SUMMARY REPORT

The Flour Fortification Initiative

Second Technical Workshop on Wheat Flour Fortification: Practical Recommendations for National Application

March 30 to April 3, 2008
Stone Mountain, Georgia, USA

Nearly 100 leading nutrition, pharmaceutical and cereal scientists and milling experts from the public and private sectors from around the world gathered for four days to harmonize advice for countries considering national wheat and/or maize flour fortification.

This report from of the Second Technical Workshop on Wheat Flour Fortification will be a valuable guide for countries planning to initiate flour fortification programs, as well as those that are already fortifying flour. We are grateful to the participants of this meeting who so freely shared their expertise and experiences toward preparing technical background reports and the final recommendations.

Disclaimer:

The selection of the type and quantity of vitamins and minerals to add to flour, either as a voluntary standard or a mandatory requirement, lies with national decision makers in each country. This meeting fully recognized this, and any guidance or recommendations should be viewed in the context of each country's situation. In addition, the official normative-setting international organizations that guide countries on food standards are the World Health Organization and UN Food and Agriculture Organization, the CODEX Alimentarius Commission and the Joint FAO/WHO Committee on Food Additives (JECFA).

The findings and conclusions in this report do not necessarily represent the official position of the participants' organization, including the Centers for Disease Control and Prevention.

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Burden of Vitamin and Mineral Deficiencies

The World Health Report [1] identified iodine, iron, vitamin A and zinc deficiencies among the world's most serious health risk factors. Micronutrient malnutrition contributes to a vicious cycle of poor health and depressed productivity, trapping families in poverty and eroding economic security in dozens of countries worldwide. Ensuring adequate intake of these essential nutrients by vulnerable populations will offer enhanced protection from a range of disabilities and diseases, help children grow and learn, and improve workplace productivity for adults.

Adequate folic acid intake by women before pregnancy and in the first weeks of gestation decreases the risk of neural tube defects (NTD) [2], the world's leading preventable birth defect. Geographic distribution of NTD prevalence is based in part on dietary patterns. For example in China, folate deficiency is more severe and the prevalence of NTDs is decidedly higher among the predominately wheat-eating populations of the northeast part of the country, where fresh vegetables are less available, than among the populations in the southern part of the country where fresh vegetables are more available year-round [3]. Such findings suggest it is likely that other populations around the world could substantially reduce NTDs by eating folic acid-fortified foods.

Iron deficiency is the most prevalent nutrient deficiency in the world [4]. It is responsible for approximately 20,854 deaths and 2 million disability adjusted life years (DALYs) among children under 5 years [5]. In addition, iron deficiency anemia in pregnancy is a risk factor for maternal mortality; 115,000 deaths per year from maternal causes and 3.4 million DALYs, have been attributed to this risk factor [5]. According to a WHO review of nationally representative surveys from 1993 to 2005, 42% of pregnant women and 47% of preschool children worldwide have anemia [5]. These analyses assume that 60% of this anemia was assumed to be due to iron deficiency in non-malaria areas while 50% was in malaria areas. Iron deficiency has its greatest impact on the health and physical and intellectual well-being of preschool children and women of childbearing age, though iron deficiency may also affect other population groups. Although often more severe in poor and rural communities, iron deficiency also occurs in wealthier and urban populations.

Zinc deficiency is responsible for approximately 4% of deaths and 16 million DALYs among children under age 5 in lower-income countries [5], and can usually be found in populations that are iron deficient. Inadequate zinc intake in young children increases the rates of diarrhea and acute lower respiratory infections and reduces linear growth and physical development [6, 7]. Adequate zinc intake is also necessary for women of childbearing age to ensure normal pregnancy outcomes [8].

There is mounting evidence of widespread vitamin B12 depletion and deficiency in many population groups that consume low amounts of animal source foods, the only natural source of B12. Even in industrialized countries, there is a high prevalence of vitamin B12 deficiency among the elderly, many of whom require synthetic sources of the vitamin due to their limited ability to release and absorb the vitamin from foods [9, 10]. Vitamin B12 deficiency has been linked to poor pregnancy outcomes and increased risk of NTDs, delayed child development, abnormal cognitive function and depression, anemia, and elevated plasma homocysteine concentrations.

Vitamin A deficiency is a widespread public health problem in developing nations where it affects more than 130 million preschool children and is the leading preventable cause of childhood blindness [11] and a major underlying cause of child mortality [12].

Sufficient vitamin A intake is essential to maintain an adequate host response to infection. Vitamin A supplementation during early childhood appears to have its greatest impact in reducing case fatality from measles, diarrhea or dysentery, malaria and other febrile illnesses [13]. Twenty million pregnant and lactating women also suffer from low vitamin A status [14], predisposing affected women to higher risks of night blindness, anemia, morbidity and mortality. Newborn vitamin A supplementation appears to be a promising way to reduce early infant mortality [12]. The most vitamin A-deficient populations are in Southern Asia and rural Africa.

