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EVALUATION AND DOCUMENTATION OF A QUALITY ASSURANCE AND CONTROL (QA/QC) SYSTEM OF FORTIFIED FOODS IN HONDURAS

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FIGURE 1.

The work that I will present was a collaborative project of the Central American Research Institute for Industry (ICAITI), the Division of Food Control of the Ministry of Health and the International Eye Foundation (FIO) of Honduras, and the Institute of Nutrition of Central America and Panama (INCAP/PAHO). We also had the collaboration of Dr. Jose Mora from the International Science and Technology Institute (ISTI), now at the project of Opportunity for Micronutrient Interventions (OMNI).

The main objective of this work was to improve and evaluate ongoing QA/QC systems for fortified foods in Honduras. We focused on sugar and salt. Our findings and project outcomes were very different for both types of foods, but at the end they brought us to similar inferences and conclusions.

First, I will present the case of sugar, then that of salt. Finally, I will introduce the general deductions and recommendations.

FIGURE 2.

We have been monitoring the evolution of fortified sugar with vitamin A at the household level in Honduras since 1993. Sugar samples have been collected through the Multiple Purpose National Household Surveys carried out by the Secretary of Planning (SECPLAN) of Honduras, excepting 1996, when we used the National Survey for Micronutrients, coordinated by OMNI. In all cases, sampling had national representation.

In 1992, INCAP with technical and financial collaboration from VITAL (USAID) started an intervention and training project aimed at improving the sugar fortification program in Honduras. Courses in analytical methodologies were given to both governmental functionaries as well as personnel from sugar mills. A new factory of the micronutrient premix was installed, and the amount of fortified sugar risen from 10% to 40% of the total annual production. The rest of sugar production (that is 60%) is non-fortified and is destined for industrial use. This combination of sugar types is clearly shown by the results obtained at households. The percentage of fortified sugar at homes were 6%, 34% and 36%, for 1993, 1994 and 1995, respectively. Average sugar retinol levels were 0.4, 2.5, and 3.5 mg/kg for those years.

We started this QC/QA project in the harvest season 1995-1996. In this occasion, we were able to convince producers to introduce the determination of retinol into their ordinary QC practices, and the use of a specific labelling of the bags destined for fortified sugar. Simultaneously, we suggested a complete framework for monitoring to the Food Control Division. The percentage of fortified sugar continued being 40%. However, the improvement at the household level was notorious: 84% of families had fortified sugar at the moment of the survey, from which 63% of the total samples had retinol levels above 5 mg/kg, which provides 50 - 100% of the Recommended Daily Allowance (RDA) for this vitamin given the current sugar intake.

FIGURE 3.

One of the reasons for this successful experience was the introduction of quality control for fortification at the sugar factories. It has been a normal situation in Central America that food fortification programs have started without an accompanying quality control system, even though INCAP has devised and promoted field methodologies with this purpose from the beginning. Similarly, actual regulations do not include QC/QA criteria.

This figure shows definitively that the quality of fortified sugar at sugar mills of Honduras was much better than that from El Salvador and Guatemala. Retinol levels in the x-axis are arranged from higher to lower values. This is intentionally, in order to present the information in a positive way, that is, how much we have succeeded instead of how much we have failed. Thus, a steeper curve from the beginning reflects a higher retinol and a narrower range. The message to the sugar producers was very simple: "to achieve 60% or more determinations between 15 and 20 mg/kg", this was so because 15 mg/kg is the expected average level at production, and because the semi-quantitative assay, that was used, has a precision of plus-minus 5 mg/kg.

Experimentally, we have determined that the variation coefficient for sugar fortification levels is 30%. Thus, in a normal operation we expect that 70% of retinol values fall between 10 and 20 mg/kg, and 95% between 5 and 25 mg/kg. Honduran results were much better: 90% were between 10 and 20 mg/kg, and 100% above 5 mg/kg. Retinol assays were performed every 2-4 hours, depending the production rate of each factory, and it represents an analysis every 25 to 50 M.T. of sugar. Samples were taken either continuously during that period or 100 g every 15 minutes to prepare a composite sample. The sampling technique is important, because frequently bad results are due to poor sampling methodologies rather than inadequate procedures of fortification for an operation of this size and type. Many difficulties created by governmental authorities arise from a single, small and non-systematically taken sample, which does not fit with the reality of the production process.

Sugar mills in Guatemala and El Salvador also introduced the retinol determination in their quality control laboratories. However, their results were not used to adjust the amount of nutrient premix that was being dosified. They persisted with the practice to attain the theoretical 1:1000 dilution of the premix over sugar, instead of looking for the final quality of the product. Therefore, more than 50% of fortified sugar in those two countries present retinol contents either below or above the recommended range of 10 to 20 mg/kg. They have already been informed regarding these results, and it is expected that for the following harvest season (1996-97) they would have adopted the new criteria, and their fortification practices been accordingly improved. We do not know this year´s results yet.

FIGURE 4.

The good work at the factory level in Honduras was revealed in the analysis of sugar at homes. In the latter case, the results appear with more variability, but this was so because they came from individual samples and not composite samples. Nevertheless, the final outcome is very good: 82% of individual samples with retinol, 64% with levels greater than 5 mg/kg, and a national mean of 6.6 mg/kg. The average is 8 mg/kg if it is estimated using only the fortified samples.

The reduction of retinol levels from the factories to households was expected for two reasons: first, 50% of retinol is lost during the shelf life of sugar, a normal situation for a fortified food with vitamin A; and second, mixing of fortified sugar with non-fortified (industrial) sugar during its distribution chain, that is "industrial sugar leakage". However, during 1996 this leakage occurred only for 18% of sugar sold for family consumption. This outstanding change from results from prior years was due to the introduction of a colored strip at both sides of sugar bags for the fortified sugar, together with the instruction to stack 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 of labelling and handling are placed in practice.

FIGURE 5

Monitoring procedures by food control inspectors also improved, but not in a degree that could be considered as significant. 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 confirmatory purposes. In effect, the producers welcomed this measure and wanted food inspectors to examine their work; it was a way to feel recognized for their participation. Those visits were made but not in a consistent manner for all sugar factories. Nevertheless, the mere knowledge that state personnel would visit sugar mills helped to maintain the interest by producers regarding quality control activities.

In summary, the "true" QC/QA system established in Honduras in 1995-96 consisted in control of sugar retinol content and bag labelling at the factories, and in creating the awareness that possible inspections by governmental personnel might be carried out. It was also very important to have a surveillance system at the household level, with which we could determine the evolution and the effects of the program.

Part of the non-fortified sugar, destined to industries, leaked to homes, but considering that it was the first time that this system was implemented, the final outcome was very good.

