benefit of flour fortification and low consumer demand.
- Government controls preventing price increases.
- Flour millers are unfairly burdened by the cost of premix due to:
  - Specification of expensive fortificants mandated by regulations.
  - Cash flow pressure due to the time lag from the purchase of premix to the receipt of customer payment.
  - Lack of sufficient information to enable effective negotiation with premix suppliers.

**STRATEGIES TO ADDRESS COST ISSUES**

In some situations when the incremental cost of fortification cannot be bourne by the millers or be passed directly to the consumer, governments may intervene and temporarily pay some or all of the additional costs of fortification. Strategies may include the following mechanisms:

- Effective and consistent enforcement of fortification regulation.
- Subsidization of fortification costs by government.
- Reductions in the costs through tax exemptions or duty free status on imported fortificants and equipment.
- Reductions in cash flow burden from premix purchase by establishing public revolving funds to be repaid as producers recoup the cost in the marketplace.
Increases in consumer demand and in the market share of fortified flour through ongoing communication strategies.

Additional innovative strategies to lower costs can be identified by open and frank public/private dialogue. These may include:

Public bulk purchasing of premix for distribution to millers;

Regional purchases of premix whenever fortification standards are sufficiently compatible across a region.

“Cross subsidization” of fortification of staple flour by large diversified companies using revenues derived from other products.

**RESEARCH**

Research is recommended to identify strategies to lower the cost of fortification. Specific objectives include:

Initiate consumer research as a strategy for adding value to fortified flour

Compile and make widely available an inventory of consumer research, related to fortified flour, particularly from developing countries.

Identify factors that create demand and will motivate consumers to pay more for a fortified food product.

Develop, test and disseminate inexpensive and robust strategies for food sampling, testing and enforcement of regulations. These strategies must be feasible in decentralized and resource-limited environments, such as those often found in developing countries.

Collect and disseminate examples of creative approaches to cost reduction and cost-sharing among public and private sectors.

**Quality Control of Premix**

**QUALITY CONTROL OF PREMIX**

There are a number of issues relating to premix quality control. These include:

Proliferation of premix producers and traders with limited technical capacity.
Products of questionable quality, including both raw materials and premix.

Lack of a standardized system for quality assurance and control that is consistently applied and accessible to new manufacturers.

Lack of clear regulatory guidance regarding the type and quantity of fortificant to be added.

Lack of information on shelf life for different compounds in premixes, flours and flour products.

**STRATEGIES TO ADDRESS QUALITY CONTROL ISSUES**

The workshop identified several strategies that may be useful in addressing quality control issues. These include:

**Utilization of a “Code of Practice” for premix manufacture**

Develop and promote a code of practice to set standards for proper procedures in premix manufacture.

The Code could be modeled on the PAHO Code of Practice, currently under development.

**Premix Standards**

- Develop national premix standards and specifications based on:
  
  ✓ Dialogue between the public and private sectors.
  
  ✓ Defined premix and product standards.
  
  ✓ Defined criteria specifying the amount of fortificant to be added versus the amount of nutrient in the final product.

**Development of standardized system that offers clear regulatory guidance**

- A standardized system should include the following:

  Consistent terminology of technical terms, for example “food grade”.

  A certificate of analysis for all micronutrients in each lot of premix.

  Traceability of raw materials from the point of origin.
- Regulatory guidance on the type and quantity of fortificant to be added should include;

Clear specifications for premix and its components.

Clear distinctions in regulations for required fortificant addition as opposed to final micronutrient value or content.

Accreditation of premix suppliers
- Foster the accreditation of premix suppliers by an independent auditing organization based on industry’s GMP, HACCP and eventually ISO 22000 systems.

Training and capacity building
- Provide training and capacity building for:
  - Food control agencies.
  - New premix manufacturers.

Public/Private Dialogue and Communication
- Facilitate communication among public and private sectors to exchange experiences, build partnerships and solve problems collaboratively.

