Manual for Sugar Fortification with Vitamin A

Part 2

Technical and Operational Guidelines for Preparing Vitamin A Premix and Fortified Sugar

Omar Dary, Ph.D.
Guillermo Arroyave, Ph.D.

Dr. Omar Dary is a research biochemist at the Institute of Nutrition of Central America and Panama (INCAP), Guatemala..

Dr. Guillermo Arroyave is an international consultant in micronutrients residing in San Diego, California

MANUAL FOR SUGAR FORTIFICATION

PART 2

TABLE OF CONTENTS

BOXES

TABLES

FIGURES

ACKNOWLEDGMENTS

This manual is based on experiences in sugar fortification at the Institute of Nutrition of Central America and Panama (INCAP). Many people have been involved in this program over the last 25 years. This publication represents the work of all those involved, who are too numerous to mention.

The presentation and content of parts 1, 2, and 3 of the manual benefited greatly from the comments and suggestions of the reviewers, whom the authors would like to thank. These include Drs. Frances R. Davidson and Timothy Quick, United States Agency for International Development (USAID); Dr. Juan R. Aguilar, United Nations Children’s Fund (UNICEF), Peru; Dr. Jose O. Mora, International Sciences and Technology Institute (ISTI); Dr. Luis Mejia, Kellogg Latin America; Mr. Alberto Nilson, Hoffman-La Roche, Brazil; Dr. Kenneth Brown, University of California at Davis; Mr. Leonardo de Leon, INCAP; and Drs. Jean Humphrey and Esse Yamini, Johns Hopkins University. Special thanks are to be given to Dr. Penelope Nestel, Opportunities for Micronutrient Interventions (OMNI) who provided extensive assistance in editing and finalizing the manual.

Part 2 is based on the collective experience of the following individuals who have been instrumental in improving the sugar fortification process in Central America over the last 10 years: Mr. Leonel Anleu, Sugar Producers’ Association, Guatemala; Dr. Oscar Pineda, formerly of INCAP, Guatemala; Dr. Vilma Estrada, Dr. Doris Chinchilla, Mr. Plutarco Murillo, and Ms. Victoria Sarai Bejarano, Honduras; and Dr. Manuel de Gracia and Dr. Enrique Murillo, Panama.

Part 3 presents the methods used at the Chemistry and Biochemistry Laboratory, INCAP, and is based on work carried out by Carolina Martinez, Dora Ines Mazariegos, Maria Elena Estrada de Sandoval, Esmeralda Morales, Monica Guamuch, and Gerardo Pirir.

The manual was translated into English by Maritza Mendez de Oliva and Carlos Cipriani. Odette Sanabria de Osorio drew the illustrations. Ingrid Cabrera, Hazel de Orellana, and Ana Ruth de Burckard typed the Spanish edition, and Lisa Sherburne was instrumental in compiling and formatting and Pamela Cubberly in copyediting and formatting the English edition; their assistance is greatly appreciated.

Support activities carried out from 1992 to 1994, which have served in part as the basis for this publication, were financed by the Regional Office for Central America and Panama (ROCAP)/USAID Project 596-0169.

FOREWORD

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

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

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

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

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

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

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

Frances Davidson
Office of Health & Nutrition, USAID
Washington, D.C.

Hernán Delgado
INCAP/PAHO
Guatemala

I. GENERAL ASPECTS OF SUGAR FORTIFICATION WITH VITAMIN A

A. Definition

Vitamin A–fortified sugar is white sugar to which a retinol compound has been added. This document describes the technical processes for making vitamin A premix and fortified sugar. The concentration of retinol to use in both the premix and fortified sugar will have to be determined in each country and the details of how to do this are given in part 1 of the manual. The examples used in this document are based on experience in Central America.

Retinol is the active form of vitamin A metabolized by humans and animals. It is naturally found in animal foods such as liver, eggs, and full fat dairy products such as milk and cheese. Plants produce provitamin A carotenoid compounds, which are transformed into retinol in the human body prior to their biochemical and physiological utilization as vitamin A; therefore, dietary sources of the active form of vitamin A can be directly obtained from foods fortified with retinol and some foods of animal origin or indirectly from vegetables.

B. The fortificant and food vehicle

The *fortificant* is the nutrient, in this case, vitamin A, which is added to a specific food known as the *food vehicle*; thus, the food vehicle becomes a means to supply that nutrient. Sugar is one of the food vehicles used for retinol.

The fortificant used in sugar is a special preparation of retinyl palmitate, which contains stabilizers that protect the retinol from both oxygen in the air and ultraviolet light. The fortifying compound presently used is the water-miscible, retinyl palmitate beadlet called "250-CWS."

C. Description of the fortification process

Manufacturing fortified sugar comprises three stages:

- Premix preparation
- Addition of the premix to sugar
- Quality control

In countries in which sugar fortification has been implemented, it has been determined that preschool children are able to get their daily basal requirements of vitamin A when the concentration of retinol in fortified sugar at the refinery is 15 µg/g. To ensure that the correct amount of retinol is in the final product, a concentrated vitamin A–sugar *premix* must be prepared. This step has two additional purposes: *(a)* to obtain a product in which the fortificant does not separate from the sugar and *(b)* to dilute the fortificant to facilitate adding the correct concentration of retinol to bulk sugar.

Vegetable oil is used as the adhesive to attach the retinyl palmitate beadlets to the sugar crystals. To reduce oxidation of the oil, which would turn the product rancid, an antioxidant suitable for human consumption is added. This addition is done in an inert atmosphere, generally by bubbling nitrogen into a mixture of oil and an antioxidant.

Once the premix has been manufactured, either at a special plant or in a sugar refinery, it is transported to the sugar refineries where it is added to the sugar being produced. The premix can be added manually or through mechanical dosifiers. The purpose of this stage is to add the premix to sugar in the correct proportion to obtain the desired final retinol concentration in sugar. In countries in which sugar is currently fortified, the premix is diluted with sugar in a ratio of 1:1,000, which yields a mean retinol concentration in fortified sugar of 15 µg/g. Irrespective of how the premix is added, it is essential that the required procedures are followed to produce a homogeneous and uniform product that meets the stipulated norms. Once produced, the fortified sugar is packaged and ready for storage, distribution, retail sale, and consumption.

Analytical procedures for determining the retinol levels in both the premix and the fortified sugar are critical components of *quality control* at the refineries and must be set up. The objective of quality control is to ensure that the fortification process is carried out efficiently and effectively and to make adjustments in processing when necessary. Together, these guarantee that the magnitude and uniformity of retinol in fortified sugar meets the required norms. The analytical methods for quality control in vitamin A sugar fortification are described in detail in part 3 of this manual.

D. Retinol stability in fortified sugar

Retinol in sugar remains active when kept at 105°C for 10 minutes.[1] This is important because the premix is usually added to sugar before it passes through the drying turbines, where it is exposed to hot air at temperatures between 65°C and 70°C for approximately 5 minutes.

The stability of retinol in fortified sugar packaged for retail sale has been determined in Guatemala[2] and Panama.[3] After 8 months of storage, which represents the amount of time between harvests, at temperatures between 13.5°C and 27.7°C and relative humidities between 62.5 percent and 78.5 percent, between 50 and 70 percent of the initial retinol remained. Indeed, the stability of

1. INCAP. 1974. *Fortification of Sugar with Vitamin A in Central America and Panama.* INCAP Publication V-36.
2. This work was carried out by E. Morales de Canahui as part of a collaborative study between the Universidad del Valle de Guatemala and INCAP.
3. This work was carried out by M. De Gracia and E. Murillo as part of a collaborative study between the Department of Chemistry, University of Panama, and INCAP.

retinol in sugar depends on environmental conditions rather than the type of packaging materials used in retail outlets. The mean half-life of retinol, that is, the period of time in which 50 percent of the initial retinol content is lost, varies from 240 days in hot, humid areas to 535 days in cooler, less humid areas. After 6 months of storage, therefore, fortified sugar can be expected to contain between 62 and 77 percent of its initial retinol level; thus, in countries in which the retinol content of sugar is 15 µg/g, the average amount of retinol that would reach the population throughout the year is 9 to 10 µg/g sugar, which is a level that would satisfy the basal vitamin A requirements of almost everyone. Assuming no other sources of vitamin A exist, a preschool child would need to eat 20 g of fortified sugar daily, that is, three to four teaspoons, and a nursing mother would need 45 g, that is, six to nine teaspoons, to meet basal requirements.

In theory, the use of airtight containers could improve the stability of retinol in sugar so that after 6 months of storage at least 75 percent would remain[4]; however, the additional cost incurred in using improved containers would be an economic constraint in developing countries.

In tests on homemade sugar-containing beverages, the stability of retinol was also good. About 80 percent and 60 percent of the initial content in beverages made from lemons and oranges respectively remained 1 to 2 days after preparation.

E. Care and precautions

Generally the premix contains one thousand times more retinol than fortified sugar. For this reason, the bags must be carefully labeled *"Not suitable for direct consumption*" and workers at the refineries must understand and respect this warning.

