The Food Fortification Formulator:

Technical Determination of Fortification Levels and Standards for Mass Fortification

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This program was conceptualized and designed by Omar Dary, Food Fortification Specialist of A2Z, the USAID Micronutrient and Child Blindness Project. Michael Hainsworth contributed his expertise and skills to make this Excel Spreadsheet program. Both O. Dary and M. Hainsworth are staff members of the Academy for Educational Development (AED), in Washington D.C.

The Formulator is based mainly on the recommendations of the WHO/FAO *Guidelines on Food Fortification with Micronutrients* (Lindsay A, de Benoist B, Dary O, Hurrell R (Eds), 2006).

The Formulator was originally conceived in a technical workshop about food fortification of the East, Central and Southern Africa (ECSA) Health Community, with the participation of nutritionists and officials of the National Bureau of Standards of Kenya, Lesotho, Malawi, Swaziland, Uganda, Tanzania, Zambia, and Zimbabwe, with the support of the USAID-funded MOST Project, in Lilongwe, Malawi, in 2005.

The first version of the Formulator (called at the time the Food Fortification Calculator) was reviewed and applied at another ECSA meeting in Arusha, Tanzania, in March 2007. On that occasion, the Formulator supported the decision of the ECSA countries to establish common guidelines of mass fortification to be recommended to the member countries. Thus far, this tool has been used with the purpose of enacting standards and designing food control procedures in Uganda, Kenya, and Malawi.

The same first version of the Formulator was presented and comments received from the Focal Points of the Ministry of Health of the Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama) in a technical meeting organized by the Project of Food Fortification as a Regional Public Health Initiative (implemented by the Central American Foundation of Food and Nutrition –FANCAP–with the technical support of INCAP, PAHO/WHO, CDC, Project Healthy Children, and the March of Dimes), in Guatemala City, Guatemala, in November 2007.

The Formulator was also applied in Chile in January 2008, when the country carried out an evaluation of its wheat flour fortification program. It helped to clarify the discrepancies between the standard and its application by the industry and governmental officials.

The name of the program, as well as part of the overall framework was inspired by the spreadsheet titled the " CSHGP Lives Saved calculator" and used by the Child Health Epidemiology Reference Group or CHERG (also known as "the Bellagio Group").

This computational program may still have errors and can be improved. Thus, we would appreciate the users to send comments, corrections and suggestions to Omar Dary, A2Z, at odary@aed.org. Academy for Educational Development (AED), 1825 Connecticut Avenue, NW, Washington, DC 20009-5271, USA.

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INTRODUCTION

This document summarizes the importance of mass food fortification and provides the reader with step by step instructions for designing and implementing this type of fortification programs. The document also explains how to use the "Food Fortification Formulator", a tool which assists in determining the potential additional intakes of micronutrient for populations following efficacious and safety comparisons; the costs associated with food fortification programs; the fortification levels that can be used as technical specifications in the factories as well as the national standards and regulations; and the amount of fortificant to be added in the micronutrient premixes. Fortificants are defined here as the source of micronutrients, while micronutrient premixes are the blends of those fortificants with other ingredients to make them suitable to be added into the fortification vehicles.

I.   OVERVIEW OF MASS FOOD FORTIFICATION

Food fortification is the practice of deliberately increasing the content of essential micronutrients in a food to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health (WHO/FAO Guidelines in Food Fortification). Mass fortification is one of the types of food fortification, which refers specifically to the addition of one or more vitamins and/or minerals to processed foods that are commonly consumed, such as flours, oils and condiments. Governments generally instigate, design, mandate, and regulate mass food fortification. Mass food fortification is being promoted as the nutritional intervention with the most favorable cost benefit to prevent the physiological and clinical consequences associated with micronutrient deficiencies. Although this statement may be true in many cases, it depends on the existence of several preconditions. These include:

- Accessibility of the food fortification vehicle by the target population
- Adequate manufacturing and industrial settings which ensure cost effective production and supervision
- Compatibility of fortificants (the source of micronutrients) with the nature and use of the food vehicle
- Affordability of additional costs resulting from the fortification process for consumers and manufacturers
- Confirmation of the quality of the product at the production site
- Reliable enforcement actions by government authorities to assure compliance of standards and regulations
- Legitimate and justifiable food labeling and nutrition and health claims that promote healthy practices

The biological impact of food fortification depends on:

- The amount of additional intake of micronutrients that are low in the diet;
- The bioavailability and bioconversion of the provided micronutrients; and
- The magnitude of the nutritional gap to be filled.

The public health significance of food fortification is a function of:

- Helping the at-risk population reach the biological efficacious threshold of micronutrient intake through the consumption of fortified food; and
- Keeping the intake below levels that may cause adverse effects due to excesses on individuals who consume the fortified food in large amounts.

Three types of food fortification have been recognized:

- **Mass fortification** consists of the addition of micronutrients to edible products that are commonly consumed by the general public, such as cereals, oils and vegetable fats, milk, sugar, and condiments.
- **Targeted fortification** is the practice of adding sufficient amounts of micronutrients to provide large proportions of the daily needs through foods designed for specific population subgroups, such as complementary foods for infants, foods for institutional programs such as those aimed at pre-school and school-aged children, and foods used under emergency situations.
- **Market-driven fortification** refers to voluntary practices of the food industry to increase the nutrient content and added value of a highly processed product with the purpose of attracting consumers and increasing sales.

Fortification practices and rules are different for each type of food fortification.

The addition of micronutrients to industrially manufactured foods is necessary for several reasons including the production of processed foods using ingredients that have low nutritional density; loss of the natural content of nutrients during food processing; imitation of the nutritional values of foods that are replaced by the processed foods, such as breakfast beverages instead of natural juices; particular metabolic needs of certain age groups; improve nutritional quality of monotonous starchy diets; and others. Food fortification is a human invention that is improving the health and the well being of people around the world. Understanding its characteristics is important so that better use can be made of this intervention.

Countries are often faced with the challenge of determining which levels of nutrients are both efficacious and safe for the population at large. In the past, efficaciousness received the most attention by public health professionals working with groups at nutritional risk. An accumulation of evidence has shown, however, that safety also deserves attention. The recent publication by WHO/FAO titled "Guidelines on Food Fortification with Micronutrients" covers both of these issues, and provides the scientific and technological basis to design, plan, implement, monitor, and evaluate food fortification programs from a public health perspective. An annex of the same publication describes a procedure for estimating fortification levels for mass fortification. Although the methodology is relatively simple, it may be challenging and confusing because of the use of multiple variables in different areas, including: public health nutrition, food standards, food control practices, food inspection, and cost estimations. The "Food Fortification Formulator" is a practical tools designed to make the methodology easy to follow and apply. This tool focuses primarily on mass fortification, but may be useful for other types of fortification with some adaptations

II.   IMPORTANCE OF MASS FORTIFICATION

Despite the scientific knowledge of the complexity of human nutrition and physiology, there are still cases in which food security is conceptualized as simply the supply of foods to provide metabolic energy. The term "hidden hunger" was coined in the 1990s to describe the deficiency of essential micronutrients. Certain sectors, including policy makers in the field of food production and human dietary need have not fully recognized the importance of micronutrient deficiencies. There are others, however, who advocate for raising the intake of only one or a few nutrients; this neglects the promotion of a balanced diet, and ignores the fact that health is associated with keeping the metabolic equilibrium (homeostasis) of many substances in human physiology.