The Opportunity of Flour Fortification

The 1990 World Summit for Children in New York challenged Member States to reduce the burden of vitamin and mineral deficiencies, and that goal was reiterated at the 1993 International Conference on Nutrition in Rome. This challenge called for the virtual elimination of vitamin A and iodine deficiency and substantial reduction of iron deficiency levels by the year 2000. Over the subsequent decade, Universal Salt Iodization (USI) was adopted by many nations, resulting in a 60 percent increase in household access to iodized salt. Today 70% of the world's households have access to iodized salt, compared to 10% in 1990.

Worldwide, more than 600 million metric tons of wheat and maize flours are milled annually by commercial roller mills and consumed as noodles, breads, pasta, and other flour products by people in nearly every nation of the world. During the production of refined white flour, essential vitamins and minerals are removed during the milling process. The nutrient-rich byproduct of milling is then used as animal feed. In addition to nutrient losses during milling, many cereal products also have elements such as phytates that block the absorption of iron and zinc.

Building on the Past to Gain Consensus

Micronutrient fortification of wheat flour was introduced in the United States and Canada in the 1940s. In Latin America, Chile began to fortify wheat flour in the early 1950s [15]. During the 1960s, a number of Latin American countries passed legislation encouraging the addition of iron and B vitamins; as a consequence, some millers began to fortify on a voluntary basis.

In 1998, the U.S. and Canada required that enriched cereal grain products be additionally fortified with folic acid to reduce the prevalence of NTDs. In the late 1990s and early 2000s, public-private sector organizations organized a movement to promote mandatory wheat and maize fortification worldwide. Among the organizations promoting fortification were the World Health Organization (especially the Pan American Health Organization and the Eastern Mediterranean Regional Office), the United Nations Children's Fund, the World Bank, the Asian Development Bank, the Micronutrient Initiative, the U.S. Agency for International Development, the Centers for Disease Control and Prevention, SUSTAIN, the International Association of Operative Millers, and the Latin American Milling Association. The effort was also backed by leading public health and nutrition scientists, milling industry executives, and other industry and NGO leaders. Significant progress toward meeting fortification goals was made in the Americas, Middle East and Central Asia. The 2002 UN Special Session on Children marked the establishment of the Global Alliance for Improved Nutrition (GAIN) with support for food fortification from the Bill and Melinda Gates Foundation, the Canadian International Development Agency and USAID. GAIN has since supported a number of countries in efforts to establish flour fortification programs, to further build national fortification alliances, and provided funds for infrastructure to help countries move towards nationwide flour fortification.

Following the 2004 International Grains Council (IGC), the Flour Fortification Initiative (FFI) was formed to accelerate wheat flour fortification in roller mills throughout the world [16]. FFI is a network of public-private-civic sector leaders representing more than 50 organizations and drawing support from the wheat growing, trading, and milling companies, mill manufacturing, pharmaceutical, and vitamin/mineral pre-mix industries and allied trades. Today flour fortification is increasingly being adopted as normal industrial milling practice in the production of quality flour. FFI network members are working with governments around the world as they change food regulations and food control systems to meet mandatory flour fortification requirements. Disability sector and other civic sector organizations are also joining the cause.

The number of countries with mandatory wheat flour fortification programs rose from 33 in 2004 to 54 in 2007 [17]. Worldwide, 540 million people had access to wheat flour fortified with iron, folic acid, or both in 2007, an 8% increase from three years before. The number of women aged 15-60 years with access to fortified wheat flour increased by 167 million, and the number of births that potentially benefited from wheat flour fortification increased by 14 million. Yet despite these successes, more than two-thirds of the world's population still lacks access to fortified wheat flour and its benefits, including millions of women of childbearing age. Also, fortification standards and practices vary from country to country as do the specifications on the type and quantity of the nutrients added. As such, FFI regularly collects and updates country-level information on fortification [18].

As flour fortification programs gained momentum in the late 1990s and 2000s, PAHO, WHO/EMRO, USAID, SUSTAIN, and MI engaged in a number of consultations with countries and regions to help establish guidelines for vitamin and mineral fortification of flour. Meanwhile, new studies suggested the selection of iron fortificant type was complicated by significant differences in the bioavailabity of various forms of iron powders and compounds. FFI, in collaboration with CDC and the Mexican Institute of Public Health, convened a technical workshop entitled, "Wheat Flour Fortification: Current Knowledge and Practical Applications," in Cuernavaca, Mexico in December 2004 [19]. A key focus of the 2004 workshop was to develop recommendations for fortifying wheat flour with iron and folic acid. The final consensus recommendations were unique in that they called for fortification of low- and high-extraction flours with only bioavailable forms of iron fortificants (ferrous sulfate, ferrous fumarate, or electrolytic iron in low-extraction flour, and sodium-iron EDTA in high-extraction flour), as well as folic acid. Recommendations from the Cuernavaca meeting are largely consistent with the recently published WHO/FAO "Guidelines on Food Fortification with Micronutrients" [20]. This is a key reference for countries considering food fortification to address the high burden of disease attributable to vitamin and mineral deficiencies. Three of the four editors of the WHO/FAO publication contributed significantly to the final recommendations of the Cuernavaca workshop.