Excessive intakes of retinol, particularly during pregnancy, can be harmful and result in congenital malformations. For this reason, WHO and IVACG recommend that when the diet of pregnant women is supplemented with vitamin A, 3,000 µg/day (10,000 IU) of retinol *"can be given safely at any time."* Given that the concentration of retinol in fortified sugar is 15 µg/g and the upper safe limit for pregnant women is 3,000 µg/day, the likelihood of them consuming more than this level from sugar is extremely low, because 200 g (30 to 40 teaspoons) of sugar would have to be consumed every day.

Despite the fact that the type of retinol used in sugar fortification is highly stable, both the premix and fortified sugar must be properly handled to minimize vitamin A losses. These products must be stored in well-ventilated rooms at low or mild temperatures (preferably not higher than 25°C), and exposure to sunlight, direct light, and humidity must be avoided.

The production of the premix and fortified sugar should be synchronized so that the premix is

4. J. C. Bauernfeind, ed. 1981. *Carotenoids as Colorants and Vitamin A Precursors.* New York: Academic Press.

used at the sugar refineries soon after its manufacture, thus, reducing its storage time. Indeed, it is important that the premix is used on a first-in/first-out basis.

Should retinyl palmitate be left over from the previous harvest, it is better to store it as the raw material (250-CWS) rather than in the premix, because the stability of the former in its original unopened container is very good. If the retinyl palmitate passes the expiration date, it can still be used, but its vitamin activity must be analytically confirmed and the necessary adjustments made to the amount used in manufacturing the premix. Premix remaining from the previous year can also be used but only after the levels of both vitamin A and peroxides have been determined to be within the accepted minimum and maximum limits.

II. PREMIX PREPARATION

A. Introduction

Premix is the product formed by combining sugar with a high concentration of retinyl palmitate, which is then added to bulk sugar produced at the refinery, hence, the term premix. As mentioned before, the premix contains sugar, retinyl palmitate, vegetable oil, and an antioxidant. The premix is a free-flowing product that is light yellow in color, slightly oily to touch, and smells like retinol. Premix that is stored for more than 2 months or that is badly prepared or inadequately stored can develop an unpleasant rancid smell indicating that the oil has oxidized.

The retinol level in premix is determined by multiplying the mean concentration of retinol required in fortified sugar by a factor equivalent to the magnitude of the dilution of the premix during industrial production of fortified sugar plus 10 percent to compensate for losses during storage and manufacturing. Countries currently fortifying sugar with vitamin A use a mean retinol level of 15 µg/g sugar, which is manufactured by diluting the premix in sugar at a ratio of 1:1,000; thus, the mean retinol concentration in the premix should be 16.5 mg/g sugar.

Premix is manufactured using sugar similar to that which will dilute it at the refinery to produce a homogeneous product. The premix is made using equipment appropriate for producing food for human consumption; it is recommended that stainless steel blenders be used. Once made, the premix should be stored and distributed in a tightly sealed, double bag comprising an exterior polypropylene bag and an interior black polyethylene bag. This packaging material reduces exposure to environmental factors that can damage the premix, that is, excessive heat, humidity, and light. The external bag must be adequately labeled indicating that the product is not appropriate for direct consumption (see appendix 2.1). Each bag should not hold more than 25 kg (55 lb) to facilitate its handling and transport to and within the refinery.

In practice, it is convenient to prepare the premix at one site from which it can be distributed to all sugar refineries. Manufacturing of the premix must start a few weeks before the sugar harvest begins. Production should be programmed to meet demand. In other words, no shortage of premix should occur during the sugar harvest season and no excess at the end. Any premix left at the end of the sugar-production season should be collected and stored in a cool, dry place. Any premix stored for more than 2 months must be checked for both its peroxide level and vitamin A activity. This is particularly important in hot, humid environments.

To initiate timely production of the premix, the necessary ingredients and materials must be ordered at least 6 months ahead of the sugar harvest (see section II.C for details).

B. Premix production plant

The production plant should be strategically located at a site as equidistant as possible to all the refineries receiving the premix and where the ambient environment is as cool and dry as possible. The premix plant can be specifically built for making only premix, but it is recommended that it be located in one of the sugar refineries. Irrespective of where the premix plant is located, it must have a continuous supply of potable water and electricity and, ideally, telephone and fax services.

The premix plant should have at least three sections: a raw material warehouse, an area for production and packaging, and a storage area for the manufactured product. Figure 2.1 on the next page presents an example of a layout plan for a premix plant.

All warehouses and storage areas should be ventilated and dry. The interior should be protected from direct sunlight and from insects, rodents, or other pests, because the ingredients, materials for packaging, and final product will be stored there. The exterior warehouse doors should be large enough to facilitate truck loading and unloading.

The production section will need to accommodate the blender, scales, a stove or water bath, and a nitrogen cylinder. Natural and artificial light should be sufficient but not excessively intense. The floor should be smooth and waterproof to facilitate cleaning; several water sources and drains should be available to facilitate this.

The packaging area can be located inside the storage warehouse, near the production area, or between the two. The packaging area should also have a weighing scale, sewing machines to close the premix bags, an imprinter to number the bags, a desk, and a file cabinet to keep production, quality-control, and dispatch records. The first-aid kit and fire extinguisher should be placed here.

C. Preparation steps

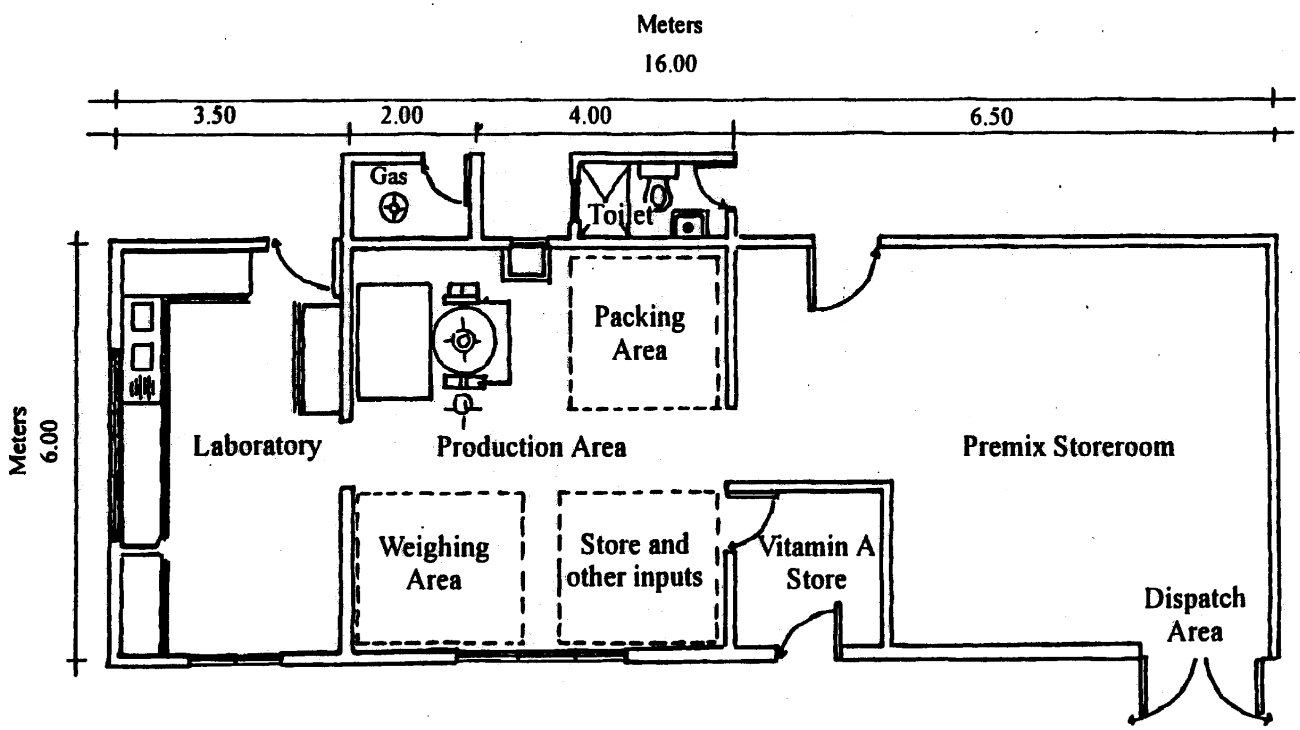
1. Equipment

a. *Stainless steel blender*, ideally with a capacity greater than 150 kg. Sufficient quantities of replaceable spare parts, suggested by the manufacturer, should be available on site. Appendix 2.2 describes a prototype blender that has given satisfactory results.

b. Two *100 kg scales*, one to weigh the sugar used to prepare the premix and the other to weigh the premix once packaged. The scales should be calibrated on a regular basis.

c. A *laboratory scale* with centigram sensitivity to weigh the antioxidant. Again, its accuracy must be checked regularly.

