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9. ABSTRACT

Nutritional surveys of low-income families in Panama and other Central American countries have shown that vitamin A deficiency is a serious problem. Thus in 1969 a research program was begun to assess the feasibility of fortifying white sugar with vitamin A. The research domonstrated the feasibility in terms of the fortification chemistry and technology, the non-affecting of the taste and odor of the fortified sugar, and the physical and chemical stability of vitamine A in the processed product. A meeting of INCAP staff was held with officials of the government of Guatemala in August 1973, to discuss the questions of whether fortification is necessary, effective, efficient, and safe, The conclusions were: under prevailing conditions in Guatemala, fortification is necessary; fortification with vitamin A in the form of retinol palmitate is effective; and the expected ratio of costs to benefits is highly favorable, in comparison with other massive public health programs (about $.03 per year per capita). Fortification of sugar does not pose any toxicity risk. The study group recommended that at a minimum the government initiate a program to supply fortified sugar to rural children aged one to nine at a level adjusted to daily intake recommended by FAO/WHO.

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FORTIFICATION OF SUGAR WITH VITAMIN A IN CENTRAL AMERICA AND PANAMA

INSTITUTE OF NUTRITION
FOR CENTRAL AMERICA AND PANAMA
(INCAP)

Guatemala, Central America
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FORTIFICATION OF SUGAR WITH VITAMIN A

IN CENTRAL AMERICA AND PANAMA

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The 10-Year Health Plan for the Americas formulated at the III Special Meeting of Ministers of Health of the Americas, and published by the Pan American Health Organization in January 1973 (Official Document No. 118), contains among others, the following two targets for the member countries:

"Reduction of the present prevalence of hypovitaminosis A by 10 to 50% (30% regional average)" and "Promotion, where necessary, of legislation required to assure the fortification of selected basic foods with iron, vitamin A, vitamin B complex, proteins, and amino acids."

The Ministers of Health of Central America and Panama, during their XVI Annual Meeting held in Panama, in June 1971, resolved to: "Recommend to the respective governments the fortification of sugar with vitamin A as a practical and effective method for correcting the prevailing vitamin A deficiency, and to urge them to take all measures necessary to overcome all economic, legal, and administrative difficulties that might occur in the application of the program in each one of the countries."

I. INTRODUCTION

The role of vitamin A as an essential nutrient has been amply documented during the past few years. (1) The consequences of vitamin A deficiency are dramatic both for animals and humans. Growth, in general, specifically the integrity of various tissues, in particular the epithelial membranes, are greatly affected. The latter alteration is actually responsible for reduced resistance to infections. The function most affected by vitamin A deficiency is vision which is early altered. The subsequent appearance of eventual ocular lesions could result in severe damage and permanent blindness. It has also been demonstrated that vitamin A deficiency leads to a decline in the utilization of dietary proteins while relatively high intakes of the vitamin increase protein utilization, particularly of low nutritional quality proteins. (2)

All these findings point out definite health benefits of adequate vitamin A intake, especially considering that millions in underdeveloped areas of the world exhibit a severe or moderate deficiency of this nutritional factor. (3) Furthermore, the problem is aggravated by the fact that vitamin A deficiency is usually accompanied by protein deficiency.

The Central American countries and Panama are no exception. (4) Severity of this nutritional condition becomes even more evident if one analyzes the distribution of vitamin A intake by the respective populations, as indicated in table I.

Levels of vitamin A in blood serum are a good indicator of the adequacy of nutritional status in regard to vitamin A. (5) Levels lower than 10 µg/100 ml are classified as "deficient" while concentrations varying between 10 and 19.9 µg/100 ml. are considered "low." In population studies it has been suggested to use as evidence of vitamin A deficiency serum levels lower than 10 µg in 5% or more of the sample, or levels lower than 20 µg in 15% or more of the study population. (6)

Table II summarizes the number of children under 15 years of age with "low" and "deficient" vitamin A levels in the Central American area.

Sources of pre-formed dietary vitamin A (retinol)*, which is the most effective form, are scarce and very expensive. Accordingly, they are not consumed in sufficient amounts by the majority of the population. Green and yellow

*Retinol is the chemical name of the pure vitamin found in foods of animal origin.

Table I

NUTRITIONAL SURVEY IN CENTRAL AMERICA AND PANAMA (1965-1967)

Country	Number of families surveyed	Level of adequacy of vitamin A in diet (percent of adequacy)				
		< 25	25-49	50-74	75-99	100 or more
		- Percent of families at each level -				
Guatemala	200	45	22	10	6	17
El Salvador	278	69	19	7	3	2
Honduras	323	57	26	9	2	6
Nicaragua	331	45	23	13	8	11
Costa Rica	414	44	26	11	7	12
Panama	352	42	32	13	5	8

TABLE II

NUTRITIONAL SURVEY IN CENTRAL AMERICA AND PANAMA (1965-1967)

Prevalence of Hypovitaminosis A in Children Younger than 15 Years
(Determined According to Serum Levels)

Country	0-4 years		5-9 years		10-14 years		0-14 years	
	Percent prevalence	Number of cases	Percent prevalence	Number of cases	Percent prevalence	Number of cases	Percent prevalence	Number of cases
Guatemala.....	26.2	219,100	16.2	108,300	11.1	62,700	18.8	390,100
El Salvador....	43.5	241,200	43.5	190,700	22.4	82,300	37.8	514,200
Honduras.....	39.5	137,000	29.0	81,200	21.9	51,609	31.3	269,800
Nicaragua.....	19.8	56,900	18.5	50,500	6.4	14,400	15.5	121,800
Costa Rica.....	32.5	96,600	25.6	60,300	11.7	22,400	24.6	179,300
Panama.....	18.4	38,300	12.1	20,600	9.7	13,600	14.0	72,500
Total	31.2	789,100	24.7	511,600	14.3	247,000	24.4	1,547,700

Note: Based on population estimates of July 1965.

vegetables, a source of carotene (provitamin A) are more readily available. However, in actual practice, their consumption is very low due mainly to economic-cultural reasons. Furthermore, the carotenes are much less effective than retinol in terms of vitamin A activity. (7)

Modification of patterns pertaining to production and consumption through socioeconomic, agricultural, and educational measures which would be the permanent solution of the vitamin A deficiency problem would take a long time. However, the extent of the problem is such that application of more rapid emergency measures is justified. An adequate measure would be the incorporation of an appropriate amount of vitamin A in the diet of the population by means of fortification of a convenient vehicle. This approach has proved to be quite effective for other nutrients in many instances. The best example is the introduction of iodine in table salt (the vehicle). The addition of iodine to all table salt consumed in Guatemala, for instance, reduced the national prevalence of endemic goiter from 38% to 5% within 9 years.