Years of deliberation and extensive consultation with stakeholders may be required before mandatory flour fortification is adopted worldwide. Three recent efforts could prove useful for countries moving toward such standards, including those of Food Standards Australia and New Zealand (FSANZ), Food Safety Authority of Ireland, and the Food Standards Agency UK on mandatory fortification of flour with folic acid [21-23]. The documents prepared as part of those deliberations are excellent sources of information for other countries considering their own programs.

Second Technical Workshop on Wheat Flour Fortification

Despite the established WHO/FAO guidelines and the specific call of experts convened in Cuernavaca, many countries where flour is fortified still use elemental iron fortificants (i.e. some forms of H-reduced iron and atomized iron) that are poorly absorbed. Also, in the past few years, consultants from different international organizations have given variable guidance and information to fortification program developers resulting in confusion and slow progress toward effective flour fortification in a number of countries.

Other challenges include recently raised concerns by a number of leading experts about the high burden of vitamin B12 deficiency in populations around the world, as well as the growing awareness and understanding of zinc nutrition, which could affect fortification goals and programs. Furthermore, while fortification of flour with vitamin A has been initiated in a few countries, questions remain about the cost of adding vitamin A to flour, as well as the stability of the vitamin A fortificant in flour and flour products.

Finally, because large populations in sub-Saharan Africa and Latin America consume maize (corn) flour products as staple foods, the organizers of this, 'Second Technical Workshop on Wheat Flour Fortification' considered it important to also provide relevant guidance related to micronutrient fortification of maize flour.

WORKSHOP OBJECTIVES - The purpose of the workshop was to provide guidance on national fortification of wheat and maize flours, milled in industrial roller mills (i.e. $\geq$ 20 metric tons (MT)/day milling capacity), with iron, zinc, folic acid, vitamin B12 and vitamin A. The guidance was to follow reviews of the latest evidence of the effectiveness of flour fortification as well as new developments in premix products and costs since the 2004 Cuernavaca meeting. The primary aim of the meeting was to develop consensus on formulations of premix based on the most common ranges of flour consumption. A secondary aim was to develop consensus around the best practices guidelines for premix manufactures and millers.

PREPARATION **-** Under the direction of the Executive Management Team (EMT) of the FFI Leaders Group and the FFI Technical Training and Support Group, the FFI Core Team established a Steering Committee for the meeting. The Steering Committee was comprised of internationally recognized nutrition scientists and a cereal chemist, representatives from UN agencies and NGOs active in flour fortification, and milling experts and staff from CDC and FFI. Expert work groups prepared technical background documents and draft recommendations on fortification of low- and high-extraction flour with iron, zinc, folic acid, vitamin A and vitamin B12 based on broad ranges of flour consumption (see Acknowledgments, page ii). The background documents served as the scientific/technical basis for discussions during the workshop.

THE WORKSHOP -The four-day workshop convened in Stone Mountain, Georgia, USA and supported by CDC, GAIN and Cargill, brought together nutrition researchers, public health experts, specialists from regulatory agencies, international development and non-governmental organizations, and representatives from the premix and milling sectors to develop consensus on "practical and feasible recommendations" for public health authorities, food regulators and the milling sector to initiate flour fortification, as well as to improve the public health benefits of existing national flour fortification programs.

The workshop included plenary presentations based on scientific/technical documents prepared by small workgroups, breakout group discussions and debates to propose recommendations, followed by a second round of plenary discussions to finalize recommendations on fortification of wheat and maize flour with iron, zinc, folic acid, vitamin B12 and vitamin A, as well as to establish best practice guidelines for millers and premix manufacturers.

THE FOLLOW-UP - FFI will provide WHO and FAO (also represented at the workshop) with the summary of the deliberations and recommendations to consider for formal adoption by UN agencies. Additionally, the technical background documents prepared for the workshop will be published as a Special Supplement of Food and Nutrition Bulletin.

General Observations from the Workshop.

The workshop deliberations affirmed that wheat and maize flour fortification:

- Increases folic acid intake by women and reduces NTDs (folic acid may also have additional public health benefits).
- Improves iron status if a sufficient level of bioavailable forms of iron is added.
- Improves zinc status if a sufficient level of zinc is added.
- Can increase vitamin A intake and improve status, but such benefits may be hindered by high fortificant cost, especially if suitable edible oil fortification options exist in countries.
- Could be a feasible approach to improve vitamin B12 status of populations.
- Should be considered when industrially produced flour is regularly consumed by large population groups in a country.
- Is only one food-based intervention and is not the only solution to eliminating micronutrient malnutrition (fortification of other appropriate food vehicles with the same and/or other nutrients should also be considered if feasible).
- While it may impact the micronutrient status of reproductive age women, fortification probably will not directly improve micronutrient status of infants and toddlers.
- Is not a “curative” intervention, but rather a preventive approach to equitably improve micronutrient status of populations over time.
- Can be expected to be most effective in achieving a public health impact if mandated at a national level.
- Will achieve optimal results when the implementation and effectiveness of the interventions are monitored.