RESEARCH

The success of guidelines for premix quality control will require the clarification of a number of operational and technical issues, including:

The impact of different fortificant mixes on organoleptic properties of various flours and flour products, under varying environmental and food preparation conditions.

The effect of fortification mixes on the shelf life of different wheat flours and flour products.

The extent of leaching of fortificants into water during the preparation of noodles.
**Workshop Conclusions**

The clear consensus of the workshop was that addition of iron and folic acid to wheat flour is a feasible, affordable and effective method to reduce the prevalence of these important micronutrient deficiencies.

It was further concluded that wheat flour fortification be an integral part of a comprehensive strategy of iron deficiency prevention and control. Other interventions include vitamins and mineral supplementation, improved access to a varied diet, promotion of adequate breastfeeding and use of fortified complementary foods for infants and other public health measures implemented throughout the life span. In addition, flour fortification with synthetic folic acid is a proven strategy to prevent NTDs and folate deficiency anemia. Other public health benefits may include reduction in cardiovascular disease in adults.

Fortification of wheat flour with appropriate levels of iron and folic acid is safe. Iron fortification causes little, if any, risk of adverse consequences even in the extremely small proportion of individuals with clinical disorders relating to iron absorption and storage. To date there have been no documented reports that folic acid fortification masks anemia in vitamin B12 deficiency.

The cost of fortification is very small in relation to the cost of flour or flour products so that the incremental cost, in itself, should not present an obstacle. If cost factors initially present a barrier, governments may assist the process in various ways. These include assuring consistent enforcement of fortification regulations, subsidizing fortification, reducing costs through tax exemptions or granting duty free status on imported fortificants and equipment, or other measures. Other steps to be considered include the public, bulk purchasing of premix for distribution to flour millers and the purchase of premix on a regional basis when fortification standards are sufficiently compatible across a region.

The workshop participants identified several strategies that may be useful in improving the quality control and quality assurance of premix. These strategies included the utilization of a “Code of Practice” for premix manufacture, development of national premix standards and specifications, accreditation of premix suppliers and training and capacity building for food control agencies and new premix manufacturers.
Annex 1 – Workshop Agenda

Wheat Flour Fortification: Current Knowledge and Practical Applications

Agenda

Day 1: The Science base
Chair: Juan Rivera

Morning:

8.30 am
Welcome: Juan Rivera and Ibrahim Parvanta

Session I: Overview of Issues in Wheat Flour Fortification
9.00 - 9:20 Public Health Perspective - Bill Dietz
9.20 - 9:40 Industry Perspective - Jeff Gwirtz

9:40 – 10:00 Discussion

10.00 – 10:30 Break

Session II: Current Guidelines

10:30 - 11:00 Review of Wheat Flour Fortification Guidelines and special requirements for iron and folic acid fortification: Commonalities and differences among the current guidelines - Peter Ranum

11.00 – 11.30 Discussion

Afternoon:

Session III: The Science Base for Wheat Flour Fortification Guidelines

1.00 – 1.30 Iron Fortification: Current knowledge and promising new technologies - Richard Hurrell
1:30 – 2:00 Discussion

2:00 – 2:30 Iron Fortification: Current research and future priorities - Sean Lynch
2:30 – 3:00 Discussion

3:00 – 3:30 Break

3:30 – 4:00 Folic Acid Fortification: Effectiveness, current research and future Priorities - Eva Hertrampf
4:00 – 4:30 Discussion
Day 2: Technical Barriers and Solutions
Chair: Anna Verster

Morning:

Session IV: Current Practices and Issues in Wheat Flour Fortification

8:30 – 8:45 Current Wheat Flour fortification practices globally - Peter Ranum
8:45 – 9:15 Discussion
9:15 – 9:45 Safety of Flour fortification with iron - Gary Brittenham
9:45 -10:15 Safety of Folic Acid and B-12 Fortification – Joe Mulinare
10.15-10.30 Discussion
10:30 -11:00 Break
11.00 – 11.30 Relative cost of micronutrient fortification of wheat flour - Omar Dary
11.15 – 12:00 Discussion

