

UNICEF / WHO / FFI  
Meeting on Implementation  
in Asia of the Recommendations  
on Wheat Flour Fortification



Manila, Philippines  
10 – 12 November 2009



Meeting Report

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## **REPORT**

### **UNICEF/WHO/FFI MEETING ON IMPLEMENTATION IN ASIA OF THE RECOMMENDATIONS ON WHEAT FLOUR FORTIFICATION**

Convened by:

**FLOUR FORTIFICATION INITIATIVE  
UNITED NATIONS CHILDREN'S FUND  
WORLD HEALTH ORGANIZATION**

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## **NOTE**

The views expressed in this report are those of the participants in the UNICEF/WHO/FFI Meeting on Implementation in Asia of the Recommendations on Wheat Flour Fortification and do not necessarily reflect the policies of the Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the UNICEF/WHO/FFI Meeting on Implementation in Asia of the Recommendations on Wheat Flour Fortification, which was held in Manila, Philippines from 10 to 12 November 2009.

## SUMMARY

Vitamin and mineral deficiencies affect not only the overall health of individuals, but also learning abilities, productivity, and overall social and economic development, therefore, constraining progress towards the achievement of the Millennium Development Goals. Food fortification in general, and flour fortification in particular, is one among several strategies that form a comprehensive and holistic approach to enhance nutrition and health by improving micronutrient status. Flour fortification has been implemented successfully and sustainably in several countries for more than 60 years; however, national standards for what micronutrients to add, which compounds are most effective, and how much to add vary widely. In April 2008, the Flour Fortification Initiative (FFI) and United States Centers for Disease Control and Prevention (CDC) organized an international meeting of nearly 100 leading nutrition, pharmaceutical and cereal scientists and milling experts from the public and private sectors to develop practical recommendations for flour fortification. Based on these findings, the World Health Organization (WHO), United Nations Food and Agriculture Organization (FAO), United Nations Children's Fund (UNICEF), Global Alliance for Improved Nutrition (GAIN), Micronutrient Initiative (MI) and Flour Fortification Initiative (FFI) released an interim consensus statement on the recommendations of the wheat and maize flour fortification meeting report. These recommendations are commonly known as the *WHO Recommendations on Wheat and Maize Flour Fortification*.

To capitalize on this new opportunity, WHO, UNICEF and FFI organized a regional meeting to disseminate the global recommendations among key stakeholders, clarify issues and support the implementation of these recommendations in the context of existing and planned flour fortification programmes in Asian countries. Eight countries were invited to attend the meeting, namely: China, India, Indonesia, Malaysia, Mongolia, the Philippines, Sri Lanka and Viet Nam. These countries have ongoing mandatory flour fortification programmes or have expressed an interest in establishing national programmes.

The objectives of the meeting were:

- (1) to inform policy-makers and millers about the new recommendations on wheat flour fortification and of the implications of these recommendations on premix costs, flour product properties and trade;
- (2) to outline steps for national adoption of the recommendations, in developing or revising national flour fortification programmes; and
- (3) to identify national and regional approaches to improve the effectiveness of national fortification programmes.

The WHO recommendations clarify and inform decisions about what compounds are most effective and about appropriate levels to achieve significant public health impact. While the recommendations are global, they recognize that fortification standards “should be viewed in the context of each country’s situation.” A major criterion for selection of fortificant compound as well as level of fortification is “the usual consumption profile of fortifiable flour (i.e. the total estimated amount of flour milled by industrial roller mills, produced domestically or imported, which could, in principle, be fortified).” In addition, the WHO recommendations stress that beyond developing a fortification profile appropriate to consumption levels, effective programmes “should include appropriate Quality Assurance and Quality Control (QA/QC) programs at mills as well as regulatory and public health monitoring of the nutrient content of fortified foods and assessment of the nutritional/health impacts of the fortification strategies.

A review of the background and supporting evidence for each of the five key micronutrients included in the WHO recommendations was presented to this regional meeting by international experts. The meeting then considered the implications of adopting the WHO recommendations. A report was presented on a series of studies undertaken in China, India, Indonesia, Malaysia, the Philippines, and Sri Lanka to see if Asian food products could be made with flour fortified as per the WHO recommendations. The study showed that the fortified foods had acceptable sensory properties and were similar to those made with non-fortified flour. Attending premix suppliers led a panel discussion to elaborate and answer outstanding questions on financing and supply issues resulting from the WHO recommendations. The industry representatives felt that the compounds and levels recommended by WHO would have no negative interaction among nutrients – either in the premix or in the flour products – and would not impact the logistics and supply of premix. In some cases, the recommended levels and compounds may marginally increase the current cost of flour fortification. Overall, millers from throughout the region stressed their support of flour fortification and the new WHO recommendations.

The meeting then discussed how to apply the recommendations in the attending countries, including considerations for writing national standards and how to calculate flour consumption and potential impacts of flour fortification. The WHO recommendations prescribe that, as the amount of flour consumed by a population increases, the amount of nutrients added decrease proportionately, to avoid excessive consumption of some micronutrients. Calculations undertaken in the meeting concluded that flour fortified with ferrous salts (sulphate or fumarate) at WHO-recommended levels would provide one to two thirds of WHO estimated average requirements (EAR) for iron (with consumption of 75–450 grams per day), and flour fortified with vitamin A and folic acid would provide approximately 30% to 100% of WHO EAR (with consumption of 25–450 grams per day). Principles of quality assurance and methods of monitoring and evaluating the process and impact of flour fortification were also discussed. It was recognized that data on the impact of large-scale fortification programmes are lacking and significantly more effort is needed to monitor and evaluate national programmes.

In the concluding session of the meeting, country teams undertook a rough assessment of flour consumption levels, using available data, and calculated the potential impact of flour fortification on nutrient intake if the WHO recommendations were adopted. They then discussed potential fortification levels and how existing standards might need to be changed. Cost implications of these changes were also calculated. Overall, all countries felt that adoption of the WHO recommendations would be possible and advantageous. The meeting also re-affirmed the importance of strong private and public sector collaboration if flour fortification is to be implemented successfully. Private sector partners at the meeting demonstrated their commitment to flour fortification and their wish to engage in stakeholder collaboration.

## 1. INTRODUCTION

A UNICEF/WHO/FFI Meeting on Implementation in Asia of the Recommendations on Wheat Flour Fortification was held in Manila, Philippines from 10 to 12 November 2009. The three-day meeting brought together more than 60 stakeholders, including policy-makers responsible for health, nutrition and food regulation, representatives of the food industry, fortification technology suppliers and other international experts to review the content and implications of the WHO recommendations on flour fortification as well as to consider how best to apply them in the national health, industrial and political environments.

### 1.1 Background

Vitamin and mineral deficiencies affect not only the overall health of individuals, but also learning abilities, productivity, and overall social and economic development, therefore, constraining progress towards the achievement of the Millennium Development Goals (MDGs) by the countries. Fortification of staple foods with micronutrients, when appropriately implemented, is an effective, simple and inexpensive strategy for supplying vitamins and minerals to large segments of the world's population (Annex 1 - Opening remarks by UNICEF). Fortification programmes are expected to be most effective in achieving a public health impact if mandated at the national level (Annex 2 - Opening remarks by WHO).

Flour fortification is one strategy among many that form a comprehensive and holistic approach to enhance nutrition and health by improving micronutrient status. For flour fortification to have the expected impact, the strategy must be based on clear, feasible and evidence-based standards and supported by enabling public policies. Flour fortification has been implemented successfully and sustainably in several countries for more than 60 years; however, national standards for what micronutrients to add, how much to add and which compounds are most effective vary widely.

Currently, 59 countries mandate fortification of one or more types of flour with iron and/or folic acid.<sup>1</sup> Several countries report reductions in the prevalence of neural tube defects (NTDs) as a result of fortifying flour with folic acid.<sup>2</sup> However, an analysis of the expected impact of the fortification of flour with iron estimated that only 9 out of the 78 existing wheat flour fortification programmes<sup>3</sup> would likely have significant positive effects on the iron status at the national level. The authors argued that the main reasons for this were the prevailing use of low-bioavailable iron fortificants, inadequate fortification levels, poor coverage, and/or low flour consumption.<sup>4</sup> In addition, questions about the impact and feasibility of wheat flour fortification with other vitamins and minerals remain unanswered. These ambiguities have hampered the

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<sup>1</sup> Flour Fortification Initiative (<http://www.sph.emory.edu/wheatflour/effects.php>).