Most micronutrients are only obtained through the diet because the human physiology cannot synthesize them. Those are **vitamins**, which are complex substances synthesized by other living organisms, and **minerals**.

Water soluble vitamins are needed for many metabolic reactions, as for example:
- **B-1** for carbohydrate processing
- **B-2** and **niacin**[1] for helping extract the energy stored in carbohydrates, fats, and proteins, for destroying undesirable molecules inside the body, and for helping in the synthesis of the own human biomolecules
- **B-6** for catalyzing changes associated with amino acids
- **B-12**, **biotin**, and **pantothenic acid** for participating as coenzymes in specific reactions of synthesis
- **Folate** as the main recycling substrate involving transference of methyl groups (one carbon moieties) during the synthesis of nucleic acids, proteins, phospholipids, and other biomolecules
- **Vitamin C** to keep the adequate oxidative stage of carbohydrates linked to proteins and fats

 Lipid soluble vitamins, as for example:
- **Vitamin A** and **D**[2], which act as gene expression modulators, and the former also as the visual pigment
- **Vitamin E** as the main antioxidant for fats
- V**vitamin K** as a participant of the reaction of blood clotting and other functions
- β**-carotene** as an antioxidant and as a precursor of vitamin A

Minerals are also essential nutrients.

- **Copper**, **iron**, **zinc**, and **sulfur** play important roles in reactions catalyzed by many enzymes. Iron also serves as the carrier and storage of oxygen, which is the last receptor of the electrons taken from the foods during the process of energy extraction from carbohydrates, fats, and proteins.
- **Sodium**, **potassium**, **calcium**, **magnesium**, and **chloride** are used to keep the adequate electric charges at both sides of biomembranes and to maintain the correct osmotic pressure

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[1] Human metabolism is able to synthesize some niacina from amino acid trypthophan.
[2] Human metabolism is able to synthesize vitamin D from dehydrocholesterol and skin exposure to ultraviolet light.

and the acid-base balance of bodily fluids. Calcium is also used in relatively larger amounts to keep the correct structure and resistance (including flexibility) of bones and, together with **fluoride**, of teeth.

- **Phosphorus**, another inorganic molecule, forms part of nucleic acids (the substances for genetic storage and expression), membrane phospholipids, proteins, and mineral structures
- **Iodine** is essential for basic thyroid hormones that act as gene expression modulator
- **Selenium** is associated to protective antioxidant functions.

This list of minerals and vitamins, and their functions, is provided here to illustrate the complexity of human metabolism, and to emphasize that all of them must be present in the correct amount for optimal functioning of the human body. The description of their functions also shows that these substances are not inert; they are very active molecules, and that is why inappropriate amounts of them in the body, either in deficiency or in excess, can provoke significant alterations. Most of these essential compounds are needed in so minute amounts that they are known as **micronutrients**. Other living organisms also need some of them in small quantities; therefore, the micronutrients may not be abundant in the diet if the specific sources with the adequate nutritional density are not present. For example, iron, zinc, vitamin B-2, vitamin B-12, vitamin A, and vitamin D, are provided mainly through foods of animal origin. Only a few sea animals and plants contain significant amounts of iodine. Vitamins B-1, niacin, folate, B-6, and vitamin C may be low in diets with low supplies of whole grains, beans, nuts, and fresh fruits and vegetables. Calcium, although not strictly a micronutrient, can be deficient if the diet contains insufficient amounts of milk and milk products.

The previous list is not complete; it should also include some amino acids and fatty acids that are not synthesized by the human body but whose study and nutritional interventions are generally not included among the micronutrients, mainly because they form part of macromolecules or supramolecular structures. The list is also lacking of less known substances, mainly from the vegetable kingdom, whose properties in human physiology still need to be revealed.

In developing countries, micronutrient deficiencies tend to exist where diets lack diversity and intake of animal products is minimal. Likewise, poor sectors of wealthy countries may also have poor diets even in combination with abundant sources of energy. Industrialization has reduced the provision of many micronutrients because of the large dependence of the food industry on sugar, vegetable fats, and refined cereals, all of which are poor sources of vitamins and minerals. Individuals whose diets depend heavily on these products often fall short of meeting the daily recommended intakes of many micronutrients. In poor countries, this deficiency is exacerbated by systemic infectious and parasitic diseases that reduce nutrient absorption and biological utilization.

Thus, incorporating vitamins and minerals that are present in low amounts in the diets into widely consumed foods has become one of the main interventions used to prevent the consequences of their deficiencies for both poor and wealthy societies. The type and amounts of micronutrients to add may vary from country to country because the epidemiological realities are different. Therefore, proper data about food/nutrient intake should be available to make an informed decision for designing efficacious and safe food fortification programs.

Mass fortification can be a very powerful intervention to improve human nutrition and health, but the planning, design, implementation, and supervision should be done correctly to ensure that the intended benefits are attained, and the probable risks minimized. The Food Fortification Formulator is a tool to help guide the design process.

III.   TEN STEPS IN DESIGNING MASS FORTIFICATION PROGRAMS

The following steps are necessary for the design of mass fortification programs. They were modified and adapted from the WHO/FAO *Guidelines on Food Fortification with Micronutrients*[3] . The steps are provided here for a quick summary of what is needed for designing safe and efficacious mass fortification programs.

Step 1: Selecting the Proper Food Vehicle for Mass Fortification

Foods that are candidates for mass fortification should be industrially produced and consumed in adequate amounts by large segments of the population. They should also comply with the following requirements:

   a. Efficacy studies demonstrate that .the fortified foods have the potential of being absorbed and bioconverted in the active forms that the human needs; i.e. fortified foods are biologically efficacious.
   b. The combination of the food and the fortificants is technologically compatible, i.e. fortification does not modify adversely the sensorial properties and physical characteristics of the foods for the customary uses, and the fortificants maintain their stability during the marketing time of the food (period that the food is stored, distributed and purchased) and do not separate from the food matrix.
   c. The fortification process is economically viable, i.e. the increment in the price due to fortification is acceptable for the consumers and the food industry under the usual rules of trade.
   d. The process requires reliable control and supervision by food producers and by the government authorities that enforce standards and regulations.

Step 2: Defining the Dietary Objectives

This step requires a study of the quality of the diet of the target population and an estimation of the gaps in micronutrient intakes. Even without detailed information of the diet, some initial objectives can be formulated based on the knowledge that populations in developing countries consume little to no seafood, meat, or dairy products. Thus, as a starting point for planning nutritional intervention programs, some values are suggested in **Table 1**. Later, once a specific intervention is established, monitoring and evaluation efforts could be used to obtain better dietary information that would be applicable to refine the formulation of the fortification program.

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[3] Allen, L., de Benoist, B., Dary, O. & Hurrell R. (2006) WHO/FAO Guidelines on Food Fortification with Micronutrients. WHO: Geneva, Switzerland. 341 p.

Table 1. Suggested nutritional objectives for increasing micronutrient intakes in developing countries.

100 % EAR	80% EAR	60% EAR	40% EAR
Iodine	Vitamin A	Vitamin B-2	Vitamin B-1
-	Folate	Calcium	Niacin
-	Vitamin B-12	(Vit. D)*	Vitamin B-6
-	Iron	-	Vit. C
-	Zinc	-	-

*In locations where skin exposure to sun light is low.