FIGURE 6

The experience just described has allowed us to recommend a complete QC/QA system, aimed at further improving the quality of the sugar fortification program. This system could seem complex, but it is not.

It considers the establishment of certification of the nutrient premix by food inspectors. This is in response to a request from the producers, because they want to be sure that the premix meets the expected requirements. The quality control at the factory level continues as described. Inspection visits by state personnel would be systematized, and they would include **"confidence assays"**, because we have confirmed that human nature is weak, and falsehood exists everywhere since "Eve was tempted by the snake in paradise". This "confidence assays" simply consist in taking randomly 4 samples from recently produced and packaged sugar, and to confirm the "presence" of retinol. We tried sampling based on statistical criteria, however, this is not only complex but also completely impractical under the actual realities of production and available resources.

The system would include monitoring at the most important warehouses, whose number and selection would be determined more based on the resources of the food control division rather than on statistical representativity. Indicators at this level would include labelling and "confidence assays". However, to avoid "bribing", that it is also another human weakness, specially in developing countries, if food inspectors find non-fortified sugar in otherwise bags they would have to report the questionable brands to a national coordinator of the program, who might organize a **Quality auditing** to the suspicious factory and their warehouses, with the presence of delegates from producers (or members of a fortified food commission, e.g.). If intentional transgressions were found, then punitive actions would be considered. Sampling for this quality auditing would use statistical criteria. We have not used this mechanism yet, and we hope not to have necessity of it. Local inspectors could confiscate sugar only if non-fortified bags are being sold for human consumption but not because their vitamin-A content.

The system would also include monitoring at smaller warehouses and retail stores, but in this case inspection would be restricted to enforce the exclusive presence of fortified-sugar bags.

The proposed system also considers mechanisms for managing imported sugar, either it be for industrial use or for direct family consumption. In the last case, it must satisfy the criteria for the fortified sugar produced in the country, including bag labelling. In addition to the certification of conformity by the exporting country, "confidence assays" would be made because the same human flaws may also exist in the exporting country.

Household surveillance, although not strictly a component of the QC/QA system, would be maintained as the main device to follow the overall quality of the program.

FIGURE 7.

For each one of these stages, the project provided us with sufficient information to suggest the quality criteria for each one of the indicators. They are simple and easily to understand.

FIGURE 8

The salt situation was different that of sugar. We were able to recover information since 1987, and judging for the data, salt fortification has had good compliance for at least the last ten years in Honduras.

Results of samples from 1996 analyzed at INCAP reveal that fortified salt was available in 80% of households, 76% with iodine content greater than 25 mg/kg. These figures, although slightly lower than official data from prior years, point out that coverage of the fortified salt program is high in Honduras.

FIGURE 9

Analyzing for the "secrets" of the relative success of salt fortification program in Honduras, we conclude that it is because of the intense and frequent monitoring activities carried out by food control inspectors at each one of the iodization centers (17-20 in the country), and the compliance with the requirement that fortified salt must be packed in 0.5-pound bags with a label including the name of the producer (iodization plant).

This case is very interesting, because the nutrient premix, called "yodocal", does not have any type of control and there is no information on which we can base inferences about its quality. On the other hand, the system of salt iodization is very primitive, it consists in mixing "yodocal" and raw sea-salt, using shovels to mix salt and iodate spread over dirt floors or, in the better case, over wooden boards. The salt is packed by hand in plastic bags, which are sealed with heat. Iodized salt is not stored for long periods, which means that fortification proceeds at the same rate as its distribution and marketing. In general, salt quality is bad: 90-95% purity and 5-10% humidity. However, the results show that it still is a good source of iodine.

Monitoring activities consist of visits to the iodization sites every two to three weeks, when food inspectors perform quantitative determinations of iodine in 4-5 randomly selected bags. If iodine levels do not meet specifications (30-100 mg/kg), all the bags from the batch are open and the iodization process is carried out again. The final result of this strategy has been a properly-fortified product.

Some non-systematic monitoring by state inspectors has also taken place at wholesalers and retail stores, but its usefulness has been more confirmatory than as an enforcing mechanism.

External technical assistance has contributed in some degree to the success of the salt fortification program in Honduras. For example, UNICEF has provided motorcycles to food inspectors, and hence they are able to cover easily the areas under their responsibility.

Nevertheless, sometimes this assistance, although with good intentions has placed the program at risk. Let me explain this: Several years ago, international assistance provided the country with a checking laboratory, strategically located in a meeting point of several roads. Its purpose was to examine each truck with a salt load passing through that site. The laboratory has not operated since its inauguration because it lacks water and electricity services. However, in spite of the absence of this "recommended" enforcing strategy, salt fortification has been doing well. Nevertheless, there have been recent plans to activate this structure, creating the possibility of replacing on-site inspections for truck monitoring, so weakening the current efficient monitoring system.

Other example of another unintentional but "interfering" intervention happened last year. An international agency has actively been working to organize producers in a way that they can "modernize" their operation and therefore improve the quality and fortification of the salt. The producers misunderstood this assistance and they waited for yodocal donations from the agency. And in December of last year, during a few weeks salt was not fortified, because producers did not purchase yodocal timely, contrary to what they had done for many years in the past. Luckily, this situation was temporary.

Similarly to the sugar case, we have recommended a QC/QA system for salt, through which we hope to reduce the amount of non-fortified salt at homes. It will need an educational campaign to influence consumers to avoid purchasing salt from bulk bags, which generally is non-iodized.

FIGURE 10

Salt iodization programs have several levels of coverage in Central America. Thus, 85% of homes in El Salvador had salt with iodine levels higher than 25 mg/kg, 76% in Honduras, and 60% in Guatemala in 1995. However, in 1996 only 11% of the Guatemalan salt was adequately fortified. Nicaraguan and Costa Rican authorities claim a coverage above 90% and 99%, respectively.

The impairment of the program in Guatemala also shows the importance of permanent supervision by governmental personnel. One of the reasons for the reduction of fortification compliance was changes in capabilities of the food control division due to current policies of restructuration and reduction of the size of the state. This situation exemplifies the weakness inherent to depending on the state monitoring rather than producers. However, the industrial development of salt production in most countries of Central America makes unrealistic the incorporation of quality control practices by salt producers. Thus, in this case the role of the state for monitoring and compliance is essential.

