Manual for Sugar Fortification with Vitamin A

Part 1

Guidelines for the Development, Implementation, Monitoring, and Evaluation of a Vitamin A Sugar Fortification Program

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FOREWORD

In many countries, vitamin A deficiency is a widespread problem that is not necessarily limited to specific groups of people or isolated communities. Among the interventions available, food fortification is an accepted method of delivering micronutrients to the population at large and is widely practiced in developed countries. In these countries, foods such as milk powder, butter and margarine, complementary infant foods, and breakfast cereals are routinely fortified with micronutrients, including vitamin A. The above foods, however, are not regularly consumed by the vast majority of the population in developing countries, especially among those at greatest risk of vitamin A deficiency. One food that is consumed by nearly the entire population in developing countries is sugar, which can be fortified with vitamin A. Sugar fortification is practical because target populations do not need to alter or adapt a new or costly distribution system. Indeed, sugar fortification only requires the existence of a well-established sugar production and marketing system. This allows for the uniform addition of vitamin A as well as the monitoring of its content. Fortification of sugar with vitamin A is one of the safest, most efficacious, and most cost-effective interventions to prevent and control vitamin A deficiency.

This manual in which technical guidelines are presented to systematize and facilitate the establishment and execution of a vitamin A sugar fortification program is divided into three parts. Part 1, *Guidelines for the Development, Implementation, Monitoring, and Evaluation for Vitamin A Sugar Fortification Program,* describes why it is important to prevent and reduce vitamin A deficiency and how to go about establishing such a program. Existing strategies are discussed and the basic elements to be considered in establishing an appropriate program for vitamin A sugar fortification are described in detail. In addition, part 1 offers an overview of the entire program so that public and private sector officials who manage and coordinate sugar-processing activities have information on the essential components to ensure an adequate operation. Technical areas presented in this document will also be useful to specialists involved in specific components of the fortification process. These include the operations involved in sugar fortification, determinates for both the efficiency and efficacy of intervention, and guidelines for determining program costs.

Part 2, *Technical and Operational Guidelines for Preparing Vitamin A Premix and Fortified Sugar,* is written specifically for technical personnel responsible for implementing sugar fortification. Chapter I covers general aspects if the fortification process, Chapter II describes how to manufacture the premix, and Chapter III describes procedures for adding the vitamin A premix to sugar. It also contains a detailed description of quality control procedures.

Part 3, *Analytical Methods for the Control and Evaluation for Sugar Fortification with Vitamin A,* presents field and laboratory methods to estimate the content of vitamin A in the premix and in fortified sugar. It also gives details on how to determine retinol levels in biological samples critical in evaluating the impact of the fortification program. Part 3 is written primarily for laboratory personnel who will be responsible for laboratory analyses.

Each part of the manual is relatively self-sufficient in the essential areas of program design and implementation. Ideally, however, it is recommended that the three parts be considered as theoretical and practical units to be used together.

Research on sugar fortification with vitamin A first began at the Institute of Nutrition of Central America and Panama (INCAP) in the 1960s under the leadership of Guillermo Arroyave with the support of Dr. M. Forman of USAID. The technology was developed over a 10-year period. Starting in 1974 Costa Rica, Guatemala, Honduras, and Panama legislated that all sugar must be fortified with vitamin A. With USAID support, the INCAP team was able to show conclusively that sugar fortification with vitamin A is both efficacious and cost-effective. USAID support, which has continued over the years, most recently through the OMNI project, has been important in ensuring that sugar fortification programs have continually improved in Central America countries. It has also stimulated the successful development of sugar fortification programs in other Latin American countries.

A sustainable sugar fortification program reflects the collaborative efforts between sugar producers, the public sector, researchers, and donors. The purpose of this document is to share the experiences of those involved in sugar fortification in Central America, so that other countries can plan and implement this important intervention to eliminate and prevent vitamin A deficiency.

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I. INTRODUCTION: WHY SHOULD VITAMIN A DEFICIENCY BE ELIMINATED?

In the last 10 to 15 years, awareness that vitamin A deficiency is a serious public health problem in many developing countries has increased. Epidemiological studies have clearly demonstrated the implications of vitamin A deficiency in the health of populations. Indeed, it is the main cause of childhood blindness and a contributing factor in infant and young child mortality. This is because vitamin A has a vital role in the physiology of vision, the integrity of epithelial cells, and adequate functioning of the body's defense system against infections.

Worldwide, it is estimated that more than 200 million children suffer from at least one of the manifestations of vitamin A deficiency; many of these children die as a consequence. One hundred and sixty countries recognized the severity of the problem by endorsing the International Conference on Nutrition's (ICN's) commitment to the prevention and control of this deficiency. A declaration by ICN includes as one of its goals eliminating vitamin A deficiency as a public health problem by the end of the century.

The geographical distribution of vitamin A deficiency is wide; it affects a large number of people in Asia, Africa, and Latin America. The underlying causes of deficiency are an inadequate intake of animal foods rich in retinol (preformed vitamin A) and of fruits and vegetables rich in carotenoids (precursors of retinol). In addition, there are precipitating factors such as a high incidence of infectious diseases, which increase the loss and physiological need for vitamin A, as well as intestinal parasites, and very low fat diets, which interfere with vitamin A absorption.

Given the above, it is understandable why the interest in developing strategies to correct and prevent vitamin A deficiency has grown. Many countries that have identified vitamin A deficiency as a problem are planning or have already implemented intervention programs. One such program is the fortification of sugar with vitamin A, which is the topic of this manual.

II. SELECTION OF THE INTERVENTIONS: WHEN AND HOW CAN VITAMIN A DEFICIENCY BE PREVENTED?

A. Characterization and diagnosis of vitamin A deficiency

In deciding on the most appropriate intervention or interventions to combat vitamin A deficiency, it is first necessary to document the characteristics of the deficiency at the national or subnational level. Mere evidence that the problem exists is not enough. Important information includes the following:

- The *extent* of the problem, that is, the number of people affected
- The *severity* of the deficiency, that is, the degree of the deficiency: marginal, moderate, or severe
- The *distribution* of the deficiency among different sectors of the population by ecological or administrative regions, age and sex groups, urban or rural habitat, and socioeconomic status

To obtain the above information, a population-based survey must be carried out with representative samples from the different population groups. This would include dietary studies that focus on the consumption of different food sources of vitamin A and ideally biochemical and clinical examinations of people. A standardized method should be used for data collection, as well as indicators established by recognized authorities such as the World Health Organization (WHO), the United Nations Food and Agriculture Organization (FAO), United Nations Children's Fund (UNICEF), and the International Vitamin A Consultant Group (IVACG). The indicators will be discussed later in this document.

B. Types of interventions

Vitamin A deficiency can be corrected and prevented by increasing the dietary intake of retinol and carotenoids and by reducing the underlying factors that prevent adequate absorption and utilization. The strategies for achieving the latter include controlling the pathological factors that favor deficiency. These actions, however, will succeed only if *the dietary provision of vitamin A* is sufficient to satisfy normal requirements.[1] Public health approaches that are aimed at improving the general health of populations and that impact on vitamin A absorption, such as the control of diarrheal diseases and deworming programs, go beyond the search for specific solutions to vitamin A deficiency and the scope of this manual.

1. The FAO/WHO requirements for vitamin A by age, sex, and physiological status are listed in appendix 1.1.

Interventions to increase the supply of vitamin A in populations whose diets are low in vitamin A include the following:

1. Dietary modification through long-term structural development

The permanent, logical solution to eliminating vitamin A deficiency should be through modifications in patterns of food production, consumption, and distribution. These can be done through the application of agricultural or horticultural, educational, and poverty alleviation strategies. Establishing such strategies and achieving positive results, however, requires a relatively long time frame, and programs are not always compatible with the scope and magnitude of vitamin A deficiency. For this reason, it is important that other interventions be applied to generate a positive impact in the short term. Of course, efforts to improve the consumption of vitamin A–rich foods must move in parallel to any short-term intervention.

2. Periodic distribution of high-dose vitamin A supplements

This intervention entails administering a high dose of preformed vitamin A, or retinol, to infants and preschool[2] children every 4 to 6 months, to women in high risk areas within 6 weeks after delivery, and to any lactating women within eight weeks after delivery. The dose recommended by WHO is 100,000 IU for infants between 6 and 12 months old and 200,000 IU for preschool children and postpartum mothers. The application of such a program has been justified in high risk areas as an *interim* solution.

This intervention is effective assuming that all the individuals requiring capsules do indeed receive the vitamin A. Its sustainability at a satisfactory level, however, is questionable for many reasons. One of the problems is the gradual loss of interest by the "target" population, because they must participate actively as direct recipients. It is also difficult to ensure a continuous and adequate supply of the capsules and to maintain an efficient distribution system at the community level. Another limitation is that, until recently, this strategy has been primarily directed to only one portion of the population: preschool children who are the highest-risk group. In countries in which the diet is poor in vitamin A, it is very possible that other subgroups are also deficient. For example, if pregnant and lactating women are deficient, newborns will have low stores of vitamin A in their livers. In addition, the mother's milk will have lower levels of vitamin A and, as a consequence, the infant will be disadvantaged from birth in terms of his or her vitamin A status. Finally, this intervention demands careful control of capsule administration to avoid recording mistakes. The latter could result in children receiving too many capsules that could cause signs of intolerance that, although reversible and temporary, could affect compliance.

2. In this manual, the term "preschool children" refers to children between 12 and 59 months of age.

3. Food fortification with vitamin A

This intervention entails adding vitamin A to one or more widely consumed foods. Its application is justified when widespread or blanket coverage is desired. This implies that vitamin A deficiency is extensive and not limited to specific groups or isolated communities; thus, evidence must exist that the magnitude of the deficiency is of public health significance. Blanket coverage increases the likelihood of reaching all the at-risk groups regardless of age, socioeconomic status, or geographic area. Coverage can include the whole country or a region. The advantages of food fortification are summarized below in box 1.1.

Box 1.1:
Advantages of Food Fortification

- Food fortification does not require people to change their eating habits; thus, the "target" population continues to eat the food chosen as a "vehicle," which, once fortified, becomes a good source of the vitamin.
- The added nutrient is provided in the diet in low but constant amounts, so there is little possibility of intakes becoming undesirably high.
- Compared with other interventions, fortification is the most cost-effective approach to preventing vitamin A deficiency.