On the basis of these observations, a program was started in 1969 to attempt fortification of a suitable vehicle with vitamin A.

II. PROJECT DEVELOPMENT

A. Selection of the Dietary Vehicle

A vehicle suitable for the purposes of the present project should present the following characteristics: (1) It must be consumed by the entire population; (2) there must be little variation in its day to day *per capita* consumption; (3) fortification should result in unappreciable change of the organoleptic characteristics of the vehicle; and (4) the cost and nature of the vehicle must be such as to allow an economically feasible industrial process.

On the basis of these characteristics, white sugar was selected as the vehicle for this project. Initially, table salt was considered. However, subsequent calculations revealed that it does not fulfill requirement No. 4, due to the low daily per capita salt consumption of the population and its high cost. In contrast, sugar does fulfill all characteristics. Besides, sugar production is centralized in a few technically well-equipped factories, so that the addition of vitamin A would not raise any serious problems.

B. Selection of the Vitamin A Preparation

The basic characteristics of the product were established as follows:

1. It must be water-miscible or water-dispersable.

2. It must be appropriate for preparation in the form of a sugar-based premix physically stable (not segregable).

3. It must be undetectable by taste, smell, or any other organoleptic characteristic, when mixed with the sugar in the proposed concentrations.

4. It must be sufficiently stable and present in a high enough concentration to assure ingestion of vitamin A at a level that would significantly contribute to preventing a deficiency of this nutritional factor in the general population.

5. Its cost should not affect significantly the price of the final product.

C. Process

All the laboratory and industrial tests made up to the present time, as well as economic considerations, indicate that we have found a process that satisfies all requirements for industrial application, and, at the same time, yields an entirely acceptable fortified sugar.

The following paragraphs describe the results of the technical tests and scientific experiments that led to the conclusion expressed above, as well as observations regarding the applicability of the project, both from the technical and the public health view points.

1. Design of the industrial process

Tests in the laboratory and on an industrial scale were started in 1969. A water-dispersable vitamin preparation especially manufactured for the purpose of being added to foodstuff intended for human consumption was initially selected.* A premix was made with 1 part retinol palmitate + 9 parts sugar. This premix was then added to the sugar in the final stage of the production line by means of a mechanical feeder activated by a motor. In many respects, the process was satisfactory. There were, however, two unsolved problems: (a) synchronization of the rate of sugar production with speed of the vitamin feeder in order to assure a fully uniform time distribution (a reduction in the sugar flow accompanied by maximum addition of the vitamin mixture could have resulted in variations in the final concentration of the various sugar lots), and (b) the tendency of retinol palmitate in the premix to separate from the sugar, another undesirable feature.

In order to solve these problems, an investigation was carried out to obtain a physically stable (non-separating) premix. This was achieved by mixing dispersable retinol palmitate with sugar by a process yielding a premix that does not segregate.

The premix thus obtained is also chemically stable. It has been stored, at room temperature (18-32° C) for 9 months, without taking

*Retinol palmitate 250 SD Hoffman-LaRoche, Basel, Switzerland.

any special precautions. It was exposed to air with only an insignificant 9% decline in strength. This particular premix was used to test, both in the laboratory and on an industrial scale, a new low-cost and very simple process for adding the vitamin to the sugar. The process provides for the addition of the premix in the centrifuge of the sugar manufacturing plant. The detailed description of this process can be found in appendix 1. The main advantages of the process are: (1) The system regulates the amount of premix added to the sugar, thus solving the problem mentioned earlier; (2) it does not require any special equipment for the addition of the premix or more personnel. Industrial scale trials made with the new method yielded excellent results (appendices 2 and 3).

2. Quality control tests of the fortified sugar

The tests applied to the fortified sugar prepared according to the new process are described in the following paragraphs.

In May 1973, an amount equal to 5 metric tons was prepared at a sugar mill in order to test the feasibility of the process described in appendix 1. The worker in charge of operating the two centrifuges added the premix practically without supervision, after having received the necessary instructions. Results on the distribution of vitamin A in the various sugar sacks sampled at the time of shipping are presented in appendix 3. The average vitamin A level was 14.7 µg/g, as compared to an expected theoretical concentration of 15 µg/g, a difference of 2%. Standard deviation was 0.35, with a variation coefficient of 0.02%.

a) Organoleptic characteristics: Acceptability

The sugar prepared in the manner described above was subjected to a series of "blind" acceptability and taste detection tests in various population groups, including INCAP's employees who ate at the cafeteria, and welfare institutions. The fortified sugar was substituted for regular sugar for periods lasting from 2 weeks to 4 months without any warning. In these tests, closely representing actual conditions, consumers failed to detect any difference in the sugar.

Furthermore, a technically better controlled test designed to allow statistical analysis of the correct and incorrect responses was also used in order to determine scientifically whether the fortified sugar had any special taste or not. The test is described in appendix 4, together with examples of the results obtained. These results indicate that the members of the panel were absolutely unable to tell the difference between the two types of sugar. Tests made with hot coffee and tea; orange, pineapple, and lemon drinks; Fresca Avena; and Incaparina yielded consistent results.

b) Physical stability

Physical stability tests were designed to determine the degree of separation of the vitamin preparation from the vehicle. Such separation could produce variation in the concentration of the vitamin in various sugar sacks. To obtain results applicable to actual practice, special care was taken so that experimental conditions resembled closely real conditions. The results obtained are summarized in table III. Test Nos. 1, 2, and 3 were performed with sacks of sugar fortified and filled in an industrial scale operation performed at the sugar mill. The sacks were stored in a warehouse at the sugar mill and, about 1 month later, moved to warehouses in the capital and to INCAP where they were used on the dates shown in the table under "Sampling Date." For this purpose, sugar from these sacks was used in a restaurant until totally consumed. Upon opening the sack, one sample was taken from the top; the second was taken 2 days later after 1/3 of the sack content had been used; the third sample was taken when the level of the sugar in the sack decreased by 2/3; finally, the fourth sample was taken from the bottom of the sack, with only about 1 pound of the sugar left. During the entire period of industrial preparation, the sugar sacks were handled normally.