Afternoon:

Session V: Premix Quality Assurance

1:15 – 1:30 Issues relating to premix quality assurance – Wilma Freire
1:30 – 1.45 Discussion
1:45 – 2:15 Establishing a code of practice for premix quality control - Hector Cori
2:15 – 2:45 Discussion
2:45 – 3:15 Break
3:15 – 3:45 Putting premix quality control into practice: applicability of a code of practice and other strategies globally - Quentin Johnson
3:45 – 4:15 General Discussion
Day 3:  
Chair: Bill Dietz

Morning:

Session VI: Finalizing Consensus Guidelines and Research Priorities
8:30 – 8:45 Presentation of Draft Consensus Guidelines and Research Priorities [Workgroup 1]
8:45 – 9:45 Discussion and finalization
9:45 – 10:15 Break
10:15 – 10:30 Presentation of Draft Summary of Technical Barriers (cost, safety, premix quality assurance) and Recommended Solutions [Workgroup 2]
10.30 – 11:30 Discussion and finalization

Afternoon:

1:00 – 1:45 Communication of Consensus Guidelines and Recommendations Role of Industry and Public Health Moderator: Bill Dietz
1:45 – 2:30 Implementing Research Priorities Role of Industry and Public Health Moderator: Bill Dietz
2:30 – 3:00 Break
<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>3:00 – 3:45</td>
<td>Addressing ongoing challenges and issues</td>
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<td>Role of Industry and Public Health</td>
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<td>Moderator: Bill Dietz</td>
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<td>3:45 – 4:15</td>
<td>Closing remarks: Juan Rivera, Ibrahim Parvanta</td>
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## Annex 2 - Participant List

