Division of Health Systems and Services Development
Organization and Management of Health Systems and Services Program
Regional Oral Health Program

FINAL REPORT TO THE W.K. KELLOGG FOUNDATION

Project # 43225

Washington, D.C. May 2000

Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas (Belize, Bolivia, Dominican Republic, Honduras, Nicaragua, Panama, Paraguay, Venezuela)

Pan American Health Organization (PAHO)
World Health Organization (WHO)

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Finally, we would like to thank Etty Alva and Olga Van Looveren for their support and Dr. Ana Arana for her contributions to the report.

GLOSSARY

µg/h	Microgram per hour
AMPES	American Region Programming and Evaluation System
CTO	Country Technical Officer
DMFT	Measure of past and present dental disease. D- Decayed, M- Missing, F-Filled, T- Teeth
DMFT-12	DMFT of 12 year old children
F	Fluoride ion
FDI	Federation Dentaire International
IEC	Information, Education and Communication component of programs.
Kellogg I	Grant of $750,000 awarded to PAHO by W. K. Kellogg Foundation for salt fluoridation in Bolivia, Dominican Republic, Honduras, Nicaragua, Panama and Venezuela.
Kellogg II	Grant of $262,006 awarded to PAHO by the W.K. Kellogg Foundation for salt fluoridation in Belize and Paraguay.
Kg	Kilogram
Mg/l	Milligrams per Liter
mL	milliliter
MoH	Ministry of Health
N	Total number of samples or persons examined or surveyed
PAHO	Pan American Health Organization
ppm	Parts per million
TAG	Technical Advisory Group to the Regional Oral Health Program at PAHO
WHO	World Health Organization
WKKF	W.K. Kellogg Foundation

SECTION I

EXECUTIVE SUMMARY

This report presents the achievements attained by the "Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas" implemented by the Pan American Health Organization (PAHO) with the support of the W.K. Kellogg Foundation, and with the collaboration of the Ministries/Secretaries of the eight participating country. PAHO was the recipient of a three-year grant from W. K. Kellogg Foundation (P-43225) for US$ 750,000, to support salt fluoridation programs in Bolivia, Dominican Republic, Honduras, Nicaragua, Panama, and Venezuela, and a second grant for US$ 262,006 to support similar programs in Belize and Paraguay.

Section II discusses the role of the W.K. Kellogg Foundation in support of oral health in the Americas, and how it has been possible with the support of the Foundation to move an oral health agenda forward. PAHO and Kellogg initiatives and leadership have enabled the success of oral health program and particularly salt fluoridation.

Section III presents the description of salt fluoridation programs, country selection criteria, project components, country program plans and PAHO's technical assistance in support of the Grant implementation.

Section IV describes the progress attained during the 1998-99 period and summarizes achievements since the program inception in August 1996. Tables 1-10 display results from baseline studies including cost-benefit ratios, communities with fluoride concentration in the drinking water above 0.9 mg/l, DMFT-T index at 12 year of age, and prevalence and severity of dental fluorosis. Tables 11-24 depict the current status of development of salt fluoridation standards in each country. Additionally, Annex I include in detail country-based activities and technical support provided. Protocols for al baseline studies are presented in Annex 2-6.

Section V describes in detail activities for salt industry assessment and general observations and provides recommendation in the area of salt industrial technology. This is a critical component of the slat fluoridation programs and limitations in this area have been the main obstacle to expedite program implementation (Annex 7 presents recommendation for country legislation).

Section VI describes the progress made in surveillance systems and PAHO's final recommendations for all countries in the Americas for appropriate surveillance of salt fluoridation programs.

Section VII describes final recommendations, including policy, salt industry and legal aspects for salt fluoridation.

A work plan was developed for each country following the guidelines described in the proposal. Activities during the second year included feasibility and cost-benefit studies for Belize and Paraguay, completion of baseline studies for countries in the second-year of program implementation, training in fluoridation techniques and quality assurance developing surveillance systems.

PAHO's Regional Oral Health Program assembled a team of consultants with wide scientific and technical expertise to assist each country in its specific needs. These consultants are affiliated to various organizations, which granted their participation in the implementation of this grant. Two organizations in

particular, the Division of Oral Health of the Centers for Disease Control, and the WHO Collaborating Center at the University of Texas Health Science Center in San Antonio, Texas, deserve special recognition on this regard. PAHO Country Representations were valuable in the coordination of in-country activities. Additionally, local coordinators and professionals devoted time and efforts on various program components. PAHO's Regional Oral Health Program maintains appropriate documents from each country including datasets and travel reports from the consultants.

SECTION II

THE ROLE OF W.K. KELLOGG FOUNDATION IN SUPPORT OF ORAL HEALTH IN THE AMERICAS

Over the past 12 years the Pan American Health Organization with the strong supports from the W.K. Kellogg Foundation (WKKF) has developed the basis for salt fluoridation programs in the Region of the Americas. During this time, PAHO has developed strategies for improving the monitoring and surveillance of national salt fluoridation programs and has fostered development and transfer of knowledge through technical cooperation. A significant part of this work has been made possible by the support of the W.K.Kellogg Foundation. PAHO and Kellogg initiatives and leadership have been decisive in the success of salt fluoridation programs in the Region of the Americas.

The support of the Foundation encompasses two periods as follows:

1st PERIOD (1954-1995)

It is true to say that the development and progress of modern dentistry in Latin America and the Caribbean is directly tied to WKKF efforts in that area. It may best be summarized in the words of a WKKF report tabled in 1991. These words remain as true today.

> **"Almost all of the milestones achieved in Latin American dentistry since the 1940's have been influenced by WKKF assisted projects. This is particularly true in the areas of dental education and oral health promotion and caries prevention. WKKF is the only major philanthropic institution, which has continually supported the advancement of oral health in the Region".**1

The WKKF strategy for its assistance to oral health has two main components. These have been:

1. A public health or mass preventative approach to dental caries, and

2. The development of dental manpower/dental health services, with emphasis on undeserved communities.

This strategy has been implemented through a series of programs summarized below.

- Study grants in dental education under their Fellowship program from 1947.
- The creation of a Dental Officer position in PAHO in 1954
- Support of sub-regional seminars on dental education conducted by PAHO in Columbia (1962), Mexico (1964), and Brazil (1966).
- Support for the Association of Schools of Dentistry, from 1962, the Latin American Association of Dental Schools (ALAFO), the Organization of Faculties, and the Schools and Departments of Dentistry of the Union of Latin American Universities (OFEDO/UDUAL).

- Promotion of water fluoridation, from 1977.

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1 W. K, Kellogg Foundation, Report to the Board, Oral Health in Latin America, Marcos Kisil, Blas Santos, Mario Chaves, Jan15th 1992.

- Development of innovative dental school curricula over period 1977-83.
- Development of salt fluoridation projects, from 1985.

A chronology of W K Kellogg Foundation assistance in oral health to the Region through PAHO is shown in the table 1.

PAHO Projects in Oral Health Financed by the W.K. Kellogg Foundation Over the Period 1954 to 1990

	Project Description	Year of Implementation	Amount
1	Consultant in dental Education	1954	$42,320
2	Textbook translation of dental public health training manual	1962	$12,005
3	Dental education seminars Bogota, Columbia	1962	$22,285
4	Water fluoridation education program	1966	$149,041
5	Strengthen primary care dental education and service in university based dental schools in Latin America	1977	$279,553
6	Support a meeting of Latin American dental leaders to assess the status of and for improving dental health services in the Region	1985	$15,079
7	Improve health of Latin Americans by holding a meeting of advisors to determine the most effective way to implement salt fluoridation	1986	$39,693
8	Assist improvement of dental curricula in Spain, Portugal and Latin America through a travelling seminar for dental educators.	1987	$48,611
9	Convey achievements in oral health in the developing countries of the Americas by conducting a symposium for dental leaders.	1987	$82,400
10	Enable Deans of various dental schools to participate in the Fifth Conference of Latin American Schools of Dentistry and Union of Latin American Universities.	1989	$17,479
	Total		$708,466

In addition to the grants channeled through PAHO programs, the W K Kellogg Foundation has awarded another $7.5million mainly to Ministries of Health and Dental Schools in the Region. These grants have gone for a variety of programs ranging from dental education to salt fluoridation.

Yet, merely describing projects and numbers of dollars awarded do not paint the entire picture. That comes in shaper focus when we view the impact of the W K Kellogg Foundation's philanthropy on people's live; health and happiness.

So for instance from 1942 to 1970, 220 dental Fellows, mainly faculty members came to the USA for advanced training. Many have on their return become leaders in their institutions.

Many innovations in dental education and services have been recorded. Amongst these are the "*operatoristas dentales*" in Columbia; the community dentist program of the University of San Carlos, Guatemala, which has been emulated by other schools and is still active more than 25years after the conclusion of WKKF assistance; and the community clinic in the favelas of Belo Horizonte, Brazil. These are but three examples among the 99 individual institutional projects implemented between 1950 and 1984.

Also of note are the efforts and results in water and salt fluoridation in the Region. Up to 1985 some 600 water engineers had been trained in fluoridation techniques. Grants of over $1.664 million to Costa Rica, Mexico and Peru have helped to establish salt fluoridation programs in those countries. The WKKF sponsorship of major conferences on Fluoridation in Medellin, Colombia in 1977, Vienna Austria in 1982, and Antigua Guatemala in 1986, has improved the knowledge base of salt fluoridation and its effectiveness.

2nd PERIOD (POST 1995)

Since 1995, Kellogg support to oral health programs has not diminished but continues to increase in impact. Over the period two grants have been awarded to the Regional Oral Health Program of PAHO. They are referred to as Kellogg I and Kellogg II.

Kellogg I was a grant in 1996 of $750,000 over a three year period. Its objective was to start salt fluoridation in Bolivia, Dominican Republic, Honduras, Nicaragua, Panama and Venezuela. Its main project components were:

1. To carry out feasibility and country baseline fluoride and DMFT studies.
2. Provide training, quality assurance and control of salt fluoridation.
3. Epidemiological surveillance and management of systemic and topical fluorides.
4. Information, education and communication programs in support of salt fluoridation.
5. Country legislation and legal enforcement of salt fluoridation.

Kellogg II was a grant in 1997 of $262,006 over a two-year period. It included the countries of Belize and Paraguay under the same terms and objectives as Kellogg I.

The post 1995 period has been characterized by greater convergence between the strategies of the W K Kellogg Foundation and PAHO with respect to oral health improvement. Quantifiable progress has been attained in the last period in terms of oral health status of the Region. Dental caries whilst still affecting millions have diminished significantly in its degree of prevalence and severity. This progress demonstrates quite clearly the synergies created when organizations such as PAHO and the WKKF collaborate.

SECTION III

PROGRAM DESCRIPTION

In 1994, PAHO's Regional Oral Health Program launched a multi-year plan to implement salt/water fluoridation programs, to coordinate support for these programs, and to achieve specific outcomes. The operating principles for this regional plan include prevention, capacity building, and sustainability, all of which are important to address the oral epidemiological profile in the Region.

Programmatically, in order to implement salt fluoridation programs, PAHO has proposed three stages of implementation (see table overleaf):

PHASE ONE *(Feasibility Assessment)*

Several preliminary studies are essential prior to determining whether a national fluoridation program may be appropriate in a given country, including cost-benefit studies and prevalence baseline of caries and fluorosis. The studies are recommended because they may provide strong support to and justification for fluoride interventions as compared to other less effective interventions. Also, under economic constraints and market-oriented economies, cost-benefit analysis is one of the best ways to justify the implementation of preventive interventions such as salt fluoridation programs.

Baseline prevalence studies provide information on the disease that the program intends to address, so that later on effectiveness of preventive programs can be evaluated.

PHASE II *(First Evaluation)*

PAHO recommends that the first evaluation of the country salt fluoridation program is to be done seven years after its implementation in the country. After this interval, early erupting teeth exposed to salt fluoridation throughout their development can be assessed for reduced caries and for the prevalence of fluorosis. The long-term effects ascertained after 14 years will subsequently measure the maximal caries preventive effects and dental fluorosis in both early and later erupting teeth. Additional biological monitoring (caries, fluorosis) examinations may be made after additional seven-year intervals.

PHASE III *(long-term evaluation)*

Countries that have successfully moved along the oral health development continuum and have an established fluoridated salt program, with a DMFT-12 of 3 or less, have reached the consolidation stage. Continued monitoring and evaluation activities are also required in this stage. These activities provide information on program progress, effectiveness, and sustainability, which are important for generating continued support for the program. PAHO's role should be to continue to provide general guidance and support for these activities through technical cooperation.

