Wheat flour fortification

in the Eastern Mediterranean Region

World Health Organization
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EXECUTIVE SUMMARY

Malnutrition is a complex challenge for the World Health Organization Eastern Mediterranean Region where countries are affected by undernutrition, including micronutrient deficiencies, as well as overweight and diet-related noncommunicable diseases. Deficiencies in micronutrients (vitamins and minerals) – most commonly a lack of iron, folate, iodine, vitamin A and zinc – hinder the Region's human and economic development.

The prevalence of anaemia among preschool children in the Region ranges from 7.4% to 80.4%, while in school-aged children, the prevalence ranges from 10.4% to 40.9%. Among pregnant women in the Region, the prevalence ranges from 14.3% to 58.4%, and for women of childbearing age it ranges from 21.3% to 63%. Vitamin A deficiency also affects up to two thirds of preschool children and one third of school-aged children in some countries of the Region. Data on folate, zinc and vitamin D status in the Region are more limited.

Efforts to improve nutrition should be based on transforming food systems to improve access to and availability of good quality diets. Strategies to tackle micronutrient deficiencies include food-based approaches aimed at the whole population – increasing dietary diversity, nutrition education and food fortification – as well as targeted interventions for at-risk groups, where appropriate. Fortification of industrially processed wheat flour when appropriately implemented is a simple, inexpensive and effective strategy for supplying vitamins and minerals.

Flour fortification has been widely used in countries of the Eastern Mediterranean Region. Most countries (17 of 22 in the Region) have some coverage of wheat flour fortified with iron and folic acid, and this is mandatory in 11 countries. Eight countries fortify flour with B-vitamins. Fortification with vitamin D, vitamin A and zinc is currently rare (two countries in each case).

Nonetheless, further action is needed to expand coverage of wheat flour fortification and ensure that it is effective. Drawing on the outcomes of a training workshop on best practices of wheat flour fortification held in Rabat, Morocco, in October 2017, this report reviews the current state of wheat flour fortification in the Region, identifies lessons learned from country experiences, and sets out the latest guidance on best practices.

In addition, a number of recommendations were proposed by the meeting participants for the Region.

- National decision-makers should be responsible for defining an appropriate fortification strategy for their specific national context.
- Updated national data are urgently needed to better inform policy and programmes in countries. Strong systems for gathering reliable data on food consumption, food composition and nutrition status are needed.

- Countries are encouraged to use cost–benefit tools with existing data to calculate the costs of non-action and of fortification for their country situation and estimate the economic benefits of fortification.
- Countries are urged to follow WHO's *Recommendations on wheat and maize flour fortification: interim consensus statement* including recommendations on appropriate micronutrient levels and compounds.
- A mandatory approach is likely to be most effective through primary legislation, food regulations or technical standards, which should apply to both imported and domestically produced wheat flour, with controls enforced at the point of importation.
- To avoid trade issues, standards should be based on scientific evidence and represent a proportionate response to a public health problem. Countries are encouraged to share draft standards with the members of the World Trade Organization and trading partners.
- Regulatory measures on food fortification should always include provisions to prevent or minimize the risk of excessive intake of vitamins and minerals. Countries are encouraged to form an advisory group responsible for *all* forms of micronutrient interventions in order to monitor dietary intakes, coordinate efforts to minimize the risk of excessive intakes, and advise on appropriate interventions.
- Monitoring and enforcement systems need both internal monitoring by the food industry through quality assurance processes and external monitoring by the government (at the appropriate level) through food inspections and technical auditing.
- Countries are encouraged to regularly report the prevalence of micronutrient deficiencies or insufficiencies, particularly in the most vulnerable population groups. Reporting prevalence data disaggregated into mild, moderate and severe levels of deficiency, where possible, may be useful. Countries are encouraged to monitor and assess coverage of food fortification, and when high coverage of high-quality fortified wheat flour has been sustained over time they should assess the expected effect on nutritional status (if regular nutrition surveillance is not in place).
- Food fortification programmes should be designed from the outset to be sustainable, and should only be initiated with short-term funding if a plan for sustainable funding in the long term has been developed.
- Member States are encouraged to learn from the experiences of other countries, and cooperation at the regional level should be expanded in order to exchange information and lessons learned. Countries with similar levels of micronutrient deficiencies and similar needs are encouraged to collaborate to pursue a harmonized approach.
- A regional alliance on micronutrients would help facilitate communication and the WHO Regional Office will facilitate its establishment.
- Further support or guidance from WHO would be welcome about the methodology for assessing micronutrient deficiencies, best practices for wheat flour fortification with vitamin D, procurement or local production of fortification premix, anaemia control, establishment of nutrition surveillance systems, recommended procedures for quality control/assurance, and how to measure outcomes and health impact.

1. INTRODUCTION

Malnutrition is a complex challenge for the Eastern Mediterranean Region, where many countries have multiple forms of malnutrition among their populations at the same time. Populations are affected by undernutrition, including micronutrient deficiencies, as well as overweight and obesity, and diet-related noncommunicable diseases.

Deficiencies in micronutrients (vitamins and minerals), sometimes known as “hidden hunger”, are estimated to affect large, vulnerable population groups worldwide. The most common forms of micronutrient malnutrition are caused by a lack of iron, folate, iodine, vitamin A and zinc.

Vitamin and mineral malnutrition also holds back economic development because it hinders cognitive development in children and therefore their future educational attainment, productivity and earning potential. Vitamin and mineral deficiencies persist in the Eastern Mediterranean Region and are an obstacle to the Region’s human and economic development.

Malnutrition is both a cause and consequence of poverty but economic growth alone is not enough to reduce malnutrition. Smart public investment in nutrition interventions, however, can close the gap between economic growth and nutrition.

Strategies to tackle micronutrient deficiencies include food-based approaches aimed at the whole population – for example, increasing the diversity of diets, nutrition education and food fortification of staple foods – and targeted interventions for specific at-risk groups, where appropriate.

Wheat flour fortification is a preventive food-based approach aimed at reducing vitamin and mineral deficiencies or insufficiencies and their consequences. Fortification of industrially processed wheat flour, when appropriately implemented, is a simple, inexpensive and effective strategy for supplying vitamins and minerals to large segments of the world’s population.

Wheat flour fortification has been widely used in countries of the Eastern Mediterranean Region. The World Health Organization (WHO) Regional Office for the Eastern Mediterranean, with support from the United Nations Children’s Fund (UNICEF) and Nutrition International (formerly Micronutrient Initiative), launched an initiative in 1999 which led to nearly all countries of the Region fortifying wheat flour with at least iron and folic acid by 2009. Considerable progress has been made in tackling micronutrient deficiencies, and wheat flour fortification has contributed to this. However, given that micronutrient deficiencies persist in the Region, further progress is needed. Furthermore, countries need to review their policies and practices to ensure that they are in line with WHO guidance on best practice in fortification and that wheat flour fortification is being appropriately implemented.

This report aims to summarize the current state of wheat flour fortification in the Region, identify common challenges and lessons learned from country experiences, outline the latest guidance on best practices, and make recommendations to advance appropriate wheat flour fortification in the Region. The report draws on the proceedings of a training workshop on best practices of wheat flour fortification held in Rabat, Morocco, in October 2017.

2. MICRONUTRIENT DEFICIENCIES IN THE EASTERN MEDITERRANEAN REGION

The burden associated with inadequate nutrition continues to grow in most countries of the Eastern Mediterranean Region, and tackling vitamin and mineral deficiencies is an important part of efforts to combat malnutrition in all its forms.

An overview of the nutrition situation in 2018 reported on progress with respect to specific nutrition indicators, including anaemia, in countries of the Region *(1)*.

This section summarizes information on the micronutrient deficiencies most relevant to wheat flour fortification. Most of the data are drawn from the nutrition situation analysis mentioned above *(1)*, and the results of up-to-date national nutrition surveys provided by nutrition focal points in the countries.

2.1 Anaemia

Anaemia impairs health and well-being in women, and anaemia during pregnancy increases the risk of death or illness in both mother and baby. Anaemia and iron deficiency reduce well-being, cause fatigue and lethargy, and impair physical capacity and work performance. It is estimated that anaemia leads to 17% lower productivity in heavy manual labour, 5% lower productivity in other manual labour and a 2.5% loss of earnings because of lower cognitive skills *(2)*.

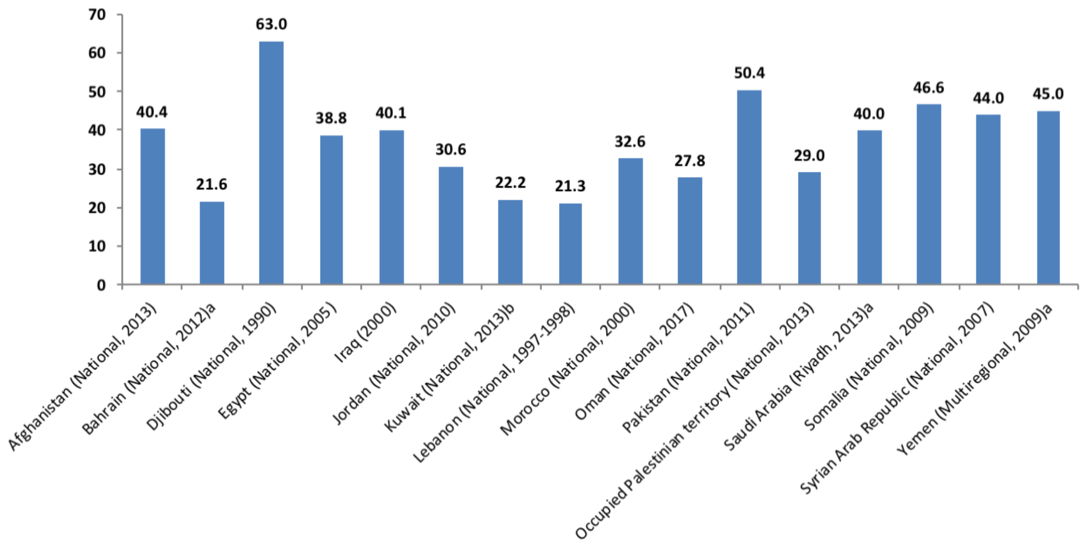
Countries are working to achieve the globally-agreed target to reduce anaemia in women of reproductive age by 50% by 2025 *(3)*. While the prevalence of anaemia decreased globally between 1995 and 2011, it has increased since 2012 *(4)*. WHO considers that a prevalence of anaemia of 40% and above is a severe public health problem. A prevalence between 20% and 39.9% is considered to be a moderate public health problem, and between 5% and 19.9% a mild public health problem *(5)*.

Iron deficiency is thought to be the most common cause of anaemia; globally 50% of anaemia is estimated to be caused by iron deficiency. A diet containing adequate amounts of bioavailable iron should underpin all efforts to prevent and control anaemia. Specific WHO recommendations for control and treatment of anaemia include supplementation for particular target groups in some contexts, exclusive breastfeeding, and fortification of wheat and maize flours and staple foods with iron, folic acid and other micronutrients *(6)*. Other interventions for the prevention and control of anaemia include malaria control and prevention, deworming, delayed umbilical cord clamping after birth, specific interventions to target adolescent girls, hygiene measures to reduce the risk of infection, and education *(6)*.

