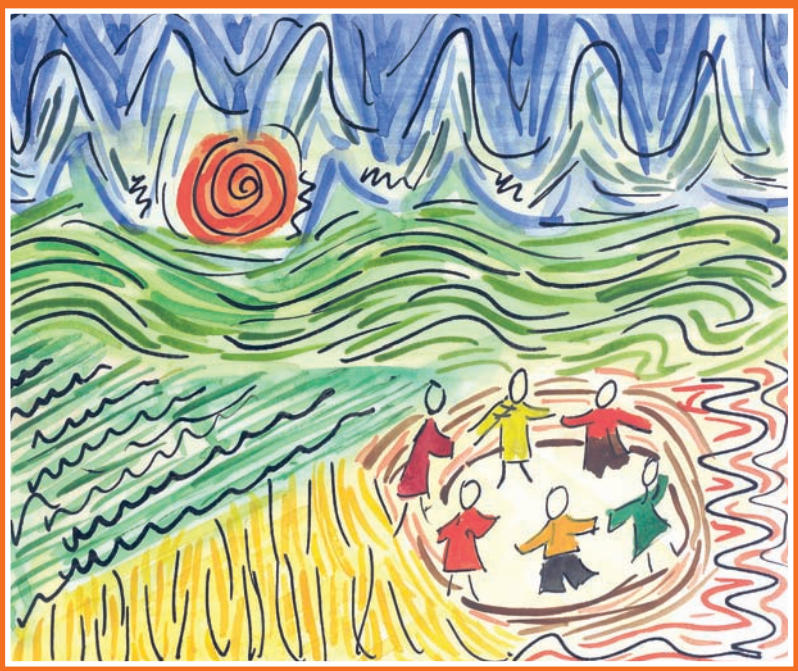

Guidelines on food fortification with micronutrients

Edited by Lindsay Allen, Bruno de Benoist, Omar Dary and Richard Hurrell

World Health Organization

Food and Agricultural Organization of the United Nations

Interest in micronutrient malnutrition has increased greatly over the last few years. One of the main reasons is the realization that micronutrient malnutrition contributes substantially to the global burden of disease. Furthermore, although micronutrient malnutrition is more frequent and severe in the developing world and among disadvantaged populations, it also represents a public health problem in some industrialized countries. Measures to correct micronutrient deficiencies aim at ensuring consumption of a balanced diet that is adequate in every nutrient. Unfortunately, this is far from being achieved everywhere since it requires universal access to adequate food and appropriate dietary habits. Food fortification has the dual advantage of being able to deliver nutrients to large segments of the population without requiring radical changes in food consumption patterns.

Drawing on several recent high quality publications and programme experience on the subject, information on food fortification has been critically analysed and then translated into scientifically sound guidelines for application in the field. The main purpose of these guidelines is to assist countries in the design and implementation of appropriate food fortification programmes. They are intended to be a resource for governments and agencies that are currently implementing or considering food fortification, and a source of information for scientists, technologists and the food industry. The guidelines are written from a nutrition and public health perspective, to provide practical guidance on how food fortification should be implemented, monitored and evaluated. They are primarily intended for nutrition-related public health programme managers, but should also be useful to all those working to control micronutrient malnutrition, including the food industry.

The document is organized into four complementary sections. Part I introduces the concept of food fortification as a potential strategy for the control of micronutrient malnutrition. Part II summarizes the prevalence, causes, and consequences of micronutrient deficiencies, and the public health benefits of micronutrient malnutrition control. It lays the groundwork for public health personnel to assess the magnitude of the problem and the potential benefits of fortification in their particular situation. Part III provides technical information on the various chemical forms of micronutrients that can be used to fortify foods, and reviews prior experiences of their use in specific food vehicles. Part IV describes the key steps involved in designing, implementing, and sustaining fortification programmes. Starting with a determination of the amount of nutrients to be added to foods, this process continues with the implementation of monitoring and evaluating systems (including quality control/quality assurance procedures), followed by an estimation of cost-effectiveness and cost–benefit ratios. The importance of, and strategies for, regulation and international harmonization, communication, advocacy, consumer marketing and public education are also explained in some detail.