Test No. 4 was performed with a 100-pound sack of fortified sugar prepared at INCAP and stored in the laboratory. The sack was subjected to ordinary handling and sugar samples were taken from the same levels as in the previous trials. The results shown in the table are representative of the concentrations identified at the various sack levels, expressed as a percent of the average value.

Results are not all surprising, considering that the premix used to prepare the fortified sugar was fully non-separable, and also taking into account its crystalline physical form (sugar crystals). Findings indicate that the mixture is physically stable and that there was no accumulation of vitamin A at the bottom of the container.

c) Chemical stability

The pure vitamin A is sensitive to the action of oxygen. However, the water-dispersable preparations used in the present sugar fortification process represent special forms of the vitamin made purposely for enrichment of food and forage, and are much more resistant to oxygen and heat. The stability data supplied by the producers were a very significant factor in the initial selection of the most suitable preparation. On the other hand, both the premix and the fortified sugar have been subjected to stability tests to determine the rate of vitamin recovery at various times after being manufactured and stored in open containers and sacks, without taking any special precaution. Results

TABLE III

TESTS FOR THE SEPARATION OF RETINOL PALMITATE FROM SUGAR

Test number	Date of manufacturing	Sampling date	Distribution of vitamin A in the bags (percent of the average)			
			Top	1/3 level	2/3 level	Bottom
1	5/16/73	6/14/73	93.3	95.6	104.5	105.2
2	5/16/73	8/20/73	102.8	99.4	99.4	98.5
3	5/16/73	1/11/74	91.8	91.8	96.6	119.6
4	8/10/73	9/4/73	101.7	99.0	99.0	100.4

of trials lasting up to 9 months indicate a rate of recovery varying from 70 to 85% of the initial strength. These rates must be regarded as highly favorable considering the average lifetime of commercial sugar in Guatemala. The new crop starts in November, when practically all the sugar obtained during the previous crop is exhausted, and lasts until May or June. Sugar produced by any one crop period is used relatively fast. Sugar produced during the last months must be kept as a reserve to cover market requirements for July to November. According to these data, the maximum storage period for some lots of sugar is about 5 to 7 months.

Nevertheless, individuals ingesting sugar fortified with 70-85% of the initial strength of 50 I.U. per gram (15 µg/g) for a short time during the year draw substantial nutritional benefit. The degree of stability determined during these tests is considered satisfactory for the application of a process of this type. The stability of vitamin A in the sugar is not any worse than that encountered in the pharmaceutical preparations available in the market and whose cost renders them inaccessible to the great majority of the population. Of course, investigations shall continue in order to find new methods for improving this particular aspect.

d) Proof of biological effectiveness

Although the biological activity of the retinol palmitate preparation used had been fully demonstrated by the manufacturers, it was decided to verify it in the stored sugar mixture by means of chemical stability tests described. Furthermore, tests were performed in experimental animals and in man with fully satisfactory results.

Figure 1 summarizes the findings of a depletion-repletion study carried out in rats. The fortified sugar used in this test was manufactured on an industrial scale and, at the time when it was administered to the animals, it had already been stored for an average of 3 months. It is evident that its potency (repletion of the hepatic stores) is similar to the control sugar containing 16 µg of retinol/gram. The expected level of vitamin in the test sample was 15 µg/gram.

A more complex study was carried out in a low socioeconomic level population in El Salvador. The biological activity of the fortified sugar ingested ad libitum was tested in a group of women over a period lasting from the 6th month of pregnancy through the 4th month of lactation. Some of the parameters used to estimate the biological availability of retinol in the sugar were the determination of vitamin A in maternal blood serum, in the sera of the nursing babies, and the vitamin content of maternal milk. The data obtained in the study group were compared with those of a control group that received unfortified

Figure 1

BIOLOGICAL ASSAY OF THE ACTIVITY OF VITAMIN A IN SUGAR FORTIFIED WITH RETINOL PALMITATE

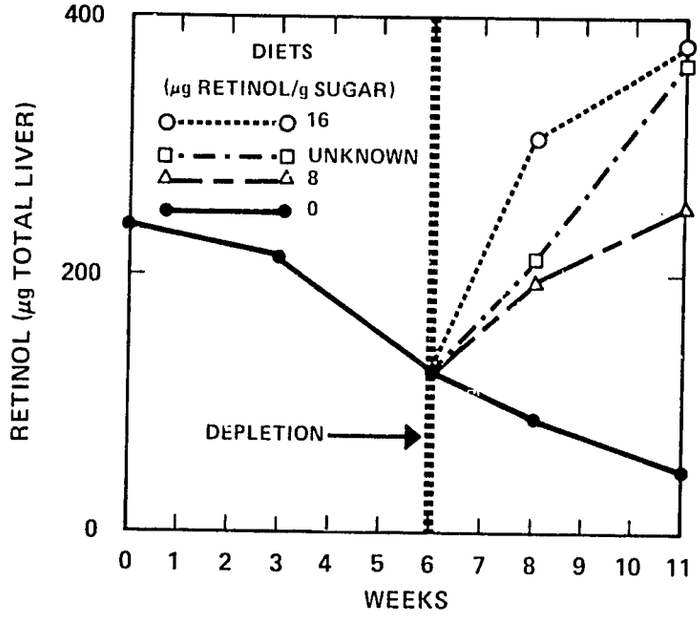
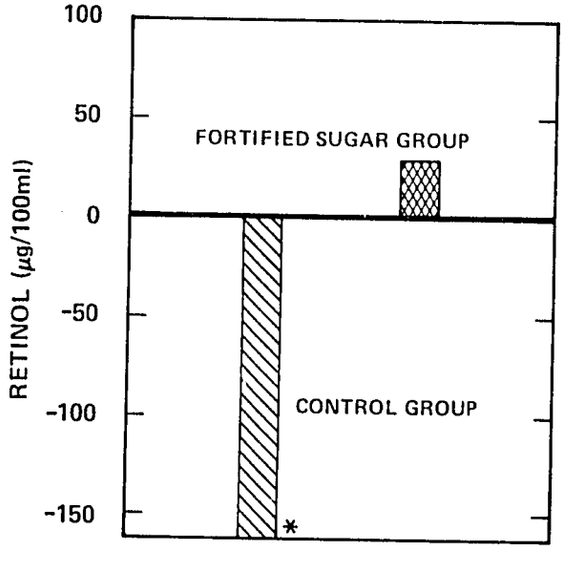