In 1996 in Guatemala, a project aimed to promote good manufacturing practices to improve salt quality and its fortification had some fair results for improving the general quality of salt but not for improving its fortification. A kit promoted by UNICEF to detect the presence of iodine in salt was recommended as a quality control tool. "The medicine was worse than the disease". Producers that in the past had controlled fortification only by means of the proportion of yodocal added to salt, now they rely on "seeing" the "color" of the fortificant in final product. Thus, they started to reduce the amount of yodocal added to salt because the "color" continued appearing in salt examined using the kit. We consider that this was another contributing factor to reduce the coverage of the salt iodization program in Guatemala during 1996.

FIGURE 11

In summary, our work in Central America, specifically in Honduras, has helped us to face 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 tendency 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, developing countries have been able to improve and maintain quality and coverage of fortified foods. The key elements have been:

- Introduction of quality control of the fortification in the routine quality control practices of the corresponding food industries. If the development of the industry does not permit quality control, then the state must take this function, that is the case of artisan-produced salt in Central America;
- 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 compliance of quality control practices. If possible, visits should be complemented with "confidence assays" to assure the presence of the fortificant in the food;

- Labelling of the fortified food must be enforced in all circumstances*; and
- A permanent surveillance system of the fortified foods at household level should exist.

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

- Monitoring fortified foods at warehouses and retail stores, mainly through labelling and packing enforcing, and if possible inclusion of "confidence assays";
- Education of consumers 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
- Restrict punitive decision to a quality-auditing structure as free of bribery as possible.

FIGURE 12

In essence, the complete QC/QA framework that we suggest is the following:

- Quality control using fast analytical assays by producers.

- Inspection visits by food control personnel, and if possible inclusion of "confidence assays".

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* Ideally, it should include the date of production. However, it may constitute a difficult requeriment to be fulfilled by some producers, and its enforcement may cause producers' opposition to introduce fortification and/or quality control practices to their current operations. The essential information in the label is the name of the producer or distributor.

- Monitoring by local authorities by means of enforcing good packing and labelling, as well as information, education and communication (IEC) activities for consumers aimed to promote their participation as their own supervisors of their foods.

- Surveillance through a permanent sampling of fortified foods at the household level, in which the use of quantitative assays should be considered.

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and

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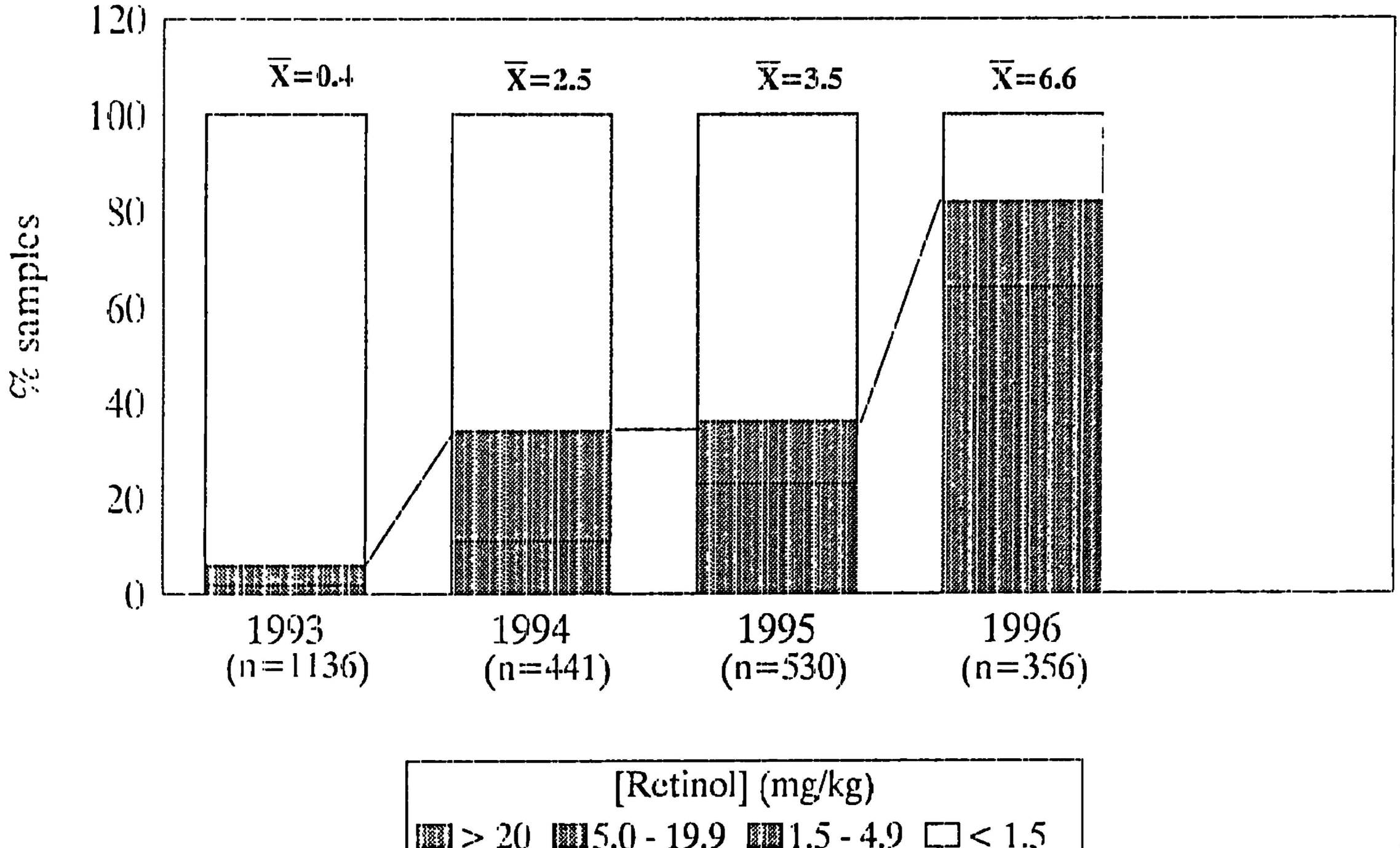
ISTI/VITAL and OMNI