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Edited by

Lindsay Allen
University of California,
Davis, CA, United States of America

Bruno de Benoist
World Health Organization,
Geneva, Switzerland

Omar Dary
A2Z Outreach – The USAID Micronutrient Leadership and Support and Child Blindness Activity,
Washington, DC, United States of America

Richard Hurrell
Swiss Federal Institute of Technology,
Zurich, Switzerland

World Health Organization

Food and Agricultural Organization of the United Nations

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Contents

List of tables

List of figures

Foreword

Interest in micronutrient malnutrition has increased greatly over the last few years. One of the main reasons for the increased interest is the realization that micronutrient malnutrition contributes substantially to the global burden of disease. In 2000, the *World Health Report*[1] identified iodine, iron, vitamin A and zinc deficiencies as being among the world's most serious health risk factors. In addition to the more obvious clinical manifestations, micronutrient malnutrition is responsible for a wide range of non-specific physiological impairments, leading to reduced resistance to infections, metabolic disorders, and delayed or impaired physical and psychomotor development. The public health implications of micronutrient malnutrition are potentially huge, and are especially significant when it comes to designing strategies for the prevention and control of diseases such as HIV/AIDS, malaria and tuberculosis, and diet-related chronic diseases.

Another reason for the increased attention to the problem of micronutrient malnutrition is that, contrary to previous thinking, it is not uniquely the concern of poor countries. While micronutrient deficiencies are certainly more frequent and severe among disadvantaged populations, they do represent a public health problem in some industrialized countries. This is particularly true of iodine deficiency in Europe, where it was generally assumed to have been eradicated, and of iron deficiency, which is currently the most prevalent micronutrient deficiency in the world. In addition, the increased consumption in industrialized countries (and increasingly in those in social and economic transition) of highly-processed energy-dense but micronutrient-poor foods, is likely to adversely affect micronutrient intake and status.

Measures to correct micronutrient deficiencies – at least the major ones – are, however, well known, and moreover relatively cheap and easy to implement. The control of iodine deficiency disorders through salt iodization, for example, has been a major accomplishment in public health nutrition over the last 30 years.

[1] World *health report, 2000*. Geneva, World Heath Organization, 2000.

The best way of preventing micronutrient malnutrition is to ensure consumption of a balanced diet that is adequate in every nutrient. Unfortunately, this is far from being achievable everywhere since it requires universal access to adequate food and appropriate dietary habits. From this standpoint, food fortification has the dual advantage of being able to deliver nutrients to large segments of the population without requiring radical changes in food consumption patterns. In fact, fortification has been used for more than 80 years in industrialized countries as a means of restoring micronutrients lost by food processing, in particular, some of the B vitamins, and has been a major contributory factor in the eradication of diseases associated with deficiencies in these vitamins. Because of the increased awareness of the widespread prevalence and harmful effects of micronutrient malnutrition, and in consideration of changes in food systems (notably an increased reliance on centrally processed foods), and successful fortification experiences in other regions, increasing numbers of developing countries are now committed to, or are considering, fortification programmes.

With so much accumulated experience, the conditions under which food fortification can be recommended as a strategic option for controlling micronutrient malnutrition are now better understood. Its limitations are also well known: food fortification alone cannot correct micronutrient deficiencies when large numbers of the targeted population, either because of poverty or locality, have little or no access to the fortified food, when the level of micronutrient deficiency is too severe, or when the concurrent presence of infections increases the metabolic demand for micronutrients. Various safety, technological and cost considerations can also place constraints on food fortification interventions. Thus, proper food fortification programme planning not only requires assessment of its potential impact on the nutritional status of the population but also of its feasibility in a given context.

The success of a fortification programme can be measured through its public health impact and its sustainability. The latter implies an intersectoral approach where, in addition to competent national public health authorities, research, trade, law, education, nongovernmental organizations and the commercial sector are all involved in the planning and implementation of the programme. It has taken time to appreciate the role of the private sector, in particular industry, and the importance of civil society in this process. These are now fully acknowledged and this recognition should strengthen the capability of interventions to combat micronutrient malnutrition.