Table 1 presents the objectives in terms of the Estimated Average Requirement (EAR[4]) instead of the Recommended Nutrient Intake (RNI[5]), because the proportion of a population with intakes below the EAR for a given nutrient corresponds to the proportion having an inadequate intake of that nutrient. The RNI values are more appropriate to analyze diets of individuals. The EAR cut-off point method works reasonably well for most nutrients, except iron because of the large individual variation in biological needs for this mineral. Although the "Formulator" focuses on the proportion of EAR that is supplied through the consumption of the fortified food, it also presents the proportion of the additional intake in terms of RNI, as well as the absolute amounts.

Another objective of mass fortification is to ensure that the population does not reach the Upper Tolerable Level of Intake (UL[6]) for those nutrients that might have some adverse effects if consumed in excessive amounts, such as vitamin A, vitamin D, niacin (if using nicotinic acid) folic acid, iron (specially if supplied by NaFeEDTA), zinc, calcium, fluoride, and iodine. It is important to point out here, that UL are not to be recommended levels of intake but safety factors to avoid occurrence of adverse effects. The UL values vary with age and gender, and the ratio with the energy and food intake also changes. In order to assure safety for all population groups, it is important to check the intakes of the mentioned micronutrients by the most vulnerable groups at risk of adverse effects due to excesses; **Table 2** shows these groups. Vulnerability to excessive intakes is a function of the ratio of the UL value over the usual energy intake of the group. Susceptibility depends on the micronutrient, but in general the two groups at risk are children 4 to 6 years old and males 14 to 18 years old. Children younger than 3 years of age are also vulnerable, but because their diets are generally different than those of the rest of the family, they are not included in the table.

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[4] 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.

[5] 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 EAR plus two Standard Deviations.

[6] UL is the highest average daily nutrient intake level that is unlikely to pose risk of adverse health effects to almost all (97.5%) apparently healthy individuals in an age- and sex-specific population group.

Table 2. Vulnerable groups at risk of adverse effects due to excessive intakes of micronutrients

Micronutrient	4 – 6 years old	Males 14-18 years old
Vitamin A	X	-
Vitamin D	-	X
Niacin as Nicotinic acid	-	X
Folic Acid	-	X
NaFeEDTA	X	-
Iron	-	X
Zinc	X	-
Calcium	-	X
Iodine	X	-
Fluoride	X	-

The Figure 1 illustrates the position of the three main dietary parameters (EAR, RNI, and UL) and their association with risk of inadequacy and risk of excess.

Figure 1. Dietary Reference Intakes (EAR, RDA or RNI, UL). Institute of Medicine, Academies of Science of the USA. Dietary Reference Intakes. Applications in Dietary Assessment, 2001.
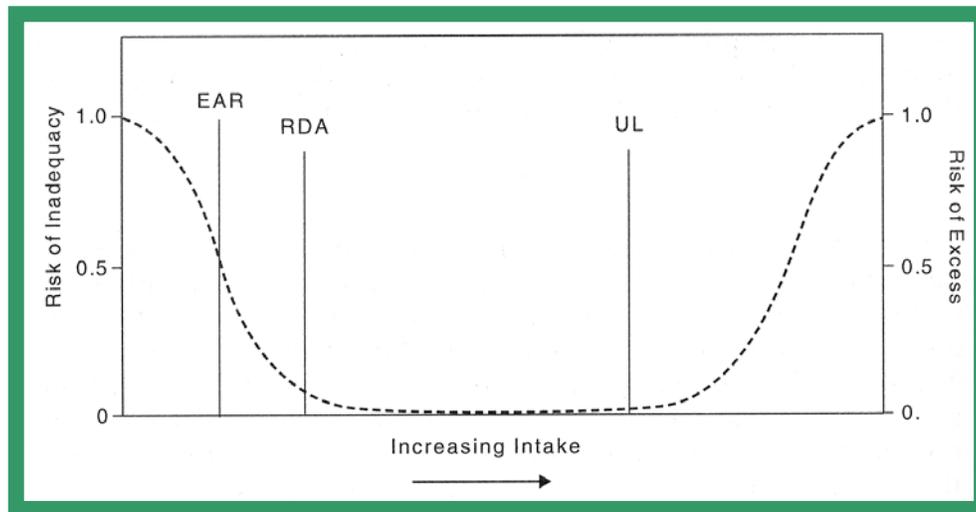
Step 3: Finding the Appropriate Combination of the Food Vehicles

Ideally, widely consumed products with a narrow range of consumption make the best vehicles for mass fortification because those products are potentially capable of providing biologically efficacious levels of micronutrients and are still within a safe range of intake for the individuals who consume the food in large amounts. Excluding salt, in most cases the food vehicles are

generally not consumed by almost everyone in the population, and the intakes might vary depending on the age, the socio-economic group, and the geographical location. Consequently, more than one food, or more than one intervention, would be needed to fulfill the objectives of a nutritional program. Both the proportion of the EAR to satisfy the requirements and the proportion of UL should be defined for all the candidate vehicles in combination. If this precaution is not applied and the formulation of only one product completes the UL for some individuals of the population, then the introduction of other mass fortification interventions could be restricted. Once the UL is reached, no other intervention with a mass coverage should be used.

The formulator suggests fortification formulas according to specific intakes for each food separately and assumes that they are the main source of the added micronutrients. However, the user must adjust the micronutrient levels of those formulas downwards when a combination of fortification programs is planned in order to maximize the benefits and to reduce the risks.

In developing countries, good candidates for mass fortification are salt, oil, and sugar, followed by wheat flour and maize flour. Sugar and oil are currently used to fortify a few micronutrients, mainly vitamin A. Wheat and maize flour may be seen as complementary vehicles for vitamin A, and even as the most important vehicles when introduction of oil or sugar fortification is unfeasible, undesirable, or difficult. Furthermore, flours can provide many other vitamins and minerals simultaneously and should be used to their full potential to prevent and reduce many micronutrient deficiencies. Fortification formulation of several types of cereals and cereal flours may be done in combination, because cereal and flour intakes are mutually complementary. In other words, individuals of the same population may consume similar amounts of all cereals and flours, but in different combinations in the diet. Thus, the fortification formulation might be common for the whole group of cereals and cereals flours as they constitute the same food group. Cereals and cereal flours are complimentary to each other. Therefore, it makes more sense to determine a common fortification formula for all of them as a group rather then individually. This strategy will reduce the variation of the individual consumption of each one of these foods.

Step 4: Estimating Usual Intakes of the Fortification Vehicles

Ideally, the consumption profile of the fortification vehicles should be determined for each of the age and gender groups as well as for geographical and socio-economical groups. Food consumption and dietary intake surveys are useful for determining food intakes. However, those studies are rarely done in developing countries. Household Income Expenditure Surveys (HIES) have been proposed as a simpler way to obtain this information[7]. The HIES collect data about household food utilization and family composition. Assuming that food intake is proportional to the energy requirements, and using the requirement of adult males as the unitary reference, it is possible to estimate the food intake in terms of male adult equivalents, i.e. dividing the household consumption by the total number of adult equivalent units of each household. This calculation approximates the consumption profile of different groups of the population by using the proportional energy requirements of each group and comparing with that of adult males.

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[7] Imhoff-Kunsch, B., Flores, R., Dary, O. & Martorell, R. (2007) Wheat flour fortification is unlikely to benefit the neediest in Guatemala. J. Nutr. 137:1017-1022.