PAN AMERICAN HEALTH ORGANIZATION
Phases of National Preventive Programs of Salt Fluoridation

Phase I Feasibility Assessment	Phase II First Evaluation	Phase III Long-term Evaluation
Baseline levels of fluoride in the drinking water	Periodic sampling and determination of fluoride in drinking water sources	Continued periodic sampling and determination of fluoride in the drinking water
Nutritional/dietary survey in preschool children (possibly already available in some countries)	Nutritional/dietary surveys in preschool children	Nutritional/dietary surveys in preschool children
Baseline study of toothpaste use in preschool children	Periodic evaluation of toothpaste use in preschool children	Continued periodic evaluation of toothpaste use in preschool children
Baseline study on marketing and use of fluoride-containing products, e.g., dietary supplements, available in the market	Periodic monitoring of fluoride-containing products in the market	Continued periodic monitoring of fluoride-containing products in the market
Development of epidemiological surveillance guidelines for quality assurance and control	Periodic monitoring and quality assurance of fluoride concentrations in water or salt	Continued periodic monitoring and quality assurance of fluoride concentrations in water or salt
Baseline DMFT and dental fluorosis surveys in 6-8, 12, and 15-year-old children	DMFT and dental fluorosis surveys in 6-8, 12, and 15-year-old children seven years after program implementation	DMFT and dental fluorosis surveys in 6-8, 12, and 15 year-old children fourteen years after program implementation
Initial assessment of urinary fluoride excretion in 3-5 year-old children, one-sample/24 hours, after 15 months of implementation.	Urinary fluoride excretion in 3-5 year-old children 15 months after program implementation (one sample/24 hours)	Periodic evaluation of urinary fluoride excretion in 3-5 year-old children (one sample/24 hours)

Source: Pan American Health Organization (PAHO), 2000

Country Selection Criteria

For this proposal, countries were selected based on, firstly - their status within PAHO's oral health development typology, secondly - donor interest, thirdly - endorsement by the professional community within the country, and fourthly - congruence with country's own health policies.

Project Components

1. Feasibility and country baseline studies

The project assisted all eight countries at the initial stage of national fluoridation programs following the guidelines of PAHO's Multi-year Plan for Salt Fluoridation by conducting an institutional analysis to develop a National Fluoridation Program for Salt Fluoridation

a Cost-benefit studies

These studies elucidated the monetary values of the costs (direct and indirect) of implementing the program and benefits due to averting treatment which would normally be required.

b. Prevalence Baseline studies:

- ***Baseline information on disease prevalence and caries experience.*** It is essential to have baseline information on the diseases that the program intends to address. The most appropriate protocols include a DMFT and dental fluorosis survey in children ages 6 to 8, and 12, and 15 years.

- ***Initial assessment of fluoride excretion in urine.*** These studies provide the physiological/metabolic information to monitor the total exposure to fluoride. The information gleaned is useful to determine whether the 250-ppm F added would require further adjustments. The most appropriate protocol includes a one twenty four-hour urine sample in children ages 3 to 5 years.

- ***Baseline levels of fluoride in the drinking water.*** These studies detect areas where the natural fluoride content precludes the introduction of fluoridated salt. Water samples should be analyzed in a laboratory that complies with technical standards, using a calibrated fluoride ion-specific electrode.

- ***Reference on nutritional survey in preschool children.*** These studies assess the consumption of salt by the population. In a number of cases this data was available from other sources.

- ***Assessment of additional sources of fluoride currently available in the market.*** These studies were designed to detect the prescriptin and use patterns of fluoride dietary supplements. Once salt fluoridation is introduced, however, the use of these supplements is not recommended.

2. *Training, quality assurance and control of salt fluoridation*

As we know from our extensive experience in providing technical assistance to many countries, there is a dearth of skilled personnel in salt fluoridation. The lack of technical expertise and human infrastructure are major factors for inefficient functioning of some of the programs in countries. However, there are numerous highly motivated individuals, from the public sector (Ministry of Health) and private sector (salt industry), who would become technical leaders, and who could influence policy and decision making, if they can be identified and armed with the proper skills and tools. This will be the objective of the training activities.

During the initial phase of each country program, appropriate training was provided for:

a. The salt fluoridation process, using solar evaporation (dry or humid);
b. quality control for salt fluoridation;
c. technical analysis;
d. management of laboratory equipment; and
e. cost of salt production.

3. *Epidemiological surveillance and management of fluorides*

The project assisted countries to develop appropriate epidemiological surveillance systems including biological and chemical monitoring of fluorides.

4. *Information, education and communication (IEC)*

The project assisted countries to develop appropriate IEC component and support the development of materials to be used in the countries in regards to fluoridated salt; these include posters, songs, and additional audiovisual materials to educate the community on salt fluoridation.

5. *Country legal enforcement and legislation of salt fluoridation*

As early as 1958, the World Health Organization recognized the importance of fluoridation. In 1969, the Twenty-second World Health Assembly recommended that Member States introduce community water fluoridation and study other methods of fluoridation, such as salt, where water was not feasible. Recently, the World Health Organization has reaffirmed its support to fluoridation as safe, inexpensive, and effective. In 1994, during the meeting of Health Ministers from the Andean and Central American countries, a resolution was passed in support of salt fluoridation.

The proposed project assisted each country's public authorities to review the existing laws and develop new ones in support of salt fluoridation programs. These were to provide the regulatory standards for quality control and the mechanisms to enforce such standards.

COUNTRY PROGRAM PLAN

First, a country annual work plan was developed to determine priority areas. Then, specific goals and objectives were set to be accomplished every year. Next, a detailed plan of programs and activities was developed, including funding sources, responsible personnel, and a timetable.

The tentative work plan for each country included the following:

- Overview of the project: background, strategy and goals
- Objectives for current year
- Annual program description
- Establishing country-specific strategic framework
- Developing a customized country activity plan, including new initiatives
- Identifying methods for monitoring and evaluating project effectiveness
- Resources, including financial, infrastructure, and human
- Staffing, training, and skills
- Evaluation plan and indicators
- Implementation issues

PAHO'S TECHNICAL ASSISTANCE

The Pan American Health Organization, through its Regional Oral Health Program, has initiated the preparation of the above-mentioned project, in order to consolidate fluoridation of the countries in the Region of the Americas. With assistance from PAHO, technical expertise has been developed in various countries were salt fluoridation programs have been initiated. PAHO developed a core team of consultants who are the leading experts in the areas of salt fluoridation techniques, epidemiological surveillance systems including biological and chemical monitoring of fluorides, training for all baseline studies, quality assurance and control of salt fluoridation, and information, education, and communication activities in salt fluoridation. These experts have provided assistance as individuals, or through a strong partnership relationship established with institutions such as the WHO Collaborating Center in San Antonio, Texas and the Centers for Disease Control and Prevention.

The eight countries identified their need for technical assistance in almost all these areas. PAHO consultants were assigned a national counterpart (usually the Director of Oral Health of the Ministry of Health). The transfer of knowledge from the consultant to the national counterpart is crucial to sustain effective and efficient salt fluoridation programs over the long term.

Specifically, the technical cooperation was used to design each country program, training and supervision of baseline studies, and develop appropriate epidemiological surveillance systems, including biological and chemical monitoring of fluorides. The W.K. Kellogg funds financed technical cooperation for the following areas:

1. Strengthening of the Ministries of Health administrative capacity

To empower the public (MOH) and private (salt industry) administrative and technical capacity to direct, monitor, and ensure compliance with salt fluoridation regulatory standards.

2. Training

The purpose of the training was to transfer technology in the areas of quality assurance and control of salt fluoridation. During the initial phase, salt industry personnel who will handle and manage fluorides were trained with the following objectives:

a. To develop appropriate skills in salt fluoridation processes, including batch production and safe handling of fluoride additive compounds.
b. To develop appropriate skills in quality assurance, quality control, analysis and laboratory equipment.
c. To understand the production costs of salt fluoridation.
d. To manage epidemiological aspects of fluorides, including biological and chemical monitoring.

Training activities took place under two primary modes: a) in-country workshops, and b) short courses.

Training was integrated into the major technical objectives of the project. To ensure that training conforms to country objectives, all training activities were included in country plans and PAHO's Regional Oral Health Advisor was responsible for ensuring uniformity and consistency of topics and training participants with country activity plans.

3. Epidemiological Surveillance

In support of appropriate surveillance systems 8 workshops were carried out in selected country.

4. Information, Education and Communication (Project monitoring, reporting, and evaluation

PAHO utilizes AMPES the logical framework to manage technical cooperation. This framework provides a clear methodology for program design and assists in the implementation and evaluation of PAHO's technical cooperation.

The proposed project used the AMPES framework to developed necessary indicators and monitor and evaluates the specific country programs and the progress of ongoing activities.

PAHO presented W. K. Kellogg Foundation with two biannual reports of the technical cooperation and the present final report.

Project Management

Dr. Daniel López Acuña, Director of the Division of Health Systems and Services Development; Dr. José Luis Zeballos, Coordinator Program on Organization and Management of Health Systems and Services; and Dr. Saskia Estupiñán-Day, Regional Advisor for Oral Health of the Pan American Health Organization, were responsible for the overall project management. All project activities and technical cooperation were under Dr. Estupiñán's supervision. She is also responsible for all reports presented to the Foundation.

SECTION IV

METHODOLOGY FOR BASELINE STUDIES

The Multi-Year Program proposed that each country conduct the following studies:

1. The biological monitoring which included recommendations for a baseline oral health survey of dental caries and fluorosis and urinary fluoride excretion studies.
2. The chemical monitoring which included an assessment of fluoride content in the drinking water and assessment of different fluoride products in the market;
3. The monitoring of fluoride content in the salt (a quality control issue).

The technical aspect of these monitoring systems was provided to the local salt fluoridation programs through workshops and visits by consultants to each country:

Standard protocols for these studies were recommended to all countries participating in salt fluoridation programs. However, some countries introduced modifications to standard protocols in order to address specific research needs. Most data was comparable to the standard recommended by PAHO, Annex 2-5 present the standardization for research protocols.

COST-BENEFIT STUDIES

The financial feasibility and cost benefit of salt fluoridation programs were conducted in all countries except as previously noted for Venezuela. These studies provide useful information on project cost over five years, plus the initiation period. The analysis takes into consideration approximate costs for equipment, personnel, supplies, baseline studies and other inherent project expenses. An estimate of dental caries prevented and savings on dental treatment that would not be incurred is made as affected by public health services availability, cost and coverage to the population. A projection of discounted savings is also made using international discounting rates, and a cost to benefit ratio is established.

It is recommended that these studies be conducted at the initial phase of the salt fluoridation program, prior to any major project involvement; the exception to this policy was Venezuela, since this country had initiated salt fluoridation efforts for some time. Table 1 presents cost-benefit ratios of salt fluoridation.

These studies provided information on the feasibility of developing a salt fluoridation program in a country. Existing information on dental caries, dental fluorosis, scope of dental public health programs, resources and facilities available, general information on the salt industry, iodination programs, institutions that might cooperate on developing a salt fluoridation program and existence of a legal framework that would permit inclusion or would facilitate development of specific standards for regulating quality and requirements for fluoride content of salt for human consumption. The study estimated the anticipated benefits of implementing a salt fluoridation program and its relationship to cost. A ratio of the benefits that would be obtained in terms of economic resources that would not need to be spent for dental treatment that otherwise would be required is made depending of dental caries prevalence, caries incidence, cost of services, program coverage, facilities available and other pertinent factors. The cost: benefit ratio varied from country to country as was influenced by local existing conditions and program scope.

DETERMINATION OF FLUORIDES IN WATER SUPPLIES

This is a very important component of the epidemiological surveillance system recommended by PAHO. It is known that fluoride is presented in various concentrations in water depending on the source of water, type of soil, well depth and other environmental and seasonal factors. It is essential for each country to identify communities where the fluoride concentration is high enough to provide caries prevention. Fluoridated salt should not be distributed in these areas to avoid the risk of dental fluorosis, in children younger than 6 years. These studies should measure all drinking water sources, therefore, progressively developed into a census.

The main objective of this study was to create a database of community water supplies in each country and categorize their fluoride concentration. Specific objectives were, to locate water supplies with fluoride concentration above optimal, location and population served. Training seminars were coordinated on study design, essential data to be recorded and methodology for laboratory analysis using specific fluoride ion electrodes and electronic meters. Results summarizing communities in each country that were identified to have a fluoride concentration of >0.9 mg/l are presented in Table 2

All participating countries have completed these requirements. A final decision to preclude distribution of salt to these communities will be made depending of the mean daily temperature, caries prevalence, fluorosis scores and community fluorosis index as well as availability of other sources of fluorides to pre-school children.

EPIDEMIOLOGICAL SURVEY ON DENTAL CARIES AND DENTAL PROGRAMS BY COUNTRY

All countries have concluded oral health examinations as part of surveys to measure the prevalence and severity of dental caries and fluorosis. These data have been utilized to calculate the DMFT-T index in children 6-8, 12 and 15 years of age. Table 3-7 summarizes the mean DMF-T and Table 8 the distribution of the population by the Dean's index of dental fluorosis. PAHO assisted all participating countries in the reporting of their results using a standardized format.

The purpose of this survey was to establish a baseline of severity and prevalence of dental caries and dental fluorosis in children 6-8, 12 and 15 years of age in each participating country. The biological monitoring of dental caries and fluorosis required specific training and calibration by qualified consultants. Baseline data will permit comparisons to be made in future periodic assessments in each country. PAHO made recommendations for survey design, sampling procedures and use of existing WHO criteria. Exceptions to WHO basic methods were made to follow PAHO's TAG recommendations and specific research needs in each country. Use of standardized criteria would facilitate future comparisons within a country and at the Regional level to assess impact of salt fluoridation programs.