The main purpose of these Guidelines is to assist countries in the design and implementation of appropriate food fortification programmes. Drawing on several recent high quality publications on the subject and on programme experience, information on food fortification has been critically analysed and then

translated into scientifically sound guidelines for application in the field. More specifically, the Guidelines provide information relating to the benefits, limitations, design, implementation, monitoring, evaluation, cost–benefit and regulation of food fortification, particularly in developing countries. They are intended to be a resource for governments and agencies that are currently implementing, or considering food fortification, and a source of information for scientists, technologists and the food industry. The Guidelines are written from a nutrition and public health perspective, to provide practical guidance on how food fortification should be implemented, monitored and evaluated within the general context of the need to control micronutrient deficiencies in a population. They are primarily intended for nutrition-related public health programme managers, but should also be useful to all those working to control micronutrient malnutrition, including industry.

The document is organized into four complementary sections. Part I introduces the concept of food fortification as a potential strategy for the control of micronutrient malnutrition. Part II summarizes the prevalence, causes and consequences of micronutrient deficiencies, and the public health benefits of micronutrient malnutrition control. It lays the groundwork for public health personnel to assess the magnitude of the problem, and the potential benefits of fortification, in their particular situation. Part III provides technical information on the various chemical forms of micronutrients that can be used to fortify foods, and reviews experience of their use in specific food vehicles. Part IV describes the key steps involved in designing, implementing and sustaining fortification programmes, starting with the determination of the amount of nutrients to be added to foods, followed by the implementation of monitoring and evaluating systems, including quality control/quality assurance procedures, before moving on to the estimation of cost-effectiveness and cost–benefit ratios. The importance of, and strategies for, regulation and international harmonization, communication, advocacy, consumer marketing and public education are also explained in some detail.

The production of the Guidelines has been the result of a long process that started in 2002. Under the aegis of the World Health Organization (WHO), an expert group was established and charged with the task of developing a set of guidelines on food fortification practice. A draft version of the guidelines was reviewed in 2003 by a multidisciplinary panel of experts who collectively represented the range of knowledge and experience required for developing such guidelines. The panel members included experts in public health, nutrition sciences and food technology, from both the public and the private sectors. Afterwards, the draft of the guidelines was circulated among field nutritionists and public health practitioners and also tested in a number of countries. All of the

comments received through this process were considered for this finalized version of the guidelines.

We are all committed to the elimination of micronutrient malnutrition. We hope that these Guidelines will help countries to meet this goal and therefore enable their population to achieve its full social and economic potential.

Lindsay Allen
Bruno de Benoist
Omar Dary
Richard Hurrell

Preface

More than 2 billion people in the world today suffer from micronutrient deficiencies caused largely by a dietary deficiency of vitamins and minerals. The public health importance of these deficiencies lies upon their magnitude and their health consequences, especially in pregnant women and young children, as they affect fetal and child growth, cognitive development and resistance to infection. Although people in all population groups in all regions of the world may be affected, the most widespread and severe problems are usually found amongst resource poor, food insecure and vulnerable households in developing countries. Poverty, lack of access to a variety of foods, lack of knowledge of appropriate dietary practices and high incidence of infectious diseases are key factors. Micronutrient malnutrition is thus a major impediment to socio-economic development contributing to a vicious circle of underdevelopment and to the detriment of already underprivileged groups. It has long-ranging effects on health, learning ability and productivity and has high social and public costs leading to reduced work capacity due to high rates of illness and disability.

Overcoming micronutrient malnutrition is therefore a precondition for ensuring rapid and appropriate national development. This was the consensus reached at the FAO/WHO International Conference on Nutrition (ICN) in December 1992, where 159 countries endorsed the World Declaration on Nutrition, pledging "to make all efforts to eliminate . . . iodine and vitamin A deficiencies" and "to reduce substantially . . . other important micronutrient deficiencies, including iron." Since then, FAO and WHO have continued to work to achieve this goal and in doing so have adopted four main strategies improving dietary intakes through increased production, preservation and marketing of micronutrient-rich foods combined with nutrition education; food fortification; supplementation; and global public health and other disease control measures. Each of these strategies have a place in eliminating micronutrient malnutrition. For maximum impact, the right balance or mix of these mutually reinforcing strategies need to be put in place to ensure access to consumption and utilization of an adequate variety and quantity of safe, good-quality foods for all people of the world. Underpinning these strategies is the realisation that when there is a dietary deficiency in any one nutrient, there are likely to be other nutrient deficiencies as

well. Consequently in the long-term, measures for the prevention and control of micronutrient deficiencies should be based on diet diversification and consumer education about how to choose foods that provide a balanced diet, including the necessary vitamins and minerals.