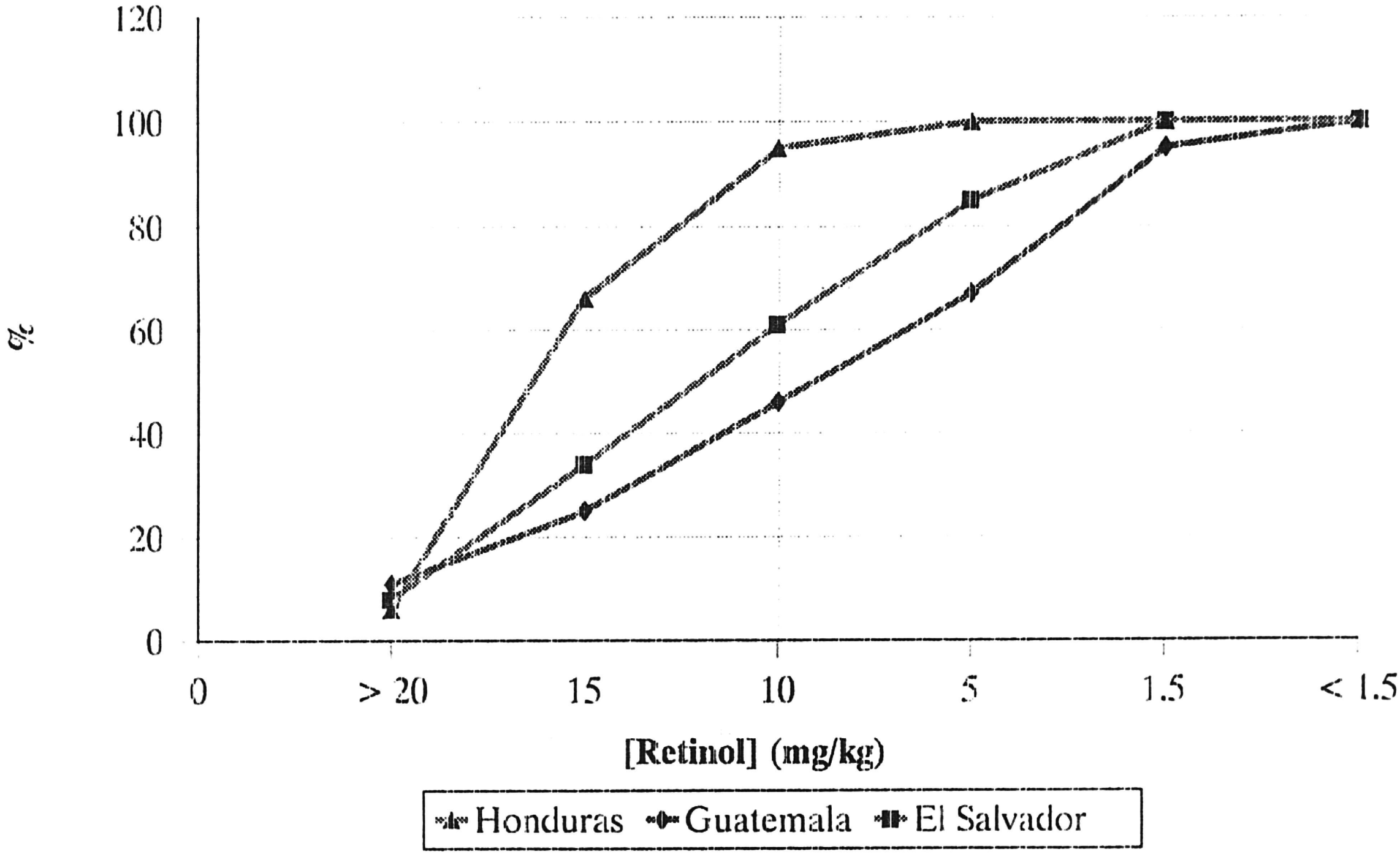
EVOLUTION OF FORTIFIED SUGAR AT THE HOUSEHOLD LEVEL
Honduras, 1993-96



QUALITY OF FORTIFIED SUGAR AT FACTORIES IN CENTRAL AMERICA

(1995-96)