<sup>2</sup> Canfield et al. *Birth Defects Res A Clin Mol Teratol*, 2005 (USA, 1995–2000); Mathews et al. *MMWR Recomm*, 2002 (USA, 1991–2001); Liu et al. *BMC Pregnancy Childbirth*, 2004 (Canada, Newfoundland, 1991–2001); De Wals et al. *Birth Defects Res Part A Clin Mol Teratol*, 2003 (Canada, Quebec, 1992–2000); Persad et al. *CMAJ*, 2002 (Canada, Ontario, 1994–2000); Gucciardi et al. *CMAJ*, 2002 (Canada, Nova Scotia, 1991–2000; Ray et al. *Lancet*, 2002 (Chile, 1990–2002); Lopez-Camelo et al. *Am J Med Genet*, 2005 (Chile, 1999–2002; Hertrampf et al. *Nutr Rev*, 2004 (Costa Rica, 1996–2000; Chen et al. *Nutr Rev*, 2004; Sayed et al. *Birth Defects Research*, 2008 (South Africa).

<sup>3</sup> These include both voluntary and mandatory programmes for iron fortification. The 59 programmes mentioned above refer only to mandatory programmes for fortification with either iron and/or folic acid.

<sup>4</sup> Hurrell et al. Revised recommendations for the iron fortification of wheat flour and an evaluation of the expected impact of current national wheat flour fortification programs. *Food and Nutrition Bulletin*, 2010, 31(1):S7–S21.

expansion of this effective and affordable technology to developing countries where micronutrient deficiencies are widespread.

The Flour Fortification Initiative (FFI) and United States Centers for Disease Control and Prevention (CDC) organized an international meeting of nearly 100 leading nutrition, pharmaceutical and cereal scientists and milling experts from the public and private sectors in April 2008. Participants developed practical recommendations for the levels of five micronutrients to add to wheat and maize flour milled in industrial roller mills (i.e. >20 tonnes/day milling capacity). The nutrients they considered were iron, zinc, folic acid, vitamin B<sub>12</sub> and vitamin A.<sup>5</sup> Based on these findings, the World Health Organization (WHO), United Nations Food and Agriculture Organization (FAO), United Nations Children's Fund (UNICEF), Global Alliance for Improved Nutrition (GAIN), Micronutrient Initiative (MI) and Flour Fortification Initiative (FFI) released an interim consensus statement on the recommendations of the wheat and maize flour fortification meeting report.<sup>6</sup> While the statement reflects the position of multiple organizations, it is commonly referred to as the “WHO Recommendations”. The background deliberations and supporting documents have been published in the March 2010 supplement of *The Food and Nutrition Bulletin*.

These officially sanctioned global flour fortification recommendations represent a tremendous effort of scientists, academics, United Nations agencies, regulatory officials, private sector representatives and other international organizations. Together, these stakeholders retrieved and summarized the evidence, debated the science, and recommended appropriate and effective levels of vitamins and minerals to add to flour (Annex 3 - Opening Remarks by FFI). The success of this process will ultimately be measured by the extent to which these recommendations are translated into effective flour fortification standards and sustained national programs which ultimately reduce vitamin and mineral deficiencies.

To capitalize on this new opportunity, WHO, UNICEF and FFI<sup>7</sup> organized a regional meeting to disseminate the global recommendations among key stakeholders, clarify issues and support the implementation of these recommendations in the context of existing and planned flour fortification programmes in Asian countries. Eight countries—China, India, Indonesia, Malaysia, Mongolia, the Philippines, Sri Lanka and Viet Nam—were invited to attend the meeting. These countries have ongoing mandatory flour fortification programmes or have expressed an interest in establishing national programmes. They are, therefore, all receiving support from FFI and are part of the FFI East Asia Leaders Group or India Flour Fortification Network.

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<sup>5</sup> Second Technical Workshop on Wheat Flour Fortification: Practical Recommendations for National Application. 30 March to 3 April 2008, Stone Mountain, Georgia, USA. Organized by the Flour Fortification Initiative.

<sup>6</sup> WHO, FAO, UNICEF, GAIN, MI and FFI. *Recommendations on Wheat and Maize Flour Fortification. Meeting Report: Interim Consensus Statement*. Geneva, World Health Organization, 2009 ([http://www.who.int/nutrition/publications/micronutrients/wheat\\_maize\\_fort.pdf](http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fort.pdf)).

<sup>7</sup> The WHO Regional Office for the Western Pacific hosted the meeting and funded related costs. The three organizations shared the costs of participants and facilitators. The majority of FFI funding for this workshop was provided by the Australian Agency for International Development (AusAID) through the Centre of Health Innovation and Partnership (CHIP) of the Sydney West Area Health Service.

## 1.2 Objectives

- (1) To inform policy-makers and millers about the new recommendations on wheat flour fortification and of the implications of these recommendations on premix costs, flour product properties and trade.
- (2) To outline steps for national adoption of the recommendations, in developing or revising national flour fortification programmes.
- (3) To identify national and regional approaches to improve the effectiveness of national fortification programmes.

The mix of representatives from the public and private sectors, including policy-makers, scientific institutions, premix producers and millers, and international and national partners, provided an opportunity to ask questions and seek answers from a variety of perspectives. It was clear that each sector has a role to play and working together will be the key to achieving a successful programme. The exchange of experiences, views and discussions on multisectoral roles and responsibilities helped identify next steps to implement the global recommendations and to further improve national flour fortification programmes.

## 2. PROCEEDINGS

### 2.1 Introduction of flour fortification

Globally, more than 600 million tonnes of wheat and maize flours are milled annually by commercial roller mills and consumed as noodles, breads, pasta and other flour products. Fortification of this food vehicle with crucial vitamins and minerals represents an enormous opportunity to improve health, prevent disease and optimize the productivity of adults and development of young children. In Asia, where consumption of flour products continues to rise (particularly in the form of instant noodles), fortified flour is becoming increasingly available (Presentation – Flour Fortification in the Region). As stated in the *Recommendations on Wheat and Maize Flour Fortification Meeting Report: Interim Consensus Statement*: “Fortification of industrially processed wheat and maize flour, when appropriately implemented, is an effective, simple, and inexpensive strategy for supplying vitamins and minerals to the diets of large segments of the world’s population.”<sup>6</sup> A number of efficacy studies undertaken in China have demonstrated improvements in anaemia, in particular with fortification by NaFeEDTA and ferrous fumarate or sulphate. China has also demonstrated reductions in neural tube defects due to consumption of fortified wheat flour by women of reproductive age (Presentation – Results of Efficacy Trials in China). These results echo numerous other efficacy studies conducted globally. There is a lack of evidence of anaemia reduction as a result of large-scale or national programmes, and countries are encouraged to improve monitoring and evaluation of large-scale programmes.

### 2.2 Presentation of the new WHO recommendations

Since the publication of its *Guidelines on Food Fortification with Micronutrients*, WHO has recognized that while “fortification of widely distributed and consumed foods has the potential to improve the nutritional status of a large proportion of the population, ... technological issues to food fortification need to be fully resolved especially with regards to appropriate levels of nutrients, stability of fortificant, nutrient interactions, physical properties

and acceptability by consumers.”<sup>8</sup> Focusing on five key vitamins and minerals (iron, zinc, folic acid, vitamin A and B<sub>12</sub>), the updated WHO recommendations are an effort to resolve these technical issues and communicate them in a clear and understandable format which addresses the needs of policy-makers, public health officials, regulators as well as millers and related industries.

The WHO recommendations clarify and inform decisions about what compounds are most effective and about appropriate levels to achieve significant public health impact. While the recommendations are global, they recognize that fortification standards “should be viewed in the context of each country’s situation.”<sup>6</sup> This includes refinement or extraction rate of flour, which limits the body’s absorption of minerals like zinc and iron. Consumer acceptance factors, such as sensory and physical effects on flour and flour products and cost, were considered. According to the WHO recommendations, a major criterion for selection of fortificant compound as well as level of fortification is “the usual consumption profile of fortifiable flour (i.e. the total estimated amount of flour milled by industrial roller mills, produced domestically or imported, which could, in principle, be fortified).”<sup>6</sup> Therefore, based on available data from the Food Balance Sheets of FAO and World Bank-supported Household Income and Expenditure Surveys (HIES), the WHO recommendations for nutrients, compounds and levels of fortification are segmented into categories of average per capita wheat flour consumption, namely: >300 grams per day, 150–300 grams per day, 75–150 grams per day and <75 grams per day. The WHO recommendations prescribe that, as the amount of flour consumed by a population increases, the amount of nutrients added decrease proportionately, to avoid excessive consumption of some micronutrients. See table below.