Comparison of anaemia prevalence data is complicated by the fact that different thresholds, or cut-offs, are used to define anaemia. WHO is currently undertaking a four-year project to update the definition of anaemia and review the guidelines for haemoglobin thresholds to define anaemia and its severity at the individual and population level *(7)*.

Anaemia in preschool children

The prevalence of anaemia in preschool children in countries of the Region for which there are data ranges from 7.4% in Bahrain *(8)* to 80.4% in Sudan *(9)*, with a high prevalence also reported in Pakistan (61.9%) *(10)*, Somalia (59.3%) *(11)* and Afghanistan (44.9%) *(12)* (Fig. 1). Unpublished data suggest that the prevalence is also high in Yemen (65%) (Ministry of Public Health and Population, National Nutrition Strategy for Yemen (Draft), 2009).



[a] Anaemia defined as haemoglobin <120 g/L.

[b] Date of publication is included as the date of survey is not specified.

[c] Definition of anaemia is not specified.

[d] Anaemia defined as haemoglobin <110 g/L for children under 60 months and haemoglobin <110.5 g/L for children of 60 months or older

Fig. 1 Prevalence of anaemia (haemoglobin < 110 g/L) in preschool children in some countries of the Eastern Mediterranean Region

Comparison with older data on preschool children in the Region suggests that efforts to tackle iron deficiency and anaemia have been successful in some countries. A 1995 publication on anaemia in the Region reported a higher prevalence of anaemia in preschool children in Bahrain (34%), Egypt (75–90%), Islamic Republic of Iran (> 30%), Morocco (27–47%), Oman (60%), Pakistan (65%), Occupied Palestinian Territory (oPt) (58–76%), Syrian Arab Republic (53%), United Arab Emirates (28–76%) and Yemen (17–66%) *(13)*. A 1996 regional publication on micronutrient deficiencies also reported a higher prevalence of anaemia in Jordan (34%) than the current rate *(14)*. More recent national data also report improvements in a number of countries. National data from the Islamic Republic of Iran report a decrease in anaemia in children aged 15–23 months, from 39% in 2001 to 17.1% in 2012 *(15)*. Decreases in the prevalence of anaemia, as well as iron deficiency and iron deficiency anaemia, in preschool children were also reported from Jordan between 2000 and 2010 (respectively 20.2%, 26.1%, 10.1% in 2000 and 17.1%, 13.7%, 4.8% in 2010) (Information from nutrition focal points). Similarly, the prevalence of anaemia among preschool children in Morocco fell from 47.8% in 2006 to 29.9% in 2008 *(16)*.

Anaemia in school-aged children

The prevalence of anaemia in school-aged children (where data were given for both sexes combined) ranged between 10.4% and 40.9% (Fig. 2). Where data were given by gender, the prevalence ranged between 1.6% and 33.3% in boys, and between 2.2% and 34.6% in girls. The highest prevalence rates were reported in Oman *(17)*, Yemen *(18)*, oPt (unpublished data, 2009), United Arab Emirates *(17,19)*, Somalia *(11)*, Egypt *(20)* and Afghanistan *(12,17)*. In addition, a small regional study in Sudan *(21)* (not shown) reported a prevalence of 96.8% and recent data from Iraq (not shown) suggest that anaemia in children between 6 and 12 years is 20.1% *(22)*. The lowest prevalence rates were in Libya *(17,23)*, Islamic Republic of Iran *(17)* and Kuwait *(24)*. It should be noted that countries used different definitions of anaemia.

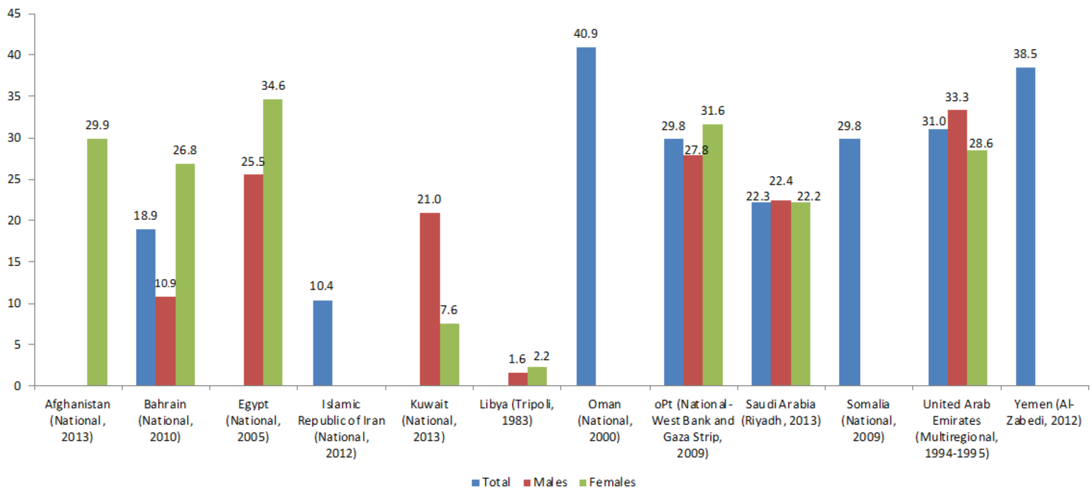


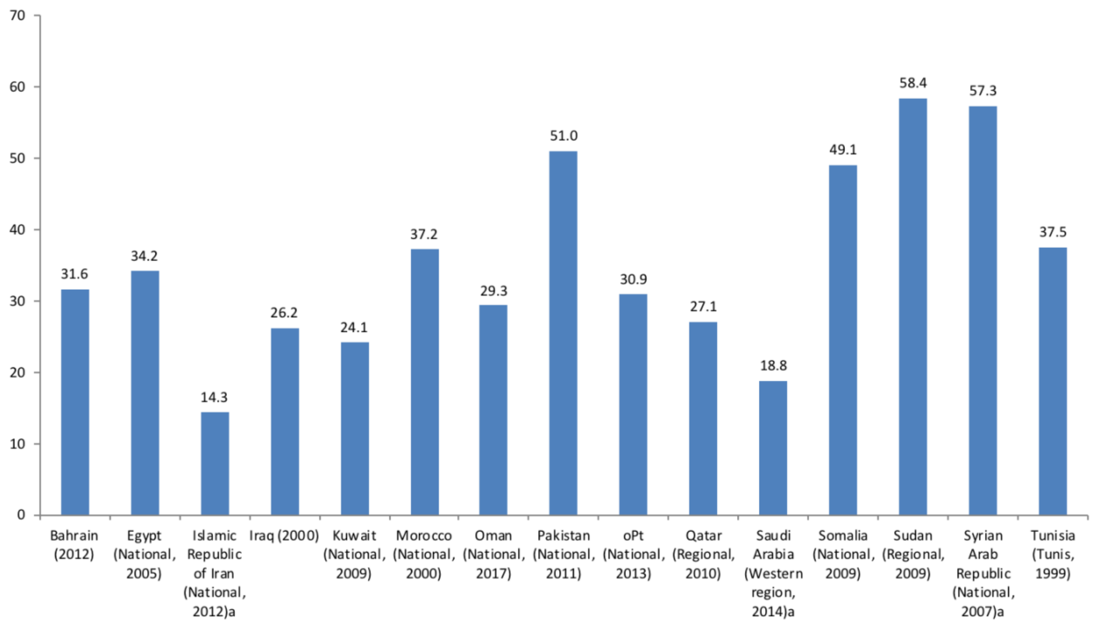
Fig. 2 Prevalence of anaemia in school-aged children in some countries of the Eastern Mediterranean Region

Although there are limited older data from the Region, a number of countries report substantial reductions in the prevalence of anaemia in school-aged children. A regional paper from 1996 reports a higher prevalence in Bahrain (32%), Oman (78%), oPt (40–67%), Saudi Arabia (55.1%, girls only) and United Arab Emirates (8–95%) *(14)*. National data from the Islamic Republic of Iran recorded a decrease from 18.2% to 9.9% in anaemia and 25.7% to 6.1% in iron deficiency among six-year-olds between 2001 and 2012 *(15)*.

Anaemia in pregnant women and women of childbearing age

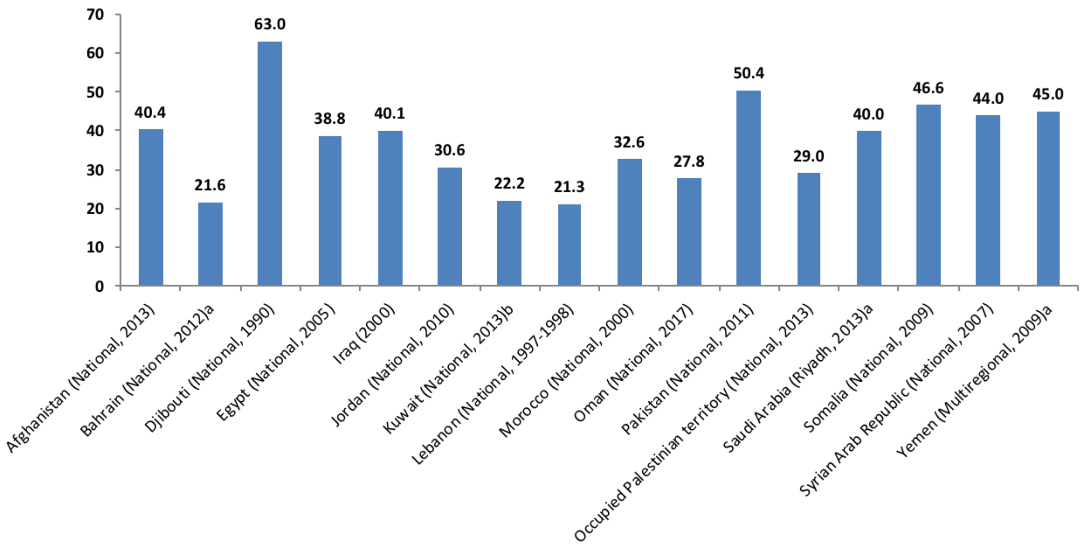
Although reducing the prevalence of anaemia in pregnant women by 50% by 2025 is a global nutrition target, the prevalence of anaemia in this group has increased globally since 2012 *(4)*. In the Region, the prevalence of anaemia in pregnant women ranged between 14.3% and 58.4% in countries for which data were available (Fig. 3). The highest prevalence rates were in Sudan (58.4%) *(25)*, Syrian Arab Republic (57.3%) (information from the nutrition focal point), Pakistan (51.0%) *(26)* and Somalia (49.1%) *(11)*. The lowest rates were in the Islamic Republic of Iran (14.3%) *(15)*, Saudi Arabia (18.8%) *(27)*, Kuwait (24.1%) *(28)*, Iraq (26.2%) *(29)*, Oman (29.3%) *(30)* and oPt (30.9%) *(31)*.