Figure 2.1:
INSTALLATION PLAN FOR A PREMIX-PRODUCING PLANT[5]



5. This plan is based on a proposal made by Norman E. Guandique, Ministry of Health, Honduras, for the Yojoa Sugar Refinery, which makes all the premix in Honduras.

d. A *water bath* or a *stove* to heat the oil, preferably equipped with a stirrer and nitrogen-bubbling device. This is not needed with the prototype blender.

e. An *electric stirrer* for continuous stirring of the oil and the antioxidant. This is not needed with the prototype blender.

f. *Nitrogen cylinder* and a bubbling system to blow the nitrogen into the oil. This is not needed with the prototype blender.

g. Two *carts* with a minimum capacity of 125 kg to transport the premix from the production site to the packaging area

h. A *sewing machine* for closing the bags

i. An *automatic imprinter* to label the premix bags sequentially

2. Materials

a. A *4 L graduated cylinder* to measure the oil

b. A *2 L flat-bottom flask* to heat the oil and antioxidant. This is not needed with the prototype blender.

c. A *spatula* to add the antioxidant

d. *Black polyethylene bags* with a capacity of 25 kg, for example, 45 cm x 70 cm

e. *Polypropylene bags* with a capacity of 25 kg, for example, 50 cm x 80 cm

f. *Registration books and forms* to record premix production and delivery

3. Ingredients and formulation

a. *Sugar*. The same type of sugar as that to which the premix will be added.

b. *Retinyl palmitate.* The retinyl palmitate comes as a beadlet and is manufactured by Hoffman-La Roche[6] and BASF.[7] The prototype is 250-CWS, which contains 250,000 IU of retinol per gram (75 mg/g) and is cold

6. Hoffman-La Roche, CH4002, Basel, Switzerland. Tel: 061-688-1111. Fax: 061-691-9600.
7. BASF, 6700 Ludwigfhafen-Rhein, Ludwigfhafen, Germany. Tel: 049-621-600. Fax: 049-621-604/622-525.

water soluble, hence its name. The retinyl palmitate is embedded in a gelatin matrix combined with antioxidants (butyl-hydroxy-toluene and butyl-hydroxy-anisol) and other substances that make it water soluble.

c. *Antioxidant*. The prototype used at present is Ronoxan-A, produced by Hoffman-La Roche. It is composed of di-á-tocopherol (50 mg/g), ascorbyl palmitate (250 mg/g) and lecithin (700 mg/g). This substance reduces the rate at which the vegetable oil used in preparing the premix is oxidized. The antioxidant can be stored for up to 9 months, but it must be refrigerated below 10°C and inside its original airtight container until used. After opening the container, the Ronoxan-A should be used within 1 month.

d. *Vegetable oil*. The oil must have the lowest possible amount of peroxides. The maximum peroxide level is 5 meq/kg, which should be confirmed before using the oil. Part 3 of this manual includes a method for this analysis. The prototype is peanut oil; however, other oils can be used, such as palm and corn oils.[8] As was mentioned before, the oil adheres the vitamin A beadlets to the sugar crystals to prevent segregation.

e. *Nitrogen.* Inert gas is not really a premix ingredient, but it is required to prevent oxidation of the vegetable oil present in both the premix and fortified sugar.

Table 2.1 shows the recommended formula for the premix. If a different retinol level is required in fortified sugar, the proportion of premix to be added to the sugar should be adjusted rather than the composition of the premix. A blender with a capacity of 150 kg or more is recommended, so that the entire contents of the original bag of fortificant (25 kg) can be used at once. If a blender this size is not available, the corresponding amount of fortificant must be weighed out to maintain the proportions listed in table 2.1.

Table 2.1: Premix Formula *(Average retinol content 16.5 mg/g)*

Ingredients	Percent weight	Quantity *(kg)*
Sugar	76.35	86.63[a]
250-CWS	22.03	25.00
Antioxidant (Ronoxan-A)	0.008	0.009
Vegetable oil	1.60	1.82[b]
Total	**100.00**	**113.46**

a. Equivalent to 190 lb.
b. Equivalent to 2.0 L.

8. Mejía, L. A. and O. Pineda. 1986. Substitución del aceite de maní usado para la fortificación de azúcar con vitamina 'A' por otros aceites vegetales disponibles en Centroamérica." *Arch. Latinoamer. Nutr.* 36: 127–34.

Table 2.2 presents a list of the ingredients and materials that must be purchased annually to produce 100,000 MT fortified sugar and their approximate costs. The amount of materials needed for a given amount of sugar to be fortified can be calculated using the data in the table and the following equations:

$$Amount\ of\ material = \frac{Q \times Production\ (MT)}{100{,}000}$$

Where Q is the quantity of each material or ingredient shown in table 2.2.

If production is measured in quintals,[9] the equation is:

$$Amount\ of\ material = Q \times Production\ (million\ qq) \times 0.454$$

Table 2.2: Ingredients and Materials Needed to Manufacture 100,000 MT Fortified Sugar *(Average retinol content of 15 µg/g)*

Ingredients and materials	Quantity	Unit cost[10]	Total cost *(US$)*[11]
Sugar	76,350 kg	$0.40/kg	30,540
250-CWS	22,030 kg	$915/25 kg	806,298
Antioxidant (Ronoxan)	8 kg	$36/kg	288
Vegetable oil	2,000 L	$200/200 L	2,000
Black polyethylene bags	4,000	$67/thousand	268
Polypropylene bags	4,000	$180/thousand	720
Nitrogen	2 100-lb cylinders	$10/cylinder	20
Total			**840,134**

4. Initial activities

A month before starting premix production, the following tasks should be carried out:

a. *Ensure* the following:

i. All necessary equipment and materials identified in section II.C.1 and II.C.2 are available.

9. One quintal (qq) equals 100 lb or approximately 46 kg.
10. Based on 1995 prices.
11. Unless otherwise noted, all dollar amounts in this document are in U.S. currency.

ii. There are sufficient quantities of all ingredients identified in section II.C.3 (see table 2.2).

iii. The packaging materials are ready and adequate, that is, a black polyethylene bag covered by an appropriately labeled bag of polypropylene or equivalent material.

b. *Check* the calibration procedures for all scales.

c. *Inspect* the blender's mechanical parts, such as seals, tips, gears, and washers.

d. *Check* the electric system and operation of the equipment's safety measures to avoid damage to the workers and the machine itself.

e. *Confirm* the adequacy of the indicated mixing time by preparing a batch of premix and determining the level and homogeneity of retinol. This can be done by taking two samples from the blender (one from the top and the other from the bottom) after different periods of mixing.

5. Procedures

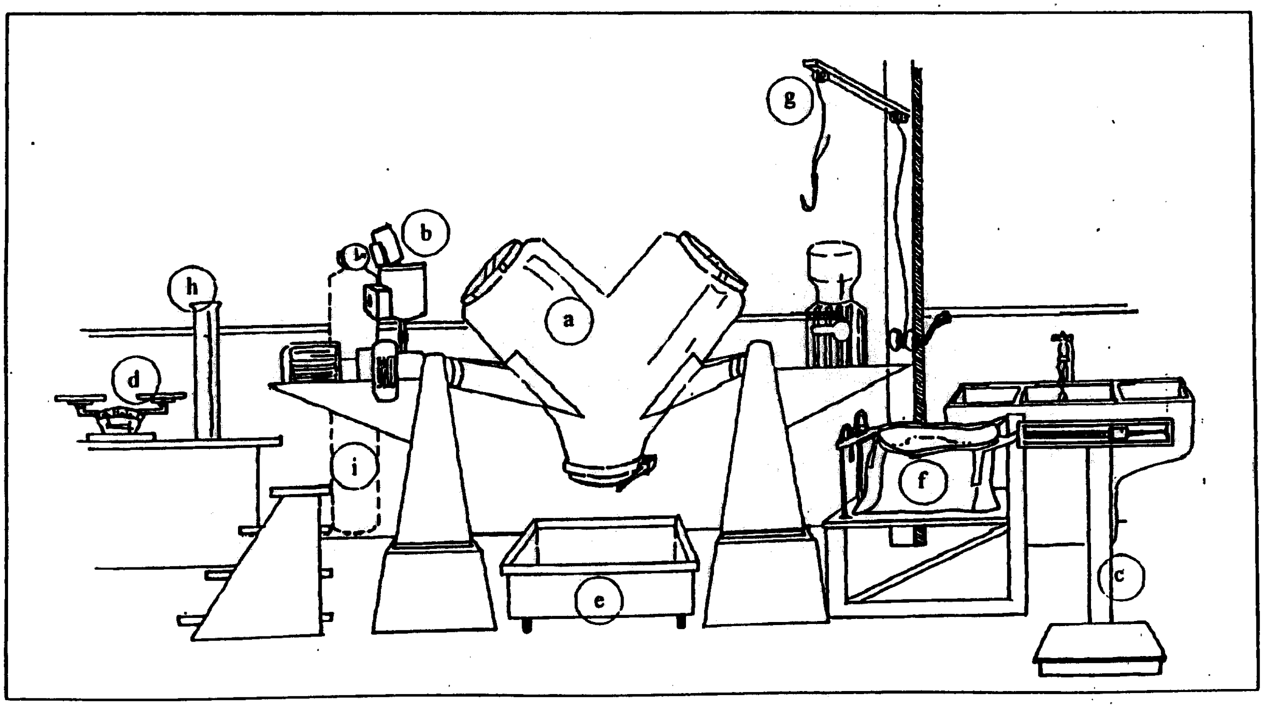
a. *Clear out, clean, and organize* the work area for the premix production to flow smoothly, safely, and speedily. Figure 2.2 on the next page shows a general view of the premix production site.

b. If the blender has a compartment for heating the oil, *check* that the annular space between the external and internal cylindrical walls is full of glycerine. Water evaporates very easily, so it must not be substituted for glycerine.

c. *Add* the right amount of sugar and retinyl palmitate to the blender. It is recommended that the ingredients be added in three layers, like a "sandwich," that is, a layer of sugar, then the retinyl palmitate, and finally the rest of the sugar (see panel A, figure 2.3). This will speed up the time required for mixing. A mechanical or semiautomatic system (for example, a manual pulley) will facilitate dispensing the ingredients into the blender (see panels B and C, figure 2.3).

d. *Mix* the premix for one-third of the total time needed to produce the premix (see section 4e above)—5 to 10 minutes—(see panel D, figure 2.3).

