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Report on the

Joint WHO/Flour Fortification Initiative harmonization workshop for wheat and maize flour fortification

Amman, Jordan
20–22 February 2012

World Health Organization
Regional Office for the Eastern Mediterranean

Flour Fortification Initiative
A Public-Private-Civic Investment in Each Nation

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1. INTRODUCTION

Wheat flour fortification is a preventative food-based approach to improve the micronutrient status of populations over time that can be integrated with other interventions to reduce vitamin and mineral malnutrition and its consequences. Fortification of industrially processed wheat 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. However, in an analysis undertaken in preparation for a meeting on flour fortification standards in 2008, only nine out of 78 ongoing wheat flour fortification programmes with iron were judged likely to have significant positive effects on the iron status of the populations.

Flour fortification has been widely implemented in countries of the Eastern Mediterranean, Middle East and North Africa region[1]. The WHO Regional Office for the Eastern Mediterranean with support from the United Nations Children's Fund (UNICEF) and the Micronutrient Initiative (MI) launched an initiative in 1999 which subsequently led to nearly all the countries in the region fortifying wheat flour with at least iron and folic acid by 2009.

In 2008, the Flour Fortification Initiative (FFI) and U.S. Centers for Disease Control and Prevention (CDC) organized a meeting of nearly 100 leading nutrition, pharmaceutical and cereal scientists and milling experts from the public and private sectors around the world. They met in Stone Mountain, United States of America. The purpose of the meeting was to provide guidance on national fortification of wheat and maize flours, milled in industrial roller mills (i.e. at least 20 metric tonnes/day milling capacity), with iron, zinc, folic acid, vitamin B12 and vitamin A. WHO, in collaboration with other partners evaluated the commissioned scientific reviews prepared by these experts, as well as the summary of discussions and conclusions from the consultation, and made recommendations on wheat and maize flour fortification for public health that were published in an interim statement.

Since the release of the WHO recommendations, many countries in Africa and Asia have harmonized their standards at both the national and regional levels. Many other countries are reviewing and revising their flour fortification standards informed by the evidence and the WHO recommendations. In East Africa, representatives of government organizations from nine countries in the area, food processors, premix suppliers, research organizations and development partners attended an East Central and Southern Africa (ECSA) Food Fortification meeting in Nairobi, Kenya in September 2009. The meeting was organized by ECSA in collaboration with the A2Z project, and was funded by the United States Agency for International Development (USAID), the World Bank and UNICEF. Participants expressed appreciation for the work of the ECSA Regional Technical Working Group on Regulations

[1] The WHO Eastern Mediterranean Region comprises Afghanistan, Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Pakistan, occupied Palestinian territory, Qatar, Saudi Arabia, Somalia, South Sudan, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates and Yemen. Most of these countries are also part of the UNICEF Middle East and North Africa region.

and Standards in developing the ECSA regional guidelines on fortification levels, which have been adopted in Uganda, Kenya and Malawi. They also “recognized that WHO has issued general guidelines on flour fortification levels, which each country and region should study and adjust to their own realities and conditions”.

In view of the above situation analysis, FFI proposed to organize a technical workshop jointly with WHO, UNICEF, CDC, the Global Alliance for Improved Nutrition (GAIN), MI and other partners to:

- review the current fortification practices in the region and discuss strategies for regional harmonization of WHO recommendations;
- inform government policy-makers and millers about the WHO recommendations on wheat flour fortification and of the implications of these recommendations on premix cost, flour product properties and trade within and outside the region;
- outline steps for national adaptation and adoption of the recommendations, in developing or revising national flour fortification programmes; and
- identify national and regional approaches to improve the effectiveness of national fortification programmes.

The workshop was held from 20–22 February 2012 in Amman, Jordan. A total of 59 participants from 19 countries were in attendance. Attendees represented Ministries of Health, Bureaux of Standards and Specifications and the milling industry in the Region, as well as United Nations agencies and other international organizations. Participants from Afghanistan, Bahrain, Egypt, Iraq, Islamic Republic of Iran, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, occupied Palestinian territory, Pakistan, Qatar, Saudi Arabia, Syrian Arab Republic, Sudan, United Arab Emirates and Yemen attended the meeting. The programme and list of participants are attached as Annexes 1 and 2, respectively.

In his welcome message, Dr Basel Al Yousfi, Acting WHO Representative, Jordan, indicated that many micronutrient deficiencies remain prevalent in the Eastern Mediterranean Region. Fortunately, most countries in the region had national fortification schemes and clearly fortification was pivotal to countries attaining the Millennium Development Goals.

Dr Haifa Madi, Director Health Protection and Promotion, WHO Regional Office for the Eastern Mediterranean, presented statistics on micronutrient deficiencies and the success of fortification in the region. She then outlined the meeting objectives and expected outcomes. In summary, the expected outcomes from the workshop were to:

- disseminate WHO recommendations on flour fortification among key stakeholders;
- review the nutritional and public health status of countries that have been fortifying flour in the past 10 years;
- review and discuss the current status of folate, zinc and vitamin D nutritional status in populations in countries of the region; and
- discuss the opportunity to include zinc and vitamin D3 in flour fortification standards and practices in the region.

Dr Quentin Johnson, FFI, noted that in 1996 Oman was the first country in the world to reach national implementation of flour fortification with folic acid. Since FFI's inception in 2004, the number of countries with mandatory flour fortification had risen from 33 to 64.

The final introductory remarks were made by Dr Mohammed Bassem Hijawy, Director of Primary Health Care, on behalf of His Excellency Dr Abdul Latif Wreikat, Minister of Health of Jordan.