C. When to consider food fortification with vitamin A an appropriate intervention

Based on experience in several countries, this manual puts forward guidelines to assist planners in deciding when fortification would be the most appropriate intervention. The decision, obviously, must be made by policymakers and program managers in each country.

National-level vitamin A fortification is indicated when at least two of the following three criteria are met:

- Twenty percent or more of preschool children have serum retinol levels below 20 μg/dL
- Twenty-five percent or more of lactating women have breast milk retinol levels below 30 μg/dL
- Twenty-five percent of preschool children consume less than 50 percent of their recommended daily allowance for vitamin A

D. Goal and objective of a vitamin A fortification program

The *goal* of vitamin A fortification is to eliminate vitamin A deficiency. The *objective* of food fortification with vitamin A is to increase the intake of this essential nutrient, thereby improving vitamin A status, in situations in which the normal diet does not provide sufficient amounts to satisfy daily requirements.

E. Issues to be considered in vitamin A food fortification

Establishing a food fortification program requires the existence of a technically developed food industry and a system of quality control and monitoring, which can guarantee that vitamin A is added correctly to the selected food(s) and does indeed improve the vitamin A status of the population.

The first step in a fortification program is selection of a food that can function as a "vehicle" for vitamin A. This selection is based on the criteria listed in box 1.2 below.

Box 1.2:
Criteria for Selecting a Vitamin A Food Fortification Vehicle

- The food vehicle must be consumed by a large proportion of the population, especially those at greatest risk of vitamin A deficiency.
- Little day-to-day and interindividual variation occurs in the amount of the food vehicle consumed. This will ensure that vitamin A intakes remain within a safe range.
- The food vehicle must go through central processing in which vitamin A can be added under controlled conditions and at a minimum cost.
- The marketing and distribution channels must be such that the delivery of the fortified food to consumers can be tracked.

The basic premise of a fortification program is that the food vehicle must be an integral component in the diet of the general population. In *developed countries,* the normal diet usually includes a great variety of foods that are often eaten and the possibility of identifying an appropriate vehicle is high. Some of the more common foods that can be fortified include margarine, milk, infant formulae, and processed breakfast cereals.

The situation in most *developing countries* is very different, especially among the lower socioeconomic groups. Their diets are often simple, with one or two predominant foods. In some Latin American countries, for example, up to 85 percent of energy intake is from white corn and beans, both of which lack vitamin A. In Asia the staple food is rice, while in Africa cereals such as sorghum and maize or roots and tubers are the major source of energy, but again, these foods lack vitamin A. In theory, these staple foods could be perceived as being appropriate vehicles due to their widespread use. They are, however, usually processed and cooked at home; thus, it is neither practical nor feasible to fortify these foods centrally under controlled conditions.

Technically, wheat flour fortification with vitamin A is feasible. Unfortunately, in many developing countries, especially those in which the staple food is maize, rice, sorghum, millet, roots, and tubers, consumption of wheat-based foods is concentrated in the upper and upper-middle socioeconomic groups, which are less vulnerable to vitamin A deficiency. In the case of rice, the basic food for millions of people around the world, the technology for vitamin A fortification has been developed. A major obstacle, however, is the fact that rice-producing countries have thousands of small-scale millers, which makes it difficult to distribute vitamin A and control the fortification process. Furthermore, the acceptability of fortified rice has not been clearly demonstrated.

In Indonesia, monosodium glutamate, a condiment, has been fortified with vitamin A, but problems exist with its stability in that it discolors the vehicle. Elsewhere, table salt has also been considered for fortification with vitamin A, but the salt consumed by the lower socioeconomic groups is often minimally refined, contains impurities, and absorbs water, (that is, it is hygroscopic), all of which make salt incompatible with the physicochemical properties of the vitamin A available for food fortification. Furthermore, per capita salt consumption is low, so a high concentration of vitamin A would be required. This would compromise both the sensory characteristics and price of salt.

In Central America, sugar was selected as the vehicle for vitamin A fortification because it is consumed in constant amounts and is centrally processed. The feasibility of sugar fortification has been proved in countries that have an organized sugar industry, for example, El Salvador, Guatemala, Honduras, and Bolivia.

Once the vehicle has been selected, the next challenge is to select the form of vitamin A that would be appropriate according to the criteria shown in box 1.3 on the following page.

Box 1.3:
Criteria for Selecting the Vitamin A Fortificant

The fortificant must have the following characteristics:

- Be miscible or dispersible in the food vehicle and not separate or segregate from it.
- Remain undetected by color, taste, odor, or other sensory characteristics once incorporated into the food at the proposed concentration.
- Not interact chemically with the food in such a way that could result in the formation of undesirable by-products or damage the original food.
- Be sufficiently stable in the food at all times to ensure that its vitamin A activity and bioavailability will be maintained during the life span or shelf life of the fortified food.
- Not significantly increase the cost of the fortified food to the consumer.

In establishing a sugar fortification program, five components need to be considered. These include assembling and operating the program, quality control and monitoring, evaluation, cost analysis, and reporting. Each of these areas is discussed in detail in the following chapters.

III. ASSEMBLY AND OPERATIONS: WHAT IS NEEDED TO FORTIFY SUGAR?

A. White sugar as a fortification vehicle

The general principles described for food fortification can be directly applied to sugar fortification, because sugar often satisfies the criteria set out in box 1.2 for the selection of an appropriate food vehicle. Nevertheless, it is essential that all the criteria listed are confirmed. In other words, data on white sugar intake by different socioeconomic and age groups as well as sex and pregnancy/lactation status are needed to ensure that fortified white sugar will reach the high-risk groups. It cannot be assumed that sugar fortification will have a positive impact on all communities that have high levels of vitamin A deficiency. Some communities may eat brown sugar, honey, or some other form of sugar, whereas others may not eat white sugar in sufficient quantities to make the intervention effective.[3]

At the other extreme will be a group of people in the higher socioeconomic strata that most likely consume sufficient vitamin A in their normal diet. For this group, fortification is unnecessary, but it would be more costly and complex to exclude them than applying the program "universally." When establishing the fortification level, care should be taken to ensure that the total retinol intake of all groups does not reach the upper limit of safety. It should be noted, however, that the risk of excessively high retinol intakes does not come from fortification but from the improper use of vitamin supplements, especially during pregnancy.

An important factor that can affect the amount of fortified sugar consumed is the potential infiltration of nonfortified sugar from neighboring countries, whether through imports of nonfortified sugar or cross-border smuggling. Rigorous control of the latter is a legal problem, which must be constantly monitored.

B. The fortificant: retinyl palmitate beadlets

Due to the dry, crystalline nature of sugar, a form of vitamin A that satisfies all the criteria for a fortificant mentioned in box 1.3 is needed.

The advent of industrially produced vitamin A compounds that are water-miscible, dry, solid compounds has greatly facilitated the development of fortification technology. At present, the prototype is 250-CWS (cold water soluble), which owes its name to the 250,000 IU of retinol

3. In this situation, it may be necessary to design and apply a small complementary intervention targeted specifically at these minority groups. For instance, high-dose vitamin A capsules could be distributed every 4 to 6 months or specially fortified foods, such as biscuits, could be produced and provided to these groups.

in each gram and its ability to dissolve in cold water. The retinol is inside a gelatin matrix, which also has antioxidizing agents that extend the life span of the vitamin A. Despite its excellent stability, 250-CWS is still sensitive to high humidity and temperatures, particularly when exposed to air; thus, appropriate handling and storage conditions, described in part 2, are important considerations when developing a program.

A light yellow powder, 250-CWS has a slight smell and taste that cannot be detected in fortified sugar at the concentrations used. Two products are commercially available at present: one from Hoffman-La Roche[4] in Switzerland and the other from BASF[5] in Germany. Technical directors of programs, however, must be constantly on the look out for a new and improved fortificant, which is also competitive in price.

In general, retinyl palmitate compounds that meet the requirements for sugar fortification are manufactured using sophisticated processes; therefore, they cannot be produced locally in countries in which fortification is necessary and must be imported. The cost of procuring and importing the appropriate retinyl palmitate accounts for the largest portion of the total cost of fortification (about 85 percent). For this reason, program managers must take into account the economic implications of maintaining an adequate supply. Governments can help keep costs down by mandating the actions necessary to facilitate acquisition of the fortificant, for example, providing import licenses and tax exemptions, given that the product has social benefits rather than purely commercial ones.

C. Fortification level

Deciding on the concentration of fortificant to add to sugar is critical and should be based on the expert opinions of professional epidemiologists and nutritionists. The underlying objective is to have effective fortification that is safe. The information required to determine the level of vitamin A to add to sugar includes:

- *The basal daily vitamin A requirement* of the highest risk target group, which comprises children between 1 and 5 years of age. The level recommended by FAO/WHO (1988) is 200 RE[6] or 650 IU retinol per day (see appendix 1.1).

4. CH-4002, Basel, Switzerland Tel: 061-688-1111. Fax: 061-691-9600.
5. 6700 Ludwigfhafen-Rhein, Ludwigfhafen, Germany. Tel: 049-621-600. Fax: 049-621-604/049-622-525
6. A retinol equivalent (RE) = 1 µg of retinol or 3.33 IU of vitamin A

- *The maximum safe intake* of supplementary preformed retinol, indicated by WHO/UNICEF (1994) and IVACG (1988), is 3,000 RE or 10,000 IU per day for pregnant women. Significantly higher intakes shortly before or during pregnancy are definitely not recommended. The maximum intake refers to supplementary retinol and not to total dietary vitamin A, which includes provitamin A carotenoids[7] that are not toxic to humans.

- *Sugar consumption in grams per person per day for the most vulnerable group.* This is usually preschool children from the lowest socioeconomic stratum or income quartile. The value for the lowest quartile of sugar intake of children in the lowest socioeconomic group can be used to determine the minimum level of vitamin A to add to sugar.

- *Maximum sugar consumption in grams per person per day,* which is generally the intake of adults in the highest socioeconomic stratum or income quartile. The mean value for the highest quartile of sugar intake of adults in the highest income quartile can be used to determine the maximum safe level of vitamin A to add to sugar.