Figure 2.2:
GENERAL VIEW OF THE SYSTEM FOR MANUFACTURING PREMIX

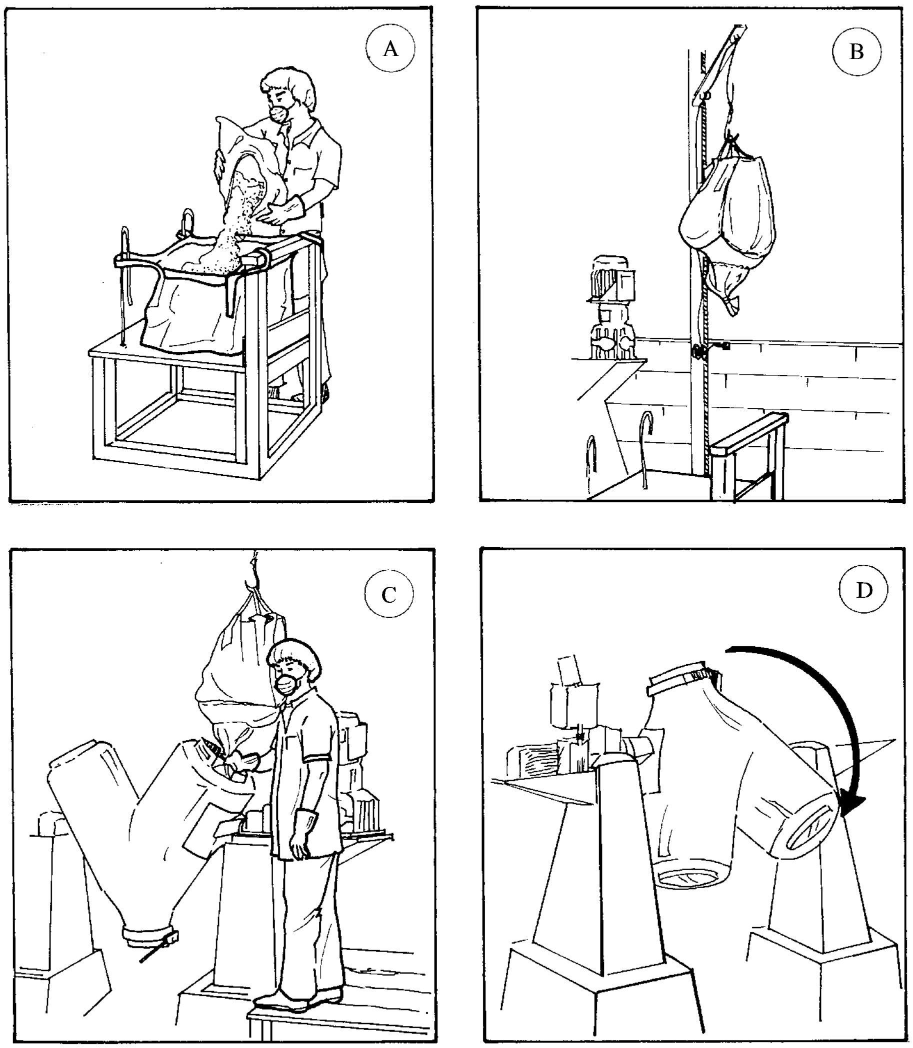


a. Blender
b. Oil heating chamber
c. Scale to weigh the antioxidant
d. Scale to weigh the sugar
e. Carrying cart
f. Polypropylene bag to combine the retinyl palmitate and sugar
g. Pulley for transporting the mixture to the blender
h. Graduated cylinder for measuring oil
I. Nitrogen cylinder

Note: The system illustrated is used by the Sugar Producers' Association in Guatemala (ASAZGUA).

Figure 2.3:
STEPS IN FORTIFYING SUGAR

Figure 2-3a



A. Producing the sugar-retinol-sugar "sandwich" in a polypropylene container.

B. Transporting the ingredient to the mixer.

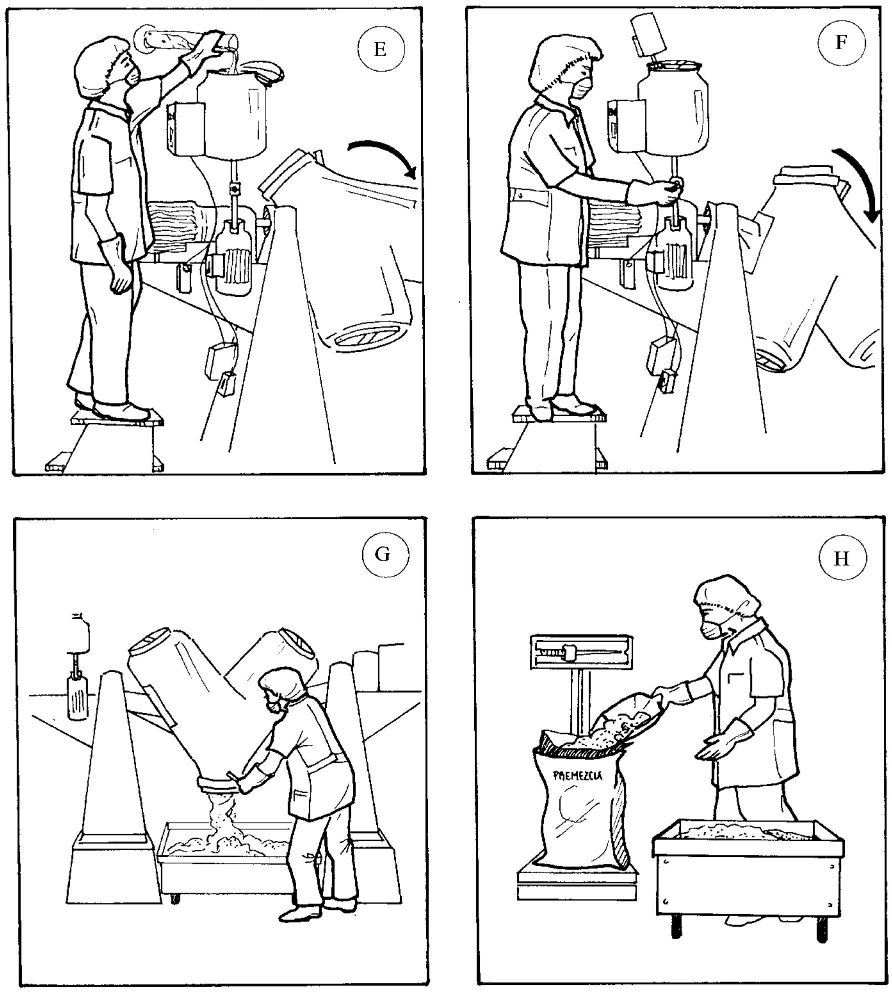
C. Adding the "sandwich" into the mixer.

D. Mixing the premix.

Figure 2.3:

STEPS IN FORTIFYING SUGAR (continued)

Figure 2-3b



E. Adding oil and Ronoxan in a water bath.

F. Transferring the oil-Ronoxan mixure into the mixer.

G. Emptying and transporting the premix.

H. Weighing and packaging of the premix.

e. While the first mixing stage is taking place, *measure* the oil into the heating chamber or a flat-bottom flask in a water bath at 60°C, using a graduated cylinder (see panel E, figure 2.3). The oil should have nitrogen bubbled through it continuously.

f. *Add* the required amount of antioxidant (Ronoxan-A) to the hot oil. Continue bubbling the nitrogen and, at the same time, mix the oil with a mechanical stirrer until all of the antioxidant is completely dissolved (approximately 5 minutes).

g. If the blender has an oil compartment incorporated, *open* the valve that leads to the mixing chamber (panel F, figure 2.3). If not, *stop* the blender and *add* the oil with the antioxident manually to the mixing chamber.

h. *Continue* with the second mixing stage (10 to 20 minutes).

i. While the second mixing stage is taking place, *measure* the amounts of sugar, antioxident, and oil necessary to produce the next batch of premix.

j. *Stop* the blender and *unload* the premix into the transporting cart (panel G, figure 2.3) and *wheel* to the packaging site.

The complete operation described here takes about twenty to thirty-five minutes per batch; therefore, about 19 batches can be produced in an eight-hour work shift, that is 2,155 kg premix if the amounts presented in table 2.1 are used. This means that forty-six working days would be required to prepare sufficient premix to fortify 100,000 MT of sugar.

D. Packaging, registration, and labeling

The packaging section must be near but independent of the production area. A carrying cart transports the prepared premix to the packaging area where the following tasks are carried out:

1. Manually *fill* the bags, and place on the scale (panel H, figure 2.3). The bags should not contain more than 25 kg (55 lb) to facilitate transportation to the refineries where the premix will be used.