Comparison with older data from the Region, where they exist, suggests that the prevalence of anaemia has declined in some countries. National data from the Islamic Republic of Iran reported reductions in the prevalence of anaemia in pregnant women from 21.4% in 2001 to 14.3% in 2012, and in iron deficiency from 43% to 14.8% *(15)*.



[a] Definition of anaemia not specified

Fig. 3 Prevalence of anaemia (haemoglobin < 110 g/L) in pregnant women in some countries of the Eastern Mediterranean Region



[a] Date of publication is included as the date of survey is not specified.

[b] Definition of anaemia is not specified.

Fig. 4 Prevalence of anaemia (haemoglobin < 120 g/L) in women of childbearing age in some countries of the Eastern Mediterranean Region

The prevalence of anaemia in women of reproductive age ranged from 21.3% to 63.0%, with the highest prevalence reported in Djibouti (63.0%) *(13)* and Pakistan (50.4%) *(10,26)* (Fig. 4). Lebanon (21.3%) *(32,33)*, Bahrain (21.6%) *(34)*, Kuwait (22.2%) *(24)*, Oman (27.8%) *(30)*, oPt (29%) *(31)* and Jordan (30.6%) *(35)* had the lowest prevalence. More recent data from a national survey in Iraq suggest that the prevalence of anaemia in women of reproductive age in 2011–2012 was 19.1% *(22)*. In two areas of Tunisia (greater Tunis and the south-west) a prevalence of 28% was found in women of childbearing age *(36)*.

2.2 Iron deficiency and iron-deficiency anaemia

Few countries have assessed the prevalence of iron deficiency among preschool and school-aged children in the Eastern Mediterranean Region. The studies that are available have, in many cases, used different definitions and diagnostic criteria to evaluate iron deficiency. Studies of preschool children in four countries that used serum ferritin (< 12 ng/mL) found a prevalence of 43.8% in Pakistan *(10)*, 26.1% in Afghanistan *(12)*, 25.2% in Lebanon *(37)* and 13.7% in Jordan *(35)*. Lower cut-offs (serum ferritin < 11 ng/mL) were used in the United Arab Emirates and Yemen, and prevalence rates of 26% and 22.5% respectively were reported *(18,38)*. A national study in Somalia, which used high serum transferrin receptor (sTfR > 8.3 mg/L) as an indicator, found 58.9% of children under 5 years were iron deficient *(11)*. Data from Iraq in 2011–2012 suggest that 14.4% of children between 1 and 5 years were iron deficient *(22)*.

Studies on school-aged children found prevalence rates of iron deficiency of 20.8% in Somali children *(11)*, 33.3% in adolescent females and 14.7% in adolescent males in Bahrain (Information from the nutrition focal point), 17.6% in schoolgirls in Sudan

(21), between 6.1% and 11.0% in Iranian children *(15)*, and (using lower cut-offs) 22.5% in children aged between 5 and 10 years and 55.0% in those aged between 10 and 15 years in Yemen *(18)*.

There is a similar lack of data on iron deficiency among pregnant women and women of childbearing age in countries of the Region. In studies of pregnant women, the prevalence of iron deficiency ranged from 14.8% to 55%, although different cut-offs were used to define iron deficiency *(1,15,25,26,28,31)*. Studies of women of childbearing age reported a prevalence of iron deficiency ranging from 24% to 41.5% *(11,12,17,22,26,32,35,39)*.

Few countries have specifically assessed iron-deficiency anaemia in children, adolescents, pregnant women or women of reproductive age *(1)*. Of those that have, the prevalence was 4.8% in preschool children in Jordan, 11.1% in Lebanon and 29.1% in south-west Islamic Republic of Iran (iron-deficiency anaemia defined as haemoglobin < 110 g/L and serum ferritin < 12 ng/mL) *(7,32,35,37,40,41)*. When lower cut-offs were used in preschool children in the United Arab Emirates and Yemen, the prevalence was reported to be 9.9% and 26.4%, respectively *(18,38)*. In Afghanistan and the Gaza Strip (using higher cut-offs), the prevalence of iron-deficiency anaemia in preschool children was 13.7% and 33.5% respectively *(12,42)*. Studies in school-aged children found 38.5% of 5–10-year-olds and 35.2% of 10–15-year-olds in Yemen had iron-deficiency anaemia (haemoglobin < 110 g/L and serum ferritin < 10 ng/mL) *(18)*, while the prevalence was 5% in the United Arab Emirates *(43)*, 8.4% among Bahraini boys and 19.2% among Bahraini girls *(34)*, and 20.35% in Iraq *(22,44)*.

Similarly, very few studies have assessed the prevalence of iron-deficiency anaemia in pregnant women and women of childbearing age. Among those that did, the definition of iron-deficiency anaemia differed or was not specified. However, some studies found that more than half of pregnant women (and in one case almost three quarters) had iron-deficiency anaemia, although much lower estimates were also reported *(28,45,46)*. Among women of reproductive age, two national studies reported iron-deficiency anaemia in 19.8% of women in Jordan, 13.4% in Lebanon, and (using a lower cut-off) 13.8% in Afghanistan *(12,17,32,35,37)*.

2.3 Vitamin A deficiency

The prevalence of vitamin A deficiency (defined as serum retinol < 20 µg/dL) in children under 5 years in the Region ranges from 0.5% to 72.9%, with the highest rates reported from oPt, Yemen, Pakistan, Afghanistan and Iraq (Fig. 4) [although the latest data from a 2011–2012 national survey in Iraq suggests the prevalence in 1 to 5-year-olds was lower (15.0%)] *(12,22,29,31,47,48)*. A low prevalence was reported from Oman, Syrian Arab Republic and Egypt, while the Islamic Republic of Iran reported the lowest rate (0.5%), but unpublished later data suggest the prevalence is higher *(30,49-52)*. In addition, results of national studies on children under 5 years suggest that 6.4%

of boys and 9.3% of girls in Kuwait had vitamin A deficiency, as did 33.3% of children under 5 years of age in Somalia *(11)*, information from the nutrition focal point).

Data on vitamin A deficiency among school-aged children are limited. Of the four countries reporting prevalence, values range from 2.3% to 31.5%, with the highest prevalence in Egypt followed by Djibouti (Fig. 5) *(47,52,53)*. The lowest prevalence rates were reported from Tunisia and Saudi Arabia *(54,55)* In addition, a study conducted in Somalia in 2009 reported a prevalence of vitamin A deficiency among school-aged children of 31.9% (based on retinol binding protein < 0.825 µmol/L) *(11)*.

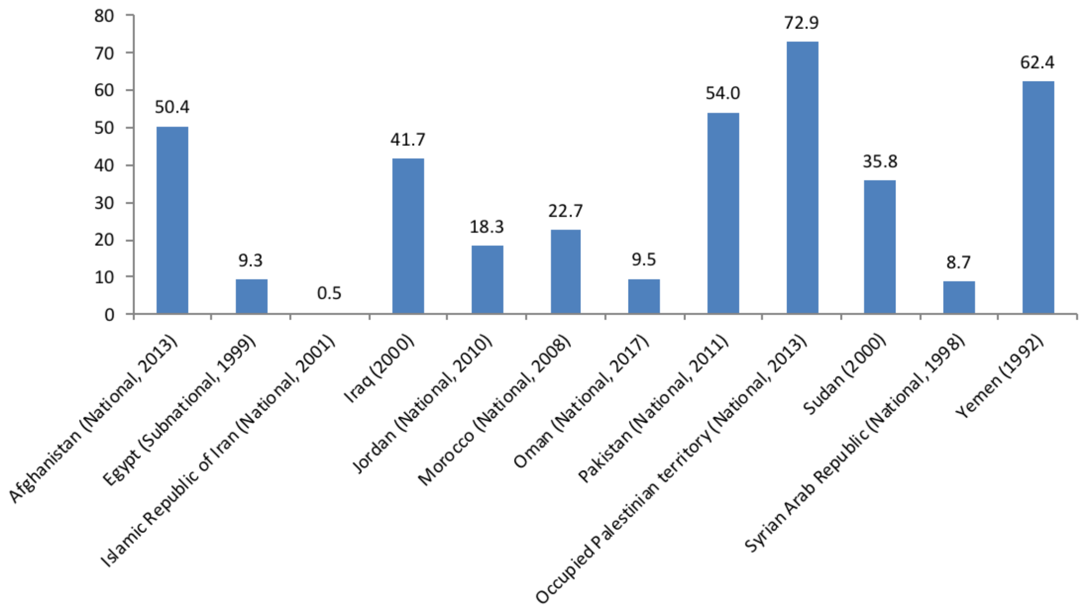


Fig. 4 Prevalence of vitamin A deficiency (serum retinol < 20 µg/dL) in preschool children in some countries of the Eastern Mediterranean Region

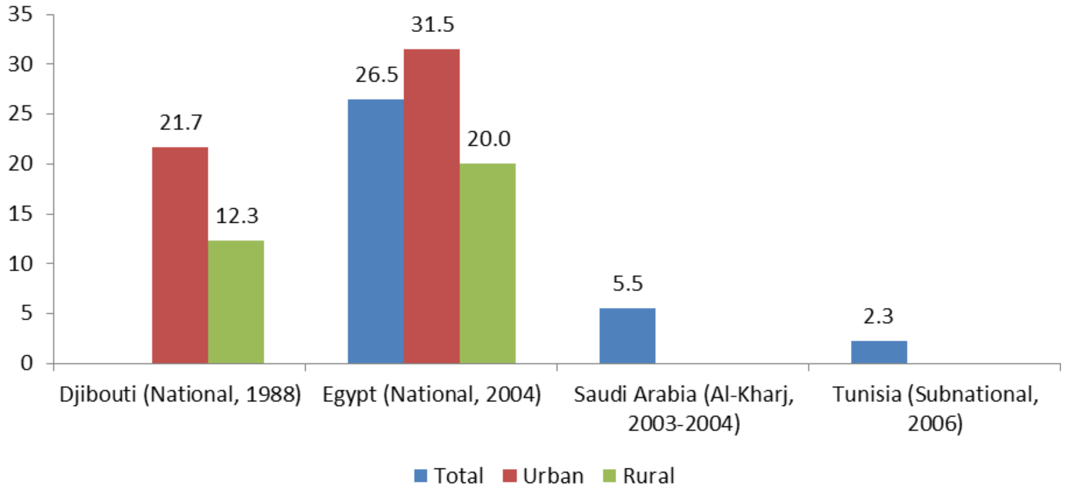


Fig. 5 Prevalence of vitamin A deficiency (serum retinol < 20 µg/dL) among school-aged children in some countries of the Eastern Mediterranean Region