Table 3 illustrates the proportional energy intake for different groups, using adult males as the reference. To estimate the adjustment factors for each group, the corresponding energy requirement is divided by the energy requirement of the adult males.

Table 3. Energy Intake Requirements and Number of Adult Equivalent Units by Age and Gender Accordingly to FAO[8]

Parameter	Children (age in years)				Females (age in years)				Males (age in years)			
	(< 1)	(1-3)	(4-6)	(7-9)	(10-18)[a]	(19-50)[b]	(51-65)	(+65)	(10-18)[a]	(19-50)[b]	(51-65)	(+65)
Energy Requirement (kcal/day)	700	1100	1400	1760	2325	2375	2350	2100	2762	3000	2950	2450
Adjustment Factor	0.23	0.37	0.47	0.59	0.77	0.79	0.78	0.70	0.92	1.00	0.98	0.82

[a] Average of the values for the groups 10-13 and 14-18 years old.
[b] Average of the values for the groups 19-30 and 31-50 years old.

In the absence of HIES, another approach is to subtract the amounts for exports and non human consumption (often available from government and/or industry statistics) from the total country food supply for human consumption and then divide that amount by the total population to get the *per-capita intake*. The *adjusted per capita intake* can be calculated by dividing the per capita intake by the proportion of the population consuming the food. The adjusted per capita intake of the overall population often approximates the median (P-50) value of intake of adult males. The estimation of the possible intakes of the other population groups can be derived by using this approach based on proportional energy requirements.

For example, if one calculates that the per capita intake of a certain food in a country is 80 g/day, but only 60 percent of the population has access to it, then the adjusted per capita intake of that food is: 80/0.6 = 133 g/day. Then, if the P-50 for women is estimated, the adjusted per capita intake is: 133 x 0.79 = 105 g/day.

The minimum and maximum intake values may be determined by dividing and multiplying, respectively, the estimated P-50 values by two to four, depending on the variation of consumption of the food in each country and for each population group. Low values would be used when the population has a homogeneous intake of the food, and large values when there is evidence of large intake differences; for example, between urban and high socio-economic groups against rural and poor socio-economic groups. Later on, when the program is implemented and monitoring and evaluation activities are carried out, the real values can be established and the values refined.

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[8] The values for the groups 10-18 years old were calculated using the average of the specified values for the groups 10-13 and 14-18 years old. Likewise, the values for the 19-50 years old were calculated using the average of the specified values for the groups 19-30 and 31-50 years old.

For example, if one assumes that the usual variation of the intake of a specific country is two times the value of the median, then the minimum and maximum intakes of that food for adult males would be 133/2 = 66 g/day, and 133 x 2 = 266 g/day, respectively.

The "Formulator" estimates the probable food intakes following this procedure. The users are permitted to modify the adult-equivalent proportions for each age group to adjust for the specific conditions of each country, as well as to apply different factors for estimating the minimum and maximum intakes.

Step 5: Determining the Feasible Fortification Levels (FFL)

The Feasible Fortification Level (FFL) is the micronutrient content that will provide the greatest number of at-risk individuals with an adequate intake while avoiding excessive intake by those who consume large quantities of the fortified food. The FFL takes into account both the safe and the technological limits[9]. The safe limit[10] needs to be calculated for each of the age groups of the population, especially for adolescent males and for children four to six years old as these are the groups most likely to reach the UL of intake consuming products used in mass fortification (see **Table 2**). The *safe limit* is calculated using **Equation 1**. The UL values can be adjusted for intakes from other sources, including natural sources in the diet.

Equation 1:

$$\text{Safe limit}^{11} \ (\text{mg/kg}) = \frac{[\text{UL(mg/day)} - \text{intake of concern from other sources (mg/day)}]}{[95^{\text{th}} \text{ percentile consumption (kg/day)}]}$$

The "Formulator" allows the user to input intake values for each one of the micronutrients with specified UL values, both from dietary sources as well as from other nutritional interventions (supplementation, e.g.), and computes the adjusted UL, and in turn calculates the safe limit using all the information. The estimated safe limit then serves as a reference to the user when he/she studies the fortification formula and assesses its impact in additional %EAR, %RNI, and approximation to the adjusted UL value. The safe, technological, and cost limits, as well as the deduced FFL, are computed for reference in one of the sheets of the "Formulator", called Technical Information

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[9] The WHO/FAO *Guidelines on Food Fortification with Micronutrients* includes as part of this definition the *cost limit*. However, because the cost limit depends on the combination of all the fortificants and process costs, and it is in essence a financial decision about how to cover the program cost, it is discussed here as an independent step.
[10] The *safe limit* is defined as the highest average fortification level that would be feasible to use without the risk for approaching the UL, or the determined proportion of the UL if more than one food vehicle is being considered.
[11] A more accurate calculation may consider micronutrient losses during distribution and storage, as well as losses during food preparation. However, because losses vary hugely according to conditions and situations, and because premixes usually are formulated with higher amounts to compensate for these losses, we recommend using this simplified approach.

Step 6: Defining the Acceptable Allowable Cost

Fortification should have a low impact on the price of the food vehicle to facilitate compliance and creation of a level playing field among producers. If the price increase is too high, the possibility of non-compliance or risks of corruption may hinder programmatic feasibility. Values ranging from 0.5 percent to 2 percent of the retail price have been found to be acceptable by producers and the general public.   In the case of targeted-fortification and market-driven fortification, increase in the price is not as sensitive as with mass fortification, because the price of their products depend on other factors, such as industrial processing, packaging, distribution, and commercial advertising. Staples and condiments used in mass fortification are very sensitive to price differences because of their large consumption and their use as ingredients for other industries.

If the cost of fortification is too high, then the program managers may decide to reduce the level of fortification of the less needed, or the less effective, or the most expensive fortificants. Cost is the most flexible of the limiting factors that influence the fortification level because external financing may make a fortification program more viable. Both the absolute and the relative cost (i.e. increase in the price of the product) influence the viability of mass fortification programs. The first defines the annual overall and per person costs of the program, while the second determines the viability of the fortified food among non-fortified alternatives. The "Formulator" calculates the cost per nutrient, the annual cost per consumer, and the annual cost for the whole process which provides program managers with sufficient information so that they may make informed decisions.

Step 7: Assessing the Nutritional Impact and Selecting the Levels of Addition

The "Formulator" processes the information about the food consumption profile of the population to select one out of two (salt), or three (oil and sugar), or four (flours) fortification formulas according to the level of food intake (low, medium, high, and very high consumption patterns). Each fortification formula specifies the amount of micronutrient to be added to the food vehicle only as a guide to the user; the user is responsible to decide for the final micronutrient levels accordingly with the objectives and the conditions of each program. The "Formulator" also uses usual losses of the micronutrients during marketing and cooking, to have a raw estimation of the micronutrient level at the consumer's table. As outputs, the "Formulator" presents the additional intake of micronutrients in terms of %EAR and %RNI, as well as absolute amounts in mg/day of each micronutrient, at the probable P-5, P-50 and P-95 percentiles of consumption. It is important to keep in mind that for designing other fortification programs, two values are important: (a) the absolute additional intake of micronutrients at P-95 percentile, which will be used for estimating new "adjusted" ULs for the next fortified food(s) to be designed; and (b) additional %EAR at the P-5 percentile, which may be subtracted from the nutritional objective of the other food vehicle(s) that are being considered as carriers of the same micronutrients.