2. *Close* the bag by machine sewing it several times, leaving the smallest amount of free space in the bag as possible.

3. Using a marker, *write* the bag number on the label using sequential numbers[12]. An example of a premix label is shown in appendix 2.1.

4. *Stack* the premix bags on wooden pallets in the coolest, driest, and least illuminated place possible. Stacking must be done so that bags are dispatched in the order in which they were produced.

5. *Register* the premix bags, the date, and the production shift on the log registration form. An example of a log form is given in Appendix 2.3.

6. *Dispatch* the premix according to the production sequence, noting the date, destination, and identification number of the bags dispatched on the appropriate registration forms. An example of the dispatch log is given in appendix 2.4.

12. It is suggested that sequential numbers be produced by the last two digits of the year that the premix manufacturing began, for example, if production began just before the 1995 sugar harvest, the identification number of the first bag would be 95-0001 and the 100th bag would be 95-0100.

E. Quality control

Premix is produced in a closed system, in which the ingredients and procedures are unchangeable, thereby minimizing the risk of errors. Nevertheless, compliance with procedures and specifications must be constantly supervised and the premix subjected to both visual inspection and chemical analysis.

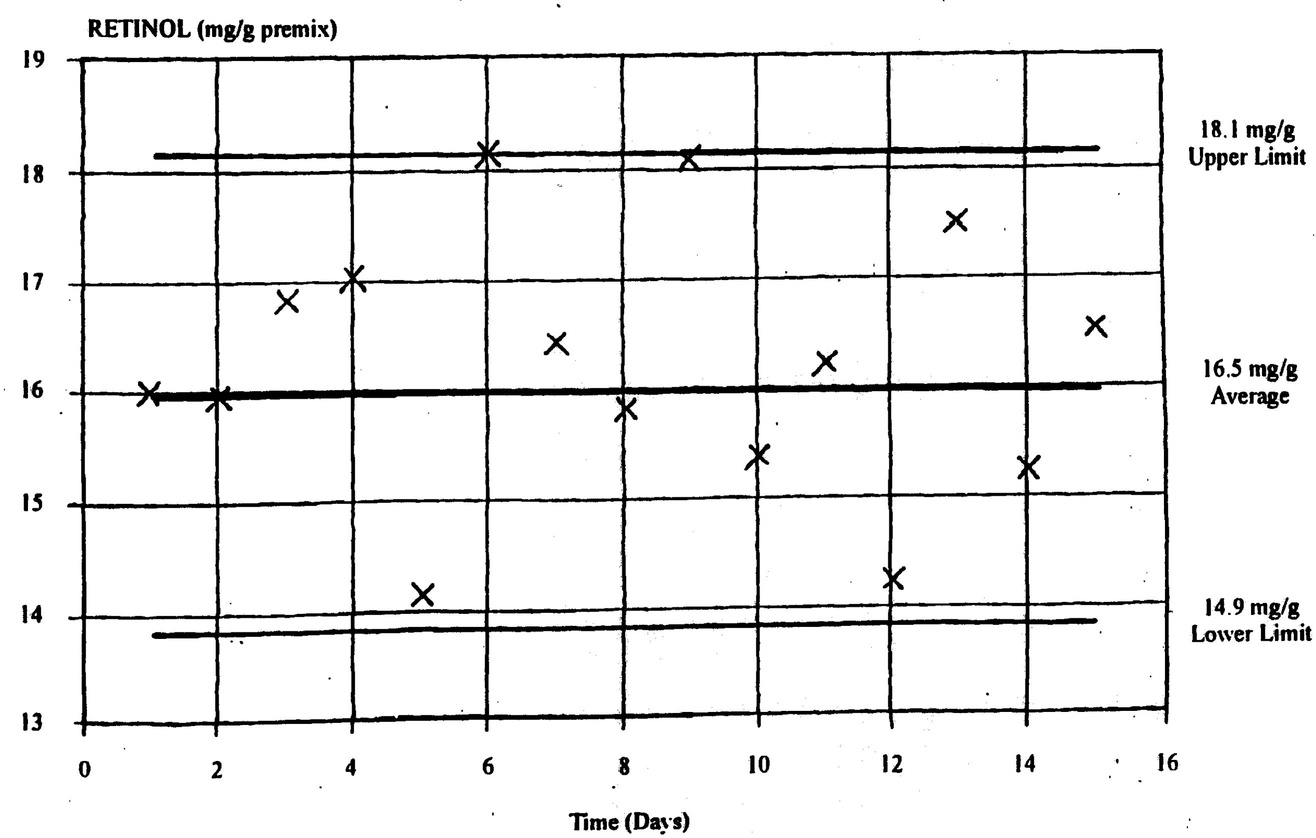
Visual control. Workers responsible for production must monitor the physical characteristics of the premix, that is, uniformly light yellow in color, free flowing, not lumpy, and with no rancid odor.

Chemical control. The premix plant should have close access to a chemical laboratory that can carry out the retinol assays.[13] Once the premix production process has been standardized, the retinol level in the premix should be determined at least twice a day by taking 10 g samples and placing them in airtight plastic or opaque glass containers. The date and shift that the sample was taken should be recorded. If the retinol content in the premix is not within the range stipulated in the norms, the supervisor of premix production should identify the source of the problem, for example, low vitamin A activity in the retinol or errors in preparing the premix. Bags of premix that contain inadequate or excessive amounts of retinol must be reprocessed and sugar or retinyl palmitate added as appropriate.

The laboratory technician in charge of quality control should send duplicate copies of the laboratory results to the premix supervisor. Records of all analytical results must be kept in the laboratory. Results can be presented in tabular or graphic form (see figure 2.4 on the next page). A good operation will be one in which 90 percent of the samples analyzed have retinol levels within 10 percent on either side of the specified mean. If the required average retinol content is 16.5 mg/g sugar, then the acceptable range would be 14.9 to 18.1 mg/g.

13. Part 3 of this manual, *Analytical Methods for the Control and Evaluation of Sugar Fortification with Vitamin A*, includes a simple and reliable method.

Figure 2.4:
PREMIX QUALITY CONTROL GRAPH



F. Equipment maintenance and care

The efficiency of the premix production process and the life span of both the machinery and the equipment will depend on their correct use and maintenance. In addition to following the preventative maintenance procedures listed in the manufacturer's instruction manuals, it is important to emphasize the tasks mentioned in box 2.1.

Box 2.1:
Maintenance Tasks for Machinery Used in Premix Production

End of each day	*Wash* the blender with water and soap or detergent. *Never* use metallic brushes, because these will damage the blender's walls. *Ensure* the blender is completely dry before the next use.
Each week	*Check and clean* accessible parts of all machine components. *Check* the parts most susceptible to damage.
Monthly	*Check* the differential and axle gear lubrication and oil levels. *Check* also the blender's aspersion system for the vegetable oil.
Beginning and end of production season	*Check* the blender's engine carbon electrodes and bearings to ensure that they are operating properly.

G. Human resource requirements

Preparing the premix requires at least two workers. One will be in charge of the blender and all production tasks and the other for transporting premix from the production site to the packaging area and all activities related to packaging, labeling, storage, dispatching, and registration. The latter worker will also take and deliver samples to the laboratory.

In addition to these two workers, a laboratory technician is needed for the chemical analysis on the premix. If the premix plant is at a refinery, quality control would be the responsibility of the refinery's laboratory; one technician should be trained and assigned to carry out the quantitative retinol assays. If this arrangement is not possible, then the plant itself must have a laboratory and a technician responsible for quality control.

III. FORTIFIED SUGAR PRODUCTION

A. Introduction

The premix received from the production plant should be stored at the sugar refinery in a storage area that meets the same conditions as those at the premix plant. The date of arrival should be registered and the bags stored so that they will be used on a first-in/first-out basis. The premix should be dispatched from the refinery warehouse shortly before it is used in appropriate quantities for addition to sugar.