Workshop participants also agreed that women of childbearing age are the primary target group for flour fortification programs because such women are often at risk of vitamin and mineral deficiencies, and because they consume sufficient quantities of flour to benefit nutritionally from fortification of wheat flour-based foods. Participants further agreed that decisions about which nutrients to add and the appropriate amounts to add to fortified flour should be based on a series of factors. These include: the nutritional needs and deficiencies of the population; population coverage and per capita consumption of “fortifiable” flour (i.e. the total estimated amount of flour milled by industrial roller mills, produced domestically or imported, which could principally be fortified); sensory and physical effects of the fortificant nutrients on flour and flour products; fortification of other food vehicles; population consumption of vitamin and mineral supplements; and cost. The workshop participants also acknowledged that:

- Fortified flour is more nutritious than non-fortified flour.
- Nutrients other than iron, zinc, folic acid, vitamin B12 and vitamin A also are important. During the wheat milling process, many essential vitamins and

minerals are removed. Restoration would include fortification with additional B vitamins as well as other vitamins and minerals.

- Questions remain about fortification standards and practices, and there is no single best approach to flour fortification. Programs should move forward guided by the best available knowledge and practices. National decisions are often based on compromising between fully meeting nutritional needs, and other factors such as not affecting sensory characteristics, consumer acceptance of fortified flour/flour products, and cost. Fortification recommendations need to balance public health benefit against risk, as is done with any other public health intervention program.
- Population-based dietary assessments should be encouraged in order to estimate intake distributions of potentially fortifiable food vehicles in countries that are considering fortifying staple commodities.
- Flour fortification programs should include appropriate quality assurance procedures in the mills and quality control inspections by food control and regulatory agencies, as well as public health monitoring of the nutrient content of fortified foods and assessment of the population coverage and the nutritional and health impacts of the intervention.

Specific Observations and Recommendations

I. Considerations in determining levels of vitamins and minerals to add to flour

To help determine the specific level of vitamins and minerals to add to fortified wheat or maize flour, program managers should:

- Estimate the per capita consumption of nationally produced and imported flour milled by industrial roller mills with a minimum production capacity of >20 MT/day. Such industrially produced flour is called “fortifiable” flour.
- Avoid risk of human exposure to excess levels of vitamins and minerals caused by very high consumption of fortified flour products.
- Consider potential sensory and physical effects of added nutrients on flour and flour products. Sensorial incompatibility is more common in high extraction flours, especially those coming from corn. Prior to selecting a fortification level, countries should conduct basic sensorial tests to confirm that the proposed amounts (mainly iron and zinc) are technologically compatible not only with the flour but also with the products manufactured with it.
- Understand that there is much less experience in fortifying maize flours than wheat flours. A detailed evaluation of maize flour fortification was not attempted in the Workshop. Compared to wheat flour, fortification of maize flour with iron and zinc is more likely to result in sensorial incompatibility. For iron and zinc it is not possible to combine the guidelines of fortification for wheat flour and maize flour. However, it is possible to extrapolate guidelines for wheat flour to folic acid, vitamin B-12 and vitamin A because sensorial incompatibility is uncommon with these fortificants.
- Consider the cost implications of the fortificant premix formulation.

We based our recommendations on four levels of consumption. Table 1 shows the distribution of per capita flour consumption across a number of countries using Food

Balance Sheet data from the Food and Agriculture Organization (FAO) and World Bank supported Household Income and Expenditure Survey (HIES) data [24, 25]. The recommended levels of iron, zinc, folic acid, vitamin B12 and vitamin A to be added to flour are based on these ranges of flour consumption.

Table 1. Estimated percentile distributions of per capita wheat flour intake (g/day) from the Household Income Expenditure Surveys for countries stratified by ranges of per capita wheat flour intake

	Ranges of Daily Per Capita Intake of Wheat Flour (g/day)			
Percentile of Wheat Flour Intake	<75	75-149	150-300	>300[1]
5th	7.5	15	30	60
50th	50	100	200	400
95th	150	300	600	800

1 Few countries have per capita consumption of >300 g/day

In planning a national flour fortification program, the per capita consumption of "fortifiable" flour should be estimated for each country. Approaches for estimating such consumption in a country are as follows:

- When population-based flour consumption data are available from individual dietary intake assessments (e.g. 24-hour diet recall data), use that information to estimate the distribution of individual flour intake (in g/day). Such data may be available from population-based surveys, but are difficult and costly to collect and few countries have up-to-date dietary data. Furthermore, dietary recall data do not usually distinguish between "non-fortifiable", "fortifiable" or fortified flour products. Thus, additional knowledge of the flour and flour products industries in the country should be used to interpret the national dietary data with regard to estimating individual consumption of "fortifiable" or fortified flour.
- When flour consumption data are available only at the household level, use that information to estimate the distribution of per capita flour intake per adult equivalent (in grams/day). Such household-level data may be available in many countries through recent World Bank supported Household Income and Expenditure Survey (HIES) data on household purchases, including flour and flour products. An important limitation of HIES or other household-level food expenditure data is that individual food intake is not measured. Thus, (adult equivalent) per capita consumption is roughly estimated based on age and sex of the total number of household members. Furthermore, it is assumed that commercially purchased flour and flour products are potentially "fortifiable"; the calculated per capita intake of such flour may be an overestimate depending on the profile of the flour industry in a particular country.
- When estimates of per capita flour intake are based only on national level data, such as from the FAO food balance sheets [24], use that source to estimate the average per capita "flour consumption".