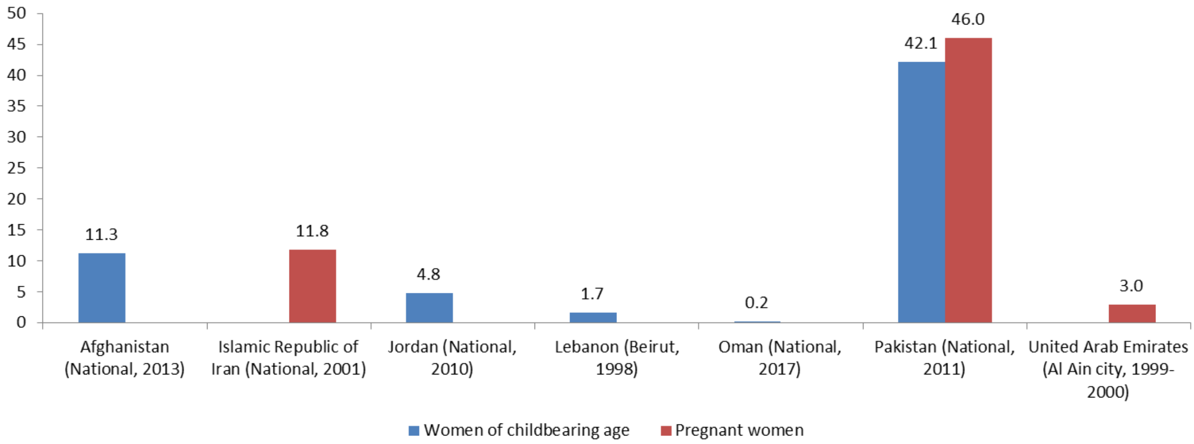


Fig. 6 Prevalence of vitamin A deficiency (serum retinol < 20 µg/dL) among pregnant women and women of childbearing age in some countries of the Eastern Mediterranean Region

The prevalence of vitamin A deficiency in pregnant women and women of childbearing age has been assessed in very few countries of the Region (Fig. 6). The highest prevalence in pregnant women was reported from Pakistan (46%) *(10,26)*, with lower rates reported from the United Arab Emirates (3%) *(56)* and Islamic Republic of Iran (11.8%) *(15,51)*. The prevalence of vitamin A deficiency in women of childbearing age ranged from 0.2% in Oman *(30)* to 42.1% in Pakistan *(10,26)*, with low prevalence rates reported in Lebanon (1.7%) *(57)* and Jordan (4.8%) *(35)*. Based on retinol-binding protein concentrations < 1.24 µmol/L, a high prevalence of vitamin A deficiency (54.4%) was reported in Somalia *(11)*.

2.4 Folate deficiency

A small number of countries in the Region have assessed the prevalence of folate deficiency or insufficiency[1] among adolescents and women of reproductive age, but there are no data for preschool children and pregnant women. Studies found that 7.4% of adolescent girls in Afghanistan *(12)*, 69% of schoolgirls in Sudan *(21)*, and 0.64% and 0.76% of Kuwaiti boys and girls respectively (information from the nutrition focal point) were deficient in folate.[2] In addition, 13.6% of women of reproductive age in Jordan *(35)*, 24.9% in the Islamic Republic of Iran (information from the nutrition focal point) and 19.0% in Iraq (22) were folate deficient.[3]

2.5 Zinc deficiency

Similarly, few countries in the Region have assessed zinc deficiency in children and women, and those studies that exist have used different definitions and diagnostic criteria. Using a cut-off for serum zinc levels of less than 60 µg/dL, Afghanistan and Pakistan found 15% and 39.2% of preschool children had low serum zinc

[1] Folate insufficiency = red blood cell folate level < 400 ng/mL (< 906 nmol/L).
[2] Folate deficiency = serum folate < 3 ng/mL (criteria not defined for Kuwait).
[3] Folate deficiency = serum folate < 151 ng/mL (criteria not defined for the Islamic Republic of Iran).

concentrations *(10,12)*[4] In the Islamic Republic of Iran, 19.1% of preschool-aged children had low serum zinc levels, but the cut-off was not defined *(15)*.

Studies in school-aged children found that 8.5% (males: 7.7%; females: 9.3%) had low serum zinc levels in Egypt (< 80 µg/dL), as were 39.2% in Pakistan (< 60 µg/dL) and 13.6% in the Islamic Republic of Iran (cut-off not specified) *(10,15,26,52)*.

The highest prevalence rates of zinc deficiency (serum zinc < 60 µg/dL) among women of reproductive age were reported in Pakistan (41.3%) *(10,26)* followed by Afghanistan (23.4%) (serum zinc < 60 µg/dL) *(12)*. Zinc deficiency was found in 47.6% of pregnant women in Pakistan *(10,26)*, 38% in Sudan (serum zinc < 80 µg/dL) *(25)* and 28% in the Islamic Republic of Iran (cut-off not specified) *(15)*.

2.6 Vitamin D deficiency

Few countries in the Region have determined the prevalence of vitamin D deficiency in preschool and school-aged children – assessed as low 25-hydroxyvitamin D ($25(OH)D_3$) concentrations. Among preschool children, the prevalence ranged from 9.5% to 90.3% (in neonates) when the cut-off of serum $25(OH)D_3$ < 20 ng/mL was used *(12,26,58,59,*information from nutrition focal points). When a lower cut-off (serum $25(OH)D_3$ < 11 ng/mL) was used, the prevalence was 19.8% in preschool-age children in Jordan *(35)*. In Morocco, the prevalence of vitamin D deficiency was 6% (criterion not specified) (information from the nutrition focal point).

Among school-aged children, a high prevalence of low concentrations of serum $25(OH)D_3$ in blood was reported in the Islamic Republic of Iran (6-year-olds: 61.8%; 14–20-year-olds: 76.3%) *(15)*, Qatar (6–11-year-olds: 61.6%) *(58)* and United Arab Emirates (15–18-year-olds: 45.4%) *(60,61)*.[5] Low prevalence rates were reported among Qatari children aged 5 to 10 years (28.9%) *(58)*. At lower cut-off criteria (serum $25(OH)D_3$ < 10 ng/mL), the prevalence of vitamin D deficiency was estimated to be 83% among Saudi children and adolescents aged 6 to 17 years *(62)*, with lower prevalence rates reported among children in United Arab Emirates (≤ 14 years: 18%) *(61,63)* Lebanon (10–16-year-olds: 21% in spring, 4% in autumn) *(60,64)*.

Of the few countries in the Region that have assessed vitamin D status in pregnant women, 88.8% in Bahrain *(59)*, 68.9% in Pakistan *(10,26)*, 40% in Kuwait *(60,65)* and 86% in Islamic Republic of Iran *(60)* had low concentrations of serum $25(OH)D_3$, although different criteria were used.[6] The prevalence of vitamin D deficiency in women of reproductive age ranged between 66.8%% and 96% in countries of the Eastern Mediterranean Region, with the highest prevalence rates reported in Jordan (96%) *(60)*, Afghanistan (95.5%) *(12)*, Islamic Republic of Iran (Tehran: 90%) *(60,66)* and Saudi Arabia (80% in summer, 85% in winter) *(60,67)*, and the lowest in Pakistan

[4] Zinc deficiency = serum zinc < 60 µg/dL for Afghanistan and Pakistan; not specified for the Islamic Republic of Iran.
[5] Defined as serum $25(OH)D_3$ <20 ng/mL in Qatar and United Arab Emirates; not specified in the Islamic Republic of Iran.
[6] Serum $25(OH)D_3$ < 20 ng/mL in Bahrain and Pakistan; serum $25(OH)D_3$ <15 ng/mL in Kuwait; Islamic Republic of Iran not specified; serum $25(OH)D_3$ < 12 ng/mL in Iraq.

(66.8%) *(10,26)*.[7] Using lower cut-off criteria, the reported prevalence was 51%, 47.6% and 74.5% in Lebanon *(60,68)*, Tunisia *(69)* and Iraq respectively (22).[8]

3. FORTIFICATION AS A MEANS TO IMPROVE MICRONUTRIENT STATUS

While efforts to improve vitamin and mineral status should always be based on transforming food systems to improve access to and availability of varied and good quality diets, fortification of widely distributed and consumed foods can also help improve the nutritional status of a large proportion of the population. Because bread is a staple food in the Region and is eaten in large quantities, wheat flour used in bread baking is an ideal carrier.

Fortification of industrially-processed wheat flour, when appropriately implemented, is a simple, inexpensive and effective strategy for supplying vitamins and minerals to the diets of large segments of the Region's population.

3.1 Evidence of the effectiveness of flour fortification

Evidence from several countries shows that fortification of staple foods is associated with sizable reductions in the incidence of deficiency-related conditions and improvements in the health status of the population *(70)*.

In relation to iron, systematic reviews have shown that fortification of staple foods with iron has improved iron status in children *(71,72)* and women *(71,73)*. However, more studies evaluating the effect of iron fortification of wheat flour on iron status and anaemia are needed. In addition, much of the experience with fortification of wheat flour with iron pre-dates the WHO recommendations on levels and compounds for flour fortification, and few of the programmes studied are in line with these recommendations *(74,75)*. Nonetheless, fortifying wheat flour with iron has been shown to improve iron status among specific populations in several countries that have measured iron status before and after fortification. In addition, a 2015 systematic review of the effect of wheat flour fortification identified consistent reductions in the prevalence of low ferritin concentrations (a marker of iron deficiency) in women and more limited evidence of its effectiveness in reducing the prevalence of anaemia in women and children *(75)*.

Studies on the effect of food fortification with folic acid on the occurrence of neural tube birth defects such as spina bifida consistently report substantial reductions in the incidence of neural tube defects after fortification. A meta-analysis of eight large population-based studies on the effect of food fortification with folic acid on neural tube defects estimated that fortification can reduce the risk by 46% *(76)*.

[7] Serum 25(OH)D_3 < 20 ng/mL.
[8] Serum 25(OH)D_3 < 15 ng/mL in Lebanon and Tunisia; < 12 ng/mL in Iraq.

3.2 Common best practices for wheat flour fortification

3.2.1 WHO recommendations

WHO recommends that fortification should be considered when industrially-produced wheat flour is regularly consumed by large population groups in a country. WHO's latest guidelines on wheat flour fortification are presented in *Recommendations on wheat and maize flour fortification meeting report: interim consensus statement (77).* This guidance on flour fortification followed up on the 2006 *Guidelines on food fortification with micronutrients,* which set forth the basic principles for effective fortification programmes, and outlined the physical characteristics of fortificants and their selection and use with specific food vehicles *(78).*

The recommendations on wheat and maize flour fortification are clear that a mandatory approach is likely to be most effective – this may require primary legislation (an act or decree) and/or technical food regulations or standards. Voluntary fortification is less likely to result in increased intakes of micronutrients in a target population.

The legislation and/or standards should include provisions to prevent or minimize the risk of an excessive intake of micronutrients beyond safe levels, especially when multiple micronutrient interventions are implemented at the same time.

The recommendations are clear that the selection of the type and quantity of vitamins and minerals to add to flour and the choice of compound lies with national decision-makers and should be made in light of each country's situation. Decisions about which nutrients to add and the amounts to add should be based on several 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 be fortified);
- sensory and physical effects of the fortificants on flour and flour products;
- fortification of other food vehicles;
- population consumption of vitamin and mineral supplements; and
- costs.