The "Formulator" allows the user to select other micronutrient levels of addition, and computes the different parameters with the new information. The user of the "Formulator" can try several

levels of addition until he/she is satisfied with the results. Users may select fortification levels that are lower than the FFL or the levels suggested by the "Formulator" because the patterns of food intakes suggest that the nutritional objectives are achievable using smaller micronutrient levels, or that more than one vehicle is being considered to deliver the same micronutrient. Once the user is satisfied with the results, she/he could then switch to other target groups to assess how the selected formula might affect the micronutrient intakes for those groups. The "Formulator" makes these calculations when the user simply switches from one population group to another in the INPUTS worksheet.

Step 8: Estimating the Production Parameters

After selecting the fortification levels, the next step is to calculate the **average**, **minimum**, and **maximum** levels of fortification at production. These parameters are obtained using simple calculations that require knowing the intrinsic content of the micronutrient in the unfortified food and the industrial variation of the fortification process. The parameters become the technical specifications for quality control and assurance for the food factories. The average content of micronutrient in the fortified food results from the addition of the selected fortification level to the intrinsic content of the corresponding micronutrient in the unfortified food. The minimum and the maximum fortification levels during production are estimated by means of subtracting and adding to the average, respectively, 1.28 coefficients of variation (CV) of the fortification process. **Equations 2** and **3** show the corresponding equations. The estimated range represents the expected analytical contents that 80 percent of adequately fortified samples would have[12]. The user of the "Formulator" may change the values of the performance specifications of the fortification process to adjust the calculations to the specific conditions of production in each country.

Equation 2:

Minimum Fortification Level (mFL) (mg/kg) =	Average x [1 – (1.28 x CV in the nutrient content of the process (%/100))]

Equation 3:

Maximum Fortification Level (MFL) (mg/kg) =	Average x [1 + (1.28 x CV in the nutrient content of the process (%/100))]

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[12] The WHO/FAO *Guidelines on Food Fortification with Micronutrients*, as well as related article (Dary O. Establishing Safe and Potentially Efficacious Fortification Contents for Folic Acid and Vitamin B-12. *Food Nutr Bull* 2008; June, in press) used 2 coefficients of variation for estimating the range that would include 95% of adequately fortified samples. However, this recommendation works only if the coefficient of variation of the fortification process is lower than 20%, and it seems that it is unrealistic for many countries. For this reason, the equations have been changed here to estimate the analytical range that would include 80% of the adequately fortified samples under the assumption that the analytical results follow a symmetric distribution around the mean.

Step 9: Calculating the Regulatory Parameters

The "Formulator" will also suggest the Regulatory Parameters, i.e. the **legal minimum** (**LmL**) and the **Maximum Tolerable Level** (**MTL**) of the fortified food for standards and enforcement purposes. The legal minimum originates from subtracting the expected decay of the micronutrients during the expected marketing life of the fortified food. **Equation 4** shows that calculation. The MTL coincides with the maximum production content, and it is mainly applicable to those micronutrients with low UL values.

Equation 4:

Legal minimum Level (LmL) (mg/kg) =	[Minimum Fortification Level (mFL) x (1 – proportion of losses during marketing)]

The LmL is useful to include as the minimum content claim in the labeling of the products. It is also useful when single samples are analyzed to confirm that the food fortification standards are being observed. At least eighty percent of the adequately fortified samples should have analytical results of the micronutrient contents above the LmLs. However, it is advised that the food standards for mass fortification include as reference values both the amount of micronutrients that should be added, as well as the average content of micronutrients that well-fortified food should contain at the factory level, and state that the LmL and the MTL are only the minimum and maximum values of the analytical allowable range when single samples are analyzed. Otherwise, the producers may aim to comply only with the LmL and will not add the amounts of micronutrients at the levels that are expected. This problem has been identified in several countries whose standards include only the LmL. In such cases, the mass fortification programs are not delivering the expected additional intakes of the needed micronutrients.

Figure 2 illustrates the position and relationships of the different food control parameters (production and regulatory) that are mentioned here.
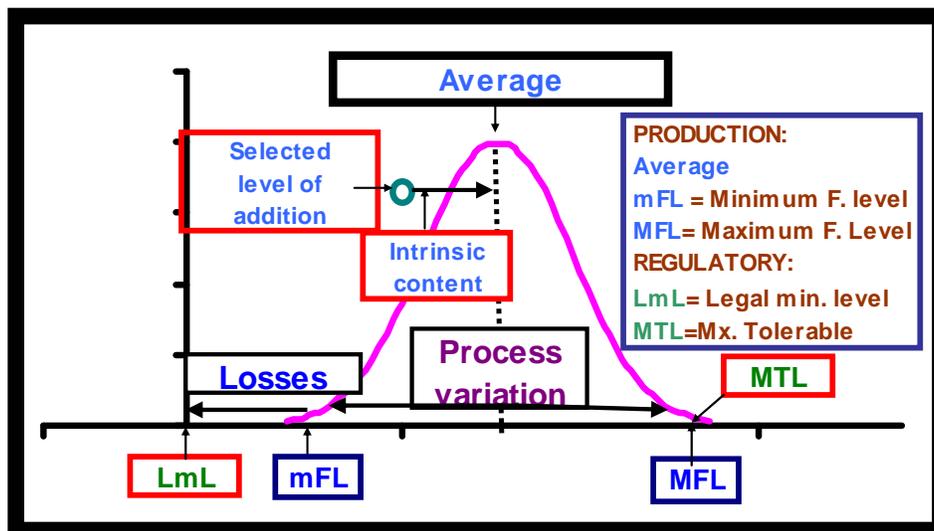
Figure 2.

Parameters for Mass Fortification. Modified from the WHO/FAO *Guidelines on Food Fortification with Micronutrients*.

Step 10: Formulating the Premix

The final output of the "Formulator" is the estimation of the premix composition. Each micronutrient is supplied by a fortificant, in which only a proportion of its composition is the micronutrient itself. Therefore, the amount of fortificant to add will be larger than the micronutrient content that is selected. Furthermore, in many occasions other substances in addition to the fortificants are incorporated to the premix to improve fluidity and stability. A minimum weight and volume for the combination of fortificants needs to be used to achieve the selected micronutrient levels. Consequently, there is a maximum dilution factor (the amount of fortified food produced per a specific amount of the fortificant premix), because there is a strict minimum amount of premix to add. It is not possible to reduce that amount of the fortificant premix without decreasing the micronutrient content in the fortified food. However, the user may decide to use larger amounts of premix to improve homogeneity through better mixing. In this case, filling material is incorporated into the premix to increase its weight and volume. More diluted premixes have lower prices than concentrated premixes because their micronutrient content is lower; however, the final cost of fortification is larger because the final content of micronutrients added to the foods should be the same, but the handling and use of larger volumes of diluted premix increases the expenses. Dilution factors around 1,000 to 2,500 are customary in mass fortification. The "Formulator" allows the users to try different premix formulations, and estimate the micronutrient composition and the cost of each one of them. The micronutrient contents that are estimated by the "Formulator" should be interpreted as the minimum levels that the micronutrient premix should contain. The premix formulators should decide to add some overages (additional amounts over the minimum content) to assure that the premix contain the claimed minimum levels up to the expiration date of the product. It is important to point out here,

that the process described here <u>does not need the calculation</u> of overages for the fortified food, which makes easier the formulation of premixes and favors a leveled playing field for the premix manufacturers.