Figure 2

ALGEBRAIC SUM OF THE EXCHANGE OF VITAMIN A IN MATERNAI MILK BETWEEN MONTHS 2 AND 4 OF LACTATION



* t (x – 0) = 4.09 (N = 11); P 0.01.

sugar. The vitamin A levels were higher in the group that received the fortified sugar. The most significant finding, however, was the fact that the breast milk of control mothers at the 4th month of lactation had alarmingly low levels of vitamin A, while the corresponding levels in the group consuming fortified sugar had not changed or were slightly elevated. This particular finding, shown in figure 2, demonstrates that vitamin A in the sugar is biologically utilizable.

III. ADDITIONAL CONSIDERATIONS

Finally, this report presents the results of the discussions of a Study Group on the Fortification of Sugar with Vitamin A held at INCAP on August 3, 1973. This group consisted of members of the INCAP scientific staff together with the Chief of the Maternal and Child Division and the Director of the Department of Nutrition of the Ministry of Public Health, Guatemala. The members of the team were representatives of the following disciplines: clinical nutrition, biochemistry, physiology, public health, dietetics, and food chemistry.

The meeting was moderated by Dr. Moisés Béhar, Director of INCAP. Topics for discussion were presented in the following sequence:

1. Is fortification necessary?

2. Is it effective?

3. Is it efficient?

4 Is it safe and free of undesirable side effects both for the individual and for the population?

5. What is the desirable level of fortification?

In considering these questions, Dr. Béhar pointed out that all technical and administrative features assuring the operation of the process had been resolved, especially those pertaining to the homogeneous and constant distribution of vitamin A in the vehicle.

1. Is fortification necessary?

An analysis was made of the evidence obtained during the various investigations conducted by INCAP showing that a large proportion of the rural population of Guatemala, especially small children (1-9 years of age), have low serum vitamin A levels indicative of inadequate stores of this vitamin in the liver. This is attributed to the type of diet. The average vitamin A intake appears greatly inadequate when compared with the daily recommended allowances of FAO/WHO. Cases of severe clinical vitamin A deficiency, such as xerophthalmia and keratomalacia, are relatively infrequent in the general population. However, such manifestations are

not rare in the pediatric wards of general hospitals where they are found accompanied mainly by severe protein-calorie deficiency. It was pointed out that the acute clinical manifestations are the final signs of vitamin A deficiency and that the available evidence indicates that deficient intake could have undesirable early consequences such as growth retardation, night blindness, and low resistance to infections. The question was raised whether it would be advisable to correct one dietary deficiency when some others are still present, in this case vitamin A, without correcting the caloric and protein deficiencies. In this regard it was mentioned that an effort must be made to supply the entire population with sufficient amounts of a given nutrient to fulfill the nutritional requirements, as a public health measure, even when there are other deficiencies which, naturally, must also be corrected. The latter concept applies to fortification, considering that no short-term changes are expected in the socioeconomic structure that would result in an improvement of the diet, including agriculture, education and economy.

Conclusion: Under prevailing conditions in Guatemala, fortification is necessary.

2. Is it effective?

The form of the vitamin A used for fortification is retinol palmitate prepared according to a special industrial process that produces a water-dispersable product. Evidence was presented to the effect that this type of product is perfectly assimilated and utilized by the organism as demonstrated by experiments carried out in both animals and humans. Vitamin A stores in the liver and serum levels increase, and milk of nursing mothers presents increased concentrations of the vitamin.

Conclusion: Fortification in the proposed form is effective.

3. Is it efficient?

Efficiency is measured by a cost-benefit ratio. The discussion revealed that, on the basis of known precedents, the application of such a program at a national level should be based on the following hypothesis: "The fortification of sugar with vitamin A should correct the deficient intake of this vitamin for the majority of the population."

The ratio of centrifuged white sugar consumption, the only sugar subjected to fortification, to unrefined brown sugar consumption indicates that one population group will benefit little or not at all from fortification. However, it is estimated that, at the present time, coverage of the program will be over 80% of the population, a figure which in terms of public health is very satisfactory. Data supplied by the national economic agencies indicate that the production and consumption of unrefined brown sugar is decreasing since the latter is not expected to compete favorably with white sugar, a product prepared in a more modern and efficient form (appendix 5).

Evidence yielded by cost studies indicates that the required investment is about $0.10 (U.S.) per 100 pounds of sugar. Another method for estimating cost is the following: It costs about $0.03 (U.S.) per year to supply each Guatemalan with an adequate supply of vitamin A representing approximately 75% of his daily recommended intake.

Conclusion: The expected cost to benefit ratio is highly favorable in comparison with other massive public health programs.

4. Is it safe for the population?

It was recognized that ingestion of vitamin A in amounts well above normal nutritional requirements is toxic. During the discussion, the following four factors were considered:

(1) Variation in sugar consumption.

(2) Variation in the consumption of vitamin A from the usual natural dietary sources.

(3) Consumption of vitamin A-fortified products.

(4) Consumption of vitamin A-containing pharmaceutical preparations, obtained with or without prescription.

Examination of variables (1) and (2) revealed that the following situations could occur: high sugar consumption (1-A) and low sugar consumption (1-B); high natural vitamin A consumption (2-A) and low vitamin A consumption (2-B), which results in the following combinations:

Sugar 1	Natural Vitamin A 2
A	A
A	B
B	A
B	B

Furthermore, it was considered that combination A-A, i.e. high sugar consumption and high natural vitamin A consumption is the most likely to result in toxic levels, and that an evaluation should be made of its possible occurrence in actual practice. Data were presented indicating that a fortification level of 60 I.U. per gram (the highest concentration taken into consideration) is practically impossible to achieve, and that the risk of occurence of this combination with the participation of natural diet and sugar only is unlikely. The data supporting this particular conclusion are to be found in an article presented by Dr. Guillermo Arroyave at the Western Hemisphere Nutrition Congress III. (8) (appendix 6).