URINARY FLUORIDE EXCRETION BY CHILDREN 3-5 YEARS OF AGE

This study provides information on exposure to fluoride regardless of the source. It is used for determining whether children are receiving an adequate amount of fluoride for protection against dental caries and to alerting public health authorities if children are being exposed to undesirable amounts of fluoride that might cause unsightly dental fluorosis. After salt fluoridation programs are implemented, data collected from future studies is used to verify whether children are being exposed to optimal amounts of fluoride with the minimum risk of occurrence of dental fluorosis. Data is used to advise the salt industry on possible adjustments that might be needed. If strict quality control is exercised by the salt industry as it relates to the concentration of fluoride present in salt for human consumption, and fluoride

excretion rates are above optimal, other sources of fluoride exposure need to be investigated as possible causes.

The recommended methodology for performing these studies follows the WHO guidelines. The recommended monitoring period for time controlled urine sampling is 24 hours. Essential data collected are volume, urinary collection period, fluoride concentration, age and weight of participating children. Fluoride concentration is determined using specific fluoride ion electrodes and electronic meters. The information obtained is used to calculate urinary fluoride excretion rate per hour and per 24-hours.

Training of personnel of the Ministry of Health was conducted in all countries. Training exercises include theory of fluoride metabolism; methodology for time controlled urinary samples, protocol requirements, necessary elements and general instructions for sample collection, analysis and calculation of urinary flow and excretion rate as well as an estimation of integral daily fluoride intake. Considerations for population sample design and survey implementation were also part of training seminars. Tables 9-10 present results from Bolivia and Paraguay.

Arrangements for procurement of equipment and supplies necessary for developing these studies were made. These elements will enable countries to develop necessary data on urinary fluoride excretion as part of the biological monitoring recommendations.

ASSESSMENT OF OTHER FLUORIDE CONTAINING PRODUCTS

This component aims to obtain information on other possible sources of fluoride available to preschool children in particular use of fluoridated toothpaste, supplemental fluoride tables, drops or vitamins. Also, it aims to obtain parent-provided information about their child use of toothpaste, age of initiation, frequency of use, brand of toothpaste and supervision during child's tooth brushing. A protocol and data collection instrument was designed for this purpose and is presented in Annex 6. A consultant has provided technical assistance to implement these studies in the six countries in their second-year of program implementation followed, later, by Belize and Paraguay.

These studies are complementary to the urinary fluoride excretion study and aim to provide additional information on fluoride exposure. Benefits of tooth brushing with fluoridated toothpaste in reducing dental caries have been recognized. Methodical administration of fluoride supplements in the form of tablets, drops or reinforced vitamins has also been used in some countries for dental caries prevention. These methods of caries prevention have been more widely used in industrialized countries, although they have also been used to various extents in developing countries. The main aim of these studies is to obtain data on use of fluoridated dentifrice and fluoride supplements by children 3-5 years of age. Recommendations for sampling and methodology to be used were made by the PAHO. A questionnaire was developed and used by interviewers for recording data from parents of children included in the studies. Identification of most popular brands of toothpaste used, amount placed in the toothbrush, tooth-brushing habits, use of fluoride tablets, drops or vitamins, age at which children initiated use and duration were recorded. A summary of results by country is presented in Annex 6.

RESEARCH RESULTS OF COUNTRY BASELINE STUDIES

Table 1. Cost-benefit ratios of salt fluoridation programs by country

Country	Population	Program cost US Dollars	Caries prevented (000)	Treatment cost saved US$ millions	Net Discounted savings US$ millions	Ratio
Belize	230,000	187,400	293,308	3	2	1:18
Bolivia	7,200,000	785,000	10,650	33	22	1:141
Dominican Republic	8,190,000	520,031	12,500	106	74	1:203
Honduras	5,461,797	527,000	8,340	64	45	1:122
Panama	2,708,000	424,279	4,133	62	43	1:146
Paraguay	5,222,000	360,248	10,606	66	46	1:183
Venezuela	22,030,000	1,528,157	39,785	597	419	1:391
Total	51,041,797	4,332,115	379,322	931	651	

Table 2. Water supplies with concentration of fluoride ≥ 0.9 mg/l by country
Water supplies with concentration of fluoride higher or equal to 0.9 mg/l by country

Country	Department or Region	Province or Municipality	Community	Source Name	F. ppm
Bolivia	Beni	Cercado	Trinidad		1.0
N=446	Chuquisaca	Oropeza	Subre-Ciudad		1.1
	La Paz	Bautista Saavedra	Charazani		0.9
	Potosi	Sud Chichas	Tupiza		1.1
	Santa Cruxz	Andrés Ibañez	Cotoca		1.8
		Cordillera	Gutiérrez		1.2
			El Cuevo		1.0
		Florida	Samipata		1.7
		Manuel Caballero	Saipena		1.3
República	I Región	Peravia	Baní/Paya arriba	Pozo	0.9
Dominicana	VI Región	San J. de Maguana	Arroyo Loro	Pozo tubular	1.1
N=549	VI Región	Azua	Galindo adentro	Manantial-arroyo	3.7
	VI Región	Azua	Barrera	Manantial Furnia	1.3
	VII Región	Montecristi	Mont/Sta. Cruz	Pozo Sta. Cruz	0.9
Honduras	Choluteca	Apacilagua	Barrio Morazán	Pozo	1.8
N=1338	Cortes	Choloma	Aldea Monterey	Pozo	1.7
		La Lima	Col. Chiquita Brand		1.5
		San Pedro de Sula	Col. Fesitranh		1.1
	Yoro	Arenal	Arenal		0.9
Paraguay	San Pedro	Yataiti del Norte	Planta del Norte	Pozo perforado	1.5
N=478		Barrio Fátima	San Estanislao	Pozo perforado	1.0
	Alto Paraná	Barrio Remansito Sec. 1	Ciudad del Este	Pozo perforado	1.1
		Barrio Fátima	Puente Franco	Pozo perforado	4.8
		Puerto Panambú	Ñacunday	Pozo perforado	8.0
		Barrio tres fronteras	Puente Franco	Pozo perforado	2.6
	Concepción	Loreto	Pacurí	Pozo perforado	1.0
		Loreto	Loreto	Pozo perforado	2.8
	Guairá	Iturbe	Candea-mí	Pozo perforado	0.9
	Caaguazú	Nueva Londres		Pozo perforado	0.9
	Paraguarí	Paraguarí		Pozo perforado	0.9
		Paraguarí	Mbatobi	Pozo perforado	1.1
		Caballero	Potrero Naranjati	Pozo perforado	1.5
	Boquerón	Filadelfia		Pozo perforado	0.9
Venezuela	Aragua	Sucre	Cagua	Pozo 19	1.3
N=1383	Barinas	Obispos	C.A. Luz	Pozo perforado	0.9
			El Tambor	Pozo perforado	0.9
	Carabobo	Montalbán	Los Cerritos	Pozo los cerritos	1.1
		Guacara	Guacara	Pozo 5	0.2-1.1
				Pozo 7	0.6-0.9
				Pozo toco norte	0.7-1.4
				Pozo 1	1.0
				Pozo 8	0.8-1.0
		Diego Ibarra	Mariana	Quebrada Guamacho	1.9
		San Joaquín	San Joaquín	Pozo 7	1.2
				Pozo 6	1.4
				Pozo 4	0.3-1.0
				Pozo 5	1.8
		Montalvan	Los Cerritos	Pozo 1	0.9
		Libertad	La Glorieta	Pozo 1	0.9

Country	Department or Region	Province or Municipality	Community	Source Name	F. ppm
		Valencia	Tronconero	Pozo 1	0.9
		Carlos Arvelo	Vigrimita	Dique toma	
	Distrito Federal	Vargas	Lachivera	Manantial aguacate	2.3
	Merida	Zea	Los Churrascos	Quebrada	1.1
		Julio F.C.	Las Virtudes	Quebrada Caño Azul	1.3
	Monagas	Maturin	La Pica	Pozo 2	1.1
	Portuguesa	Araure	Poblado I	Pozo	1.6
		Esteller	Uveral	Pozo	0.9
		Santa Rosalia	Cogote Mantecal	Pozo	0.9
		Jauregui	San José Bolívar	Quebrada paujeles	0.7-1.0
		Panamericano	Caño Amarillo	Quebrada blanca	0.9
		R. Rangel	Tres de Febrero	Pozo	1.2
		La Ceiba	Pto. La Ceiba	Pozo	1.7
			Santa Apolonia	Pozo	0.7-1.7
			Km. 12	Pozo	1.4
	Zulia	Sucre	Bobures	Pozo 2	0.6-0.9
			Santa María	Pozo	0.9
		Baralt	San Pedro	Pozo subterráneo	2.2
		Sucre	La Dificultad	Pozo	1.0
		Miranda	Quisiro	Pozo	1.3
		Colón	La Cordillera	Pozo	0.8-1.0
		Miranda	Consejo de Ziruma	Pozo San Antonio	1.0
Nicaragua	Zelaya Central	Rama	Puerto La Esperanza		> 7
N=514			Centro Salud Rama		
			Inst. Nac. Nindiri		
			Los Madrigales, Nindiri		
			El Raizo		
			La Curva, Km 201/2		
			San Juan		
			Dulce nombre		
			Pozo INAA Monogalpa		
			Casco Urbano		
			Brasiles, Bo. San Franc.		
			Ciudad Sandino		
			Bello Amanecer C.S.		
			Esquipulas, Calle Costa Rica		
			Los Vanegas		
			Comarca Nejapa		
			Ticomo		
			Casco Urbano		
			El Crucero		
			Bo. Mampie, Ticuantepe		
			Las Maderas		
			San Juan Plywood		
			San Rafael del Sur		
			El Salto		
			San Pablo		

Table 3. Percentage of children with one or more teeth with history of decay and one or more teeth with untreated decayed teeth. Data from countries participating in the *Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas*

Country	AGE									
	% with DMFT >0					% with D >0				
	6	7	8	12	15	6	7	8	12	15
Belize	7.5	8.4	15.4	29.4	50.8	6.8	8.4	10.6	26.6	42.2
Bolivia	36.4	52.9	73.4	87.9	Na	36.1	51.9	71.5	84.0	na
Dominican Republic	43.3	62.0	74.0	86.5	94.0	42.8	61.5	72.3	85.0	92.3
Honduras	28.4	48.5	59.0	88.3	90.1	27.6	47.9	57.4	84.3	86.8
Nicaragua	24.9	47.3	60.0	79.2	87.9	24.9	47.0	60.0	78.1	85.2
Panama	31.1	31.3	59.2	77.9	90.3	30.4	30.1	54.1	65.2	75.3
Paraguay	25.2	48.5	56.6	81.6	89.9	25.2	45.5	53.9	79.6	84.2
Venezuela	14.7	25.5	36.7	63.1	76.3	13.3	24.1	34.2	55.1	65.0

Table 4. Mean Number of Decayed, Missing and Filled Teeth in the Permanent Dentition (DMF-T) in Children from Countries Participating in the *Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas*

Country	AGE				
	6	7	8	12	15
Belize	0.08	0.11	0.24	0.63	1.38
Bolivia	0.84	1.39	2.26	4.61	na
Dominican Republic	0.96	1.50	2.21	4.31	6.61
Honduras	0.56	1.04	1.34	4.00	5.67
Nicaragua	0.46	0.92	1.32	2.80	4.50
Panama	0.51	0.59	1.33	3.60	5.30
Paraguay	0.44	1.02	1.42	3.83	5.41
Venezuela	0.24	0.51	0.81	2.12	3.41

Table 5. Severity of Dental Caries (DMFT) Using WHO Cut-off Points Among 12-year-old Children from Countries Participating in the *Multi-year Plan for Salt Fluoridation Programs in the Region of the Americas*

Country	DMFT=0	0 < DMFT≤ 3	4 ≤ DMFT≤ 6	DMFT ≥7
Belize	70.6	24.8	3.7	0.9
Bolivia	12.1	30.8	29.0	28.0
Dominican Republic	13.5	35.0	28.0	24.0
Honduras	11.7	35.8	34.2	18.2
Nicaragua	20.8	44.4	26.9	8.0
Panama	22.1	30.2	30.9	16.8
Paraguay	18.4	41.4	24.4	15.8
Venezuela	36.9	38.3	18.4	6.4

Table 6. Percentage Contribution of Decayed (D), Missing (M), and Filled (F) Teeth in the DMFT Index Among 12-year-old Children with Caries Experience (DMFT > 0) *Multi-year Plan for Salt Fluoridation Programs in the Region of the Americas*

Country	% DMFT>0	%D ÷DMFT	%M ÷DMFT	%F ÷DMFT
Belize	29.4	87.4	4.3	8.3
Bolivia	87.9	90.3	3.6	6.1
Dominican Republic	86.5	94.0	3.0	3.0
Honduras	93.3	92.1	1.8	6.1
Nicaragua	79.2	95.9	2.5	1.6
Panama	77.9	80.4	10.1	9.5
Paraguay	84.7	88.0	7.5	4.6
Venezuela	63.1	75.5	7.5	17.0

Table 7 Mean Number of Decayed, Missing and Filled Teeth in the Primary Dentition (DMFT) in Children from Countries Participating in the *Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas*

