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World Health Organization

# Recommendations on Wheat and Maize Flour Fortification Meeting Report: Interim Consensus Statement

## PURPOSE

This statement is based on scientific reviews prepared for a Flour Fortification Initiative (FFI) technical workshop held in Stone Mountain, GA, USA in 2008 where various organizations actively engaged in the prevention and control of vitamin and mineral deficiencies and various other relevant stakeholders met and discussed specific practical recommendations to guide flour fortification efforts being implemented in various countries by the public, private and civic sector. This joint statement reflects the position of the World Health Organization (WHO), Food and Agriculture Organization of the United Nations (FAO), The United Nations Children's Fund (UNICEF), Global Alliance for Improved Nutrition (GAIN), The Micronutrient Initiative (MI) and FFI. It is 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.

## BACKGROUND

WHO and FAO published in 2006 the *Guidelines on Food Fortification with Micronutrients* (WHO/FAO, 2006). These general guidelines, written from a nutrition and public health perspective are a resource for governments and agencies implementing or considering food fortification and a source of information for scientists, technologists and the food industry. Some basic principles for effective fortification programs along with fortificants' physical characteristics, selection and use with specific food vehicles are described. Fortification of widely distributed and consumed foods has the potential to improve the nutritional status of a large proportion of the population, and neither requires changes in dietary patterns nor individual decision for compliance. 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 (WHO/FAO, 2006). 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 many countries. 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. It is estimated that the proportion of industrial-scale wheat flour being fortified is 97% in the Americas, 31% in Africa, 44% in Eastern Mediterranean , 21% in South-East Asia , 6% in Europe, and 4% in the Western Pacific regions in 2007 (FFI, 2008).

## THE FFI SECOND TECHNICAL WORKSHOP ON WHEAT FLOUR FORTIFICATION

Nearly 100 leading nutrition, pharmaceutical and cereal scientists and milling experts from the public and private sectors from around the world met on March 30 to April 3, 2008 in Stone Mountain, GA, USA to provide advice for countries considering national wheat and/or maize flour fortification. This *Second Technical Workshop on Wheat Flour Fortification: Practical Recommendations for National Application* was a follow up to a FFI, the US Centers for Disease Control and Prevention (CDC) and the Mexican Institute of Public Health, first technical workshop entitled "Wheat Flour Fortification: Current Knowledge and Practical Applications," held in Cuernavaca, Mexico in December 2004 (FFI, 2004). The purpose of this second workshop was to provide guidance on national fortification of wheat and maize flours, milled in industrial roller mills (i.e. >20 metric tons/day milling capacity), with iron, zinc, folic acid, vitamin $B_{12}$ and vitamin A and to develop guidelines on formulations of premix based on common ranges of flour consumption. A secondary aim was to agree on the best practices guidelines for premix manufactures and millers. Expert work groups prepared technical documents reviewing published efficacy and effectiveness studies as well as the form and levels of fortificants currently being added to flour in different countries. The full reviews will be published in a supplement of *Food and Nutrition Bulletin* in 2009 and the summary recommendations of this meeting can be found in http://www.sph.emory.edu/wheatflour/atlanta08/ (FFI, 2008).

## RECOMMENDATIONS FOR WHEAT AND MAIZE FLOUR FORTIFICATION

Wheat and maize flour fortification is a preventive food-based approach to improve micronutrient status of populations over time that can be integrated with other interventions in the efforts to reduce vitamin and mineral deficiencies when identified as public health problems. However, fortification of other appropriate food vehicles with the same and/or other nutrients should also be considered when feasible. Wheat and maize flour fortification should be considered when industrially produced flour is regularly consumed by large population groups in a country. Wheat and maize flour fortification programmes could be expected to be most effective in achieving a public health impact if mandated at the national level and can help achieve international public health goals. Decisions about which nutrients to add and the appropriate amounts to add to fortify flour should be based on a series of factors including the nutritional needs and deficiencies of the population; 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); 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 costs. Flour fortification programs 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. Though the wheat and maize flours can be fortified with several micronutrients, the technical workshop focused on iron, folic acid, vitamin $B_{12}$, vitamin A and zinc, which are five micronutrients recognized to be of public health significance in developing countries.

## 1. IRON

The suggested levels for fortification of wheat flour with iron were reviewed by experts from published efficacy and effectiveness studies with various iron-fortified foods (Hurrell R *et al,* 2009). The authors estimated the daily amounts of selected iron compounds, including NaFeEDTA, ferrous sulphate, ferrous fumarate and electrolytic iron that have been shown to improve iron status in populations. 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 and therefore the choice of compounds as well as quantities should be viewed in the context of each country's situation. Based on available data from the Food Balance Sheets of FAO and World Bank-supported Household Income and Expenditure Surveys (HIES), it was proposed that four wheat flour average consumption ranges be considered in designing flour fortification programs: >300 g/day, 150-300 g/day, 75-150 g/day and <75 g/day.