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jack Bagriansky</td>
<td>Consultant</td>
<td><a href="mailto:bagriansky@comcast.net">bagriansky@comcast.net</a></td>
</tr>
<tr>
<td>Bob Baldwin</td>
<td>CDC</td>
<td><a href="mailto:RBaldwin@cdc.gov">RBaldwin@cdc.gov</a></td>
</tr>
<tr>
<td>Erick Boy</td>
<td>MI</td>
<td><a href="mailto:eboy@micronutrient.org">eboy@micronutrient.org</a></td>
</tr>
<tr>
<td>Gary Brittenham</td>
<td>Columbia University, U.S.A</td>
<td><a href="mailto:gmb31@columbia.edu">gmb31@columbia.edu</a></td>
</tr>
<tr>
<td>Ram Chaudhari</td>
<td>Fortitech</td>
<td><a href="mailto:ramc@fortitech.com">ramc@fortitech.com</a></td>
</tr>
<tr>
<td>Visith Chavasit</td>
<td>Mahidol University, Thailand</td>
<td><a href="mailto:nuvca@mucc.mahidol.ac.th">nuvca@mucc.mahidol.ac.th</a></td>
</tr>
<tr>
<td>Hector Cori</td>
<td>DSM/Roche</td>
<td><a href="mailto:hector.cori@dsm.com">hector.cori@dsm.com</a></td>
</tr>
<tr>
<td>Omar Dary</td>
<td>MOST</td>
<td><a href="mailto:odary@istiinc.com">odary@istiinc.com</a></td>
</tr>
<tr>
<td>William Dietz</td>
<td>CDC</td>
<td><a href="mailto:WDietz@cdc.gov">WDietz@cdc.gov</a></td>
</tr>
<tr>
<td>Wilma Freire</td>
<td>PAHO</td>
<td><a href="mailto:freirewi@paho.org">freirewi@paho.org</a></td>
</tr>
<tr>
<td>Maria Garcia-Casal</td>
<td>Venezuelan Institute of Scientific research, Venezuela</td>
<td><a href="mailto:mngarcia@medicina.ivic.ve">mngarcia@medicina.ivic.ve</a></td>
</tr>
<tr>
<td>Gary Gleason</td>
<td>International Nutrition Foundation, IDPAS, U.S.A.</td>
<td><a href="mailto:ggleason@inffoundation.org">ggleason@inffoundation.org</a></td>
</tr>
<tr>
<td>Jeff Gwirtz</td>
<td>IAOM</td>
<td><a href="mailto:Jeff@Jagsi.com">Jeff@Jagsi.com</a></td>
</tr>
<tr>
<td>Eva Hertrampf</td>
<td>Institute of Nutrition and Food Technology</td>
<td><a href="mailto:ehertram@uec.inta.uchile.cl">ehertram@uec.inta.uchile.cl</a></td>
</tr>
<tr>
<td>Christine Holtz</td>
<td>Cuernavca Institute of Public Health, Mexico</td>
<td><a href="mailto:chotz@correo.insp.mx">chotz@correo.insp.mx</a></td>
</tr>
<tr>
<td>Christopher Howson</td>
<td>March of Dimes</td>
<td><a href="mailto:chowson@marchofdimes.com">chowson@marchofdimes.com</a></td>
</tr>
<tr>
<td>Lena Hulthen</td>
<td>Institute of Internal Medicine, University Hospital, Sweden</td>
<td><a href="mailto:lena.hulthen@medfak.gu.se">lena.hulthen@medfak.gu.se</a></td>
</tr>
<tr>
<td>Bo Hu</td>
<td>Höganäs, AB</td>
<td><a href="mailto:bo.hu@nah.com">bo.hu@nah.com</a></td>
</tr>
<tr>
<td>Richard Hurrell</td>
<td>Swiss Federal Institute of Technology</td>
<td><a href="mailto:richard.hurrell@ilw.agrl.ethz.ch">richard.hurrell@ilw.agrl.ethz.ch</a></td>
</tr>
<tr>
<td>Quentin Johnson</td>
<td>MI</td>
<td><a href="mailto:quentin@quican.com">quentin@quican.com</a></td>
</tr>
<tr>
<td>Venkatesh Iyengar</td>
<td>Consultant</td>
<td><a href="mailto:venkygaru@yahoo.com">venkygaru@yahoo.com</a></td>
</tr>
<tr>
<td>Huo Junsheng</td>
<td>Institute of Nutrition and Food Safety, China</td>
<td><a href="mailto:jshuo@mail.263.net.cn">jshuo@mail.263.net.cn</a></td>
</tr>
<tr>
<td>Vinod Kapoor</td>
<td>Kapoor Brothers Roller Flour Mills, India</td>
<td><a href="mailto:kapvinod@hotmail.com">kapvinod@hotmail.com</a></td>
</tr>
<tr>
<td>Sean Lynch</td>
<td>Eastern Virginia Medical School, U.S.A.</td>
<td><a href="mailto:srlynch@visi.net">srlynch@visi.net</a></td>
</tr>
<tr>
<td>Glen Maberly</td>