Nutrient	Flour Extraction Rate	Compound	Level of nutrient to be added in parts per million (ppm) by estimated average per capita wheat flour availability (g/day) <sup>1</sup>			
			<75 <sup>2</sup> g/day	75-149 g/day	150-300 g/day	>300 g/day
Iron	Low	NaFeEDTA	40	40	20	15
		Ferrous Sulfate	60	60	30	20
		Ferrous Fumarate	60	60	30	20
		Electrolytic Iron	NR <sup>3</sup>	NR <sup>3</sup>	60	40
	High	NaFeEDTA	40	40	20	15
Folic Acid	Low or High	Folic Acid	5.0	2.6	1.3	1.0
Vitamin B <sub>12</sub>	Low or High	Cyanocobalamin	0.04	0.02	0.01	0.008
Vitamin A	Low or High	Vitamin A Palmitate	5.9	3	1.5	1
Zinc <sup>4</sup>	Low	Zinc Oxide	95	55	40	30
	High	Zinc Oxide	100	100	80	70

<sup>8</sup> *Guidelines on Food Fortification with Micronutrients*. Geneva, WHO/FAO, 2006.

WHO recommends that “Countries should re-examine standards on the types and levels of iron fortificants and should consider per capita consumption of ‘fortifiable’ flour when revising guidelines.” In addition, the WHO recommendations stress that beyond developing a fortification profile appropriate to consumption levels, effective programmes “should include appropriate Quality Assurance and Quality Control (QA/QC) programs at mills as well as regulatory and public health monitoring of the nutrient content of fortified foods and assessment of the nutritional/health impacts of the fortification strategies.”<sup>6</sup>

A review of the background and supporting evidence for each of the five key micronutrients included in the WHO *Recommendations on Wheat and Maize Flour Fortification* was provided to the UNICEF/WHO/FFI Meeting on the Implementation in Asia of the Recommendations on Wheat Flour Fortification by international experts and is summarized below.

#### 2.2.1 Recommendations for folic acid fortification of wheat flour and maize meal

WHO recognizes that fortifying wheat and maize flour with folic acid increases the intake of folate by women and can reduce the risk of neural tube and other birth defects. “Well conducted studies from the United States, Canada, and Chile have documented decreases of 26%, 42%, and 40%, respectively, in the rate of neural tube defects (NTD) affected births after implementation of national regulations mandating wheat flour fortification with folic acid.”<sup>6</sup> Concerns about the safety of folic acid fortification were addressed. New data from the United States (which currently has mandatory flour fortification, voluntary fortification of several foods such as ready-to-eat breakfast cereals, and widespread supplement use) indicate that only 2.7% of the total population currently exceeds the upper level<sup>9</sup> for folic acid. The data also demonstrate that upper levels were only reached in groups consuming folic acid-containing supplements with more than 400 micrograms. Australia, New Zealand, the United Kingdom, Ireland and the Netherlands have all thoroughly reviewed data on the safety of flour fortification with folic acid and found it to be safe. It was also emphasized that existing studies which suggest increased risk, for example of cancer, have seldom randomized the consumption of folic acid; when use of folic acid is not randomized, then the comparison is likely between supplement users and non-supplement users, which makes such studies difficult to interpret. Finally, detailed analysis of recent ecological studies from Chile and the United States of the purported association between the incidence of colorectal cancer and the introduction of mandatory folic acid fortification programmes in those countries was presented and it was illustrated why this association is unlikely to be true.

#### 2.2.2 Recommendations for vitamin B<sub>12</sub> fortification of wheat flour and maize meal

While data on actual prevalence of vitamin B<sub>12</sub> deficiency in developing countries are scarce, it is widely known that 40%–80% of people with low intake of animal foods are deficient in vitamin B<sub>12</sub> because animal foods are the only source of this critical micronutrient.<sup>10</sup> Since

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<sup>9</sup> According to the Institute of Medicine (2000), the upper level is the “maximum daily intake level at which no risk of adverse health effects is expected for almost all individuals in the general population, including sensitive individuals when the nutrient is consumed over long periods of time.” Thus, the upper level (UL) is a tolerable (safe) level that is set in order to ensure that no one in the population exceeds the lowest observed adverse effect level (LOAEL). In 1998, the Institute of Medicine determined that for the population of the United States, the LOAEL for consumption of folic acid was 5000 µg/day among those adults with pernicious anaemia. The IOM divided the LOAEL by 5 to create a UL of 1000 µg/day for the adult US population.

<sup>10</sup> McLean E, de Benoist B, Allen LH. Review of the magnitude of folate and vitamin B<sub>12</sub> deficiencies worldwide. *Food Nutrition Bulletin*, 2008, 29:S38–S51.

animal foods are relatively expensive and typically not affordable on a regular basis to the majority of populations in developing countries, the deficiency is considered to be widespread. Although not widely practised, there are no technological constraints to adding vitamin B<sub>12</sub> to wheat flour—including vitamin stability, product quality and other parameters. While the cost is relatively high compared to other micronutrients commonly used in fortification, the ultimate cost of delivering the full estimated average requirements (EAR) of 2 micrograms (mg) of vitamin B<sub>12</sub> daily is very affordable. While “evidence is still lacking about the population impact of fortification of wheat flour with B<sub>12</sub>,” fortified flour has been “shown to increase plasma B<sub>12</sub> concentrations slightly within six months.”

### 2.2.3 Recommendations for vitamin A fortification of wheat flour and maize meal

Vitamin A deficiency (VAD) is a major global public health problem threatening the health and survival of an estimated 190 million preschool children. Since VAD is largely due to chronic dietary insufficiency of preformed vitamin A and proactive carotenoids, food fortification can offer an effective approach to prevention. While there is no published effectiveness data on a national-scale programme, two published efficacy trials from the Philippines and Bangladesh have reported the impact of vitamin A fortification of wheat flour on vitamin A nutritional status. WHO believes that “Wheat and, more broadly, other cereal grain flour (e.g. maize) can be considered as a vehicle for delivery of vitamin A to populations at risk of vitamin A deficiency.”<sup>10</sup> Although vitamin A is most often used in the fortification of oils and fats, currently 11 countries are fortifying or proposing to fortify wheat and/or maize flour with vitamin A. Factors to guide a decision to fortify flour with vitamin A include extent of deficiency, availability of other food vehicle options, the centrality of milling, market reach and population intake and distributions of the flour products, and associated costs.

### 2.2.4 Recommendations for iron fortification of wheat flour and maize meal

Anaemia and iron deficiency are associated with a range of negative outcomes including inadequate growth, impaired immunity, suboptimal cognitive development, maternal and perinatal mortality as well as adult work productivity in a range of environments. Based on an analysis of 24 studies, WHO concluded that “fortification of flour with appropriate levels of the most bioavailable forms of iron can improve the iron status of populations with very little risk of adverse effects” and that a highly efficacious programme may “decrease iron deficiency to <10% and iron deficiency anaemia to <5% over a period of 2–3 years.”<sup>4</sup> Successful programmes should ensure daily iron consumption of 7.1 mg/day as ferrous sulphate or fumarate, equivalent to 4.6 mg/day as NaFeEDTA or 10 mg/day electrolytic iron. Only these four iron compounds are considered effective and the WHO recommendations define consumption levels and flour extraction rates appropriate for each of these compounds. WHO found that fortification programmes that did not reduce the burden of iron deficiency “use reduced elemental iron powders with low bioavailability,” and cautioned that “atomized, reduced and H-reduced elemental iron powders should NOT be used in flour/food fortification programmes.”<sup>4</sup> WHO believes that iron fortification is safe as well as effective because “physiological mechanisms exist to maintain iron balance.”<sup>4,11</sup>

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<sup>11</sup> In rare cases where genetic conditions cause potential systemic iron overload due to alteration of this physiological mechanism, even non-fortified diets pose significant threats to health and these disorders should be treated and screened.

### 2.2.5 Recommendations for zinc fortification of wheat flour and maize meal

Adequate zinc nutrition is necessary for optimal child health and physical growth and normal pregnancy outcomes. After a systematic review of the scientific literature and application of an existing prediction equation to estimate zinc absorption, WHO concluded that zinc intake and absorption are increased when zinc-fortified foods are consumed, and that zinc fortification of cereal flour is a safe and appropriate strategy for enhancing the zinc status of population sub-groups who consume adequate amounts of fortified cereal flour.<sup>12</sup> While there is little information available on the biological impact of large-scale fortification programmes, studies suggest that there are no disadvantages of the recommended ranges of zinc fortification with regard to the sensory properties of zinc-fortified foods, and most research indicates that there are no adverse effects of zinc fortification on the utilization of other minerals.

