DOCUMENTOS-7
MANSUGHON.V04
07-September-1998

# PERFORMANCE OF A QUALITY ASSURANCE AND CONTROL (QA/QC) SYSTEM OF FORTIFIED FOODS IN DEVELOPING COUNTRIES: Sugar Fortification with Vitamin A in Honduras

**Omar Dary M.**[1], Ph.D., and **Doris Chinchilla**, M.Sc.
Institute of Nutrition of Central America and Panama (INCAP/PAHO)

**Maria del Carmen de Arriola**
Central American Research Institute for Industry (ICAITI)

**Vilma Estrada**
Food Control Division, MOH, and International Eye Foundation (IEF), Honduras

and

**Jose O. Mora**, M.D.
Opportunities for Micronutrient Interventions (OMNI).

August, 1998

INCAP Publication DCI/013

---

[1] INCAP, Apdo. 1188, Guatemala City, Guatemala.
Tel. 502-471-9912
Fax. 502-473-6529
E-mail: odary@incap.org.gt

# PERFORMANCE OF A QUALITY ASSURANCE AND CONTROL (QA/QC) SYSTEM OF FORTIFIED FOODS IN DEVELOPING COUNTRIES: Sugar Fortification with Vitamin A in Honduras

## INTRODUCTION

Sugar fortification with vitamin A was the main strategy selected by the government of Honduras to prevent and control the deficiency of this nutrient in its population. A law was enacted in 1976 (Decree #385, 28 September, 1976) with the purpose that all sugar for internal consumption were fortified with vitamin A at an average level of 15 mg/kg. The program started but its quality was never evaluated nor documented (Estrada *et al.*, 1992). In the middle of the 80s the producers requested from the government that the sugar aimed for industry were exempted, because it was difficult to obtain sufficient foreign currency to purchase the fortificant (retinyl palmitate in the form of a water-soluble beadlet) and other ingredients. The government agreed to this petition, and introduced changes in the regulation to allow production of non-fortified sugar for industrial use (Government Accord #1566, 28 September, 1984). In spite of this concession, in 1993, when the program was evaluated through a national surveillance system, supported by USAID through the International Institute of Science and Technology (ISTI), where sugar samples at the household level were collected, it was determined that barely 6% of sugar was fortified. Based on this result, the government decided to enforce the law, but maintaining the authorization that only sugar for direct domestic consumption be fortified. Producers claimed that 30-40% of the national consumption was destined to that market, and committed themselves to fortify that proportion. Government and international cooperation agencies collaborated backing the installation of a premix factory and the organization of technical training courses to reactivate the sugar fortification process. In 1994, when the surveillance was repeated, it was found that 34% of sugar at homes appeared as fortified, but only 12% presented a content equal or higher than 5 mg retinol per kilogram of sugar (data obtained in this study). This retinol content in sugar provides from 50 to 120% of the Recommended Daily Allowance (RDA) of this nutrient, accordingly to the individual sugar intake. It is considered that the nutritional goal will be achieved once this criterium is satisfied. Before the sugar-harvest season of 1994-95, several analytical courses to determine vitamin A in sugar were given by the Institute of Nutrition of Central America and Panama (INCAP), both to the sugar producers as well as officials of the Food Control Division of the Ministry of Health (FCD/MOH). The 1995 household evaluation showed improving in the fortification quality of the program, but its coverage was still low: 36%.

The improvement of the quality and coverage of the sugar fortification program in Honduras required an additional effort. However, all conditions were adequate for trying to introduce a Quality Assurance and Quality Control (QA/QC) system, suitable for implementation in developing countries, that are characterized for insufficiency of human, material and financial resources. The task was undertaken jointly by INCAP, the Central American Research Institute for Industry (ICAITI), the International Eye Foundation (IEF), and the FCD/MOH of the Honduran Government. Financial and technical assistance was provided by USAID through the International Life Science Institute (ILSI) and the Project of Opportunities for Micronutrient Interventions (OMNI). This article provides a brief description of the implemented interventions and their results.

## MATERIALS AND METHODS

### Design of the QA/QC System

A flow chart of the production and marketing processes of fortified sugar was prepared. Critical control points were determined, and for each of them the indicators, criteria of success, sampling and analytical methodologies, data recording, corrective actions and main responsible were established. Mainly, it consisted in quality assurance and control procedures by the producers during sugar production and fortification; inspection and technical auditing by means of periodical visits (every 15 days) by personnel of the Food Control Division of Ministry of Health (FCD/MOH); monitoring of the product at warehouses and retail stores by personnel of the same Division in all the country.