Using the above information, the next step is to establish the level of fortification that the program should reach. The public health sector should, with proper counseling, determine the proper level. For example, the ministry of health may decide that, "The highest risk group should receive sufficient vitamin A from fortified sugar to satisfy their basal needs," but this may vary according to scientific opinions and political decisions in each country.

The basal needs are the amounts required to prevent clinical signs and symptoms of deficiency. These amounts, however, are not enough to create liver reserves of vitamin A. It is expected that when vitamin A from sugar is added to that from the normal diet, the total amount should reach or nearly reach the daily intake recommended by FAO/WHO (see appendix 1.1) even among the vulnerable groups. This recommended intake will ensure accumulation of adequate vitamin reserves in the body.

Using the above criteria, the following exercise shows the steps needed to establish the desired level of retinol per gram of sugar.

7. Carotenoids represent about two-thirds of the total dietary vitamin A intake available naturally in foods.

1. Exercise

Estimate the fortification level that ensures that vitamin A needs are met for the group at the highest risk of deficiency and that, at the same time, will not result in excessive intakes for individuals having a high sugar intake.

2. Data

x = Sugar consumption of preschool children in the lowest income quartile, for example, 20 g/day

y = Sugar consumption of adults in the highest income quartile, for example, 150 g/day

3. Calculations

a. The most vulnerable group, that is, preschool children from the lowest socioeconomic stratum:

For 20 g of sugar to provide the basal retinol needs (200 µg/day), the concentration must be:

$$200/20 = 10 \text{ µg/g of sugar}$$

b. The group with high sugar consumption:

For 150 g not to provide more than 3,000 µg of retinol per day, the maximum concentration must be:

$$3{,}000/150 = 20 \text{ µg/g of sugar}$$

c. The decision might be to select, for example, the midpoint between 10 µg/g and 20 µg/g, that is, 15 µg/g. This level will allow also for losses of vitamin A incurred during the normal shelf life of sugar. It will also reduce the likelihood that the sugar will not have the amount of retinol necessary to meet the established nutritional goals.

d. Rationalization of sufficiency (minimum) and safe (maximum) levels of retinol.

The 15 μg/g level of retinol in sugar will more than satisfy the basal needs of preschool children from the lowest socioeconomic group and, at the same time, remain below the maximum acceptable limit for the group with highest sugar intakes. Therefore:

20 g x 15 μg = 300 μg/day of retinol from sugar (minimum)

150 g x 15 μg = 2,250 μg/day of retinol from sugar (maximum)

The safety margin, thus, is 750 μg (that is, 3,000 μg/day - 2,250 μg/day) of retinol per day, which can come from natural sources of retinol in the diet.

On the other hand, if the loss of retinol in the fortified sugar during its distribution and storage over a 1-year period (time between harvests) is accounted for, estimates of the minimum and maximum intakes will be proportionally lower but still sufficient and safe. For example, if chemical analyses show that over the year the annual mean concentration of retinol in sugar is 10 μg/g instead of the original 15 μg/g, a recalculation of the minimum and maximum intakes shows that:

20 g x 10 μg = 200 μg/day of retinol from sugar (minimum)

150 g x 10 μg = 1,500 μg/day of retinol from sugar (maximum)

Thus, after correcting for degradation, the minimum intake will not be less than 200 μg/day, which is the basal need of the most vulnerable group, and the maximum intake will provide an even greater safety margin of 1,500 μg below the maximum recommended intake of 3,000 μg/day.

D. Technology and inputs

The technology developed for vitamin A sugar fortification includes the following two processes:

- Preparation of a premix
- Addition of the premix to sugar at the refinery

Fortification of sugar requires very little modification of the usual sugar production process. A premix plant, which makes sugar containing a high retinol content, can be installed at only one or a few sugar refineries in the country and the premix distributed to all sugar mills, where it is added to sugar as it comes off the production line. The manufacturing of both premix and fortified sugar are described in detail in part 2 of this manual.

There are two reasons to prepare the premix *(a)* to ensure that there is no segregation of the retinyl palmitate beadlets from sugar crystals because the premix contains vegetable oil that acts as an adhesive and *(b)* to dilute the retinyl palmitate, which contains 250,000 IU or 75,000 µg retinol/g. This dilution is necessary to facilitate the addition of retinyl palmitate to sugar, because the production of a homogeneous fortified product would be more difficult if the undiluted retinyl palmitate beadlets were added to a large quantity of sugar. Based on the experience of preparing premix, it is recommended that it be diluted four to five times, which means that the resulting concentration of the premix can vary between 15.0 mg/g and 18.8 mg/g (50,000 IU/g to 62,500 IU/g).

To avoid oxidation of the vegetable oil and, thus, rancidity, an antioxidant acceptable for human consumption is added under an inert atmosphere generally created by nitrogen bubbling.

Although the preparation of the premix is a simple operation, it requires strict adherence to regulations to guarantee its quality. This includes mixing all the ingredients (sugar, retinyl palmitate, oil, and antioxidant) and immediate packaging in bags of an appropriate material (usually a polyethylene bag inside a polypropylene bag) to reduce retinol losses resulting from exposure to air and light during storage. The norms must stipulate storage conditions that avoid high temperatures and humidity, both in the production plant and in the refinery warehouses. The warehouse should be well ventilated, dry, and at low or moderate temperatures.

It is advisable that preparation of the premix be synchronized with production of fortified sugar so that the premix is used soon after it is manufactured, thus, reducing storage time.

Premix is added to sugar at the refinery; it is absolutely essential to follow correctly the procedures for adding the premix to sugar. This will ensure homogeneity and uniformity in the distribution of retinol in sugar.

Once produced, the fortified sugar should be packaged according to the recommendations in part 2 of this manual. The packaged fortified sugar is ready for distribution, sale, and consumption. As will be shown below, the entire production process should be subject to a rigorous quality control and monitoring system.

E. Steps to be followed in a fortification program

In most sugar-producing countries, particularly in tropical and subtropical areas where sugar cane is the raw material, production is seasonal and may last for about 6 months during the dry season. This has important implications for planning the different stages in the fortification process, which include the following:

1. Procuring the materials needed for the vitamin A premix

Sugar is obtained locally, but program managers should ensure that sufficient amounts of unfortified sugar from the previous harvest are kept to begin manufacturing the premix on time. Vegetable oil that meets the quality specifications, which means it must be free from peroxides and have a low tendency to go rancid, may or may not be available locally. Such oils include peanut oil, which is the prototype, but palm oil and corn oil are also appropriate. The imported components, which include retinyl palmitate, antioxidants, and possibly vegetable oil, must be ordered early. In most cases, this would be 6 months before the sugar harvest begins.

2. Preparing the premix

Preparation of the premix should start about a month before sugar harvest starts. As mentioned before, the premix should be packaged in bags made of appropriate materials to protect the product against loss of vitamin A activity. The premix bags must be clearly labeled before being dispatched to the sugar mills. Labeling requirements should be mandated by law or through appropriate regulations.

3. Adding the premix to white sugar

The premix should be added to the sugar according to approved procedures. Appropriately fortified sugar is packaged in suitable sacks (for example, polypropylene) for distribution and retail sale. The labels for these sacks, as with the premix, should be determined by law or a corresponding set of regulations.

4. Quality control

The fortification process will be complete once the correct retinol levels in the sugar are verified. Specific forms should be developed and available to register laboratory results. When deviations from the norms are observed, corrective actions should be documented.

F. Pilot studies

Sugar fortification with vitamin A has been carried out at the national level in several countries, and its technological and operational feasibility is well established. Nevertheless, directors of new programs are advised to carry out a pilot study before implementing a national-level program. The objective of such a study would be to ensure that all the system components are operating properly. This means that both the premix and fortified sugar are produced with the correct level of retinol and adequately fortified sugar reaches consumers.

Fortified sugar has been tested to confirm its chemical and physical stability under various environmental and handling conditions.[8] The acceptance of fortified sugar by consumers has also been demonstrated; however, because the acceptability of foods differs between cultures, program managers may want to confirm that any sensory changes in fortified sugar are acceptable to eliminate any doubts.

G. Program development process

1. Preparing a plan

Prior to implementing the sugar fortification program, a plan that clearly describes its purpose, characteristics, and components should be prepared. The public sector is usually responsible for this through an intersectoral commission, often led by the *health sector*. Alternatively, another entity may be given official responsibility for this, depending on the political and administrative structure of the country. Irrespective of who is responsible, preparing the plan requires the active participation of other government sectors, such as economics, finance, commerce, trade, customs and excise, agriculture, and education, and also the private sector, notably the sugar producers. If possible, universities and research institutes as well as consumer organizations should also be included. It is also advisable to seek support from international agencies, such as WHO, UNICEF, FAO, and bilateral donors, as well as financial institutions, that is, the World Bank and Inter-American Development Bank (IDB), to ensure support for the program.

8. Part 2, section I D., refers to studies on the stability of retinol in sugar that have been carried out.

The basic structure of the fortification plan can be effectively presented following the guidelines suggested in box 1.4 but adjusted appropriately to specific country situations.

Box 1.4:
Content of a Fortification Plan

- *Program background,* including a description of the problem the intervention intends to solve. It should also include the government's *official declaration* of support and commitment to establishing the program, because this will ensure the availability of technical, material, and financial resources.
- *Proposed and/or modified legislation and regulations* that will facilitate program implementation.
- *Goals and objectives* with a clearly defined "target" population.
- *Characteristics and components of the program,* including development of activities and necessary resources (human, material, financial, and technical assistance).
- *Quality control, inspection, and monitoring systems.*
- *Evaluation plan.*
- *Reports* to be produced and the dates they are due.

2. Generating the political commitment

The *health sector* is responsible for identifying that vitamin A deficiency exists as well as its repercussions on vision, physical development, morbidity, and mortality. As a consequence, this sector should emphasize to the government, private sector, and consumers the need to control and prevent this deficiency. Professional health organizations, medical and pediatric associations, universities, and international organizations (WHO, FAO, and UNICEF) can also play an important role in promoting and supporting the campaign.

