INCAP Publication CI/028

DOCUMENTOS-9/ IVACG MIN5/17-Jul-00

A METHOD TO ESTIMATE THE MINIMUM LEVEL OF MICRONUTRIENTS TO ADD IN THE FORTIFICATION OF STAPLE FOODS

Omar Dary[1] and Penelope Nestel[2]

ABSTRACT

Food fortification of a staple is aimed to complement the dietary intake of specific micronutrients. The amount of nutrients to add are usually calculated based on average intakes of the food vehicle displayed by the target group, and the corresponding legislation is written to request the estimated amount. This procedure has several limitations because it rarely takes in consideration (1) the normal variation of the fortification process, (2) the nutrient stability during the marketing life of the food, and (3) the safety precautions for the high-intake groups. This situation has caused several conflicts between governmental authorities and the producers. The public sector enforces the law literally. In turn, the industry requests, among other things, a statistically based sampling procedure, in order to establish the degree of compliance with the law. Moreover, both sectors expect the solution of the nutritional problem to come from the simple addition of nutrients to a selected food. To overcome these limitations, we propose the use of the "minimum level" concept.

Under the minimum level concept, all liable food samples should satisfy the claimed "Legal Minimum" during their claimed "Guaranteed Date"[3]. To this end, we propose empirical equations based on the "Nutritional Minimum", the "Tolerable Maximum", the nutrient stability and the variation of the fortification process. The examples given demonstrate that in many occasions safety considerations limit the amount of nutrients that can be added to foods, and therefore more than one strategy should be introduced in order to overcome the nutrient deficiencies. Among these strategies are the fortification of more than one food with the same nutrient(s) and preventive supplementation.

INTRODUCTION AND OBJECTIVE

Food fortification is one of the most cost-effective interventions to reduce micronutrient deficiencies. To be effective, the food vehicle must deliver the desired amount of micronutrient(s) to targeted individuals at the time of consumption. Fortification levels for micronutrients are generally based on the usual amount of the food vehicle consumed by the target population. Micronutrient levels, however, should not be so high as to make total intake unsafe for those who consume large amounts of the food vehicle. To overcome this dilemma, fortification levels have regularly been set as the midpoint between a minimum effective and a maximum safe level, given the usual intakes of the food vehicle by the target and the high-intake groups, respectively. In Central America, and possibly in other regions of the world, the estimated average plus and minus a theoretical variation was specified in the food fortification legislation. This, however, created problems once the legislation was enforced for three reasons. First, it did not take in consideration the real process variation, and the fortified product contained a wider range of nutrient concentration than the theoretical specified value. Second, micronutrients are not completely stable and losses occurred during processing, storage and delivery. Third, processors demanded that auditing activities be based on statistically valid averages, which require very complex and unfeasible sampling procedures. Because of the above, the micronutrient content of fortified foods at the household level has been much lower than the desired level. Moreover, it created many conflicts between the processor and food control authorities.

---

1 Institute of Nutrition of Central America and Panama (INCAP), Guatemala, Central America.

2 Independent Consultant in Nutrition, Washington, D.C., United Stated of America.

3 It is similar but different that the "Date of Minimum Duration", that applies to the food itself and refers to the period in which the product is marketable and maintains its qualities. The "Guarantee Date" refers to the period of time in which the level of the claimed nutrient(s) fulfills the claimed "minimum" content.

Presented at IVACG Meeting, 5-17 July, 2000.

A new approach to setting fortification levels is to focus on a minimum level instead of an average or a range[4]. Fortification regulations should stipulate that this level be present throughout the product's "marketing" life[5]. This approach has three advantages. First, it simplifies the monitoring and sampling procedures, because all samples should fulfill the claimed minimum. Second, it avoids conflicts between producers and food control authorities, because it specifies only one point of reference. Third, producers may be motivated to improve the quality of fortification to save money, by means of the reduction of the variation of the fortification process. Nevertheless, one should be aware that this system requires that producers know the stability of the nutrient during production and throughout the marketing life in order to establish the correct amount at the moment of the addition. Furthermore, a reliable quality control program must be implemented to avoid any excess caused by the fear of not fulfilling the minimum.

The objective of this paper is to introduce a method to estimate the minimum level of nutrient(s) to add in the fortification of staple foods. It is mainly based on four parameters: the nutritional minimum, the tolerable maximum, the percentage of the nutrient stability and the process variation.

METHODS:

Theoretical Basis:

Nutritional Minimum: It is the minimum effective level for the target group. It is calculated dividing the biological goal (nutritional requirement or "nutritional gap", e.g.) by the 25th percentile of consumption of the food vehicle by the target group[6].