These guidelines are meant to assist countries in the design and implementation of appropriate food fortification programmes as part of a comprehensive food-based strategy for combating micronutrient deficiencies. Fortification of food can make an important contribution to the reduction of micronutrient malnutrition when and where existing food supplies and limited access fail to provide adequate levels of certain nutrients in the diet. To ensure that the target population will benefit from a food fortification programme, an appropriate food vehicle must be selected that is widely consumed throughout the year by a large portion of the population at risk of a particular deficiency. In order to reach different segments of the population who may have different dietary habits, selecting more than one food vehicle may be necessary. Fortification of a staple food affects everyone, including the poor, pregnant women, young children and populations that can never be completely covered by social services. In addition, fortification reaches secondary at-risk groups, such as the elderly and those who have an unbalanced diet. Food fortification is usually socially acceptable, requires no change in food habits, does not alter the characteristics of the food, can be introduced quickly, can produce nutritional benefits for the target population quickly, is safe, and can be a cost-effective way of reaching large target populations that are at risk of micronutrient deficiency.

However, there are limitations on the benefits of fortification and difficulties in its implementation and effectiveness. There may, for example, be concerns raised about the possibility of overdose or a reluctance to fortify on human rights grounds where consumer choice may be an issue. There may be reluctance on the part of the food industry to fortify out of fear of insufficient market demand for fortified foods or concern about consumer perceptions that the food product has been altered. Food fortification also raises production costs through such expenses as initial equipment purchases, equipment maintenance, increased production staff needs and quality control and assurance facilities. Economically marginalised households may not have access to such foods and other vulnerable population groups, particularly children under five years of age, may not be able to consume large enough quantities of the fortified food to satisfy an adequate level of their daily requirements. All these issues need to be carefully assessed and these are discussed in detail.

This publication is a useful guide to assist decision makers in ensuring that the nutritionally vulnerable and at-risk populations benefit from food fortification programmes and FAO and WHO would like to express our thanks to all who have been involved in this process. We reaffirm our support to achieve the Millennium Development Goals set by governments for overall nutrition

improvement and will collaborate with international and national agencies so as to accelerate the planning and implementation of comprehensive and sustainable food fortification programmes as one element of national nutrition improvement policies, plans and programmes.

Kraisid Tontisirin,
Director,
Nutrition and Consumer Protection Division,
Food and Agriculture Organization

Denise C. Coitinho,
Director,
Department of Nutrition for Health and Development,
World Health Organization

List of authors

Lindsay Allen
Center Director
USDA, Agricultural Research Service
Western Human Nutrition Research Center
University of California
Davis, California 95616, United States of America

Bruno de Benoist
Coordinator, Micronutrient Unit
Department of Nutrition for Health and Development
World Health Organization
CH 1201, Geneva 27, Switzerland

Omar Dary
Food fortification specialist
A2Z Outreach/The USAID Micronutrient Leadership and Support and Child Blindness Activity
Academy for Educational Development (AED)
Washington D.C. 20009-5721, United States of America

Richard Hurrell
Head, Human Nutrition Laboratory
Food science and Nutrition, Human Nutrition,
ETH (Swiss Federal Institute of Technology)
CH 8092 Zurich, Switzerland

Sue Horton
Professor and Chair Division of Social Sciences
Department of Economics
Munk Center for International Studies
University of Toronto (UTSC)
Toronto, Ontario M5S 3K7, Canada

Janine Lewis
Principal Nutritionist, Nutrition and Labelling programme
Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610, Australia

Claudia Parvanta
Chair and Professor
Department of Social Sciences
University of the Sciences in Philadelphia
Philadelphia, Pennsylvania, United States of America

Mohammed Rahmani
Département des sciences alimentaires et nutritionnelles
Institut agronomique et vétérinaire Hassan II
BP 6202-Instituts
10101 Rabat, Morocco

Marie Ruel
Division Director
Food Consumption and Nutrition Division
International Food Policy Research Institute
Washington D.C. 20006, United States of America

Brian Thompson
Senior Officer
Nutrition and Consumer Protection Division
Food and Agriculture Organization
Via delle Terme di Caracalla
00100 Rome, Italy

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Lastly, we wish to thank the Global Alliance for Improved Nutrition for its support to the publication of the guidelines.