During the promotion phase, it is very important that the mass media (newspapers, radio, and television) be well informed about the objectives of the fortification program and their role in establishing a successful intervention. Through their messages, the media can generate and maintain a high level of awareness and acceptance among the general public and the other sectors involved.

3. Involving the sugar producers and private sector

The establishment, implementation, and sustainability of a vitamin A sugar fortification program requires the active participation of the sugar sector; thus, this sector must be aware of and committed to the benefits for the population that the program implies. Sugar manufacturers must also be aware of and understand the social and humanitarian implications of their unreserved cooperation, which is critical to achieving the program's objectives. Without the commitment of the sugar manufacturing sector, the intervention will not be efficacious.

Preparation of the premix, its addition to sugar, packaging, and wholesale commercial distribution will be managed by the sugar refineries. It is recommended that they form an official association to represent themselves in discussions with the government.

The government must dictate the regulations for quality control of fortified sugar, but sugar manufacturers are responsible for their application.

4. Consumer participation

The general population must be informed of the importance of vitamin A for good health and nutrition and the risks associated with deficiency. Consumers will, thus, know that they have the right to demand vitamin A–fortified sugar. Fortified sugar should be clearly labeled to show that it is fortified, following national labeling regulations. Countries in which consumer organizations exist should include in their program the promotion of fortified sugar and monitor compliance using established norms. It is important that the information presented to the public does not imply that consumption of sugar should be increased to control or eliminate vitamin A deficiency.

5. Legislation

The strongest expression of *political commitment* is legislative action to make the program official. Such legislation will define the basic norms for implementing fortification, including the responsibilities of each sector involved. At the same time, the legal consequences of failing to comply with the norms must be established. The law must be complemented by specific regulations that describe in detail the guidelines for correct implementation of activities.

The commitment of the different sectors, especially the sugar industry, however, is potentially more important and more decisive in terms of program success than the imposition of laws. It is advisable, therefore, that the different sectors that will be affected by the law and its specific regulations be involved in the process of developing fortification legislation; thus, it is important that the legal instruments not overemphasize restrictive and punitive aspects but rather provide a clear definition of program objectives, basic activities, and the role of each of the sectors involved. This will promote cooperation between the sugar sector and the different government

bodies. If the different sectors involved are not willing to make a political commitment to controlling and preventing vitamin A deficiency through fortification, debating the importance of legislation will become an academic exercise.

The legislation must clearly state that it is not appropriate to promote high consumption of the food vehicle (sugar in this case) by ascribing healing properties to the fortified food. The fortification program must be seen to have nutritional rather than medicinal or commercial objectives.

As an example, appendix 1.2 contains the Guatemalan "Food Enrichment Law" and "Regulation for Vitamin A Sugar Fortification." In Guatemala, a general law was passed to support and regulate the fortification of foods as a public health measure to prevent nutritional deficiencies. The technical details of fortification are included in individual regulations for specific food vehicles or nutrients. The Guatemalan government chose this strategy because the promulgation and modification of regulations only requires approval by the Executive Office, whereas laws need to be passed and approved by the legislature, which would make adjustments and modifications very slow and difficult. A general law for food fortification should include the items listed in box 1.5.

Box 1.5:
Components of a General Law for Food Fortification

- Consideration of the health implications resulting from the addition of nutrients to selected, widely consumed foods
- Formation of a National Committee for Food Fortification (see next section)
- Identification of the entities responsible for production, quality control, and monitoring of fortification programs
- Consideration of the financial and tax exemption agreements relevant to the importation of materials and equipment necessary for fortification
- Description of the sanctions to be applied to guarantee adequate program operation

The regulations for vitamin A sugar fortification must specify the type of vitamin A (retinol) fortificant, the level of fortification, and the permitted range for retinol content of fortified sugar both at the refinery and at the point of sale. The regulations must define the precautions and food-safety conditions to be observed during production, transportation, storage,

and sale of sugar. They must also specify the information to be included on the labels for both the premix and fortified sugar and stipulate that misleading advertising ascribing healing properties to the consumption of vitamin A–fortified sugar is not permitted. The regulation must also indicate the procedures to be followed for the release of imported sugar for sale in the country.

6. National Food Fortification Committee

In implementing a fortification program, collaborative participation of various government sectors, food producers, private organizations, and international agencies is needed. The official creation of a specific committee with representatives from the different sectors involved is recommended. When consumer organizations exist, they should also be represented. This "National Food Fortification Committee" should be under the "National Food And Nutrition Committee" or its equivalent. In countries in which a "Committee for the Control and Prevention of Micronutrient Deficiencies" exists, the link between the National Food Fortification Committee and the National Food and Nutrition Committee should be through the Committee for the Control and Prevention of Micronutrient Deficiencies.

The National Food Fortification Committee could be organized and directed by the ministry of health or another entity officially responsible for food and nutrition within the political and administrative structure of each country. Its functions would include the items listed in box 1.6 on the following page.

Box 1.6:
Role of the National Food Fortification Committee

- Monitors program implementation and analyzes the information coming from the different operating units, that is, production, quality control, inspection, and monitoring. The committee and any subcommittees should ensure that operating units comply with their responsibilities.
- Directs problems that might arise to the relevant institutions to ensure their prompt solution.
- Updates regulations, such as the level of vitamin A in sugar or the characteristics required for the fortificant, depending on the prevailing situation.
- Coordinates the activities of the various sectors and the operating units involved.
- Works as a "pressure front" at the political and administrative decision-making levels.

7. Legal framework

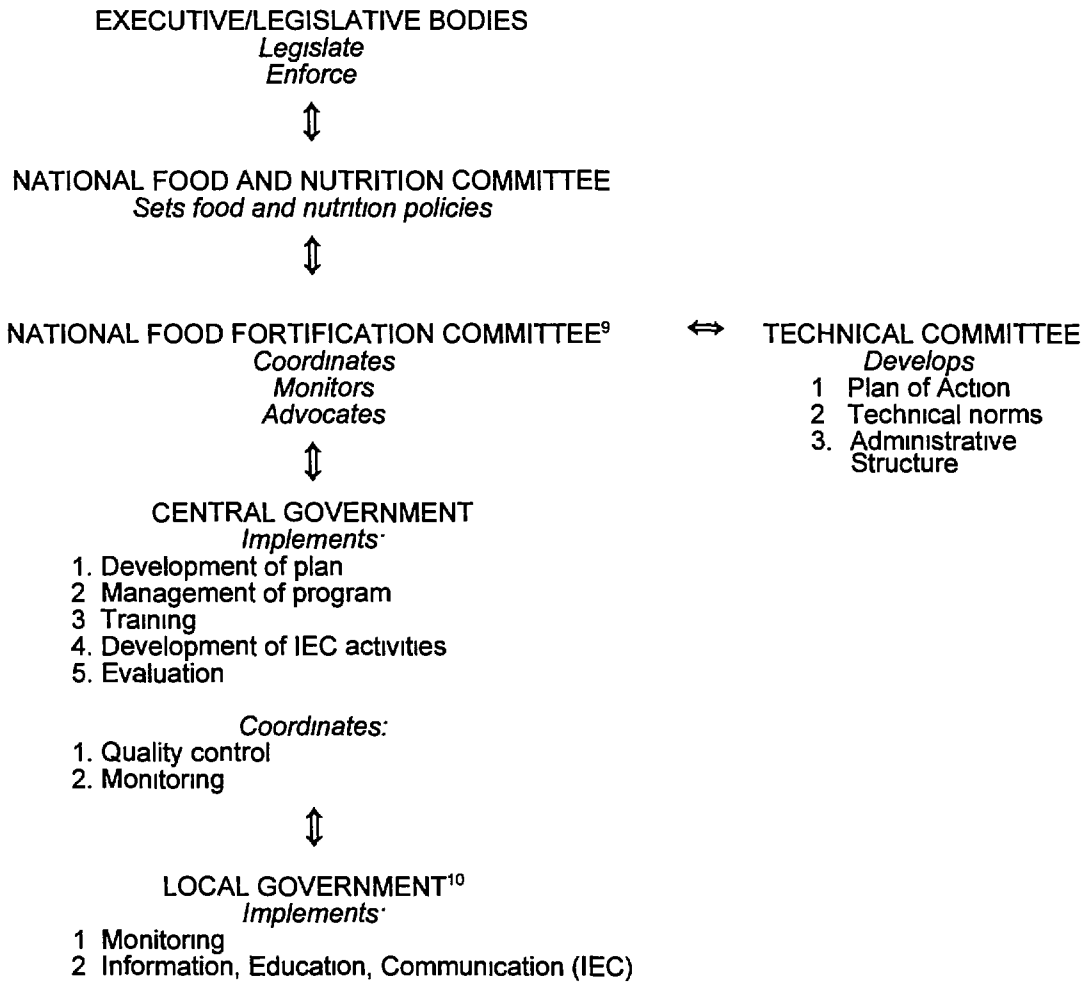
The vitamin A sugar fortification program should be embedded institutionally within a legal framework that defines the authority and responsibilities of the agencies and other entities involved. The details of this framework must be determined by each country and a general model is proposed in figure 1.1 on the next page.

The legislation for food fortification should have identified the organization(s) responsible for coordinating and monitoring sugar fortification activities, for example, the National Food Fortification Committee. The latter also has an important role in advocating for sugar fortification to ensure that sufficient resources are available for the program.

The National Food Fortification Committee can be advised by a technical committee, whose role includes developing the plan of action, the technical norms, and the administrative structure of the program.

Actual program implementation is the responsibility of the government. At the central level, the government will *implement* a number of activities, including development of the sugar fortification plan; management of the program; training of personnel; development and implementation of information, education, and communication activities (IEC); and conducting the evaluations. In addition, it will *coordinate* quality control and monitoring activities.

Figure 1.1:
Legal Framework for Sugar Fortification Program



9 Includes representatives from the ministries of health, agriculture, education, economy, finance, commerce, and customs; universities; research institutions; consumer associations; and the sugar industry.

10 Local representatives from the food control department and customs, as well as the ministries of health, agriculture, and education.