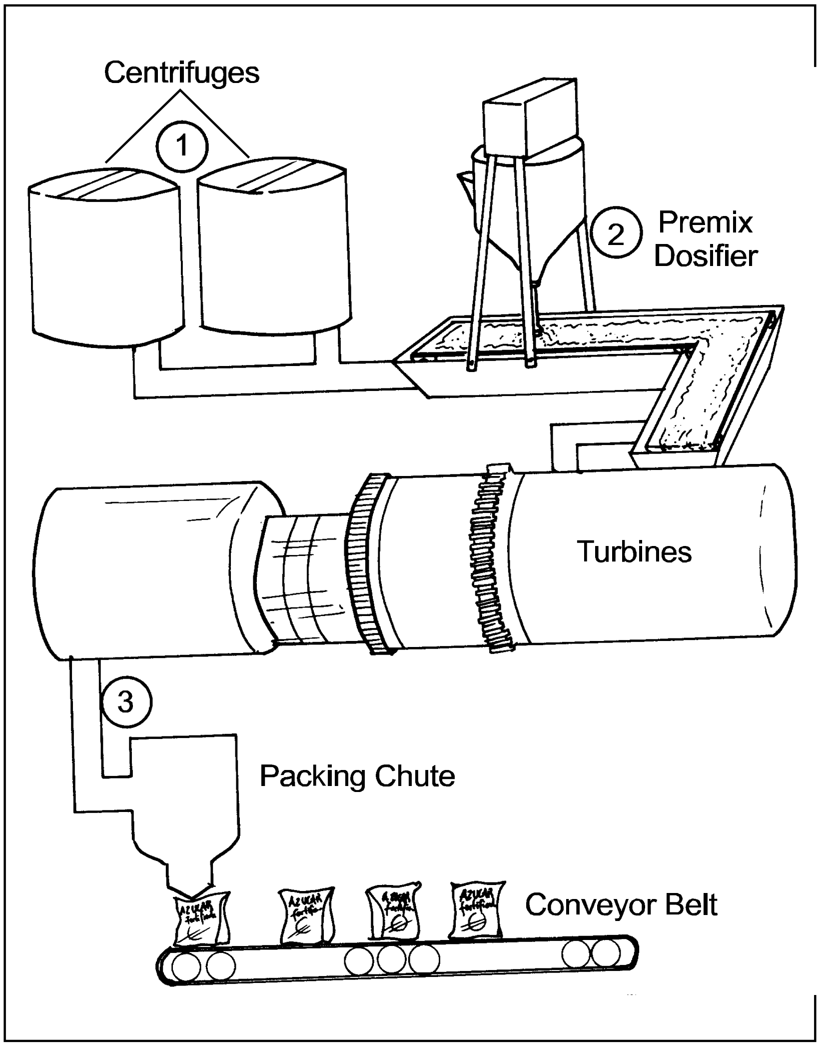
The premix can be added to the sugar at any point between the centrifuges and the packaging chutes, as illustrated in figure 2.5 on the next page. The usual point for adding premix is before sugar enters the drying turbines, where the mixing action is most intense. Adding the premix before the drying stage results in retinol losses. This is because retinyl palmitate beadlets segregate from the sugar crystals during the drying stage and are lost in the "dust" that escapes from the dryer. One study carried out in Honduras[14] reported these losses to be between 10 and 20 percent, but the magnitude will depend on the factory conditions and should be determined in each particular situation. This can be done by comparing the level of retinol in fortified sugar with the theoretical level at the time of production. The latter is based on the retinol content of the premix and takes into account the dilution of the premix when added to sugar. To compensate for this loss, the premix is prepared with excess retinol.

Premix can be added to sugar in two ways: manually or using an automatic dosifying machine. In a *manual* operation, a worker adds the premix to sugar inside each centrifuge using a container that holds a known weight of premix. This is done immediately before the sugar is emptied from the centrifuge (see point 1, figure 2.5) or when sugar begins to pass along the conveyor belt (see point 2, figure 2.5) The *automatic* procedure requires a dosifier, which dispenses the premix on the conveyer belt leading to the drying turbines at a rate corresponding to the amount of sugar passing along and will be described in detail later.[15]

---

14. This work was carried out by P. A. Murillo Martínez as part of a collaborative study between the Department of Chemical Engineering, National University of Honduras, and INCAP.
15. The Sugar Producers' Association of Guatemala (ASAZGUA) is currently testing the efficiency of placing a mechanical dosifier between the drying turbine and the packing chute (see point 3, figure 2.5). In theory, adding the premix after the drying process would reduce vitamin A losses. To date, the mechanisms tested, which involve perforated plates in the canal that takes sugar to the packaging chutes, have had limited success.

Figure 2.5:
DIAGRAM OF THE POSSIBLE POINTS FOR PREMIX ADDITION DURING SUGAR PRODUCTION



1. Into the centrifuge
2. On the conveyor belt between the centrifuges and the drying turbine
3. Between the drying turbine and the packing chute

B. Manual addition of premix

The workers operating the centrifuges should be responsible for adding the premix. Premix is placed in a 10 kg plastic container, located near the worker operating the centrifuge at a distance and height that are easy to reach. Using a calibrated container made of plastic or another stainless material, the worker extracts the correct amount of premix, which is calculated according to the sugar crystallization yield and the centrifuge's load weight (dry sugar equivalent). The calibrated premix container should hold the required amount of premix when full and leveled off. If the sugar refinery has centrifuges of different sizes, each one must have its own calibrated container for adding the premix.

The amount of premix required for each centrifuge load is calculated using this equation:

$$P(g) = \frac{C(kg) \times Rf(\mu g/g)}{Ri(mg/g)}$$

Where:

P = amount of premix

C = centrifuge's load capacity, equivalent to dry sugar weight

Rf = final retinol concentration in sugar

Ri = minimum retinol concentration in the premix

If the centrifuge's capacity is expressed in pounds the equation is:

$$P(g) = \frac{0.454 \times C(lb) \times Rf(\mu g/g)}{Ri(mg/g)}$$

For example, if a centrifuge yields 350 lb of dry sugar and the desired retinol content is 15 µg/g from a premix whose retinol content is 15 mg/g, then:

$$P(g) = \frac{0.454 \times 350(lb) \times 15(\mu g/g)}{15(mg/g)} = 158.9\ g$$

The centrifuge worker, therefore, must add approximately 160 g premix to each centrifuge load of sugar.

C. Automatic addition of premix

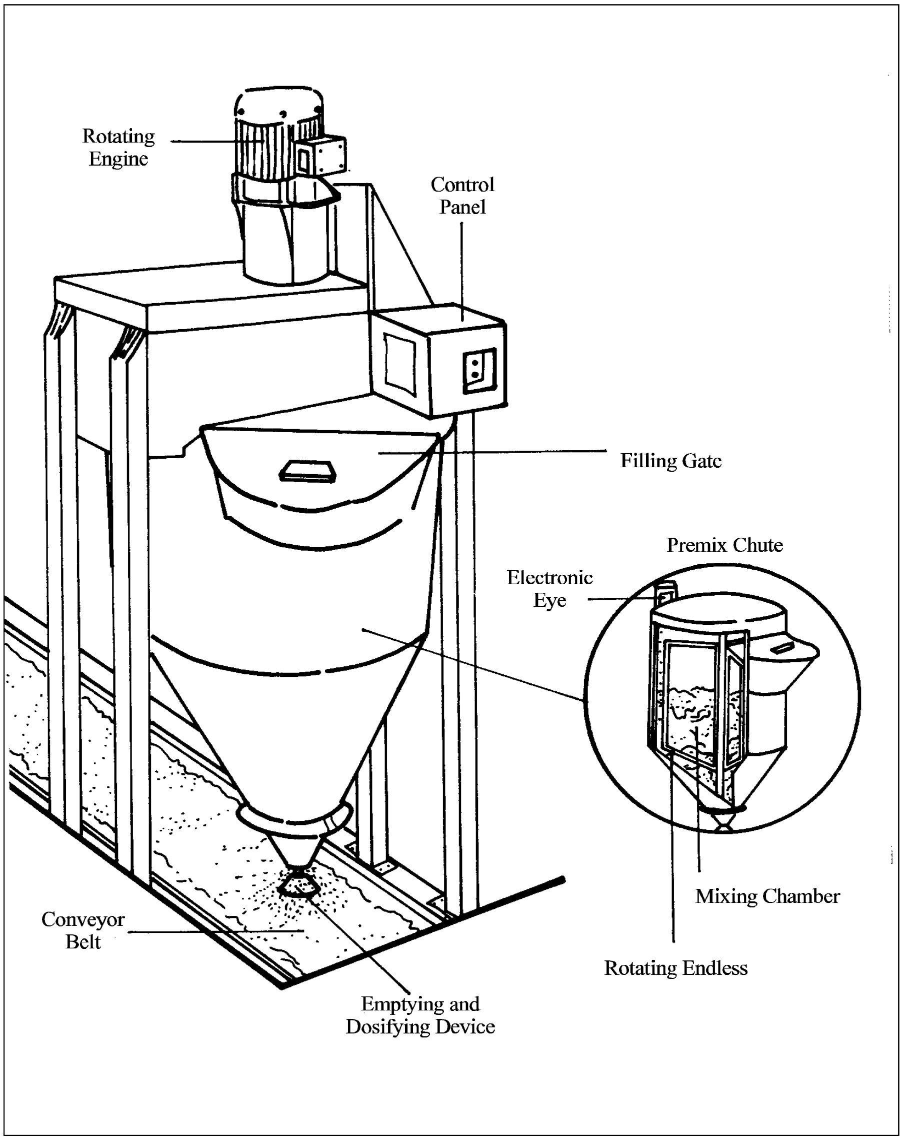
The types of dosifier and synchronization system to be used depends, to a large extent, on each refinery's mechanical structure. This manual only suggests some alternatives, but the final decision should be made by an experienced mechanical engineer. If the refineries do not have this expertise among their staff, it is advisable that one be contracted on a temporary basis. An inefficient premix addition system will result in variable fortification levels that produce fortified sugar that does not meet the established norms.

Recent technological advances in sugar manufacturing have led to development of closed automatic centrifuges, making manual addition of premix impossible; thus, automatic dosifiers have been placed above the conveyor belt going to the drying turbine (see point 2, figure 2.5). Since the drying turbine is an efficient blender, there are advantages to placing the dosifiers before it.