The recommendations reviewed the evidence on the efficacy and effectiveness of fortification and proposed average levels of nutrients to consider adding, focusing on iron, folic acid, vitamin B12, vitamin A and zinc. There is currently no recommendation for fortification with vitamin D; WHO guidance on this is being prepared.

Iron

Fortification of wheat flour with iron is well established and dates as far back as the 1940s in North America and Europe. Fortification with the suggested levels of each compound (Table 1), and depending on the estimated per capita availability of wheat flour consumption, has been shown to improve iron status in populations *(77).*

Folic acid

Wheat flour fortification with folic acid increases dietary folic acid intakes and might reduce the risk of neural tube defects and other folate-preventable congenital anomalies. WHO recommendations concluded that studies in the Americas have shown decreases of between 26% and 40% in births affected by neural tube defects after implementation of mandatory wheat flour fortification with folic acid *(77)*. More recent evidence, from a meta-analysis of eight studies in five countries published in 2010, confirms an overall reduction in the risk of neural tube defects of 46% *(76)*. Estimated cost–benefit ratios of fortification for the prevention of spina bifida range from 1:12 up to 1:48 *(79–81)*.

Vitamin B12

The consensus statement noted that evidence was lacking about the population impact of fortification with vitamin B12 but concluded that, nonetheless, this could be a feasible approach to ensure optimal vitamin status *(77)*.

Vitamin A

Although there is some fortification of vegetable oil with vitamin A, the experience of wheat flour fortification with vitamin A is limited. Although there is evidence of its efficacy from trials, evidence on the effectiveness of fortification at the national level is lacking. Nonetheless, the recommendations concluded that wheat flour fortification with vitamin A, at the levels proposed in Table 1, could be considered for populations at risk of vitamin A deficiency. It is important to note, however, that vegetable oil is widely consumed in the Region and vitamin A fortification of oil is likely to be more cost-effective than adding vitamin A to wheat flour.

Zinc

Evidence from trials and from fortification of other foods suggests that fortification with zinc could increase intake and improve absorption, although data on the public health effect of national fortification programmes are lacking. The recommendations concluded that further research is needed, but noted that fortification with the levels suggested in Table 1 could, in theory, improve population nutrition status. A 2016 Cochrane systematic review found that zinc fortification had a better effect if zinc were the only added micronutrient *(82)*.

Vitamin D

Increasingly, countries are interested in fortification with vitamin D because it occurs naturally in only a small number of foods. A careful approach is needed, however, to reach the whole population, and particularly at-risk groups, while minimizing the risk of excessive intake. In addition, there is no clear consensus on what constitutes adequate vitamin D status. Currently, there is no WHO recommendation for fortification with vitamin D and guidance is being prepared on this issue.

Recommended levels for food fortification

The WHO recommendations specify suggested average levels of nutrients for wheat flour fortification (Table 1). These levels are based on wheat flour being the main fortification vehicle and, if other mass-fortification programmes are implemented, these levels need to be adjusted downwards.

3.2.2 Regulatory monitoring and enforcement

Effective monitoring to ensure adherence to national food fortification standards and regulations requires multiple points of assessment of the food fortification system. Regulatory monitoring should have both external and internal monitoring systems.

Table 1. WHO recommendations on average levels of nutrients to consider adding to fortified wheat flour based on extraction, fortificant compound and per capita flour availability

Nutrient	**Flour extraction ater**	**Compound**	**Level of nutrient to be added in parts per million (ppm) by estimated average per (capita wheat flour availability (g/day[9]**			
			75>[10]g/day	**149-75 g/day**	**300-150 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[11]	NR[11]	60	40
	High	NaFeEDTA	40	40	60	40
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[12]	Low	Zinc oxide	95	55	40	30
	High	Zinc oxide	100	100	80	70

[9] These estimated levels consider only wheat flour as main fortification vehicle in a public health programme. If other mass-fortification programmes with other food vehicles are implemented effectively, these suggested fortification levels may need to be adjusted downwards as needed.
[10] Estimated per capita consumption of <75 g/day does not allow for additional 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.
[11] NR=Not Recommended because very high levels of electrolytic iron needed could negatively affect sensory properties of fortified flour.
[12] These amounts of zinc fortification assume 5 mg zinc intake and no additional phytate intake from other dietary sources.

At the food plant level, the manufacturer is responsible for systematic monitoring and documentation through quality control/quality assurance processes, such as good manufacturing practice (GMP), hazard analysis critical control point (HACCP) or the International Organization for Standardization (ISO) standards on quality management. The government should also conduct inspections and technical auditing for compliance at the factory level, and is also responsible for inspection and control at import entry points.

Analysis of samples is an important element of the monitoring activities to determine compliance, but reliance on sampling only is not enough. Regulatory monitoring needs to look at the system as a whole and should make effective use of data and documentation that are collected systematically.

Fig. 7 illustrates the different elements – above the dotted line – of regulatory monitoring (food control).

3.2.3 Monitoring of the effect on public health

In addition to regulatory monitoring of compliance with fortification requirements, governments need to evaluate the fortification process and monitor its effect on public health. This can include monitoring and evaluating the process, as well as the effect on individuals, households and communities in terms of behaviour, nutritional status and health or other outcomes (Fig. 7, below the dotted line).

Fortification programmes will take time to have an effect on public health and show up as improvements in nutritional status or health outcomes. Sustained high coverage of good quality, fortified flour over time is necessary before an effect on micronutrient status will be detectable.

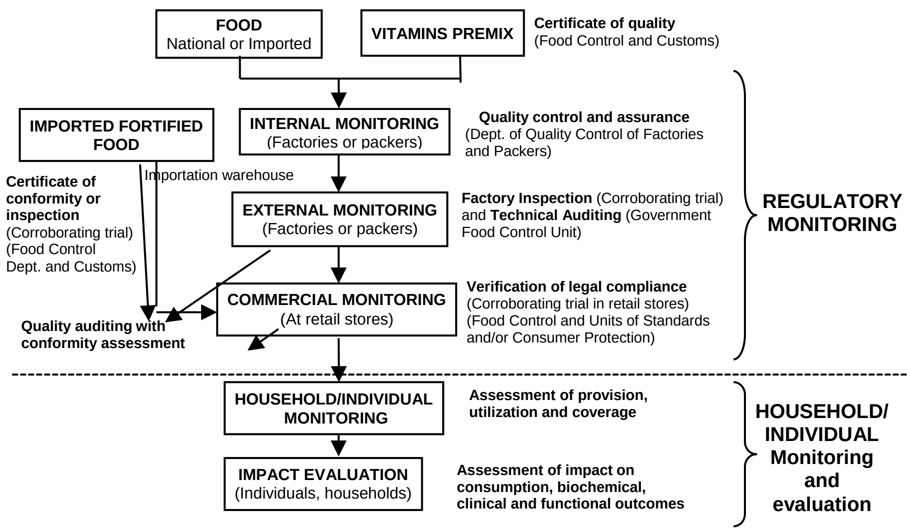


Fig. 7 Systems for regulatory monitoring (food control), and monitoring and evaluation of food fortification and its effect on public health [Source: *(77)*]

The Fortification, Monitoring and Surveillance tool (FORTIMAS) is available to help authorities track trends in population coverage and the effect of flour fortification over time. FORTIMAS is not designed to replace representative nutritional surveillance, but can inform decisions about when a full nutrition survey might be appropriate to examine the effect of fortification. FORTIMAS, developed by the Food Fortification Initiative and Smarter Futures, uses data from existing national systems, from sentinel site and purposive data collection and convenience sampling.[13]

3.2.4 Food safety

It is essential that all food fortification initiatives avoid oversupply of the added nutrient(s). Regulation and/or technical standards should include provisions to prevent or minimize the risk of excessive intake. Such safety considerations need to take into account all interventions to improve micronutrient status and the total micronutrient intake of the population.

There have been attempts to classify nutrients into three categories according to the difference between the recommended (or actual) intakes and estimated upper safe intake levels:

- *Large safety margin* (upper safe intake level is almost impossible to set) – vitamins B1, B2, B12, phylloquinone (vitamin K1), biotin and pantothenic acid
- *Moderate safety margin* (upper safe intake level is 5–100 times above the recommended levels) – vitamins B6, C and E.[14] Consideration should be given to side-effects or interactions with other components in the diet
- *Narrow safety margin* (upper safe intake level is 5 or fewer times above the recommended levels) – vitamins A, D, niacin and folic acid, as well as all minerals. Great caution is required *(83).*

The simultaneous implementation of different interventions to deliver micronutrients – including food fortification – presents several challenges in terms of safety. This is particularly the case where there are overlaps in the population groups targeted by various interventions because these groups might be at risk of excessive intakes. In response to these challenges, and following a technical consultation in October 2017, WHO is preparing further guidance to help Member States make informed decisions on the implementation of programmes delivering micronutrients. It is clear that a coordinated approach to the implementation of multiple interventions is essential. A situation analysis of the interventions that are in place or planned and their contexts can provide a useful framework for more effective public health micronutrient interventions. In addition, the establishment of national coordination mechanisms to monitor the situation, with an overview of interventions and potential intakes, is advisable to minimize the risk of excessive intakes.

[13] See http://www.smarterfutures.net/fortimas, accessed 7 February 2019.
[14] Please note that vitamin C is not recommended as a fortificant in cereal flours.

3.2.5 Trade considerations

Policy-makers need to take account of trade considerations when implementing food fortification initiatives in order to pre-empt any potential problems. Codex provides guidance and recommendations that are relevant to fortified foods, including general principles for the addition of essential nutrients to foods, guidelines on food labelling and claims, as well as a standard for wheat flour.

Governments need to ensure that standards comply with international agreements to which they are party. Members of the World Trade Organization are allowed to adopt measures necessary to protect health, but such measures are not to be applied in a way that would constitute arbitrary or unjustifiable discrimination between members. This means that if standards are not based on all available scientific evidence, they may be vulnerable to challenge from other countries through the World Trade Organization. Countries are encouraged to share draft standards with trading partners in advance, in order to pre-empt any potential trade issues.

4. PROGRESS WITH WHEAT FLOUR FORTIFICATION

Globally, there has been considerable progress in implementing wheat flour fortification in recent years (Table 2). The number of countries with mandatory wheat flour fortification (with at least iron and folic acid) increased from 33 WHO Member States in 2004 to 84 by 2015.

It is estimated that, worldwide, 28% of flour in industrialized mills was fortified in 2015, up from 18% in 2004.

The extent of fortification varies between regions, with near universal fortification in the Americas (Fig.). The Eastern Mediterranean Region had the second highest proportion of flour fortified (54%) in 2016.