In reference to point 3, there was agreement that the addition of vitamin A to any other foodstuff such as flour, beverages, etc., must be ended upon the practical application of sugar fortification at the national level. As for point 4, it was recommended that an intensive campaign be made by the public health authorities (and by INCAP) to prevent the indiscriminate use of vitamin supplements containing high vitamin A levels once the sugar fortification programs were implemented.

Mention was made of the fact that the dangers of toxicity which, in actual practice, occur only as a result of overdoses of pharmaceutical preparations, will not increase significantly subsequent to fortification.

Conclusion: Fortification of sugar does not imply any toxicity risk.

5. What is the desirable level of fortification?

Considerations discussed in previous paragraphs are closely related to decisions regarding the levels of fortification. The following proposals were discussed:

a) The addition of 750 µg retinol to the average amount of sugar (36 grams) consumed in rural Guatemala (daily intake recommended by FAO/WHO). Considering that even underpriviledged groups already ingest certain amounts of vitamin A, this vitamin A level was considered unnecessarily high.

b) Fortification at a level capable of correcting the average deficiency of vitamin A consumption in the general population. For example, if the average ingestion is only 50% of the recommended allowance, 375 µg of vitamin A would be added to 36 grams of sugar.

c) The addition to the average amount of sugar consumed by 1 to 9-year-old children in the rural area of the amount of vitamin A recommended by FAO/WHO for this age group. Considering that epidemiological evidence indicates that this is the most vulnerable population group, decision was made in favor of the latter alternative. Example: If average daily sugar consumption in this age group averages 20 grams, the amount of added retinol would be 300 µg (approximate recommended daily intake) or 15 µg/g.

Conclusion: The recommended level was that that shown in alternative c). Finally, the Study Group pointed out the need for a suitable system of supervision and awareness of the process and its effect on the population, not only for evaluation purposes but also for dispelling any existing doubts regarding the various aspects of the program and application of any changes that might be necessary.

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APPENDIX 1

PROCESS FOR THE INDUSTRIAL PRODUCTION OF VITAMIN A FORTIFIED SUGAR

Objective

The purpose of the process is to add a certain amount of vitamin A to sugar for human consumption in order to increase intake of this vitamin in countries where the diet does not supply sufficient amounts of this nutrient to meet the daily requirements.

Basis

The history and justification for implementing this process have been discussed earlier; the characteristics of the mixture of the vehicle and the fortifying agent have also been commented. Basic research in this respect has been completed at INCAP.

This experience includes studies on the type of sugar and the vitamin A preparation to be used, stability of the vitamin A activity in the fortified sugar, physical stability of the mixture (lack of separation), biological effectiveness, and flavor and acceptability tests. Results of these studies are presented in a series of INCAP reports and lead to the conclusion that the process described in this document is feasible and effective. In addition, it does not imply any risk for the population.

A careful estimate of the possible intake of toxic amounts of the vitamin as a result of ingesting fortified sugar led to the conclusion that, based on normal consumption, such a probability does not exist.

Description of the Process

Sugar. Selection of the type of sugar depends on consumption habits of the great majority of the population at risk. In Guatemala, for example, white table sugar, centrifuged and washed ("Plantation White"), was chosen. In other countries the process can be equally applied to refined sugar.

Vitamin A. The product must be water-dispersable and meet the appropriate physical and chemical conditions to avoid alteration of the organoleptic characteristics of sugar, while yielding a stable mixture. At this time, tests have shown that the product used, based on retinol palmitate (Hoffman-LaRoche), fulfills these conditions. Of course, other products could also be considered, after careful testing of their characteristics.

Premix. Tests in this respect have been carried out in the laboratory and on an industrial scale with a premix consisting of 1 part of the vitamin preparation and 9 parts sugar. When applied according to the addition process (in the centrifuge) described below, the method yields highly

satisfactory results, including good physical stability of the final product (lack of separation). A physically stable mixture of sugar and retinol palmitate containing 30,800 I.U. vitamin A per gram and presenting even more suitable properties was prepared at the Hoffman-LaRoche laboratories, in Basel, Switzerland. This premix was also tested at industrial level with excellent results.

Level of fortification. This parameter must be determined according to characteristics of each particular region or country, taking into account sugar consumption and degree of vitamin A deficiency in the diet. For example, on the basis of conclusions reached by a Study Group at INCAP,* the proposed level for Guatemala and Costa Rica is 50 I.U. (15 μg) per gram of sugar.

Description of the Process

The process described herein is the one that research has demonstrated to be the most feasible, economical, and suitable. As shown below, it does not require either special equipment or additional personnel. No additional supervision is required at the sugar mill. The same employee who supervises the other production operations (most of them much more complex) is in a perfect position to take care of it.

The premix is added at the level of the centrifuges in the production line during the manufacturing of white sugar. The addition of the premix is done at the end of the centrifugation operation, after washing, and immediately prior to discharge from the centrifuge. The addition at this stage prevents loss of vitamin A in molasses and washings, as demonstrated by laboratory analyses, and can be performed by the same worker who operates the centrifuge. Automatic centrifuges do not present any drawback.

The amount of premix to be added is measured with a metal (tin can) container filled with the amount required. The necessay amount of premix is calculated according to the weight of the load of the centrifuge (dry sugar equivalent) and the level of fortification desired. For example, at the El Salto sugar mill in Guatemala this amount was determined as follows:

Load of the centrifuge (dry equivalent)	2.60 qq** (119,600 grams)
Concentration of the premix	30,800 I.U./gram
Desired concentration in the sugar	50 I.U./gram
Amount to be added per centrifuge:	50 x 119,600 = 5,980,000 I.U.
	$\frac{5,980,000}{30,800}$ = 194 grams of premix or 74.6 grams per qq

* The Group consisted of INCAP professionals in the field of Nutrition and Public Health, and representatives of the Direction General of Health Services of the Government.
** 1 qq = 100 lb. (46 kg).

Following its discharge from the centrifuge, sugar enters the dryer where a perfect mixture is achieved. Specific tests performed at this stage have demonstrated that no destruction of vitamin A takes place as a result of the heat in the dryer. Distribution is fully satisfactory.