IV. FOOD FORTIFICATION FORMULATOR

A. DESCRIPTION OF THE "FORMULATOR"

The "Formulator" is a spreadsheet written in the program Excel with 15 linked worksheets with data entry, reference values and calculations. The first two worksheets are an introduction, and a summary table that includes parameters of interest to public health nutrition (additional intakes of micronutrients in absolute amounts, and percentages of EAR and RNI values), technical specifications about micronutrient levels in the fortified foods for food industries, fortification standards for governments, premix formulation, and costs.

The worksheets are identified with a different color depending on the use. Thus:

- **Purple**: Instructions
- **Green**: Summary of data
- **Yellow**: Input data. **Note**: Cells in yellow in other worksheet also indicate data to be entered by the user.
- **Clear Yellow**: Data suggested by the "Formulator" but that can be overwritten by the user. **Note**: Cells in clear yellow in other worksheets also indicate data to be entered by the user.
- **Blue**: Output data
- **Gray**: Reference values

Some other color codes have been used in specific cells to notify the user of their importance. Thus:

- **Red**: If a criterion specified by the user is not complied (e.g. per cent of the price increase due to fortification larger than planned), the formulator warns the user using a red color in the corresponding cell.
- **Pink**: Reference data
- **Clear green**: Important calculations that are needed for making decisions

The sequence of the worksheets is as follows:

1. Introduction (Purple)	9. EAR Values (Gray)
2. Summary (Green)	10. RNI Values (Clear Yellow)
3. Inputs (Yellow)	11. UL Values (Clear Yellow)
4. Selecting Levels (Yellow)	12. Conversion Factors (from RNI to EAR) (Gray)
5. Fortification Parameters (Blue)	
6. Premix Formulation (Yellow)	13. Price of Fortificants (Clear Yellow)
7. Food Intake (Clear Yellow)	14. Intrinsic Micronutrient Contents (Clear Yellow)
8. Technical Information (Clear Yellow)	
	15. Fortification Formulas (Gray)

Thus far, "Formulators" have been produced for the following foods:

- Salt
- Sugar
- Oil
- Refined wheat flour
- High extraction wheat flour
- Maize flour (without a germ)
- Maize meal
- Mesa-maize flour

In the near future, similar worksheets are planned for the following foods:

- Powder milk
- Fluid milk
- Rice

Other foods may be added if the need is identified.

B. SPECIAL FEATURES OF THE "FORMULATOR"

Some of the "Formulators" include features that are specific for each application. The special characteristics to underscore are as follows:

Salt Formulator:

- The list of possible micronutrients to add includes iodine, vitamin A, iron (from micronized ferric pyrophosphate), and fluoride. The user can use the Formulator to estimate the technical and economic implications to add these micronutrients to salt.
- Although the Formulator recommends potassium iodate as the source of iodine, the user can also compare the results using potassium iodide.

- The sheet about the Premix Formulation permits the selection between the dry method of fortification (using a dry premix of potassium iodate or iodide) and the wet method (using a solution of any of the iodine fortificants). The dry method may be used for all the micronutrients mentioned above, while the wet method is only applicable to iodine and fluoride fortifications.
- In the case of the wet method of fortification, the Formulator helps in the determination of fortification conditions depending on whether the fortification is done in batch or in line. Both the amounts of fortificant as well as the rate of application accordingly to the rate flux of the salt production are estimated.
- Only two levels of salt intake are considered; one for a per capita intake below 10 g/day (low), and the other for more than that amount (high). The current dietary advice is that salt intake should be reduced to less than 5 g/day to avoid high blood pressure and associated chronic diseases. If in the future this recommendation is applied, only the fortification formulation for low salt consumption would be valid.

Sugar Formulator:

- In addition to vitamin A, the Formulator can be used to make estimations for fortification of sugar with folic acid, iron (from NaFeEDTA and ferrous bisglycinate), and iodine (using potassium iodate). Although some of these fortifications have been tried in the past, none has been established as a feasible program. Proof that the micronutrients do not segregate (separate) from the sugar crystals, as well as the stability of folic acid and iodate are lacking. Analysis of technological compatibility with the sensorial properties of sugar and the product made with it is still needed, especially for NaFeEDTA and ferrous bisglycinate.

Oil:

- The list of possible micronutrients to add includes vitamin D. This nutrient might be needed for countries where exposure to sunlight is reduced because of their distance from the Equatorial line or for cultural reasons to keep the body covered.
- In the sheet for Premix Formulation, the calculations are done for the fortification process of batch and in line. If the fortification is done in line, the rate of application is estimated in addition to the amount and micronutrient content of the oily solution delivered to the unfortified oil.

Refined Flours (wheat and maize flour (no germ)):

- The Formulator has been constructed in a way to select either the dietary parameters (EAR and RNI) corresponding to two types of diet: moderate bioavailability and low bioavailability. The user decides between these two alternative diets in the Inputs worksheet.
- Although the Formulator recommends the use of ferrous fumarate as the iron source, the user can compare the results with the following types of iron: ferrous sulfate dried, electrolytic, encapsulated ferrous sulfate, and NaFeEDTA. The EAR and RNI

values for these iron compounds have been adjusted based on experimental findings as compared with the bioavailability of ferrous sulfate reported in the literature.

- The Formulator also includes vitamin D in dry form, calcium carbonate, and potassium iodate for the user who wants to estimate the nutritional, technological, and economic implications of these other types of fortification.

High Extraction Flours (wheat, maize and masa-maize flour):

- The Formulator has been constructed to select only the dietary parameters (EAR and RNI) corresponding to low bioavailability diets.
- Although the Formulator recommends the use of NaFeEDTA as the iron source for these types of flours, the user can compare the results with the following types of iron: electrolytic, encapsulated ferrous sulfate and ferrous fumarate. Ferrous sulfate was not included because it interacts negatively with the fats and other substances easily oxidized in these flours.
- The Formulator also includes vitamin D in dry form, calcium carbonate, and potassium iodate so the user can estimate the nutritional, technological, and economic implications of these other types of fortification.

C. INSTRUCTIONS FOR THE USE AND INTERPRETATION OF THE FORMULATOR

1. INTRODUCTION

This first worksheet presents a short description of the structure of the "Formulator", and the meaning of the different colors, both for worksheets and cells. It also lists the basic information that is required from the user.

2. SUMMARY

Worksheet 2 summarizes the main outputs provided by the "Formulator". The cells of the different parameters are filled with examples, but those values are going to change after the user introduces his or her own data into the Inputs worksheet.

This page contains: the target group that is being analyzed (e.g. females 19-50 years, or any of eleven possibilities that the "Formulator" allows; only pregnant and lactating women are not included because they require special attention); the country's name; the food being analyzed; and the type of diet in terms of the bioavailability of minerals, either moderate or low.

The first two lines of data of the page are dedicated to reporting the most important variables for a program manager. Those are:

- **Adjusted Per Capita Intake:** the per capita intake of the food corrected for the proportion of the population that has access to the food.