2. SUMMARY OF PRESENTATIONS

2.1 Overview of micronutrient deficiencies and strategic interventions in the Eastern Mediterranean Region

Dr Ayoub Aljawaldeh, WHO Regional Office for the Eastern Mediterranean

There is an urgent need in the region for updated national data to better inform policy and programme formation in countries. Among 21 countries in the region, anaemia in preschool age children ranged from 17% in Jordan to 85% in Sudan. The highest prevalence of anaemia was consistently observed in pregnant women ranging from 21% to 61% in women from the Islamic Republic of Iran and Afghanistan, respectively. Among non-pregnant women of childbearing age, the prevalence of anaemia ranged from 19% to 51% in Jordan and Yemen, respectively. Iron deficiency is not considered to be the primary cause of anaemia in all countries. In Afghanistan, Egypt, Islamic Republic of Iran and Oman, iron deficiency is estimated to account for less than 30% of anaemia in preschool age children. Clearly, iron interventions will only reduce the prevalence of anaemia, when iron deficiency is the leading cause of it.

Other micronutrient deficiencies are also prevalent in the region. Iodine deficiency affects 15% of school-age children in the Islamic Republic of Iran and up to 90% in Pakistan. Zinc deficiency is evident in preschool-age children, based on national studies completed in Afghanistan (54%), Egypt (8%), India (19%) and Pakistan (39%). The proportion of preschool children with night blindness presumably due to vitamin A deficiency is less than 1% in 15 countries and 2% in Somalia, suggesting that vitamin A deficiency is not a public health problem in these countries. Nevertheless, in Sudan a reported 9% of preschool age children present night blindness.

The 2008 Copenhagen Consensus ranked five interventions as being the most cost-effective for addressing malnutrition: micronutrient supplementation for children (vitamin A and zinc); micronutrient fortification (iron and salt iodization); biofortification; deworming and other nutrition programmes at school; and community-based nutrition promotion.

Nutrition interventions should not be conducted in isolation, but rather should be integrated into other sectors' policies and programmes. Further, food fortification should be considered part of an integral solution to addressing micronutrient malnutrition, and not the only intervention. Different intervention approaches can be considered based on the severity of iron deficiency. For example, if there is mild or moderate iron deficiency in the population, mandatory iron fortification of staple foods such as wheat flour should be encouraged.

However, if there is a severe iron deficiency in the population, supplementation should also focus on targeted groups. In summary, there are three groups of micronutrients that the region is considering for flour fortification: iron and folic acid added in a mandatory way in most countries; a few countries add vitamin A and B-complex vitamins (B1, B2, B3, B6, B12); and zinc and vitamin D which are being considered in a few countries.

2.2 Flour fortification: a global and regional overview

Dr Quentin Johnson, Flour Fortification Initiative

Fortification requires a multisectoral approach, with participation by public, private and civic sectors. By reducing micronutrient malnutrition, fortification can help achieve six Millennium Development Goals (MDGs):

- Eradicate extreme poverty and hunger
- Achieve universal primary education
- Promote general equality and empower women
- Reduce child mortality
- Improve maternal health
- Combat HIV/AIDS, malaria and other diseases.

Cost–benefit data from several countries show that investing US$ 1 in folic acid fortification, for example, leads to savings in the order of US$ 12 to 48 for Chile and the United States of America, respectively. Below is a timeline of progress in the Region.

- In the 1970s, Saudi Arabia was the first country in the region to start wheat flour fortification.
- In 1996, Oman was the first country in the region to add folic acid to wheat flour.
- In 2000, the WHO/MI Fund accelerated progress with fortification in the region.
- From 2002 to 2012, the region benefitted from additional support from other United Nations partners (UNICEF and World Food Programme [WFP]) and donors (GAIN, MI, USAID).

Today, all countries in the region except Lebanon, Libya and Tunisia are fortifying flour, in either a voluntary or mandatory fashion.

Within the region, at least 350 million people now have access to wheat flour fortified with at least iron and folic acid. The Eastern Mediterranean Region has had a significant influence on advancing flour fortification in Central Europe and the Eurasia region, West Africa and East Africa.

The importance of the type and concentration of fortificant used in flour fortification was described. For example, Kuwait’s monitoring data showed little decrease in anaemia prevalence among women 20 years of age and older between 2001 and 2006. This prompted changes in the fortificant from reduced iron to more bioavailable electrolytic iron. This change resulted in consistent reductions in anaemia prevalence for adult and adolescent girls and women.

A study conducted in Kenya showed that at the same nutrient concentration (56 mg/kg), the more bioavailable fortificant sodium iron EDTA (NaFeEDTA) led to a greater increase in ferritin concentration (67%) than the fortificant electrolytic iron (6%). Further, NaFeEDTA (28 mg/kg) had a 6-fold greater increase in ferritin concentration than electrolytic iron at twice the concentration (56 mg/kg), among school-age children consuming fortified maize flour.

The issue of how long it takes for fortification to show a biological impact was discussed. Once an intervention programme is successfully implemented, which can take several years, the following could be observed within one year: an increase in serum folate levels and a decrease in the number of cases of neural tube defects. However in the case of iron, a reduction in iron deficiency is not expected to be demonstrated for at least 2–3 years after the fortification has been successfully implemented at the flour mill level.

It is important that once fortification impact has been demonstrated, fortification continue. For example, in 1995 Sweden stopped iron fortification in wheat flour. Five years later, investigators found a 27% increase in iron deficiency among adolescent girls, despite an increase in the use of multivitamin and iron only supplements.

2.3 Flour fortification in public health: WHO recommendations

Dr Juan Pablo Peña Rosas, WHO headquarters

WHO policy on food fortification in general, and wheat flour fortification in particular, were discussed. Recent World Health Assembly resolutions of relevance to food fortification include resolutions on birth defects and maternal, infant and young child nutrition. Resolution WHA63.17 was adopted to redress the limited focus to date on preventing and managing congenital anomalies, especially in low- and middle-income countries. Congenital anomalies can be the result of congenital disorders or preventable factors such as infections or poor nutrition of the mother during pregnancy, vaccine-preventable diseases, consumption of alcohol, tobacco or drugs, or exposure to chemical substances such as pesticides. The resolution called on Member States to prevent birth defects wherever possible, implement screening programmes, and provide ongoing support and care to children with birth defects and their families; specifically optimizing women’s diet before and throughout pregnancy by promoting the use of a staple food fortified with folic acid, and of supplementary multivitamins with folic acid to prevent neural tube defects and other malformations and promoting an adequate general diet with sufficient protein, energy and iron.