- When no published data are available, estimates of “fortifiable” flour may be obtained using industry information as follows:
    - Number of mills with >20 MT/day capacity.
    - Running times of the mills, and the percent of capacity at which they operate (usually confidential industry information).
    - Flour extraction rates.
    - Estimated flour imports and exports.

  Such milling industry information can also augment any population-based flour consumption data to maximize the public health impact of flour fortification.

It is essential not to rely on national level estimates of flour consumption when not all population groups of a country are regular consumers of flour. Furthermore, in countries with large differences in geographic distribution of flour consumption, monitoring the potential impact of a “national” flour fortification program should distinguish between national and geographically specific data and information. The paucity of data giving rise to this tiered approach to rapid estimation of intake distributions underscores the need for countries to consider conducting nationally or regionally representative wheat flour intake surveys prior to scaling up national flour fortification initiatives.

II. Iron Fortification

The iron fortification workgroup focused on developing updated guidance based on a thorough review of both published efficacy and effectiveness trials of iron-fortified foods and of current wheat and maize flour fortification regulations [7]. The workgroup concluded that the “Cuernavaca recommendations” were valid, but they had not been implemented by the majority of national flour fortification programs around the world.

Workgroup members also agreed that the fortification of flour with appropriate levels of the most bioavailable forms of iron will improve the iron status of populations with very little risk of adverse effects. Efficacy studies indicate that daily consumption of 7.1 mg iron as ferrous sulfate (equivalent to 7.1 mg iron as ferrous fumarate, 4.6 mg iron as sodium-iron EDTA (NaFeEDTA) or 10 mg electrolytic iron) through fortified flour products will improve iron status in women of childbearing age. Such public health benefits could also be achieved in high extraction flours –or low-extraction flours without a yeast fermentation process – by fortifying with the same level of NaFeEDTA. Encapsulation of NaFeEDTA, ferrous sulfate and ferrous fumarate would be especially helpful in making bioavailable forms of iron compounds “fortification friendly” by eliminating the adverse sensory and physical effects of adding such iron compounds to flour. Although an encapsulated form of ferrous sulfate, which would not be separated by sieves in industrial mills, has been developed and documented to be efficacious [8 submitted to British Journal of Nutrition, submitted to British Journal of Nutrition], such products are not yet commercially available.

A review of current national flour fortification programs suggests that many programs are not effective in reducing the burden of iron deficiency because most use reduced elemental iron powders (e.g. atomized reduced and H-reduced iron) that have low bioavailability. Furthermore, in many countries, less than 80% of flour is fortified. Consequently, the iron status of only those who have regular access to fortified flour products--rather than the population as a whole--would be expected to improve. Better approaches are therefore needed to ensure that the maximum number of women has regular access to fortified flour.

Iron Recommendations

- Table 2 presents the recommended levels and types of iron fortificants based on ranges of per capita flour consumption and extraction of wheat flour.
- The preferred order of iron fortificants for wheat flour are NaFeEDTA, ferrous sulfate and ferrous fumarate. If these fortificants cannot be used, then electrolytic iron powder is the only alternative iron compound recommended provided flour consumption is high enough.
- Atomized, reduced and H-reduced elemental iron powders should NOT be used in flour/food fortification programs.
- If other forms of iron fortificants are demonstrated to be adequately bioavailable in human efficacy studies, they could be considered for flour fortification.
- Maize flour is processed into several different products, including degermed flour (the most similar to refined wheat flour), whole flour and lime-treated (nixtamalized) flour. PAHO has issued fortification guidelines for these types of maize flour (Iron compounds for food fortification: Guidelines for Latin America and the Caribbean 2002. Nutrition Reviews 2002: (11) S50-S61
- Countries currently regulating fortification of flour with iron should re-examine their standards to account for the above recommendations on the types and levels of iron fortificants and should consider per capita consumption of "fortifiable" flour when revising guidelines.
- Development of small particle size (< 150um) encapsulated NaFeEDTA, ferrous sulfate and ferrous fumarate should be encouraged to help eliminate sensory and physical effects of adding iron compounds to flour.
- Further evaluation, including human efficacy studies, of potentially less expensive forms of highly bioavailable iron fortificants, including mixtures of NaFeEDTA and other iron compounds, should be encouraged.
- Better monitoring and documentation of the biological impact of existing national flour fortification programs on iron status of relevant population groups using WHO/CDC guidelines [9] should be encouraged.
- National studies assessing consumption patterns of dietary iron, flour/flour products, and vitamin/mineral supplements should be supported.