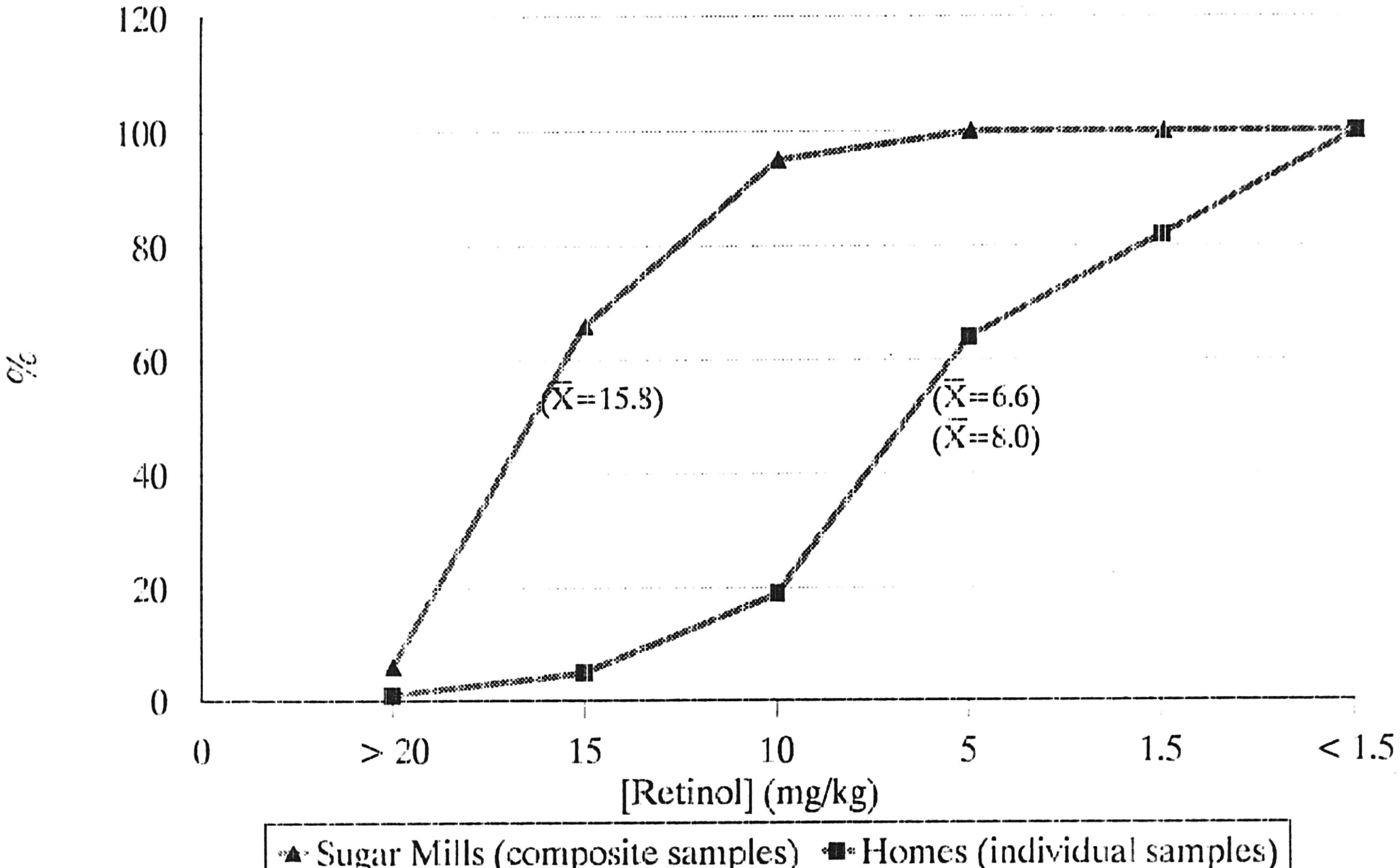
Cumulative percentages



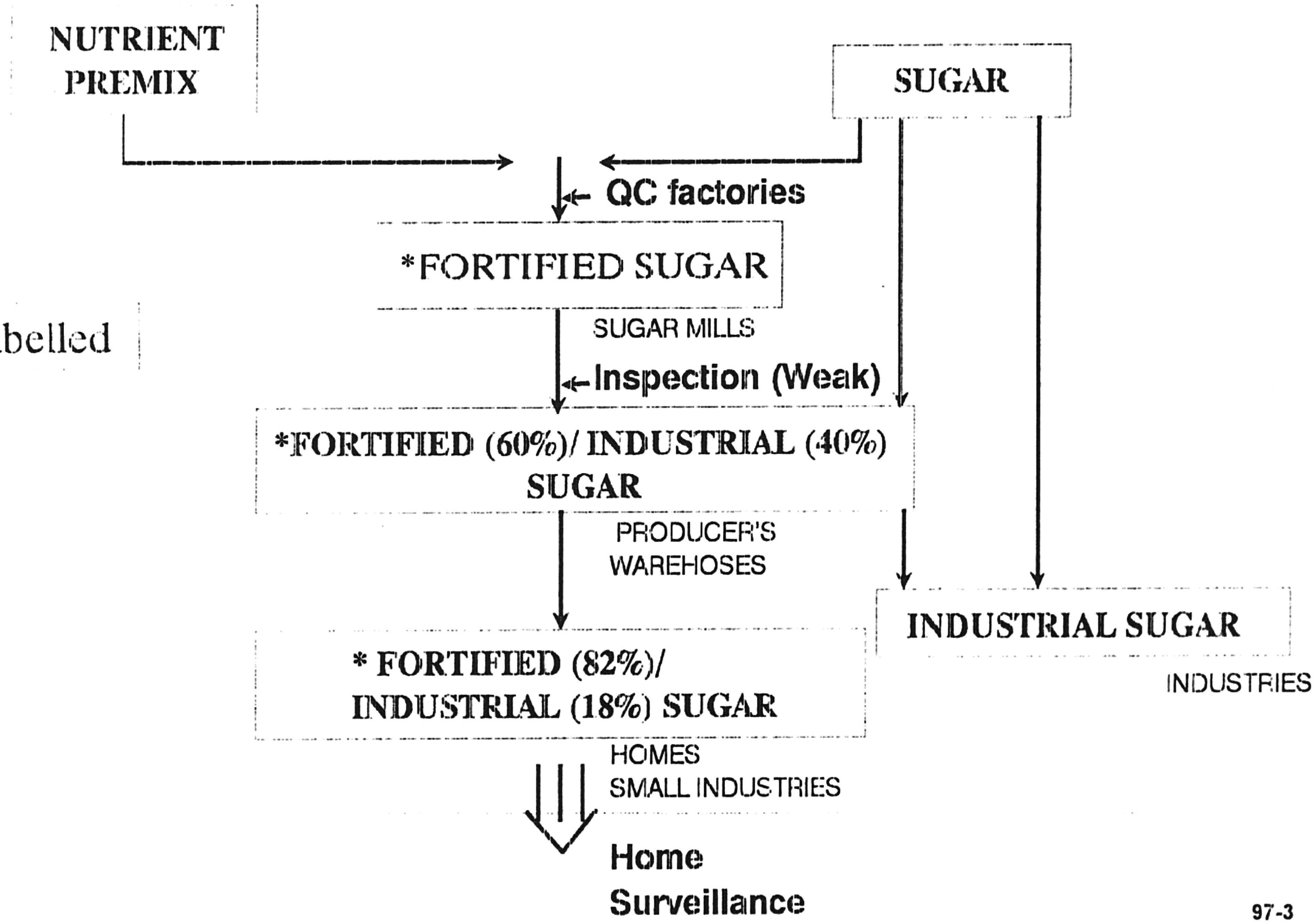
CHANGES IN THE SUGAR RETINOL CONTENT FROM FACTORY TO HOME

(Honduras, 1995-96)

