

VITAMIN A

SUGAR FORTIFICATION IN CENTRAL AMERICA

EXPERIENCE AND LESSONS LEARNED



The USAID Micronutrient Program



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Foreword

In the industrialized world, the fortification of both staple and non-staple processed food items has proven to be a successful way to reduce the risk of micronutrient deficiencies in the population at large. As part of its micronutrient program over the years, USAID has made significant investments to help countries in the developing world learn from and replicate the experiences of countries in North America and Europe. However, as it is with so many of the technological advances that have improved the quality of life in the industrialized world, the translation of technological solutions to long-standing problems in diverse settings is not a simple process.

Central America has decades of experience in the application of fortification technology to the reduction of vitamin A deficiency. Upon review of this experience, one is struck immediately by a major difference between the developed and the developing world. The vehicle selected for fortification with vitamin A in Central America was sugar; not milk, not cereal. To reach the children of the poor with a micronutrient such as vitamin A, it is essential that a food commodity be chosen that is purchased in the local market, manufactured by relatively few producers, inexpensive, widely consumed, and, of course, amenable to a fortification technology. In Central America, as in many African and Asian countries, there are few food commodities with these characteristics. Sugar is one.

The historical record of sugar fortification in Central America, recounted in this document, should leave the reader with two important lessons. First, the path taken to develop and maintain a public-private partnership to accomplish the fortification of a locally produced food commodity is not a straight one. The process is not simple nor does it ever end. And, as the political and/or economic environment changes, vigilance must be maintained in the public health community to adjust the partnership, to respond to changing world markets, and to withstand political tinkering. The second and more important lesson is that, despite all of the difficulties, fortification can become a regular practice and can be maintained. It is, after all, a viable and effective strategy to reduce micronutrient deficiencies in developing countries.

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Omar Dary, Ph.D., is chief of the Food Analysis and Protection Unit, Institute of Nutrition of Central America and Panama (INCAP). For the last decade, Dr. Dary has engaged in food fortification research and development of appropriate technology, as well as in advocacy, policy, and program development, implementation, and evaluation in developing countries, with emphasis on sugar, wheat flour, and salt fortification in Central America. Dr. Dary conducted the project leading to the development, field testing, and establishment of food fortification monitoring and evaluation systems in Central America, and has provided technical assistance in several aspects of food fortification to a number of countries.

Ms. Doris Chinchilla, a chemical engineer, has gained long experience in food fortification in Central America through active participation in the efforts leading to resumption and strengthening of the Honduran sugar fortification program, as well as in the development, testing, and establishment of fortification monitoring and evaluation systems, and in providing assistance to other countries of the region.

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Abbreviations

FAO	Food and Agriculture Organization of the United Nations
GDP	Gross domestic product
IMPACT	Food and Nutrition Monitoring and Support Project
INCAP	Institute of Nutrition of Central America and Panama
MOST	The USAID micronutrient program
MT	Metric ton
OMNI	Opportunities for Micronutrient Interventions project
PAHO	Pan American Health Organization
RDA	Recommended daily allowance
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
VAD	Vitamin A deficiency
VITAL	Vitamin A Field Support project
WHO	World Health Organization
WTO	World Trade Organization

Summary

Vitamin A deficiency (VAD) is a far-reaching public health problem in developing countries, affecting large sectors of the population, with serious consequences for child health and survival. Several countries have already developed or are in the process of developing policies, intervention strategies, and programs designed to increase vitamin A consumption in order to reduce the prevalence of VAD. Fortification of staple foods has proven to be an effective vitamin A deficiency strategy. During the 1970s, the Institute of Nutrition of Central America and Panama (INCAP), which is associated with the Pan American Health Organization (PAHO), developed fortification technology and also carried out activities aimed at promotion, advocacy, and implementation of sugar fortification programs in various countries in the region. Since that time, a wealth of program experience has accumulated. The purpose of this paper, prepared by INCAP in collaboration with MOST, the USAID Micronutrient Program, is to document and disseminate information about this experience, with specific reference to the sugar fortification efforts in El Salvador, Guatemala, and Honduras.

The Sugar Fortification Experience

Advocacy and Promotion

After the existence of significant vitamin A deficiency in the Central American region was documented and appropriate technology for fortifying sugar developed, the sugar fortification program was first implemented in Guatemala in 1975. The population's vitamin A intake practically tripled as a result of the program, the prevalence of VAD decreased from 22 to 5 percent over a one-year period, and retinol levels in breast milk and in hepatic reserves increased significantly. Sugar producers were not included in program development and promotion, however, and this subsequently led to the program's being halted by producers during the 1977–78 harvest. The consequences of this were seen 10 years later, when it was found that the prevalence of VAD in Guatemala had returned to its 1960s levels. The program was reinstated in 1988—this time with the conscientious support and participation of the sugar industry. Since then, the program has continued uninterrupted. Today, more than 95 percent of households consume sugar, and above three-quarters of sugar samples collected in households contain the desired levels of vitamin A (equal to or greater than 5 mg/g).

During the 1970s, the program was also promoted in other Central American countries, although sugar producers were not initially included in the process. In Costa Rica, the program was launched in 1975 but was suspended in 1981 upon confirmation of sufficient vitamin A intake and a dramatic decrease in the prevalence of VAD among children. The program was implemented in Honduras in 1977, suspended in 1980, reinstated in 1983, and continued irregularly with very low coverage levels until 1993. However, since 1993, coverage levels have progressively increased, reaching more than 80 percent of households by 1996, with above two-thirds of collected sugar samples containing adequate levels of vitamin A. In El Salvador, the program was formally launched in 1994 and continues to operate, with coverage and quality levels similar to those in Guatemala.

INCAP has played a key role in the program, with respect both to its introduction and reinstatement, and has enjoyed the support of the participating governments, especially the ministries of health and international cooperation agencies, including USAID. Another factor

contributing to the success of the program has been the creation of multisectoral national commissions on micronutrients or food fortification committees. Although sugar fortification is the most widely used method for improving vitamin A coverage in El Salvador, Guatemala, and Honduras, it constitutes only one component of the comprehensive strategy for the prevention and control of micronutrient deficiencies. Nevertheless, vitamin A coverage achieved through fortification in these three countries has reached much higher levels than with other interventions.

Legislation and Regulations

Mandatory sugar fortification has been established through a variety of legal instruments, whether by presidential decrees based on a legal framework or by laws passed by legislative bodies, complemented with regulations prepared by the ministries of health or other regulatory agencies. Agreements signed with the World Trade Organization and the FAO/WHO *Codex Alimentarius* have begun to have an impact on food legislation in the countries of the region.

Technological Development

Fortification technology involves the preparation of a vitamin A-sugar premix, which is then added to sugar at the refineries. Initially, this process was carried out manually by loading the needed amount of premix inside the centrifuge where sugar is separated from the molasses. However, the progressive automation of sugar processing since 1987 has required the use of mechanical dosifiers, which created problems with respect to the accurate amount of premix to add and the homogenous blending of premix within the product. It was also observed that some vitamin A is lost in the drying process. To solve these problems, mechanical dosifiers equipped with a variable flow mechanism and a mixing system that guarantees uniform blending of premix throughout the product are currently being tested. In addition, new fortifying compound formulas with greater stability and different methods for attaching vitamin A to sugar crystals are being developed.

Quality Assurance and Control

Development and testing of a quality assurance system was carried out in Honduras and subsequently transferred to the other countries in the region. The system, which was finally implemented on a permanent basis in 1995, consists essentially of a quality control and assurance process for fortified sugar by producers and the inspection and monitoring of sugar quality at production centers and retail locations by the Department of Food Control of the Ministry of Health. In Honduras, the system has proven to be effective in improving fortified sugar quality and coverage levels. The key elements of the system have been continuous quality assurance by producers, periodic government inspections, the introduction of product labeling, and the analysis of the vitamin A content in household sugar samples, collected through multipurpose annual surveys.

Program Monitoring and Evaluation

A monitoring and evaluation system has been useful in determining the extent to which a population is covered and the program quality at the consumer level. Epidemiological surveillance has been carried out through national surveys in order to evaluate the program's biologi-

cal effects. Results indicate that significant quantities of vitamin A are received by the population through sugar consumption, which constitutes the main dietary source of the vitamin. In 1995, fortified sugar was the source of approximately half of the vitamin A intake of Guatemalan children between two and five years of age. National surveys conducted between 1995 and 1998 in the three countries demonstrated a significant reduction in VAD among pre-school-aged children with respect to earlier surveys. However, the program has had less of an impact on under-two children, possibly because this group consumes less sugar.

Cost Analysis

The total annual cost of the program per 100,000 metric tons (MT) amount to US\$940,125 or \$9.40 per MT, of which 98 percent (US\$918,125) is covered by the sugar industry and passed on to consumers, while the remaining 2 percent (US\$22,000) is assumed by the government. During the 1998–99 harvest, approximately 700,000 MT of sugar were fortified in the three countries studied, serving a total population of 24 million inhabitants. In terms of annual costs, this represents a total cost of US\$6.58 million; a per capita cost of US\$0.27; a cost of US\$0.30 per person covered; a cost of US\$0.51 per high-risk person covered; and a cost of US\$0.76 per vulnerable high-risk person covered.

Lessons Learned

The Central American Context

The experience gained from sugar fortification in Central America should be examined within the specific context of the three relatively small countries studied. The poor in these countries represent between two-thirds and three-quarters of the total population. Between 1960 and 1997, the countries achieved reductions in their infant and child mortality rates of between 70 and 80 percent. All three countries have democratic systems of government. However, the public sector in each is limited in its capacity and efficiency to set standards and monitor compliance with legislation, as opposed to the better-organized and responsive private sector. Sugar production in the three countries constitutes one of the most active industries of the economy; it is essentially a private sector activity, with a relatively small number of easily accessible refineries set up in strategic locations. Sugar production in all three countries is sufficient to meet domestic demand, and between one- and two-thirds of production is exported. Sugar is consumed by most of the population, from all socioeconomic strata. Initially, fortification costs were covered by producers, but were later passed on to consumers as part of inflationary price increases.

Advocacy and Promotion

1. The starting point in developing a food fortification program with public health objectives is thorough documentation of nutritional deficiency to establish the scope, severity, distribution, and characteristics of the problem.
2. The widespread dissemination of information—regarding vitamin A deficiency, its implications for health and the country's social development, the analysis of alternative interventions, the advantages of fortification, and how to identify fortified products—is an essential element in sensitization, advocacy, and program development.

3. The presence of an institution with the capacity to bring the involved actors together can help establish and maintain food fortification and other nutrition programs.
4. The participation of producers in a program from its early planning stage is necessary in order to enlist the industry's support for and commitment to these programs.

Legislation and Regulations

5. Adequate legal or statutory instruments—including a fortification law, standards of identity, technical regulations, and universal labeling—should be in place to support sugar fortification.
6. The establishment of legal criteria regarding the nutrient content of the fortificant in terms of a minimum acceptable level for the consumer is preferable to establishing criteria to govern the production process.
7. The harmonization of legislative instruments and technical regulations among neighboring countries is needed to satisfy free trade initiatives and agreements.
8. Given the limited stability of vitamin A in the industrial processing of some soft drinks, the sugar used in the production of such soft drinks can be exempted from mandatory fortification.

Technological Development

9. The level of vitamin A fortificant should be established based upon per capita sugar consumption and the size of the vitamin A intake gap in the population.
10. Both producers and governments should be kept abreast of advances made in the development of more stable fortifying compounds and better techniques for adding premix in order to incorporate program changes in a timely manner.

Quality Assurance and Control

11. It is crucial for governments to adopt a positive and collaborative attitude toward producers—instead of a repressive and punitive regulatory disposition—and for producers to assume responsibility for conscientiously ensuring the quality and control of their products.
12. Depending on the local industry's level of development, it may be necessary for governments to provide training and guidance in quality assurance to refineries, especially during the initial program stages.
13. The governmental entity responsible for the fortification program may need to design and implement a formal plan for external auditing at the central level, which may gradually shift emphasis from production plants to retail outlets.

Monitoring and Evaluation

14. Program monitoring and evaluation activities can be strengthened at low cost by assessing levels of vitamin A in sugar during other, scheduled household surveys.
15. The development of practical, low-cost epidemiological micronutrient surveillance systems is needed to facilitate both program monitoring and impact evaluation.
16. Under-two children and other groups that may not be covered by the program because they do not consume sufficient sugar on a regular basis should be targeted for periodic supplementation.

Cost Analysis

17. To a large extent, the economic feasibility of fortification depends on whether producers are sufficiently motivated and willing to make the initial investment in necessary equipment, facilities, and inputs, which can be passed on to consumers as part of inflationary price increases.
18. The government can help facilitate the initial first-year capital investment by acting as the industry's guarantor on financing applications.
19. Start-up costs can be reduced by adapting existing facilities for use as premix processing plants, donation of equipment used in premix preparation, or the use of existing laboratory equipment at refineries.

Sustainability of Supply

Financial Sustainability

20. It is important that external cooperation agencies concentrate their financial support in technological development and the design and implementation of policies and programs rather than in assuming operating costs for the system of inspection and monitoring.

Institutional Capacity

21. A governmental unit with adequate managerial and logistic capability, and charged with specific responsibility for program coordination and management, is essential for a well-functioning program.
22. Research and development organizations at the regional level and national associations/groups can play an important role in providing technical assistance to strengthen institutional capacity.
23. Human resources development and periodic retraining are essential institutional-strengthening activities.

Political Environment

24. A solid political commitment of both the government and the industry and an effective policy development and implementation process are key elements for ensuring long-term sustainability of fortification programs.
25. The political sustainability of fortification programs is strengthened by the creation and effective operation of a multisectoral committee or commission.
26. Regional research and development institutions in the field of nutrition and external cooperation agencies can play a critical role in maintaining communication and dialog in order to ensure the stability of the political commitment to sugar fortification.
27. It is essential that the government abide by its commitments to the private sector in order to promote the level of confidence necessary to ensure the political sustainability of the program.
28. Appropriate fortification technology and compatibility between the capacity of existing technology to achieve certain quality results and the technical specifications established by the government are needed to ensure a solid industry commitment.
29. Reinforcing policy decision making within the government and the industry requires long-term, ongoing efforts in promotion and advocacy in key areas.