In May 2010, the World Health Assembly adopted resolution WHA63.23 on infant and young child nutrition. Inter alia, it urged Member States to increase political commitment to preventing and reducing malnutrition in all its forms, to expedite implementation of the global strategy on infant and young child feeding, and to expand interventions. The World Health Assembly also requested that the Director-General provide support to Member States in expanding their nutritional interventions and to develop a comprehensive implementation plan on infant and young child nutrition as a critical component of a global multisectoral nutrition framework.

In 2011 WHO informed the World Health Assembly of a comprehensive implementation plan on maternal, infant and child nutrition. The plan aims to alleviate the double burden of under- and over-nutrition in children, starting from the earliest stages of development and proposed a global target of a 50% reduction of anaemia in women of reproductive age by 2025, indicating that some countries had demonstrated a reduction in the prevalence of anaemia in non-pregnant women, with suitable strategies including food fortification. The final resolution and commitments from Member States to this latter comprehensive plan will be discussed in May 2012.

WHO and FAO collaborated to develop guidelines for food fortification, which were published in 2006. The guidelines include considerations for deciding whether or not to fortify, what food vehicle(s) to use, with what nutrient(s) and in what concentration(s). Subsequent to that, WHO began an evidence-informed guideline development process following procedures for the WHO Guidelines Review Committee established in 2007 for many interventions, including flour fortification. A technical meeting held in the United States laid the ground work for WHO and partners' interim consensus statement on wheat and maize flour fortification. The interim consensus statement suggests that wheat and maize flour be fortified with specific fortificants (for iron) in specific concentrations (for some nutrients), depending on the usual intake of wheat flour in the country (see Table 1). It was indicated that worldwide, there is less experience with fortifying maize flour than wheat flour.

As part of WHO's "statement development process", the following evidence-informed guidelines are expected to be issued during the biennium 2012–2013.

- Food fortification in public health: Condiments and seasonings
- Food fortification in public health: Salt
- Food fortification in public health: Oils and margarine
- Food fortification in public health: Wheat flour
- Food fortification in public health: Corn meal and maize flours
- Food fortification in public health: Rice
- Food fortification in public health: Sugar

Table 1. Average levels of some 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)			
			<75** g/day	75–149 g/day	150–300 g/day	>300 g/day
Iron	Low	NaFeEDTA	40	40	20	15
		Ferrous sulphate	60	60	30	20
		Ferrous fumarate	60	60	30	20
		Electrolytic iron	NR	NR	60	40
	High	NaFeEDTA	40	40	20	15
Folic acid	Low or high	Folic acid	5.0	2.6	1.3	1.0
Vitamin B12	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†	Low	Zinc oxide	95	55	40	30
	High	Zinc oxide	100	100	80	70

Source: WHO et al. *Recommendations on wheat and maize flour fortification. Meeting report and interim consensus statement*. Geneva, World Health Organization, 2009.

* These estimated levels consider only wheat flour as the main fortification vehicle in a public health programme. If any other mass fortification programmes with other food vehicles are implemented effectively, these suggested fortification levels may need to be adjusted downwards as needed.

** Estimated per capita consumption of <75 g/day does not allow for the addition of a sufficient level of the fortificant to cover micronutrients needs for women of childbearing age. Fortification of additional food vehicles and other interventions should be considered.

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

† These amounts of zinc fortification assume 5 mg zinc intake and no additional phytate intake from other dietary sources.

2.4 The impact of folic acid fortification on neural tube defects

Dr Heather Hamner, U.S. Centers for Disease Control and Prevention

The March of Dimes Foundation estimates that there are 300 000 neural tube defects annually in the world. Neural tube defects are serious birth defects of the brain and spine. Research has shown that 50–70% of neural tube defects can be prevented if women consume 400 micrograms of folic acid before and during early pregnancy. Folic acid is a B vitamin and is found in supplements or fortified food.

The WHO/CDC (2011) logic model for micronutrient interventions in public health can be followed to assess the success of fortification. Within the WHO/CDC logic model, there are several outcomes that can be assessed for folic acid fortification including improved nutritional status and a decrease in morbidity and mortality. Improved nutritional status can be assessed by determining the change in blood folate concentrations post-fortification. Data from several countries, including, Canada, Chile, Costa Rica and the United States, have indicated significant increases in blood folate concentrations after fortification with folic acid.

A reduction in morbidity and mortality can be assessed by determining the change in neural tube defect prevalence post-fortification. A decrease in neural tube defect prevalence was reported in the United States, Canada, Chile, Costa Rica and South Africa as well as several areas in the Eastern Mediterranean Region. It should be noted that these reductions in neural tube defects were observed in countries fortifying wheat flour (Canada, Chile, Islamic Republic of Iran, Oman, Jordan, Saudi Arabia and the United States), as well as multiple food products such as wheat flour, maize flour, rice, and milk (Costa Rica) and wheat and maize meal (South Africa).

Cost effectiveness has been another way to assess the success of folic acid fortification. In the United States, research has indicated that for every US$ 1 invested in folic acid fortification, US$ 45 have been saved in medical costs. In the 10 years since folic acid fortification of enriched cereal grain products began in the United States, an estimated 10 000 more babies have been born without a neural tube defect, with an estimated US$ 4.5 billion saved in direct costs.

2.5 Impact of iron fortification of staple foods in public health: overview of evidence

Dr Sean Lynch, WHO Temporary Adviser

The most bioavailable fortificants are the most soluble in the human gut. However, they tend to interact with food vehicles, causing adverse changes in storage and organoleptic properties. Greater concentrations of low bioavailability fortificants are needed to have an impact equivalent to that of high bioavailability fortificants. Research has demonstrated that the most efficacious iron fortificant is sodium iron EDTA (NaFeEDTA).