Country	AGE		
	6	7	8
Belize	2.25	2.39	2.69
Bolivia	5.75	7.84	7.25
Dominican Republic	2.39	2.66	2.35
Honduras	5.93	5.93	5.20
Nicaragua	4.30	4.60	3.90
Panama	4.20	3.80	3.80
Paraguay	4.54	4.84	4.41
Venezuela	3.20	3.38	3.05

Table 8. Dental Fluorosis (Dean's Index) Using the Maximum Score in the Six Upper Anterior Teeth in 12-Year-Old Children from Countries Participating in the *Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas*

Country	N	0	0.5	1	2	3	4
Belize	323	66.3%	10.8%	14.8%	5.3%	1.2%	1.5%
Bolivia	287	58.5%	23.7%	15.7%	1.7%	0%	0%
Dominican Republic	192	68.8%	8.3%	11.5%	8.9%	1.0%	0%
Honduras	307	92.1%	5.6%	1.3%	0.0%	0.7%	0.3%
Nicaragua	365	82.7%	9.9%	4.9%	1.9%	0.6%	0.0%
Panama	NA						
Paraguay	348	57.8%	26.4%	11.2%	3.4%	0.6%	0.6%
Venezuela	1055	84.5%	10.0%	4.0%	0.8%	0.8%	0%

Table 9. Urinary fluoride excretion by children from Venezuela, 1998
Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas

Location	Region	Number of children	Age	Concentration ppm	F Excretion rate µg/h
	Metropolitan	13	3	0.67± 0.40	7.85 ± 2.70
		11	4	0.57 ± 0.34	5.66 ± 2.73
		18	5	0.76 ± 0.26	8.77 ± 4.35
Caracas		Total 32*	3-5	**0.66** ± 0.35**	**7.46** ± 3.30**
	Guarico	10	3	0.69 ± 0.33	11.38 ± 5.90
		10	4	0.65 ± 0.20	8.45 ± 3.19
		11	5	0.63 ± 0.36	11.97 ± 8.16
San Juan de los Morros	Total	Total 31*	3-5	**0.66** ± 0.03	**10.60** ± 1.89

* Total
** Mean

Table 10. Urinary fluoride excretion by children 3-5 Years of Age from Asuncion - Paraguay, 1999
Summary of Statistical analysis
Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas

	Concentration of fluoride ppm			Urinary Flow ml/h			Urinary excretion rate µgF/h			Fluoride excretion		
										µg/h	µg/Kg/ 24h	µg/2 4h
	Period			Period			Period					
	1st	2nd	3d	1st	2nd	3d	1st	2nd	3d			
N	89	65	96	89	65	96	89	65	96	61	61	61
Min	0.02	0.02	0.09	0.4	1.6	0.4	0.1	0.3	0.1	1.1	1.6	26
Max	1.10	0.98	0.83	60.3	203.1	48.0	28.9	49.2	16.2	13.9	17.6	334
Median	0.25	0.19	0.25	17.1	32.0	13.2	3.3	6.3	3.4	3.7	5.3	89
Mean	0.31	0.26	0.29	18.4	38.6	14.3	4.8	8.1	4.0	4.7	6.3	112
SD	0.24	0.20	0.16	13.9	30.2	8.7	4.9	7.3	3.0	2.5	3.6	61
Coefficient of Variation	76	76	54	76	78	61	103	90	74	55	56	55
SE	0.03	0.02	0.02	1.48	3.75	0.89	0.52	0.90	0.31	0.3	0.5	8
Total No. of subjects		100		Confidence limits P=0.95								
Subjects with complete collections		61		"Student's t test" for p=0.05, DF=N-1 es: 2.001								
No. of successful collections		250				Lower limit				4.0	5.4	96
Collections per subject		2.50				Upper limit				5.3	7.2	128

SECTION V

TRAINING IN FLUORIDATION TECHNIQUES AND QUALITY ASSURANCE

During the last two years, PAHO's Regional Oral Health Program secured the services of an expert fluoridation engineer. This expert has conducted an assessment of the salt industry in each of the eight participating countries. Technological gaps and needs have been identified and recommendations have been made.

COUNTRY ACTIVITIES

Belize and Paraguay: These two countries are the only ones that do not produce their crude salt locally. All salt consumed is imprted. This leads to a variety of quality and distribution modes. Belize imports salt of high quality, nearly all of it being refined and packaged. Paraguay, imports a majority crude salt and processes and packages in a variety of facilities. There is some importation of refined and packaged salt.

Bolivia, Honduras, and Nicaragua: The operations of the salt industry in these countries have a high manual content. A large percentage of the salt processed would not meet international standards. The price of salt to the consumer in Bolivia is between 0.12 to 0.18 US which makes it the lowest in the Region. In Honduras it rages between 0.21 to 0.43 US/kg. In Nicaragua cost to the consumer ranges between 0.11 to 0.53 US/kg. The iodination program has been successful in these countries and the packaging and iodine content are referred to be satisfactory. Industry is fragmented in several small producers. There are problems with humidity. At the present time there is absence of quantitative analysis facilities of raw materials or finished products. In Bolivia PISABOL will soon have adequate quality control equipment. Producers in other countries have also demonstrated the capacity to change and improve.

Dominican Republic: The production of coarse salt in this country is highly manual. The processing of salt however is quite sophisticated using the dissolution and evaporation process. However not all household salt is processed in that form. About 60% for table use is ground coarse salt called *sal en grano*. This salt is not of very good quality and packaging and weight control is loose. Via a government owned monopoly, DiSal, all crude salt is purchased then sold to processors and distributors. This causes salt prices to the consumer to be the highest in the Region. The processors are willing to support any salt fluoridation plan. Recnt developments have led to the disbanding of Disal.

Panama: The situation of salt industry in Panama is somewhat different to other countries. There are operations for crude salt production that are still manual, but the salt processing is fully mechanized. The industry is differentiated between crude salt production/producers and processed salt production processors. The price of salt to the consumer is between 0.53 and 0.63 US/kg. The quality meets international standards. The capacity exists with some producers to carry out the full range of quantitative analyses of raw materials and finished products. The iodination program is successful and producers have demonstrated the capacity and willingness to improve if necessary.

Venezuela: Operations in this country are fully mechanized for the vast majority of salt producers. The industry can be considered fully mature and consolidated and the product quality is fully

competitive in the international market. It should be noted however, that the concentration of fluoride is only 60 to 90 PP, which is far below the recommended 200 to 250 ppm to have the optimal cariostatic effect. The price of salt to the consumer ranges between 0.10 and 0.35 US/kg.

Recommendations: It is considered necessary to joint efforts to improve and modernize the salt industry. This need is much more evident in countries such as Bolivia, Honduras and Nicaragua. It is advisable to strengthen the organization of salt producers in order to disseminate information and to offer suggestions for improvement. Identification of financial aid for salt producers to be able to mechanize processing methods and to acquire quality control equipment. Training exercises would be needed and travel seminars to visit adequate processing plants will be most beneficial. Continuing education should be made available to all salt producers so that they are aware of the latest and most efficient processing techniques. Constant update of distribution network should be instituted.

REPORT ON SALT INDUSTRY TECHNOLOGY DEVELOPMENT

During the period of the project, all countries grant were visited for the process of assessment of their salt industries and their readiness to begin, continue or consolidate programs of salt fluoridation. Table 11 presents the main characteristics of the countries salt industry.

Following on these assessments visits a series of reports detailing the salt industries and their main characteristics have been published. These reports chronicle the main problems being faced with the industry and proffer recommendations to overcome these in order to being sustainable programs of salt fluoridation. The reports are as follows:

- The Honduran Salt Industry – An Assessment (prospects for salt fluoridation)
- The Nicaraguan Salt Industry – An Assessment (prospects for salt fluoridation)
- The Panamanian Salt Industry – An Assessment (prospects for salt fluoridation)
- The Venezuelan Salt Industry – An Assessment (prospects for salt fluoridation)
- The Bolivian Salt Industry – An Assessment (prospects for salt fluoridation)
- The Dominican Republic Salt Industry – An Assessment (prospects for salt fluoridation)
- The Paraguayan Salt Industry – An Assessment (prospects for salt fluoridation)
- The Belize Salt Industry – An Assessment (prospects for salt fluoridation)

In addition a plant trials at the PANASAL and FENCOSPA salt hydro-refining and packaging plants in Panama were carried out successfully.

Findings

Table 11. Main Characteristics of the Countries Salt Industry

Country	Salt Flows (000 ton)			Producers #		Salt Characteristics		Industry
	Production	Import	Export	Crude Salt	Processors	Price	Quality	
Honduras	42	8	0	189	50	Low	Low	Fragmented Artisan Methods
Nicaragua	52	5	2	174	10	Low	Low	Fragmented Artisan Methods
Panama	18	12	0	15	5	High	Good	Consolidating Modernizing
Venezuela	705	35	125	10	10	Low-Med	Good-Excel	Sophisticated Efficient
Bolivia	45	0	0	+ 300	42	V Low	Low-Good	Fragmented Artisan Methods
Dom. Rep.	30	15	0	70	8	V High	Low-Excel	In state of Flux

SALT INDUSTRY ASSESSMENTS

Under the period of this project detailed assessments of the countries salt industries were compiled and published. These countries were Bolivia, Dominican Republic, Honduras, Nicaragua, Panama, Paraguay and Venezuela

The assessments were carried out with the strategic objective of raising the standard of efficiency of the salt producers in order to produce high quality salt, ensuring the sustainability of salt as an effective vehicle for the addition of fluoride and other micronutrients. Hence technology and information was made available at the producer level on developments and innovations in not only fluoridation technology but salt processing, quality control, packaging and distribution in order to improve the industry's competitiveness.

During the project period numerous technical problems were solved leading to the consolidation of salt fluoridation in Bolivia and Venezuela, successful pilot trials and the start of addition in Panama, and the establishment of the commitment of producers to fluoridate salt as soon as legal and regulatory issues are settled in Dominican Republic, Honduras, Nicaragua and Paraguay.

The program was also able to act as a resource guide in an initiative led by the Association of Mexican Salt Producers, AMISAC, to form a combined Salt Producers Federation of Latin America and the Caribbean.

Status of Salt Industry

The comparative data of the tables 12 and 13 overleaf show data on salt production, industry status, and other characteristics of salt from a number of countries in the Region.

Table 12. Salt production and consumption for various countries in the Americas

Country	Population million	Total Crude Salt Prod (000) T/yr.	Type of production (000) t/yr.		Salt Consumption (000) T/yr.			Number of Salt Processors		
			Soln Mining	Solar Evap.	Total	Direct Human	Fluoridated	Large scale > 100K Ton/yr.	Med scale 100 to 20K Ton/yr.	Small scale < 20K Ton/yr.
*Belize **	*0.2*	*0*	*0*	*0*	*1*	*0.8*	*0.4*	*0*	*0*	*3*
*Bolivia**	*7.9*	*45*	*0*	*0*	*45*	*30*	*2*	*0*	*0*	*42*
Colombia	37.7	1100	600	500	500	140	70	3	5	50
Costa Rica	3.7	20	0	20	18	13	10	0	2	0
*Dom. Rep**	*8.2*	*50*	*0*	*32*	*53*	*30*	*0*	*0*	*0*	*80*
Ecuador	12.2	75	0	75	75	44	36	1	2	10
Guatemala	11.6	60	0	60	58	40	0	0	0	150
*Honduras**	*6.1*	*42*	*0*	*42*	*50*	*21*	*0*	*0*	*0*	*250*
Jamaica	2.5	1	0	1	16	10	10	0	1	0
Mexico	95.8	7900	600	7300	1600	350	250	3	6	10
*Nicaragua**	*4.5*	*52*	*0*	*52*	*52*	*16*	*0*	*0*	*0*	*300*
*Panama**	*2.8*	*18*	*0*	*18*	*30*	*11*	*0*	*0*	*1*	*55*
*Paraguay**	*5.2*	*0*	*0*	*0*	*80*	*20*	*0*	*0*	*1*	*5*
Peru	24.8	180	0	180	100	87	40	1	2	50
Uruguay	3.2	0	0	0	40	11	9	0	3	2
*Venezuela**	*23.2*	*705*	*0*	*705*	*615*	*85*	*60*	*2*	*2*	*10*
Total	244.2	10248	1200	8985	3252	888	487	10	25	1017

* Kellogg I & II countries

Table 13. Salt quality for various countries in the Americas

Country		Analysis % by wt			
		NaCl	Insoluble	Chemical Impurities	Moisture
Bolivia	Crude	97	0.5	0.5	2.0
	Proc'd	98.0	0.5	0.5	1.0
Dominican Republic	Crude	94.5	1.5	1.0	3.0
	Evap	98.5	0.05	0.5	0.9
Honduras	Crude	94	1.5	0.75	3.75
	Proc'd	95	1.0	0.75	3.25
Nicaragua	Crude	94	1.5	0.75	3.75
	Proc'd	95	1.0	0.75	3.25
Panama	Crude	96	0.5	0.5	3.0
	Proc'd	99.1	0.3	0.35	0.25
Venezuela	Crude	97	0.5	0.5	2.0
	Proc'd	99.25	0.15	0.35	0.25
	Evap	99.8	0.005	0.15	0.001

Table 14. Salt prices for various countries in the Americas

Country	Crude Salt ($/ton FOB)	Refined/ Packaged ($/ton Marketplace)
Bolivia	8.00	180-120
Dominican Republic	93.00	1790-850
Honduras	45.00	210-417
Nicaragua	50.00	550-150
Panama	83.00	630-550
Venezuela	12.00	350-100

COUNTRY DETAILS

Belize

Table 15. Salt Balance for Belize

Imports	Production	Consumption		Exports
Mexico: 1200 Jamaica: 200 USA: 100 Others: 100	Salt production: 0	Household/ Domestic/ Table (Direct Human)	800	Exports 0
		Industrial Food/ Bakery/ Cattle. (Indirect Human)	500	
		Industrial Non-Food (No Human Consumption)	300	
Total Imports 1,600	Total Production 0	Total consumption 1600		Total Exports 0
Total imports + total production = 1,600		***Total consumption + total exports = 1600***		

As there is no crude salt production in Belize, all salt consumed is imported. As well no processing facilities exist. A few retailers do some repackaging from bulk sacks to 1 or 1/2 kilo packages.