Sustainability of Demand

30. Information media are key to ensuring that consumers are fully informed and aware of the importance of fortification in health and nutrition, can identify the fortified food-stuff, and, if needed, can eventually take part in social mobilization in support of the program.

In summary, fortification of sugar, as well as that of other staple foods, is a feasible and cost-effective public health measure with a great deal of potential for long-term sustainability in terms of coverage, quality, and impact. Sugar fortification, along with other specific food-based initiatives, represents a major contribution toward finding a permanent solution to the problem of VAD. Even under favorable economic and social conditions, food fortification is still a type of nutritional insurance that protects the population from changes in the availability and consumption of essential nutrients.

Introduction

Vitamin A deficiency (VAD) is widely recognized as one of the most important nutritional problems having a negative impact on public health in developing countries, given the large sectors of the population affected and the serious consequences for the health and survival of children (Sommer and West, 1996). VAD is usually the result of a prolonged deficiency in vitamin A intake and is frequently complicated by infectious diseases. Generally, staple foods consumed in the everyday diet of the populations at risk are poor in vitamin A. Many countries where VAD represents a significant public health problem have developed or are in the process of developing policies, intervention strategies, and programs designed to increase vitamin A consumption. Strategies include periodic supplementation with high doses of vitamin A and food-based strategies, including food-fortification programs and dietary diversification (World Health Organization, 1997).

In the early 1970s, sugar was proposed as an appropriate vehicle for vitamin A fortification. Pioneer research by the Institute of Nutrition of Central America and Panama (INCAP), which is associated with the Pan American Health Organization (PAHO), led to the development of sugar fortification technology. This effort was complemented by the promotion of a sugar fortification program, enactment of fortification legislation, and implementation of the program in several Central American countries. The U.S. Agency for International Development (USAID) has supported the development of this initiative from its inception. In recent years, the United Nations Children's Fund (UNICEF) has also contributed to the program.

For more than two decades now, a vast amount of sugar fortification experience has been accumulating in Costa Rica, El Salvador, Guatemala, Honduras, and, more recently, in Nicaragua. Important lessons have been learned from both the successes and shortcomings of this experience that can be applied to other countries where VAD is a significant public health problem and the fortification of sugar, or other staple foods, can be considered as a VAD control strategy.

INCAP and MOST, the USAID micronutrient program, have joined forces to document these experiences in Central America. INCAP, a regional organization with responsibility for providing technical assistance to the countries of Central America and Panama, is the primary source of valuable experience with respect to the formulation, implementation, and evaluation processes of nutrition and food security policies and programs. MOST provides global leadership and technical support to developing countries with a view to strengthening their capacity to control micronutrient deficiencies.

The objective of this document is to identify, consolidate, and disseminate information and lessons learned from these experiences and to derive recommended activities/approaches for developing countries and the international community. The ultimate goal is to strengthen the planning, implementation, and evaluation of vitamin A-fortified foodstuffs in order to accelerate the sustainable reduction of VAD.

The Sugar Fortification Experience

First Steps

Problem assessment

Since its creation in 1949, INCAP has steadily accumulated a body of evidence pointing to the serious consequences of vitamin A deficiency for public health in Central America. Before developing programmatic interventions to combat the problem, INCAP conducted a cross-sectional study (nutrition survey) in six countries—Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama—to determine the extent to which the population was affected by VAD; its severity or degree of nutritional damage; and VAD distribution trends among different sectors of the population: ecological or administrative zones, age groups, sex, urban or rural habitat, and socioeconomic level.

The results of the study, which was carried out over a two-year period (1965–66) in collaboration with the U.S. Interdepartmental Committee on Nutrition for National Defense, revealed that VAD was a widespread problem affecting large sectors of the population. The study found that children and women of childbearing age were particularly affected and that vitamin A intake was very deficient (between 67 and 88 percent of families consumed less than 50 percent of the recommended daily allowance [RDA] of vitamin A). The study also found a high prevalence of subclinical vitamin A deficiency as measured by biochemical indicators (serum retinol levels lower than 20 µg/dl), which, in preschool-aged children, ranged from 18 percent in Panama to 44 percent in El Salvador. While the prevalence of subclinical VAD among the population from five to nine years of age was somewhat lower, it was nonetheless significant (12 percent to 44 percent) (see Table 1). Clinically evident VAD (e.g., xerophthalmia) was infrequent.

Table 1
% Prevalence of VAD among Children and
% of the Population with Low Vitamin A Intake Levels
Central America, 1965–66

Country	% Population by Intake			% Prevalence of VAD*		
	<25%	<50%	<75%	Ages 0–4	Ages 5–9	Ages 10–14
Costa Rica	44	68	79	33	26	12
El Salvador	69	88	95	44	44	22
Guatemala	45	67	77	26	16	11
Honduras	57	83	92	40	29	22
Nicaragua	45	68	81	20	19	6
Panama	42	74	87	18	12	10

* Serum retinol <20 µg/dl

Source: Arroyave, G. et al. PAHO Scientific Publication No. 384 (1979)

Selection of food vehicle

Based on these results, INCAP proposed food fortification as a potentially effective intervention. The idea was to add the vitamin to one or several processed staple foods in order to close the population's gap in vitamin A intake. The intervention was based on the premise that, through selection of an adequate food vehicle, the vitamin could be delivered to high-risk groups, regardless of their age, place of residence, or socioeconomic level. The initial stage involved the identification of the most appropriate food vehicle(s) for fortification, using the following criteria: a) the food selected should be consumed by the vast majority of the population, including groups at high risk for developing VAD; b) there should be little daily variation in the amounts of the product consumed by individuals to ensure that vitamin A intake would remain within safe limits; c) product processing should be carried out through a system of centralized processing plants in order to add the vitamin under controlled conditions and to minimize costs; and d) the product marketing and distribution system should facilitate monitoring of delivery to and consumption of the fortified product by consumers.

Upon completion of an exhaustive selection process, it was determined that sugar was the food product that best met these criteria. Corn and corn flour were widely consumed in several Central American countries but were mostly produced and/or processed directly in households, making it difficult to fortify them under controlled conditions. From the technical standpoint, the fortification of wheat flour was also feasible; however, its consumption was largely concentrated in medium- and high-income groups, which were at a lesser risk for developing VAD, thus limiting potential benefits. While salt was consumed by practically the entire population, its crude production techniques, poor quality, and hygroscopic conditions are incompatible with the physicochemical characteristics of vitamin A. Moreover, because the daily per capita consumption of salt is relatively low (less than 10 g), it would require an excessively high concentration of fortificant, which would in turn affect both its organoleptic characteristics and price.

Determination of level of fortification

The physicochemical characteristics of vitamin A in its original form (retinol) preclude its being used as a fortifying compound, as it is oily, hydrophobic, and highly susceptible to oxidation. However, the industrial preparation CWS-250* developed by Hoffman-LaRoche, a microencapsulated retinyl palmitate in a pale-yellow powder that is water-soluble and stable-to-oxygen, proved to be an adequate fortificant. Determining the level of fortification required careful analysis in order to guarantee both an effective and safe level, which was defined as a concentration of retinol per gram of sugar that would adequately satisfy the vitamin A needs of the most high-risk groups but, at the same time, would not result in excessive intake of the vitamin by the most affluent groups of the population. Thus, the resulting level of fortification took into account the daily mean per capita sugar consumption of groups with the highest consumption of the product (high-income groups), as well as those with the lowest consumption (preschool-aged children in low-income rural families).

*a cold water soluble fortificant with 250,000 I.U. of vitamin A per gram

Advocacy and Promotion

First national program—Guatemala

The next step was to implement a fortification program at the national level; the first such program in the region was in Guatemala. INCAP drafted a strategic plan with clearly defined program objectives, characteristics, and components. The Guatemalan Ministry of Health, in conjunction with the Ministry of Economy, designed a work plan based on INCAP's technical specifications. A major challenge involved promoting the program in such a way as to secure a political commitment from all governmental sectors. At the outset, there was a need to clarify that sugar fortification did not involve the addition of harmful or contraceptive substances. The program was presented to the health sector as a response to the serious problem of VAD and its impact on eye health, human growth and development, morbidity, and mortality. Technical officials from the Ministry of Health's Nutrition Department were assigned to work with INCAP on a campaign to generate program support from professional health organizations—medical and pediatric associations and professional organizations of chemists, pharmacists, and chemical engineers; as well as from the public sector—including institutions such as the National Committee for the Blind and Deaf (Comité Pro-ciegos y Sordos), whose high degree of credibility and political influence eventually became a decisive factor in passing fortification legislation through the Guatemalan Congress.

The interinstitutional team, comprising representatives from the Ministry of Health, the National Committee for the Blind and Deaf, and INCAP, drafted a proposal to the Guatemalan Congress for mandatory sugar fortification legislation. However, under lobbying pressure from sugar producers opposed to the program, the Congress rejected this measure in September 1973. This rejection served to strengthen promotional activities, which included public demonstrations organized by the National Committee for the Blind and Deaf, medical and other health professional associations, and other civic groups. After a second round of negotiations, the first sugar fortification law was enacted in June 1974. This decision was influenced by an earlier Costa Rican presidential decree for the same purpose, issued in April of the same year.

In 1975, INCAP prepared the program's first operations manual and implementation began in November of that year (Arroyave et al., 1975). Supervision guidelines; the inspection and monitoring process for fortified sugar in warehouses, distribution centers, and retail sales locations; a semiquantitative colorimetric method to provide a rapid estimate of the vitamin A content in sugar; and portable kits for routine quality inspections at refineries were all developed to facilitate program implementation.

Once the program was launched, an evaluation component was developed. Because this was the first time this particular measure had ever been applied, determining the program's nutritional impact was of crucial importance. The evaluation was carried out in 12 rural communities of Guatemala, using a pre- and post-evaluation design to establish the degree to which program goals were achieved. Essentially, this refers to the increase in vitamin A intake needed to correct the deficiency and the positive results achieved with regard to improvements in vitamin A status. A baseline study was carried out before the fortification program was implemented and followed up with four assessments conducted at consecutive six-month intervals. These assessments used the following indicators: a) family vitamin A intake from

natural foods and from sugar; b) serum retinol levels in preschool-aged children and in the breast milk of nursing mothers of the same families; and c) hepatic reserves of retinol taken through autopsies performed on accident victims.

Vitamin A intake practically tripled as a result of the fortification program (Table 2). The prevalence of VAD, measured as a percentage of children with serum retinol levels lower than 20 µg/dl, fell from 21.5 to 5.1 percent over a one-year period; similar changes were observed in breast milk retinol levels and in hepatic reserves (Table 3). These results conclusively demonstrated the program's biological impact. A document describing the scientific grounds as well as the technical and programmatic development of the intervention was published and disseminated with a view to guiding program implementation (Arroyave et al., 1979).

Table 2
Daily Intake per capita of
Retinol Equivalents among Rural Families
Guatemala, 1975–76

Survey	Natural Foods	Sugar	Total
Basal (Oct–Nov 75)	221	0	221
April–May 1976	178	336*	514
Oct–Nov 1976	198	425*	623

* Estimated level of 10 mg/kg of sugar
Arroyave, G. et al. PAHO Scientific Publication No. 384 (1979)

Table 3
Impact of Vitamin A-Fortified Sugar after One Year
Guatemala, 1975–76

Indicator	Subject	% Prevalence of Inadequate Retinol Levels	
		Basal Oct–Nov 1975	After One Year Oct–Nov 1976
Blood serum <ug/dl	Children aged 1–5 (rural)	21.5	5.1
Breast milk <30 ug/dl	Nursing mothers (rural)	24.1	11.1
Hepatic Reserves <50 ug/g	Adults (urban)	25.1	6.3
<20 ug/g		6.2	0.0

Arroyave, G. et al. PAHO Scientific Publication No. 384 (1979)

Unfortunately, promotion and implementation of the fortification program, including the strategic planning stages and preparation of legislation, was carried out without producer participation. Since sugar production in Guatemala and other Central American countries is a private sector activity, this oversight gave rise to serious repercussions that affected implementation of the program. Not all producers were committed to the program and, consequently, did not assume the responsibilities called for under the program, viewing the legislation as an

unjustified state intrusion into private sector matters. Despite proof of its effectiveness, the program, which began with the 1975–76 harvest, was suspended by producers during the 1977–78 harvest on the grounds that they lacked the currency needed to import the fortificant. However, government price controls on staple foods and the fact that producers had not been initially invited to participate in program planning and were still unconvinced it was justified or important were probably more significant reasons influencing the decision to suspend the program.

In 1987, 10 years after the program had been suspended, the prevalence of VAD in Guatemala was found to have returned to its 1960s levels. INCAP, together with the Ministry of Health and UNICEF, again took a leadership role in reinstating the program. This time sugar producers participated in the planning of program activities. Reinstated during the harvest of 1988–89, the program has since continued without interruption. Today, more than 95 percent of households consume sugar, and above three-quarters of sugar samples collected in households contain the desired levels of vitamin A (equal to or greater than 5 mg/g).

In 1995, UNICEF published a program progress report (UNICEF, 1995), and in 1996 it publicly recognized the government and people of Guatemala for being the world's first country to achieve universal sugar fortification. This distinction was widely covered by the media and raised public awareness with respect to the program's importance. However, in January 1998, as a result of political and economic concerns, the president and the cabinet voted to repeal the existing legislation for mandatory sugar fortification (Solomons and Bulux, 1998). Essentially, the legislation was abolished to counteract a 10 percent sugar price increase established by producers at the end of 1997. Social mobilization swelled in response to the decision, however, as politicians, social services organizations, journalists, professional associations, and the general public organized in defense of the original legislation. Two weeks later, public pressure had forced the reinstatement of mandatory sugar fortification through the enactment of new legislation, while simultaneously, producers suspended the price increase.

Programs in other Central American countries

INCAP also promoted the program in other Central American countries throughout the 1970s. Promotional efforts drew on the experiences gained in Guatemala as a model for other countries, but were not as intense as the original campaign. As in Guatemala, sugar producers in these countries did not participate in the process initially. In Honduras, sugar fortification legislation was approved in 1976, and the program was implemented during the 1977–78 harvest. Although the program was suspended in 1980, it was reinstated in 1983 but fortificant was added only intermittently, resulting in very low coverage levels until 1993. Since then, INCAP has worked with USAID's VITAL, IMPACT, and OMNI projects to intensify financial and technical assistance to the Ministry of Health and to sugar producers. Coverage levels have steadily improved since 1994, reaching coverage of 82 percent of households by 1996, with more than two-thirds of collected sugar samples containing the prescribed levels of vitamin A.