Abbreviations

AI	Adequate Intake
CDC	Centers for Disease Control
CHD	Coronary heart disease
DALY	Disability-adjusted life year
DFE	Dietary folate equivalents
DRI	Dietary Recommended Intake
DRV	Dietary Reference Value
EAR	Estimated Average Requirement
EDTA	Ethylenediaminetetraacetic acid
FAO	Food and Agriculture Organization of the United Nations
FFL	Feasible Fortification Level
FNB	Food and Nutrition Board
GAIN	Global Alliance for Improved Nutrition
GDP	Gross domestic product
GMP	Good manufacturing practice
HACCP	Hazard analysis critical control point
ICCIDD	International Council for Control of Iodine Deficiency Disorders
IDD	Iodine deficiency disorders
IIH	Iodine-induced hyperthroidism
ILO	International Labour Organization
INACG	International Nutritional Anemia Consultative Group
IOM	Institute of Medicine
IRLI	International Resource Laboratory for Iodine
IVACG	International Vitamin A Consultative Group
IZiNCG	International Zinc Nutrition Consultative Group
LmL	Legal Minimum Level
LQAS	Lot quality assurance sampling
mFL	Minimum Fortification Level
MI	Micronutrient Initiative
MMR	Maternal mortality rate
MNM	Micronutrient malnutrition
MTL	Maximum Tolerable Level
MW	Molecular weight

NGO	Nongovernmental organization
NRV	Nutrient Reference Value
PAHO	Pan American Health Organization
PAR	Population attributable risk
PEM	Protein–energy malnutrition
QA	Quality assurance
QC	Quality control
RBV	Relative bioavailability
RDA	Recommended Dietary Allowance
RE	Retinol equivalents
RNI	Recommended Nutrient Intake
RR	Relative risk
SUSTAIN	Sharing United States Technology to Aid in the Improvement of Nutrition
TBT	(Agreement on) Technical Barriers to Trade
UNICEF	United Nations Children's Fund
UL	Tolerable Upper Intake Level
USI	Universal salt iodization
VAD	Vitamin A deficiency
WFP	World Food Programme
WHO	World Health Organization

Glossary

The **Average Intake** (**AI**) is a recommended intake value based on observed or experimentally determined approximations or estimates of nutrient intake by a group or groups of apparently healthy people that are assumed to be adequate.

Cost limit refers to the maximum acceptable increment in price of a food due to fortification.

A **Dietary Recommended Intake** (**DRI**) is a quantitative estimate of a nutrient intake that is used as a reference value for planning and assessing diets for apparently healthy people. Examples include AIs, EARs, RDAs and ULs.

Effectiveness refers to the impact of an intervention in practice. Compared to efficacy, the effectiveness of a fortification programme will be limited by factors such as non- or low consumption of the fortified food.

Efficacy refers to the capacity of an intervention such as fortification to achieve the desired impact under ideal circumstances. This usually refers to experimental, well-supervised intervention trials.

Enrichment is synonymous with fortification and refers to the addition of micronutrients to a food irrespective of whether the nutrients were originally in the food before processing or not.

Essential micronutrient refers to any micronutrient, which is needed for growth and development and the maintenance of healthy life, that is normally consumed as a constituent of food and cannot be synthesized in adequate amounts by the body.

The **Estimated Average Requirement** (**EAR**) is the average (median) daily nutrient intake level estimated to meet the needs of half the healthy individuals in a particular age and gender group. The EAR is used to derive the Recommended Dietary Allowance.

Evaluation refers to the assessment of the effectiveness and impact of the programme on the targeted population. The aim of an evaluation is to provide evidence that the programme is achieving its nutritional goals.