The distribution system is multi-tiered. Importers bring salt from the USA, Mexico or Jamaica. Mexican and Jamaican salt is already fluoridated. The importers then sell directly to large wholesalers, and large and small retailers.

Bolivia

Table 16. Salt Balance for Bolivia

Imports	Production	Consumption		Exports
Imports, Negligible	Salt production all from naturally occurring salt flats 45,000	Household/ Domestic/ Table (Direct Human)	29,000	Exports, Negligible
		Industrial Food/ Bakery/ Cattle. (Indirect Human)	10,000	
		Industrial Non-Food (No Human Consumption)	6,000	
Total Imports 0	Total Production 45,000	Total consumption 45,000		Total Exorts 0
Total imports + total production = 45,000		***Total consumption + total exports = 45,000***		

The Bolivian Salt Industry may be characterized as mainly artisan. The processing and packaging plants suffer from under-capitalization and inefficient methods. The following lists show the main characteristics of this industry.

a. ***Operations have a high manual content.*** This is so for all areas of the operation. In the production of crude salt manual labor is used for the extraction, bagging, and loading and unloading of the salt. Only in the transportation of salt is machinery in the form of trucks utilized consistently. In most of the packaging plants although machinery is employed, all transfer points, and storage activities are manual.

b. ***The industry is in a state of "immature stability."*** This characterization may seem quite paradoxical, but it is an accurate one. The industry appears fragmented with 47 processors, but due to the overall country demographics and production size is not so. There is only one clearly defined outstanding individual or group of producers. There is not likely to be much change in the near future given the particular cost structure of the Bolivian salt industry. Of the six Kellogg grant countries Bolivia has the lowest price of crude salt at source and the lowest price of packaged salt to the consumer. There is no possibility to squeeze the required capital out of the national market in order to reinvest and upgrade the industry. Short of serious export growth, which again seems unlikely given the present state of the regions salt production, self-generation of reinvestment or investment capital is unlikely. Hence the stability at the present state.

c. ***The wholesale price of packaged salt is in the range of U$ 0.12/kg to U$ 0.08/kg.*** Even if the final price to the consumer were to be 50% higher, this would put the final range of packaged salt to the consumer at between U$ 0.18/kg to U$ 0.12/kg. This is the lowest price of salt within the region and certainly of the six Kellogg grant countries. It is even far below that of the most efficient producer in Venezuela.

d. ***The operational facilities of the typical producer are extremely cramped for space.*** This is as a result of his overall lack of capital and his necessity to "make do" with scarce resources in a low margin industry. However this will further militate against plant upgrading and the safe handling and storage of fluoride chemicals.

e. ***There exist some brands with acceptable international standard quality. However a significant quantity of packaged salt, approximately 50%, is below what may be considered normal international standards.*** The main shortcoming of salt quality in Bolivia are: inconsistent particle size, caking or hardening of salt during storage, substandard packaging quality, high degree of sealing defects and poor weight control. Package weights are normally far below the declaration, with some processors simply labeling the weight as approx. insufficient evidence is available from the monitoring authorities to make a judgement on additive control.

f. ***There is no capacity among the producers to carry out any quantitative analysis on raw material or finished products.*** There is an absence of analytical facilities at the producer level. PISABOL will have laboratory facilities at their new plant location.

g. ***The program of iodination from all indications has been successful with 95% compliance by processors.*** Three processors have taken the initiative to commence fluoridation.

Recommendations for Bolivian Salt Industry

It is unrealistic to expect that rapid upgrading of the majority of salt processing facilities in Bolivia will take place. This is obviously what is needed to enable these facilities to start a program of salt fluoridation to move the production of fluoridated salt from 4% of salt at present to 95%. Rather what should be envisioned is a gradual approach, facilitating the existing fluoridated salt producers and encouraging those who are enthusiastic to fluoridate. It would be logical to concentrate on Oruro where 75% of salt production takes place, and to try to convert at least 80% of the producers there by centralizing and sharing common requirements. E.g. laboratory and storage and handling of the fluoride chemicals. The widespread fluoridation of salt in Bolivia will probably take more time than in other countries. It is recommended that the following strategies be pursued.

That the Government of Bolivia ensure the continuation of bulk buying and distribution of Fluoride chemical to ensure the lowest possible cost of this input to the salt processor.

That PISABOL, COPISAL and Molienda de Oriente be encouraged in all ways possible so that their addition program is successful and may be expanded.

That the other producers whom have shown an interest in fluoridation be given any available assistance to implement fluoridation.

That Oruro being the main salt production center, be focused on to see if sharing of facilities may be accomplished in that area.

That PAHO develop a "Travelling Seminar " to expose the Bolivian Producers to appropriate developments in salt process technology.

That a detailed study of the salt distribution and marketing system be made.

That PAHO explore the possibility of obtaining funding for improvement of salt production methods and for setting up of analytical facilities for fluoride analysis.

Dominican Republic

Table 17. Salt Balance for the Dominican Republic

Imports		Production		Consumption	
Venezuela	15,000	Solar Salt (Sal Solar)	32,000	Household/ Domestic/ Table (Direct Human)	30,000
Columbia	4,500			Industrial Food/ Bakery/ Canning (Indirect Human)	23,000
Ecuador	1,000			Animal Feeds	
Jamaica	500			Industrial Non-Food (No Human Consumption)	
Total Imports	21,000	Total Production	32,000	Total consumption	53,000
Total imports + total production 53,000				***Total consumption 53,000***	

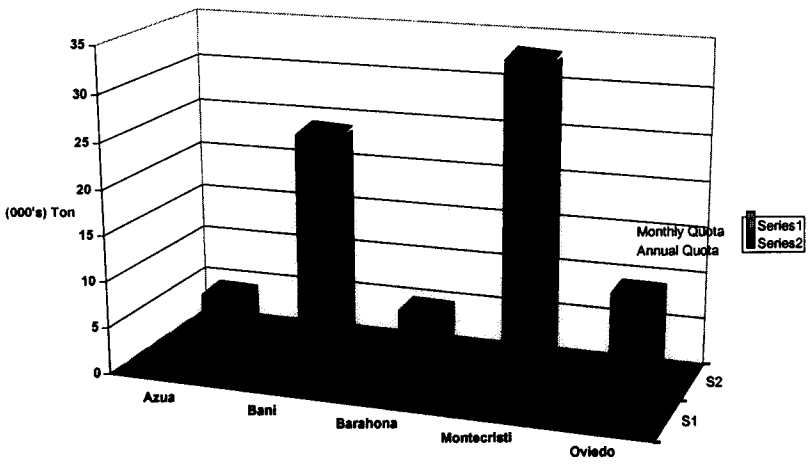
The Dominican Salt Industry is full of contradictions and paradoxes. On the one hand crude salt production methods are artisan and outdated, whilst refined salt production uses modern methods and is of high quality. On the one hand over 60% of table salt is sold as "sal en grano", whilst there is a sophistication of marketing of refined salt. The following points list the main characteristics of this industry.

a. ***Operations in crude salt production are highly manual.*** Although crude salt production is organized into production regions and co-operatives, they have failed to modernize over the years. A big contribution to this has been the protection given by the DISSAL monopoly.

b. ***The existence of the DISSAL monopoly has had a severe impact on the salt industry.*** All crude salt produced in the Dominican Republic is required by Law # 125 dated February 10th 1966, to be sold to DISSAL. This involves specific quotas to each salt producing area in the Dominican Republic. Figure 1 below shows the quotas for each salt producer from DISSAL.

   The impact of DISSAL has unfortunately been a negative one. The existence of protected prices and set quotas has stifled development and modernization of crude salt production. At the present time therefore production costs are high and quality low. What will be the likely result is a virtual wipeout of the local crude salt production as cheaper, higher quality crude salt becomes available from Venezuela, the Bahamas or Columbia.

Figure 1. DISSAL's Monthly & Annual Quotasfor Crude Salt



It should be noted that after the assessment of the Dominican salt industry, steps have been taken to liberalize the salt industry, with the closedown of DiSal, and the end of restrictions of importation of crude salt. As had been predicted earlier this has led to dislocation among the crude salt producers and the; lowering of salt prices.

c. The production methods employed for salt refining are fairly modern. The island's salt refineries manufacture good quality salt. Management however has to work on improving efficiency and overall plant productivity. In an effort to cut costs and improve profitability the highest contribution to cost is being dealt with at first. That is the cost of crude salt. The possibility of obtaining imported crude at one-forth the price is too much to ignore.

d. Over 60% of the market for domestic or table salt is in the form of "sal en grano." This long-standing tradition will have implications for salt fluoridation. The quality of **sal en grano** is such that it would not be suitable for fluoride addition. Also the fragmented nature of its distribution would effectively erase the advantages of salt fluoridation Vis a Vis other fluoridation interventions.

e. The presentation and quality of refined salt is of high standard and apart from price can compete internationally. The overall marketing of refined salt in the Dominican Republic is quite sophisticated and highly competitive. If other aspects of the production-supply chain are freed up, dynamism in the industry will spread.

f. The processed salt producers will be able to upgrade their analytical facilities to do fluoride analysis. The present salt processors operate at a fairly sophisticated level. There should be no problem for them to improve their analytical facilities to include fluoride analyses.

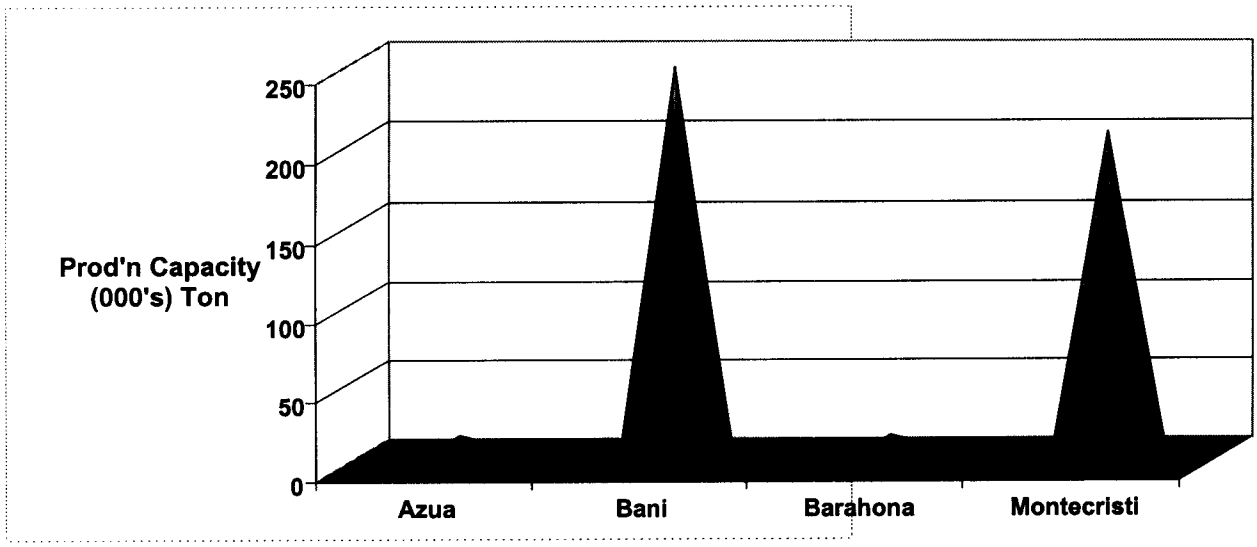
Recommendations for Dominican Salt Industry

The main obstacle facing a program of salt fluoridation in the Dominican Republic would be the low level of universality, relative to other countries, that such a program would have. This is because a majority, over 60% of household salt are sold as *sal en grano*. It is logical to conclude therefore that only 40% of the population would benefit from a program of salt fluoridation if the present market conditions do not change. In addition the lower socio-economic levels would benefit least as they consume less refined salt. A strategy must therefore be formulated to convert the salt market in the Dominican Republic, away from *sal en grano* and towards the consumption of more processed salt, which can be fluoridated. The lynchpin of any strategy to convert the market must have processed salt competing with sal en grano on the basis of price.