### 2.2.6 Recommendations for other micronutrients

Other key micronutrients, which are not included in the WHO recommendations, are being added to flour in several countries to meet both voluntary and mandatory flour fortification standards. The most common vitamins being added are thiamine (vitamin B<sub>1</sub>), riboflavin (vitamin B<sub>2</sub>) and niacin (vitamin B<sub>3</sub>). They are typically added at levels to restore nutrients found in whole grain wheat and maize. In North America, these vitamins have been added since the 1930s when deficiencies were noted in the general population. Vitamin D<sub>3</sub> can also be added to flour in powder form. Calcium is added to low extraction flour at what is called “restoration levels” (restoring the calcium level to that of the whole grain). At these levels, the potential adverse impact on iron and zinc absorption in fortified flour is insignificant.<sup>13</sup> Calcium addition is mandatory in the United Kingdom for wheat flour and voluntary in North America. Canada has a voluntary standard for magnesium but it is not widely used.

## 2.3 Implications of adoption of the WHO recommendations

### 2.3.1 Impact on Asian food products

A key success criterion for food fortification programmes is that the added fortificants do not cause product changes, including taste, texture, colour, smell and other organoleptic features. In order to test whether the new WHO recommendations could be successfully used to produce foods commonly consumed in Asian countries, a series of studies were carried out in China, India, Indonesia, Malaysia, the Philippines and Sri Lanka between August and October 2009. The studies were coordinated by FFI in collaboration with national teams, and Mühlenchemie and Hexagon Nutrition (P) Ltd donated the premix used.

Participating institutions, including government nutrition and technology institutions and private food manufactures, prepared fortified flour as per the WHO recommendations and used it to make a range of commonly eaten products. Tests were run to assess impact on processing factors, sensory and physical attributes and, where feasible, retention of the nutrients. Some small but acceptable changes in sensory characteristics and colour were noted in several products. Overall, results of the study showed that the fortified foods had acceptable sensory properties and are similar to those made with non-fortified flour.

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<sup>12</sup> Brown KH, Hambidge KM, Ranum P, Tyler V. and the Zinc Fortification Working Group. Zinc fortification of cereal flours: current recommendations and research needs. *Food and Nutrition Bulletin*, 2010, 31(1 Suppl):S62–S74.

<sup>13</sup> Bauernfiend JC and Lachance PA, eds. *Nutrient additions to foods: nutritional, technological and regulatory aspects*. Turbull, CT, Food and Nutrition Press, 1991.

### 2.3.2 Implications for cost and procurement of premix

All UNICEF-approved premix suppliers were invited to the meeting. Those who attended led a panel discussion to answer outstanding questions on financing and supply issues resulting from the WHO recommendations. The industry representatives felt that the compounds and levels recommended by WHO would have no negative interaction among nutrients either in the premix or in the flour products—and would not impact the logistics and supply of premix. In some cases, the recommended levels and compounds may marginally increase the cost of flour fortification. Even though the benefit is high and the cost per person low, the overall financial outlays for millers may be perceived as significant. The premix suppliers stressed that within the context of the WHO recommendations, they would continue to provide analytical services including certifications of premix quality and levels of fortificants. Moreover, on a case by case basis, premix suppliers could provide training, including assistance in establishing laboratories, operation of equipment like High Performance Liquid Chromatography (HPLC) and proper use of rapid test kits.

The GAIN premix facility (GPF) is a centralized procurement and certification facility that enables national programmes as well as individual millers to access large and small orders of premix from prequalified suppliers at competitive prices and credit terms. The GPF has prequalified group of premix suppliers and vitamin and mineral manufacturers based on defined quality standards. Premix suppliers are required to source vitamins and minerals from approved manufacturers only, guaranteeing the integrity of the supply chain from the point of raw material manufacture to the point of delivery. Each premix order is subject to competitive bidding among the approved premix suppliers. Millers, private sector food producers, NGOs and government agencies benefit from the lower costs and quality outcomes for their own projects. It is open to all organizations fortifying foods and is not restricted only to GAIN-supported projects.

### 2.3.3 Implications of flour fortification for flour millers

Overall, millers from throughout the region stressed their support for flour fortification and the new WHO recommendations. They indicated, however, that implementation of the new recommendations would require a thorough review and fuller understanding of the cost implications, including initial financial outlays by the mills as well as eventual price rises at the consumer level. This would require careful and thoughtful communications and dialogue among all stakeholders. Nevertheless, the discussions among millers suggested that the premix cost remains a minor issue compared to overall issues of implementation, including the quality of public-private sector collaboration. Issues discussed included the following:

- (1) need for national data to show benefits of their efforts in fortification;
- (2) insufficient investment in monitoring and enforcement to ensure a level playing field for responsible producers;
- (3) alternative staples may deliver specific micronutrients like vitamin A more cost effectively and should be considered; and
- (4) greater attention to potential challenges of non-fortified imports and international trade obligations under the World Trade Organization (WTO).

## 2.4 Application of the WHO recommendations to countries and regions

### 2.4.1 Considerations in writing national standards based on WHO recommendations

The WHO recommendations indicate average levels of nutrients to be added to flour in order to achieve an optimal public health impact. These levels represent added nutrition delivered to the consumer and are not the same as flour product standards. Fortified flour includes both micronutrients added through fortification as well as those naturally present in the non-fortified flour. The level of micronutrients found in non-fortified flour varies according to the extraction rate—the degree of refinement of the flour. Therefore, establishing clear and enforceable national fortification standards needs to be based on overall vitamin and mineral content of the flour. In writing national standards for fortified flour, countries should consider the following:

- (1) Codex standard guidance on flour should be incorporated;
- (2) minimum-level standards should be established;
- (3) maximum levels may be prescribed but should not be necessary with good manufacturing practices (GMP); and
- (4) tolerances or deviations may also be prescribed.

Standards established should be enforceable by government authorities based on sampling and analytical testing of micronutrients in the flour. However, as governments place greater responsibility on businesses to ensure the safety and quality of food, process standards may be a cost-effective option. These process standards would require millers to identify, monitor and record their fortification process controls and compliance—and these could be integrated with quality assurance and Hazard Analysis Critical Control Point (HACCP) systems requirements.<sup>14</sup> In addition, advantages of establishing parallel standards for the fortification of premix include:

- (1) easier measuring of higher concentrations of nutrients;
- (2) regulators and millers empowered to require certification of quality premix;
- (3) a level playing field on which premix suppliers can transparently compete on quality as well as price.

### 2.4.2 Considerations in calculating flour consumption in a country

Added intake of micronutrients from flour fortification is determined by the level of fortificant added to flour as well as by the level of individual flour consumption. The WHO recommendations are therefore indicated for four categories of average flour consumption. These categories range from less than 75 grams per day, representing a pack of noodles or a thick slice of bread, to more than 300 grams a day, suggesting flour products are an essential staple food and part of every meal. Scenarios based on flour fortification at WHO-recommended levels

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<sup>14</sup> Hazard Analysis and Critical Control Point (HACCP) is a systematic preventive approach to food safety and pharmaceutical safety that addresses physical, chemical, and biological hazards as a means of prevention rather than finished product inspection. HACCP is used in the food industry to identify potential food safety hazards, so that key actions, known as Critical Control Points (CCPs) can be taken to reduce or eliminate the risk of the hazards being realized. The system is used at all stages of food production and preparation processes including packaging, distribution, etc. Source: [http://en.wikipedia.org/wiki/Hazard\\_Analysis\\_and\\_Critical\\_Control\\_Points](http://en.wikipedia.org/wiki/Hazard_Analysis_and_Critical_Control_Points)

were presented for the various categories and summarized in the table below.<sup>15</sup> For vitamin A and folic acid, consumption of fortified flour ranging from 25 grams to 450 grams would provide from 30% to 100% or more of WHO estimated average requirements (EAR). For iron, fortification with ferrous salts (sulphate or fumarate) at WHO-recommended levels would provide one to two thirds of WHO EAR with consumption of 75 grams per day or more.