Feasible Fortification Level (**FFL**) is that which is determined, subject to cost

and technological constraints, as the level that will provide the greatest number of at-risk individual with an adequate intake without causing an unacceptable risk of excess intakes in the whole population.

Food commodities are staple foods, condiments and milk.

Fortification is the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

Legal Minimum level (LmL) is the minimum amount of micronutrient that a fortified food must contain according to national regulations and standards. This value is estimated by adding the intrinsic content of a micronutrient in the food to the selected level of fortification.

Market-driven fortification refers to the situation where the food manufacturer takes the initiative to add one or more micronutrients to processed foods, usually within regulatory limits, in order to increase sales and profitability.

Mass fortification refers to the addition of micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk.

Maximum Tolerable Level (MTL) is the maximum micronutrient content that a fortified food can present as it is established in food law, in order to minimize the risk of excess intake. It should coincide or be lower than the safety limit.

Minimum Fortification Level (mFL) is the level calculated by reducing the Feasible Fortification Level by three standards deviations (or coefficients of variation) of the fortification process, in order that the average coincides or is lower than the calculated Feasible Fortification Level.

Monitoring refers to the continuous collection and review of information on programme implementation activities for the purposes of identifying problems (such as non-compliance) and taking corrective actions so that the programme fulfils its stated objectives.

Nutritional equivalence is achieved when an essential nutrient is added to a product that is designed to resemble a common food in appearance, texture, flavour and odour in amounts such that the substitute product has a similar nutritive value, in terms of the amount and bioavailability of the added essential nutrient.

Nutrient Reference Values (NRVs) are dietary reference values defined by the Codex Alimentarius Commission with the aim of harmonizing the labelling of processed foods. It is a value applicable to all members of the family aged

3 years and over. These values are constantly reviewed based on advances in scientific knowledge.

Nutrient requirement refers to the lowest continuing intake level of a nutrient that will maintain a defined level of nutriture in an individual for a given criterion of nutritional adequacy.

Processed foods are those in which food raw materials have been treated industrially so as to preserve them. Some may be formulated by mixing several different ingredients.

A **premix** is a mixture of a micronutrient(s) and another ingredient, often the same food that is to be fortified, that is added to the food vehicle to improve the distribution of the micronutrient mix within the food matrix and to reduce the separation (segregation) between the food and micronutrient particles.

Quality assurance (QA) refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards. The performance of quality assurance can be expressed numerically as the results of quality control exercises.

Quality control (QC) refers to the techniques and assessments used to document compliance of the product with established technical standards, through the use of objective and measurable indicators.

Relative bioavailability is used to rank the absorbability of a nutrient by comparing its absorbability with that of a reference nutrient that is considered as having the most efficient absorbability.

Restoration is the addition of essential nutrients to foods to restore amounts originally present in the natural product, but unavoidably lost during processing (such as milling), storage or handling.

Recommended Dietary Allowances (RDAs) are defined by the United States Food and Nutrition Board and are conceptually the same as the Recommended Nutrient Intake (RNI), but may have a slightly different values for some micronutrients.

The **Recommended Nutrient Intake (RNI)** is the daily intake that meets the nutrient requirements of almost all apparently healthy individuals in an age- and sex-specific population group. It is set at the Estimated Average Requirement plus 2 standard deviations.

Safety limit is the greatest amount of a micronutrient that can be safely added to specific foods. It considers the UL for the nutrient and the 95th percentile of consumption of a food, and makes allowances for the fact that the

nutrient is also consumed in unfortified foods, and may be lost during storage and distribution, and/or cooking.

Targeted fortification refers to the fortification of foods designed for specific population subgroups, such as complementary weaning foods for infants.

The **technological limit** is the maximum level of micronutrient addition that does not change the organoleptic or physical properties of the food.

The **Tolerable Upper Intake Level (UL)** is to the highest average daily nutrient intake level unlikely to pose risk of adverse health effects to almost all (97.5%) apparently healthy individuals in an age- and sex-specific population group.

Universal fortification is equivalent to mass fortification.

Universal salt iodization (USI) refers to the addition of iodine to all salt for both human and animal consumption.

Usual intake refers to an individual's average intake over a relatively long period of time.