Control. Efficiency of the process can be controlled by sampling the sugar during packaging. INCAP has developed two methods for the determination of vitamin A in the sugar. One of these methods is more accurate and requires a laboratory with facilities not readily available in industry. This method is used at a higher level for a more accurate quality control of the process. The other method is simpler and cheaper and indicates whether the sugar is fortified and the degree of fortification with an approximation of ± 2 µg/gram. The simplicity of this method renders it applicable in any public health laboratory and also in the sugar mill itself. It does not require qualified laboratory personnel or special instrumentation. The method can be used to analyze a large number of samples daily, at the rate of 3-5 minutes per analysis. Cost per sample amounts to 2-3 cents (U.S. dollar).

APPENDIX 2

TESTS MADE WITH A SIMPLIFIED METHOD FOR THE INDUSTRIAL BLENDING OF VITAMIN A IN SUGAR

March 5, 1973

Initially, a system was designed for the addition of a premix of 1 part retinol palmitate* and 9 parts sugar by means of a feeder activated by an independent motor. The set-up was placed at the end of the production line, at the point where the sugar leaves the dryer and is ready to enter bags. The premix fell by gravity over an inverted cone which distributed it in a fan-shaped form over the flowing sugar. Rate of feeding was regulated by adjustments in the feeder, although the entire set-up was independent of the rate of the sugar flow. The facility described presented two drawbacks: (1) The chance of obtaining a perfect mixture was limited, since the feeder was not followed by any mixing operation; (2) the rate of the sugar flow could vary while the rate of the feeder remained constant, thus yielding occasional variations in concentration.

As a result of these problems, a new and more constant method was considered for adding the premix in the form of batches at the level of the centrifuges, before the dryer.

The new system presented at least two advantages. The amount of sugar in the centrifuge (the load) is fixed and well known, except for instances of poor yields (although in this case the weight of sugar in the load can be predicted). Since the load is known, the operation consists of adding the exact amount of premix to each load, before the washed sugar enters the dryer. The dryer in this case also performs as a mixer, since the sugar is tumbled there for 1-2 minutes. The suspected drawback, at the time, was the possible degradation of vitamin A by the heat in the dryer (+90° C). This possibility was tested by humidifying fortified sugar at the 1% level (the humidity level prevailing in the centrifuge), drying it in the laboratory at a temperature of 105° for 1, 3, 5, and 10 minutes. The following results were obtained:

1 minute	16.9 μg/g
3 minutes	16.3 μg/g
5 minutes	16.4 μg/g
10 minutes	16.9 μg/g

According to these findings, the product remained completely stable.

*Hoffman-LaRoche 250 SD.

Pilot trial made at the El Salto Sugar Mill

A batch of 50 kg. of premix was prepared in the laboratory using El Salto sugar and retinol palmitate. According to the weight of the wet load (1% humidity), 2.63 qq*, it was estimated that the amount of dry sugar in each centrifuge was 2.60 qq. Metal measures were made to contain the necessary amount of premix to be added to the sugar.

Each sugar batch in the centrifuge was supplemented with the amount of premix at the end of the washing cycle before it left the centrifuge. By falling on the axis of the centrifuge, the mixture was distributed in a fan-shaped form.

An amount of 400 qq fortified sugar was prepared in this manner. Two samples were taken in order to determine the stability of the vitamin and its preliminary distribution. Results demonstrate perfect stability.

	Retinol (µg/g)	% of expected
Bag # 50	17.3	101
Bag #150	17.6	104

Preliminary evidence suggests that the addition of the premix to the still wet sugar results in adhesion of the retinol palmitate powder to the sugar, thus yielding a mixture with better physical stability and fewer chances of separation than when added to the dry sugar. This feature was tested in the laboratory with the fortified sugar prepared during the test trial.

Observation

The method described is very simple and has a very low cost. The operator in charge of the centrifuge is in a perfect position to prepare the mixture (as was the case during the pilot trial) while waiting for it to exit from the centrifuge. Furthermore, it does not require any additional equipment, thus reducing costs, and prevents occurrence of any irregular mixing.

* 1 qq = 100 lb. (46 kg).

APPENDIX 3

TESTING OF THE "ADDITION TO THE CENTRIFUGE" METHOD FOR THE INDUSTRIAL FORTIFICATION OF SUGAR WITH VITAMIN A

Date: May 21, 1973

Location: "El Salto" Sugar Mill, Guatemala

Premix: Stable (non-separating) mixture based on retinol palmitate (30,800 I.U./gram) prepared by Hoffman-LaRoche, Basel, Switzerland (lot Ro.OI-5852 389 F).

Level of fortification: 15 µg/g

A 100 qq mixture was prepared by adding to each centrifuge 75 g of premix per qq of dry sugar equivalent, or 2.6 x 75 - 195 g of premix. This amount was added at the end of the washing cycle when the centrifuge was ready to stop and to discharge its load into the dryer.

Sugar samples subjected to analysis yielded the following results:

Results

Sack No.	µg/g
31	14.4
50	14.6
70	14.6
100	15.2

Results demonstrate consistency of the fortification levels obtained during the process.

APPENDIX 4

FLAVOR AND ACCEPTABILITY TESTS OF VITAMIN A FORTIFIED SUGAR

Date: June 14, 1973

Sugar: White, centrifuged, produced by El Salto, S.A. Guatemala

Vitamin A: Premix with retinol palmitate, 30,800 I.U./gram (Ro. OI-5852 389 F) made by Hoffman-LaRoche.

Level: 50 I.U./gram of sugar

Vehicle: Hot coffee

Test subjects: The six tasters were INCAP workers. The group had the following characteristics:

Subject	Occupation	Nationality
1	Physician	Guatemalan
2	Doctor (Ph. D)	Salvadorean
3	Graduate student	Argentine
4	Graduate student	Peruvian
5	Laboratory technician	Guatemalan
6	Laboratory technician	Guatemalan

Method: Each member of the group was given daily, for 9 consecutive days, a cup of hot coffee sweetened with sugar according to taste. The sugar was either fortified or not, according to the schedule presented on the next page. The tasters filled a confidential form answering yes or no to the following question: "Do you think that the coffee you drank had vitamin A?"

A summary of the results obtained is presented below:

		Answers	
		Without	With
Sample	Without	20	9
	With	21	4

Statistical analysis of the responses indicates that the difference is insignificant. In any event, the results obtained indicate that the tasters thought that the taste of the coffee was more "normal" in the presence rather than in the absence of vitamin A.