There are pros and cons for three sets of outcomes that have or could in the future be used to assess the impact of iron fortification. The first set is haemoglobin concentration and anaemia prevalence. Haemoglobin is not a specific indicator of iron deficiency. There are many other causes of anaemia. A low haemoglobin value, used as the sole indicator of the prevalence of iron deficiency in a population, may be misleading. Haemoglobin can however be employed as a qualitative measure of impact in iron deficient individuals. The second outcome set is serum ferritin and iron deficiency prevalence. In the absence of infection or inflammation, serum ferritin is an accurate specific indicator of iron status if iron stores are present. The problem is that it only tells half the story; once stores are exhausted, the body continues to incur an iron debt if iron balance is not restored. Serum ferritin is already close to the detection limit and does not capture the continuing iron debt. We have to go back to haemoglobin to measure the size of the debt or to see a reduction in the debt if fortification is introduced.

The third outcome set, which the presenter recommended although it is not yet widely available, is the body iron measured as the ratio between serum transferrin receptor and serum ferritin. This method provides a more comprehensive evaluation of the overall distribution of iron status in a population sample. It identifies individuals with normal and high iron stores as well as those with iron deficiency and a functional deficit. It is not dependent on haemoglobin concentration. While infection affects serum ferritin concentrations, it has less of an effect on serum transferrin receptor concentrations. The effect of infection on the serum transferrin

receptor/serum ferritin ratio (body iron) has not been evaluated rigorously. For programmatic purposes there are currently two important limitations to using body iron. First, there is inadequate standardization of commercial kits for measuring serum transferrin receptor. The Biomarkers of Nutrition for Development (BOND) project in collaboration with CDC in the United States is in the process of calibrating a reference standard to overcome this problem. Secondly, measuring transferrin receptor is expensive at the present time. There are however no technical reasons why both of these barriers cannot be overcome.

2.6 Discussion

Is anaemia the best indicator to assess nutritional impact due to iron fortification of wheat flour?

No, because anaemia has many causes, of which iron deficiency is only one. The best indicator to use is one (or several) that assesses iron status directly. Two were discussed at the meeting: serum ferritin and “body iron” (the ratio of serum transferrin receptor/serum ferritin).

How long does it take to see a nutritional impact of wheat flour fortification?

There are two factors that affect how long it will take fortification to have a demonstrable impact on people. First, how long it takes for a country to have its fortification programme working reliably. For a country that is initiating fortification, this can take upwards of two years.

The second factor is how long it takes for the nutrient to affect biomarkers of nutritional status. In the case of iron, content experts said that impact could be observed in approximately one year. In other words, if wheat flour is reliably fortified with iron, and if vulnerable populations consume products prepared with fortified wheat flour daily, a demonstrable impact on iron status can be expected within 12 months. Taken together, in a country that is initiating iron fortification, nutritional impact could be reasonably expected approximately three years after the programme began.

With respect to folic acid fortification, changes in folate status can be observed within 3–4 months of fortification. It would take at least 12 months and possibly a little longer to see an impact on neural tube defects because for this to occur, women need to be consuming folic acid when they conceive.

How can a country assess if its fortification programme is working reliably? When should a country evaluate the impact of their fortification programme?

Evaluation of a fortification programme should be conducted no sooner than one year after the programme is reliably being implemented, as evidenced by the monitoring system.

Is there a relationship between folic acid consumption and cancer risk?

The preponderance of human studies on all types of cancer found no increased risk associated with increased intake of folic acid, and the scientific literature suggests folic acid might decrease the risk of certain cancers, for example paediatric cancers and cervical cancer. As with any conflicting findings, continued study is warranted; however, at this time, the majority of studies have not found a statistically significant association of high folic acid intake leading to increased cancer risk.

There has also been some concern about the association between folic acid use and colorectal cancer. Twenty-three studies ranging in dates from 2007 to 2011 were reviewed by researchers at CDC, and none of these studies found a significant increased risk in colorectal cancer associated with folate or folic acid intake. However, several of these studies found higher folate and folic acid intakes to be associated with a decreased risk of colorectal cancer. In addition, both colorectal cancer incidence and mortality have decreased in the United States in the years since fortification.

In terms of the association between folic acid and breast cancer, there is limited evidence. While most studies suggest no increased risk overall for breast cancer related to consumption of folic acid, the possibility that folic acid may be associated with increased risk of certain subtypes of breast cancer (e.g. estrogen receptor-positive breast tumours in premenopausal women have been found to have a positive association with folic acid in more than a single study) cannot be ruled out. As with any negative and conflicting research findings, continued study is warranted; however, at this time, the majority of studies have not found a statistically significant association between high folic acid intake and increased risk of breast cancer.

In the United States, enriched cereal grain products are fortified at a level of 140 micrograms/100 g and reports estimate that this results in a folic acid intake from fortified foods of approximately 120 micrograms of folic acid. Additionally, research in the United States has shown consuming folic acid from fortified foods alone does not result in exceeding the Tolerable Upper Intake Level (UL) for folic acid, but consuming folic acid containing supplements can.

2.7 Zinc fortification of cereal flours: current recommendations and research needs

Dr Grant Aaron, Global Alliance for Improved Nutrition

There is no global estimate of the prevalence of zinc deficiency. Instead the International Zinc Nutrition Consultative Group (IZiNCG) has developed a proxy indicator of the percentage of the population at risk for zinc deficiency, using country-level FAO food balance data and other information. With respect to measuring zinc status, zinc is highly homeostatically controlled in the body. Consequently, plasma or serum zinc of an individual is not a good measure of an individual’s zinc status. However, for a population-based assessment, plasma or serum zinc is the best available biomarker.