1. That the Government of the Dominican Republic examines and reassesses the role costs and benefits of DISSAL. From the limited vantage point of this consultant it is clear that DISSAL does not add any value to the salt production supply chain. Indeed what it has ended up doing is creating an unsustainable artificial environment of high prices for the salt producers, which has resulted in the lack of technical and organizational development. It should be noted that this recommendation has been followed with the close down of DiSal and the liberalization of salt importation.

2. It is the considered opinion of this consultant that Salinas Bani has the best potential from a technical point of view to convert to an efficient crude salt production operation. Figure 2 below shows the potential of each existing solar salt site for salt production. The strategy should therefore be to convert one of those sites to efficient production so that it can compete with crude salt from anywhere in the Caribbean Basin.

Figure 2. Production Capacity of Salinas



3. That the present salt processors be given every encouragement and assistance to improve their production processes and thereby reduce the cost of refined salt to the consumer. Amongst this should be attendance of their technical personnel at the intended PAHO sponsored travelling seminar in Venezuela later in 1998.

4. That *Refinera de Sal Dominicana* and *Industrias de Sal Dominicana* be given every assistance to begin the addition of fluoride to their salt product. This should include carrying out plant trials at the earliest possible opportunity.

5. That the present *sal en grano* producers and packagers be exposed to the technology of small-scale *mollida, lavada secada* salt processing, along the lines of the Venezuelan micro-plants. This would be so as to encourage them upgrading their product offering away from *sal en grano* and towards a higher quality, but economical to produce processed salt, which may be fluoridated and iodized.

6. That a detailed study of the salt distribution and marketing system be made. This study should focus on ways of converting the market away from *sal en grano* and towards refined salt.

Honduras

Table 18. Salt Balance for Honduras

Imports		Production		Consumption	
Mexico		Solar Salt (Sal Solar)	31,400	Household/ Domestic/ Table (Direct Human)	21,000
El Salvador				Industrial Food/ Bakery/ Canning. (Indirect Human)	29,000
Nicaragua		"Cooked" Salt (Sal Cocida)	10,600	Industrial Non-Food (No Human Consumption)	
Total Imports	8,000	Total Production	42,000	Total consumption	50,000
Total imports + total production 50,000				***Total consumption 50,000***	

The Honduran Salt Industry may be characterized for the main part as still utilizing traditional techniques and methods. The following lists the main characteristics of this industry.

a. ***Operations are highly manual.*** This is so for all areas of the operation. In the production of crude salt all tasks except for the pumping of seawater are performed manually. In the packaging plants although machinery is employed, all transfer points, and storage activities are manual. Only in the transportation of salt is machinery in the form of trucks or vans utilized consistently.

b. ***The price of salt to the consumer is in the range of U$ 0.43/kg to U$ 0.21/kg.*** The majority of brands are priced in the lower range of U$ 0.21/kg, but higher quality imported brands and local brands that are well known are priced at a premium. See Appendix 3.

c. ***The salt quality is below what can now be considered normal international standards.*** No producer in Honduras is able to present local salt to the consumer at less than about 4% moisture. Appearance and particle size suffer from inconsistency. Package weights are normally far below the declaration. However packaging quality and the consistency of Iodide levels are considered satisfactory.

d. ***The industry is highly fragmented, consisting of close to 200 producers.*** Table 19 below shows the number of producers in each production capacity cohort. The size categories may be considered overgenerous by international standards. Only one producer encountered, ReSal, has the level of installed capacity, to be categorized as a small plant by international norms. The other producers, even those stated in this table to be large producers, would be considered micro-producers by international standards.

Table 19. Number of Producers Categorized by Size and Respective Production

Category of Producer	Number of Producers	% of Total Producers	Production (ton)	% of Total Production
Small < 225 t per annum	151	79.9	13,200	31.4
Medium 225t to 550t per annum	21	11.1	6,800	16.2
Large > 550 t per annum	17	9.0	22,000	52.4
Total	189	100	42,000	100.0

e. ***There is no capacity among the producers to carry out any quantitative analysis on raw material or finished products.*** There is an absence of analytical facilities at the producer level.

f. ***The producers have demonstrated the capacity to change and improve.*** In the case of the iodination program there has been good co-operation on the part of the producers.

Most of the above stated characteristics will increase the level of difficulty of trying to start a sustainable salt fluoridation program. For one such to succeed, conventional wisdom dictates that a higher level of salt quality is required. This is especially so with respect to moisture content, a dry, (<0.25 % moisture), and salt being required.

The important questions therefore are: a) what strategies can be used to bring Honduras's Salt Industry to a stage where it can begin a sustainable program of salt fluoridation? b) How long will it take to be effective? and c) Are there alternate means of providing fluoridated salt?

Production processes will have to be improved in order to efficiently produce an acceptable quality salt. This is so for two reasons: a) to be able to start a regime of Salt Fluoridation, and b) to be able to compete effectively with imported salt from highly efficient producers such as Mexico, Venezuela or Columbia.

The obstacles that are in the way of and suggestions in order to achieve the goal of improved production and productivity are:

a. ***Interpersonal.*** It will be necessary to reduce the hostility and to improve the relations between various camps of the salt producers. It is paramount that the producers see that their individual interest is best served in the long run by forming strategic alliances with each other. There is the fear however that the short term view of "trying to go it on my own", is likely to be the prevailing one. Changing that view through sensitive and sophisticated handling will have to be foremost on the agenda of a Salt Fluoridation Program.

b. ***Financial.*** The improvements necessary will require investments in plant and equipment. Some of the producers have an estimate of U$650,000 for a 5 ton per hour plant. The cost of a plant can vary considerably depending on the specific features of the plant and options such as the local fabrication of, or purchase of second hand equipment. A 5 ton per hour plant's cost could vary between U$300,000 and U$700,000, and a 10 ton per hour plant between U$400,000 and U$1,000,000. It is possible though for the fabrication of a micro-plant of capacity 1ton per hour or 5,000 ton per year for approximately U$100,000. This size plant has been erected successfully in Venezuela.

   At the present interest rates in Honduras, investing in, or borrowing money to invest in a salt plant, could not be justified on purely financial grounds. Concessionaire interest rates would therefore have to be applied for this type of activity. It is a possibility that funding through multi-lateral funding agencies could be obtained given the social benefit that could result.

c. ***Institutional/Organizational.*** The production methods and techniques in Honduras is highly artisan. It will be important to provide the levels of exposure and training needed to upgrade the producers' knowledge of more modern techniques and methods.

Recommendations for Honduran Salt Industry

It is recommended that the following strategies be pursued:

1. That more full time effort is placed on managing the process of improving and modernizing the salt industry. This will require a multi-disciplinary committee with understanding of the social, economic and engineering issues involved.

2. That a formal association of salt producers is formed. There are about 8 existing producer cooperatives. However an overall producers association is required, in order to disseminate information and improvements and in order to set the stage for the possibility of producers merging and becoming more efficient. The possibility of offering some incentive should be explored in order to ensure active participation of as many of the producers as possible.

3. That Refinadora de Sal is approached/encouraged to accelerate their program of quality improvement. This company is the best poised, in all respects to begin a program of salt quality improvement and the addition of fluoride. It may be necessary to grant assistance in the form of engineering design, procurement of equipment and analytical facilities.

4. That the Honduran Government/ Salt Fluoridation Committee develops a detailed strategic plan to bring about the necessary changes to the salt industry in order to make fluoridated salt available to the population. This plan would involve looking at a number of scenarios.

5. The development of a single large, (10 ton per hour?), plant.

6. The encouragement of the small producers to modernize along the lines of the Venezuelan "***Micro Plants***". Importing table quality salt already fluoridated or for dosing with fluoride and packaging.

7. That PAHO develop a "Travelling Seminar " to expose the Honduran Producers to appropriate developments in salt process technology.

8. That a detailed study of the salt distribution and marketing system be made.

9. That PAHO explore the possibility of obtaining funding for improvement of salt production methods and for setting up of analytical facilities for fluoride analysis.

Nicaragua

Table 20. Salt Balance for Nicaragua

<table>
<tr><th colspan="2">Imports</th><th colspan="2">Production</th><th colspan="2">Consumption</th><th colspan="2">Exports</th></tr>
<tr><td rowspan="3">Costa Rica</td><td rowspan="3">4,000</td><td rowspan="2">Solar Salt (Sal Solar)</td><td rowspan="2">52,000</td><td>Household/ Domestic/ Table (Direct Human)</td><td>15,500</td><td rowspan="3">Honduras
Costa Rica</td><td rowspan="3">2,000
2,500</td></tr>
<tr><td rowspan="2">Industrial Food/ Bakery/ Cattle. (Indirect Human)</td><td rowspan="2">36,500</td></tr>
<tr><td>"Cooked" Salt (Sal Cocimienta)</td><td>500</td><td>Industrial Non-Food (No Human Consumption)</td></tr>
<tr><td colspan="2">Total Imports 4,000</td><td colspan="2">Total Production 52,500</td><td colspan="2">Total consumption 52,000</td><td colspan="2">Total Exports 4,500</td></tr>
<tr><td colspan="4">Total imports + total production = 56,500</td><td colspan="4">Total consumption + total exports = 56,500</td></tr>
</table>

The Nicaraguan salt industry whilst highly artesian has a number of players with the potential for developing and modernizing the industry. It is recommended that the following strategies be pursued.

Recommendations for Nicaraguan Salt Industry

1. That more full time effort is placed on managing the process of improving and modernizing the salt industry. This will require a multi-disciplinary committee with understanding of the social, economic and engineering issues involved.

2. Those steps are taken to strengthen the existing salt producers' associations. Efforts should be made to form an umbrella group, to disseminate information and to offer suggestions for improvements and to set the stage for more producers merging and becoming more efficient.

3. That ENISAL & PROCOSALNIC be encouraged and assisted in every way possible to accelerate their merger to the new entity ENIPROSAL. This new entity will be the best poised in all respects, to begin a program of salt quality improvement and the addition of fluoride.

4. It should be noted that since the original assessment, another player has entered the scene and built a modern salt processing facility of capacity 15,000 ton per year. This facility can commence salt fluoridation.

5. That the Nicaraguan Government/ Salt Fluoridation Committee develops a strategic plan detailing to bring about the necessary changes to the salt industry in order to make fluoridated salt available to the population. This plan would involve looking at a number of scenarios.

6. Assistance and/or soft loans to the merged ENIPROSAL entity.

7. The encouragement of other small producers to modernize along the lines of the Venezuelan ***"Micro Plants"***.

8. Importing table quality salt already fluoridated or for dosing with fluoride and packaging.

9. That PAHO develop a "Travelling Seminar " to expose the Nicaraguan Producers to appropriate developments in salt process technology.

10. That a detailed study of the salt distribution and marketing system be made.

11. That PAHO explore the possibility of obtaining funding for improvement of salt production methods and for setting up of analytical facilities for fluoride analysis.

Panama

Table 21. Panama Salt Balance

Imports		Production		Consumption	
Mexico		Solar Salt (Sal Solar)	18,000	Household/ Domestic/ Table (Direct Human)	11,000
Colombia				Industrial Food/ Bakery/ Cattle Feed. (Indirect Human)	11,250
Costa Rica				Industrial Non-Food (No Human Consumption)	7,750
Total Imports	12,000	Total Production	18,000	Total consumption	30,000
Total imports + total production 30,000				***Total consumption 30,000***	

The Panamanian Salt Industry may be characterized as being well established. It has the characteristics of an industry in advanced, albeit slow transition. Different levels, stages, and techniques of production coexist but the trend is to improvement and increased sophistication. The following lists the main characteristics of this industry:

a. ***Operations are manual for crude salt production but fully mechanized for salt processing.*** In the production of crude salt, operations generally follow the traditional manual process. Low labor productivity and high prices relative to neighboring countries is the outcome. In the processing plants modern processes and techniques are employed. The trend is for modernization and improvement.

b. ***The industry is differentiated between crude salt production/producers, and processed salt production/processors.*** The crude salt producers have been going through a process of consolidation. For example FENCOSPA which produces 12,600 ton or 70% of the total crude salt production is a federation of 3 co-operatives totaling 303 producers. There are a total of 9 salt processors. PANASAL and FENCOSPA are by far the largest salt processors. PANASAL has about 75% of the **"table salt"** market, whilst FENCOSPA has about 31% of the processed salt market. (This includes table salt, industrial salt, and bulk packaged salt.). Both PANASAL and FENCOSPA would be considered micro or very small processors on an international scale.

c. ***The price of salt to the consumer is in the range of U$ 0.63/kg to U$ 0.53/kg.*** The price varies depending on the brand and quality. Some imported brands from the USA are available at slightly higher prices.

d. ***The salt quality is on par with what can now be considered normal international standards.*** Salt from PANASAL is comparable in all respects with similar processed salt anywhere in the world. Packaging, presentation and weight control is all good. **FENCOSPA**'s moisture content will have to be reduced to below 0.5 % from the present 1.5% to be considered competitive internationally. This is to be implemented shortly. Iodide control in all brands is good.

e. ***The capacity exists, with some producers, to carry out the full range of qualitative analyses on raw material and finished products.***

f. ***They have a successful salt iodination program***

g. ***The producers have demonstrated the capacity to change and improve.*** Panama has all the ingredients in place to begin a sustainable Salt Fluoridation program. In summary these are:

- Governmental backing and the will to implement the program.
- Institutional support for the program, i.e. PAHO, INCAP, Government Food Control Section monitoring.
- High quality salt production that has been iodized for many years.
- Marketing systems and traditions that allow high quality salt to reach all the population.
- No technical impediments to the addition of fluoride.
- Willing and enthusiastic salt processors, who are anxious to start the addition of fluoride.