SCHEDULE AND RESULTS

Subject	Type of data	Number of days								
		1	2	3	4	5	6	7	8	9
1	Actual	+	+	-	+	-	+	-	+	-
	Response	+	-	+	-	+	-	+	-	-
2	Actual	-	-	+	-	+	-	+	-	-
	Response	-	+	-	-	-	-	-	-	-
3	Actual	-	+	-	+	-	+	-	-	+
	Response	-	-	-	-	+	-	+	-	-
4	Actual	+	+	-	+	-	+	-	+	+
	Response	-	+	-	-	-	-	-	+	-
5	Actual	-	-	+	-	+	-	+	-	-
	Response	+	-	+	-	-	-	-	+	+
6	Actual	-	+	-	+	-	+	-	-	+
	Response	-	-	-	-	-	-	-	-	-

+ With vitamin A.
- Without vitamin A.

Date: July 9, 1973

Sugar: White, centrifuged

Vitamin A: Premix with retinol palmitate, 30,800 I.U. per gram.

(Ro. 01-5852 389 F - Hoffman-LaRoche)
(Prepared industrially)

Level: 50 I.U./gram of sugar

Vehicle: Orangeade

Test Subjects: Six individuals not connected with the study were invited to participate. The group had the following characteristics.

Subject	Occupation	Nationality
1	Biochemist	Guatemalan
2	Secretary	Guatemalan
3	Laboratory technician	Guatemalan
4	Chemist	Mexican
5	Chemist	Salvadorean
6	Teacher	Guatemalan

Method: Each member of the group was given daily, for 8 consecutive days, one glass of cold orangeade sweetened with sugar according to taste. The sugar used was either fortified or not, according to the schedule on the next page. The tasters answered confidentially by yes or no on a questionnaire asking the following question: "Do you think that the orangeade you drank had vitamin A?"

The detailed results are presented in the table on the next page, while a summary of the results is presented below:

Answers

Sample	Without	With
Without	18	6
With	18	6

Statistical analysis of the answers indicate a completely random effect, showing that detection was not possible.

SCHEDULE AND RESULTS

Subject	Type of data	Number of Days							
		1	2	3	4	5	6	7	8
1	Actual	+	+	-	-	+	-	+	-
	Response	-	-	-	-	-	-	-	-
2	Actual	-	-	+	+	-	+	-	+
	Response	-	-	-	+	+	-	+	-
3	Actual	+	-	-	+	-	+	-	+
	Response	-	-	-	-	-	-	+	-
4	Actual	-	+	-	+	-	-	+	+
	Response	-	+	+	+	-	+	+	+
5	Actual	+	-	+	-	+	+	-	-
	Response	-	-	-	-	-	-	-	-
6	Actual	+	-	+	-	+	-	-	+
	Response	-	-	-	-	+	-	+	-

Date: July 30, 1973

Sugar: White, centrifuged

Vitamin A: Premix with retinol palmitate, 30,800 I.U. per gram
(Ro. 01-5852 389 F - Hoffman-LaRoche)
(Prepared industrially)

Level: 50 I.U./gram of sugar

Vehicle: Fresca-Avena

Test subjects: Six individuals not involved in the study were invited to participate. The test group had the following characteristics:

Subject	Occupation	Nationality
1	Agronomist	Guatemalan
2	Laboratory technician	Guatemalan
3	Student	Guatemalan
4	Student	Guatemalan
5	Student	Argentine
6	Laboratory technician	Guatemalan

Method: Each member of the test group was given daily, for 8 consecutive days, one glass of cold Fresca-Avena sweetened according to taste. The drink was either fortified or not according to the schedule on the next page. The tasters were asked to fill out a confidential questionnaire by answering yes or no to the following question: "Do you think that the Fresca-Avena drink that you drank had vitamin A?"

The detailed responses are shown in the table on the next page while a summary of the results obtained is presented below:

Answers

Sample	Without	With
Without	15	9
With	20	4

Statistical analysis of the answers indicates a completely random effect, showing that detection was not possible.

SCHEDULE AND RESULTS

Subject	Type of data	Number of days							
		1	2	3	4	5	6	7	8
1	Actual	+	+	-	-	+	-	+	-
	Response	-	-	-	+	-	-	-	+
2	Actual	-	-	+	+	-	+	-	+
	Response	-	-	-	+	-	-	-	-
3	Actual	+	-	-	+	-	+	-	+
	Response	-	-	-	-	-	-	-	-
4	Actual	-	+	-	+	-	-	+	+
	Response	-	-	+	-	-	-	+	-
5	Actual	+	-	+	-	+	+	-	-
	Response	-	-	-	+	-	-	+	+
6	Actual	+	+	-	-	+	-	-	+
	Response	+	-	-	+	+	+	+	-

Date: September 5, 1973

Sugar: White, centrifuged

Vitamin A: Premix with retinol palmitate, 30,800 I.U. per gram
(Ro. 01-5852 389 F - Hoffmann LaRoche)
(Prepared in the laboratory)

Level: 50 I.U./gram of sugar

Vehicle: Grape Drink (Fresqui-Top)

Test Subjects: Six individuals not involved in the study were invited to participate. The group had the following characteristics:

Subject	Occupation	Nationality
1	Physician	Panamanian
2	Student	Guatemalan
3	Laboratory technician	Guatemalan
4	Secretary	Colombian
5	Social Worker	Guatemalan
6	Social Worker	Guatemalan

Method: Each member of the test group was given daily, for 8 consecutive days, one glass of fresh grape drink sweetened with sugar according to taste. The sugar was either fortified or not, as shown in the schedule on the next page. The tasters were asked to answer the following question by yes or no on a questionnaire: "Do you think that the glass of drink that you drank had viatmin A?"

The detailed results are presented in the table on the next page while a summary of the findings is shown below:

Answers

Sample	Without	With
Without	15	9
With	16	8

Statistical analysis demonstrates a completely random effect, thus showing that detection was not possible.