Tolerable Maximum: It is the maximum nutrient level completely safe for most individuals. It is calculated dividing the maximum recommended intake of the nutrient by the 75th percentile of consumption of the food vehicle by the population group that shows the largest intake of the food vehicle[7].

Percentage of Nutrient Stability: It is the percentage of nutrient that remains during production and throughout the marketing life of the product, when it is handled and stored under the conditions that are common in a given country or region.

Process Variation: It is the maximum allowable variation for the fortification process. It should be based on experimental evidence, and in principle it should not be larger than 30%.

"Optimal" Minimum: It is the ideal nutrient content of the food vehicle at the time of production that will ensure sufficient supply of the micronutrient to the consumer. It is estimated correcting the **Nutritional Minimum** by adding the proportion that is normally lost as measured by means of the **Percentage of Nutrient Stability.**

Safe Minimum: It is the reference level of the nutrient that the food vehicle should have at the time of production to avoid the risk to reach the **Tolerable Maximum**. It is calculated reducing the tolerable maximum by an amount that is proportional to the normal value of the process variation.

---

4 The policy of a minimum value, claimed on the food label, has already adopted by the US Food and Drug Administration.

5 It is not the "shelf life" of the food vehicle, but the usual period of time in which the food is distributed and sold.

6 Ordinarily, it is difficult to obtain this figure. To have an "approximate" value to make the first calculations, it is suggested to divide by two the median intake of the target group.

7 As in the case of the 25th percentile of the target group, this figure is also difficult to obtain. Under the argument that the consumption pattern is skewed toward the high values, to obtain an "approximate" value, it is suggested to multiply by two the median consumption value of the high intake group.

Technical Minimum: It is the minimum content of the nutrient that the food vehicle must have at the moment of production. It is selected between the values of the **"Optimal" Minimum** and the **Safe Minimum**, whatever is the lowest. Ideally, to fulfill the nutritional goal, the "Optimal" Minimum must be lower than the Safe Minimum.

Legal Minimum: It is the claimed amount on the food label that the government authorities should enforce. It is estimated multiplying the **Technical Minimum** by the **percentage of nutrient stability** corresponding to the "marketing" life specified by the producer on the label.

In the legislation it is sufficient to declare the values of the **Legal Minimum** and the **Tolerable Maximum**. The rest of parameters are important only for the technical personnel.

The most peculiar characteristic of this method is the introduction of the **Safe Minimum** concept, whose estimation is based on one of the simplest statistical parameters: the variation coefficient (s.d./mean x 100) of the fortification process when working under "acceptable" conditions of performance. It is assumed that a nutrient level lower than two variation coefficients from the **Tolerable Maximum** would ensure that at least 80% of the total production would present nutrient amounts lower than the maximum allowable value. Indeed, the degree of protection to persons of the high-intake group is larger than this figure, because the probability to receive multiple batches of fortified food with a high content of nutrient is low. On the other hand, the nutrient losses during storage and delivery are not taken into consideration for the calculation, making the safety factor even larger. The prior arguments justify why the 75^{th} percentile of food consumption is used instead of the "highest" possible intake.

Similarly, the "lowest" possible intake of the food vehicle by the target group is also no necessary for the calculations, because the "average" supply of nutrients through the fortified food would be larger than the **Legal Minimum.** Therefore, using the 25^{th} percentile of food consumption assures that more than 75% of all individuals of the target group would be reaching the nutritional goal. The "average" content of the fortified food at consumer level can be theoretically calculated adding a proportion corresponding to one variation coefficient of the fortification process. Indeed, the true average of the nutrient content at the consumer level would be larger than this estimation, because the population would be consuming fortified food during several periods after its production. Hence they would be receiving during the year nutrient amounts larger than the calculated average and legal minimum.

Empirical Equations:

The former mentioned parameters could be calculated by means of the following empirical equations:

Nutritional Minimum = (RDA – Dietary Intake)/(25^{th} percentile of food consumption) *Target group*

"Optimal" Minimum = Nutritional Minimum / (%Nutrient Stability/100)

Tolerable Maximum = Maximum Safe Intake/75^{th} percentile of food consumption *High-intake group*

Safe Minimum = Tolerable Maximum x [1 - (% Process Variation x 2/100)]

Technical Minimum = The lowest between the "Optimal" and the Safe Minimums

Legal Minimum = Technical Minimum x (%Nutrient Stability/100)]

Average at Consumer Level = Legal Minimum x [1 + (%Process variation/100)]

RESULTS AND DISCUSSION

The enclosed table shows the results of applying the empirical equations to several staple foods. Sugar fortification with vitamin A exemplifies how the nutritional needs and the industrial development can influence the characteristics of the program. At one extreme is Costa Rica, where there is less variation of the fortification process and best nutrient stability, as it is measured by means of the nutrient content of the fortified foods. In this case, the **"Optimal" Minimum** is lower than the **Safe Minimum**, and therefore, it is feasible to reach the nutritional goal for the entire population. To prevent excesses from food fortification is also easy and safe.