Researchers evaluated if plasma zinc responds to supplementation and fortification. Plasma zinc increases after zinc-supplementation intake. In young Senegalese children, providing a zinc-fortified food for two weeks did not increase plasma zinc concentration. In Senegalese adults, providing a zinc-fortified food for four weeks did not increase plasma zinc concentration. It remains unknown whether zinc fortification for longer periods of time will increase plasma zinc concentration. A study in China provided fortified wheat flour with 25 mg/kg of zinc (with the compound zinc oxide) and iron (elemental iron or EDTA) on a daily basis to adults. At baseline and 12 months later, serum zinc concentration was not different between the group that received zinc and iron in the wheat flour and the control group. However, at months 24 and 36, serum zinc concentration was statistically higher in the group that consumed zinc and iron fortified wheat flour.

In 2008, experts conducted simulations with dietary data of the potential effects of fortifying flour with zinc. They recommended different concentrations of zinc fortification, based on different extraction levels (Table 2). It should be noted that these zinc concentrations do not affect sensory or baking properties.

Table 2. Recommended levels of zinc fortification in wheat flour depending on extraction level and daily intake of flour

Flour intake (g/day)	80% extraction	95% extraction
50	95	135
75	70	110
100	55	100
200	40	80
300	30	75
400–500	30	70
600–800	25	70

Source: Brown et al. Zinc fortification of cereal flours: current recommendations and research needs. *Food and Nutrition Bulletin*, 2010, 31:S62–74.

Five zinc fortificants are Generally Recognized as Safe (GRAS[2]). Of these, zinc oxide (ZnO) and zinc sulfate ($ZNSO_4$) are equally effective in improving zinc absorption, and either is recommended for use in flour fortification programmes. Zinc oxide is mostly used because of its lower cost.

2.8 Impact of vitamin A fortification of staple foods: overview of evidence

Dr Omar Dary, International Economic Growth

Hebron and Gaza City have recent experience with fortification under the aegis of the USAID A2Z project. In the West Bank, wheat flour is fortified with several nutrients,

[2] Generally recognized as safe (GRAS) is an American Food and Drug Administration (FDA) designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act food additive tolerance requirements.

including vitamin A. Studies have shown the impact of vitamin A fortification in different food vehicles: wheat flour, oil, sugar, salt and monosodium glutamate (MSG). Studies have further shown that vitamin A is stable to heat and cooking, so that it is reasonable to expect that vitamin A will remain in products made from fortified wheat flour.

Salt and monosodium glutamate (MSG) are not suitable vehicles for vitamin A because the increase of the price due to fortification as compared with the original price of the unfortified products is too high, which makes the fortification unviable. The other reason is the high amounts of the premix (source of micronutrients) that need to be added in those two vehicles, which are consumed in very low amounts. In order to provide the same amounts of vitamin A that are in other vehicles, such as oil, sugar, or wheat flour, the contents would be so voluminous that the technological process difficult to introduce. It would be necessary to have very large blending machines. In the West Bank, fortified flour is being inspected using a method developed in the Central Public Health Laboratory of the Ministry of Health of the Palestinian Authority.

2.9 Vitamin D in the Eastern Mediterranean Region

Dr Ghada El-Haij Fuleihan, WHO Temporary Adviser

There are no population-based studies in the Region for the prevalence of nutritional rickets, which is caused by vitamin D deficiency. Desirable levels of serum/plasma vitamin D levels range from 20–30 ng/mL (or, 50–75 nmol/L). A study among the elderly in Lebanon showed greater deficiency than a similar study among the Dutch elderly. Vitamin D supplementation has been found to be protective for hip fractures and to reduce the risk of falling in the elderly. Individuals' response to vitamin D depends on their genetic profiles. Other health outcomes that have been ascribed to vitamin D are undergoing evaluation with large trials.

There are two different guidelines on what serum/plasma vitamin D levels should be. The Institute of Medicine recommends a desirable level of 20 ng/ml in the general population. In comparison, the Endocrine Society recommends a desirable level of 30 ng/ml for populations at risk of vitamin D deficiency. Different vitamin D assays are giving different prevalence of vitamin D deficiency. Until this is resolved, it is difficult to compare vitamin D statistics from country to country, and within countries at different time points. During the question and answer period, Dr El-Haij Fuleihan described one experience with vitamin D intoxication that was observed in dairy products in Boston.

2.10 Other micronutrients used in flour fortification

Dr Anna Verster, WHO Temporary Adviser

A number of other micronutrients are also used in flour fortification, i.e. thiamin (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), pyridoxine (vitamin B6), vitamin D, calcium and magnesium.

Flour milling depletes whole grain of naturally present vitamins and minerals. In view of the important public health consequences of the deficiencies caused by the lack of many of

these vitamins and minerals, they are often added in flour fortification programmes. Vitamins B1 (thiamin), B2 (riboflavin) and B3 (niacin) are in many countries added to wheat flour to restore these vitamins to whole grain level. This is known as restitution or restoration. The KAP complex, for example, is a premix formulation used in Central Asia to restore the nutrient profile of white flour.

There are several food vehicles to which vitamin D is added through fortification or can be feasibly added including: vegetable oil, margarine, milk and dairy products, wheat flour and maize flour. For use in flour fortification, the liquid form of vitamin D is spray dried and converted to a powder form. Calcium fortification of flour is mandatory in the United Kingdom and voluntary in Canada and the United States. Finally magnesium fortification of flour is voluntary in Canada.

2.11 Vitamin B12 fortification of flour

Dr Joe Mulinare, U.S. Centers for Disease Control and Prevention

The laboratory tests that are used to assess vitamin B12 status include plasma B12, methylmalonic acid and homocysteine. Vitamin B12 deficiency has been observed in Latin America, Africa, Asia and the United States. Risk factors for vitamin B12 deficiency include low dietary intake, inability to absorb vitamin B12 in the gut, surgery, infections, diabetes, and age (young children and the elderly are especially susceptible to vitamin B12 deficiency).