Nevertheless, although the overall situation is decidedly optimistic, an analysis of the price competitiveness of Panamanian salt, will lead to the conclusion that this industry will be threatened in the near run by the increasingly aggressive, lower cost producers of Mexico, Colombia and Venezuela. Today they are exporting crude salt to Panama; tomorrow it will be processed salt. From the perspective of ensuring a sustainable salt fluoridation program in an environment of free trade, the following measures should be taken.

- Ensure that salt that is imported is fluoridated and iodized, except for salt used in the manufacture of industrial or chemical products.

- Encourage further restructuring and the mechanization of Panama's crude salt production so as to ensure a reduction in the price of crude salt to compete with imported crude salt.

Since the initial assessment importation of crude salt mainly from Venezuela grew but has now been restricted by the imposition by the government on an 80% import duty on crude salt. It is not sure how long this can be maintained in the face of increased trade liberalization in the Region.

Recommendations for Panamanian Salt Industry

It is recommended that the following strategies be pursued:

1. That PANASAL begin a plant test as soon, as is practical. This test should be approximately one week's duration and would serve to test the addition and laboratory systems under real production conditions. Any shortcomings revealed during the plant test should be rectified.

2. That following on the outcome of their plant test PANASAL incorporate the improvements required and proceed to full time implementation of salt fluoridation.

3. That in the case of PANASAL, Potassium Fluoride be used to fluoridate. The addition point should be at the present iodide addition point. The fluoride solution should be made up with the present iodide solution, in the present mixing tank or *receptor de disolución.*

4. That as soon as their plant improvements leading to dry salt is completed FENCOSPA make preparations to begin a fluoridation test.

5. That every assistance be given to FENCOSPA in the form of improvements to their laboratory facilities. Specifically, it is recommended that PAHO explore the possibility of obtaining funding of equipment and the first years supply of chemicals for fluoride analysis for FENCOSPA. See Appendix 3, for details.

6. That a detailed study of the salt distribution and marketing system be made.

It should be noted that recommendations 1 through 4 were followed and have implemented. Both plants have undergone successful fluoridation plant trials. The addition of fluoride to salt therefore awaits a final political decision.

Paraguay

Paraguay has no indigenous production of salt. All local consumption is imported from Argentina and Brazil. Paraguay also has the distinction of having more heads of cattle than people have and so a significant proportion of their salt consumption goes into the preparation of cattle feed.

Table 22. Paraguay Salt Balance

Imports	Production	Consumption		Exports
Imports, Brazil Argentina	Salt production negligible	Household/ Domestic/ Table (Direct Human)	20,000	Exports, negligible
		Industrial Food/ Bakery/ Cattle. (Indirect Human)	60,000	
		Industrial Non-Food (No Human Consumption)	6,000	
Total Imports 80,000	Total Production 0	Total consumption 80,000		Total Exports 0
Total imports + total production = 80,000		***Total consumption + total exports = 80,000***		

At present there is only one processor of salt in Paraguay. The producer of Yucky brand salt has just recently completed a 30,000-ton per year processing plant. This will provide good quality salt and the ability to iodize and fluoridate the salt for human consumption produced there.

There are many salt packagers in the country, which take the imported rock salt, reduce the size by milling and then iodize then package in a variety of sizes. These enterprises produce for both human and animal consumption.

The main concern of producers in Paraguay is the possibility of imported salt at a lower price flooding the market and reducing the price. They want government to enforce the laws concerning additives and to offer some protection for locally processed salt.

The following strategies are recommended to ensure the commencement of salt fluoridation as soon as possible in Paraguay.

Recommendations for Paraguayan Salt Industry

1. The government should ensure the formulation and passing of the law for additives in salt to include fluoride in salt, as soon as is possible.

2. Greater enforcement of the law with regards fortified salt and a ban on the importation of non-fortified salt for human consumption should be done.

3. The possibility of a subsidy on the additives to salt should be examined.

4. A plant trial to add fluoride to salt at Yucky should be carried out as soon, as is possible. This will test the existing system and point to modifications that will be necessary.

Venezuela

Table 23. Venezuela Salt Balance

Imports		Production		Consumption		Exports	
Crude Columbia Bonaire	30,000	Solar Salt (Sal Solar)	705,000	Household/ Domestic/ Table (Direct Human)	85,000	Crude	70,000
Processed Columbia	5,000			Industrial Food/ Bakery/ Cattle. (Indirect Human)	145,000	Processed Dom. Rep. Colombia Martinique Brazil Trinidad Nigeria USA	55,000
				Industrial Non-Food (No Human Consumption)	385,000		
Total Imports 35,000		Total Prod'n 705,000		Total consumption 615,000		Total Exorts 125,000	
Total imports + total production = 740,000				***Total consumption + total exports = 740,000***			

The Venezuelan Salt Industry may be characterized as being sophisticated and well developed. It is a net exporter of salt and has installed capacity to produce at about 75% above present production. Although different levels, stages, techniques and scales of production coexist, the vast majority of production takes place in enterprises that are efficient and well run. This is as true of the small and micro-plants that could well become a model for other similar sized salt producers in Latin America.

The marketing of their salt is highly competitive, reflected by the many brands, packages and labels developed for salt in Venezuela.

1. ***Operations are fully mechanized for the vast majority of salt processors.*** The Venezuelan salt industry has very large producers of processing capacity 400 ton per day to micro producers of 10 ton per day. The large producers are fully mechanized, even moving to the stage of sophisticated instrumentation and computer process control. The small and micro producers for the most part have adopted very innovative techniques and machinery modifications in order to improve their efficiency and quality of product. Those producers whom have lagged in their improvements are either facing closure or are about to implement improvements.

2. ***The industry is mature and consolidated. It is able to be world competitive.*** The table *below* shows the salt processors and their categories in the Venezuelan salt industry.

Table 24. Number of Producers Categorized by Size and Respective Production

Category of Processor	Number of Processors	% of Total Processors	Production (ton)	% of Total Production
Small < 5000 ton per annum	8	57	20,000	6.7
Medium 5,000 to 50,000 ton per annum	4	28	55,000	18.3
Large > 50,000 ton per annum	2	14	225,000	75.0
Total	14	100	300,000	100.0

3. ***The industry is for the most part differentiated between crude salt producers and salt processors.*** Most salt processors are independent entities and operations from the crude salt producer. Crude salt is purchased from the most convenient source with regards to the best quality and price. This ensures competition and keeps the crude salt producers efficient. In the case of TECNOSAL and INDULSALCA, they have salt processing facilities coupled to their crude salt production facility.

4. ***The price of salt to the consumer is in the range of U$ 0.35/kg to U$ 0.10/kg.*** In this highly competitive market there is a lot of marketing effort to create different brands, sizes, qualities, and types of products. This is most evidenced, and may be seen throughout this report, by the varieties of packaging and labeling designs and brand names.

5. ***The salt quality is on par with what can be considered normal international standards.*** In some cases the overall quality of salt and packaging is at a higher level than generally available to the consumer in even well developed countries. E.g. **Sal Bahia** 750 gm carton packaged salt can compete anywhere in the world. In addition salt quality parameters such as fluoride and iodide levels, soluble and insoluble impurities and package weights are for the main part consistent and within targeted values.

6. ***The capacity exists, with some producers, to carry out the full range of quantitative analyses on raw material and finished products.***

7. ***They have a successful salt fluoridation and iodination program.*** The targeted value, as set by the Venezuelan Ministry of Health at present is *Iodide 40 to 70 ppm,* and *Fluoride 60 to 90 ppm.*

Venezuela has for some time now carried out a successful salt fluoridation and iodination program. It is estimated that some 75 % of the salt for direct and indirect human consumption are fluoridated to a level of 90 to 100 ppm. It is hoped that in the near future Venezuela will see it fit to adopt the PAHO guidelines of 200 - 250 ppm fluoride for addition to their domestic salt. There will be no problems for producers to increase the dosage and to become compliant with a higher level of fluoride

content. All that will be necessary in all the cases observed, would be to increase the addition rate of the fluoride chemical being used.

In all cases except *Sal Bahia* and MOLISOCA, storage and handling procedures for fluoride additive chemicals are less than ideal. The salt processors need to pay attention to improvements in this area of their process, so as to avoid any unfortunate long-term consequences.

In the case of *TECNOSAL,* where the finest salt product has a higher level of fluoride than targeted, this should not be seen as a major problem. This is as a result of the salt process. To try and change the process in order to rectify this will be at too high a cost for the benefit that may accrue. Rather, a better approach would be to simply take this additional amount of fluoride being consumed by the population and lower the main target by a few points to compensate for this. An approach of an overall national fluoride balance can easily lead to fine-tuning of the target fluoride level, within the recommended PAHO range.

It is also recommended that a detailed study of the salt distribution and marketing system be carried out.

Lastly, it is important to recognize the importance of the Venezuelan salt industry as a model for those underdeveloped salt industries of Central America and the Caribbean. The solutions to some common problems in salt processing technology have been implemented in a graceful fashion by the Venezuelan salt processors. The countries and processors that are attempting to improve their salt process to the point where fluoride may be added to the salt can benefit tremendously from their Venezuelan counterparts.

It is recommended therefore, that a travelling seminar for producers and processors from Honduras, Nicaragua, Panama, Bolivia and Dominican Republic be held in Venezuela, to give processors from these countries access to the imaginative and innovative, techniques and equipment modifications of the Venezuelan processors.

SECTION VI

SURVEILLANCE SYSTEMS AND MONITORING OF SALT FLUORIDATION PROGRAMS

The PAHO Regional Oral Health Program recommends that at each local PAHO Program, an individual country technical officer (CTO) be designated to act as liaison and project coordinator. In addition, this individual provides assistance on funds disbursements and coordinates consultant activities within the country on the various tasks or missions being developed for each of the project components.

The CTO would also assists on the periodic meeting of the Salt Fluoridation Commission in each country and expedites development of legal documentation to enforce salt fluoridation. The CTO would also coordinate and assist the program to identify funding sources to aid program development that might not be directly funded by the W.K. Kellogg Foundation.

At the International level, the Regional Oral Health Program through the PAHO Advisory Board on Oral Health Programs makes recommendations for project improvement and sets protocol guidelines and specific requirements based on scientific evidence. Research experiences and specific country studies are discussed and a consensus presented to the in country project directors for implementation. An international epidemiological surveillance workshop on salt fluoridation was held in San Jose, Costa Rica in August 4-8 of 1997. The Task-Force Meeting to Review Current Recommendations for Concentration of Fluoride in Salt, was held in Washington, D.C., February 23-26, 1998 to revise existing recommendations for biological and chemical monitoring of fluoride as part of the epidemiological surveillance system recommended by PAHO, and to discuss the concentration of fluoride in salt that would be recommended to all participating countries. The recommended concentration of fluoride in salt is 200 to 250 ppm (mg/kg). This is the concentration that will have the maximum a cariostatic effect with minimum risk of causing fluorosis.

An epidemiological surveillance workshop was held in Quito, Ecuador, July 26-29 of 1998 to inform participants of the latest recommendations for countries engaged or considering development of salt fluoridation programs.

PAHO'S RECOMMENDATIONS FOR SURVEILLANCE OF SALT FLUORIDATION PROGRAMS

The following are the recommendations proposed by the Technical Advisory Group (TAG) meeting conducted in Washington D.C. in January 1998 and later presented and approved by the participating countries in the Regional Workshop for Surveillance and Quality Control for Salt Fluroridation, conducted in Quito-Ecuador in July 1998. The 10 recommendations included items related to the type of fluoridation programs to be maintained in each participating country, those that need to be faced out, and the instruments for data collection to monitor program implementation. The latter group was an extension of the monitoring sections included in the grand proposal and the country results has been presented and discussed before in this report. Two qualifiers were introduced in the recommendations. "Essential" items are those that need to be implemented because they are vital for the success of the program. "Non-essential" recommendations are important but not vital and also include alternative options for essential items; non-essential recommendations could be opted by countries if necessary.

1. Only one systemic source of fluoride is recommended in each country. This should be either salt or water, but not both.

2. Dental caries should be monitored to evaluate the effectiveness of the preventive program. Both, baseline and follow-up studies were recommended; however, only the baseline study was within the scope of the Grant Proposal). The baseline survey of dental caries is essential and should target 6 to 8, 12 and 15-year-old children. The recommended survey uses a tooth-based index (DMFT) and the diagnostic criteria and coding recommended by WHO. A surface-based index (DMFS) is not essential but could be utilized by the countries.

3. Dental fluorosis monitors past exposure to fluoride and should be monitored to assess unacceptable cosmetic effects of systemic fluoride overuse during the permanent teeth formative years. Dental fluorosis was measured by a modified version of Dean's Index that included only the upper anterior teeth (cuspid to cuspid). Only the facial surfaces were evaluated using the six categories described by Dean. Other teeth could be included but their inclusion is non-essential.

