

WHO GUIDELINE¹: FORTIFICATION OF MAIZE FLOUR AND CORN MEAL WITH VITAMINS AND MINERALS

EXECUTIVE SUMMARY

Fortification of industrially processed flour, when appropriately implemented, is an efficient, simple and inexpensive strategy for supplying vitamins and minerals to the diets of large segments of the population. Maize, also referred to as corn,² is cultivated in most parts of the world, as it grows in diverse climates. Industrial fortification of maize flour and corn meal with at least iron has been practised for many years in several countries in the Americas and Africa, where these ingredients are used in the preparation of many common national dishes.

Decisions about which nutrients to add to fortified white or yellow maize flour, and how much of each nutrient to use, should be based on the nutritional needs and intake gaps of the target populations; the usual level of consumption of maize flour, corn meal and products made from these staples; the sensory and physical effects of the fortificant on white and yellow maize flour, corn meal and flour products; the fortification of other food vehicles; the population use of vitamin and mineral supplements; costs; feasibility; and acceptability.

Maize flour can be fortified with several micronutrients, such as iron, folic acid and other B-complex vitamins, vitamin A and zinc – some used for restitution of nutritional contents and others used for preventing micronutrient deficiencies of public health significance in several countries.

PURPOSE OF THE GUIDELINE

This guideline aims to help Member States and their partners to make informed decisions on the appropriate nutrition actions to achieve the [Sustainable Development Goals](#) and the global targets set in the [Comprehensive implementation plan on maternal, infant and young child nutrition](#).

The recommendations in this guideline are intended for a wide audience, including policy-makers, their expert advisers, economists, and technical and programme staff in ministries and organizations involved in the design, implementation and scaling-up of nutrition actions for public health, particularly in the design and implementation of appropriate food fortification programmes as part of a comprehensive food-based strategy for combating micronutrient deficiencies.

These recommendations supersede the previous WHO recommendation on fortification of maize flour.³ The guideline complements the WHO/FAO (Food and Agriculture Organization of the United Nations) [Guidelines on food fortification with micronutrients](#)⁴ and the Pan American Health Organization (PAHO) 2002 document, [Iron compounds for food fortification: guidelines for Latin America and the Caribbean](#).⁵

¹ This publication is a World Health Organization (WHO) guideline. A WHO guideline is any document, whatever its title, containing WHO recommendations about health interventions, whether they be clinical, public health or policy interventions. A recommendation provides information about what policy-makers, health-care providers or patients should do. It implies a choice between different interventions that have an impact on health and that have ramifications for the use of resources. All publications containing WHO recommendations are approved by the WHO Guidelines Review Committee.

² The terms maize and corn are used synonymously throughout this guideline.

³ Recommendations on wheat and maize flour fortification. Meeting report: interim consensus statement. Geneva: World Health Organization; 2009 (WHO/NMH/NHD/MNM/09.1).

⁴ Allen L, de Benoist B, Dary O, Hurrell R, editors. Guidelines on food fortification with micronutrients. Geneva: World Health Organization and Food and Agriculture Organization of the United Nations; 2006 (<http://www.who.int/nutrition/publications/micronutrients/9241594012/en/>).

⁵ Dary O, Freire W, Kim S. Iron compounds for food fortification: guidelines for Latin America and the Caribbean 2002. *Nutr Rev.* 2002;60:S50–61.

GUIDELINE DEVELOPMENT METHODOLOGY

WHO developed the present evidence-informed recommendations using the procedures outlined in the [WHO handbook for guideline development](#). The steps in this process included: (i) identification of priority questions and outcomes; (ii) retrieval of the evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of recommendations, including research priorities; and planning for (v) dissemination; (vi) implementation, equity and ethical considerations; and (vii) impact evaluation and updating of the guideline. The *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) methodology was followed, to prepare evidence profiles related to preselected topics, based on up-to-date systematic reviews.

The guideline development group consisted of content experts, methodologists and representatives of potential stakeholders and beneficiaries. One guideline group participated in a meeting concerning this guideline, held in Geneva, Switzerland on 22–25 February 2010, where the guideline was scoped. A second guideline group participated in a meeting held in Cancun, Mexico, on 3–6 November 2014, to discuss the evidence and finalize the recommendations. External experts, as resource persons, assisted the guideline development group during the guideline development process, in presenting the evidence and identifying research priorities. Seven technical experts were invited to peer-review the draft guideline.

AVAILABLE EVIDENCE

Eight systematic reviews on the effect on critical nutrition and health-related outcomes of fortification of staple foods, including maize flour and corn meal, with vitamins and minerals, served to inform this guideline. These showed positive effects on nutritional status of using fortified foods to supply sufficient amounts of micronutrients that are otherwise inadequate in the diet, compared to no intervention. Evidence on the effect of fortified maize flour or maize-flour products was scarce for vitamin A, zinc, vitamin D and calcium, or it was not possible to isolate the effect of the intake of fortified maize flour on the outcomes, as was the case for programmes in Brazil and Venezuela where more than one food item was fortified simultaneously.