Table 2. Countries with legislation on fortification of industrially milled flour and rice[a]

Type of flour fortified	No. of countries	Countries
Wheat flour	61	Antigua and Barbuda; Argentina; Australia; Bahamas; Bahrain; Barbados; Belize; Benin; Bolivia, Plurinational State of; Burkina Faso; Cabo Verde; Cameroon; Canada; Chile; Colombia; Congo; Cote d'Ivoire; Cuba; Djibouti; Dominica; Dominican Republic; Ecuador; Fiji; Ghana; Grenada; Guinea; Guyana; Haiti; Honduras; Indonesia; Iraq; Jamaica; Kazakhstan; Kiribati; Kosovo, Republic of; Kuwait; Liberia; Mali; Moldova, Republic of; Morocco; Nepal; Niger; Oman; oPt; Paraguay; Peru; Saint Kitts and Nevis; Saint Lucia; Saint Vincent and the Grenadines; Saudi Arabia; Senegal; Solomon Islands; Suriname; United Republic of; Togo; Trinidad and Tobago; Turkmenistan; United Kingdom of Great Britain and Northern Ireland; Uruguay; Viet Nam; Yemen.
Rice	1	Papua New Guinea
Wheat flour and maize flour	14	Brazil; Burundi; El Salvador; Guatemala; Kenya; Malawi; Mexico; Mozambique; Nigeria; South Africa; Tanzania, United Republic of; Uganda; Venezuela, Bolivarian Republic of; Zimbabwe.
Wheat flour and rice	3	Nicaragua, Panama, Philippines
Wheat flour, maize flour and rice	2	Costa Rica, United States of America

[a] Legislation mandates grain fortification with at least iron or folic acid.

Source: Food Fortification Initiative, March 2017 (http://www.ffinetwork.org/).

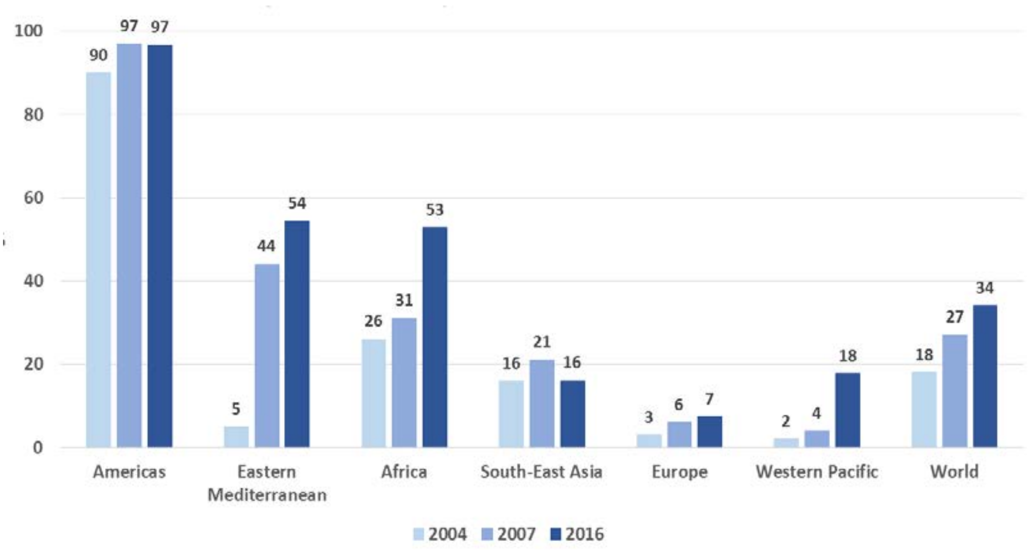


Fig. 8 Percentage of industrially milled wheat flour that is fortified, by WHO Region (Source: Food Fortification Initiative www.ffinetwork.org)

4.1 Wheat flour fortification in the Region

There has been considerable progress with flour fortification in the Region. Most countries (17 of 22 countries) have some coverage of wheat flour fortified with iron and folic acid, and this is mandatory in 11 Member States (Table 3). Eight countries fortify wheat flour with B vitamins, while fortification with vitamin D, vitamin A and zinc is currently rare (two countries in each case).

Some countries have made good progress despite conflict and/or civil unrest. In other countries, however, political instability or complex administrative arrangements have impeded progress.

Fortification strategies – often combined with other efforts to improve micronutrient status, including nutrition education and, where appropriate, supplementation – are having an effect. A number of countries with good coverage of flour fortification, and with the necessary data, report reductions in the prevalence of anaemia and iron deficiency, and in the incidence of neural tube defects.

4.2 Status of wheat flour fortification in countries

4.2.1 Afghanistan

Afghanistan has a voluntary programme for fortifying wheat flour with vitamin B12, zinc, iron, folic acid and vitamin A. Recently it has introduced fortification of oil with vitamins A and D. Large-scale flour fortification started in 2006, with support from the United Nations World Food Programme. Fortification is not yet mandatory, but legislation is currently in preparation, and training on quality control/assurance has been provided to nutrition officers and millers in five provinces.

A major challenge is that 95% of wheat flour is imported and the system for inspection and control of imported flour has not functioned well so far. Other challenges include the low quantity and quality of locally produced wheat flour. In addition, awareness of the importance of fortified flour is low among traders, who tend to import non-fortified flour from neighbouring countries.

Priorities for future action include ratification of the legislation for flour and oil fortification, and advocacy and awareness-raising efforts to create public awareness of food fortification, supplementation and dietary diversification. A micronutrient promotion strategy will be pursued through mass media and information education communication (IEC) materials. Food fortification will be integrated into the nutrition surveillance system.

Table 3. Summary of wheat flour fortification status in the Eastern Mediterranean Region

Country	Fortification status	Nutrients					Estimated coverage (according to estimates of the Food Fortification Initiative)
		Iron (level and type where available)	Folic acid (level)	Vitamin D	B vitamins	Other	
Afghanistan	Voluntary, but legislation in process	✔(15 ppm, sodium iron EDTA)[a]	✔(1 ppm)[a]	✗	B12	Vitamin A	Only 26% of flour is produced in industrial mills, only 2% of which is fortified
Bahrain	Mandatory	✔(60 ppm, elemental iron)[b]	✔(1.5 ppm)[b]	✗	✗	✗	All of the flour is produced in industrial mills, 90% of which is fortified
Djibouti	Mandatory	✔ (60 ppm, electrolytic iron)[c]	✔(1.5 ppm)[c]	✗	✗	Zinc	All flour is industrially milled by 1 mill , 95% of which is fortified
Egypt	Stalled since 2011, discussions ongoing	✔(30 ppm)[d]	✔(N/A)	✗	✗	✗	All flour is produced in industrial mills, but none is fortified
Iran, Islamic Republic of	Mandatory since 2007	✔(30 ppm)[b]	✔(1.5 ppm)[b]	Proposal in development	✗	Zinc: proposal in development	All flour is produced in industrial mills, 100% of which is estimated to be fortified
Iraq	Mandatory since 2008, government provision of premix stalled since 2014	✔(30 ppm as ferrous sulfate/60 ppm electrolytic iron)[c,d]	✔(2.1 ppm)[c]	✗	✗	✗	All flour is produced in industrial mills, but premix provision has stalled recently
Jordan	Mandatory since 2002	✔ (32 ppm, Ferrous sulphate)[b]	✔(1 ppm)[b]	✔	B1, B2, B3, B12, B6	Zinc, vitamin A, vitamin D	About 93% of Jordan’s wheat flour production is fortified
Kuwait	Mandatory	✔ (30 ppm as ferrous sulfate/60 ppm electrolytic iron)[c,d]	✔(1.75 ppm)	✗	B1, B2, B3	✗	All flour is produced in industrial mills, 100% of which is estimated to be fortified
Lebanon	No mandatory or voluntary fortification	✔ (No recommended levels)[b]	✔	✗	B1, B2, B3	✗	All flour is produced in industrial mills and none is fortified (one mill may be voluntarily fortifying)
Libya	No mandatory or voluntary fortification	✗	✗	✗	✗	✗	No flour is reported to be fortified
Morocco	Mandatory since 2006	✔(45 ppm)[b]	✔(N/A)	✗	✗	✗	All flour is produced in industrial mills, 70% of which is estimated to be fortified

Occupied Palestinian territory	Mandatory standard in place	✔(34 ppm average, ferrous sulphate)[b]	✔(1.5 ppm)[b]	✔	B1, B2, B6, B12, B3	Vitamin A, Zinc	All flour is produced in industrial mills, 100% of which is estimated to be fortified
Oman	Mandatory since 1996	✔(30 ppm)[d]/(120 ppm, multiple compounds allowed)[c]	✔(1.5 ppm)[c]	✗	✗	✗	All flour is produced in two industrial mills, 89% of which is estimated to be fortified
Pakistan	Mandatory in some provinces, national roll-out planned	✔(15 ppm)[a]	✔(1 ppm)[a]	✗	B12[a]	Zinc[a]	60% of flour is produced in industrial mills, 2% of which is estimated to be fortified
Qatar	Voluntary fortification	✔(30 ppm as ferrous sulfate/60 ppm electrolytic iron)[c,d]	✔(1.75 ppm)[c]	✗	B1, B2, B3	✗	All flour is produced in two industrial mills, 90% of which is estimated to be fortified
Saudi Arabia	Mandatory	✔(36 ppm)[c]	✔ (1.75 ppm)[c]	✗	B1, B2, B3	✗	All flour is produced in industrialized mills, 100% of which is estimated to be fortified
Somalia	No mandatory or voluntary fortification	✗	✗	✗	✗	✗	All flour is produced in one industrial mill but none is fortified
Sudan	Voluntary fortification by one mill. Law for mandatory fortification in development	✔voluntary (N/A)	✔ voluntary (N/A)	✗	✗	✗	80% of flour is produced in industrial mills, 40% of which is estimated to be fortified
Syrian Arab Republic	Voluntary fortification	✔(30 ppm ferrous sulfate)[d]	✔	✗	✗	✗	80% of flour is produced in industrial mills, 5% of which is estimated to be fortified
Tunisia	No national fortification programme, but the policy is being reconsidered	✗	✗	✗	✗	✗	All flour is produced in industrial mills but none is fortified
United Arab Emirates	Voluntary fortification	✔(30 ppm)[c,d]	✔ (1.75 ppm)[c]	✗	B1, B2, B3	✗	All flour is produced in industrial mills, 90% of which is estimated to be fortified
Yemen	Mandatory fortification	✔ (30 ppm as ferrous sulfate/60 ppm electrolytic iron)[c,d]	✔	✗	✗	✗	All flour is produced in industrial mills, 100% of which is estimated to be fortified

EDTA = ethylenediaminetetraacetic acid; N/A = not available.

[a] Proposed levels for new standard. Information from country representative.
[b] Source: country representative.
[c] Source: Food Fortification Initiative.
[d] Source: (41).

4.2.2 Bahrain

Flour fortification started in November 2002 in the country's only milling company, and there is now a mandatory requirement for locally produced or imported flour to meet the national wheat flour fortification standard (fortification with iron and folic acid according to WHO recommendations). Monitoring and enforcement is carried out by the food inspection section of the Public Health Directorate, which sends inspectors to visit mills once every two months. Generally, a very high level of compliance has been found.

As well as fortification, national strategies to improve iron status include supplementation and nutrition education. The prevalence of anaemia in children aged between 6 and 18 years decreased between 2005 and 2011, the proportion of people with normal haemoglobin levels has increased, the prevalence of iron deficiency anaemia among pregnant women has declined, and the incidence of neural tube defects has fallen since 2000 (information from the nutrition focal point).