Cumulative percentages

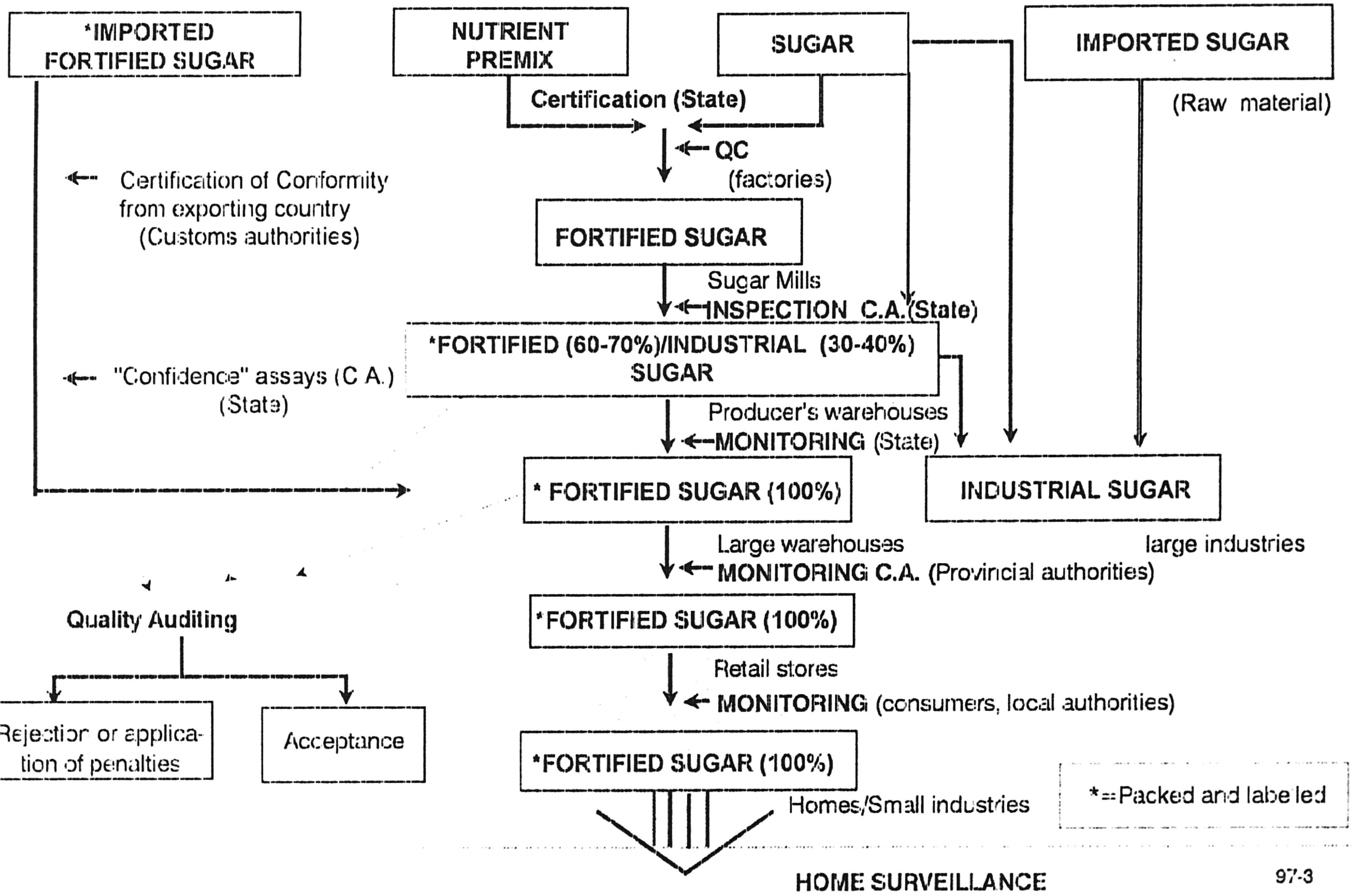


"TRUE" QC/QA SYSTEM OF FORTIED SUGAR IN HONDURAS DURING 1995-96



*Labelled

RECOMMENDED QC/QA SYSTEM OF FORTIFIED SUGAR



$\bar{X}$=16.5 g/kg
> 80% 15-18 g/kg

>60%>15 mg/kg

$\bar{X}$ = 12-18 mg/kg
> 80% 10-20 mg/kg

100% >2 mg/kg
>40% >15 mg/kg

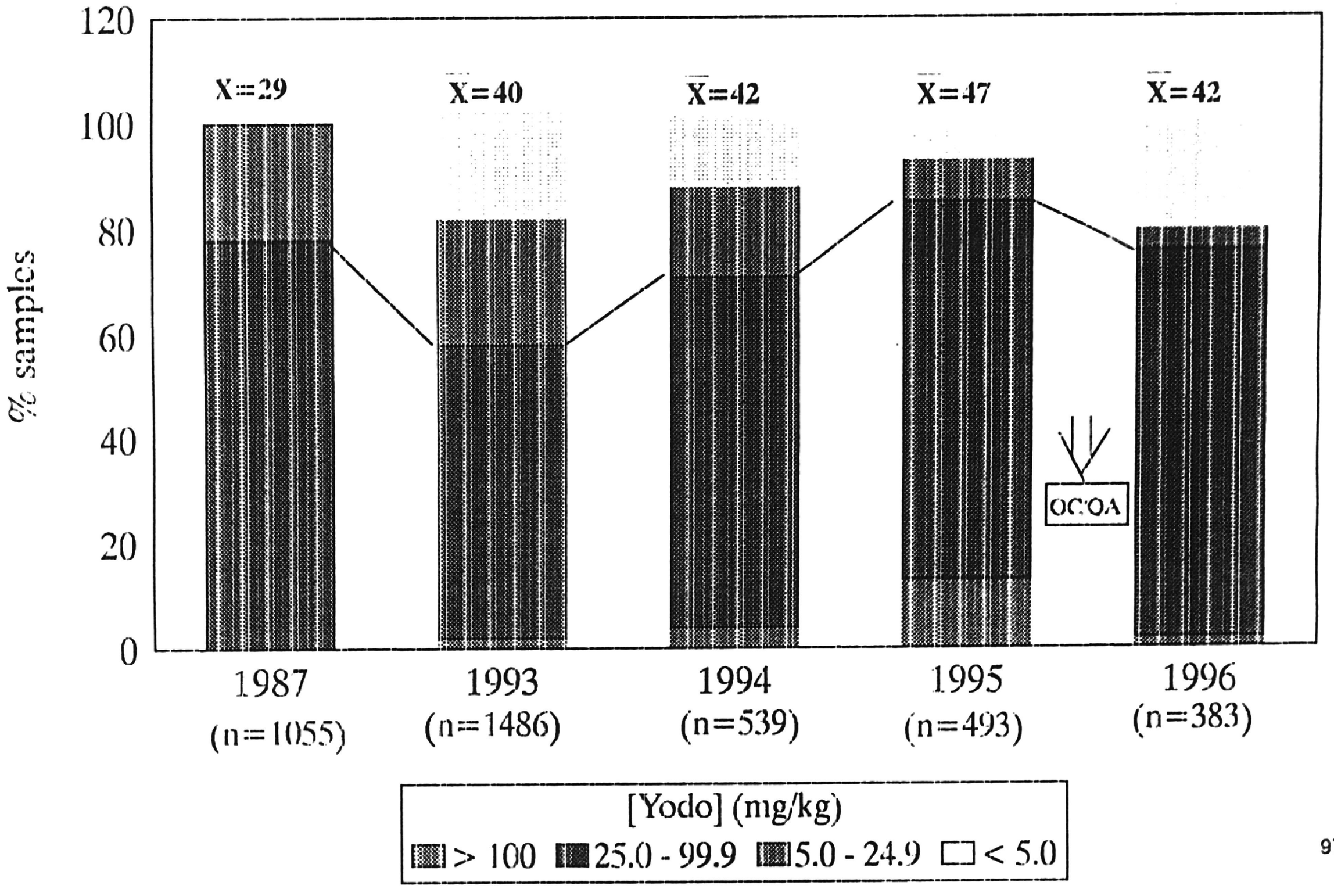
100%> 2 mg/kg