III. Zinc Fortification

While the importance of zinc nutrition is increasingly understood and the International Zinc Nutrition Consultative Group (IZiNCG) has developed guidance on intervention programs [28], this Second Technical Workshop on Wheat Flour Fortification was the first forum for multi-sector experts and specialists to directly address zinc fortification of wheat and maize flours.

Infants and young children are believed to be at greatest risk of dietary zinc insufficiency, as are pregnant and lactating women, adolescents, and the elderly. Small-scale efficacy trials indicate that zinc fortification can increase total daily zinc consumption and the amount of absorbed zinc, both in children and adults [29].

The quantity of zinc absorbed from fortified flour depends on the amount or regularly consumed fortified flour and the levels of total dietary zinc and phytate. Recent information suggests that flour can be fortified with at least 100 mg zinc/kg flour without adverse effects on the sensory properties or acceptability of zinc-fortified flour products. While there is no evidence of clinically important adverse effects of zinc fortification on iron or copper status, questions remain about the potential effects of zinc fortification on other minerals [30].

The workshop concluded that fortification of flour with zinc should be strongly encouraged as a strategy to increase zinc intake in countries with an elevated risk of zinc deficiency, although more information is needed to confirm the effectiveness of zinc flour fortification. A number of zinc fortificants meet "Generally Recognized as Safe" (GRAS) standards, though current evidence suggests that zinc oxide is the most suitable fortificant due to its low cost and negligible effect on sensory characteristics of fortified flour and flour products.

To determine what level of zinc to add to fortified flour as a commodity food staple, the workshop relied upon simulations of estimated zinc absorption under different dietary conditions based on updated parameter estimates of the Miller equation [31, 32]. In the simulations (based on fortification of 80% to 95% extraction flour), adults were assumed to consume about 3, 5, or 7 mg of zinc per day and 0, 500, or 1,000 mg phytate per day from dietary sources other than flour.

Zinc Recommendations

- Table 2 presents the recommended levels of zinc (as zinc oxide) to add to fortified flour based on ranges of per capita flour consumption and extraction of flour, assuming 5 mg zinc intake and no additional phytate intake from other dietary sources.
- Countries currently regulating addition of zinc to fortified flour should re-examine their requirements based on the above recommendations regarding levels of zinc fortification based on per capita consumption of "fortifiable" flour.

IV. Folic Acid Fortification

It is widely recognized that adequate consumption of folic acid before pregnancy and during the early weeks of gestation protects most, but not all, fetuses from prenatal death or birth with debilitating NTD. Evidence also suggests that adequate folic acid consumption is associated with risk reduction for other types of birth defects (e.g. cardiac defects) [10, 11] and cardiovascular illness such as stroke [12].

Recommending that women take a periconceptional supplement containing 400 ug of folic acid has been the mainstay of public health measures for the primary prevention of NTD in many countries. While education campaigns can increase the use of supplements, their effectiveness is limited because the maximum level of use is usually much less than 50% and does not reach all segments of the population equally; women at highest risk of having NTD affected infants are those least likely to be taking supplements. Even in the U.S., where substantial promotion efforts have been implemented, only 30% to 35% of women of childbearing age report adhering to the daily supplementation guideline of 400 ug of folic acid [12]. In addition, because women move through their child-bearing phase within a relatively short time (just a few years),educational activities to promote the use of supplements must be designed to reach at-risk women in perpetuity.

To protect newborns from NTDs, both the U.S. and Canada mandated fortification of cereal-grain products at a level of 1.4 ppm in 1998. Soon after, Chile mandated fortification of wheat flour used for making bread with 2.2 ppm of folic acid. Currently, more than 50 countries mandate folic acid fortification of flour [13, 14]. Still, folic acid in fortified foods provide only about one-quarter of the daily recommended amount.

Clinical folate deficiency is defined as serum folate <3 ŋg/mL (~7 ŋmol/L) or red blood cell (RBC) folate <140 ŋg/mL (~300 ŋmol/L). In the only prospective study [15] of the subject to date, the lowest prevalence of NTDs was associated with a higher serum folate concentration of >7 ŋg/mL (~16 ŋmol/L) and a RBC folate concentration of >400 ŋg/mL (~900 ŋmol/L). Thus, the definition of folate deficiency in women of childbearing age should not be based solely on avoiding signs of clinically defined folate anemia, as seen with blood folate levels below the clinical laboratory cutoff (as is the case with other vitamins). Rather "sufficient" blood folate levels need to be established by experts. Currently, limited evidence suggests a serum folate concentration of 7ng/mL or higher would be sufficient to protect all women of reproductive age from having an NTD-affected pregnancy. Raising blood folate to the higher concentrations associated with maximum NTD risk reduction requires that women consume folic acid from supplements and/or fortified foods in addition to a healthy diet containing natural folate. Mandatory folic acid fortification of cereals and flours has been proven to be a low-cost and highly effective public health strategy in various countries [16].