In El Salvador, the program, financed by the government of Japan, was initially implemented without legislation during the 1990–91 harvest. Although sugar producers were consulted, these efforts were unsuccessful in securing their commitment to the program or even convinc-

ing them of its importance. Thus, in El Salvador, as in both Guatemala and Honduras two decades earlier, the program was suspended during the following harvest (Pineda, 1993). Legislation was finally approved in 1994 with producer support, and fortification resumed in the 1994–95 harvest. INCAP, USAID (working through the OMNI project), and UNICEF provided technical assistance to the program, which continues to operate with coverage and quality levels similar to those of Guatemala (Dary, 1994).

Costa Rica approved sugar fortification legislation before Guatemala, as the former was established through a presidential rather than a legislative decree. In Costa Rica, the program was first implemented in 1975 and was suspended in 1981 after a national study (nutrition survey) revealed that vitamin A intake through diet was adequate and that the prevalence of VAD among children had decreased from 32.5 percent in 1966 to 1.8 percent by 1980. With respect to Panama, no sugar fortification program has ever been implemented, although legislation for this purpose was approved in 1976.

Role of INCAP, national commissions on micronutrients, and food fortification committees

INCAP has played a key role regarding both the introduction and reinstatement of the program in Central America. Since its creation in 1949, INCAP has enjoyed the support and respect of the concerned governments, especially the ministries of health, as well as that of international cooperation agencies. With regard to reinstatement, another important factor has been the creation of multisectoral national commissions on micronutrients and/or food fortification committees, which have been formally established in Guatemala and El Salvador and informally in Honduras. The active presence of these groups represents an important step toward sustaining the political commitment of both governments and the industry. Although sugar fortification is the most effective and widely used method for improving vitamin A coverage in the three countries studied (El Salvador, Guatemala, and Honduras), it represents only one component of a comprehensive strategy for the prevention and control of micronutrient deficiencies, which also includes supplementation and dietary diversification. Nevertheless, vitamin A coverage through fortification in these countries has reached much higher levels than through other interventions.

INCAP has continued to provide technical assistance for development of quality control, inspection, and monitoring systems, as well as for laboratory analysis of fortified sugar samples. In 1996, a collaborative effort between INCAP and USAID through the OMNI project produced the *Manual for the Fortification of Sugar with Vitamin A* (Arroyave and Dary, 1996). Application of this manual has facilitated the introduction and maintenance of the program's quality assurance system. Likewise, under an OMNI Research Program grant, INCAP developed and tested in Honduras a prototype food fortification monitoring and evaluation system that was formally established in the country and then transferred to Guatemala and El Salvador in 1998.

Legislation and Regulations

The countries of Central America have established mandatory sugar fortification through a variety of legal instruments. Costa Rica enacted the program through a presidential decree based on a compatible legal framework, while El Salvador, Guatemala, and Honduras did it through legislative instruments, complemented with regulations prepared by the ministries of health. The strategy used by Costa Rica provides for greater flexibility, allowing the country to modify and adapt food fortification legislation in a time-efficient manner. Guatemala changed its strategy in this regard in 1992, when the Congress established a legal framework (General Law on Fortified Foodstuffs) that designated responsibility to the Ministry of Health for establishing regulations on individual fortified foods. With respect to Nicaragua, where the sugar fortification program was launched during the 1999–2000 harvest, producers demanded that the government pass the necessary legislation to ensure that both domestically produced and imported sugar conform to legal requirements.

Agreements signed with the World Trade Organization (WTO) and the FAO/WHO *Codex Alimentarius* have begun to have an impact on food legislation in the countries of the region. For example, in Nicaragua, technical standards for mandatory sugar fortification to be applied countrywide have been developed following *Codex Alimentarius* specifications regulating world trade. In general, responsibility for food legislation is being delegated to government agencies in charge of standardization and/or application of the *Codex Alimentarius*. For public health reasons, sugar fortification continues to be mandatory in Central America.

Universal and selective fortification

Guatemala and El Salvador have established fortification of all sugar, whether for direct human consumption or industrial use. This measure has facilitated high levels of coverage—greater than 95 percent—with no need for the state to invest in extensive infrastructure for the control of fortified foods. Given the limited stability of vitamin A in the industrial processing of some soft drinks, the fortification of sugar in this application may not be recommended (Dary, Guamuch, and Nestel, 1998). This exemption may significantly reduce the cost of the program but implies stricter monitoring requirements, which many governments are not in a position to carry out.

Despite Honduran legislation establishing universal sugar fortification, a new regulation was passed in 1984, at the insistence of producers, that allows for the production of unfortified sugar to be used in industrial applications. However, the government has not allocated the necessary human and financial resources needed to carry out state monitoring and inspection activities. Today, unfortified sugar is still consumed in approximately 20 percent of Honduran households—either through the leakage of unfortified sugar for industrial use or insufficiencies in fortified sugar production targets. Consequently, both producers and the government are considering a return to universal fortification in order to overcome these limitations.

Level of fortification

The initial objective of the sugar fortification program was to provide the RDA of vitamin A for preschool-aged children from the most disadvantaged strata of the population. Based on the then daily requirement of 300 equivalents of retinol and average sugar consumption of 20

g, the level of fortification was set at 15 mg per kg of sugar (300 RE/20 g). Thus, legislation established that the average level of sugar fortification at refineries should be 15 mg per kg, with a range of variation between 13.5 and 16.5 mg per kg. This regulation was the source of frequent conflicts between Guatemalan producers and the Food Control Department, especially when the program was reinstated in 1988, as refineries were often sanctioned for non-compliance with this technical standard. INCAP and sugar producers studied the problem and found that under actual production conditions, fortification technology resulted in a greater range of variation than was previously thought. As a result, Guatemala issued a new regulation in 1993 establishing tolerance limits between 10 and 20 mg of vitamin A per kg of sugar.

The conflict between producers and officials at the Food Control Department continued, however, as the Ministry of Health applied the same standard at the point of sale where retail sugar did not meet the expected vitamin A content. It was then found that, depending on environmental conditions, between 20 and 60 percent of the vitamin A present in fortified sugar is lost over a period of nine months. For this reason, it was recommended that the technical requirement be modified: set to a minimum level of 5 mg of vitamin A per kg of retail sugar. It was further recommended that refineries maintain an average fortification level of 15 mg of vitamin A per kg of sugar, with a tolerance interval of between 10 and 20 mg per kg. The revised regulations in January 1998 introduced these changes, which have successfully eliminated the previous conflicts and have served to maintain program quality and coverage levels. A method to estimate the minimum level of fortification has been recently proposed (Dary and Nestel, 1999.)

Imports and donations

The countries of Central America are self-sufficient sugar producers. However, the fall in sugar prices on the international market increases the possibility of unfortified sugar entering the countries. For example, at the end of 1998, in the wake of the devastation caused by Hurricane Mitch in Honduras, a local branch of the Ministry of Health's Food Control Department authorized importation of unfortified sugar for "industrial use." This action was based on an importer's claim that there was a shortage of sugar on the market. In reality, there was no shortage. This unfortified sugar was consequently sold directly to consumers. A similar situation could have occurred in Guatemala when, as a result of the same hurricane, another importer attempted to bring in unfortified sugar. Fortunately, this situation was discovered in time to stop shipment of the product. Undoubtedly, the risk of legal or illegal importation of unfortified sugar persists due to the price difference between the international and domestic markets and to the inability of customs authorities to control contraband products.

The new Guatemalan regulation of 1998 provides for the possibility of importing unfortified sugar to be fortified later domestically. This option is meant to avoid artificial price increases that may result from monopolistic practices in a captive market. However, what is true for selective fortification is also true here: the advisability of allowing imported or donated sugar to be fortified in country depends on whether or not efficient fortification and packaging and labeling systems for consumers are in place and, furthermore, on the State's capacity to provide the resources and infrastructure required to guarantee adequate supervision and monitoring. Unfortunately, these conditions do not exist in most developing countries.

Packaging and labeling

In the past, little importance was given to the packaging and labeling of retail sugar. However, this practice is now considered to be one of the most powerful tools of control and consumer information. New legislation proposed includes labeling regulations that clearly identify the manufacturer of the product, information regarding its nature, the guaranteed level of fortification, and unit weight. Sugar producers in El Salvador, Guatemala, and Honduras have already begun factory packaging in consumer-size bags properly labeled, although this initiative has found opposition with intermediary merchants.

Requiring food products to be adequately packaged and labeled is essential for monitoring the success of food fortification programs and provides a means for defending consumer rights. At the time when fortification programs were first implemented, product labeling was not permitted to disclose that sugar contained vitamin A. The rationale in this regard was to prevent an increase in sugar consumption, as it is known that excess sugar consumption is associated with dental caries and other health problems. Currently, it is recommended that labels disclose the fact that sugar contains vitamin A, which facilitates its identification by consumers as a fortified product and helps identify it for supervision and control purposes. However, labels and/or advertising that attribute therapeutic or medicinal qualities to fortified sugar continue to be banned.

Enforcement of regulations

Prior to the 1980s, government regulations as well as state inspection and monitoring systems were geared largely toward imposing sanctions for noncompliance with technical standards. Producers were first given warnings, followed by progressive fines, and could even face having their refineries closed down by the state. Government inspectors adopted a regulatory attitude toward the program, carrying out punitive supervisory functions. Producers were seen as essentially profit-driven individuals who sought ways to systematically evade compliance with the law. This created a climate of mutual distrust, due to inconsistencies between the available technology and the technical specifications set out in legislation, as well as the opportunities for corruption associated with the inspectors' coercive power. This situation changed notably in the 1990s as a result of adapting regulations to the limits posed by technology and the implementation of monitoring systems that emphasize the collaborative role of government, in contrast to the previous regulatory approach. As a result, relations between the state and the sugar industry have improved markedly.

Regional harmonization

During the 1970s, initial food fortification legislation in Costa Rica, Honduras, and Panama followed the model established in Guatemala. Subsequently, changes were introduced in legislation that created differences among the countries. An interesting case in point is El Salvador, whose 1994 legislation was patterned after the Guatemalan model but did not take into account subsequent changes introduced to the original model as a result of new information and experience. Since 1997, Central American countries have intensified their free trade initiatives and improved intergovernmental lines of communication. These measures have been taken with a view toward market integration and have facilitated the establishment of mutual regulations.

Between 1997 and 1998, INCAP organized a series of regional meetings to promote consensus on technical specifications, labeling, control, and monitoring of fortified foods. Support for this endeavor was provided by USAID's Central America Regional Micronutrient Initiative (CARMI), in collaboration with UNICEF and the Micronutrient Initiative of Canada. The meetings provided opportunities for the exchange of information among government officials in different areas (health, technical standards, and economics) and between the public sector and the industry. Agreements and basic recommendations were reached with respect to regional harmonization of fortification regulations on sugar, wheat flour, and salt (see Annex for prototype legislation developed for sugar fortification). These agreements served as a foundation for updating regulations in Guatemala. Even though El Salvador and Honduras have not yet formally modified their original regulations, in practice they follow the guidelines established in the region. Nicaragua's technical regulations are also based on these guidelines. Central America is now in a better position to justify, on public health grounds, mandatory fortification of some basic food staples, including sugar, in accordance with the *Codex Alimentarius* and the WTO.

Technological Development

Addition of premix to sugar

For a period of six years, beginning in 1967, INCAP carried out laboratory research and pilot tests that led to the development of a practical sugar fortification technology. Working in collaboration with scientists at Hoffman-LaRoche, a formula for a fortificant premix was developed that successfully prevented the segregation of ingredients. The premix retinol concentration was 15 g per kg of sugar. This premix was to be added to sugar at a ratio of 1 part per 1000, so that the final product would contain 15 mg per kg, the equivalent of 50 I.U. of vitamin A per g of sugar. Development of the technology for addition of premix to sugar included the participation of a Guatemalan sugar refinery owner, who voluntarily agreed to carry out pilot tests with INCAP over a four-year period until the process had been satisfactorily developed. In this process, the operator of the centrifuge to separate the crystallized sugar from molasses added the premix manually. Using a calibrated container, the operator would add the correct amount of premix, which was calculated according to the sugar crystallization yield and the centrifuge's load weight (dry sugar equivalent).

The progressive automation of sugar processing in Guatemala since 1987 has led to the development of closed automatic centrifuges, making manual addition of premix impossible. Automatic dosifiers have been placed above the conveyor belt leading to the drying turbine, which does not allow for the manual adding of premix. The introduction of automatic dosifiers created a new problem: the flow of premix addition from the dosifier to the conveyor belt is fixed, but the sugar flow on the conveyor belt is variable. This resulted in a wider range of variation in vitamin A content than occurred with manual addition of premix. Recently, it has been found that some vitamin A is lost during the drying process, due to the air flow inside the drying turbine, which separates a certain proportion of vitamin A microcapsules or beadlets from sugar crystals. In order to overcome these limitations, tests are being conducted on automatic dosifiers equipped with a variable flow mechanism that adapts to the sugar flow on the conveyor belt and can be installed just before the sugar is packaged (Dary, 1998b). This change requires a mixing system that guarantees product homogeneity. Consequently, the appropriate solution depends on the specific characteristics of individual sugar refineries.

Stability of vitamin A in sugar

Sugar samples obtained from refineries in Guatemala and Honduras have been analyzed as well as samples taken from households, the latter from representative sample surveys at the national level. With respect to the results, in Guatemala 63 percent of the retinol in sugar at production plants reaches the final consumer; in Honduras, this figure is only 51 percent—a difference that may be attributable to more favorable environmental conditions in Guatemala. The stability of vitamin A in sugar is similar to that found in other foods, such as cooking oil, milk, beverages prepared in the home, and bakery products. When used as a sweetener in homemade beverages, such as coffee, lemonade, etc., sugar retains 80 percent of its retinol content over a 24-hour period at room temperature (Dary, 1998b).