100% > 2 mg/kg
>60%> 10 mg/kg

Statistical Sampling
100% > 2 mg/kg
>80% > 5.0 mg/kg

EVOLUTION OF FORTIFIED SALT AT THE HOUSEHOLD LEVEL

HONDURAS, 1987-96



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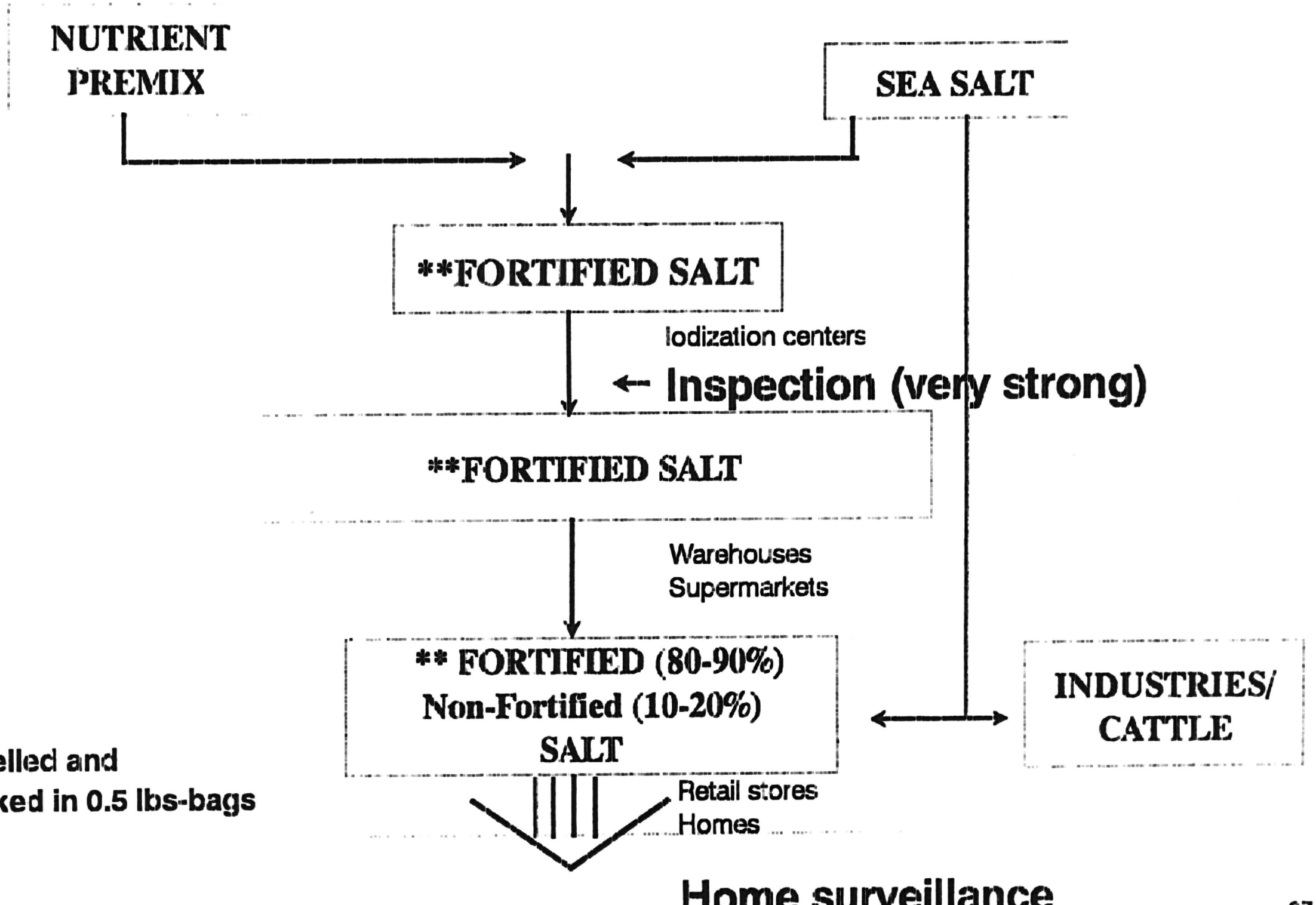
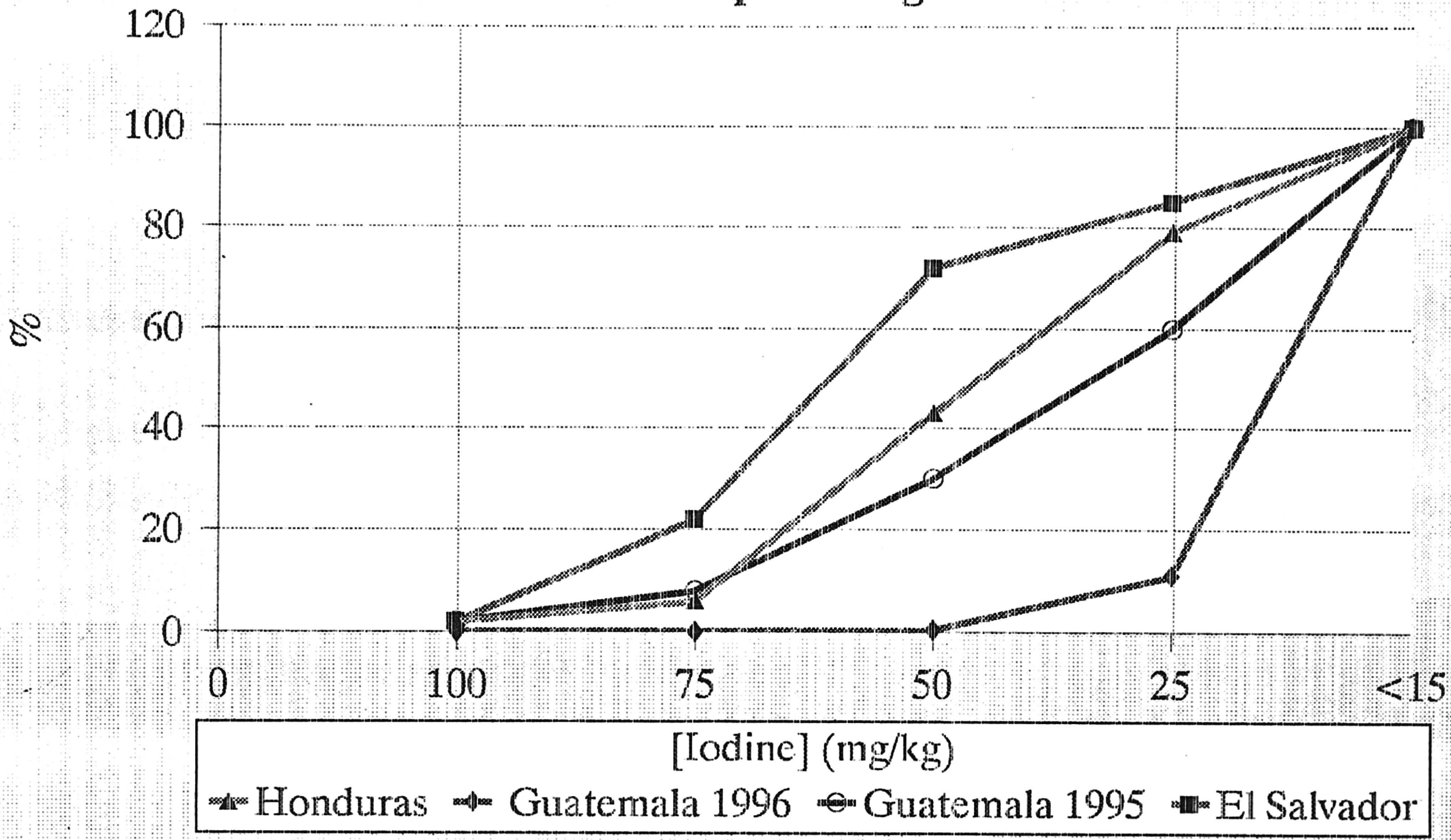
" TRUE" QC/QA SYSTEM OF FORTIED SALT IN HONDURAS DURING 1987-96