With respect to vitamin B12 fortification, the following is known. Vitamin B12 is stable and does not affect bread quality. Some evidence shows that vitamin B12 fortification improves vitamin B12 status. However, there have been no population-level trials, or effectiveness trials, of the impact of vitamin B12 fortification. There are no known safety concerns related to vitamin B12 fortification. The levels of vitamin B12 added to flour fortification will not help in reducing pernicious anaemia because these individuals would need higher doses of vitamin B12 than the flour would provide. In the Eastern Mediterranean Region, Afghanistan, Jordan, Morocco and the occupied Palestinian territory fortify wheat flour with vitamin B12.

2.12 Fortification with iron and other micronutrients: emerging issues for programmes

Dr Grant Aaron, Global Alliance for Improved Nutrition

Several calculations were broached from the perspective that countries may be faced with tradeoffs between purchasing more expensive forms of iron fortificants or adding other nutrients to the premix. Dr Aaron presented mathematical calculations completed to evaluate premix costs and implications when more than one micronutrient is included in the premix. For example, if different iron formulations are modelled, premix costs could increase up to 342%, compared with countries' status quo. He then showed estimates of the marginal cost of adding to iron, an additional nutrient. Some countries combine different fortificants, such as a higher cost fortificant with a lower cost one, to reduce overall premix costs. Another strategy that countries may consider is dividing micronutrients among two or more food vehicles.

2.13 Working with the private sector to ensure effective flour fortification

Dr Noor Ahmad Khan, Micronutrient Initiative

Fortification is among the key approaches for improving the micronutrients status of the population, especially women and children. There are a number of factors constraining and enabling private sector investment in fortification. It is important to have a clear understanding among partners in a country when technical support will be phased in and when it will be phased out. The vital elements of a successful flour fortification programme are: ownership of the private sector, clear understanding on the roles and division of labour among various partners, placement of a sound regulatory mechanism, market driven procurement strategies for ensuring premix and fortification equipment availability, political commitment, capacity building of industry and government and, last but not the least, a strong push and support from the government, civil societies and academia. A successful flour fortification programme requires strong collaboration among the private sector and other partners, which would ensure a win–win situation for all.

Dr Khan concluded that:

- Flour fortification could play a significant role in providing meaningful quantities of key micronutrients to a population on a continuous and self-sustaining basis at a low-cost (< US$ 1/person/year).
- The private sector has an important role to play in the production and distribution of fortified cereals.
- Complementary effort by all relevant private sector players is important.
- Governments need to support private sectors' efforts through effective policies, legislation, monitoring, and enforcement.
- Civil organizations also need to inform and educate consumers to accept and consume fortified food.

Discussion

A cross-sectional study showed an association among high folate status, low vitamin B12 status and increased cognitive decline. Since this was a cross-sectional study, causality cannot be established. Previous studies have shown a direct link between vitamin B12 deficiency and cognitive impairment. Therefore, it is possible that folate status may not have influenced the cognition status of the study participants.

2.14 The process for adapting the WHO guidelines on flour fortification in the region: guiding principles

Dr Ayoub Aljawaldeh, WHO Regional Office for the Eastern Mediterranean

Key considerations for Member States include the prevalence of micronutrient deficiencies, current and future interventions, food market analysis and others. This was followed by factors to be considered in a situation analysis such as health systems, cultural practices, and monitoring activities. A new way of thinking for national fortification

programmes is needed, such as cooperation across multiple sectors, and sharing lessons learned. Clearly, national leaders are the people to drive the process. And, fortification programmes should be mandatory, not voluntary in nature. A voluntary market-based approach is more difficult and expensive to implement. These country-led efforts must also recognize and learn from international expertise and experiences. Finally, flour fortification is one of the recommended national safety nets to address poverty and malnutrition among the most vulnerable groups.

2.15 Principles of monitoring quality control and safety to flour fortification programmes

Dr Mohamed Elmi, WHO Regional Office for the Eastern Mediterranean

Monitoring quality control and safety in flour fortification programmes encompasses the following: food and chemical safety control (including good manufacturing practices (GMP) and hazards analysis and critical control points (HACCP)), monitoring, documentation, trained staff, management commitment, and audit and review of the programme (internal and external). The purpose of quality control is to ensure delivery of the declared fortificant. Food safety systems must be in place, and fortificants should be analysed like any other “hazard”. As such, the benefits of fortifying should outweigh the risks of doing so. For this to work, the roles and responsibilities of different groups need to be determined and followed. These different groups would include: milling plant staff, mill quality manager, mill on-site laboratory personnel, milling plant management, and government food safety authorities. In summary, the prerequisites for the safe production of fortified flours are that mills must be subject to government food safety inspection, HACCP analysis, presence of on-site quality control managers, and food safety monitoring with verification procedures at the mill.

Discussion

With respect to the type of laboratory that should be used for internal monitoring, the laboratory should be able to conduct simple analyses, not complex ones. Further, spot test techniques can also be used.

Regulatory authority officials need to know the nutrients level in fortified flour in order to evaluate nutrient levels in products such as bread. Food safety laboratories and mill laboratories have to work together to know the nutrients level in fortified flour. For consumers, it is the responsibility of the regulatory food safety laboratory to assess the content of nutrients in bread. Total diet studies are a source of information on the levels of various nutrients in foods; consumption patterns derived from these studies are available for the region.

Reviewing the national fortification programmes based on the regional nutrition strategy and action plan gives a platform to Member States to develop their national plans, which include the strategic interventions based on the nutrition situation in the country.