Subnational or local government will be responsible for implementing inspection, monitoring, and IEC activities and report directly to the central level, who in turn will report to the National Food Fortification Committee. The feedback received by the National Food Fortification Committee will be provided to the National Food and Nutrition Committee, through the Committee for the Control and Prevention of Micronutrient Deficiencies, when it exists. The National Food and Nutrition Committee should only have to interact with the executive/ legislative body when regulations need to be modified or enforced.

IV. HOW IS THE EFFICIENCY OF SUGAR FORTIFICATION WITH VITAMIN A DETERMINED?

Establishing a fortification program would be incomplete if the efficiency of the intervention is not determined. This section describes the activities needed to ensure that fortified sugar in the market contains sufficient vitamin A to get the expected increase in vitamin A intake. The efficiency of fortification is determined through quality control and monitoring *Quality control* refers to the procedures needed to guarantee that the premix and fortified sugar meet the stipulated norms at the site of production. *Monitoring* is the process of determining the adequacy of fortification in sugar at the retail and household level and includes inspection activities at refineries and retail outlets.

A. Quality control

Sugar producers must understand that their participation in the fortification program is not limited only to the addition of vitamin A to their product. They are also required to introduce the determination of retinol levels as part of their routine quality control practices; therefore, they need to incorporate this component into their sugar sampling, analytical laboratory methods, registration forms, and reports. The purpose of quality control is to facilitate immediate corrective actions during the manufacturing of both the premix and fortified sugar.

1. Premix

A vitamin A content of a premix different than the level expected could be due to:

- Using a vitamin A fortificant that does not contain the specified amount of retinol.
- Using the wrong proportion of ingredients in the premix being manufactured.
- Insufficient mixing time.

The quality of premix, which reflects the manufacturing process, is determined both visually and through chemical analysis. Details of the analytical procedures can be found in part 3 of the manual.

The vitamin A content of the premix should be such that it takes into account the extent to which it is diluted when added to the sugar at the refinery. In addition, vitamin A should be added to compensate for the losses incurred during storage of the premix and production of fortified sugar. The extent of these losses is determined by comparing the actual level of retinol in fortified sugar with the theoretical level it should have at the time of production, based on the retinol content of the premix and taking into account the dilution of the premix when added to sugar. In Central America, this has been estimated to be around 10 percent. For example, if the norm stipulates that fortified sugar should contain 15 µg retinol/g sugar, which is prepared by diluting the premix one thousand times, the vitamin A level in the premix should be 16.5 mg/g.

Ninety percent of the premix samples analyzed must show a retinol content within a range of 10 percent on either side of the stipulated mean. Using the above example, the acceptable range would be 14.9 mg/g to 18.1 mg/g.

2. Fortified sugar

Fortified sugar is made by adding the vitamin A premix to sugar, either in the centrifuge at the end of centrifugation, over the conveyor belts that lead to the drying turbines, or after drying when the sugar is moving down the packing chutes. This operation requires a reliable mechanism to ensure that homogeneity of the vitamin A content in sugar is maintained; thus, adding premix to sugar should be carefully supervised by a trained worker to ensure that the system is operating properly.

The following activities are important in quality control of fortified sugar:

- Calculations of the ratio of the amount of fortified sugar produced to the amount of premix used during each shift or every 24 hours. For example, if the premix has a retinol concentration of 15 mg/g and the sugar must have 15 µg/g retinol, then a 25 kg bag of premix is needed to fortify 500 50-kg sacks of sugar.

- Chemical analysis to determine the level of retinol in sugar samples at the end of the processing line just before packaging. There are several analytical methods to choose from, both semiquantitative and quantitative. These are described in part 3 of the manual. It is important to have timely results to correct immediately any failures in the process. The sampling frequency depends on the rate of sugar production at each sugar refinery. It is suggested that this be done at the same time that samples are routinely taken to the refinery laboratory for impurity and color tests, which is approximately every 1 to 2 hours.

The *mean* vitamin A level in fortified sugar must be that level stipulated in the norms, for example, 15 µg/g of sugar. The level of retinol in *individual* samples must fall within the stipulated norms. The extent of the variability or range for the norm is determined by the variation in the retinol content of fortified sugar at the refinery. This should be determined by pilot studies and is closely related to the technical efficiency of the system in a particular country. For example, if the accepted variation is 30 percent, the vitamin A content in the individually analyzed samples should be between 10.5 µg/g and 19.5 µg/g of sugar.

B. Monitoring fortified sugar

The government, through the food control authorities, must guarantee that the public receives fortified sugar with sufficient vitamin A to produce the expected increase in vitamin A intake. To comply with this function, the government food control entities must supervise the production, transportation, and marketing of fortified sugar. They must also report to a specific body such as the National Food Fortification Committee on a regular basis, for example, every 6 months.

1. Premix and fortified sugar production

Food inspectors must visit the premix production plants and each of the sugar refineries regularly, for example, every two weeks. Inspection guidelines and registration forms must be developed to expedite the inspections. The visits must be long enough, for example, 2 to 4 hours, to allow for detailed observations of all the production activities. These visits must take place in accordance with a schedule that is sufficiently flexible to take into account the need to assist the premix plant or refinery in improving its quality control system and verifying the efficiency of their process. These inspections will also enable the inspectors to review the laboratory results, collect sugar samples to be sent to a central reference laboratory, and discuss any obstacles or difficulties in the production process.

2. Imported sugar

In some countries local sugar production may be insufficient to satisfy demand, making sugar importation necessary. When vitamin A–fortified sugar is imported, its retinol content must meet the same requirements as locally produced sugar. To this end, customs authorities should collaborate with food control inspectors to prevent any imported vitamin A–fortified sugar being released until its compliance with the norms is verified. A proper sampling plan should be in place to determine the retinol content of all imported sugar that is fortified. This will depend on factors such as the amount of sugar being imported and the source of the sugar. When countries import nonfortified sugar, the government must ensure that this sugar is fortified before it goes into the market.

For groups of countries that share a specific geopolitical area, it is recommended that specific regional marketing agreements be promoted that govern the exchange of fortified foods, including sugar. This will enable authorities to control smuggling across borders. Many countries already have regional legislation regarding other aspects of common concern.

3. During transportation and retail marketing

Inspection activities also include examining the quality of the fortified sugar that is being transported and marketed. The local food control authorities play an important role in this and should be trained and instructed by central level staff. The fortification program must include a system for regular and random sampling of sugar. It is recommended that retinol analysis be carried out at the inspection site using the portable semiquantitative method[11] and the results sent monthly to the central level. Acceptable vitamin A levels in the sugar at different inspection sites should take into account the possible decrease in vitamin A levels during storage and transportation. This level should be determined from data obtained from pilot testing of the retinol content of fortified sugar once it is in the market.

C. Monitoring at the household level

One of the purposes of monitoring is to confirm that the sugar reaching households has sufficient vitamin A. This can be done using semiquantitative or quantitative methods on samples taken from households. The sampling procedure must be representative of the population. Where the semiquantitative method is used, the testing can be done at the local level, for example, in a health center or school, where more appropriate facilities are available to do the test safely and efficiently. Monitoring operations can be simplified if local sectors such as schools, health centers, or community organizations are involved. Irrespective of which local sectors are involved, they must be officially recognized by the body responsible for overseeing the program and their participation and responsibilities must be formally defined. Some countries carry out periodic household surveys to measure socioeconomic status. This infrastructure could be used to facilitate the collection of sugar samples.

11. This is described in part 3 of the manual.

D. Resources required for sugar fortification program

The basic information required to determine the amount of resources needed for a sugar fortification program is listed in box 1.7.

Box 1.7: Information to Determine Resource Requirements for a Sugar Fortification Program

- Number and location of sugar refineries and volume of sugar produced at each refinery
- Quantity of imported vitamin A fortificant needed to fortify the sugar produced for direct consumption over a 1-year period
- Quantities of other ingredients, for example, antioxidant and vegetable oil, used annually in the preparation of the premix
- Type and number of workers trained to carry out the fortification process
- Type and number of field and laboratory technicians trained to take and analyze the premix and fortified sugar samples
- Type and number of workers trained in the supervision and control of all stages of the fortification process and data registration

V. HOW IS THE IMPACT OF SUGAR FORTIFICATION WITH VITAMIN A EVALUATED?

Evaluation is an essential and integral component of the fortification program. A clear definition of the program's objectives is the basis for designing and implementing an evaluation. In this case, the objective is to increase vitamin A intake, thereby improving the vitamin A status of the population when the normal diet does not provide sufficient amounts to satisfy the recommended daily allowance.

In this manual, *evaluation* refers to assessing the biological impact or efficacy of the fortification program. It entails determining and interpreting the changes in vitamin A intake (an intermediate effect) and vitamin A status (a biological effect). This section describes the steps to be followed in carrying out the evaluation.

A. Design and frequency of the impact evaluation

Given that vitamin A sugar fortification is usually planned as a universal program, it is not possible to use an experimental design that includes a *control group* that does not receive fortified sugar versus an *experimental group* that does receive fortified sugar. For this reason, the design must compare indicators *before* and *after* fortification is implemented. This entails carrying out a baseline survey prior to the start of fortification and at least one more survey after the intervention has been in place for some time. Experience indicates that 1 or 2 years postimplementation would be appropriate for the latter.

The data to be collected in the evaluation include both household- and individual-level dietary data as well as an individual-level biochemical variable or variables. The same representative sampling frames and survey methods must be used at both times, with the most vulnerable groups being adequately represented in the sample. It is very important that the postintervention survey or surveys be done at the same time of year as the baseline survey. This will minimize seasonal effects on the availability of dietary sources of vitamin A, which could complicate the interpretation of results.

The evaluation surveys must be programmed according to a predetermined schedule. Once the data from the baseline survey are available and fortification has begun, postintervention evaluation surveys are done to determine trends in the intermediate indicator as well as the biological indicator or indicators. Based on experience, the following periodicity is suggested:

1. Initial evaluation

The first *postintervention dietary consumption survey* should be done 6 to 12 months after confirmation that the production of fortified sugar is operating efficiently. This survey will provide information on an early increase in vitamin A intake through consumption of fortified

sugar. The first *postintervention biochemical survey* should be done 6 to 12 months after the consumption survey.