Evidence on fortification of maize flour with folic acid or iron showed a positive effect on health outcomes in the general population. Fortification of maize flour with iron, in combination with other micronutrients, reduced the risk of iron deficiency but had no effect on anaemia in children. Addition of folic acid to wheat and maize flour in the United States of America (USA) and other countries has had a significant impact on multiple measures, including folate intake, blood folate concentrations and the prevalence of neural tube defects and, for some subpopulations, fortification of nixtamalized maize flour with folic acid could potentially reduce the disparity in folate intake that is common between Latino women living in the USA and white populations.

The overall quality of the direct evidence for fortification of maize flour and corn meal with vitamins and minerals as a strategy to improve the health of populations was very low¹ for the critical outcomes of iron status, iron deficiency anaemia and folate status. There was no direct evidence for the critical outcomes of iron deficiency anaemia, neural tube defects and other congenital anomalies, zinc status and deficiency, growth, and adverse effects in children, including constipation, nausea, vomiting, heartburn or diarrhoea, as measured by trialists.

¹ According to GRADE, According to GRADE, very low-quality evidence indicates that we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect.

RECOMMENDATIONS

- Fortification of maize flour and corn meal with iron is recommended to prevent iron deficiency in populations, particularly vulnerable groups such as children and women (*very low-quality evidence*).²
- Fortification of maize flour and corn meal with folic acid is recommended to reduce the risk of occurrence of births with neural tube defects (*very low-quality evidence*).²

Note: Although evidence in maize flour or corn meal is rather limited, addition of other vitamins and minerals in fortification of maize flour and corn meal is a common and optional practice. The remarks section includes important considerations that can be used to inform design and implementation.

REMARKS

The remarks in this section are intended to give some considerations for implementation of the recommendations, based on the discussion of the guideline development group.

- Although limited direct evidence was found from fortification of maize flour or corn meal to supply effective amounts of micronutrients, there is documented evidence from several countries that fortification of other staple foods with zinc, vitamin A, folic acid, vitamin D and calcium is associated with significant reductions in the incidence of deficiency-related outcomes, and improvements in the health status of populations.
- Countries can integrate fortification of maize flour and corn meal as part of their national programmes for prevention and control of micronutrient deficiencies and insufficiencies. The choice and concentration of nutrients for fortification of maize flour or corn meal should be considered in the context of the strategy, including consideration of the vitamin and mineral nutritional needs and intake gaps of the target populations; the usual level of consumption of maize flour, corn meal and products made from these staples; the sensory and physical effects of the fortificant on white and yellow maize flour, corn meal and flour products; the fortification of other food vehicles; the population use of vitamin and mineral supplements; other ongoing nutrition interventions; costs; feasibility; and acceptability.
- Since some of the B-complex vitamins naturally present in the maize grain are removed during milling and degerming, the restoration of niacin, riboflavin and thiamine in maize flour should remain a regular practice in fortification, especially niacin for non-nixtamalized maize flour. This strategy has contributed to the virtual elimination of beriberi and pellagra in many countries.
- Countries that fortify maize flour also frequently fortify wheat flour. A combined fortification strategy using multiple vehicles appears to be a suitably effective option for reaching all segments of the population. In this context, selection of a combined fortification formula that is applicable to both types of flour may be appropriate.

² This is a conditional recommendation. A *conditional recommendation* is one for which the guideline development group concludes that the desirable effects of adherence probably outweigh the undesirable effects, although the trade-offs are uncertain. Implications of a conditional recommendation for populations are that while many people would desire fortification of maize flour and corn meal with vitamins and minerals, a considerable proportion would not. With regard to policy-makers, a conditional recommendation means that there is a need for substantial debate and involvement from stakeholders before considering the adoption of fortification of maize flour and corn meal with these vitamins and minerals in each setting.

- The choice of iron compound is a compromise between cost, bioavailability, micronutrient interactions and the acceptance of texture, taste, smell and/or colour. Nixtamalized flour (lime treated), commonly used in the Americas, is more reactive to ferrous compounds. The use of electrolytic iron does not appear to be effective in fortification of nixtamalized maize flour.
- The addition of vitamin C and the removal of phytates in maize flour and corn meal could increase the bioavailability of iron.
- Food fortification should be guided by national standards, with quality-assurance and quality-control systems to ensure quality fortification. Continuous programme monitoring should be in place as part of a process to ensure high-quality implementation.

RESEARCH GAPS

Discussions between the members of the WHO guideline development group and the external review group highlighted the limited evidence available in some knowledge areas, meriting further research on the fortification of maize flour and corn meal, particularly in the following areas:

- the bioavailability of different iron compounds for use in maize flour and corn meal produced with different technological processing, including mixtures of different compounds;
- the bioavailability and stability of folic acid and vitamin A in maize flour and corn meal with different methods of processing (e.g. nixtamalized maize flour);
- evaluation of the efficacy and effectiveness of programmes for fortification of maize flour and corn meal, either alone or in combination with wheat-flour fortification, in all age groups;
- determination of appropriate levels and combinations of nutrients and their interactions, the stability of micronutrient compounds, and their physical properties and acceptability to consumers;
- biomarkers of individual micronutrient status under different conditions of infection and inflammation;
- the impact of maize use for biofuel production on food security and on the sustainability of programmes for fortification of maize flour and corn meal;
- the feasibility of small-scale fortification of maize flour and corn meal for public health programmes.