	Individual consumption	Added level	Retention level	Nutrient added to daily intake		Nutrition protection for adult women % WHO EAR		WHO EAR for adult woman
	grams/day	Ppm	%	Low range Units/day	High range Units/day	Low range % WHO EAR	High range % WHO EAR	Unit/day
<b>Iron</b> mg/day	25–74	60	99%	1.5	4.4	11%	33%	8.9, 13.4, 26.8 ug/day for high, mid and low bioavailability
	75–149	60	99%	4.5	8.9	34%	66%	
	150–300	30	99%	4.5	8.9	34%	66%	
	300–450	20	99%	5.9	8.9	44%	66%	
<b>Zinc</b> mg/day	25–74	95	99%	2.4	7.0	59%	171%	2.5, 4.1, 8.2 ug/day for high, mid and low bioavailability
	75–149	55	99%	4.1	8.1	100%	198%	
	150–300	40	99%	5.9	11.9	144%	290%	
	300–450	30	99%	8.9	13.4	217%	327%	
<b>Folic Acid</b> ug/day	25–74	5	85%	106	315	30%	88%	357 ug/day
	75–149	2.6	85%	166	329	46%	92%	
	150–300	1.3	85%	166	332	46%	93%	
	300–450	1	85%	255	383	71%	107%	
<b>Vitamin A</b> ug/day	25–74	5.9	70%	103	306	32%	96%	320 ug/day
	75–149	3	70%	158	313	49%	98%	
	150–300	1.5	70%	158	315	49%	98%	
	300–450	1	70%	210	315	66%	98%	

Since most countries have limited reliable official data on individual flour consumption, a range of sources, methods and strategies were presented as options for estimating average flour consumption. Some potentially available data sources include FAO Food Balance Sheets, USDA Grain & Feed Reports, Household Income and Expenditure Surveys and other government and industry sources.

Within the four consumption categories defined by the WHO recommendations, flour intakes will vary by age and sex, as well as domicile, ethnic group and other consumer factors. Therefore, a computer modelling tool was introduced to enable participants to estimate the range of consumption from the 5th to 95th percentile by both sex and age. Based on this range of added intake, the "projection tool" estimated effectiveness, based on additional micronutrients delivered to each group, as well as safety, based on the tolerable upper level (UL).

<sup>15</sup> For the purposes of these scenarios several assumptions were made: commonly agreed upon retention rates were assumed for labile vitamins; lowest consumption was set at 25 grams per day (about half a slice of bread) and highest consumption of 450 grams per day (about 750 grams of bread); iron form is a ferrous salt, fumarate or sulphate. B12 was not included in the modelling due to limited data on the prevalence of B12 deficiency and the impact of fortification.

## 2.5 Implementation of improved national standards for flour fortification

### 2.5.1 Principles of quality assurance

Flour fortification quality is assured at two important levels. The first level, which is the responsibility of producers at the mill, is to ensure that the flour is properly and homogeneously fortified to the correct levels. The milling industry should implement good process controls that follow international standards such as ISO 9000, which is the standard for quality systems<sup>16</sup> of the International Organization of Standardization (ISO), and ISO 22000, which is the standard for HACCP that is specific for food and pharmaceutical safety. Reliance on post production analytical testing alone is not recommended.

The second level is the responsibility of the food control and inspection agencies of the national government. Sampling and analysis by these agencies should recognize that large variations in laboratory results due to a number of issues, including sampling error, mean that enforcement should not rely solely on laboratory analysis of samples. Government agencies are advised to inspect the total quality system at the mill and verify that a process control system is operational.

### 2.5.2 Principles of monitoring of flour fortification programmes

Monitoring is the continuous, ongoing collection, review, analysis and use of information and outcomes to assess how the programme is performing against predefined criteria. The monitoring and evaluation process should be simple and affordable, particularly in low-resource settings. Existing systems should be used whenever possible. This will be greatly facilitated by developing clear plans with well-defined data sources, indicators and protocols for data collection, analysis and use. The main sources of monitoring data need to be determined based on programme needs and resources and should focus on concrete and measurable inputs, activities and outputs. Responsibility for data collection at each level needs to be defined and answers to the following questions should be clear:

- For whom are the data collected (stakeholders)?
- What types of data are collected (questions and indicators)?
- How are data collected (methodology)?
- Who collects the data (personnel)?
- When are data collected (frequency)?
- Who analyses the data?
- Who reports the data and when?
- Who does what based on the information?

### 2.5.3 Evaluation of food fortification programmes

While monitoring usually focuses on inputs, activities and outputs (often called process indicators), evaluation usually focuses on the outcomes (anticipated effects or the impact of a programme on the target population). Programme evaluation helps to objectively determine the relevance and fulfilment of objectives, quality of performance, outcome achievements, cost-

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<sup>16</sup> This standard applies to all industries, not only the food industry.

effectiveness, and sustainability. In this context, evaluation helps to explain why certain things are or are not happening in a programme.

The types of data collected to evaluate a programme depend on the purpose of the evaluation. Data used for evaluation do not always need to be collected through independent surveys. Convenient and existing sources are often available from programme-based monitoring, such as sentinel sites at health clinics, schools and worksites, and from population-based monitoring, such as national or subnational household-based surveys. Evaluation should be done periodically, but only once a process monitoring system indicates adequate programme implementation and adequate programme coverage. Most evaluations of fortification programmes are conducted after one year. Finally, it is critical to justify and share conclusions with stakeholders to have them embrace results and take actions accordingly.

### 3. COUNTRY RESPONSES

Using a range of strategies for mixing and matching available data sources, country teams made an initial assessment of which of the four WHO consumption categories was most appropriate for their flour fortification programme. Country teams provisionally estimated average per capital flour consumption as well as variation between the highest and lowest volume consumers (5th to 95th percentile). These estimates were entered into the "flour consumption, EAR and UL projection tool" developed for the meeting. Based on these inputs, the projection tool was able to calculate the effectiveness and safety of fortification at the WHO-recommended levels. Effectiveness is based on the WHO EAR, while safety is based on a very conservative UL. Based on this exercise, country teams reanalysed, and in some cases revised, potential fortification levels. Using computer modelling and their own inputs into the projection tool,<sup>17</sup> all country teams found that flour fortification would be an effective and safe intervention for iron, zinc, folic acid and vitamin A, providing substantial levels of EAR, while remaining below the UL.

#### 3.1 China

The team reconfirmed that fortification should be based on WHO recommendations for average consumption in the 150–300 gram category. Costs estimated for the indicated levels of ferrous sulphate, folic acid and vitamin A were US\$ 17.32 per kilogram of premix, and US\$ 2.25 per tonne of flour. Projections for impact and safety were based on average consumption of 150 grams per day with a wide variation by a factor of 3 from mean to highest consumption (95th percentile) as well as from mean to lowest consumption (5th percentile).

The team noted that the current voluntary flour standard—indicating a range of 24–48 ppm of iron in the form of NaFeEDTA or ferrous sulphate/fumarate—is in compliance with the WHO recommendations. Likewise, the national flour standard specifies a range for folic acid (1–3 ppm) that is consistent with the 1.3 ppm recommended by WHO. Zinc is also included in the current national standard in the correct amounts but as a different compound. It is anticipated that the normal process for updating and reforming food standards will address this issue. The team suggested that vitamin B<sub>12</sub> should be included if B<sub>12</sub> deficiency is found to be widespread.

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<sup>17</sup> B<sub>12</sub> was not included in the modeling due to limited data on the prevalence of B<sub>12</sub> deficiency and the impact of fortification.

### 3.2 India

Given the wide variation in government engagement as well as cereal consumption, flour fortification policy is developed on a state-by-state basis. Gujarat has state regulations and fortifies wheat flour with iron (ferrous sulphate, 30 ppm) and folic acid (1.5 ppm). State governments in Bihar and Madhya Pradesh are considering the Gujarat model along with the possibility of adopting mandatory fortification for the government-sponsored food distribution schemes. For the workshop exercise, the case of Madhya Pradesh was considered, where flour is consumed by about 50% of the population with daily intakes of an estimated 200 grams per day.

While current experience and future planning is based on the use of ferrous sulphate, the high extraction (98%) <sup>18</sup>atta flour, which possibly represents an 80% market share for flour in India, requires that a higher bioavailability compound such as NaFeEDTA should be used.<sup>19</sup> Because fortification is under way with other compounds, there may be a need for an efficacy trial to provide additional evidence for policy-makers and implementers prior to changing iron fortificant compounds. Such a trial would provide an opportunity to add zinc and vitamin B<sub>12</sub>, important micronutrients given the likelihood of deficiencies among the vegetarian populations.