2. Subsequent evaluations

a. *Vitamin A consumption* surveys should be repeated at 1- or 2-year intervals. These subsequent surveys can be done using a less extensive sample than in the baseline survey to increase operational and economic feasibility, especially if resources are limited. Their purpose is to confirm that the program is operating well and that no important changes in the diet or sugar intake have occurred that would require an adjustment in the fortification level.

b. *Biochemical* surveys will confirm the nutritional impact of the intervention. These are generally more complex and costly and, therefore, should be repeated every 5 years. As with dietary surveys, the sample can be smaller, as long as it is statistically representative of the target population.

B. Evaluation of the intermediate effect

The *intermediate effect* is the change in vitamin A intake resulting from the fortification program, which will result in a biological improvement in vitamin A status. The basic elements for this evaluation are presented below in box 1.8.

Box 1.8:
Data Required to Determine the Intermediate Effect of a Sugar Fortification Program

The following data are needed from a representative sample of the target population, including the groups at highest risk of vitamin A deficiency:

Baseline: (a) Sugar consumption (these data are necessary to monitor any changes in sugar consumption patterns after fortification is initiated) and *(b)* vitamin A consumption from natural food sources.

Postimplementation: (a) The vitamin A intake from sugar (these data are calculated from the quantity of fortified sugar consumed and the mean concentration of vitamin A per gram of fortified sugar as determined by chemical analysis) and *(b)* the vitamin A intake from natural food sources.

The purpose of the program is to ensure that after 12 months of program implementation no more than 15 percent of the population has total vitamin A intakes below 100 percent of their recommended daily allowance and no more than 5 percent have intakes below 75 percent of their recommended daily allowance. The *primary indicator* is vitamin A intake from fortified sugar, and the *criterion* is the increment in the intake of vitamin A as a result of the consumption of sugar.

The information needed to determine the intermediate effect should be obtained using research methods that accurately reflect real vitamin intake and not general tendencies or consumption patterns. Weighed and measured food intakes or even the 24-hour dietary recall, when carefully done, have proved satisfactory.

C. Evaluation of the biological effect

The *biological effect* is the impact of the intervention as defined in the goals and objectives of the program, that is, adequate vitamin A status among the population.

The *primary indicator* is a biochemical parameter for vitamin A status. Either the serum or plasma level of retinol is recommended due to their objectivity and sensitivity. A very useful *complementary indicator* is the concentration of retinol in human milk. The *criterion* is the reduction in the prevalence of low blood and/or breast milk retinol levels as a result of consuming fortified sugar. The recommended methods for analyzing retinol in biological samples are described in detail in part 3 of the manual.

The WHO/UNICEF (1994) cutoff points to define vitamin A deficiency and critical prevalence levels based on serum and human milk are shown in table 1.1.

Table 1.1: Biochemical Indicators of Vitamin A Deficiency (VAD)

Sample	Retinol Level	Critical Prevalence (%)	
	µg/dL (µmol/L)	*Mild VAD*	*Severe VAD*
Serum or plasma	<20 (<0.70)	10–19.9	≥20
Human milk	<30 (<1.05)	10–24.9	≥25

In addition to presenting results as the proportion of the sample having retinol levels below or within the range noted in table 1.1, it is recommended that the results be presented graphically as a frequency distribution or tabulated using 10 µg/dL (0.35 µmol/L) intervals. This will show the extent to which the distribution curve for retinol levels has shifted. The data required for determining the biological effect are shown in box 1.9 on the next page.

Box 1.9:
Data Required to Determine the Biological Effect of a Sugar Fortification Program

The following data are needed from a representative sample of the target population, including the groups at highest risk of vitamin A deficiency:

Baseline:
Distribution of serum retinol levels and, if possible, in human milk as well as the prevalence of retinol levels below the cutoff points defining deficiency.

Postimplementation:
Distribution of serum retinol levels and, if possible, in human milk as well as the prevalence of retinol levels below the cutoff points that define deficiency. These data should be collected 6 to 12 months after the intermediate effect has been reached.

D. Sample selection

To ensure the validity of the evaluation, the surveys must be carried out with a *statistically representative sample* that includes the different sectors in the population covered by the fortification program. As mentioned before, adequate representation of the groups most susceptible to vitamin A deficiencies must be given priority. If possible, it is recommended that the sample be stratified by rural and urban categories and by socioeconomic levels (for example, below the 25th, between the 25th and 75th, and above the 75th income percentiles) with particular emphasis on the lowest socioeconomic stratum.

Evaluators may find they have limited resources to study a large sample. In this case, an alternative would be to choose a smaller sample, which represents only the most vulnerable sector or sectors. This may be preschool children from the lowest socioeconomic stratum, who are at greatest risk of vitamin A deficiency and who eat the least amount of sugar. If fortification has an impact on this group of children, then it is logical to assume that the rest of the population will also benefit; thus, this group of children can be used as a good indicator of the program's efficaciousness. Similarly, the diet of pregnant and lactating women in the lowest socioeconomic strata is likely to be insufficient in vitamin A in relation to their requirements; they too could be used in evaluating the program's efficaciousness.

If there is any reason to believe that total retinol intake from sugar would significantly surpass the maximum safe limit during pregnancy (3,000 µg/day), it is suggested that a specific dietary study be conducted on a representative sample of pregnant women in the group or groups in which this may occur. These women would usually be in the highest socioeconomic stratum.

For *dietary surveys,* households can be used as the sampling unit. Households chosen must have at least one preschool child. The food consumed by a household can be obtained from a 24-hour recall, with particular attention being given to sugar and other food sources of retinol and carotenes. In addition, detailed individual 24-hour recalls are needed for preschool children. All lactating women in selected households should be registered individually, because they could provide human milk samples for retinol analysis. For the *biochemical surveys*, priority should be given to blood samples from preschool children and/or breast milk samples from lactating mothers.

E. Resources required for evaluation

It is important to determine carefully the resources needed for the evaluation or evaluations to ensure that they are available for the necessary activities. It is recommended that the costs of the *impact evaluation* are estimated separately from the cost of the program itself, because the evaluation will vary in extent and frequency, depending on the decisions made by the program director or directors. The resources required for the evaluation are shown in box 1.10 on the following page.

Box 1.10:
Resources Required to Evaluate a Sugar Fortification Program

Dietary surveys

- Statistical and computer expertise for sample design and data analysis
- Technical and auxiliary field and office personnel
- Transportation and per diem expenses for field personnel trained for the dietary survey
- Funds for printing reports

Biochemical surveys

- Statistical and computer expertise for sample design and data analysis
- Technical and auxiliary personnel for taking, handling/preserving, and transporting biological samples (blood and milk)
- Transportation and per diem expenses for field personnel
- Laboratory facilities and professional and technical personnel for carrying out chemical analyses of biological samples
- Funds for printing reports

VI. HOW ARE THE PROGRAM COSTS ANALYZED?

Estimating program costs is an important exercise in planning a fortification program. It serves not only to determine the economic feasibility of carrying out the activities, but it also justifies the use of resources. Prior to making a political decision and commitment to carry out a fortification program, the government and other sectors involved must understand the economic implications in terms of the necessary investment, recurrent costs, and financial commitments. A careful estimation of costs also identifies components that may require donor support. Finally, information on costs is essential to deciding whether the expected improvement in vitamin A status can be achieved through sugar fortification at a lower cost than through other kinds of interventions, that is, its relative cost-effectiveness.

The economic costs of a program can be calculated in a number of ways. These are presented below, based on the hypothetical characteristics of a country shown in table 1.2.

Table 1.2: Characteristics of Country X

Cost of fortification *(US$)*[12]	3,327,800
Sugar production *(MT/year)*	350,000
Total population	9,200,000
Number of preschool children	1,290,000
Percent coverage with fortified sugar	90
Percent of population consuming <70 % RDA	60

A. Total annual cost

Table 1.3 on the next page offers a guide for estimating the costs of establishing and operating a vitamin A sugar fortification program. Total costs include capital investment and recurrent costs for fortifying 350,000 MT sugar/year. Evaluation costs have been apportioned over 5 years.

12. Unless otherwise noted, all dollar amounts are U.S. currency in this document.

Table 1.3: Cost Components in a Vitamin A Sugar Fortification Program

CAPITAL INVESTMENTS	Total cost (A) ($)	Life span (B) (years)	Annual cost (A/B) ($)
Building & Equipment Costs			
(Number)			
Building	50,000	20	2,500
Mixers (2)	30,000	15	2,000
Dosifiers (15)	90,000	15	6,000
Spectrophotometers (2)	12,500	5	2,500
Scales and other equipment	30,000	10	3,000
Laboratory glassware	10,000	5	2,000
Computer systems (2)	10,000	5	2,000
Subtotal	***232,500***		***20,000***

RECURRENT COSTS	Government	Industry	Total
Personnel			
Directors/administration	30,000	30,000	60,000
Technicians (20)	20,000	100,000	120,000
Inspectors (3)	33,000	30,000	63,000
Training (annual)	4,000	2,000	6,000
Subtotal	***87,000***	***162,000***	***249,000***
Operations and Maintenance			
a. Premix production			
Sugar (270,000 kg @ $0.40/kg)		108,000	108,000
Antioxidants (28 kg @ $36/kg)		1,000	1,000
Vegetable oil (7,000 L @ $1/L)		7,000	7,000
250-CWS vitamin A (77,000 kg @ $37/kg)		2,850,000	2,850,000
Packaging (15,000 @ $0.07 + 15,000 @ $0 18)[a]		3,800	3,800
Laboratory and storage		10,000	10,000
Transportation		5,000	5,000
Maintenance		2,000	2,000
b. Fortified sugar production			
Laboratory and storage		12,000	12,000
Packaging and storage		[b]	[b]
Maintenance		5,000	5,000
c. Monitoring	25,000		25,000
d. Evaluation (apportioned/5 years)	30,000		30,000
Subtotal	***55,000***	***3,003,800***	***3,058,800***
Total	**142,000**	**3,165,800**	**3,327,800**

a. Interior polyethylene and exterior polypropylene bags respectively

b These costs are insignificant because fortification does not alter the packaging process or storage requirement.

B. Cost per metric ton (CMT)

$$CMT = \frac{Total\ annual\ cost}{MT\ produced}$$

$$CMT = \frac{3{,}327{,}800}{350{,}000} = \$9.51\ MT$$

that is, \$0.009/kg or \$0.004/lb.