2.16 Flour fortification – the European perspective

Dr Ibrahim Elmadfa, WHO Temporary Adviser

Statistics show that there is micronutrient malnutrition in Europe, such as vitamin B6, folate and thiamin deficiencies in the Austrian elderly. The scale of flour fortification is limited in Europe compared with most regions of the world. In part, this is due to the large number of small mills, with the exception of the United Kingdom and the Netherlands. Clearly, fortification should provide enough nutrients to provide a deficit, but it should not over-supply a nutrient. In Europe, there is mandatory restoration in wheat flour of vitamin A, folic acid, niacin and all minerals. There are European standards for assessing the risk of toxicity of all vitamins and minerals. Several Western European countries are voluntarily fortifying wheat flour, they include: the United Kingdom, Ireland, Austria, Portugal, Spain and Switzerland. Regulation IEC No. 1925/2006 in the European parliament encompasses a list of micronutrients whose addition to food is permitted and a list of the respective chemical forms. Eastern Europe has many countries that are in the process of establishing flour fortification programmes.

2.17 Impact evaluation of flour fortification

Dr Mary Serdula, U.S. Centers for Disease Control and Prevention

A monitoring and evaluation framework for flour fortification was developed by WHO/FAO (2006) based on a CDC framework for programme evaluation in public health (1999). The framework helps answer the question “is the programme working well?”

Deciding when to perform an impact evaluation depends on many factors, including the time that has progressed since reliable implementation of the programme. There are several data-collection approaches for monitoring and impact evaluation. A population-based assessment is considered the gold standard. Further quantitative information can be gathered through laboratory and market surveys, and qualitative information can be gathered through interviews and focus groups. A vital component is the feedback loop, whereby monitoring and impact are used to inform programmes. While established fortification programmes may need to monitor less frequently than new fortification programmes, monitoring and evaluation should be a continuous part of all fortification programmes. In the future, FFI will be writing case studies of countries’ successful flour-fortification monitoring systems to share widely, and FFI will begin developing a global database of flour fortification monitoring.

Discussion

In the Islamic Republic of Iran, iron-fortified bread caused excess iron intake in some groups of the population. This points to the importance of considering the totality of the diet when designing a flour fortification programme, as well as any nutrition intervention. In other words, the nutrient intake of the population from other food and supplement sources needs to be considered when defining how much of the nutrient should come from fortified flour, and therefore at what concentration the flour should be fortified.

3. GROUP WORK

The workshop participants were divided into four groups who met to discuss four topics. The first group discussion was entitled “Recommended actions and policy interventions to address micronutrient deficiencies”. Specifically, each group was asked to discuss the following.

- What are the current national nutrition policies?
- What are the current action plans?
- What are the gaps?
- What is needed to fill the gaps?

Some responses to the last two questions follow:

- A risk analysis system is needed at the regional level that is in line with existing international systems.
- Capacity building in quality control systems is needed.
- Monitoring and evaluation committees require strengthening, including the issuing of clear terms of reference.

The second group discussion was on “Key challenges facing the current fortification process and proposed solutions”. Here, the groups touched on these points.

- What are the key current challenges facing food fortification?
- What are the current challenges facing flour fortification?
- What are the proposed solutions?

Some of the challenges discussed were as follows.

- Information is missing on the nutritional status of the population and food intake.
- A lack of coordination among international organizations distributing fortified foods to different population groups.
- No guidelines for specific additives.
- Small scale household milling.
- There is no fortification programme in some countries.
- Planning and follow up is difficult because the health and food ministries are decentralized.

The third group discussion examined “Harmonizing WHO standards and specifications with the national standards of fortified wheat flour of the Member States”. The specific questions each group answered were as follows.

- How close are the current standards to the WHO recommendations?
- What is needed to harmonize existing standards?

Responses to these questions were as follows.

- In some countries, their nutrient levels are in line with the WHO recommendations, but iron compounds are not in line with the guidelines.
- In some countries, their current standards are much lower or much higher than the nutrient levels in the WHO recommendations.
- A multisectoral approach is needed to strengthen the national food fortification programme, which includes wheat flour, oil and salt.
- Mandatory legislation for micronutrient fortification per the WHO recommendations would ensure harmonization.
- A user-friendly "fortification formulator" needs to be developed and upgraded by WHO to assist with setting the country-specific nutrient levels.

The final group discussion was for "Developing a 100-day action plan by countries". As part of this discussion, the groups considered the recommendations presented in the following section.

4. RECOMMENDATIONS

Recommendations that emerged from the workshop are organized into two parts. Part A comprises regional recommendations targeting countries which have adopted flour fortification. Part B contains specific recommendations for Afghanistan, Libya and Pakistan.

Part A

Network creation

1. The development of nutrition-based networks of stakeholders in the Eastern Mediterranean Region should be led by WHO for flour and food fortification; stakeholders should include Member States, other United Nations agencies, nongovernmental organizations, academia and the private sector.

Adoption of current WHO recommendations

2. Most countries that are already fortifying with iron and folic acid meet the current WHO recommendations. Those countries that have not started fortification or do not use the recommended levels of iron and types of iron compounds should take steps to adjust their national standards where applicable.
3. Countries should consider the inclusion of vitamin B12 and zinc where applicable.
4. Countries that have already adopted vitamin A fortification of vegetable oil should consider vitamin A fortification of wheat flour if vitamin A intakes are insufficient from other foods.

Monitoring and evaluation

5. Countries should develop baseline studies to identify nutritional deficiencies including dietary patterns and the biochemical status of populations' staple foods, flour, vegetable oil and salt.
6. Countries should establish nutrition surveillance systems.
7. Unified methods for monitoring and evaluation should be developed for Member States by WHO, FFI and other key partners.

Food control systems

8. WHO in collaboration with FFI and other key partners should provide technical assistance needs to the milling industries to improve the internal monitoring systems for flour fortification.
9. Countries should strengthen food control and regulatory systems, including the adoption of Hazard Analysis and Critical Control Points (HACCP) for flour and other food fortification.
10. Countries should include food safety risk analysis as part of flour and food fortification implementation plans.

Support for countries not fortifying

11. WHO in collaboration with FFI and other partners should develop technical support for Djibouti, Libya, Lebanon, Sudan and the Syrian Arab Republic to implement mandatory flour fortification at the national level.
12. WHO, FFI and countries should seek to engage additional international partners and UN agencies such as UNICEF, WFP, World Bank, GAIN and MI to provide technical and financial support to initiate flour fortification (and other staples as required).