Quality assurance and control procedures at sugar mills were based on the correct storage and handling of the premix, supervision of the addition of the premix over the sugar, and vitamin A determination of composite samples of sugar. These samples were prepared mixing 100 g-samples taken every 30 minutes until a period of 2 to 4 hours was completed, depending on the size of the mill; the purpose was to have a retinol determination for each 25 to 50 M.T. of sugar. Retinol was measured by means of a semi-quantitative assay (Dary y Arroyave, 1996), that is able to detect differences each 5 mg/kg. The message to the producers was to achieve 60% or more samples with a retinol content between 15 and 20 mg/kg.

The inspection by the state was conceived initially to have a statistically-representative sampling frame from the stored sugar in the warehouses of the mills or the distributors. This plan was immediately abandoned because it was completely impractical and to try to obtain samples from the thousands of sugar bags was even dangerous. It was decided to limit this action to supervise that the QA/QC process was indeed applied by producers, and to take a few samples to confirm that the data provided by the producers were reliable. Retinol determination was carried out with the same semi-quantitative assay, and the results were named "verification assays", to imply that they came from a non-statistical based sampling; however, they were useful enough to verify that fortification was taking place under a controlled system.

Monitoring was planned as a systematic visit to the main warehouses and retail stores, where a few sugar samples to support "verification assays" would be obtained. However, in practice this program showed to be unfeasible, because the FCD/MOH lacked sufficient economical resources, and was restricted to the main suppliers.

### The evaluation and surveillance system

The quality of the sugar fortification program had been evaluated at the household level since 1993. Sugar samples had been collected through the Multiple purpose National Household Surveys carried out by the Secretary of Planning (SECPLAN) of Honduras. For this study, it was planned to estimate the impact of the introduction of the QA/QC system by the same mechanism. However, in the same year of this study (1996) a national biochemical survey was carried out in Honduras, reason by which its sampling frame was used to obtain a national representative sampling of sugar from homes. Three hundred fifty six sugar samples were obtained approximately six months after the end of the 1995/96 harvest season. The retinol content was determined quantitatively using an spectrophotometric method (Dary and Arroyave, 1996) at the laboratories of INCAP.

### Labeling and handling of the fortified sugar bags

In Honduras, all sugar is packaged in 100-pound bags. At the large grocery stores in the main cities, sugar is repacked in smaller presentations inside non-labeled transparent bags made of thin polyethylene. However, most retail stores sell sugar from the original 100-pound bags, serving directly the amount of sugar required for the consumers. Therefore, with the purpose to tag the fortified sugar, an identification feature should be added to 100-pound bags. The label consisted in a color strip of about one inch wide at both sides of the bag. The instruction to the personnel in charge of the sugar storage and handling was to maintain the fortified product (that with color strips) separated from the non-fortified sugar, and to distributed only the former type for direct domestic consumption.

## RESULTS

### QA/QC at sugar mills

The percentage of fortified sugar continued being 40% of the total production aimed for internal consumption in Honduras, but for the first time sugar producers introduced clear identification of the fortified product, as well as the determination of retinol into their ordinary QC practices. The amount of premix was increased to fortify approximately 800 its sugar volume, against 1000 that was the theoretical rate. This change was needed in order to keep retinol level with an average of 15 mg/kg, because it was established that the fortification process, when the premix is added just before the sugar drying during its production, had an efficiency of about 70-80%. The data from the producers showed that 66 and 95% of analyzed samples had a retinol content equal or higher than 15 and 10 mg/kg, respectively. The national average was estimated in 15.8 mg/kg. These data demonstrated that producers achieved the proposed aim, and that the fortification quality of their product was excellent.

The "verification assays" performed by the FCD/MOH confirmed the results reported by the producers: 57 and 82% of samples had a retinol content equal or higher than 15 and 10 mg/kg, respectively. It is important to point out, that in this case the data came from single samples instead of composite samples as was the case of the QA/QC results from the producers, and this explains the small difference that was found between the data from the producers and those from the inspection activities.

### Evaluation and surveillance at households

The impact of the intervention in the quality of the fortified sugar at the consumer level was remarkable: coverage rose from 36 to 82%, and the percentage of sugar with a content equal or higher than 5 mg/kg increased from 23 to 64%. The national average raised from 2.9 to 6.6 mg/kg. Figure 1 summarizes the evolution of the sugar fortification program in Honduras from 1993 to 1996.

These results show that the intervention was very successful, and that most of the fortified sugar was adequately channel to domestic consumption. However, there was still 18% of non-fortified sugar that appeared at households. This sugar was a leakage of non-fortified product into the marketing system of sugar for domestic consumption. This percentage indeed corroborated an initial assumption that the proportion of sugar needed for domestic consumption was nearly 60% rather than 40% as initially claimed by the producers. If the non-fortified sugar is omitted from the calculations, the average content of retinol of the fortified sugar at the household level is 8.1 mg/kg, a value that supports the experimental estimated half-life of vitamin A in sugar of six to eight months.