The challenges in Bahrain include an insufficient number of food inspectors and not been enough regular sampling from local bakeries.

There are plans to raise awareness of the results of flour fortification and the WHO recommendations. There are also plans to extend the programme to include fortification with vitamin D. This will require updating the legislation and expanding the remit of the stakeholder committee to plan for implementation and monitoring.

4.2.3 Djibouti

There is mandatory fortification of wheat flour with iron, zinc and folic acid in the one industrial mill that provides all the flour in the country. Fortification is reported to cover 95% of the industrially milled flour in the country.[15]

4.2.4 Egypt

Following five years of preparation for a three-phase introduction of flour fortification (with iron and folic acid), the programme has stalled since the political changes in 2011.

The main challenges have been funding, a lack of political will and political instability leading to frequent personnel changes within ministries. There have also been changes to the subsidy programme for the local (*baladi*) bread. There are now ongoing discussions between the Ministry of Health and Population, the Ministry of Supply and the World Food Programme to try and restart the programme.

Priorities for future action include forming a stakeholders' committee for social marketing, beginning premix production, and providing training to workers and analytical laboratories. Work is planned on legislation, monitoring and evaluation.

[15] Information from the Food Fortification Initiative.

4.2.5 Islamic Republic of Iran

Following fortification efforts at the provincial level, a national flour fortification plan was developed between 2004 and 2006 and mandatory flour fortification started in 2007. Flour is fortified with iron and folic acid. Quality assurance/control components are in place at the mills and analytical testing takes place in both factory and government laboratories.

The prevalence of low serum folate and hyperhomocysteinaemia was lower after flour fortification, and mean serum folate increased between 2006 and 2009. A 31% reduction in the incidence of neural tube defects was recorded between 2005/2006 and 2008/2009. The prevalence of anaemia and iron deficiency also fell in all age groups between 2001 and 2012 (Z. Abdollahi, personal communication, 2017).

The priorities for future action are to:

- increase coverage of flour fortification with iron and folic acid by holding advocacy meetings with the private sector (mills), and improve government monitoring and enforcement;
- improve the efficacy of flour fortification with iron and zinc, and provide technical support to small bakeries on the fermentation approach;
- develop a technical proposal for fortification of flour with zinc and vitamin D, after carrying out research on the amount of phytic acid in breads, with a pilot study in one province in 2018 and scale-up in 2019.

4.2.6 Iraq

A wheat flour fortification programme was introduced in August 2006 with support from UNICEF. Since 2008, the specification has been mandatory and the government allocated the necessary budget to procure the premix. Provision of the premix (ferrous sulfate and folic acid) continued until 2013 but stopped in 2014.

Fortification, combined with supplementation and nutrition education, has been a successful part of national nutrition efforts. The prevalence of anaemia in women (15–49 years) decreased from 35% in 2008 to less than 20% in 2014. The prevalence of anaemia among children under 5 years decreased from 26% in 2010 to 21% in 2014 (W. Rasheed, personal communication, 2017).

The main challenges have been the unstable security and economic situation, together with problems with electricity supply, premix provision, and shortage of equipment and training. In addition, most mills are privately run and maintaining feeders is difficult.

Priorities for future action include reviewing and updating legislation, in light of the recent national nutrition survey, in order to expand flour fortification to include other micronutrients. Other priorities are to strengthen the monitoring and evaluation system, and sustain the funding that is already allocated for fortification of flour.

4.2.7 Jordan

A mandatory national wheat flour fortification programme has been in place in Jordan since April 2006. Mills that do not comply with national standards are subject to fines. To begin with, iron and folic acid were added to the premix and, since 2006, zinc, vitamins A, B1, B2, B3, B6 and B12 have been added. In 2010, vitamin D was added. The monitoring system has two basic components – internal monitoring by the millers and external monitoring by the government.

The prevalence of iron deficiency and iron deficiency anaemia decreased in women aged 15–49 and children under 5 years between the baseline study in 2000 *(84)* and a national study in 2010 (H. Masa'd, personal communication, 2017).

Challenges include funding for the premix, the cost of subsidized bread for the refugee population and the need to train more personnel in the many mills across the country.

Priority actions for the future include conducting an impact study on fortification, and improving the monitoring and enforcement system through capacity building, financial support and strengthening of the reporting system. In addition, technical support on fortification will be provided to mills.

4.2.8 Kuwait

Wheat flour fortification (iron, folic acid, niacin, riboflavin, thiamine) is mandatory in Kuwait. One industrial mill in the country produces all of the flour, and 100% coverage of fortification is reported.[16]

4.2.9 Lebanon

Lebanon does not have mandatory or voluntary wheat flour fortification. A maximum upper limit for wheat fortification of special 60% extraction flour (not the usual breadmaking flour) was cited in the 2006 standard, but this was removed in the 2014 revised standards.

The main challenges include: difficulty in harmonizing standards and procedures for inspection, and coordinating the involvement of three government ministries; an inactive national coordination committee on wheat flour fortification; the high cost of the proposed measures; and the absence of testing for iron in wheat flour.

The priorities for the future are to: conduct a baseline survey on micronutrient status, develop recommendations, and prepare legislation on wheat flour fortification.

4.2.10 Libya

There is no wheat flour fortification in Libya.[17]

[16] Information from the Food Fortification Initiative.
[17] Information from the Food Fortification Initiative.

4.2.11 Morocco

Morocco's micronutrient deficiency control programme includes supplementation, nutrition education, fortification and public health measures.

Flour fortification started in 2004 and has been mandatory since 2006, with a sentinel monitoring and evaluation system. Coverage has been increasing since 2007 and, by 2010, 72% of flour in the country was fortified. The flour fortification system was reviewed and revised in 2015–2016.

The prevalence of anaemia in young children (2–5 years) decreased from 47.8% in 2006 to 29.9% in 2008 (16). Folic acid deficiency in women also decreased between 2006 and 2008, and the incidence of neural tube defects decreased between 2008 and 2011 (16).

Priorities for future action include revision of the fortification legislation and introduction of a new premix with iron (ferric sodium EDTA) and folic acid recently approved by the national nutrition committee. The surveillance system will also be reinforced, with support from experts, and research completed on the effectiveness of wheat flour fortified with ferric sodium EDTA.

4.2.12 Oman

Fortification of wheat flour has been mandatory in Oman since 1996. All flour produced in the country is produced in industrial mills, and the fortification programme covers 89% of the flour in the country. Flour is fortified with iron and folic acid. [18]

The annual incidence of spina bifida fell sharply in 1997 and continued to fall until 2006 *(85)*.

4.2.13 Pakistan

Many small-scale wheat flour fortification projects were conducted between 2005 and 2011. A key challenge in Pakistan is that each province is responsible for its own legislation. Mandatory fortification was introduced in Punjab in 2017, and is planned for Sindh and Islamabad Capital Territory in 2018 and Balochistan in 2019.

A national fortification alliance was established in 2013 in order to provide a forum for the relevant stakeholders from different government ministries, international/national agencies and partners to plan, monitor and support food fortification efforts. Provincial fortification alliances have also been established. Vitamin and mineral premixes for use in fortification are now exempt from duties and sales tax.

A five-year food fortification programme, funded by the United Kingdom Department for International Development, is focusing on wheat flour and oil fortification, and the gradual expansion to all provinces.

[18] Information from the Food Fortification Initiative.

Priorities for future action include introduction of mandatory legislation, and allocation of government funding for the implementation and strengthening of monitoring and enforcement of legislation. In addition, efforts to improve the quality assurance/quality control and monitoring through training and capacity-building activities for industry and monitoring staff are planned for 2017–2019.

4.2.14 Occupied Palestinian territory (oPt)

Flour fortification started in the oPt in 2006. The 40% of flour consumed by Palestinians which is milled in the West Bank (eight mills) and Gaza (three mills) has to meet the technical standard. Flour is fortified with folic acid, iron, vitamins B12, B1, B2, B6, A and D, niacin and zinc. The premix is manufactured in the oPt by pharmaceutical companies. About 60% of flour in the West Bank is fortified with iron, although only around 40% complies with the Palestinian technical regulations. In Gaza, only 11% of flour appears to be fortified with iron and only 1.7% meets the regulations.

The main challenges include the difficulty of border controls, weak monitoring, a lack of funding, and incomplete application of the law. In Gaza, only flour provided by the United Nations complies with the regulations. In addition, the premix is not subsidized by the government and mills have to purchase it.

Future priorities are to find a way to subsidize the premix in order to ensure sustainability, and to improve enforcement of the law by increasing the monitoring capacity of inspectors. An additional priority will be to build capacity for micronutrient testing.

4.2.15 Qatar

Qatar has voluntary fortification of wheat flour with one mill producing all the industrially-milled flour. It is reported that 90% of industrially milled flour is fortified (iron, folic acid, niacin, riboflavin and thiamine).[19]

4.2.16 Saudi Arabia

Saudi Arabia has mandatory flour fortification (iron, folic acid, niacin, riboflavin and thiamine). All the flour is produced in industrial mills, and 100% coverage of fortification is reported.[20]

4.2.17 Somalia

There is no wheat flour fortification in Somalia.[21]

4.2.18 Sudan

Strategies to control micronutrient deficiencies in Sudan include supplementation and a home fortification (with micronutrient powders) project that has recently started in

[19] Information from the Food Fortification Initiative.

[20] Information from the Food Fortification Initiative.

[21] Information from the Food Fortification Initiative.

some states. A law on mandatory food fortification is currently in development and is expected to be passed soon.

A national fortification alliance – bringing together different government sectors, United Nations agencies, private sector, nongovernmental organizations and academia – was established in January 2005 and reactivated in 2013. One of the six large wheat flour mills (which together produce more than 90% of wheat flour in the country) has been fortifying flour voluntarily with iron and folic acid since 2005. A new four-year food fortification project was established in 2017 to support food fortification in Sudan.

An important challenge is to ensure the sustainability of financial support for fortification.

Future priorities include enforcing a national specification for fortified flour, increasing awareness of the importance of using fortified food, boosting industry commitment, building capacity of governmental and nongovernmental personnel, and supporting surveillance systems.

4.2.19 Syrian Arab Republic

Voluntary fortification is reported to cover an estimated 5% of industrially milled flour, which, in turn, accounts for 80% of the country's flour supply.[22]

4.2.20 Tunisia

There is no national programme for wheat flour fortification. A project to fortify flour with iron was established with UNICEF but has not been implemented.

A recent national survey has shown that anaemia is a public health problem (29.2% total prevalence in 2016), and therefore the flour fortification project will be revised and implemented. A national survey is required to determine the extent of vitamin D deficiency and to consider whether fortification of flour or milk with vitamin D is necessary.

4.2.21 United Arab Emirates

A voluntary fortification programme covers 90% of the industrially milled flour produced in the country. This includes fortification with iron, folic acid, niacin, riboflavin and thiamine.[23]

Future priorities include assessment of micronutrient status in the country, establishment of a specification to standardize nutrient levels to be added to flour, raising of community awareness and improvement in monitoring of flour fortification.