SCHEDULE AND RESULTS

Subject	Type of data	Number of days							
		1	2	3	4	5	6	7	8
1	Actual	+	+	-	-	+	-	+	-
	Response	-	-	+	+	-	-	-	+
2	Actual	-	-	+	+	-	+	-	+
	Response	-	+	-	+	-	-	-	-
3	Actual	+	-	-	+	-	+	-	+
	Response	+	-	-	-	-	-	-	-
4	Actual	-	+	-	+	-	-	+	+
	Response	-	+	-	+	-	-	-	+
5	Actual	+	-	+	-	+	+	-	-
	Response	+	+	-	+	+	-	+	-
6	Actual	+	+	+	-	+	-	-	+
	Response	+	+	+	+	+	+	+	-

APPENDIX 5

CONSUMPTION OF SUGAR AND RAW UNREFINED BROWN SUGAR IN GUATEMALA

Food consumption in Guatemala was investigated by means of food surveys of population samples living in various areas of the country. The first such surveys were performed by recording daily, for 7 days, the weighted amount of food consumed during this period by each family and those living with the families. Later on, other surveys covered fewer days although the amount of food was also established by weighing the daily amount of food consumed by each family on a scale graduated in grams.

The national dietary survey carried out in 1965 revealed that the rural population consumed 36 grams of white sugar and 17 grams of raw sugar per day, while the urban population was using 70 grams of white sugar and no raw sugar.

Sugar consumption in rural areas was subjected to further analysis by classifying the families according to a socioeconomic index. For this purpose, the total number of rural families was subdivided into quartiles, with the first quartile consisting of 25% of the families with the lowest socioeconomic status and the last quartile of 25% of the families with the highest socioeconomic status. The two quartiles in between the extremes were composed of families with intermediate socioeconomic status. It was determined that families belonging to the lowest socioeconomic group were consuming 20 grams of white sugar and 22 grams of brown sugar, and that white sugar consumption is increasing progressively as the socioeconomic status increases. Furthermore, brown sugar consumption declines as the socioeconomic status increases.

Analysis of the official figures regarding availability of white sugar and brown sugar for 1964-1966 reveals that per capita consumption in Guatemala during this period amounted to 53 grams of white sugar and 14 grams of brown sugar. The respective figures for 1970 indicate that per capita white sugar consumption increased to 60 grams while brown sugar declined to 12 grams. According to the latter figures based on the national production of brown sugar, especially the amount intended for human consumption, the consumption of the latter tends to decrease, the product being used for some other industrial purposes, and the amount available for human consumption declines.

CONSUMPTION OF SUGAR AND BROWN SUGAR IN THE REPUBLIC OF GUATEMALA

	Sugar	Brown sugar
	Grams per person per day	
RURAL AREA:		
Region I	34	19
Region II	39	12
Region III	42	18
Region IV	22	25
Region V	37	14
Region VI	40	8
Average for all regions	36	17
URBAN AREA:		
Guatemala City	70	0

CONSUMPTION OF SUGAR AND BROWN SUGAR IN RURAL GUATEMALA ACCORDING TO THE ECONOMIC INDEX

	Economic index		
	Low	Average	High
	- Grams per person per day -		
White sugar	20	38	47
Brown sugar	22	18	10

Data yielded by the 1965 INCAP Survey -- Daily recording for 3 days.

APPENDIX 6

OBSERVATIONS ON THE INNOCUOUSNESS OF VITAMIN A IN SUGAR AT THE FORTIFICATION LEVELS RECOMMENDED BY INCAP

Based on the knowledge that the ingestion of large amounts of vitamin A is toxic, an analysis was made of the probability of reaching the toxic doses subsequent to the ingestion of sugar fortified with 15 μg of retinol/g. Premises for the basis of this analysis were: (1) ingestion levels demonstrated to be toxic for man; (2) its magnitude with respect to the expected maximum vitamin A consumption following the practical application of the fortification program.

A review of the literature indicates that most of the adult toxicity cases have been the result of the ingestion of vitamin A doses varying between 300,000 and 600,000 I.U., daily for several months (1-4). The minimum amount of vitamin A that produced toxic effects was the case of a 52-year-old women who took 100,000 I.U. vitamin A daily for 4 years (5). In 1- to 5-year-old children, toxicity was reported subsequent to the chronic ingestion of vitamin A in doses varying from 80,000 to 500,000 I.U. daily for long periods of time. Finally, a study of 5 infants 3 to 5 months of age reported signs of toxicity subsequent to the ingestion of vitamin A doses varying between 18,000 to 60,000 I.U. daily. (5)

Could it be that such levels might be reached subsequent to the consumption of fortified sugar? The answer is no. The proposed level of fortification is approximately 50 I.U. per gram of sugar. According to this level, an adult must consume 2,000 grams of sugar per day in order to reach a vitamin A intake equal to 100,000 I.U. A 1- to 5-year-old child would have to eat more than 1.5 kg of fortified sugar daily in order to reach the toxic level of 80,000 I.U. per day, while an infant would have to be fed 360 g of fortified sugar in order to ingest the minimum toxic dose of 18,000 I.U./day (see following table).

In order to determine the magnitude of the toxic levels with respect to the predicted maximum consumption of the population using sugar fortified at the proposed level, data were collected on the daily intake of vitamin A and sugar for 100 families in Guatemala City, and from this total 25 families with the highest vitamin A intake were subjected to further analysis. Of this group of 25, 10 families with the greatest per capita sugar consumption per day were analyzed in detail. The average figures revealed 8,660 I.U. vitamin A and 117 g sugar, respectively. Assuming that the sugar consumed were fortified (50 I.U./g), the total ingestion of vitamin A would reach 14,500 I.U., a level much lower than the toxic levels mentioned earlier.

The evidence cited indicates that the fortification of sugar with vitamin A does not present any risk regarding the possible ingestion of toxic levels by the population.

TOXIC DOSES OF VITAMIN A AND DAILY CONSUMPTION OF FORTIFIED* SUGAR
REQUIRED TO REACH THESE DOSES

Age group	Toxic dose (I.U.)	Daily intake over:	Sugar consumption required to reach the toxic doses
			(g/day)
Adults (All but 1)	300,000 - 600,000	Several months	6,000 - 12,000
1 case	100,000	4 years	2,000
Children (1-5 years)	80,000 - 500,000	Several weeks	1,600 - 10,000
Infants (3-5 months)	18,000 - 60,000	Several weeks	360 - 1,200

*At the rate of 50 I.U./g.

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