QUALITY OF FORTIFIED SALT AT HOME LEVEL IN CENTRAL AMERICA

(1996)

Cumulative percentages



FACED CHALLENGES:

* Public sector with little resources
* Reduction of state personnel
* Formal sampling methodologies too confusing and impractical
* Illiteracy of consumers

KEY FACTORS OF SUCCESS:

* QC by producers (semi-quantitave assays)
* "Possibility" of State inspections ("confidence" assays)
* Product with label
* Existent and permanent surveillance system (household level) with national representativity

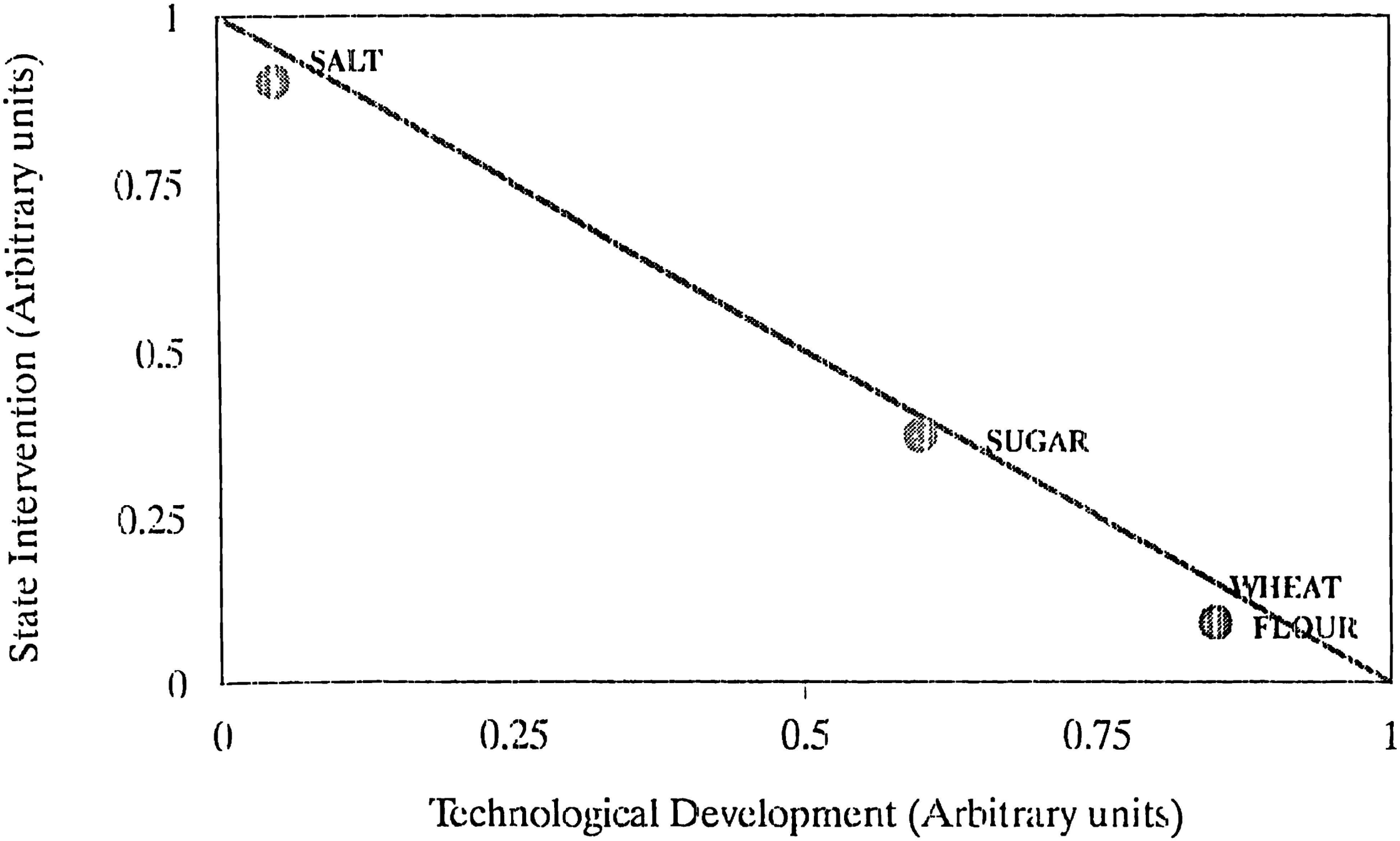
POTENTIAL IMPROVERS:

* Warehouse/retail stores monitoring
* Consumer's awareness (label and logotype)
* Coordination between food control and customs authorities
* Quality-auditing structure (food fortification committees).

THEORETICAL FRAMEWORK OF QA/QC SYSTEM FOR FORTIFIED FOOD IN DEVELOPING COUNTRIES

COMPONENT	RESPONSIBLE
Quality Control (fast analytical assays)	Producers
Inspection ("confidence" assays)	Food Control (Industrial section)
Monitoring (Labelling)	Local Authorities (and Consumers)
Surveillance (quantitative analytical assays)	State + consumer protection groups

INTENSITY OF INSPECTION/MONITORING versus TECHNOLOGICAL DEVELOPMENT OF FORTIFIED FOOD INDUSTRIES



PROBABLE IMPACT OF THE SUGAR FORTIFICATION PROGRAMS IN CENTRAL AMERICA

Plasma Retinol in Pre-schoolers