Guatemala and Zambia represent another situation. In these two countries, the nutritional need is high, food vehicle consumption is largely variable between the target group and the high-intake group, and the fortification process is less precise. In this case, the **Safe Minimum** is lower than the **"Optimal" Minimum**, and therefore, the nutritional demand of the target group is not attained. Nevertheless, fortified sugar is still an excellent source of the nutrient, representing a supply of nearly 25% the RDA for the target group. Thus, other complementary interventions such as fortification of other foods as well as preventive supplementation are important and necessary in order to cover most individuals of the target group. This does not mean that the fortification program is unsuccessful or inefficient. For example, in Guatemala, fortified sugar has been shown to prevent vitamin A deficiency in children over 2 years old, and it supplies at least 50% of the vitamin A RDA for children over that age, making it the single best source of this nutrient for the population at large. Vitamin A supplementation is a complementary measure for infants, but its effectiveness and sustainability can be further improved by targeting children 6 to 24 months old, whose intake from fortified sugar is not sufficient to meet their requirement. In Zambia, the low sugar intake by all age groups of low-income communities demands that other centrally processed and widely consumed food vehicles should also be fortified. Nevertheless, fortified sugar is probably the best source of this nutrient currently.

The case of sugar fortification with vitamin A serves to illustrate that the concept of the "minimum" facilitates obtaining the harmonization of regulations between neighboring countries, because the minimum values are closer than the averages or ranges. Thus, it would be relatively easy to use standardized levels of fortification. This fact is very important, especially considering the economical policies of free trade that are increasingly growing in the actual world.

Salt fortification with iodide in Costa Rica exemplifies this program in the industrialized world. If the industry is well developed, then the precision of the fortification process and the nutrient stability are excellent. If those conditions are coupled with a narrow range of consumption pattern of the food vehicle, it is possible to reach the nutritional goal with the fortification of only one food. The **"Optimal" Minimum** is lower than the **Safe Minimum**. However, that is the exception and not the rule. For example, in spite of the fact that fortification of flours with folic acid is precise and highly stable, the large difference of consumption among different social groups impedes that the nutritional goal be achieved with the fortification of only one the mentioned flours. In the case of the countries of the North of Central America (El Salvador, Guatemala and Honduras) for example, corn flour is a much better vehicle than wheat flour. However, the former needs to be complemented with the latter in order to complete the four hundred micrograms of folic acid that needs to be supplied.

The example with the flours also illustrates that if several foods are available for fortification, it is possible to reduce the amount of nutrient to add to each one of them, without risking the achievement of the nutritional goal. This is the case of the industrialized countries, where the food fortification practices are efficient, effective and safe. A general policy for food fortification may be to permit that commercially produced foods could be enriched with micronutrients, in amounts between 10 to 25% of the RDA values. If large proportions of nutrients were needed, then that situation would be a matter of governmental regulations and close inspection, because the food vehicle fortified with these large amounts would become the base of a program of public health importance.

The method described here for estimating the minimum level of micronutrient to add to staples foods is simple and it is also useful for predicting the degree of coverage and approximation to the nutritional goal. With this information, one can know beforehand if a specific food fortification program would require the coupled action of another fortified food or another micronutrient intervention, such as supplementation.

CONCLUSIONS

1. In the developing world, due to the large nutritional gap and variations of the food consumption patterns, the minimum micronutrient level for food fortification depends on the food consumption by the high-intake population rather than the consumption by the target group.
2. In order to approach the nutritional goal, it is necessary to reduce the losses of the nutrient during the marketing life of the fortified food as well as the variation of the fortification process.
3. It is uncommon for the fortification of only one food to meet the nutritional requirements of all persons within the target group. Nevertheless, the additional supply of nutrient(s) by means of the fortified foods is very important (usually more than 25% of the RDA value).
4. Food fortification is a favorable, cost-effective intervention to reduce micronutrient deficiencies, but to overcome completely the deficiencies of all population it is usually necessary to combine several strategies (including the fortification of more than one food with the same nutrient).
5. Adoption of the "minimum" level concept may facilitate free trade, because it is easier to harmonize only one criterion. On the other hand, the "minimum" values are usually very similar between neighboring countries.