While concerns about potential negative health consequences associated with folic acid fortification have arisen since 2004, the general view from this workshop is that most of the questions raised in recent literature on folic acid probably result from conditions where study participants received high dosages of folic acid in supplements, not levels typically found in fortified foods [17, 18]. Furthermore, it was agreed that when flour is fortified with appropriate levels of folic acid, based on appropriate estimates of per capita consumption of "fortifiable" flour, the intervention does not appear to pose a public health risk.

Folic Acid Recommendations:

The Workshop re-affirmed the "Cuernavaca recommendations" supporting national efforts for mandatory fortification of wheat and maize flour with folic acid [7]. The recommended levels of folic acid to add to flour, based on per capita consumption of flour, are presented in Table 2.

V. Vitamin B_{12} Fortification

The only dietary sources of vitamin B_{12} are animal-based food products, including meat, dairy and fish. Thus, populations with poor access to these animal source foods are at high risk of vitamin B_{12} deficiency. Even among well-nourished U.S. populations, people who reported consuming the lowest amounts of dairy and meat products, and who also did not take nutrient supplements, had low and deficient plasma vitamin B_{12} concentrations [19]. Furthermore, individuals of all ages, both male and female, are at risk of vitamin B_{12} deficiency when they have limited intake of animal source foods.

Elderly people are at special risk of vitamin B_{12} deficiency because with aging, the gastrointestinal tract may gradually lose its ability to absorb the vitamin. The primary cause of this “food-bound cobalamin malabsorption” (FCM) is loss of gastric acid resulting from gastric atrophy (often caused by chronic Helicobacter pylori infections), and subsequent inability to release vitamin B_{12} from proteins in animal source foods, although there may be multiple causes that are poorly understood [20]. In addition, populations affected by HIV/AIDS suffer from reduced vitamin B_{12} absorption, and thus require adequate daily intake of this nutrient.

The consequences of vitamin B_{12} deficiency include megaloblastic anemia (although this condition tends to be most prevalent among infants exclusively breastfed by mothers who are strict vegetarians and patients with severe B12 deficiency due to lack of intrinsic factor); neurological disorders, including sub-acute degeneration of the spinal cord; cognitive impairment, including depression; and possibly increased risk of NTDs. Previously, folic acid intake was thought to "mask" vitamin B_{12} deficiency anemia which could lead to neurological degeneration, but such concerns are no longer considered valid.

Individuals with vitamin B_{12} deficiency should take high-dose oral supplements to counteract the condition. Fortification of flour with vitamin B_{12} is intended to protect populations against becoming deficient, but there are no documented studies of the effectiveness of mass flour fortification. A pilot study in Israel [21] showed that vitamin B_{12} added to flour was stable during baking, did not affect the quality of the bread, and increased plasma B_{12} concentrations slightly within six months. Addition of vitamin B12 (9.6 ug/day) to dough before baking increased serum vitamin B_{12} by 45% in 12 weeks when given to healthy adults aged 50 to 75 years in The Netherlands [22]. However this is a larger dose than is likely to be provided through mass fortification. A study by the American Institute of Baking reported that the addition of vitamin B_{12} in quantities up to 1,000 ug/100 g flour did not impact dough handling or fermentation rates of white pan breads, nor did it produce any noticeable sensory and physical changes in the flour [23].

Vitamin B_{12} Recommendations

- Vitamin B_{12} (as cyanocobalamin) should be included in the mix of nutrients used in flour fortification. The addition levels are presented in Table 2.
- Both low- and high-extraction flour should be fortified.
- Efficacy trials to determine effective fortification levels in several locations and among subjects with different ranges of vitamin B_{12} status should be supported.
- Research on the bioavailability of vitamin B_{12} from fortified products, especially in persons with food bound cobalamin malabsorption, should be supported.
- The impact of flour fortification on vitamin B_{12} status for target populations should be monitored.

VI. Vitamin A Fortification

Vitamin A deficiency is estimated to affect at least 130 million children under age 5 and at least as many school-aged children and adolescents in the developing world. Furthermore, approximately 20 million women during pregnancy and the early phase of lactation face this public health burden [14].

Fortification of foods with vitamin A is intended to help at-risk groups whose daily requirements are not met due to inadequate intake, absorption and/or utilization of vitamin A. Fortification of margarine and milk with vitamin A has been practiced in some European countries and North America for many years, while fortification of sugar has also been shown to be effective and sustainable in a number of Latin American countries. Typical vitamin A fortification programs have sought to deliver 30% to 60% of the Recommended Dietary Allowances (RDAs) for specific target populations [45].

As with other nutrients, the biological effectiveness of vitamin A fortification depends on whether target populations consume enough of the proposed food vehicle(s). In addition, the cost of fortification must be absorbed by the marketplace. Thus, in countries where daily consumption of wheat flour is 50 g or less, adding relatively high amounts of vitamin A (i.e. 8,250 IU/kg) will only provide ~25%, 15% and 13% of the RDA for preschoolers, school-age children and women, respectively, while the cost of fortification will amount to $3.62/MT of flour. Alternately, where wheat flour consumption is high (e.g. 300 g/d among adolescents and adults), a more moderate level of vitamin A fortification (e.g. 4,950 IU/kg) will increase vitamin A intake by 53% and 45% of the RDA for adolescents and women of childbearing age, respectively, at a considerably lower cost of about $2.17/MT of flour.