Recent studies have confirmed that retinol is very stable in sugar when used by the food industry as an additive in foodstuffs. When applied in the production of bread, cookies, and other baked goods, 70 to 85 percent of retinol is retained after baking; however, from that moment on it slowly begins to lose potency. Retinol's stability in candy is 95 percent, indicating that the fusing point of sugar during candy production does not affect the vitamin's stability (Dary, 1998b). However, this does not hold true with respect to some soft drink production, as about two-thirds of the vitamin A added to refined sugar remains in the final product, and only 30 percent of the total retinol remains in bottled soft drinks one week after production, with little additional loss thereafter. In Guatemala, soft drinks prepared with this type of sugar contain a certain amount of vitamin A. However, if unrefined standard white sugar is used directly in soft drink production, virtually all retinol is lost during the process. This is caused by the use of activated charcoal and diatomaceous earth during syrup "bleaching" to reduce color and to eliminate odors and organic impurities, which also eliminates retinol (Dary, Guamuch, and Nestel, 1998).

Suppliers are developing new fortifying compound formulas to overcome limitations associated with vitamin A instability during product storage. It is hoped that these new formulas will reduce program costs by providing a fortificant with greater stability. Moreover, different mechanisms are being tested for attaching vitamin A to sugar crystals. The most effective technique to date is the use of vegetable oils (peanut, palm, or coconut) with the lowest possible amount of unsaturated fatty acids, which reduces the formation of peroxide during sugar storage.

Quality Assurance and Control

At the inception of the sugar fortification program, INCAP prepared operations and supervisory manuals (Arroyave et al., 1975), which have recently been improved and updated (Arroyave and Dary, 1996). In practice, however, control and supervisory activities were neglected until the early 1990s. The development and systematic testing of the program's quality assurance system for sugar fortification was carried out in Honduras as part of a project sponsored by the OMNI Research Program and finally implemented on a permanent basis in 1995 (see Figure 1, page 14). Essentially, the system consists of three stages: a) a quality control and assurance process for fortified sugar, under the responsibility of the producers; b) a quality inspection and auditing process for sugar at production centers, supervised by the Food Control Department of the Ministry of Health; and c) a product monitoring