### 3.3 Indonesia

Based on data of national instant noodle consumption, the multisectoral team from Indonesia provisionally estimated average flour consumption at 83.5 grams per person per day with a variation by a factor of 2.5 from mean to highest consumption (95th percentile) as well as from mean to lowest consumption (5th percentile).

The Indonesian team envisions a comprehensive work programme to align the current national mandatory standards with WHO recommendations. Further analysis on the range of consumption is necessary to determine whether Indonesia falls in the category of <75 grams per day or 75–150 grams per day. In either case, WHO recommendations indicate the need to change the iron compound from electrolytic iron to ferrous fumarate/sulphate and the need for a review of folic acid levels in the premix. This will involve discussions with stakeholders regarding implications for cost as well as product quality. The team noted that given overages currently added at the mill, in actual practice, levels for some micronutrients, including folic acid, may already be in line with WHO recommendations.

### 3.4 Malaysia

The multisectoral team from Malaysia provisionally calculated average flour consumption at 83.9 grams per person per day with a variation by a factor of 2.5 from mean to highest consumption (95th percentile) as well as from mean to lowest consumption (5th percentile). Although Malaysia is considering standards for a more comprehensive mix of nutrients, the indicated costs for fortification at levels recommended by WHO for folic acid, zinc and iron (ferrous fumarate) only was calculated at US\$ 9.97 per kilogram of premix or US\$ 2.74 per tonne of flour.

The team recognized that originally proposed standards with electrolytic iron were not recommended for the estimated consumption level of flour. However, developing a revised standard with ferrous fumarate will require additional discussions with stakeholders to address

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<sup>18</sup> Name commonly given to whole wheat flour used widely in the South Asian continent.

<sup>19</sup> The WHO recommendations indicate only NaFeEDTA for high extraction flour (>80%) at all consumption levels.

implications for product quality, specifically the shelf-life of instant noodles. Since fortification in Malaysia may be at least partially financed by Government, the additional cost of using ferrous fumarate needs to be reviewed with the appropriate ministries and the private sector.

### 3.5 Mongolia

After weighing merits of data from FAO, World Bank, United States Department of Agriculture (USDA) and Ministry of Food Agriculture and Light Industry (ministry responsible for flour production and import data), the team provisionally concluded that the WHO high-consumption category, more than 300 grams per day, was appropriate for Mongolia. Therefore, the team concluded that fortification to the WHO guidelines represents a safe and effective intervention. The cost of fortification with the appropriate mix of electrolytic iron, folic acid and zinc was estimated at US\$ 9.03 per kilogram, or US\$ 0.82 per tonne of flour.

Prior to reforming standards in conformity with WHO recommendations, the national team defined the need to integrate flour fortification into a comprehensive national nutrition and food security plan, which includes other health and nutrition interventions as well as the fortification of other vehicles such as milk and oil with a range of additional nutrients including vitamins A and D. This national strategic document will in turn provide the basis for finalizing the national situation analysis, conducting an economic impact and benefit–cost analysis and ultimately moving forward to reform the national standard and build relevant capacity in government and industry.

### 3.6 Philippines

Based on data from the National Nutrition Survey, FAO Food Balance Sheets and private milling sources, average flour consumption was estimated to be 73 grams per person per day. While additional research and analysis to confirm the consumption estimate will be necessary, the group concluded that flour fortification using the WHO recommendations would be a safe and effective intervention; however, they noted that in the Philippines, there is also mandatory fortification of other staple foods. The estimated cost of the fortificant mix used in these projections, including appropriate levels of ferrous sulphate, folic acid, vitamin A and zinc, totalled US\$ 17.02 per kilogram or US\$ 6.81 per tonne of flour.

A review of nationally mandated wheat flour, rice, cooking oil and sugar fortification is planned as part of the Updated Medium-Term Philippine Plan of Action for Nutrition 2008-2010. The WHO recommendations will provide major inputs into this review which will include: consideration of need for inclusion of folic acid in the flour fortification regulations, evaluation of appropriate bioavailable iron compound to be specified for flour, and a multi-vehicle assessment of levels mandated for vitamin A.

### 3.7 Sri Lanka

The team from Sri Lanka provisionally calculated average flour consumption in the <75 grams per day category. The cost of the indicated iron and folic acid premix was estimated at US\$ 10.05 per kilogram, or US\$ 3.22 per tonne of flour. However, HIES data suggest that consumption varies widely among urban, rural and estate sectors of the population with some segments potentially falling into the highest consumption categories. Therefore, additional analysis of consumption is planned to inform a policy decision that balances risks and benefits of fortification.

Recognizing that flour fortification could have a significant beneficial impact upon the nutritional status of people, especially the urban and estate sector, Sri Lanka has decided to draft

a justification for a mandatory regulation on flour fortification to be submitted to Cabinet by the Ministry of Health under the existing Food Act. Mandatory rice fortification is also of interest as rice is the main staple food. The plan of action developed by the team includes:

- (1) assessing overall situation of the rice and wheat flour industry, mill numbers and location, laboratory capacity and other relevant factors.
- (2) developing justification document for regulation on mandatory flour fortification;
- (3) developing a pilot study on feasibility and cost analysis of rice and rice flour fortification

### 3.8 Viet Nam

Viet Nam's National Institute of Nutrition, with the support of UNICEF and a donation of premix by Mullenchemie, is currently undertaking an efficacy trial comparing the current national voluntary standard of 60 ppm electrolytic iron and 2 ppm folic acid to the relevant WHO-recommended levels for ferrous fumarate. The results will provide the basis for a national dialogue among public and private stakeholders on how to best adjust existing standards for iron, folic acid, B<sub>1</sub>, B<sub>2</sub> and zinc. The team projected that fortification should be based on WHO recommendations for average consumption in the 75–150 grams per day category. Addition of ferrous fumarate, zinc and folic acid at the indicated levels would require US\$ 9.97 per kilogram of premix, adding US\$ 2.74 to the cost of a tonne of flour.

## 4. CONCLUSIONS AND RECOMMENDATIONS

*The Recommendations on Wheat and Maize Flour Fortification Meeting Report: An Interim Consensus Statement* offers an authoritative, concise and implementation-friendly crystallization of global evidence on effectively implemented flour fortification. Implementation is feasible and affordable, particularly in large roller mills. Based on these WHO recommendations, significant reduction of the burden of micronutrient deficiencies is realistic and achievable. However, much work remains to be done to see global recommendations translated into national objectives for nutrition as well as clear and enforceable national standards that establish a true enabling environment for flour fortification. Moving to this next stage of implementation is a multisectoral challenge, and for this reason, the WHO recommendations are “intended for a wide audience including food industry, scientists and governments involved in the design and implementation of flour fortification programs as public health interventions.”<sup>6</sup> In the words of one speaker, “Public-private partnerships are crucial in addressing micronutrient deficiencies through flour fortification. It is not a convenience, but a necessity for success.”<sup>20</sup>

Overall conclusions of the meeting are:

3.1 The new WHO recommendations provide much-needed, evidence-based affirmation of the efficacy and effectiveness of flour fortification and guidance on what nutrients to add, at what levels and in what form.

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<sup>20</sup> Dr Festo Kavishe, UNICEF Deputy Regional Director for East Asia and Pacific Region, during his opening presentation.

3.2 The meeting provided a valuable opportunity for participants to understand better the content of the recommendations and how they were developed and to address concerns, such as on the safety of folic acid fortification.

3.3 Flour fortification offers an opportunity to increase consumption of some essential vitamins and minerals, even in Asian countries where flour and wheat may not be the staple cereal food.

3.4 The meeting recognized that data on impact of large-scale fortification programmes are lacking and significantly more effort is needed to monitor and evaluate well-implemented national programmes.

3.5 The meeting also re-affirmed the importance of strong private and public sector collaboration if flour fortification is to be implemented successfully. Private sector partners at the meeting demonstrated their commitment to flour fortification and their wish to engage in stakeholder collaboration.

3.6 Indonesia and the Philippines, which already have mandatory fortification, confirmed their commitment to review existing standards that could benefit from the WHO recommendations to strengthen the food and flour fortification strategy overall. Specifically, Indonesia will consider changing the iron compound, and the Philippines will deliberate on including folic acid and increasing levels of vitamin A fortification in consideration of other vitamin A fortification programmes.

3.7 Malaysia and Sri Lanka are both committed to making a proposal for mandatory flour fortification; however, before they apply the WHO recommendations to the standards under development, some flour consumption and technical questions need to be resolved.