Using this cost, it is possible to estimate the percentage increase in consumer price that the fortification process adds to the product. For example, assuming that a kilogram of sugar costs \$0.45 before fortification, when vitamin A is added, the price would increase to \$0.459, that is, 2 percent above the original price of sugar.

C. Cost per person (CPP)

Given that fortification is "universal," the potential recipients of a national program are the entire population.

$$CPP = \frac{Total\ annual\ cost}{Total\ population}$$

$$CPP = \frac{3{,}327{,}800}{9{,}200{,}000} = \$0.36/person\ per\ year$$

D. Cost per person covered (CPC)

$$CPC = \frac{Total\ annual\ cost}{Covered\ people}$$

$$Population\ covered = 9{,}200{,}000 \times 90/100 = 8{,}280{,}000$$

$$CPC = \frac{3{,}327{,}800}{8{,}280{,}000} = \$0.40/person\ covered\ per\ year$$

E. Cost per "possible beneficiary" (CPB)

Possible beneficiaries are all the people covered who are not getting enough vitamin A from natural food sources prior to sugar fortification. In this example, they are all the individuals whose vitamin A intake is less than 70 percent of the recommended daily allowance.

$$CPB = \frac{Total\ annual\ cost}{Percent\ of\ population\ consuming\ 70\%\ RDA}$$

Possible beneficiaries = 8,280,000 x 60/100 = 4,968,000

$$CPB = \frac{3{,}327{,}800}{4{,}968{,}000} = \$0.67/possible\ beneficiary\ per\ year$$

F. Cost-effectiveness

By combining the results of the program's impact evaluation, that is, its efficacy, with the cost figures, the intervention can be characterized by its *cost-effectiveness*. Using this expression, a comparison can be made between the sugar fortification program and other vitamin A interventions.

1. Cost per "protected" beneficiary (CPrB)

"Protected" beneficiaries are the potential beneficiaries whose vitamin A intake meets the recommended daily allowance as a result of sugar fortification. Intake is calculated as total vitamin A intake from natural sources plus vitamin A from the fortified sugar (grams of sugar eaten multiplied by the mean vitamin A concentration per gram of sugar).

$$CPrB = \frac{Total\ annual\ cost}{Protected\ beneficiaries}$$

For example, if 80 percent of the 4,968,000 (that is, 8,280,000 x 60/100) possible beneficiaries reached an adequate intake due to the fortification, then:

Protected beneficiaries = 4,968,000 x 80/100 = 3,974,400

$$CPrB = \frac{3{,}327{,}800}{3{,}974{,}400} = \$0.84/protected\ beneficiary/year$$

2. Cost per "recovered" beneficiary (CRB)

The biochemical data from the evaluation, for example, serum retinol levels, especially among the high-risk population, can be used to calculate the number of "recovered" individuals, that is, those who moved from the inadequate category (serum retinol levels less than 20 μg/dL or breast milk retinol levels less than 30 μg/dL) to the adequate category or who remained in the latter category because of fortification. The "maintenance concept" is very important because, in the absence of the fortified product, the population would return to a deficient state.

$$CRB = \frac{Total\ annual\ cost}{Recovered\ beneficiaries}$$

The prevalence and number of children with serum retinol levels less than 20 μg/dL were:

Baseline Survey: 30% prevalence or 387,000 children, that is, 1,290,000 x 30/100
Evaluation: 5.5% prevalence or 70,950 children, that is, 1,290,000 x 5.5/100

Then:

$$Number\ of\ recovered\ children = (387{,}000 - 70{,}950) = 316{,}050$$

$$CRB = \frac{3{,}327{,}800}{316{,}050} = \$10.53/recovered\ child/year$$

This approach by itself may be too restrictive, because it assumes that the "recovered" children were the only ones in the country who benefited. In reality, many other children as well as pregnant and lactating women and even other adults would have benefited from the program. Evidence exists that individuals with serum retinol levels between 20 μg/dL and 30 μg/dL respond to vitamin A therapy; thus, the benefits of fortification go beyond what was estimated using the 20 μg/dL cutoff point.

Despite its restricted focus, the CRB is valid when comparing the cost-effectiveness of fortification with other interventions such as widespread, periodic distribution of high dose capsules, which are known to reverse deficiency.

VII. REPORT PREPARATION

In a vitamin A sugar fortification program, two kinds of reports should be prepared on a routine basis. These reports should be targeted to the following audiences:

- *Officials and other nontechnical personnel,* who will be making decisions based on the conclusions and recommendations, that is, public health authorities and planners. The report should emphasize the operational aspects (including any problems as well as outcomes) and significance in terms of meeting the program's objectives. The report should be submitted annually before the next sugar harvest to stimulate timely decisions during the course of the program. Finally, the report should be written in a style that is readily understood by nontechnical people.

- *The scientific community,* for whom an annual report should be produced that includes a description of the intervention along with a full description of the way in which all activities were carried out, including the monitoring design with details of the methods and procedures used, results, discussion, and conclusions. This report must reflect the degree of scientific and technical input so that readers can judge the quality of the operation and the reliability of the conclusions. The evaluation should also be written up as a technical report.

Once the fortification program is operating efficiently and effectively, shorter annual reports can be written that emphasize program-monitoring activities.

VIII. SUMMARY

- Sugar fortification is one of the most appropriate interventions in countries in which vitamin A deficiency is widespread.

- The technology to fortify sugar exists.

- The establishment of a national sugar fortification program should be in response to the political decision and government commitment to correct vitamin A deficiency.

- The first step in any sugar fortification program is to prepare a plan describing the program characteristics and components, as well as the activities that should be developed for implementation.

- All sectors involved in the sugar fortification program must participate in preparing the program plan, its implementation, and its follow-up. These will include both the public and private sectors, that is, government, sugar producers, academic institutions, and consumer groups. It is also important to have the support and collaboration of bilateral and multilateral donor agencies as well as international financial institutions.

- To ensure operational efficiency, a strict quality control and monitoring system is needed.

- Evaluation of the dietary and nutritional impact will determine the degree to which the program's objectives have been reached.

- Program costs, including those for monitoring and evaluation, must be carefully determined to determine the program's feasibility and cost-effectiveness.

IX. SUGGESTED READING MATERIAL

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FAO/WHO. 1988. *Requirements of Vitamin A, Iron, Folate and Vitamin B_{12}.* Food and Nutrition Series No. 23. Rome.

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Appendix 1.1
VITAMIN A REQUIREMENTS

GROUP	AGE (years)	BASAL REQUIREMENTS[b] (RE[a] [µg]/per day)	RECOMMENDED INTAKE[c] (RE[a] [µg]/per day)
Both sexes	0–1	180	350
	1–6	200	400
	6–10	250	400
	10–12	300	500
	12–15	350	600
Men	15–18	400	600
	18+	300	600
Women	15–18	330	500
	18+	270	500
Pregnant Women	–	370	600
Lactating Women	–	450	850

Source: FAO/WHO (1988)

a One RE is equal to 3 33 IU of vitamin A

b. Amount needed to avoid changes due to deficiency but insufficient to produce reserves

c. Amount that maintains health and appropriate reserves in almost all healthy people

Appendix 1.2
FOOD FORTIFICATION LEGISLATION WITH RESPECT TO VITAMIN A IN SUGAR

Decree Number 44-92

THE CONGRESS OF THE REPUBLIC OF GUATEMALA[13]

CONSIDERING:

That it is the state's duty to look after the health of all the country's inhabitants and that, in the field of preventive medicine, one of the most efficacious means of combating nutritional deficiencies and other health problems is the fortification, enrichment, or restoration of food with the essential nutrients for prevention of such deficiencies.

CONSIDERING:

That in research carried out by specialized technical institutions, it has been shown that the Guatemalan population suffers from deficiencies that could be prevented through fortification, enrichment, or restoration of some foods used as vehicles for nutrient transfer.

THEREFORE,

Exercising the attributions conferred in clause (a), Articles 171 and 176, of the Political Constitution of the Republic

DECREES:

The following:

GENERAL LEGISLATION FOR FOOD ENRICHMENT

ARTICLE 1. Enrichment, fortification, or restoration of foods to supply nutrients that are absent or insufficient in the population's habitual diet is mandatory. The Ministry of Health must issue the necessary agreements and regulations in consultation with the Institute of Nutrition for Central America and Panama (INCAP).

13. Unofficial translation.

ARTICLE 2. The National Commission for Food Fortification, Enrichment, or Restoration is created to serve a coordinating and monitoring role. The commission will be formed by an official representative and a substitute from each of the following organizations and institutions: Ministry of Health; Ministry of Economy; Ministry of Agriculture, Livestock, and Food; Ministry of Finance; Ministry of the Interior; the Producers Association for each of the foods subject to this law; and the Consumer Association.

The National Commission for Food Fortification, Enrichment, or Restoration will have as consultants and advisors: the San Carlos University of Guatemala (USC), UNICEF, the Pan American Health Organization (PAHO), the Institute of Nutrition for Central America and Panama (INCAP), and others deemed necessary.

ARTICLE 3. It is the Ministry of Health's direct responsibility, through the Food Registration and Control Department of the Bureau of Health Services, to ensure compliance with the present law, and the agreements and regulations derived from it.

ARTICLE 4. It is the direct responsibility of the national producers and importers to fortify, enrich, or restore food in accordance with this law and all provisions derived from it. All distributors are responsible for selling national or imported products that are adequately fortified, enriched, or restored, in accordance with the regulations established in this law.

ARTICLE 5. The machinery, laboratory equipment, accessories, spare parts, specific micronutrients, and chemicals needed for food fortification, enrichment, or restoration are free from import duties subsequent to confirmation and approval from the National Commission established in Article 2 of this law by the Ministry of Finance and a resolution issued by the Ministry of Economy's Political and Industrial Bureau.

ARTICLE 6. The costs and supplies required for the processes mandated by this law will be absorbed by the producers. Where there are increases in the cost of the micronutrients needed for food fortification, enrichment, or restoration, the commission created in Article 2 of this law will recommend mechanisms for financing.