## 2. FOLIC ACID

Well conducted studies from the United States (Williams LJ *et al,* 2002), Canada (De Wals P *et al,* 2007), and Chile (Hertrampf E & Cortes F, 2004) 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. Wheat and maize flour fortification with folic acid increases the intake of folate by women and can reduce the risk of neural tube and other birth defects.

## 3. VITAMIN $B_{12}$

An unpublished pilot study testing the feasibility of adding B-complex vitamins and iron to flour in Israel 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 (Allen L *et al,* 2008). However, evidence is still lacking about the population impact of fortification of wheat flour with vitamin $B_{12}$ to improve vitamin $B_{12}$ status. Nevertheless, fortifying flours with vitamin $B_{12}$ could be a feasible approach to improve vitamin $B_{12}$ intake and the status of populations as there are no known adverse consequences of vitamin $B_{12}$ fortification, and there are no known adverse effects of high intakes of the vitamin.

## 4. VITAMIN A

Wheat and maize flour can technically be fortified with vitamin A as vitamin A is stable in flour without producing organoleptic changes. As is the case for some other vitamins, high humidity and high temperatures can adversely affect vitamin A content during the preparation of wheat and maize flour products. Experience with vitamin A fortification of wheat and maize flour in developing

Table 1. Average levels of nutrients to consider adding to fortified wheat 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 availability (g/day)[1] | | | |
|---|---|---|---|---|---|---|
| | | | <75[2] 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[3] | NR[3] | 60 | 40 |
| | High | NaFeEDTA | 40 | 40 | 20 | 15 |
| Folic Acid | Low or High | Folic Acid | 5.0 | 2.6 | 1.3 | 1.0 |
| Vitamin $B_{12}$ | 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[4] | Low | Zinc Oxide | 95 | 55 | 40 | 30 |
| | High | Zinc Oxide | 100 | 100 | 80 | 70 |

1. These estimated levels consider only wheat flour as main fortification vehicle in a public health program. If other mass-fortification programs with other food vehicles are implemented effectively, these suggested fortification levels may need to be adjusted downwards as needed.
2. Estimated per capita consumption of <75 g/day does not allow for addition of sufficient level of fortificant to cover micronutrients needs for women of childbearing age. Fortification of additional food vehicles and other interventions should be considered.
3. NR = Not Recommended because very high levels of electrolytic iron needed could negatively affect sensory properties of fortified flour.
4. These amounts of zinc fortification assume 5 mg zinc intake and no additional phytate intake from other dietary sources.

countries is increasing. Although vitamin A is most often used in the fortification of oils and fats, currently 11 countries are fortifying or propose to fortify wheat and/or maize flour with this vitamin. Two published efficacy trials have reported the impact of vitamin A fortified wheat flour on vitamin A nutritional status but there are no published studies that have evaluated the effectiveness of this intervention on a national scale (West KP *et al*, 2009). 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.

### 5. ZINC

Unpublished results from a trial of wheat flour fortification in China suggests that zinc fortified flour could improve zinc status in women of childbearing age (Brown K *et al,* 2009). Fortification of other foods with zinc has shown that zinc intake and absorption increase when some zinc fortified foods are consumed but the impact as a public health intervention remains unknown. More research on efficacy and effectiveness of large scale zinc fortification programs is needed. The levels of nutrients to consider adding to fortified wheat flour based on extraction, fortificant compound, and estimated per capita flour availability are presented in Table 1. These levels and compounds could theoretically improve the nutritional status of the populations consuming the fortified wheat flour regularly in different preparations.

## SUMMARY OF STATEMENT DEVELOPMENT

This statement was prepared by the core group from WHO's Department of Nutrition for Health and Development in close collaboration with FAO, the nutrition section of UNICEF, GAIN, MI and FFI. The core group members were: Dr Francesco Branca (WHO), Dr Juan Pablo Pena-Rosas (WHO), Mr Brian Thompson (FAO), Mr Arnold Timmer, (UNICEF), Dr Regina Moench-Pfanner (GAIN), Dr Annie Wesley (MI) and Dr Glen Maberly (FFI). The core group evaluated the commissioned scientific reviews prepared by international nutrition, pharmaceutical and cereal scientists and milling experts from the public and private sector working in the area of micronutrients, milling and food fortification, as well as the summary of discussions and conclusions from the consultation. This position statement is based on these documents and was initiated at WHO headquarters and further discussed and reviewed by members of the core group who provided technical and editorial advice. This statement contains all the consensus recommendations of the core group.

## CONFLICTS OF INTEREST

All members of the core group were asked to submit and sign Declaration of Interest statements which are on file. There were no known conflicts of interest disclosed among the core group members developing this statement.

## PLANS FOR UPDATE

It is anticipated that the recommendations in this statement will remain valid until December 2010. The Department of Nutrition for Health and Development at WHO headquarters in Geneva will be responsible for initiating a review following formal *WHO Handbook for Guideline Development* procedures at that time.

## ACKNOWLEDGEMENT

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