3.8 The remaining countries intend to review existing voluntary standards to bring them in line with the WHO recommendations. The WHO endorsement of flour fortification will also be used with appropriate advocacy arguments for adopting mandatory fortification.

Opening Remarks at the Opening ceremony of the WHO/UNICEF/FFI Meeting on  
Implementation in Asia of the Recommendations on Wheat Flour Fortification  
Manila, Nov. 10-12, 2009

By Dr. Festo P. Kavishe  
UNICEF Deputy Regional Director for East Asia and Pacific Region

Prof. Dr. Shin Young-Soo, Regional Director, WHO WPR,  
Ms Hye Kim, Executive Officer, FFI Global Secretariat,  
Government Officials from the participating countries: China, India, Indonesia,  
Malaysia, Mongolia, Philippines, Sri Lanka and Vietnam;  
Colleagues from WHO, FAO, UNICEF,  
Representative from NGOs (GAIN, World Vision and other);  
Technical experts from the Academia;  
Representatives of the Private Sector (Millers, Pre-mix suppliers and others present),

First let me join Prof. Young-Soo, WHO Regional Director for the Western Pacific Region in welcoming you to this important meeting on wheat flour fortification as a strategy to addressing micronutrient deficiencies.

Just before the meeting started, I was telling Prof. Young-Soo that I participated in the meeting last year that elected him as the new WHO Regional Director for the Western Pacific Region. He replied that he hope that I gave him my vote! And I said that I was just an observer from UNICEF Regional Office for East Asia and Pacific and was very happy to see him elected. So let me take this opportunity to congratulate you again Prof. Young-Soo on your new and challenging job and hope that you will continue and consolidate the long tradition of a strong WHO-UNICEF collaboration in the region.

Secondly, let me give you greetings from my Regional Director, Ms Anupama Rao Singh who co-chairs the FFI chapter for East Asia and Pacific, who for reasons beyond her control was unable to participate in this meeting and requested me to represent her. I am happy to do so, because most of my early work on nutrition was focused on the prevention and control of micronutrient deficiencies especially of vitamin A, iodine and iron, which resulted in several publications. Most of this work was done in the 1980s and 1990s first as the Managing Director of the Tanzania Food and Nutrition Centre and secondly as the UNICEF Regional Nutrition Adviser in the Eastern and Southern Africa Regional Office based in Nairobi, Kenya.

UNICEF is pleased to be co-organizing this important workshop with WHO Western Pacific Regional Office and the Flour Fortification Initiative. I would particularly like to pay special tribute to WHO for hosting this meeting and our colleagues from both UNICEF and FFI who have worked closely with their WHO counterparts to ensure a successful meeting.

Around the world, billions of people especially children and women, live with vitamin and mineral deficiencies. The impact of micronutrient deficiencies is disastrous: for example vitamin A deficiency annually claims the lives of almost 670,000 children under five, and iron deficiency anemia during pregnancy is associated with 115,000 deaths

each year, accounting for one fifth of total maternal deaths<sup>21</sup>. Iodine deficiency reduces IQ by as much as 14 points, and iron deficiency by nine points. Vitamin A deficiency is known to contribute to as much as 23% of under-five mortality and some studies done in India in the 1980s in extreme vitamin A deficient populations to as much as over 40%.

With the probable exception of vitamin A and iodine deficiencies that have witnessed large scale control programmes, the number of people affected or at risk of developing micro-nutrient deficiencies has not changed much during the last decade, despite great efforts made by the Scientific Community to narrate the negative impact of micronutrient deficiencies. It is important like it was done for iodine deficiency disorders (IDD) for the Scientists to link up with public policy processes and the private sector to ensure that the knowledge and evidence of the efficacy of prevention measures are scaled up for large scale impact. I believe this meeting between the Public, Civil Society, Private and the Academia is a partnership that needs to be nurtured for sustainable and large scale impact on addressing micronutrient deficiencies through flour fortification.

Tomorrow UNICEF will be launching a Nutrition Report “Tracking Progress on Child and Maternal Nutrition: A Survival and Development Priority” showing that maternal and child undernutrition is largely a preventable cause of more than one third of all deaths in children under the age of five. The challenges of micronutrient deficiencies feature significantly in this report which I urge you to read.

Micronutrient deficiencies affect not only the overall health of individuals, but also learning abilities, productivity, and overall social and economic development, therefore, constraining our progress towards the achievement of the Millennium Development Goals (MDGs).

The causes of micronutrient deficiencies are multiple and interconnected. While lack of nutrient-rich foods in people’s diets is an underlying cause, together with diseases, inadequate health care and sanitation, and poor caring practices; the basic causes remain poverty and inadequate public policy.

As the global food, fuel and financial crisis unfolds, developing countries in particular have been hit hardest and the impact will last much longer than in developed countries. The impact on the poor, who spend most of their income on food, is devastating. The major risk of course is that public expenditure on social safety nets and social protection mechanisms will be the first to suffer from budget cuts, and as we have seen the financial stimulus packages that countries have given are prominent by the lack of adequate social expenditures.

The strategies to address micronutrient deficiencies are well known: supplementation, fortification, dietary diversification and control of diseases that cause these deficiencies. But for these technical strategies to work, they must be supported by conducive public policies, advocacy and appropriate monitoring and evaluation frameworks to gauge progress. Food fortification, particularly flour fortification (for which we are meeting

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<sup>21</sup> Investing in the future: a united call to action on vitamin and mineral deficiencies. Global report 2009.

here today) can deliver sustainable improvements not only to the current generation of people at risk but also to the generations to come.

Let me again refer to the success story of the control of iodine deficiency disorders (IDD) through fortification of salt by iodine. UNICEF's support to salt iodization programs around the world shows our commitment to address micronutrient deficiencies, particularly iodine deficiency disorders, through what has been so far "the most cost-effective fortification strategy". It is with the same enthusiasm that we have committed ourselves to support flour fortification programs considering its tremendous potential to improve populations' nutritional status and health. UNICEF has been actively involved in the efforts that led to the development of the WHO recommendations on Wheat and Maize Flour Fortification. Our commitment even extends by having our Regional Director on the Flour Fortification Initiative's Executive Management Team.

This workshop brings various stakeholders to review, understand and discuss implications of the new recommendation for flour fortification is extremely important as it will assist countries to outline the steps that are necessary for adopting the WHO recommendations. While a number of components need to be in place to ensure that flour fortification programmes are effective, I am confident that your commitment, supported by strong partnerships will bring what it takes to make a difference. Let me reiterate: Public Private Partnerships (PPP) is crucial in addressing micronutrient deficiencies through flour fortification! It is not a convenience, but a necessity if we are to succeed.

Let me end by wishing you all a productive workshop over the next three days, and again acknowledge our co-organizers, WHO and FFI for making this meeting a reality. The challenge to the participating countries is only one: will you take forward for implementation the agreements reached at this meeting for the benefit of the millions of girls and boys and women and men who suffer or are at risk of developing micronutrient deficiencies, or will you take this as just another meeting?

Thank you for your attention.

OPENING REMARKS BY DR SHIN YOUNG-SOO  
AT THE UNICEF/WHO/FFI MEETING ON IMPLEMENTATION IN ASIA OF THE  
RECOMMENDATIONS ON WHEAT FLOUR FORTIFICATION  
10-12 November 2009, Manila, Philippines

DISTINGUISHED PARTICIPANTS,

DEAR COLLEAGUES,

LADIES AND GENTLEMEN.

It is a pleasure for me to open this meeting on the implementation in Asia of the new recommendations on wheat flour fortification.

Fortification of staple foods can be a very effective way of improving nutritional status and public health, as it does not require a change in eating habits. Salt iodization provides perhaps the best example of what we can achieve when the food industry works with governments to improve public health. With more than 400 million tons of wheat consumed globally each year, flour fortification presents another great opportunity to improve vitamin and mineral status, and to prevent many deadly diseases. I am therefore happy to welcome to Manila a variety of partners—from the public and private sectors, policy-makers, scientific institutions, national and international nongovernmental organizations, millers, the Flour Fortification Initiative and United Nations partners—willing to join hands to promote flour fortification in the Region.

Economists gathered at the Copenhagen Consensus meeting in 2008, rated food fortification with micronutrients among the most cost-effective interventions available to improve national health and productivity.