[22] Information from the Food Fortification Initiative.
[23] Information from the Food Fortification Initiative.

4.2.22 Yemen

Mandatory fortification with iron and folic acid is estimated to cover 100% of the industrially-milled wheat flour in Yemen (where all the flour is produced in industrial mills).[24]

4.3 Common challenges for wheat flour fortification in the Region

A number of common challenges can be identified from the experience of countries with implementation (or attempted implementation) of wheat flour fortification. These include:

- lack of political will and general low awareness of the importance of tackling micronutrient deficiencies, coupled with inadequate data on food consumption and nutrient status to inform public policy-making and monitor progress;
- coordinating different ministries and government bodies from multiple sectors, and mobilizing the private sector;
- securing sustainable funding (especially for the provision of the premix);
- controlling imports of wheat and/or wheat flour;
- expanding coverage of fortification when a substantial proportion of flour is produced by many small-scale mills;
- insufficient numbers of food inspectors and/or training for inspectors;
- shortage of equipment and the costs of long-term maintenance of equipment (e.g. feeders);
- building capacity by training mill workers, managers, inspectors etc.;
- evaluating the effect of fortification because it is often implemented with other micronutrient strategies (e.g. supplementation, measures to promote dietary diversity);
- limited research that shows the cost–benefit of flour fortification for countries in the Region (flour fortification can reduce iron deficiency and iron deficiency anaemia thus improving productivity, and has been shown to reduce neural tube defects thus lowering the economic burden on families).

4.4 Lessons learned

Experiences from some countries of the Eastern Mediterranean Region can provide useful lessons for other countries that want to introduce or expand wheat flour fortification.

Countries that have successfully implemented food fortification and seen improvements in micronutrient status, have identified several key elements for success.

- Government commitment, at the highest possible level, is essential.
- Strong advocacy is needed to convince the government of the importance of taking action.
- A mandatory approach, with clear technical standards, is more likely to be effective.
- A multisectoral alliance, bringing together all relevant stakeholders – government, United Nations agencies, donors and the private sector – can help

[24] Information from the Food Fortification Initiative.

drive the process forward, provided that strong safeguards are in place to prevent and manage conflicts of interest.

- Strong monitoring and enforcement systems, which combine both internal monitoring (in the mills) and external monitoring by food control inspectors, are essential.
- Financial support, particularly for the provision of the premix, is sometimes necessary.
- The costs of maintaining equipment can be reduced by negotiating with suppliers of equipment to provide an after-sales warranty for repairs, for a very small additional initial cost.

Salt iodization: an example of fortification success

Iodine deficiency disorders are a serious public health threat worldwide and are a leading cause of mental development disorders in young children. Salt iodization is a simple, inexpensive solution that can eliminate iodine deficiency disorders, and universal salt iodization has been recommended by WHO and UNICEF since 1994. Salt is a suitable vehicle to delivery iodine because it is consumed daily by almost everyone, is made by a limited number of producers, is technically easy and inexpensive, and iodine does not affect the colour, taste or smell of salt. It is estimated that the cost–benefit ratio of salt iodization, when only the health benefits are counted, is 1:3. If the benefits of educational attainment and productivity are included, then every dollar invested should return 10 dollars in benefits.

Considerable progress has been made with salt iodization. Over 120 countries now implement salt iodization programmes – this number increased by about a third between 2002 and 2007 – and 34 countries have reached the goal of universal salt iodization. It is estimated that the proportion of households worldwide using iodized salt increased from less than 20% in the early 1990s to around 70% by 2000. The number of countries with iodine deficiency has fallen from 54 in 2003 to 31 in 2013. Nonetheless, more progress is needed – 28.5% of the world's population still have insufficient dietary iodine intake.

In the Eastern Mediterranean Region, it is estimated that nearly 64% of households consume adequately iodized salt. Countries of the Gulf Cooperation Council have now been declared free of iodine deficiency disorders. Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Kuwait, Oman, oPt, Qatar, Saudi Arabia, Tunisia and United Arab Emirates have achieved the goal of universal salt iodization and now need to sustain the achievement. In Jordan, 96% of households used adequately iodized salt in 2010 according to the national survey on iodine deficiency disorders. In Afghanistan, Iraq, Lebanon, Libya, Morocco, Pakistan, Somalia, Syrian Arab Republic and Yemen household consumption of adequately iodized salt is less than 50% and programmes need to be strengthened to achieve the target. In Sudan, only 11% of the salt used in households is adequately iodized.

The global experience in implementing universal salt iodization in over 150 countries over the past 50 years can provide some guidance on how to implement and drive forward successful fortification to tackle micronutrient deficiencies. Key factors for success include:

- mandatory legislation to achieve higher coverage;
- regulatory monitoring to assess quality and assure the compliance of all producers;
- close collaboration with industry on implementation;
- cost recovery systems for the procurement of premix – and no external subsidization;
- tracking coverage in the population to determine whether programmes are reaching everyone, especially the most vulnerable.

Based on the experiences with salt iodization, for fortification to be successful it is essential that a fortified product is available in the marketplace, consumers are aware of the importance of using the product, an adequate proportion of the population consistently uses the product, and periodic measurements show changes in nutrient status.

5. CONCLUSIONS

While efforts to improve nutrition should always be based on transforming food systems to improve access to and availability of diverse and good quality diets, food fortification can also play a role in tackling vitamin and mineral malnutrition, known as “hidden hunger”.

Wheat flour fortification is an effective way to tackle micronutrient malnutrition in the Eastern Mediterranean Region and countries are encouraged to use this approach together with efforts to increase dietary diversity, nutrition education and, as appropriate, supplementation for particular groups as part of national strategies to improve nutrition.

5.1 Defining an appropriate food fortification strategy

- National decision-makers are responsible for deciding whether fortification is justified and defining an appropriate fortification strategy (type and quantity of vitamins and minerals to include and choice of compound). This should be based on the country context (nutritional needs of the population, regular consumption patterns, technical considerations, micronutrient intakes from other sources and costs) and take into account existing recommendations on wheat and maize flour fortification.
- Member States considering implementing or amending a fortification strategy should conduct a situation analysis and use this to inform transparent policy decisions.

5.2 Up-to-date data for informed decision-making

- To be able to define an appropriate strategy, evaluate the risks and benefits of fortification, and track progress in implementing a food fortification strategy, countries need strong systems to gather reliable national data on food consumption (and related data on food composition) and nutrition status.
- It is important to take into account possible interactions between micronutrients, both in assessing nutrient status and in foods.
- Updated national data are urgently needed in the Eastern Mediterranean Region to help countries make informed policy and programme decisions.
- Member States are encouraged to use cost–benefit tools to estimate, based on existing data, the country-specific costs of non-action and fortification, and calculate the economic benefits of fortification.

5.3 Implementing a wheat flour fortification programme

- When implementing fortification, countries are urged to follow the latest WHO recommendations on best practice for wheat flour fortification, including recommendations on appropriate micronutrient levels and compounds *(77)*.
- A mandatory approach to flour fortification is recommended through primary legislation, food regulations or technical standards. Voluntary fortification is less likely to result in increased intakes of micronutrients in a target population.

- For fortification strategies to be effective, legislation and standards must apply to both imported and domestically produced flour, and these should be enforced at the point of importation.
- To avoid international trade issues, standards should be based on the scientific evidence and should represent a reasonable response to a public health problem. Countries are encouraged to share draft standards with members of the World Trade Organization and trading partners.

5.4 Safety considerations

- Legislation, standards and/or specifications related to fortification should always include provisions to prevent or minimize the risk of excessive intake.
- Countries are encouraged to form an advisory group that covers all micronutrient interventions in order to monitor intakes, coordinate efforts to minimize the risk of excessive intakes, and advise on appropriate interventions.

5.5 Regulatory monitoring and enforcement

- Monitoring and enforcement systems need both internal monitoring by the food production industry through quality assurance processes, and external monitoring by the government (at the appropriate level) including food inspections and technical auditing.
- Sampling and analysis are important elements of monitoring to determine compliance, but are not enough on their own. Regulatory monitoring needs to look at the system as a whole and should make use of data and documentation collected systematically.

5.6 Evaluating the effect on public health

- Regular data on food consumption and nutritional status are needed to define an appropriate strategy and to monitor progress. Countries have obligations to report on progress towards global nutrition targets (including anaemia in women of reproductive age), and are encouraged to regularly report on other nutrition indicators, including the prevalence of micronutrient deficiencies, particularly in vulnerable groups.
- Reporting prevalence data disaggregated into mild, moderate and severe levels of deficiency, where possible, is useful to track progress that is not immediately apparent from total prevalence figures.
- When reporting prevalence data, it is important that countries provide details of the indicators, methodology and cut-offs used.
- Countries are encouraged to monitor and assess coverage of fortification. When high coverage of good quality, fortified flour has been sustained over time, they should assess the effect on nutritional status (if regular nutrition surveillance is not in place). Tools such as FORTIMAS can help track trends in population coverage and the effect of flour fortification over time using existing data.

5.7 Sustainability/funding

- Fortification programmes need to be designed to be sustainable from the start. Short-term funding should only be used to kick-start a programme when a plan for sustainable funding in the long term has also been developed.

5.8 Regional cooperation

- Cooperation between Member States at the regional level should be expanded in order to exchange information on best practice, learn from the experience of other countries, and ensure that all policy-makers are aware of new technological developments and innovations.
- Although strategies need to suit the country context, countries are encouraged to pursue a harmonized approach between countries with similar levels of micronutrient deficiencies and similar needs. This would also maximize access to fortified flour and facilitate trade within the Region.
- A regional alliance on micronutrients is recommended to facilitate communication between Member States. The Regional Office can help establish such an alliance.

5.9 Requests for guidance and support

Member States that participated in the training workshop on best practices of wheat flour fortification in Rabat in October 2017 identified several areas where further support or guidance from WHO would be welcome.

- methodology for assessing micronutrient deficiencies and indicators for reporting the prevalence of micronutrient deficiencies;
- in relation to anaemia in particular, thresholds for mild, moderate or severe anaemia;[25]
- best practice for wheat flour fortification with vitamin D;
- procurement or local production of premix across the Region;
- anaemia control, in relation to technical, financial, scientific and social marketing issues;
- establishment of nutrition surveillance systems (laboratory analyses, standard operating practices, cut-offs) and criteria for intervention;
- recommended procedures for quality control/quality assurance and how to measure outcomes and effect.

[25] This is an area of ongoing work and WHO already published recommendations on *Haemoglobin concentrations for the diagnosis of anaemia and assessment of severity* (WHO/NMH/NHD/MNM/11.1)) in 2011. These are available from: http://www.who.int/vmnis/indicators/haemoglobin.pdf, accessed 7 February 2019).

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This report summarizes the current state of wheat flour fortification in the Eastern Mediterranean Region. It identifies some of the common challenges faced by countries and highlights the lessons learned from their experiences. The latest guidance on best practices is outlined and recommendations made to advance appropriate wheat flour fortification in the Region. The report draws on the proceedings of a training workshop on best practices of wheat flour fortification held in Rabat, Morocco, in October 2017.

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