Database development

13. WHO in collaboration with FAO should develop databases covering food composition tables, food consumption patterns and dietary modelling that are specific to the countries of the Region.

Social marketing and communication

14. In collaboration with partners, countries should develop and implement health and nutrition awareness programmes to support the consumption of fortified foods.

Partnership with stakeholders in the region

15. The Regional Office should encourage collaboration among all stakeholders at the national and regional level in flour fortification and other staple fortified foods.

Part B

To Afghanistan

1. With technical support from WHO, develop national flour fortification standards.
2. Establish a national food fortification committee.
3. Support both the national flour industry and importers to ensure flour is fortified.
4. Develop social marketing programmes to raise public awareness and emphasize the benefits of the importance of fortified foods in the diet.

To Libya

1. Develop and carry out a baseline survey to determine micronutrient status.
2. Establish a national flour (and other food) fortification committee to include all relevant stakeholders.

3. Develop national standards, food regulations and legislation for fortified wheat flour.
4. Prepare and present advocacy activities to highlight the national importance of food fortification to policy-makers and decision makers.
5. Control flour imports to ensure that imported flour is fortified.
6. Develop national systems for internal and external monitoring of flour fortification.
7. Develop a national programme for the monitoring and evaluation of national food fortification.

To Pakistan

1. Establish a federal (national) food fortification alliance made up of government bodies including the Planning Commission, Cabinet Division, Ministry of Agriculture.
2. Establish a provincial food fortification alliance of stakeholders in Punjab province.
3. Convene a high-level inter-ministry advocacy meeting to restart food fortification in the country. International agencies and donors should provide support for the meeting.
4. Allocate resources to restart food fortification in the country.
5. Engage the private sector and other stakeholders in the process.

Annex 1

PROGRAMME

Monday, 20 February 2012

08:30–09:00	Registration
09:00–10:00	Message from the Regional Director, WHO EMRO Objectives and expected outcomes of the meeting *Dr Haifa Madi, Director Health Protection and Promotion, WHO EMRO* Opening Address by Flour Fortification Initiative (FFI) *Dr Quentin Johnson, FFI* Opening message from H.E. Dr Abdul Latif Wreikat, Minister of Health, Amman, Jordan
10:30–10:45	Introduction of participants
10:45–11:00	Overview of micronutrient deficiencies in the Eastern Mediterranean
11:00–11:15	Region and regional strategies for addressing micronutrient
11:15–11:30	deficiencies *Dr Ayoub Aljawaldeh, Regional Adviser Nutrition, WHO EMRO* Overview of status of flour fortification in the Region *Dr Quentin Johnson, FFI* Discussions
11:30–11:45	WHO position/policy on food fortification in general and wheat flour fortification in particular *Dr J. Pena-Rosas, Coordinator, Evidence and Programme Guidance, WHO HQ*
11:45–12:00	Discussion
12:00–12:15	Overview of evidence of impact of folic acid and B12 fortification *Dr Mary Serdula, CDC*
12:15–12:30	Overview of evidence of impact with iron fortification *Dr Sean Lynch; Professor, Eastern Virginia Medical School*
12:30–12:45	Discussion
13:45–14:00	Overview of evidence of impact with zinc fortification *Dr Quentin Johnson, FFI*
14:00–14:15	Overview of evidence of impact with Vitamin A fortification *Dr Omar Dary, Principal Associate/Scientist, International Economic Growth*
14:15–14:30	Vitamin D deficiency in the Region and recommended intake levels *Dr Ghada Fulleihan, WHO Temporary Adviser*
14:30–14:45	Discussion
15:00–15:15	Overview of experiences of fortification with other nutrients e.g. B1, B2, B3, vitamin D, calcium and vitamin K *Dr Anna Verster, Senior Advisor, Smarter Futures, The Flour Fortification Initiative*
15:15–15:30	General/remaining questions and discussions

15:30–15:45	Folic acid and birth defects *Dr Joe Mulinare and Dr Heather C. Hamner, CDC*
15:45–16:00	Presentation on fortification of complimentary food and food supplements *Dr Grant Aaron, Senior Associate, GAIN*
16.00–16.15	Working with the private sector to ensure effective flour fortification *Dr Noor Khan, Senior Technical Adviser, MI*
16:15–16:30	Discussion

Tuesday, 21 February 2012

08:30–08:45	The process for adapting the WHO guidelines in the region: challenges and benefits *Dr Ayoub Aljawaldeh, Regional Adviser Nutrition, WHO EMRO*
08:45–09:00	Principles of monitoring quality control and safety to flour fortification programmes *Dr Mohamed Elmi, Regional Adviser FCS, WHO EMRO*
09:00–09:15	Discussion
09:15–09:30	Safety aspects of flour fortification: experience from Europe
09:30–09:45	*Dr Ibrahim Elmadfa, President of IUNS* Principles of conducting an impact evaluation of flour fortification programmes *Dr Laird Ruth, CDC*
09:45–10:30	Country Group Work Facilitators: Dr Quentin Johnson and Dr Anna Verster Key challenges facing the fortification process in the region
10:45–13:00	Country Group Work (Cont.)
14:00–14:45	Group Work Facilitators: Dr Juan Pablo Pena-Rosas and Dr Omar Dary Recommended actions and policy intervention to address micronutrient deficiencies
15:00–15:45	Country presentations
16:00–17:00	Working group and discussions (continue)

Wednesday, 22 February 2012

08:30–10:30	Working groups on harmonizing WHO standards and specifications with the national standards of fortified wheat flour of Member States Facilitator: Dr Ibrahim Elmadfaa and Dr Sean Lynch
10:45–11:30	Working groups (continue)
11:30–13:00	Working group presentations and discussions
14:00–15:30	Main conclusions and recommendations Facilitators: Dr Quentin Johnson and Dr Haifa Madi
15:30	Closing remarks

Annex 2

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