Two billion people globally are estimated to suffer from iron deficiency. More than half of them live in South Asia. Since wheat is a staple food in many countries, fortified flour has the potential to reduce substantially the burden of anaemia, at a very low cost. Anaemia and even mild to moderate iron deficiency can gravely affect the learning capacity and physical growth of children, immune status, susceptibility to infections and the work performance of people of all ages. Anaemia during pregnancy affects overall infant mortality and is responsible for 20% of maternal mortality. Fortification is a simple and cost-effective way of reducing this global burden of disease.

The WHO Regional Office for the Western Pacific began work on fortification in 2002, through a study on opportunities for micronutrient fortification in countries of the Western Pacific Region. A study on the micronutrient food fortification in Pacific island countries was conducted in 2006.

Following decisions made at the Meeting of Ministers of Health for the Pacific Island Countries in Vanuatu in 2007, WHO and partners launched the Food Secure Pacific Initiative, aiming to improve food security, quality and safety. A Pacific Food Summit is planned for next year. Food fortification is an important part of these efforts. The fortification programme should be viewed as a component of an integrated strategy

to address micronutrient deficiencies, together with efforts to improve diets, to promote breastfeeding, to improve hygiene and sanitation, and to scale up deworming and supplementation for the groups at high risk, especially women and young children.

WHO has worked closely with UNICEF and the Flour Fortification Initiative to promote fortification in Asian countries as well, by taking part in the First Regional Flour Fortification Workshop for East and South-East Asia in 2007, and in the East Asia and Pacific Leaders' Group Meeting in 2009.

While there has been major success with salt iodization in most Asian countries, there seems to be still a need for high-level advocacy of food fortification to address the other important deficiencies of iron, vitamin A, folate and zinc.

These are highly cost-effective interventions that will be important to achieve the Millennium Development Goals, especially MDGs 1, 4 and 5 that deal with poverty and hunger, child and maternal health. We also can learn from other WHO Regions, for example the Eastern Mediterranean Region, where 14 countries have flour fortification programmes.

I would like to acknowledge gratefully the support provided by the Australian Agency for International Development for fortification efforts in the Region.

I wish you success in your meeting and a pleasant stay in Manila, and I look forward to reviewing your conclusions and recommendations.

Thank you.

## OPENING REMARKS

BY MS HYE KIM, EXECUTIVE OFFICE, FFI, USA

AT THE UNICEF/WHO/FFI MEETING ON IMPLEMENTATION IN ASIA OF THE  
RECOMMENDATIONS ON WHEAT FLOUR FORTIFICATION  
10-12 November 2009, Manila, Philippines

Ladies and Gentlemen, good morning.

On behalf of the Flour Fortification Initiative, it is with great pleasure I welcome you to this workshop. I would like to begin by extending a very special thank you to the WHO Western Pacific Regional Office for recognizing the value of implementing these new standards and hosting this meeting. Likewise, I would also like to thank UNICEF, Sydney West Area Health Services, and GAIN for supporting this workshop, some of our participants, and our joint vision for improving public health through cost-effective solutions like flour fortification.

In my experience with FFI, as a private sector partner in the network and now as the FFI Executive Officer, I've been amazed by the power of collaboration.

The creation of flour fortification standards was a tremendous effort of scientists, academics, UN agencies, regulatory officials, private sector representatives and other international organizations, researching the evidence together, debating the science, and ultimately recommending appropriate levels of vitamins and minerals to add to flour in order to make a difference. The recommendations that came out of the technical workshop in Stone Mountain, GA in Spring 2008 have since been reviewed and endorsed by the World Health Organization in a consensus statement that came out in April 2009. Several years, two technical workshops, and many, many meetings later, we now have these recommendations, which will be published with their supporting documents next March by the Food and Nutrition Bulletin with support from GAIN.

And the collaboration didn't stop there.

Since that time we have shared these recommendations as much as possible. The amount of effort that has gone into debating and understanding the science, the implications, and potential benefit of implementing such standards is huge. This workshop we are at today is yet another example of this huge collaboration. And your active involvement in this week's sessions is a testament to what the Flour Fortification Initiative is all about.

Rather than a traditional organization, FFI is a network of public, private, and civic groups that work to promote national scale flour fortification around the world. If you look around the room, you'll see some of those active participants in the FFI network. UNICEF and WHO are both major partners in this effort, and serve roles on FFI's Executive Management Team. Sydney West Area Health Services, also on FFI's Executive Management Team, and AusAID are 2 of FFI's strongest supporters in this region. Interflour, who co-chairs FFI's East Asia leaders group with UNICEF's regional office, is a private sector champion, demonstrating the ease of incorporating flour fortification as part of a normal business practice. The list goes on and on.

All of FFI's work is geared toward supporting and facilitating national action. The effort to persuade the political leadership of a country to fortify flour with vitamins and minerals at appropriate levels must be led and supported by the business, medical, public health and nutrition communities of the country. We can provide knowledge and support, and we can get some scale efficiencies by conducting training sessions at a regional level. Ultimately, however, national leaders must persuade their political leadership, and flour fortification efforts at the country level must be driven by national advocates like you.

FFI's role is to foster interaction between sectors so that together we can achieve results that none of us could achieve independently. We have these flour fortification recommendations because numerous people willingly partnered together to support public health. We have this regional workshop because of the collaborative support from leaders in this region. The next step is up to you. So as we proceed over the next few days, and you learn more about these flour fortification recommendations and what it takes to implement them in your country, please consider what role you want to play in this collaborative effort.

Thank you.

## PROGRAMME OF ACTIVITIES

### Tuesday, 10 November 2009

08:00 – 08:30 Registration

#### Opening

08:30 – 09:00 Opening  
 Dr Shin Young-soo, Regional Director, WHO/Western Pacific Region  
 Mr Festo Kavishe, Deputy Regional Director, UNICEF/EAPR  
 Ms Hye Kim, Executive Officer, FFI Global Secretariat

09:00 – 09:30 Introduction of participants and nomination of officers  
 Group photo

09:45 – 10:15 Coffee break

#### Introduction to flour fortification

10:15 – 10:30 Food fortification: An opportunity to reduce micronutrient deficiencies in Asia

10:30 – 10:45 Flour fortification in the region

10:45– 11:00 Results of efficacy trials in China

11:00 – 11:15 Questions and discussions

11:15 – 11:35 Introduction to the new WHO recommendations for wheat flour fortification

11:35 – 12:15 WHO recommendations on folic acid and B12 fortification

12:15 – 13:30 Lunch

#### Presentation of the new WHO recommendations

13:30 – 14:10 WHO recommendations on iron and zinc fortification

14:10 – 14:30 WHO recommendations on vitamin A fortification

14:30 – 15:00 Coffee break

15:00 – 15:20	Recommendations and experiences on wheat flour fortification with other nutrients
15:20 – 16:00	General remaining questions and discussions
16:00 – 16:15	Closing Day 1
16:15 – 17:15	Additional session on folic acid fortification
18:00	Informal reception

### **Wednesday, 11 November 2009**

#### **Implications of adoption of the WHO recommendations**

08:30 – 09:20	Implications for cost and procurement of premix
09:20 – 09:50	Presentation of GAIN premix facility
09:50 – 10:35	Impact on Asian food products
10:35 – 11:00	Coffee break
11:00 – 11:50	Implications of flour fortification for flour millers
11:50 – 12:00	Open discussion
12:00 – 13:00	Lunch

#### **Application of the WHO recommendations to countries and regions**

13:00 – 13:45	Considerations in calculating flour consumption in a country
13:45 – 14:15	First session of country group work to work out flour consumption
14:15 – 14:30	Plenary feedback, questions and comments about exercise
14:30 – 14:45	Background to calculating additional nutritional intake from fortification
14:45 – 15:15	Coffee break
15:15 – 16:00	Second session of country group work to calculate additional nutrition intake from fortification to propose appropriate fortification level
16:00 – 16:45	Country presentations and discussion on preliminary proposal for fortification levels and expected additional intake

16:45 Closing Day 2

**Thursday, 12 November 2009**

**Implementation of improved national standards for flour fortification**

08:30 – 08:45	Rapid estimation of premix cost changes as a result of country decisions
08:45 – 09:20	Issues for consideration in writing national standards for flour fortification
09:20 – 09:55	Principles of quality assurance
09:55 – 10:20	Coffee break
10:20 – 11:00	Principles of monitoring and impact evaluation of flour fortification programmes
11:00 – 11:30	Final session of country discussion on next steps
11:30 – 12:25	Country feedback
12:25 – 12:30	Official closing of the meeting
12:30 – 13:30	Lunch
13:30	Departure for visit to Foremost Flour Mill
17:30	Return from flour mill

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