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graph TD
    QA([QA System])
    Food[FOOD Domestic or Imported]
    Vit[VITAMIN ADDED & BLENDED]
    QA --> Food
    QA --> Vit
    Food --> Fort1[FORTIFIED FOOD Producer or Packager]
    Vit --> Fort1
    Fort1 --> Fort2[FORTIFIED FOOD Producer or Packager]
    Fort2 --> Fort3[FORTIFIED FOOD Distribution Center or Retailer]
    Fort3 --> Fort4[FORTIFIED FOOD Households]
    Fort4 --> Effects[EFFECTS OF FORTIFIED FOOD Sentinel Sites & National Surveys]
    Effects --> ME([Monitoring & Evaluation System])
    ME --> QA
    ME --> Vit
    ME --> Fort1
    ME --> Fort2
    ME --> Fort3
    ME --> Fort4
    ME --> Effects
```

QA System

FOOD
Domestic or Imported

VITAMIN ADDED & BLENDED

Certification of Quality Assurance or Inspection
(Food Safety Dept. & Customs)

IMPORTED FOODSTUFF (FORTIFIED)

FORTIFIED FOOD (Producer or Packager)

Quality Control and Assurance
(Quality Control Dept. of Producer or Packager)

Import Warehouses

FORTIFIED FOOD (Producer or Packager)

Certification of Compliance or Inspection
(Inspection Program)
(Food Safety Dept. & Customs)

Inspection (Inspection Program) and Quality Monitoring
(Government Food Safety Dept.)

FORTIFIED FOOD (Distribution Center or Retailer)

Monitoring (Inspection Program)
(Food Safety Dept. and Standards Unit and/or Consumer Protection Agency)

Quality Monitoring & Evaluation of Compliance
(Food Safety Dept. & Private Sector)

FORTIFIED FOOD (Households)

Process Monitoring
(Nutrition Dept. & Collaborators)

EFFECTS OF FORTIFIED FOOD
(Sentinel Sites & National Surveys)

Epidemiological Surveillance
(Result Indicators: Consumption & Risk
(Depts. of Epidemiology, Nutrition & Collaborators))

Monitoring & Evaluation System

The results obtained in Honduras since 1998 attest to the effectiveness of the system in terms of increased quality and coverage of sugar fortification. Furthermore, a weakening of the Ministry of Health's inspection system in 1997, due to several reasons, brought with it a drop in fortification levels. When inspection activities were fully reestablished during the 1998–99 harvest, vitamin A levels in sugar returned to desirable levels. The basic factors responsible for achievements in this regard have been continuous quality control by producers, periodic state verification, and the introduction of product labeling including a colored band or logo printed on both sides of product packaging, which facilitates consumer identification of fortified and unfortified sugar and separation of these products for storage at the refineries. Another important factor has been analysis of the vitamin A content in sugar samples collected from households through multipurpose annual surveys carried out by state statistics and census bureaus.

Although the program has generally continued to operate adequately in Guatemala, some refineries have not yet completely assumed their responsibilities regarding quality control, for which the Association of Guatemalan Sugar Producers is ultimately responsible. The Food Control Department of the Guatemalan Ministry of Health has also been unsuccessful in providing constant supervision of the program. Generally, the food control divisions of the ministries of health have had to cope with chronic shortages of human and material resources. Moreover, none of the countries has yet developed systematized procedures for the control and supervision of fortified foods at the point of sale.

Program Monitoring and Evaluation

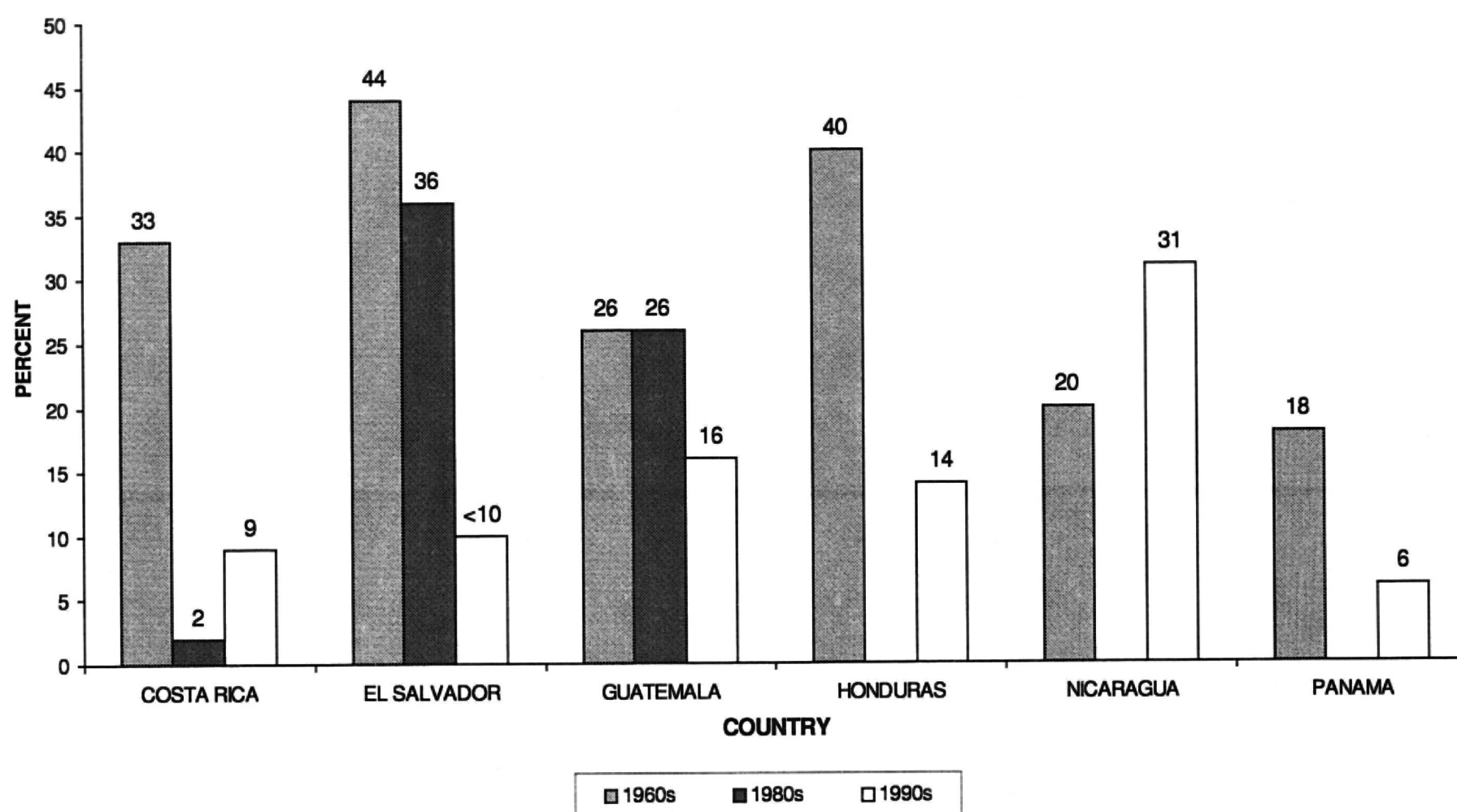
In addition to the quality assurance system, a program monitoring and evaluation system has also been developed that provides a means for estimating population coverage and program quality at the consumer level. The monitoring and evaluation system (Figure 1) includes two components: a) household monitoring, which is carried out through annual studies to assess the quality of fortified foods (including sugar), obtained directly from households using representative sample surveys conducted at the national level; and b) epidemiological surveillance, which facilitates objective confirmation of program impacts through the evaluation of biochemical and nutritional parameters of the population. The latter component, however, has been carried out through high-cost national surveys at long (8–10 year) intervals.

Results from household monitoring reveal that the population gets sufficient quantities of vitamin A through sugar consumption. In fact, sugar is the principal source of the vitamin in the diet. A 1995 national survey on micronutrients in Guatemala (MSPAS, 1996) found that fortified sugar was the principal source of vitamin A in all regions of the country, constituting approximately half of the dietary supply of the vitamin for children from two to five years of age. Similar findings were obtained through studies in other sectors of the population, further confirming the results of the 1995 survey (Solomons and Bulux, 1998; Kraus et al., 1998; Riva-Clement et al., 1998).

INCAP estimated the amount of fortified sugar provided in the diet of the Guatemalan population and found that, based on actual consumption and a minimum fortification level of 5 mg per kg, sugar provides at least 50 percent of the RDA of vitamin A for the population over two years of age (Dary, 1998a). It is estimated that this amount, together with the amount provided in the daily diet, is enough to meet the vitamin A requirements and prevent VAD in the majority of the population. However, children under 24 months of age should obtain vitamin A from other sources besides fortified sugar; hence, the supplementation program for this age group should be maintained.

The effectiveness of sugar fortification has been demonstrated through biological indicators (WHO, 1996) obtained from national surveys conducted between 1995 and 1998. These surveys indicate a significant reduction in the prevalence of VAD among preschool-aged children in El Salvador, Guatemala, and Honduras (see Figure 2, page 16), as compared to previous surveys. The prevalence of low serum retinol (less than 20 µg/dl) in the mid-1990s was <10 percent in El Salvador, 16 percent in Guatemala, and 13 percent in Honduras, as compared with 44 percent, 26 percent, and 40 percent, respectively, during the mid-1960s. The impact of sugar fortification has been somewhat less impressive on children under two

Figure 2
Trend in the Prevalence of Vitamin A Deficiency in Preschool-age Children
Central America, 1960s–1990s



years of age, possibly because this group consumes less sugar. In Costa Rica, sugar fortification between 1975 and 1980 achieved a noteworthy reduction in the prevalence of VAD, from 33 to <2 percent. Fortification was suspended in 1981, and by 1996 the prevalence of VAD had increased to 9 percent. In Nicaragua, the prevalence of VAD increased from 20 percent in the 1960s to 31 percent by 1993; the country began implementation of a sugar fortification program during the 1999–2000 harvest. In Panama, which has never had a fortification program, VAD decreased from 18 percent in the 1960s to 6 percent by 1991; this decrease has been largely attributed to improved socioeconomic conditions.

The reduction of VAD in El Salvador, Guatemala, and Honduras between the 1960s and 1990s can reasonably be credited to sugar fortification, given that there was no significant improvement in socioeconomic indicators during the period and that population coverage by other specific interventions (e.g., supplementation) was extremely low. Moreover, additional evidence from the 1995 survey in Guatemala mentioned earlier confirms that the decline in VAD was attributable to fortified sugar; the prevalence of VAD was significantly lower among the population that consumed only fortified sugar, as opposed to those who consumed mainly *panela* or brown sugar loaf (unfortified).

Cost Analysis

Table 4 (page 19) provides a summary (in US\$) of average sugar fortification costs in Central America for the 1998–99 harvest. Available estimates do not include cost data on a) initial research conducted to assess VAD, the initial development of sugar fortification technology by

INCAP, or dissemination of the technology; b) subsequent technological development of formulas to improve fortificant stability or to increase homogeneity and stability of fortificant premix in fortified sugar; c) advocacy, dissemination of information, promotional activities, preparation and approval of legislation, and development of technical regulations, the costs of which are difficult to calculate and have largely been covered by external cooperation agencies; d) consumer information campaigns that have been recommended but have not yet been carried out in Central America (the first campaign of this type was recently carried out in Nicaragua); and e) program impact assessment studies. However, the information available is of practical importance with regard to evaluating the economic feasibility and cost of establishing a new program, after the corresponding adjustments warranted by the situation in each country have been made.

In order to facilitate calculation of new program costs, fortification costs are stated in terms of 100,000 metric tons (MT) of sugar, assuming one premix processing plant and a total of five sugar refineries (average production of 20,000 MT/refinery). Two large cost categories must be estimated: a) industry costs, which include capital investment in the plant for premix preparation, equipment for addition of the premix to the sugar at refineries, and for quality control, as well as operating costs for the preparation and transport of premix and its quality control process, and addition of premix to sugar at refineries and its quality control process; and b) government costs, which include capital investment in laboratory equipment for inspection, program monitoring and supervision, as well as the operating (recurrent) costs associated with them. Information on industry costs was obtained from the national associations of sugar producers, whereas government costs were estimated based on information obtained through interviews with government officials. The cost of the fortificant and other supplies, which represents by far the largest proportion of the total program cost, was verified with the suppliers.

Industry costs

The capital investment needed to construct and equip a premix processing plant can reach as much as US\$100,000; the cost of land and construction of a small plant of approximately 150 square meters, including a storeroom for raw materials, an area for production and packaging, and a storeroom for processed premix, is estimated at US\$50,000. The capital investment in equipment for adding premix to sugar and for quality control processes of five processing plants is US\$50,000 (US\$10,000 per refinery). Thus, the total capital investment for a premix processing plant and five refineries is estimated to be US\$150,000.

The annual operating cost to the industry amounts to US\$918,125 (US\$183,625 per refinery with production of 20,000 MT). Of this amount, 92 percent (US\$845,500) corresponds to the cost of fortificant and other materials and ingredients (packaging bags, antioxidant, vegetable oil, nitrogen) used in the preparation of premix, while 3 percent (US\$26,250) corresponds to quality control processes. The remaining 5 percent is distributed among salaries, transportation costs, as well as amortization, depreciation, and maintenance on equipment. Assuming production of 100,000 MT of fortified sugar, the cost per MT would be US\$9.18 (\$0.000918 per kg). The current retail price of sugar in Central America is approximately US\$460 per MT (US\$0.46 per kg); thus, the total cost of fortification to the industry represents about 2 percent of the retail price of sugar. This cost does not include eventual import tariffs (e.g., 1 percent in El Salvador).

Even though the increase in the price of sugar attributable to fortification is relatively low (about 2 percent), it may slightly affect the competitiveness of the product on the free market, especially in poor countries where many consumers make choices based on price rather than quality and where production costs are higher than normal and profit margins are small. Essentially, Central American sugar producers have given their support to the sugar fortification program because they have a guaranteed opportunity to operate in a partially controlled market, in which the addition of vitamin A is required. Free market advocates have criticized mandatory fortification as a technical non-tariff barrier to free trade, but public health arguments have prevailed over economic interests. In reality, the market is not restricted, but rather requires both domestic producers and importers to comply with the same technical specifications.

Government costs

Government investment in equipment for program monitoring and supervision is difficult to estimate. Generally, the government uses equipment that is already available to it for the general control and monitoring of foodstuffs. The proportion of this investment in Central America is estimated to be US\$5,000 per country, with annual amortization, depreciation, and maintenance costs of US\$1,250. The operating costs of a state inspection and supervision system (salaries, transportation, per diems, laboratory analyses, and training, every two to three years) is estimated at US\$15,000 for a system that includes a premix processing plant and five refineries. Household monitoring includes the annual collection and analysis of about 600 sugar samples, at a cost of US\$5,750.

Total program costs

The total annual cost of the program is estimated to reach US\$940,125 or \$9.40 per MT. Of this total, 98 percent (US\$918,125) is covered by the industry and passed on to the consumer, while the remaining 2 percent (US\$22,000) is covered by the government. Total program costs vary somewhat from country to country, depending on the size of the population, the quantity of sugar to be fortified, import tariffs, the cost of salaries and travel expenses, etc. However, the relative cost structure remains constant because the fortificant represents the greatest proportion of total cost. The initial investment for construction of a premix processing plant, for equipment costs associated with preparation and addition of premix (mixer, dosifiers), and for laboratory quality control equipment could be reduced by converting existing facilities into premix processing plants (Guatemala, Honduras), by government donation of premix plant equipment (Honduras), or by using existing laboratory equipment at refineries (Guatemala) and/or at the ministries of health (all three countries).

During the 1998–99 harvest, the three countries fortified approximately 700,000 MT of sugar, for a total population of 24 million, at a total cost of US\$6.58 million (\$9.40 per MT) and a total annual cost per capita of US\$0.27. Assuming that 10 percent of the population does not consume sugar on a regular basis, the annual cost per person covered would be US\$0.30. In the absence of fortified sugar, it is estimated that at least 60 percent of the population (14.4 million) consume less than 70 percent of the RDA of vitamin A and are consequently considered to be at high risk for developing VAD. Thus, if 90 percent of this population group consumes sugar, the annual cost per high-risk person covered would be \$0.51. Generally, children under five years of age and women in their childbearing years

are considered to be especially vulnerable to VAD. In Guatemala, Honduras, and Nicaragua, these groups represent approximately 40 percent of the total population or 9.6 million. Assuming that 90 percent of these groups consume sugar, the annual cost per vulnerable high-risk person covered would be US\$0.76.

Table 4
Costs of Sugar Fortification in Central America 1998/99
(100,000 metric tons and 5 refineries)

	TOTAL (US\$)	ANNUAL (US\$)
I. INDUSTRY COSTS		
A. PREMIX PROCESSING PLANT		
1. Capital Investment		
Land and plant construction	50,000	5,000
Mixer and installation	25,000	2,500
Other (scales, labeling machine, lab glassware, spectrophotometer, etc.)	25,000	2,500
Total Capital Investment for Premix Processing Plant	100,000	10,000
2. Operating Costs		
10% annual depreciation on equipment		4,500
5% annual maintenance on equipment		2,250
Salaries (2 technicians for 6 months at US\$200 per month)		2,400
Premix transport (3 trips at US\$50 each to 5 refineries)		750
Quality control (materials and laboratory reagents)		1,100
Total Operating Costs for Premix Processing Plant		11,000
Total Annual Costs for Premix Processing Plant		21,000
B. REFINERIES (5)		
1. Capital Investment *		
Dosifiers and installation (US\$7,500 x 5 refineries)	37,500	3,750
Laboratory and quality control (\$2,500 x 5 refineries)	12,500	1,250
Total Capital Investment for Refineries	50,000	5,000
2. Operating Costs		
10% annual depreciation on equipment		3,750
5% annual maintenance on equipment		1,875
Fortificant (100,000/1,000 x 4.5 = 23,000 kg x 36.50/kg)		839,500
Other ingredients (packaging, antioxidant, vegetable oil, nitrogen)		6,000
Salaries (2 technicians x 50% x 6 months x \$200/month x 5 refineries)		6,000
Quality control (US\$ 5,000 x 5 refineries)		25,000
Total Annual Operating Costs		882,125
Total Annual Costs for Refineries		887,125
Total Industry Costs		918,125
Total Annual Costs per Refinery		183,625
Cost per metric ton of fortified sugar		9.18
Retail price per metric ton of sugar		460
Cost of fortificant as a % of retail price		2%
II. STATE COSTS (inspection and household monitoring)**		
1. Capital Investment and Maintenance		
Equipment (spectrophotometer, scales, lab glassware, computer, etc.), 20% use	5,000	500
10% depreciation on equipment		500
5% annual maintenance on equipment		250
2. Inspection and Monitoring		
Salaries and benefits (inspectors), 20% time		5,000
Transportation, per diem expenses, and collection of samples		4,000
Laboratory analysis and reports (including salaries of technicians)		4,000
Quality assurance and monitoring training		2,000
3. Household Monitoring		
Travel, per diems, and collection of samples		1,750
Laboratory analysis and reports (including technician salaries)		4,000
State Costs		22,000
TOTAL PROGRAM COSTS		940,125
Cost per Metric Ton		9.40

* Amortization over 10 years

** Monitoring is conducted through multipurpose household surveys

Lessons Learned

The Central American Context

In order to evaluate the relevance of lessons learned from sugar fortification in Central America, with a view to application of this knowledge in other countries and regions, it is important to examine the particular context in which this experience has developed. Although the countries of this region are, in many respects, similar to other developing countries, there are some specific and important characteristics that warrant consideration.

The Central American region includes six relatively small countries. In 1999, the total population of El Salvador, Guatemala, and Honduras was estimated to be 6, 12, and 6 million, respectively (the urban population accounts for between 40 and 46 percent). The gross domestic product (GDP) per capita in recent years has reached approximately US\$1,700 in El Salvador, US\$1,500 in Guatemala, and US\$600 in Honduras. The percentage of the population living in poverty is between two-thirds and three-quarters of the total, with one-quarter to one-third living in extreme poverty. The annual growth in GDP per capita has been significant in El Salvador since 1992 following the end of a 12-year armed conflict, increasing from 1.5 percent in the period 1965–1980 to 3.5 percent in the period 1990–96. In Guatemala, this figure has followed a downward trend, from 3.0 percent in the period 1965–80 to 0.5 percent in the period 1990–96, while remaining low and stable in Honduras at approximately 1.2 percent. The average rate of inflation between 1990 and 1996 was 11 percent in El Salvador, 13 percent in Guatemala, and 20 percent in Honduras.

Life expectancy at birth in the region ranges between 67 and 70 years. The most recent aggregate rate of malnutrition (low weight-for-age) in under-five children was 12 percent in El Salvador, 33 percent in Guatemala, and 21 percent in Honduras, with a rate of stunting (low height-for-age) of 23 percent, 50 percent, and 40 percent, respectively. Despite relatively low coverage of basic health care services, some public health programs have achieved high coverage levels, especially in immunization (93–97 percent in El Salvador, 74–87 percent in Guatemala, and 89–98 percent in Honduras), environmental health, and food fortification programs. Between 1960 and 1997, the three countries had reduced their infant and child mortality rates by between 70 percent and 80 percent, which by 1997 were only 31–36 per 1,000 live births in El Salvador, 43–55 in Guatemala, and 36–45 in Honduras. In the three countries, approximately 10–11 percent of the national budget is allocated to health, 16–19 percent to education, and 7–11 percent to defense. (UNICEF, 2000)

All three countries have democratic systems based on three branches of government: the legislative (national congress or legislative assembly), the executive (president, ministers), and the judicial. In recent decades, El Salvador and Guatemala have endured long-standing armed conflicts. Generally, the public sector is characterized by its limited capacity and efficiency to set standards and enforce and monitor compliance with legislation, as opposed to the countries' better-organized and more responsive private sector. Problems facing the public sector include frequent rotation of key personnel, low salaries, insufficient resources, lack of technical infrastructure, and high turnover rates among technicians. Food fortification programs are coordinated and monitored by the ministries of health, especially by the departments of food control.