The most common vitamin A fortificant for cereals is vitamin A palmitate, a dry form that is stable in flour. With addition levels of up to ~500 ug RE/kg, there is little evidence of sensory and physical changes either in the flour or in wheat-based flour products. However, baking of flour products typically results in ~30% loss of the vitamin.

Vitamin A Recommendations

- Vitamin A fortification of wheat and maize flour in commodity foods should be considered when fortification of more cost-effective food vehicles is not feasible and when the target population consumes enough flour to deliver sufficient amounts of vitamin A. Table 2 presents the fortification levels necessary to meet roughly 30% of the RDA for women of childbearing age.
- When possible, fortify multiple foods with fractions of RDA for vitamin A.

Table 2. Average levels of nutrients to consider adding to fortified flour based on extraction, fortificant compound and estimated per capita flour availability.

Nutrient	Flour Extraction Rate	Compound	Level of nutrient to be added in parts per million (ppm) by estimated average per capita wheat flour intake (g/day)[1]			
			<75[2] g/day	75-149 g/day	150-300 g/day	>300[3] g/day
Iron	≤80%	NaFeEDTA	40	40	20	15
		Sulfate/Fumarate	60	60	30	20
		Electrolytic Iron	NR[4]	NR[4]	60	40
	>80%	NaFeEDTA	40	40	20	15
Folic Acid	All	Folic Acid	5.0	2.6	1.3	1.0
Vitamin B_{12}	All	Cyancobalamin	0.04	0.02	0.01	0.008
Vitamin A	All	Vitamin A palmitate	5.9	3.0	1.5	1
Zinc[5]	80%	Zinc Oxide	95	55	40	30
	95%	Zinc Oxide	100	100	80	70

1 These levels consider only wheat flour as main fortification vehicle in a public health program. For maize flour programs, levels can be extrapolated to folic acid, B_{12}, and vitamin A, but not iron and zinc. If other mass-fortification programs with other food vehicles are implemented effectively, these suggested fortification levels may need to be adjusted accordingly.

2 Per capital intake of <75 g/day does not allow for addition of sufficient level of fortification to cover micronutrient needs for women of childbearing age. Fortification of additional food vehicles and other interventions should be considered.

3 Few countries have per capita consumption of >300 g/day.

4 NR = Not Recommended because very high levels of electrolytic iron needed could negatively affect sensory properties of fortified flour.

5 These are the recommended amounts of zinc fortification assumes 5 mg zinc intake and no additional phytate intake from other dietary sources.

VII. Premix Manufacturers' Best Practices Guidelines

The Premix Manufacturers Best Practices Document has been developed to provide fortification stakeholders in countries with the guidelines for premix production. This will ensure that flour fortification premixes are produced to meet government regulations and standards for premixes (where applicable). When added to flour, the premixes will provide micronutrients to meet national fortification regulations and standards.

Following several rounds of comments before the Workshop, the document was presented to, and discussed and endorsed by, the participants and can be obtained through the FFI website [16].

VIII. Millers' Best Practices Guidelines

The Millers Best Practices Document was developed to provide milling companies that fortify flour with minimum and best guidelines for milling practices. The document was circulated to milling organizations and milling schools in different parts of the world for comments and revisions.

Following several rounds of comments before the workshop, the document was presented and then discussed and endorsed by the participants. The document can be obtained through the FFI website [16].

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List of Abbreviations

ADB	Asian Development Bank
CDC	Centers for Disease Control and Prevention
EMRO	Regional Office for the Eastern Mediterranean
EMT	Executive Management Team
FAO	Food and Agriculture Association
FFI	Flour Fortification Initiative
FCC	Food and Chemical Codex
GAIN	Global Alliance for Improved Nutrition
GRAS	Generally Recognized as Safe
HIES	Household Income and Expenditure Survey
IGC	International Grains Council
IAOM	International Association of Operative Millers
IDPAS	Iron Deficiency Project Advisory Service
INF	International Nutrition Foundation
IZiNCG	International Zinc Nutrition Consultative Group
FSANZ	Food Standards Australia and New Zealand
MI	Micronutrient Initiative
MOD	March of Dimes
MT	Metric tons
NIH	United States National Institutes of Health
NGOs	Non-Governmental Organizations
NTD	Neural Tube Defect
PAHO	Pan American Health Organization
QA/QC	Quality Assurance and Quality Control
RDA	Recommended Dietary Allowance
RBV	Relative Biological Value
USAID	United States Agency for International Development
UC	University of California
UN	United Nations
UNICEF	United Nations Children's Fund
USDA	United States Department of Agriculture
WB	World Bank
WHO	World Health Organization
WFP	World Food Program

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