The Sugar Producers' Association of Guatemala (ASAZGUA) has designed a dosifier whose rate of premix addition can be electronically regulated according to the quantity of sugar passing along the conveyor belt (see figure 2.6 on the next page). This machine consists of a vertical endless screw; the amount of premix added is directly related to the rotating speed of the screw. An electronic eye inside the chute activates a light and an alarm when the level of premix is below a critical level inside the mixing chamber. The reproducibility of the rate of dosification with this machine is very good. The vertical orientation of the screw prevents the premix from clogging and, therefore, restricting its flow through the dosifier; however, the sugar flow on the conveyor belts is not always uniform and problems can arise in regulating the addition of premix to sugar. An irregular sugar flow will reduce the uniformity in the distribution of retinol in fortified sugar.

Although accurate amounts of premix can be added with the ASAZGUA dosifier, the amount of sugar flowing along the conveyor belt is not uniform; thus, it is not yet possible to ensure optimal uniformity in the distribution of vitamin A in the final product. Nevertheless, two methods for estimating the amount of sugar passing under the dosification point are being considered. The first is to place one or more electronic "eyes" on the conveyor belt at a height at which the ray between the transmitter and the receiver will pass only when the thickness of the layer of sugar on the conveyor belt drops below the critical height, indicating that insufficient or no sugar is on the conveyor belt. When the ray is blocked, the dosifier receives a signal that activates its operation and vice versa. The second option is an electronic system that responds to the weight of the sugar on the conveyor belt.

Figure 2.6:
EXAMPLE OF DOSIFIER WITH ELECTRONIC CONTROL



Designed by ASAZGUA, Guatemala.

Until the ideal system is found, it is essential that dosifiers have a built-in alarm system that warns when the premix level in the chute is about to be exhausted. The worker assigned to adding the premix should be trained to check that *(a)* the premix flow from the dosifier is regular, *(b)* the unloading canal is not obstructed as sugar passes onto the conveyor belt, and *(c)* the delivery of premix stops when no sugar is passing on the conveyor belt.

The dosifier should be made of stainless steel with a chute large enough to hold 25 kg or more premix. To calculate whether the amount of premix the dosifier releases results in the required dilution, equations similar to the ones used for the manual method can be applied. In this situation, P and C would represent respectively the premix addition rate from the dosifier (g/min) and sugar flow (dry weight, equivalent in kg or qq/min).

D. Packaging, labeling, and storing

At the refinery, fortified sugar is handled in the same way as unfortified sugar, that is, following the same procedures and using the same packaging sacks; however, the sacks must show that they contain fortified sugar by a written message, preferably complemented by a logo that can be easily understood by illiterate people. In Guatemala, for example, aclearly colored eye is used for this purpose, whereas Honduras uses a capital A formed by sugar cane. The message is especially important in countries in which unfortified sugar is also produced for industrial use, because it will help to ensure that fortified sugar is available for direct consumption and it will also facilitate monitoring, inspection, and observance of the law. The labels must not assign healing properties or promote increased sugar consumption on the basis that the sugar is fortified.

Where unfortified sugar is also produced for export or industrial use, fortified sugar should be stored separately from unfortified sugar. An inventory system for fortified sugar, showing the production date, should be put in place; distribution should be on the basis of first-in/first-out.

E. Quality assurance

Quality assurance of fortified sugar production is more than simply taking samples for chemical analysis and providing the results to production supervisors. Instead, it should comprise a set of feasible and complementary activities, which provide indicators of operational efficiency. These include the supervision and control of all operations at each refinery, as well as the inspection activities carried out by the regulatory body.

1. Quality control at the sugar refinery

With the advent of fortification, quality control personnel at the refinery must include supervising the addition of premix to their functions. Two approaches are proposed:

a. Theoretical approach

The simplest approach is to verify the ratio of the amount of white sugar produced to the amount of premix used in a predetermined period of time. This quotient provides general information on whether the required amount of premix is being added. To obtain these data, the refinery must track the number of premix bags used to manufacture a known number of sacks of fortified sugar. For example, if sugar is normally packaged in 50 kg sacks, the premix in 25 kg bags, and the dilution is 1:1,000, then one bag of premix should be used for every 500 sacks of fortified sugar produced. If fortified sugar is packed in 1 qq sacks, one bag of premix should be used for 550 sacks of sugar. This ratio can be determined every 8 hours or every work shift as shown in appendix 2.5.

The premix sugar ratio only provides information about the average amount of premix added in a specified period of time, but it does not reflect whether the premix was added uniformly or not. Despite this limitation, this approach has proved useful and practical. Indeed, the efficiency of the process, that is, the proportion of retinol actually transferred, can be confirmed when the ratio of fortified sugar produced to the premix used is combined with the results of the chemical analyses.

b. Chemical analysis

Two laboratory methods can be used to determine the retinol content in fortified sugar. One is semiquantitative and the other quantitative.[16]

Semiquantitative colorimetric method. The rapid colorimetric method involves adding a chromogenic reagent to a volume of solubilized sugar. The reagent reacts with retinol to produce a blue color. The intensity of this blue color is proportional to the amount of retinol in the fortified sugar and is measured against a set of standards that show the amount of retinol in a given shade of blue. At the time of production, the concentration of retinol should be between 15 and 20 µg/g sugar.

16. A detailed description of the methods is found in part 3 of this manual, *Analytical Methods for Control and Evaluation Assessment of Sugar Fortification with Vitamin A*.

Due to its simplicity, low cost, and the fact that it provides immediate results, one sugar sample should be analyzed every time the refinery conducts routine quality control procedures (for example, for color and impurities) for a batch of sugar produced (approximately every 2 hours). A total of about 1 kg of sugar should be accumulated from a series of small samples in the interval between the routine quality-control sampling. These samples should be pooled, mixed thoroughly, and a 50 g sample taken for analysis. At refineries with a high sugar output, this could take place after every 50 MT (about 1,100 qq) of production. Because the results are available immediately, this test allows for prompt adjustments in the amount of premix added.

Quantitative methods. Quantitative methods provide accurate data on the retinol concentration in sugar and reflect the efficiency of the entire process; however, because of the high cost and the time required to do the assays, these methods can be used to show the retinol level in sugar produced in each production shift (8 or 12 hours). Ideally, the same sugar samples collected for the semiquantitative method should be pooled and analyzed. Samples must be kept in dark, airtight containers. The pooled samples should be mixed well before being analyzed. The results can be presented in graphical or tabular form (see figure 2.4 and appendix 2.5).

Data obtained from quantitative methods have legal implications because the fortification levels can be compared with the minimum requirement and acceptable ranges indicated in the norms. For example, if the norms require an average retinol level of 15 µg/g of sugar with a variability range of 30 percent (10.5–19.5 µg/g) and sugar batches are found to contain only 5 µg/g, the specifications are clearly not being met. Because the sugar production process, including packaging, is rapid and involves huge volumes, it is neither practical nor feasible to reprocess sugar that does not meet the stipulated norms. Nevertheless, this sugar should not be made available for retail sale but instead diverted to the industrial sector. A good quality-control system will ensure that fortified sugar meets the norms and reduces the likelihood of any sugar being diverted for other uses.

Quantitative data on the retinol level in sugar at the refinery are also important for determining retinol losses that might occur during transportation, storage, and distribution of fortified sugar. These losses can be determined by comparing the results of the retinol levels in sugar after production with those from samples collected at different points in the distribution chain.

2. Inspection

Personnel from the governmental entity responsible for overall program supervision must plan their activities so that they not only fulfill the inspection objectives but also improve the fortification process. It is recommended that site visits be conducted by technical personnel from both the public sector as well as the industry itself, such as the Sugar Producer's Association. During the production of fortified sugar, site visits should be made to each refinery at least every two weeks.

The specific purposes of these visits are the following:

Ë *Observe and inspect* the fortification process (manual or automatic) and obtain information from the different workers on aspects of their specific tasks, such as premix storage, moving the premix to the refinery, adding the premix to sugar, and quality control in general.

Ë *Instruct and exchange* ideas with the refineries' technical personnel. In this way, external supervisors can exchange and disseminate ideas and experiences on sugar fortification among personnel at different refineries.

Ë *Provide feedback* on the quality control components so that corrective actions can be applied when necessary. This feedback should be made available to the refinery managers.

F. Equipment care and maintenance

When premix is added manually, the containers used for storing and applying the premix must be properly maintained. This includes simple, basic cleaning.

When premix is added using an automatic system, the procedures for cleaning, checking, and maintaining the dosifiers detailed in the manufacturer's instructions should be followed. Each refinery, or at least a group of them, should have replacement dosifiers to prevent an emergency situation should the machinery break down.

G. Human resource requirements

The sugar fortification process at the refinery requires only the following few additional personnel:

- A part-time worker responsible for moving the premix to the site where it is added to sugar

- A worker responsible for continuously observing and regulating the dosifier (automatic addition). Where premix is added manually, the worker responsible for the centrifuge could add the premix.

- A laboratory technician responsible for the retinol assays

Finally, emphasis should be given to training and supervising the workers involved in the fortification process to ensure that fortification is successful. Training courses must be organized annually, including a motivation component, to emphasize each worker's social responsibility and the care needed in handling the premix and machinery.