Sugar production in the three countries constitutes one of the most active industries in the economy, representing between 10 and 15 percent of export revenues. Sugar production is essentially a private sector activity, with a relatively small number of easily accessible refineries set up in strategic locations—six in El Salvador, 19 in Guatemala, and seven in Honduras. The three countries are self-sufficient sugar producers and export between one-third and three-fourths of their production. Guatemala is the third largest sugar exporter in Latin America, after Cuba and Brazil. About 30 percent of the sugar produced for the domestic market in each country is used for industrial applications (soft drinks, candy, baked goods, etc.). Sugar is consumed by most (>90 percent) of the population, from all socioeconomic strata. The average daily per capita sugar consumption is >80 g (20 g for preschool-aged children), although approximately 10 percent of the population consumes unfortified brown sugar loaf instead of or together with fortified sugar. This is especially true in isolated rural areas; however, this percentage seems to be declining progressively.

On the whole, the sugar industry is relatively well developed in all three countries, although sugar refineries vary greatly with respect to size and degree of efficiency. In each country, sugar producers have formed strong national associations to represent their interests, and the Central American Sugar Producers Association has established an efficient system of constant communication between national associations. The solid organization of sugar producers in each country, together with their economic power and great political influence, have, in practice, allowed the sugar industry to be protected and somewhat monopolistic. Even so, the industry is always interested in promoting its image and the excellent quality of its product, as well as in protecting its domestic market and in preventing competition from unfortified sugar. Recently, it has begun to expand marketing activities, producing packaged and labeled sugar in a variety of sizes to satisfy consumer needs. With respect to fortification premix, its production is centralized and managed by the national producer associations.

In Central America, sugarcane farming and sugar production is carried out according to an annual harvest system that generally spans six months, from November to April, while the interval between production and the time the product reaches the market can take as much as nine months. Moreover, most sugar produced and marketed for domestic consumption is the sulfated or standard white type, with a relatively small proportion of refined sugar. Central American sugar generally meets the technical specifications set out in the *Codex Alimentarius*, and the fortification technology was developed for this type of sugar. Fortification costs in all three countries, including the original capital investment in equipment and maintenance costs, have initially been covered by producers and subsequently passed on to consumers as part of inflationary price increases.

The lessons learned with respect to sugar fortification in Central America are grouped into the following seven areas: advocacy and promotion; legislation and regulations; technological development; quality assurance and control; program monitoring and evaluation; cost analysis; and sustainability.

Advocacy and Promotion

1. **The starting point in developing a food fortification program with public health objectives is thorough documentation of the nutritional deficiency to establish the scope, severity, distribution, and characteristics of the problem.**

Ideally, this information should be obtained through representative population surveys at the national level; if this is not possible, the dimensions of the problem can be estimated on the basis of partial or regional studies. It has been proposed that universal fortification of one or more foods with vitamin A should be considered when a country meets at least two of the following criteria (Arroyave and Dary, 1996): a) at least 20 percent or more of preschool-aged children have serum retinol levels of less than 20 µg per dl; b) at least 25 percent or more of lactating mothers have breast milk retinol levels of less than 30 µg per dl; c) at least 25 percent or more preschool-aged children consume less than 50 percent of the RDA of vitamin A.

2. **The widespread dissemination of information—regarding vitamin A deficiency, its implications for health and the country's social development, the analysis of alternative interventions, the advantages of fortification, and how to identify fortified products—is an essential element in sensitization, advocacy, and program development.**

This information should be disseminated through all media to the public, and it is especially important that it be provided to sensitize health professionals, academicians, and others (nutritionists, pediatricians, physicians, chemical engineers, etc.) who can form pressure groups in support of policies and programs to control the problem. This information should be both clear and concise and made available to the decision-making levels of the appropriate public (ministries of health, treasury/finance, agriculture) and private (food and pharmaceutical industries, nongovernmental organizations) sectors, with a view to sensitizing them and obtaining their support and commitment to policies and programs.

Before promoting negotiations with the food industry concerning the possibility of fortifying one or several foodstuffs, the public sector needs to be adequately prepared. It should enlist the support of health professionals, academicians, and others, and then prepare itself for the initiative, identifying commitments the government is willing to make to the industry. Otherwise, the industry may lack the incentive to cooperate. The issues surrounding the problem should be discussed openly from all perspectives: causes, consequences, alternatives, potential, limitations, estimated cost, and effectiveness, as well as the market potential and perspectives associated with food fortification.

Universal fortification of staple foods need not require changes in consumer eating habits to be effective. However, media campaigns should be used to begin creating a fortification culture among consumers and to instruct them as to how to identify the fortified product(s). The objective is to generate awareness about fortification as an inherent characteristic of food quality, as well as the importance of demanding and consuming fortified foods. In the case of sugar, this should not prompt consumers to

increase consumption. Labeling of fortified food products, in addition to facilitating government control over these products, is a useful consumer information tool. An effective method for getting the message out about the advantages of fortified foods is to enlist the support of social communicators and journalists, whose articles and programs can help generate public awareness. Public recognition of actors contributing to the achievements of food fortification programs, especially those in the industry, goes a long way in sustaining the commitment and support for these programs and also helps to educate consumers.

In Central America, information was disseminated through meetings, TV and radio interviews, and press releases, but no specific mass media information campaigns geared toward the consumer were implemented to let them know of the advantages of food fortification and the fact that sugar was being fortified with vitamin A. This type of media campaign was implemented for the first time in Nicaragua for wheat flour fortification in 1997 and for fortified sugar in 2000.

3. The presence of an institution with the capacity to bring the involved actors together can help establish and maintain food fortification and other nutrition programs.

International cooperation agencies, working through provision of technical and financial support, may assign priority to the creation and/or strengthening of such national or regional institutions. Media promotion among neighboring countries, with respect to the priority for and decisions regarding the social benefits of fortification, will also contribute to generating the political commitment and will ensure that governments approve the necessary legal instruments to implement the programs. External cooperation agencies can also be effective in catalyzing governments and the industry, disseminating information on the advances and achievements made in other countries, and promoting healthy competition between the countries toward achieving fortification objectives.

4. The participation of producers in a program from its early planning stage is necessary in order to enlist the industry's support for and commitment to these programs.

Legislation, regulations, and technical standards requiring mandatory staple food fortification are necessary, but alone are insufficient to establish and maintain programs. Given the limited capacity of the government in developing countries to ensure compliance with food fortification legislation, it is important to enlist the industry's support for and commitment to these programs. Producers should be invited to participate in a program from its early planning stage; for example, in discussions aimed at preparing the appropriate legislation. The idea is to build an alliance between the public sector and the industry that will mobilize the industry to fulfill concrete public health objectives without negatively affecting its economic/market goals (Slater and Saade, 1999). Ideally, public-private collaboration should lead to an environment in which market-based incentives for both producers and consumers are sufficient to secure the long-term sustainability of fortification. State agencies responsible for drafting and approving legislation and regulations, as well as program monitoring and surveillance activities, should be adequately prepared to assume their responsibilities

in an efficient manner. Inefficient, bureaucratic, and slow-to-respond government agencies may weaken the industry's commitment to the program.

Legislation and Regulations

- 5. Adequate legal or statutory instruments—including a fortification law, standards of identity, technical regulations, and universal labeling—should be in place to support sugar fortification.**

In Central America, mandatory universal sugar fortification as a public health intervention was felt to be needed since the beginning and has been effectively implemented as such. Given the general educational level of the population, consumer-driven voluntary fortification of sugar was not thought an effective way to improve vitamin A intake of those at risk. When mandatory fortification of a staple food is not possible, market-driven voluntary fortification may have a significant contribution to improve micronutrient intake if the fortified foods are made economically accessible to the population at risk. Even when mandatory staple fortification is in place, a policy environment that encourages voluntary fortification of non-staple foods may be developed, with appropriate regulations.

Legislation alone is not sufficient to guarantee adequate fortification. It is crucial to formalize the commitment of producers, importers, and merchants, as well as to secure law enforcement and systematize government monitoring. Each country should determine how to develop the legal instruments needed to establish and regulate fortification (Nathan, 1999.) It is often the case that general “umbrella” legislation or a legal framework is already in place (e.g., health or sanitary code, food code, general health law) that empowers state agencies (e.g., ministry of health) to institute and/or regulate fortification. In such cases, there is no need to follow the long and complicated processes involved in seeking approval for specific laws on individual food products from legislative bodies (i.e., congress or legislative assembly).

Requiring universal labeling of fortified food products is important for monitoring the success of fortification programs and provides a means for defending consumer rights. Universal labeling of commercially processed fortified food products may not yet be possible in some developing countries; however, efforts should be made towards this end as it greatly facilitates government monitoring and consumer education.

In regard to regulations on imported sugar in countries with mandatory fortification, the most practical advice would be to require that all sugar imported or donated for domestic consumption comply with national legislation.

- 6. The establishment of legal criteria regarding the nutrient content of the fortificant in terms of a minimum acceptable level for the consumer is preferable to establishing criteria to govern the production process.**

In cases where a fortificant loses its potency during the marketing phase of a product, as is the case with vitamin A-fortified sugar, it is useful to establish the legal criteria

regarding the nutrient content of the fortificant in terms of a minimum acceptable level for the consumer. This helps facilitate state supervision and also encourages technological improvements. It provides producers with incentives to develop more efficient fortification and marketing techniques to comply with legislation while reducing costs, as less fortificant is required. Likewise, it is important to establish a maximum level of tolerance in order to ensure that the product does not provide an excessive amount of the supplied nutrient.

7. The harmonization of legislative instruments and technical regulations among neighboring countries is needed to satisfy free trade initiatives and agreements.

Free trade initiatives and agreements of the WTO require harmonization of legislative instruments among neighboring countries wherever possible. The harmonization of technical regulations helps to promote trade, compliance with technical standards, and improvements in the quality of processed foods. Harmonization also helps to eliminate possible objections to the mandatory fortification of some foods on the grounds that it constitutes a non-tariff technical barrier to free trade.

8. Given the limited stability of vitamin A in the industrial processing of some soft drinks, the sugar used in the production of such drinks can be exempted from mandatory fortification.

This would also represent a significant cost savings to the industry. However, this measure should only be implemented in cases where there is a system of packaging and labeling in place to identify the producer and prevent leakages of unfortified sugar to the market, and where the government is able to assume efficient supervision and monitoring of the process. In the event that these conditions cannot be guaranteed, it is preferable to establish a universal fortification program. Indeed, universal fortification may be more attractive for producers, as they are not forced to compete with unfortified sugar imports (e.g., those intended for industrial use).

Technological Development

9. The level of vitamin A fortificant should be established based upon per capita sugar consumption and the size of the vitamin A intake gap in the population.

With respect to Central America, it is clear that sugar fortification has had a measurable biological impact on the population, despite the relatively high losses of vitamin A potency (40–60 percent) throughout the production and marketing processes. Given the actual per capita sugar consumption in the region (>80g/day), a level of vitamin A that is equal to or greater than 5 mg per kg of sugar is sufficient to achieve the needed biological effect. If improved fortification technology were to reduce vitamin A loss, these levels could be achieved with less fortificant, thus reducing costs while increasing program effectiveness. Reducing costs is extremely important considering the relatively large amount of economic resources needed to import most of the fortificant and related supplies—resources that are always scarce in developing countries.

10. **Both producers and governments should be kept abreast of advances made in the development of more stable fortifying compounds and better techniques for adding premix in order to incorporate program changes in a timely manner.**

Considerable technological improvements are needed in two areas: a) in the development of more stable fortifying compounds, and b) in the method for adding premix to facilitate better synchronization between the quantity of fortificant added with respect to the amount of sugar to be fortified, thus achieving a more uniformly distributed product. Technological developments in these two areas may eventually lead to revised regulations and technical specifications. External cooperation agencies can play a dynamic role by disseminating any information available in this regard.

Quality Assurance and Control

The absence or inadequate operation of quality assurance systems was one of the most important causes of deficient quality and coverage and of the eventual suspension of fortification programs in Guatemala and Honduras. The advances achieved in program quality and coverage are largely attributable to the implementation of effective systems of quality assurance and control, and monitoring and evaluation. The system that was developed, tested, and implemented in Central America may serve as a basis for designing systems that can be adapted to the specific conditions of other countries.

11. **It is crucial for governments to adopt a positive and collaborative attitude toward producers—instead of a repressive and punitive regulatory disposition—and for producers to assume responsibility for conscientiously ensuring the quality and control of their products.**

The advances made in quality and coverage levels can be attributed largely to the implementation of effective systems of quality assurance and control and monitoring and evaluation that are based on mutual trust between producers and the government, a clear definition of each sector's responsibilities, and the development of simple, efficient, and realistic systems in accordance with available resources.

12. **Depending on the local industry's level of development, it may be necessary for governments to provide training and guidance in quality assurance to refineries, especially during the initial program stages.**

This is needed to establish quality assurance systems in accordance with regulations until the process has been adequately consolidated. However, a government's assistance and monitoring is no substitute for producer responsibilities with respect to quality control and assurance of fortified sugar but is intended to verify that the industry's quality control and assurance system functions adequately. When this does not occur, quality deteriorates. The government and the industry should carry out a joint evaluation of program performance at the end of each harvest. This evaluation should also include data on household monitoring, identify problems that have not been solved, and determine the necessary preventive and corrective measures so that the problems are not repeated during the following harvest.

- 13. The governmental entity responsible for the fortification program may need to design and implement a formal plan for external auditing at the central level, which may gradually shift emphasis from production plants to retail outlets.**

The preparation of premix and its addition to sugar are carried out at the refineries and, together with all other operations, are supervised by the chief production engineer and his or her technicians. Experience suggests there is a need to establish a system of routine supervision for critical operations. This should include a review of records with respect to how much sugar was produced, the amount of premix used, the results of laboratory fortification levels, and periodic routine inspections of refineries to ensure that the vitamin A content of fortified sugar meets the required technical standards.

As the industry modernizes, the production process will improve and efficient quality controls will become established on-site at production facilities. Once that happens, the government's primary focus should be product monitoring at retail locations. When the food industry assumes full responsibility and is equipped with adequate technology, and requirements are established for labeling as well as for the minimum level of vitamin A in retail sugar, government inspections of refineries will become less critical. Effective monitoring can then be carried out through periodic inspections of retail locations and analysis of random sugar samples to determine their vitamin A content. However, this is not possible without an effective system of product labeling. Labeling is particularly crucial in countries that do not have universal sugar fortification.

Program Monitoring and Evaluation

- 14. Program monitoring and evaluation activities can be strengthened at low cost by assessing levels of vitamin A in sugar during other, scheduled household surveys.**