- **Estimated median intake (P-50) of the target group:** either as reported by the user, or computed by the "Formulator" following the assumptions of proportional energy intake in terms of adult equivalent units (using as reference the energy requirements of the adult males, and accepting that the adjusted per capita intake approximates their P-50 intake).
- **Cost per consumer:** yearly average cost of the fortification program calculated by multiplying the estimated fortification cost by the adjusted per capita intake of the population.
- **Increase Product Price**: the estimated increment, due to fortification, in the retail price of the food expressed in percent and calculated by dividing the fortification cost by the price of the foods as reported by the user. If this cell appears in red, this means that the increment in price due to fortification was higher than the value originally identified as tolerable by the user.
- **Fortification Cost**: a rough estimation of the probable cost of the fortification program, assuming that 90 percent of the total cost is attributable to the premix cost.
- **Premix Cost:** the estimated cost of the premix as computed by the "Formulator". The two last columns of the table in the worksheet present details of the distribution of this cost per micronutrient and other costs.
- **Amount of Premix**: amount of premix in grams per metric ton of fortified food as selected by the user.
- **Dilution Factor of the Premix**: the inverse of the amount of premix expressed in the same weight units as the fortified food.

The summary worksheet also includes a table with several columns with important information for each micronutrient added to the food and classified in three categories. Thus:

a. **Nutritional Estimations**:
   - Additional daily intakes in absolute amounts (mg/day)
   - %EAR of the additional intakes for the population group under analysis
   - %RNI of the additional intakes for the population group under analysis
b. **Food Control Parameters**:
   - Average level of addition of the micronutrient (mg/kg) that is selected by the user as the fortification levels
   - Production Parameters: minimum, average, and maximum levels (mg/kg) as computed by the "Formulator", where the intrinsic content of the micronutrients in the unfortified food and the variation of the process are used
   - Regulatory Parameters: minimum legal and maximum tolerable levels (mg/kg) as computed by the "Formulator", using the estimated losses during the usual marketing life of the fortified food
c. **Premix Formula**:
   - List of the fortificant compounds (source of the micronutrients)
   - Amount of fortificants (grams) per kilogram of premix
   - Amount of micronutrients (grams) per kilogram of premix.
   - Cost (US$/kg) for each one of the added fortificants

- Percent of the cost of each fortificant over the estimated total cost of the premix as computed by the "Formulator"

3. INPUTS

Worksheet 3 requires the basic input data from the user, as follows:

- **Cell B3 and B5**: Name of the country and the food that is being considered for fortification, respectively
- **Cell B7**: Selection of the target group from 11 possible options
- **Cell B9**: Retail price of the food before fortification
- **Cell B11**: Maximum acceptable increase in the price of the food due to fortification
- **Cell B13**: Number of micronutrients that are being considered to add. This information would be used in the Technical Information worksheet to compute the Feasible Fortification Level for each micronutrient.
- **Cell B15**: Per capita intake of the food in the population
- **Cell B17**: Proportion of the population that consumes or has access to the food
- **Cell B19**: The "Formulator" reports here the estimated Adjusted Per Capita Intake, dividing the Per Capita Intake by the proportion of the population consuming the food.
- **Cells B22, B24 and B26**: The user should input estimated intake values at low (P-5), median (P-50), and high (P-95) levels of consumption by the target population group under analysis. The "Formulator" presents the estimations of these values in Cells C22, C24, and C26, respectively. The latter values are calculated, in the worksheet named D. FOOD INTAKES, using the principle of proportional energy intake for each age and gender group.
- **Cell B28:** The user should select if the diet is rich or not in iron absorption inhibitors. This cell does not appear for non-refined flours. If the response is YES, the "Formulator" will select the EAR and RNI values corresponding to the low bioavailable diet. Otherwise, the values will be those for a diet with moderate bioavailability for minerals.
- **Cells B33 to B55**: The user can input here the estimated intakes of the nutrients whose excessive intakes are a matter of concern, even from dietary sources. Those are: vitamin A, vitamin D, calcium, iodine, and fluoride.
- **Cells C33 to C55**: These cells are for the estimated intakes of the nutrients whose excessive intakes are a matter of concern and that are supplied from sources different to the diet (other fortified foods, supplements, e.g.). The micronutrients included are: vitamin A, vitamin D, niacin (only from nicotinic acid), iron (excepting NaFeEDTA, which has the following cell specifically assigned), NaFeEDTA (expressed as iron), zinc, calcium, iodine, and fluoride
- **Cells D33 to D55**: The "Formulator" computes the total intake of the micronutrients whose intake should not be excessive. These values are used by the "Formulator" to calculate an adjusted UL value; i.e. UL – total basal intakes.

- **Cells E33 to E55**: The user can input the nutritional objectives (additional intakes) in terms of %EAR that should be achieved through the fortification of this and other fortified foods or nutritional interventions.

4. SELECTING LEVELS

Worksheet 4 is the most important spreadsheet. It is here where the user will make decisions regarding micronutrient levels.

- **Cells C10, G10 and K10**: The "Formulator" copies the P-5, P-50, and P-95 values of the food intake as specified in the INPUTS worksheet.
- **Cells EF12 to 15**: The "Formulator" shows the user the reference ranges of food intakes that are used to classify the consumption pattern of the population. Number of categories depends on the food. Thus: 2 for salt (low and high); 3 for sugar and oil (low, medium, and high); and 4 for the flours (low, medium, high, and very high).
- **Cell H13**: The "Formulator" classifies the intake profile of the population under study based on the largest intake value of each category.
- **Cell L13**: The "Formulator" reminds the user of the type of diet and the minerals bioavailability that he/she has selected.
- **Column B of the Table**: List of nutrients that can be analyzed for the type of food, and in the case of iron using different options of fortificants.
- **Column C of the Table**: The "Formulator" shows the Technological Limits of fortification for each micronutrient as specified in the TECHNICAL INFORMATION worksheet.
- **Column D of the Table**: The "Formulator" shows the computed Safe Limit for the micronutrients whose intakes should not be excessive. This value is estimated using Equation (1), and it is specific for the target group that is being analyzed.
- **Column E of the Table**: The "Formulator" reproduces the suggested fortification levels accordingly to the formulas shown in the last worksheet: FORTIFICATION FORMULAS. These values are only for reference, because they do not take in consideration that the user may be considering programs integrated with several fortified foods or interventions.
- **Column F of the Table**: The user inputs the Selected Levels of Addition of the micronutrients in the fortified food that best satisfy the nutritional objectives of the program. The user analyzes the additional intakes due to the consumption of the fortified food in terms of %EAR[13] (**columns I to K**), absolute amounts in mg/day[14] (**columns L to N**), and %RNI (**columns P to R**). He/she can also compare how much the nutritional objectives (**column H**) have been approached at the three different levels of food consumption, and how much the intake at P-95 (**column N**) comes near to the adjusted UL value (**column O**). He/she can also examine the preliminary cost estimations per each selected micronutrient (**column**

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[13] The intakes of folic acid are multiplied by 1.7 for estimating the %EAR and %RNI taking into consideration the larger bioavailability of the synthetic forms than in the natural sources.
[14] These calculations take in consideration the losses of some micronutrients during marketing, as well as cooking, as assumed in the Technical Information worksheet.

G). Columns C (Technological Limit) and D (Safe Limit) are used as references to avoid selecting fortification levels that may have probabilities of being technological unfeasible or increasing the risk of adverse effects due to excessive intakes, respectively.

5. FORTIFICATION PARAMETERS

Worksheet 5 does not allow modifications by the user because it contains outputs of the "Formulator" using the conditions specified in the worksheets designated as SELECTING LEVELS, TECHNICAL INFORMATION and INTRINSIC MICRONUTRIENT CONTENTS.