Appendix 2.1
EXAMPLE OF PREMIX LABEL

“GOOD HEALTH” SUGAR REFINERY

VITAMIN A PREMIX

(Minimum guaranteed retinol level: 15 mg/g premix)[17]

<u>THIS PRODUCT IS NOT SUITABLE FOR DIRECT HUMAN CONSUMPTION</u>

IDENTIFICATION NUMBER: (YEAR)-_______

Date of manufacture: ____________________

Date of receipt at the refinery: ____________

17. Minimum guaranteed levels should be indicated, instead of the average one, because refineries will calculate the premix dilution based on this figure.

Appendix 2.2
PROTOTYPE BLENDER FOR MANUFACTURING VITAMIN A PREMIX[18]

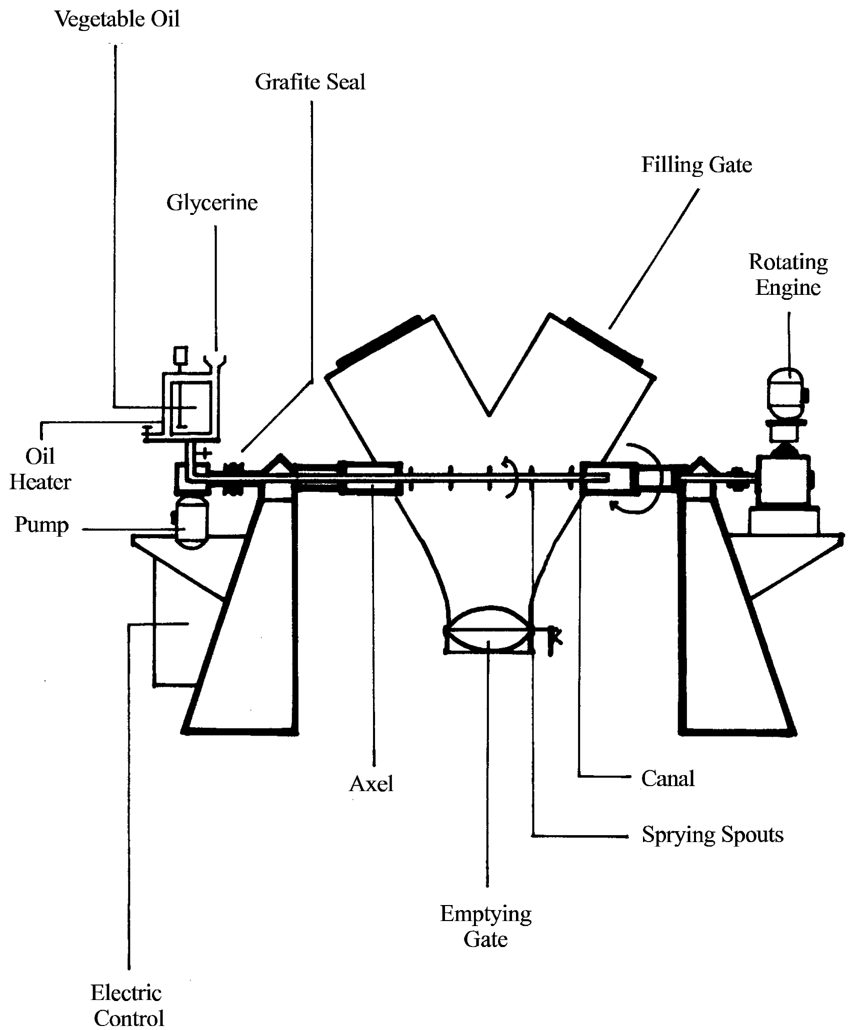
A rotating 150 kg (330 lb) capacity, V-type blender (see appendix figure 2.2a)[19] made of stainless steel and mounted on a solid metal base is used to make the premix. It comprises two filling and one emptying gate, which are closed with rubber gaskets locked in place by central screws. The system is operated by an electric control panel. The rotating engine is located at one end of the base and the oil heater, also made of stainless steel, is located at the other end. The oil heater is connected to the blender's axle by a pump. A cylindrical canal passes through the center of the axle, and vegetable oil is sprayed directly into the blender through stainless steel spouts, located at regular intervals along the canal. The base and blender's axle are joined by a cylindrical graphite seal, which does not interfere with the rotation of the blender. Before this joint at the end of the pump is a butterfly valve, which controls the addition of the vegetable oil.

The vegetable oil deposit (see appendix figure 2.2b) is surrounded by a chamber made of two cylindrical and concentric stainless steel walls, about 4 cm apart. The chamber contains a heating element and is filled with an efficient heat exchange fluid, for example, glycerine, light oil, ethylene-glycol, or a similar substance, which must never be replaced by water or other liquids with a boiling point lower than 100°C. The heat exchange fluid is added through a stainless steel funnel welded to the top. The oil deposit, which holds about 6 l, is covered with a lid equipped with an electric stirrer. An annular perforated tube, connected to the low pressure nitrogen cylinder (±5 psi), is located at the base of the oil deposit.

---

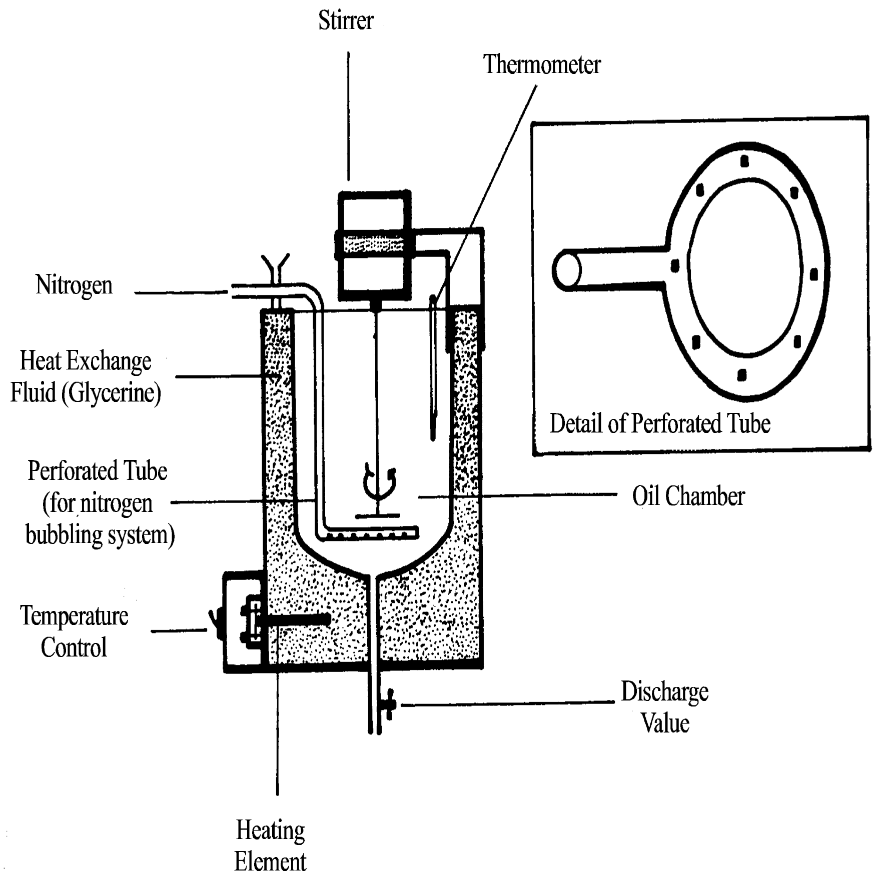
18. Pineda O. 1993. *Hacia el Control de la Vitamina A en El Salvador*. UNICEF.
19. This blender is manufactured by the Hernandez Machine Shop, 13 Avenida 4-27, Zona 1, Guatemala, Guatemala. Tel: 502-2-515-512/534-965. The approximate price is US$15,000.

Appendix Figure 2.2a
PROTOTYPE PREMIX BLENDER



Source: O. Pineda. 1993. *Hacia el Control de la Defiencia de la Vitamina A en El Salvador*. San Salvador: UNICEF.

Appendix Figure 2.2b
DIAGRAM OF OIL DEPOSIT



Source: O. Pineda. 1993. *Hacia el Control de la Defiencia de la Vitamina A en El Salvador*. San Salvador: UNICEF.

Appendix 2.3
QUALITY CONTROL AND PREMIX PRODUCTION LOG

Date	Shift (hours)	ID no. of premix	Vit. A (mg/g)	Observations

Plant manager ____________ Date________ Inspector_____________ Date________

Appendix 2.4
PREMIX DISPATCH LOG

Date	ID no. of premix	Total no. sacks dispatched	Destination (refinery)

Plant manager ______________________

Appendix 2.5
QUALITY CONTROL OF FORTIFIED SUGAR, "GOOD HEALTH" SUGAR REFINERY

Date: ____________

Shift	Semi-quantitative[a] *(µg/g)*	No. sugar sacks produced (A)	No. premix bags used (B)	A/B	Quantitative[20] *(µ/g)*	Observations[21]

a. ND = not detected
<5 = less than 5 µg/g
5–10 = between 5 and 10 µg/g
10–15 = between 10 and 15 µg/g
15–20 = between 15 and 20 µg/g
20+ = more than 20 µg/g

Laboratory manager ____

20. This column is filled when data are obtained by spectrophotometric or HPLC methods.
21. Explanations regarding missing or anomalous data and the corrective measures taken.

Inspector__________________________ Date_____________________