ARTICLE 7. Any violation of the present law, regulations, or health provisions derived from it will be penalized, in accordance with the Health Code (Congress of the Republic Decree 45-79), excluding actions or omission offenses, in which case the health authorities will take the case to court.

ARTICLE 8. Article 167 from the Health Code is reformed as follows:

"Article 167. The sanctions imposed by the health authorities as a result of violations of the present code, health laws, Food Fortification, Enrichment, and Restoration Law, its regulations, and the provisions dictated by health authorities are as follows:

PRINCIPAL SANCTIONS:

1. Written warning

2. A fine, which can vary from the equivalent of two (2) to one hundred and fifty (150) times the officially approved, monthly, minimum wage not to exceed one hundred (100) percent of the value of the goods or services

3. Publishing of the reason for the sanction in at least two (2) newspapers with a high circulation in cases of recurrence.

4. Suspension of business or commercial activities for no less than one (1) month nor longer than six (6) months, including suspension of licenses and health registrations

5. Closure of the establishment, business, or enterprise with annulment of registrations and health licenses

ADDITIONAL SANCTIONS:

Confiscation of raw materials, foods, tools, materials, and objects related to the violation committed. When the seized objects are not of legal trade, the authorities will decree confiscation, even if they belong to a third party."

ARTICLE 9. The Ministry of Health must verify and monitor that in the manufacturing of foods subject to this law, the fortification, enrichment, or restoration process is carried out in accordance with the specific regulations of this law. If the existence of nonfortified, nonenriched, or nonrestored foods is determined, an immediate inventory of stock must be made to control the potential commercialization of this product. From this time forward, any production and distribution process is prohibited if it does not observe the present law.

ARTICLE 10. The regulations for this law must be issued by the Executive Branch within the next thirty (30) days after the effective date of this decree.

ARTICLE 11. Any disposition that counteracts this law is revoked.

ARTICLE 12. This decree was declared to be of national urgency and approved in one reading with favorable votes from more than two-thirds of the total legislators from Congress. It will be effective 15 days after it is published in the official newspaper.

THIS SHALL BE SENT TO THE EXECUTIVE OFFICE FOR PUBLICATION AND COMPLIANCE.

ENACTED IN THE LEGISLATIVE PALACE, GUATEMALA CITY, ON THE TWENTY-THIRD OF JULY, 1992.

EDMOND MULET
PRESIDENT

REGULATION FOR VITAMIN A SUGAR FORTIFICATION[14]

GOVERNMENTAL AGREEMENT NUMBER 497-93

National Palace: Guatemala, September 24, 1993

The President of the Republic,

CONSIDERING:

That it is the state's obligation to look after the population's health and welfare requiring the development of actions for prevention, promotion, recuperation, rehabilitation, and coordination and any others necessary for ensuring physical, mental, and social well-being.

CONSIDERING:

That in accordance with the General Food Enrichment Law, or Decree 44-92 of the Congress of the Republic and of the Health Code, it is mandatory to enrich, fortify, or restore foods to supply the nutrients that are absent or insufficient in the habitual diet of the population.

CONSIDERING:

That vitamin A sugar fortification or enrichment is necessary and expedient to guarantee the health of the inhabitants of the country in terms of this micronutrient deficiency; therefore, the necessary regulations to apply the General Food Enrichment Law, in consultation with the Institute of Nutrition for Central America and Panama must be issued.

THEREFORE:

Exercising the functions conferred in Article 183, clauses (a) and (e) of the Constitution of the Republic of Guatemala and based on Article 110 of the Health Code, Decree 45-79 of the Congress of the Republic: First and Tenth of Decree 44-92 from the Congress of the Republic,

AGREES:

To issue the following Regulations for Vitamin A Sugar Fortification.

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14. Unofficial translation.

CHAPTER I:

GENERAL PROVISIONS

ARTICLE 1. All sugar intended for national marketing, whatever its type, must be fortified with vitamin A in accordance with these regulations.

ARTICLE 2. Any individual or legal person entity who imports, subdivides, or markets sugar must obtain a health registration number from the appropriate authorization of the Ministry of Health to operate. Both the health registration and authorization will be valid for five years and can be temporarily or definitely suspended if the present regulation is violated.

ARTICLE 3. The cost of the health registration authorized by the Health Code provisions will be established by law, for five years. The money will go into the Ministry of Health's Food Registration and Control Department account. Such funds must be used only for vitamin A sugar fortification control activities.

ARTICLE 4. The fee for a five-year license as required by the Health Code will go into the Ministry of Health's Food Registration and Control Department's account and may only be used for vitamin A sugar fortification control costs.

CHAPTER II:

VITAMIN A–FORTIFIED SUGAR PRODUCTION

ARTICLE 5. The vitamin A product added to sugar must be water-dispersible and must meet the physical and chemical conditions required to ensure acceptable stability during the shelf life of the sugar with no alteration of its organoleptic characteristics.

ARTICLE 6. Vitamin A will be added to sugar in the form of water-dispersible retinyl palmitate in such a way that it results in a stable homogeneous mixture. To achieve this, a premix containing 15,000 mg (50,000,000 IU) of retinol per kilogram of sugar will be prepared. The containers for this premix must be sequentially numbered, with the first two digits to the left indicating the year the harvest was initiated. The container must be clearly labeled to indicate that: THIS PRODUCT IS NOT SUITABLE FOR HUMAN CONSUMPTION.

ARTICLE 7. Vitamin A sugar fortification is the responsibility of each sugar refinery dedicated to production of sugar for national consumption. The fortification level will be 15 mg (50,000 IU) of retinol per kilogram of sugar. Acceptable limits for retinol will be 10 mg (33,300 IU) minimum and 20 mg (66,600 IU) maximum per kilogram of sugar. This fortification level and/or the acceptable limits can be modified by the Ministry of Health, with approval from the National Commission for Food Fortification, Enrichment, or Restoration.

ARTICLE 8. The sacks used to pack fortified sugar at the sugar refineries must be new and free from contamination by substances harmful to health The label must respond to the stipulations of the National Norms Commission (COGUANOR) regarding weight, registration number, and producer's brand. It must include the designation: VITAMIN A–FORTIFIED SUGAR.

ARTICLE 9. The costs of the fortification process and materials will be absorbed by the producers who, according to Congressional Decree 44-92, Article 6, may suggest mechanisms to minimize any increase in the cost of sugar to the consumer in cases of confirmed increases in the cost of supplies, for consideration by the National Food Fortification, Enrichment, or Restoration Commission.

ARTICLE 10. The Food Registration and Control Department of the Bureau of Health Services, will inspect the refineries and perform field analyses to ensure that sugar is being fortified correctly, taking samples from the factories as well as retail outlets. The analyses will be performed in the Ministry of Health laboratories.

CHAPTER III:

FORTIFIED SUGAR MARKETING

ARTICLE 11. Vitamin A–fortified sugar must only be packaged or subdivided at sites approved by the Ministry of Health and previously endorsed by the National Food Fortification, Enrichment, or Restoration Commission.

ARTICLE 12. Establishments, machinery, and tools used for the packaging, subdivision, transportation, and sale of vitamin A–fortified sugar must meet the minimum sanitary-hygiene norms stipulated in the Health Code and the Food Control Regulations.

ARTICLE 13. The containers and packaging used to dispense and sell fortified sugar must be new and free from contaminants and substances harmful to health. The label must respond to the stipulations of the National Norms Commission (COGUANOR) regarding weight, registration number, brand, and subdivider's address. It must include the designation: VITAMIN A–FORTIFIED SUGAR and a symbol that allows illiterate people to recognize it. The symbol will be a green or red eye in the middle of the package.

CHAPTER IV:

FINAL PROVISIONS

ARTICLE 14. Advertising attributing therapeutic properties to fortified sugar is prohibited, as well as any advertising that presents sugar as the only source of vitamin A. Furthermore, products manufactured using fortified sugar must not indicate it as a special quality of that product.

ARTICLE 15. The Ministry of Health assisted by specialized organizations through the Food Registration and Control Department will provide technical assistance for adequate production, transportation, and marketing of fortified sugar.

ARTICLE 16. Based on the provisions in Article 17, Chapter 6, of the Health Code, the Ministry of Health, through the Food Registration and Control Department of the Bureau of Health Services, can establish agreements with the institutions that form the National Food Fortification, Enrichment, or Restoration Commission to delegate and assign responsibilities to ensure the adequate observance of Decree 44-92 of the Congress of the Republic and these regulations.

ARTICLE 17. Nationally produced sugar lots that do not meet the requirements stipulated in these regulations will be confiscated. An inventory will be made and a certificate will be drawn up by the corresponding health authority and the owner or person in charge of the business. If the owner does not sign the document, it will still be valid. Copies of the document will be sent to the affected establishment, the Ministry of Health, the sugar producer, and the National Food Fortification, Enrichment, and Restoration Commission. Confiscated sugar will be auctioned for industrial use in products for export, following the enactment of the administrative procedures established in Book III of Decree 45-79 of the Congress of the Republic.

ARTICLE 18. Before imported sugar can be marketed, it must be consigned to a fiscal warehouse until the Food Registration and Control Department certifies its quality and compliance with the regulations for fortification, packaging, and labeling. If the sugar does not meet the stipulated requirements, the procedure outlined in Article 17 will be followed.

ARTICLE 19. Funds raised by the application of Articles 17 and 18 will become part of the Food Registration and Control Department's private funds to be used exclusively for the sugar fortification control process.

ARTICLE 20. All violations of these regulations will be considered as health offenses and will be penalized according to Congressional Decree 44-92, Article 8.

ARTICLE 21. The Ministry of Health and the National Food Fortification Enrichment, and Restoration Commission will periodically review these regulations to make any modifications considered necessary.

ARTICLE 22. The Bureau of Health Services, in consultation with the National Food Fortification, Enrichment, and Restoration Commission, will solve any situation that arises that is not contemplated in these regulations or any doubts that might arise regarding compliance.

ARTICLE 23. Labeling and packaging stipulations will go into effect as of the 1993–94 harvest.

ARTICLE 24. This agreement will be effective after its publication in the OfficialNewspaper.

APPROVED FOR PUBLICATION

Ramiro de León Carpio
PRESIDENT

Gustavo Hernández Polanco
MINISTER OF HEALTH