- **Columns B and C:** These columns list the name of micronutrients and the fortificant compounds, respectively.
- **Column D:** The "Formulator" copies here the selected fortification level.
- **Column E**: the expected minimum content during production, as determined through chemical analysis, of each micronutrient for 80 percent of adequately fortified food using Equation 2.
- **Column F**: the expected average micronutrient level during production, as determined through chemical analysis. This level is calculated by adding the intrinsic contents of the unfortified food, as specified in the worksheet named INTRINSIC MICRONUTRIENT CONTENTS, and the selected fortification levels.
- **Column G**: the expected maximum content during production, as determined through chemical analysis, of each micronutrient for 80 percent of adequately fortified food using Equation 3.
- **Column H**: the estimated Legal minimum Level that is expected in 80 percent of the adequately fortified foods even after the completion of its usual marketing time. This value is estimated using Equation 4 and may be used for labeling.
- **Column I**: the Maximum Tolerable Level, which is the same as the maximum micronutrient level during production. This value can be used as a reference to avoid supplying excessive micronutrient amounts to the population and to compel producers to achieve small variation for the fortification process.

6. PREMIX FORMULATION

Worksheet 6 helps determine the formulation of the premix. The user has the option to increase the amount of premix per metric ton of fortified food (which is equivalent to reduce the dilution factor). The "Formulator" calculates the maximum dilution factor that is possible using the minimum amount of the micronutrient premix that is necessary to attain the micronutrient levels that have been selected. The "Formulator" also estimates the dilution factors if the amounts of the premix are increased by using more diluted premixes. This worksheet includes a table at the bottom that shows the estimated cost of the fortificants per metric ton of the fortified food, as well as the percent of price increase. The calculations are repeated for each premix that is being assessed. The cost

of the micronutrient premix usually corresponds to 90 percent of the total cost of fortifying the foods.

- **Cell D9**: The "Formulator" reports the minimum amount of premix (grams per metric ton of food) that is needed to attain the selected micronutrient levels of addition. This value is computed by adding the weights of each fortificant that supplies the micronutrients, and using the proportions of the micronutrient in each fortificant as specified in the worksheet named PRICE OF FORTIFICANTS.
- **Cell D10**: The user can increase the amount of the premix with the purpose of reducing the dilution factor and improving homogeneity. The additional weight that is needed to incorporate in the micronutrient premix will be added as filling material, and it is calculated at the bottom of column F.
- **Cells I9 and I10**: These are the dilution factors of the micronutrient premix in the fortified food for the minimum amount of premix (maximum dilution factor), and for the amount of premix selected by the user (selected dilution factor), respectively. These values are computed dividing one metric ton of the fortified food by the amount of micronutrient premix that is used, both expressed in the same units of weight.
- **Columns B and C**: These columns list the names of micronutrients and the fortificant compounds, respectively.
- **Column D:** The "Formulator" copies here the selected fortification level.
- **Column E**: The "Formulator" computes the amount of each fortificant (source of micronutrient) that is needed in order to attain the selected fortification level, using the proportion of the micronutrient in the fortificant as specified in the worksheet PRICE OF FORTIFICANTS.
- **Column F:** The "Formulator" adjusts the amount of each fortificant (in grams) per each kilogram of micronutrient premix, and following the instructions of the user regarding the amount of premix that should be added to each metric ton of food, as has been selected in Cell D10.
- **Column G**: the same information as column F but expressed in terms of the micronutrient content.
- **Column H**: The "Formulator" computes the cost of the premix by estimating the cost of each fortificant and using the prices specified in the worksheet named PRICE OF FORTIFICANTS, and the assumed process cost that appears in the cell at the bottom with a clear yellow color. The user can modify the estimated cost of the process in the cell with the clear yellow color.
- **Column I**: the same information as column H but expressed in terms of the percent of the total premix cost.

7. FOOD INTAKE

Worksheet 7 shows how the "Formulator" estimates the food intake profile of the target group that is being analyzed. It assumes that the adjusted per capita intake reflects the median intake of adult males (adult equivalent unit). Then, using the adult equivalent units for each gender and age groups, the "Formulator" estimates the proportional intake

of the food for each one of these groups (median values). The possible P-5 and P-95 intake values are then estimated by dividing or multiplying, respectively, the factors of estimations that are shown in **Cells G8** and **J8**, respectively.

The user can change both the adult equivalent units of each gender and age group, as well as the factors to estimate the low and high extremes of food intake, with the purpose of fitting the estimations to the specific conditions of each country or circumstance.

8. TECHNICAL INFORMATION

Worksheet 8 contains several parameters that are used for the calculations made by the "Formulator". The user can change the values that are in cells with clear yellow color. The parameters included are:

- **Column D**: Losses of the micronutrients during marketing as %.
- **Column E**: Losses of the micronutrients during cooking as %.
- **Column F**: The "Formulator" estimates an expected average of micronutrient losses before consumption.
- **Column G**: Coefficient of variation of the fortification process, which may vary from fortificant to fortificant, is influenced by several variables: variation of the process, nature of the fortificants and the food, sampling framework and sample size, and the analytical variation of the specific chemical assays.
- **Column H**: Technological Limit. The maximum amount of each micronutrient that does not affect the sensorial and physical properties of the fortified food or the products manufactured with it. These values should be determined experimentally, both for the fortified food as well as for the products in which it is used as an ingredient.
- **Column I**: Safe Limit: the maximum content of micronutrients that can be added to prevent reaching the adjusted UL of intake at the maximum consumption value for the target group under analysis.
- **Column J**: Cost Limit: the maximum content of micronutrients that can be added within the price increase specified in the Inputs worksheet. This is included here only as a reference parameter to be compared with the Technological and Safe Limits. Indeed, the cost limit is a function of the combination of micronutrients that are added, as well as the costs of manufacturing the premix and its distribution and use in the food factories.
- **Column K**: The Feasible Fortification Level, i.e. the lowest value among the technological, safe and cost limits.

9. EAR VALUES

Worksheet 9 presents the estimated EAR values for 11 age- and gender- groups, calculated from the WHO/FAO RNI values and the conversion factors specified in the CONVERSION FACTORS worksheet. In the case of iron and zinc, values for moderate and low bioavailability diets are specified. Approximate figures for different types of iron compounds are also included.

10. RNI VALUES

Worksheet 10 presents the RNI values for 11 age- and gender- groups, as recommended by WHO/FAO. In the case of iron and zinc, values for moderate and low bioavailability diets are specified. Approximate figures for different types of iron compounds are also included. The user can input here other values.

11. UL VALUES

Worksheet 11 presents the currently accepted UL values by WHO/FAO. Some of the data come from the Institute of Medicine, Academies of Science of the USA. The user can input other values.

12. CONVERSION FACTORS

Worksheet 12 presents the conversion factors as recommend by the WHO/FAO *Guidelines on Food Fortification with Micronutrients* in order to transform RNI values into EAR values.

13. PRICE OF FORTIFICANTS

Worksheet 13 presents current prices from vitamin and mineral providers, as well as the proportion of micronutrient in each fortificant. The user can input other values.

14. INTRINSIC MICRONUTRIENT CONTENTS

Worksheet 14 shows the micronutrient content of the 8 foods for which "Formulators" have been made. The user can also input other values.

15. FORTIFICATION FORMULAS

Worksheet 15 suggests micronutrient levels that can be used to select the final fortification level. The user cannot modify this worksheet but can choose other fortification levels he/she would like to use in Column F of the worksheet with the name SELECTING LEVELS.