<td>Emory University, U.S.A.</td>
<td><a href="mailto:maberly@sph.emory.edu">maberly@sph.emory.edu</a></td>
</tr>
<tr>
<td>Nune Mangasaryan</td>
<td>UNICEF</td>
<td><a href="mailto:nmangasaryan@unicef.org">nmangasaryan@unicef.org</a></td>
</tr>
<tr>
<td>Joe Mulinare</td>
<td>CDC</td>
<td><a href="mailto:JMulinare@cdc.gov">JMulinare@cdc.gov</a></td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
<td>Email Address</td>
</tr>
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</tr>
<tr>
<td>Godfrey Oakley</td>
<td>Emory University</td>
<td><a href="mailto:GPOakley@mindspring.com">GPOakley@mindspring.com</a></td>
</tr>
<tr>
<td>Maureen Olwevnik</td>
<td>American Institute of Bakers (AIB)</td>
<td><a href="mailto:MOLEWNIK@aibonline.org">MOLEWNIK@aibonline.org</a></td>
</tr>
<tr>
<td>Ibrahim Parvanta</td>
<td>CDC</td>
<td><a href="mailto:IParvanta@cdc.gov">IParvanta@cdc.gov</a></td>
</tr>
<tr>
<td>Peter Ranum</td>
<td>MI/Contractor</td>
<td><a href="mailto:Doughmaker@aol.com">Doughmaker@aol.com</a></td>
</tr>
<tr>
<td>Juan Rivera</td>
<td>Cuernavca Institute of Public Health, Mexico</td>
<td><a href="mailto:jrivera@insp.mx">jrivera@insp.mx</a></td>
</tr>
<tr>
<td>Geoffry L. Smith</td>
<td>AKZO Nobel</td>
<td><a href="mailto:geoff.smith@akzonobelchemicals.com">geoff.smith@akzonobelchemicals.com</a></td>
</tr>
<tr>
<td>Nicolas Tsikhlakis</td>
<td>The Modern Flour Mill, Jordan</td>
<td><a href="mailto:Nicolas@cyberia.io">Nicolas@cyberia.io</a></td>
</tr>
<tr>
<td>Liz Turner</td>
<td>SUSTAIN</td>
<td><a href="mailto:lturner@sustaintech.org">lturner@sustaintech.org</a></td>
</tr>
<tr>
<td>Katie Tripp</td>
<td>CDC</td>
<td><a href="mailto:KTripp@cdc.gov">KTripp@cdc.gov</a></td>
</tr>
<tr>
<td>Rick Trowbridge</td>
<td>CDC</td>
<td><a href="mailto:r.trowbridge@comcast.net">r.trowbridge@comcast.net</a></td>
</tr>
<tr>
<td>John Vanderveen</td>
<td>Consultant</td>
<td><a href="mailto:John.Vanderveen@cfsan.fda.gov">John.Vanderveen@cfsan.fda.gov</a></td>
</tr>
<tr>
<td>Anna Verster</td>
<td>GAIN</td>
<td><a href="mailto:Averster@gaingeneva.org">Averster@gaingeneva.org</a></td>
</tr>
<tr>
<td>Salvador Villalpando</td>
<td>Cuernavca Institute of Nutrition, Mexico</td>
<td><a href="mailto:svillalp@correo.insp.mx">svillalp@correo.insp.mx</a></td>
</tr>
<tr>
<td>Wolfgang A. Vogl</td>
<td>Lohmann</td>
<td><a href="mailto:W.A.Vogl@lohnmann-chemikalien.de">W.A.Vogl@lohnmann-chemikalien.de</a></td>
</tr>
<tr>
<td>Sun Wei</td>
<td>DSM China</td>
<td><a href="mailto:Wei.Sun@DSM.com">Wei.Sun@DSM.com</a></td>
</tr>
<tr>
<td>Name</td>
<td>Organization</td>
<td>Email</td>
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</tr>
<tr>
<td>Annie Wesley</td>
<td>MI</td>
<td><a href="mailto:awesley@micronutrient.org">awesley@micronutrient.org</a></td>
</tr>
<tr>
<td>Monte White</td>
<td>Research Products</td>
<td><a href="mailto:montewhite@researchprod.com">montewhite@researchprod.com</a></td>
</tr>
<tr>
<td>Carel Wreesmann</td>
<td>AKZO Nobel</td>
<td><a href="mailto:carel.wreesmann@akzonobel-chemicals.com">carel.wreesmann@akzonobel-chemicals.com</a></td>
</tr>
<tr>
<td>Yu Xiaodong</td>
<td>Public Nutrition &amp; Development Center, China</td>
<td><a href="mailto:zhangweimin@pndc.gov.cn">zhangweimin@pndc.gov.cn</a></td>
</tr>
<tr>
<td>Elizabeth Yetley</td>
<td>NIH</td>
<td><a href="mailto:yetleye@od.nih.gov">yetleye@od.nih.gov</a></td>
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</tbody>
</table>