## DISCUSSION

One of the main reasons for this successful experience was the introduction of QA/QC procedures by the sugar producers. It has been a common practice in Central America that food fortification programs have initiated without an accompanying quality control system, even though INCAP has designed and promoted field methodologies with this purpose from the beginning of the programs. This work has demonstrated that simple interventions and semi-quantitative assays, in due time and with a good a sampling system, could be sufficient to achieve good quality.

The other cause of the outstanding change from prior years was due to the introduction of a colored strip at both sides of sugar bags for fortified sugar, together with the instruction to store this sugar separately from the non-fortified sugar, and to provide only this type of sugar to retail vendors. This case illustrates that universal fortification is not required, if proper procedures for labelling and handling are implemented. It also shows that a simple but very easy to interpret label could be more useful than making the printing of the production or expiration date of the product mandatory, specially considering that staple foods are generally very stable commodities with a very long shelf life. Nevertheless, if the industrial development allows to specify the production date and/or the date of guarantee of the minimum level of fortification (the period of time that a producer can ensure that the product maintains a specific fortification quality), it will improve the task of the food control authorities, and will avoid conflictive situations between producers and governmental enforcement units due to results corresponding to an old product.

During 1996, inspection and monitoring procedures by food control inspectors also improved, but not in a significantly degree. The system was designed in a way that inspection activities would be based on assuring that producers were carrying out quality-control practices, and sampling only for ratifying purposes. In fact, the producers welcomed this measure and wanted food inspectors to examine their work; it was a way to acknowledge recognition for their participation in the fortification program. Some visits were carried out, but not consistently, for all sugar factories and their warehouses. Nevertheless, the mere knowledge that state personnel would visit sugar mills helped to maintain the producer interest regarding their quality control activities.

In summary, our work in Honduras has helped us to face the challenges of food fortification programs in developing countries: The public sector has little resources to carry out extensive monitoring activities; the state is suffering drastic budget reductions, and this trend will continue in the near future; formal sampling methodologies recommended for good manufacturing practices in developed countries and industries are confusing and impractical, specially for monitoring activities; and illiteracy is still a limitation for many consumers. Despite this unfavorable situation, Honduras, a developing country, has been able to improve the quality of the fortified sugar. The key elements are:

- Introduction of fortification quality assurance and control in the routine control practices of the corresponding food industries;
- The presence of the state's supervision must be felt, even though it could be limited to simple visits to observe the fortification process and to verify the compliance of quality control practices. If possible, these visits should be complemented with "verification assays" to assure the reliability of the producers data;

- Labelling of the fortified food must be enforced in all circumstances[1]; and
- A permanent evaluation and surveillance system of the fortified sugar at household level should exist, with the purpose to assess the output of the program.

Other complementary actions, although not essential, could contribute to further improvements. They include:

- Monitoring fortified sugar at warehouses and retail stores, mainly through labelling and packing enforcing, and if possible the inclusion of "verification assays";
- Consumers' education to demand packed and labelled fortified foods;
- Coordination between food control authorities and customs authorities to check imported foods that must be fortified and properly labelled; and
- Restricting punitive actions to a quality-auditing structure as free of bribery as possible.

In essence, the complete QA/QC and evaluation/surveillance framework that originated from this work is as follows:

- Quality assurance and control using fast analytical assays by producers.

- Inspection and technical auditing visits by food control personnel to verify that QA/QC procedures are taking place, and if possible the inclusion of "verification assays".

- Monitoring of warehouses and retail stores by local authorities by means of enforcing good packing and labelling practices. This action may be enforced by information, education and communication (IEC) program activities to consumers aimed at promoting their participation as their own food supervisors.

- Evaluation and surveillance through an annual permanent sampling of fortified foods at the household level, in which the use of quantitative assays should be considered.

REFERENCES

Dary O., and Arroyave G. 1996. *Sugar Fortification with Vitamin A. Part 3: Analytical Methods for the Control and Evaluation of Sugar Fortification of Vitamin A.* 2 ed. USAID/OMNI, INCAP. 81 p.

Estrada de Aviles, V., Hernandez Santana, A., and Caceres R. 1992. *Evaluación del Proceso de Fortificación del Azúcar con Vitamina A en Honduras.* Ministry of Health, Division of Food Control, and INCAP/PAHO.

---

[1] Ideally, it should include the production and guarantee date of the minimum fortification level. However, it may constitute a difficult requirement to be fulfilled by some producers, and its enforcement may cause producers' opposition to introduce fortification and/or quality control practices into their current operations. The main information in the label is the name of the responsible or distributor.

# EVOLUTION OF THE SUGAR FORTIFICATION PROGRAM IN HONDURAS

## (Fortification quality at households)