- Analysis of the vitamin A content of sugar specimens collected from a nationally representative sample of households provides relevant information on program coverage and quality. However, implementing household surveys for this purpose only would be too costly. Food samples may be collected periodically (e.g., annually) through multipurpose household surveys carried out by either the ministry of health or other government units. By assessing levels of vitamin A in sugar during existing periodic national surveys, the cost of household monitoring and evaluation of fortified foods can be greatly reduced to include mostly the laboratory analysis. Other low-cost options involve using sentinel schools or communities for collecting household samples (UNICEF, 1996). Despite its low cost, household monitoring and evaluation of fortified foods has depended largely on external financing. Regular budgetary allocations, however small, by the government are needed to secure the long-term maintenance of periodic household monitoring.
- 15. The development of practical, low-cost epidemiological micronutrient surveillance systems is needed to facilitate both program monitoring and impact evaluation.**
- The development of practical epidemiological sentinel surveillance systems on micronutrient deficiencies that can facilitate both continuous program supervision and the

collection of useful data for evaluating program impacts is recommended. Sentinel school systems have been successfully used in iodized salt programs to control iodine deficiency disorders (UNICEF, 1994) and may be worth trying in other fortification programs.

- 16. Under-two children and other groups that may not be covered by the program because they do not consume sufficient sugar on a regular basis should be targeted for periodic supplementation.**

The effectiveness of food fortification programs in significantly reducing the prevalence of VAD among the at-risk population, especially among those over two years of age, has been proven in Central America. However, it is unlikely that this measure alone will be enough to completely eradicate the prevalence of VAD in the entire population, as under-two children and other groups may not regularly consume sufficient amounts of sugar and thus are not sufficiently covered under the program. Accordingly, these groups should be targeted for periodic supplementation with high doses of vitamin A.

Cost Analysis

A highly attractive feature of sugar fortification as a public health measure is its low cost, particularly to the government. Government investment in equipment and operating costs for inspection and monitoring systems for a production of 100,000 MT is estimated at US\$22,000 per year. The overall cost of the program is estimated at \$940,125 (\$9.40 per MT), of which \$918,125 (98 percent) is covered by the industry/consumer, and \$22,000 (2 percent) by the government. The cost of fortification supplies represents about 90 percent of the total.

The following annual estimated costs per person are based on 60 percent of the population at high risk and 90 percent of them consuming sugar, and can be used by other countries as a point of reference for estimating costs:

Annual Costs	
Per capita:	US\$0.27
Per person covered:	US\$0.30
Per high-risk person covered:	US\$0.51
Per vulnerable high-risk person covered:	US\$0.76

- 17. To a large extent, the economic feasibility of fortification depends on whether producers are sufficiently motivated and willing to make the initial investment in necessary equipment, facilities, and inputs, which can be passed on to consumers as part of inflationary price increases.**

In contrast to other interventions, one of the most obvious advantages of food fortification as a prevention and control strategy for micronutrient deficiencies is its low cost to the government. This is because most of the associated costs are passed on to consumers in the form of price increases. The annual cost to the industry for fortification of 100,000 MT of sugar amounts to US\$918,125 (US\$9.18 per MT). About 92

percent (\$845,500) corresponds to the cost of the fortification compound and other premix materials, and 3 percent to the quality assurance/control processes. The total cost of fortification to be covered by the industry and transferred to the consumer is US\$9.18 per MT of sugar, approximately 2 percent of the retail price. With the income derived from the increase in the retail price of sugar, the industry can create a revolving fund to ensure the long-term economic sustainability of sugar fortification. In general, food price control policies are not likely to ensure sustainability of food fortification programs.

18. The government can help facilitate the initial first-year capital investment by acting as the industry's guarantor on financing applications.

In Nicaragua, where sugar fortification was launched in the 1999–2000 sugar harvest, the government assisted the industry in gaining access to sources of financial assistance through a convenient long-term soft loan to cover first-year supplies, while the industry covered the initial capital investment from its own resources. The proceeds from a 2 percent increase in the price of sugar will be used to create a revolving fund to secure long-term financial sustainability.

19. Start-up costs can be reduced by adapting existing facilities for use as premix processing plants, donation of equipment used in premix preparation, or the use of existing laboratory equipment at refineries.

The initial investment for construction and installation costs of a premix processing plant is estimated at US\$100,000, while equipment for addition of premix to sugar and for quality control and assurance processes would cost about US\$10,000 per refinery. The total capital investment for a premix processing plant and the corresponding equipment for five sugar refineries amounts to US\$150,000. Essentially, the initial investment depends on the number of refineries, the schedule of import tariffs, and whether more than one premix processing plant is needed. However, costs can be reduced by adapting existing facilities for use as premix processing plants, donation of equipment used in premix preparation, or the use of existing laboratory equipment at refineries. With respect to the initial capital investment required per refinery, no significant differences among countries are seen.

Sustainability

The long-term impact of a food fortification program depends on the availability of the fortified product, the population's accessibility to it, its quality, and program sustainability. Sustainability is a key element in ensuring a program's effectiveness over the long term. Generally, food-based micronutrient strategies are considered more sustainable than supplementation programs. For the purposes of this document, *sustainability* is understood as the potential for maintaining fortification in terms of coverage, quality, and impact, using local financing sources.

The conceptual framework used to analyze the sustainability of sugar fortification has been adapted from the one proposed for health and family planning programs of USAID's Bureau for Africa, Office of Sustainable Development (USAID, 1999). Two elements are considered

to be fundamental for program sustainability: a) sustainability of supply and the delivery of services (fortified sugar), and b) sustainability of demand for these services by the population (consumers). Both supply and demand systems are framed within the specific political and socioeconomic context of each country or region. Experience with sugar fortification in Central America suggests that the following factors have a significant effect on the different aspects of the program's sustainability.

Sustainability of Supply. The sustainability of supply systems includes three components: a) financial sustainability; b) institutional capacity; and c) political environment.

Financial sustainability

Because the program is almost completely financed by the consumer, it is highly sustainable in financial terms. The cost of inputs used in fortification, especially the cost of the fortificant, represents the largest proportion of program costs (about 90 percent). Generally, the industry is able to assume the initial investment and operating costs (to be subsequently passed on to consumers), representing around 98 percent of program total costs. The public sector contribution amounts to only 2 percent, which makes sugar fortification a very appealing strategy, considering the low cost to the government and its proven effectiveness. Because the program is almost completely financed by the consumer, it is highly sustainable in financial terms; and its sustainability is essentially contingent upon the political commitment of both the government and the industry.

20. **It is important that external cooperation agencies concentrate their financial support in technological development and the design and implementation of policies and programs rather than in assuming operating costs for the system of inspection and monitoring.**

The government is more likely to fail in its efforts to mobilize and allocate the resources needed to fulfill its commitments when external cooperation agencies, in their eagerness to achieve tangible results, substitute the government's role by assuming operating (recurrent) costs for the system of inspection and monitoring (e.g., travel expenses, laboratory materials, and reagents). Frequently, this situation can lead to the government's becoming chronically dependent on these agencies, partly as a result of a weak political commitment, which is encouraged through continuous financial support for operating costs. Instead, external cooperation agencies should concentrate financial support in technological development and technical assistance for the design, implementation, and evaluation of policies and programs. Furthermore, they should avoid covering operating costs, as these costs are ultimately a government responsibility. However, agencies may consider the possibility of sponsoring the establishment of a household monitoring system, which may provide a useful advocacy tool in support of the political commitment and could aid in improving program quality.

Institutional capacity

21. **A governmental unit with adequate managerial and logistic capability, and charged with specific responsibility for program coordination and management, is essential for a well-functioning program.**

The government must possess the minimum infrastructure needed to meet its political commitment to the program and to fulfill functions with respect to political and technical decision making, coordination, the gathering and dissemination of information, legislation and technical regulations, inspection, monitoring, and epidemiological surveillance. Government capacity to fulfill some of these functions can be developed and increased through technical assistance. The minimal initial infrastructure should include the creation of a specific government unit with responsibility for coordinating and managing the program. Accordingly, this unit should have the managerial and logistic skills necessary to fulfill the aforementioned functions. Some of these functions are not limited to the ministry of health, but also include other ministries (treasury/finance, among others) and governmental institutions (e.g., customs). Without the necessary minimum infrastructure, the chances for the program's success are limited. Generally speaking, the sugar industry's infrastructure, and, to a lesser degree, the capacity of the government, have been adequate in Central America; however, this may not be the case in other countries.

22. Research and development organizations at the regional level and national associations/groups can play an important role in providing technical assistance to strengthen institutional capacity.

Traditionally, state agencies have been limited in their capacity to develop and implement food fortification policies and programs. The creation of a national committee or commission with the capacity to bring together actors from all sectors and unite them in a central body for the purpose of promoting fortification could help correct institutional deficiencies and improve the institutional sustainability of the program. Regional organizations may provide valuable support to national commissions. Likewise, the existence of organized producer associations, such as national and regional associations of sugar producers, facilitates a dialog with the public sector, while supporting the political commitment and institutional sustainability of the program.

23. Human resources development and periodic retraining are essential institutional-strengthening activities.

Institutional strengthening is often crucial to the sustainability of fortification programs. Many problems stem from the lack of adequate response from government institutions to program demands regarding continued political commitment, the capacity for law enforcement and monitoring compliance, and the establishment and maintenance of epidemiological surveillance activities. In some cases, these weaknesses are further exacerbated by overly bureaucratic public officials and conflicts of interest that cause distrust among those in the industry, thus limiting program sustainability. Effective institutional development constitutes a public sector problem that has not yet been resolved in many developing countries. The organizational reforms needed in management systems are difficult, slow, and often limited by resistance to change.

The most frequently used strategy for institutional strengthening has consisted of human resources development and periodic retraining. In addition to the need for periodic retraining, the frequent rotation of personnel from different institutional

levels of government represents a challenge for training plans and has significant financial implications. Periodic retraining should be selective, should include both public sector and industry personnel, and should be complemented with follow-up activities. In some cases, limited government technical capacity can be overcome in part by contracting private services, such as laboratory services; however, state responsibility for control and monitoring should never be relinquished. One of the most frequently observed weaknesses of government workers involves their capacity to gather, process, analyze, and use information. Consequently, specific training activities in these areas are viewed as priority.

Political environment

- 24. A solid political commitment of both the government and the industry and an effective policy development and implementation process are key elements for ensuring long-term sustainability of fortification programs.**

Ultimately, factors affecting the political environment can have an influence on the level of political commitment of the government and the industry to ensure the continuity, coverage, and quality of sugar fortification programs. These factors include the dissemination of information and the initial sensitization activities carried out by program promoters at political decision-making levels, both in areas of the public sector (health, finance, commerce) as well as in the sugar industry. Inadequate initial sensitization and the lack of sufficient and timely information were two factors responsible for the relatively low level of political commitment on the part of the sugar industry, which ultimately led to the temporary suspension of the programs in Guatemala and Honduras. With a view to achieving its objectives, the institution charged with promotion of the program should prepare itself in an adequate and timely manner. Thus, before beginning advocacy activities aimed at securing the political commitment and participation of the industry, the promoting institution must first provide the industry with key information aimed at raising awareness among the different decision-making levels and should involve the industry from the earliest planning stages of the program.

In this context, the key information to share with the industry includes the scope, distribution (groups affected), and severity of VAD in the country; its implications for health, the survival and development of children, costs and consequences for the country's economic and social development; as well as possible solutions to the problem, including the advantages and disadvantages of alternative interventions, comparative costs, and the expected biological and social impacts of the fortification program. Identification of the costs and benefits to industry is also important. Activities aimed at the dissemination of information and sensitization of high-level government decision makers and the industry helped to strengthen the political commitment needed to reinstate fortification programs in Guatemala and Honduras, after they had been suspended for several years.

- 25. The political sustainability of fortification programs is strengthened by the creation and effective operation of a multisectoral committee or commission.**

This body is needed to channel information, sensitize, and serve both in an advisory capacity and to bring pressure to bear on the highest decision-making levels. One of the most important functions of such a committee is to guarantee the development of a systematic policy decision-making process for food fortification.

- 26. Regional research and development institutions in the field of nutrition and external cooperation agencies can play a critical role in maintaining communication and dialog in order to ensure the stability of the political commitment to sugar fortification.**

Instituting the program in one country with the support of a prestigious regional institution could stimulate the political commitment of neighboring countries. This would hold particularly true if this regional institution is credible and could bring together actors to advocate, promote, and raise awareness in different countries. Social mobilization and the sustained demand for services can maintain and increase the political commitment to the program. The agreements and commitments reached by countries at international summits, as well as consensus achieved through regional meetings, have played a part in securing government commitments to control VAD.

- 27. It is essential that the government abide by its commitments to the private sector in order to promote the level of confidence necessary to ensure the political sustainability of the program.**

Once the industry has committed to the process, it tends to be more firm and consistent in its resolve than the government. However, the industry's political commitment may deteriorate when faced with public sector indecision, inefficiency, weak law enforcement capacity, and weakened political commitment on the part of the government. In large measure, this reflects differences in the capacity and strength of the industry and the government to fulfill their commitments, as well as in their managerial efficiency.

- 28. Appropriate fortification technology and compatibility between the capacity of existing technology to achieve certain quality results and the technical specifications established by the government are needed to ensure a solid industry commitment.**

Situations in which the government requires technical specifications that are incompatible with available technology give rise to frustration among industry members, weakening their commitment to the process, and also invite corruption of the government bureaucracy.

- 29. Reinforcing policy decision making within the government and the industry requires long-term, ongoing efforts in promotion and advocacy in key areas.**

Oftentimes, the political commitment of the government can become weakened due to factors that cause a change in motivation and/or interest among government decision makers. These include conflicts between priorities and emerging needs of the public health sector (e.g., cholera epidemics, AIDS, measles, natural disasters), interference from economic and commercial interests (e.g., free trade agreements), price-control policies, financial difficulties (fiscal deficits, difficulties in securing foreign currency), rotation of high-level personnel, and conflicts of interest. In Central America, epidem-

ics and natural disasters have tended to cause a shift in government priorities away from ongoing health and nutrition programs, including those for food fortification.

Simply securing a solid initial political commitment does not guarantee the political sustainability of fortification programs. Reinforcing policy decision making within the government and the industry requires long-term, ongoing efforts in promotion and advocacy in key areas, thus ensuring the minimum commitment needed for the political sustainability of the program. Continuous advocacy and promotion is usually undertaken by micronutrient advocates (e.g., local professional groups or individuals), local institutions (e.g., Institute of Nutrition), and/or, more frequently, by international cooperating agencies (USAID, UNICEF, WHO, etc.).

These continuous activities are even more important when personnel responsible for political decision making are rotated frequently. This continuity can be fostered if there is an exchange of timely and accurate information and if mutual distrust is eliminated from the outset of the program. In this way, the conditions would be in place for forming a mutually beneficial alliance between the public sector and the sugar industry. Eventually, formal agreements would harmonize the interests of both parties (i.e., the efficient means of communication would also be established based on mutual respect, ethics, and social responsibility). Important steps to achieving this goal include guaranteeing equal representation of the sugar industry in the multisectoral national commissions on micronutrients and/or food fortification, understanding and being sensitive to the economic and market concerns of the industry, and providing the industry with timely and accurate information on program implementation and impact. In addition, economic and other incentives should be created, such as public recognition of sugar producers for their performance in the program and tax exemptions or reductions on import tariffs for fortification supplies.

Sustainability of Demand. Sustained demand for services is another essential element of program sustainability. The steady demand for fortified sugar helps to sustain a favorable political climate and industry commitment. Essentially, the sustainable demand for a service or product, such as sugar, depends on consumer purchasing power, attitude, and behavior.

The cost of fortification that is passed on to consumers through a price increase is generally so low as to have little effect on the population's purchasing power. Despite the limited purchasing power of the majority of the population at risk for VAD, the portion of the retail price of sugar attributable to fortification passed on to consumers through a price increase at the inception of the program is generally so insignificant (2 percent) as to have little effect on the population's purchasing power. Moreover, when fortification is mandatory and universal, consumers' options are limited because they have to purchase what the market provides.

30. **Information media are key to ensuring that consumers are fully informed and aware of the importance of fortification in health and nutrition, can identify the fortified foodstuff, and, if needed, can eventually take part in social mobilization in support of the program.**

In theory, universal mandatory sugar fortification does not require specific changes in consumer behavior, as there is no option to identify and choose among fortified and

unfortified food products. This is one of the advantages most often cited with respect to mandatory fortification of staple foods. There is, however, a need for communication activities aimed at mobilizing society that provide information to and raise the awareness of health professionals, academicians, consumer-protection advocates, and others, as well as health sector personnel and the general population. The social mobilization efforts that counteracted the 1998 attempt in Guatemala to suspend the fortification program were led by pressure groups made up of health professionals, academicians, and others. In some countries, consumer information on food brands that comply with technical regulations for mandatory sugar fortification have proven effective in increasing the motivation and interest of producers in product quality.

In summary, fortification of sugar, as well as that of other staple foods, is a feasible and cost-effective public health measure with a great deal of potential for long-term sustainability in terms of coverage, quality, and impact. Sugar fortification, along with other specific food-based initiatives, represents a major contribution toward finding a permanent solution to the problem of VAD. Even under favorable economic and social conditions, food fortification is still a type of nutritional insurance that protects the population from changes in the availability and consumption of essential nutrients.

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Annex

PROTOTYPE OF REGULATIONS FOR VITAMIN A SUGAR FORTIFICATION

PROPOSAL PREPARED BY:

**FOOD SAFETY DEPARTMENT OF THE MINISTRY OF HEALTH
REPUBLIC OF HONDURAS**

INSTITUTE OF NUTRITION OF CENTRAL AMERICA AND PANAMA (INCAP)

**INTERNATIONAL EYE FOUNDATION (IEF)/
USAID/OMNI OPPORTUNITIES FOR MICRONUTRIENT INTERVENTIONS PROJECT**

THIRD DRAFT

**Tegucigalpa
September 1998**

GOVERNMENTAL AGREEMENT N° _____
(city, date/year)

THE CONSTITUTIONAL PRESIDENT OF THE REPUBLIC

WHEREAS Article __ of DECREE NUMBER ____-__, of the CONSTITUTION OF THE REPUBLIC, establishes that the State, through its lawfully formed dependencies and Agencies, is responsible for the regulation, supervision and control of foodstuffs.

WHEREAS the SOVEREIGN NATIONAL CONGRESS APPROVED DECREE NUMBER ____-__ of __/__/19__, establishing THE HEALTH CODE, published in the Official Gazette “_____,” number _____ on __/__/19__, and in BOOK __ of HEALTH PROMOTION AND PROTECTION, TITLE __ OF FOOD AND BEVERAGES, regulating food in its different forms.

WHEREAS the SOVEREIGN NATIONAL CONGRESS, acting through DECREE NUMBER ____-__, of __/__/19__, approved the GENERAL FOOD FORTIFICATION LAW regulating domestic production of fortified foodstuffs as well as the importation of foods subject to fortification, published in the Official Gazette “_____,” number _____ of __/__/19__.

WHEREAS Article __ of DECREE NUMBER ____-__ establishes that the MINISTRY OF HEALTH shall issue the necessary regulations for the enforcement of the GENERAL FOOD FORTIFICATION LAW, and shall impose sanctions on those that would violate it.

WHEREAS the CONSTITUTION OF THE REPUBLIC establishes in Article __ that the EXECUTIVE BRANCH shall advocate integrated programs with the aim of improving the nutritional status of _____, as this is a fundamental obligation of the State. Accordingly, the State shall promote and implement measures designed to safeguard the nutritional status of the population.

THEREFORE

In exercise of the faculties and regulatory power therein invested, and in view of that contained in Articles __, __ and __ of the CONSTITUTION OF THE REPUBLIC; BOOK __, TITLE __ of THE HEALTH CODE; and Article __ of DECREE ____-__ of the GENERAL FOOD FORTIFICATION LAW,

APPROVES

THE FOLLOWING:

REGULATIONS OF DECREE NUMBER ____-__: GENERAL FOOD FORTIFICATION LAW.

REGULATIONS FOR VITAMIN A SUGAR FORTIFICATION

CHAPTER I SCOPE OF APPLICATION AND BINDING FORCE

Article 1

The provisions set forth in these Regulations shall apply to all sugar, regardless of type (vitamin A fortified, white, direct-consumption, standard, or brown), sold within the national territory for direct or indirect human consumption, whether domestically produced, imported or donated. These Regulations also include small quantities of sugar prepackaged in envelopes, generally dispensed for use at public eating establishments (restaurants).

Article 2

Sugar sold within the national territory for direct or indirect human consumption shall be vitamin A fortified, in accordance with the GENERAL LAW ON FOODSTUFF ENRICHMENT, as well as that established in the present Regulations.

CHAPTER II DEFINITIONS

Article 3

Insomuch as the present Regulations are concerned, the following definitions shall apply:

Quality Assurance refers to a set of systematic and planned activities designed to ensure that a product or service fulfills established quality standards. Among other facets, the system requires documentation of all quality control activities, definition of system components, designation of responsibilities for each production stage, identification of critical control points, and empirical performance indicators.

Quality Inspections consist of systematic and independent evaluations for the purpose of determining whether quality activities and their corresponding results meet preestablished requirements, and to ensure that such processes have been effectively implemented with a view to attaining the proposed objectives. With respect to **quality audits and compliance assessments**, random sampling shall be conducted in accordance with technical specifications and standard statistical principles.

Sugar refers to the commercial product, the main ingredient of which is saccharose that has been purified and crystallized from vegetable sources (i.e., sugarcane or sugar beets).

Fortified sugar is sugar to which vitamin A has been added in the form of a dry, cold-water-soluble retinol ester.

Unfortified sugar is sugar containing no vitamin A. Unfortified sugar is intended for export, industrial applications that do not involve food (and the industrial manufacture of soft drinks or candy).

Sugar for direct human consumption is vitamin A fortified sugar meeting the technical specifications provided for under the present Regulations, used as a sweetener in the preparation of foods for human consumption.

Sugar for indirect human consumption is vitamin A fortified sugar used by the food industry (sugar used in the manufacture of soft drinks and candy is exempted from this category).

Certificate of compliance is a document issued by governmental authorities or authorized private entities, which officially certifies that a specific product meets the requirements specified in established standards or requirements.

Quality control procedures are techniques and activities carried out by producers to document compliance with technical standards. Accordingly, these procedures employ the use of objective and empirical indicators.

Compliance assessment is a statistical verification that a specific product complies with the corresponding provisions of technical standards or regulations.

Guaranteed date of minimum fortification level is the date, under specified storage conditions, after which the minimum micronutrient content declared on a product's label is no longer guaranteed. Once this date has passed, products should be removed from the market for examination and reconditioning (where applicable) in order to ensure compliance with standards for direct or indirect human consumption.

Inspection is the act of measuring, examining, testing and verifying one or more characteristics of a product or service for purposes of comparison with established standards and regulations.

Tolerance interval is an established range of the acceptable minimum and maximum levels of micronutrient content. Accordingly, 90% or more of individual samples analyzed for purposes of quality control or inspection should fall within this range.

Monitoring, for the purposes of the present Regulations, is used to describe the periodic and systematic verification of product quality and labeling during transport from production centers as well as at distribution and marketing centers.

Prepackaging refers to all packaged or prepackaged foodstuffs prepared for retail sale or use by the food industry in the preparation of consumer foods and beverages.

Corroborating test is an analysis carried out on a reduced number of individual samples as a means for fast confirmation of the characteristics declared on product labels during quality audits and monitoring.

CHAPTER III FORTIFICATION

Article 4

All sugar sold within the country for direct or indirect human consumption shall be fortified with vitamin A at a level guaranteeing a minimum concentration of 5 mg per kg of sugar throughout the

storage life of the product during the marketing stage. With a view to ensuring compliance with this criterion, it is recommended that sugar be fortified during the production process at an average level of 15 mg per kg (tolerance level of 10 to 20 mg/kg). In the case of sugar that is fortified over the course of the year during packaging, compliance with this criterion may vary, but must always guarantee the minimum level established during the marketing stage of the product.

Article 5

Sugar shall be fortified with a dry, cold-water-soluble and nonsegregating retinol ester, which remains stable over the marketing stage and does not alter the organoleptic characteristics of the product. Accordingly, the vitamin A compound employed in fortification is attached to sugar crystals by means of vegetable oil, or any other substance suitable for human consumption, containing the least possible amount of peroxides. The compound containing vitamin A beadlets and the substance used to attach these to sugar crystals shall be known as vitamin A premix.

Article 6

The sale of unfortified sugar shall be solely permitted for non-food industry applications (or for that used in the production of soft drinks and candy), in which cases the seller is required to maintain formal balance sheets detailing these transactions. These balance sheets are provided to the Food Safety Department of the Ministry of Health on a quarterly basis, in accordance with procedures established for this purpose.

CHAPTER IV PACKAGING AND LABELING

Article 7

Sugar produced for direct or indirect human consumption shall be packaged and transported in bags or containers that safeguard the hygienic, nutritional, technical and organoleptic qualities of the product. These bags/containers are to be produced exclusively with safe materials designed for this purpose, and must not subject the product to toxic substances, nor transmit any unpleasant odors or tastes. With respect to the prepackaging of sugar for direct human consumption, it is recommended that the product be packaged in containers of no more than 10 kg.

Article 8

Packaging of sugar for direct or indirect human consumption shall be labeled in the ____ language and include the following information:

- **SUGAR (type) FORTIFIED WITH VITAMIN A;**
- Commercial brand name;
- Net weight in kg (equivalent in pounds may also be included between parentheses);
- Name or registered trade name of producer/packager/importer;
- Country of origin. If Honduras, include the phrase: **MADE IN HONDURAS**. Otherwise, indicate the country of origin and, where applicable, include the phrase: **PACKAGED IN HONDURAS**;

- Corresponding product number in the Food Sanitary Registry; and
- Minimum guaranteed fortification date prominently displayed, employing the phrase: **MINIMUM VITAMIN A LEVEL OF 5 MG/KG, GUARANTEED THROUGH** (month and year).

Article 9

Optionally, to assist the illiterate population in identifying fortified sugar, the product label may contain the letter “A” formed by two stalks of sugarcane; different logos may be included on sugar packaged in other countries.

Article 10

Unfortified bulk sugar (sacks of 50 kg or 100 lbs. or more) shall be packaged and labeled with the phrase **UNFORTIFIED SUGAR FOR INDUSTRIAL USE**. The remaining information on the label shall be in accordance with the corresponding regulations.

CHAPTER V SANITARY REGISTRY AND QUALITY ASSURANCE

Article 11

In order to operate in the country, any individual or legal entity involved in the production, packaging, or importation of sugar shall obtain a license issued by the **Ministry of Health**.

Article 12

Sugar for human consumption shall be assigned a number in the corresponding sanitary registry, to be issued by a competent authority of the Ministry of Health. This registration number shall be included on product packaging.

Article 13

The individual or legal entity (producer/packager/importer) identified on the label of sugar products for direct human consumption is responsible for including the aforementioned information on product labels with respect to quality control and assurance activities, and for maintaining the corresponding records.

Article 14

Facilities and installations used in the fortification and packaging of sugar for direct or indirect human consumption shall comply with the general requirements established in the Health Code and its regulations with regard to environmental health and the suitability of equipment used in the processing of foods for human consumption. The Ministry of Health shall authorize these facilities once the National Commission on Fortified Foods has issued an establishment a certificate of technical compliance.

Article 15

Distributors and vendors of sugar for human consumption shall ensure that retail sugar has been assigned a number in the corresponding sanitary registry and complies with the packaging and labeling provisions set out in the present Regulations.

Article 16

The Food Safety Department of the Ministry of Health is responsible for ensuring product compliance with the provisions set forth in the present Regulations, through site inspections and quality audits at production and packaging centers, monitoring at distribution and marketing centers and, in the case of imported sugar, at customs warehouses. These activities can be based on the results obtained from corroborating tests, performing a quality audit and compliance assessment when warranted.

Article 17

The Ministry of Industry, Commerce and Tourism shall collaborate in fortified sugar monitoring activities at the point of sale, with specific regard to product packaging, labeling and quantity.

CHAPTER VI IMPORTS AND DONATIONS

Article 18

Prepackaged fortified sugar intended for sale within the national territory shall be fortified and labeled in accordance with the provisions set forth in the present Regulations, and stored in customs warehouses until such time as the **Food Safety Department**, in coordination with **Customs authorities**, determines that these products comply with the established procedures in this regard.

Article 19

Fortified sugar imports to be packaged within the national territory and sold for direct or indirect human consumption are only permitted by those individuals or legal entities holding the required license. Sugar imports shall be released in accordance with the procedure described in the preceding article. Centers that package sugar imports must be authorized by the Ministry of Health, after the establishment obtains a certificate of technical compliance from the National Commission on Fortified Foods.

Article 20

Donated sugar shall comply with all provisions set forth in the present Regulations, except for specific cases involving emergency shortages of the product on the national market. Under such circumstances, the State may authorize the provisional importation of sugar with vitamin A fortification levels other than that provided for under the present Regulations, although for limited periods.

CHAPTER VII

VIOLATIONS, SANCTIONS AND PROCEDURES

Article 21

Any activity or omissions found to contravene the present Regulations is considered a breach of public health laws, and shall be sanctioned in accordance with the severity of each case.

Article 22

The sanctions imposed by health authorities for violations of law, regulations, and health provisions regarding sugar fortification are as follows:

- a) Written warnings;
- b) Confiscation of products, raw materials, substances, devices or equipment associated with the violation;
- c) Temporary suspension of imports;
- d) Temporary suspension of sanitary register authorization;
- e) One-time or consecutive fines ranging between ____ to ____, according to the severity of the violation, but not to exceed 100% of the product's value; and
- f) Temporary closure of establishments.

Article 23

The health authorities shall identify and impose sanctions for the violations described in the preceding article, according to their jurisdiction and follows: local authorities, sanctions (a) and (b); regional authorities of the Food Safety Department, sanctions (a), (b), (c), (d) and fines of up to ____; national authority of the Food Safety Department, sanctions (c), (d) and fines of up to ____; and the director-general of the Office on Institutional Development and Regulation, sanction (f).

Article 24

In the event that a fortified sugar producer, importer or packager disagrees with a decision taken by personnel of the Ministry of Health, the Ministry of Industry, Commerce and Tourism, or the Treasury regarding inspection and monitoring activities, the establishment has the right to request a quality audit and compliance assessment within a period of no more than 2 (two) months from the date of the disputed violation. The National Committee on Fortified Foods shall receive advanced notification of the audit date and the corresponding results thereof.

CHAPTER VIII FINAL PROVISIONS

Article 25

In order to ensure compliance with the aims and objectives of the present Regulations, the General Office on Regulation and Institutional Development, through the Food Control Department, shall establish the appropriate mechanisms for institutional and inter-sectorial coordination.

Article 26.

Sugar producers, importers and packagers shall have a period of 6 (six) months to comply with the prepackaging and labeling requirements and the administrative provisions established in the present Regulations.

Article 27

All areas not expressly addressed in the present Regulations shall be adjusted in accordance with DECREE NUMBER ____-__ of the GENERAL LAW ON FOOD FORTIFICATION; DECREE NUMBER ____-__ of the HEALTH CODE; DECREE NUMBER ____-__ of the GENERAL LAW ON PUBLIC ADMINISTRATION; DECREE NUMBER ____-__ of the LAW ON ADMINISTRATIVE PROCEDURES; and AGREEMENT ____-__ of the REGULATIONS FOR THE SANITARY CONTROL OF FOODSTUFFS.

Article 28

AGREEMENT NUMBER ____, containing the regulations established by DECREE NUMBER ____-__, which ordered the fortification of sugar, issued on the ____ day of ____ of 19____, is hereby repealed, together with all other provisions that oppose it.

Article 28.

The present Regulations shall enter into force 20 (twenty) days following its publication in the Official Gazette “____.”

Let the foregoing be known,

MINISTER OF HEALTH

Tables and Figures

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