4. Urinary fluoride excretion should be monitored to evaluate the current exposure to fluoride. Therefore, the target population for these studies included 3 to 5-year-old children. This study was highly recommended but considered non-essential. According to the WHO recommendations these studies should be implemented immediately before the introduction of the systemic fluoride and thereafter at 6-months and 12-months. PAHO recommendations were modified to include only one evaluation 24 months after the program was initiated, but indicated that a baseline study could be included if the country considers it necessary. A 14 to 18 hours collection period was considered an acceptable protocol for urine collection. In addition, this study should be conducted in clusters of 30-35 children in communities with sub-optimal, optimal and above optimal concentration of fluoride in the drinking water and, during follow-up studies, in communities were the salt is distributed.

5. The baseline study of fluoride concentration in the water supplies for human consumption is essential. In all participating countries fluoride occurs naturally and its concentration may experience variations by season of the year and other geological activities. As a consequence, all water sources with concentrations higher than 0.5 parts per million of F should be monitored on a permanent basis to avoid overexposure if the fluoride content of the water increases after the introduction of salt fluoridation.

6. A nutritional survey to determine the consumption and ingestion of salt is non-essential. Data from previous nutritional studies could be used and/or extrapolated.

7. Regarding other sources of fluoride:

   a. Systemic fluoride, i.e., dietary fluoride supplements (drops, tablets, and in multi-vitamin combinations) should be eliminated. Monitoring of this recommendation could be used through market presence of these products and surveys of health practitioners or parents.

   b. In a country with a national systemic fluoride program, fluoride mouthrinse programs provide additional topical preventive effect and should not be used if the DMFT at age 12 falls below 3. In countries without national fluoridation program, these programs should be continued if the DMFT index is greater than 3. If the index is less than three, these programs could continue if shown to be cost-effective. When used, fluoride mouthrinses should only be

provided to children older than 6 years when the swallowing reflex is developed enough to avoid accidental ingestion of the product. When used in older children and swallowed, the effect on dental fluorosis is negligible because most anterior teeth are completely formed at that age.

c. The use of fluoridated toothpaste is highly recommended. In younger children, less than 6 years, only a "pea" size of toothpaste should be delivered by the parent/guardian. In addition, toothbrushing with fluoride toothpaste among children less than 3 years of age should be supervised directly by the mother or guardian. It is recommended that children under 6 years should use toothpaste with a fluoride concentration between 400 and 550 ppm. Children over 6 years or age should use the standard formulated fluoride toothpaste (between 1000 and 1500 ppm). A baseline and periodic survey of toothpaste use is part of the ongoing monitoring recommendation. Periodic evaluations could be performed thorough sales and import data.

d. Oral health promotion and toothbrushing training should continue after the implementation of national programs using systemic fluoride.

8. The recommended range of fluoride concentration in the salt for human consumption is 200-250 mg per kilo (equivalent to 250 ppm F). The actual concentration should be adjusted based on the level of urinary fluoride excretion, the level of fluoride in the drinking water and the prevalence and severity of fluorosis, accounting for the time-lapse between the fluorosis observed and the time when exposure occurred.

9. Countries should assess the existing and regulatory framework that supports or hampers the introduction and sustainability of fluoridation programs. This requires the review of existing laws, regulations, and the promotion of new or supplementary ones. Also, a regulatory mechanism for quality control should be part of the regulations concerning dosage. The Regional Program of Oral Health will promote the introduction of fluoridated salt in the *condex alimentarius.*

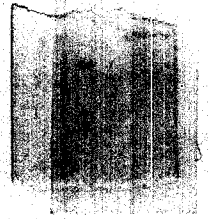
10. Continuing education to the public and to health professionals is essential.

SECTION VII

GENERAL POLICY RECOMMENDATION AND LEGAL FRAMEWORK FOR SALT FLUORIDATION

As noted in the previous report, PAHO continued providing assistance for development of an adequate legal framework for salt fluoridation programs. As the efforts of multi-national consortiums to facilitate inter-country trade are being studied, the structure, wording and implications of legislation have become an issue that deserves careful consideration. Standardization bodies have recommended harmonization of standards worldwide, and it is strongly supported by industry and other agencies. Further, strict product quality control is necessary for consumer protection and to assure program effectiveness. Suggestions have been made to include requirements of both iodine and fluoride in a single salt standard. The factors mentioned above suggest the need to further revise the legal framework of salt fluoridation standards for the Region. Annex 2 summarizes the status of the standard development in each of the participating countries in the salt fluoridation program in the Region, and presents recommendations for legislation and regulation of salt fluoridation.

ANNEXES



ANNEX 1

REPORT OF COUNTRY ACTIVITIES

Multi-Year Plan for Salt Fluoridation Programs in the Region of the Americas

Belize, Bolivia, Dominican Republic, Honduras, Nicaragua, Panama, Paraguay, Venezuela

COUNTRY	EXPECTED RESULTS	INDICATORS	ACTIVITIES
Belize	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies.	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. 2. Cost-benefit study. ***C*** 3. DMFT and dental fluorosis survey: 3.1 Survey design and methodology. ***C*** 3.2 Personnel training and calibration. ***C*** 3.3 Survey implementation and data collection. C 3.4 Data analysis and report. C 4. Study of fluoride concentration and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. C 4.4 Data analysis and resort. ***C***
Bolivia	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with Baseline studies. – Bolivia reports production of fluoridated of over 1200 metric tons.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies. 5. Survey of fluoride supplements and toothpaste 6. Salt Industry Technology Development in progress 7. Assessment of Fluoride Excretion in urine 8. Country surveillance systems for fluorides	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. 2. Cost-benefit study. ***C*** 3. DMFT and dental fluorosis survey: 3.1 Survey design and methodology. ***C*** 3.2 Personnel training and calibration. ***C*** 3.3 Survey implementation and data collection. ***C*** 3.4 Data analysis and report. ***C*** 4. Study of fluoride concentration and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. ***C*** 4.4 Data analysis and resort. C 5. Study of fluoride supplements and toothpaste 5.1. Study design and methodology C 5.2. Personnel trained and calibration of examiners C 5.3 Survey implementation and data collection C 5.4.Data analysis and report C 6. Salt Industry technology development 6.1. Workshop conducted C 6.2. Salt industry personnel trained C 7. Study of fluoride excretion in urine 7.1. Procurement and elements and supplies C 7.2. Survey design C 8. Surveillance systems Task force meeting to review current recommendations on fluoride concentration in salt C

COUNTRY	EXPECTED RESULTS	INDICATORS	ACTIVITIES
Dominican Republic	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies. 5. Survey of fluoride supplements and toothpaste 6. Salt Industry Technology Development in progress 7. Assessment of Fluoride Excretion in urine 8. Country surveillance systems for fluorides	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. ***C*** 2. Cost-benefit study. ***C*** 3. DMFT and dental fluorosis survey: 3.1 Survey design and methodology. ***C*** 3.2 Personnel training and calibration. ***C*** 3.3 Survey implementation and data collection. ***IP*** 3.4 Data analysis and report. ***IP*** 4. Study of fluoride concentration and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. ***C*** 4.4 Data analysis and resort. ***C*** 5. Study of fluoride supplements and toothpaste 5.1. Study design and methodology *C* 5.2. Personnel trained and calibration of examiners *C* 5.3 Survey implementation and data collection *IP* 5.4.Data analysis and report *IP* 6. Salt Industry technology development 6.1. Workshop conducted *C* 6.2. Salt industry personnel trained *C* 7. Study of fluoride excretion in urine 7.1. Procurement and elements and supplies *C* 7.2. Survey design C 8. Surveillance systems 8.1. Task force meeting to review current recommendations on fluoride concentration in salt *C*

COUNTRY	EXPECTED RESULTS	INDICATORS	ACTIVITIES
Honduras	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies. 5. Survey of fluoride supplements and toothpaste 6. Salt Industry Technology Development in progress 7. Assessment of Fluoride Excretion in urine 8. Country surveillance systems for fluorides	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. ***C*** 2. Cost-benefit study. ***C*** 3. DMFT and dental fluorosis survey: 3.1 Survey design and methodology. ***C*** 3.2 Personnel training and calibration. ***C*** 3.3 Survey implementation and data collection. ***C*** 3.4 Data analysis and report. 4. Study of fluoride concentration in water and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. *C* 4.4 Data analysis and resort. *C* 5. Study of fluoride supplements and toothpaste 5.1. Study design and methodology. ***C*** 5.2. Personnel trained and calibration of examiners ***C*** 5.3 Survey implementation and data collection. ***C*** 5.4.Data analysis and report. C 6. Salt Industry technology development 6.1. Workshop conducted ***C*** 6.2. Salt industry personnel trained ***C*** 7. Study of fluoride excretion in urine 7.1. Procurement and elements and supplies ***C*** 7.2. Survey design. ***IP*** 8. Surveillance systems 8.1. Task force meeting to review current recommendations on fluoride Concentration in salt. ***C***

COUNTRY	EXPECTED RESULTS	INDICATORS	ACTIVITIES
Nicaragua	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies. 5. Survey of fluoride supplements and toothpaste 6. Salt Industry Technology Development in progress 7. Assessment of Fluoride Excretion in urine 8. Country surveillance systems for fluorides	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. *2.* Cost-benefit study. ***C*** 3. DMFT and dental fluorosis survey: 3.5 Survey design and methodology. ***C*** 3.6 Personnel training and calibration. ***C*** 3.7 Survey implementation and data collection. C 3.8 Data analysis and report. C 4. Study of fluoride concentration and report. 4.5 Study design. ***C*** 4.6 Personnel training in sample collection and analysis. ***C*** 4.7 Study implementation and data collection. C 4.8 Data analysis and resort. ***C*** 5. Study of fluoride supplements and toothpaste 5.1. Study design and methodology. ***C*** 5.2. Personnel trained and calibration of examiners. ***C*** 5.3 Survey implementation and data collection. ***C*** 5.4.Data analysis and report C 6. Salt Industry technology development 6.1. Workshop conducted ***C*** 6.2. Salt industry personnel trained ***C*** 7. Study of fluoride excretion in urine 7.1. Procurement and elements and supplies ***C*** 7.2. Survey design ***IP*** 8. Surveillance systems ***8.1*** Task force meeting to review current recommendations on fluoride concentration in salt ***C***
Paraguay	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies.	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. *2.* Cost-benefit study. ***C*** 3. DMFT and dental fluorosis survey: 3.9 Survey design and methodology. ***C*** 3.10 Personnel training and calibration. ***C*** 3.11 Survey implementation and data collection. C 3.12 Data analysis and report. C 4. Study of fluoride concentration and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. C 4.4 Data analysis and resort. ***C***

COUNTRY	EXPECTED RESULTS	INDICATORS	ACTIVITIES
Panama	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies. 5. Survey of fluoride supplements and toothpaste 6. Salt Industry Technology Development in progress 7. Assessment of Fluoride Excretion in urine 8. Country surveillance systems for fluorides	1. Initial situation analysis: status of salt industry, oral health, oral health care services and costs. 2. Cost-benefit study. 3. DMFT and dental fluorosis survey: 3.1 Survey design and methodology. ***C*** 3.2 Personnel training and calibration. ***C*** 3.3 Survey implementation and data collection. ***C*** 3.4 Data analysis and report. ***C*** Study of fluoride concentration and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. ***C*** 4.4 Data analysis and resort. ***C*** Study of fluoride supplements and toothpaste 5.1. Study design and methodology ***C*** 5.2. Personnel trained and calibration of examiners. ***C*** 5.3 Survey implementation and data collection. ***C*** 5.4.Data analysis and report C Salt Industry technology development 6.1. Workshop conducted ***C*** 6.2. Salt industry personnel trained ***C*** Study of fluoride excretion in urine 7.1. Procurement and elements and supplies ***C*** 7.2. Survey design C Surveillance systems ***8.1*** Task force meeting to review current recommendations on fluoride concentration in salt ***C***

COUNTRY	EXPECTED RESULTS	INDICATORS	ACTIVITIES
Venezuela	– Selection of National Salt Fluoridation Committee. – Coordination with this Committee in the initial implementation of the project. – Initiate implementation of project with baseline studies.	1. Situation analysis. 2. Cost-benefit study for salt fluoridation program. 3. National survey of DMFT and dental fluorosis in school children. 4. National study of fluoride concentration in water supplies. 5. Survey of fluoride supplements and toothpaste 6. Salt Industry Technology Development in progress 7. Assessment of Fluoride Excretion in urine 8. Country surveillance systems for fluorides	Initial situation analysis: status of salt industry, oral health, oral health care services and costs. Cost-benefit study. ***C*** DMFT and dental fluorosis survey: 3.1 Survey design and methodology. ***C*** 3.2 Personnel training and calibration. ***C*** 3.3 Survey implementation and data collection. ***C*** 3.4 Data analysis and report. ***C*** Study of fluoride concentration and report. 4.1 Study design. ***C*** 4.2 Personnel training in sample collection and analysis. ***C*** 4.3 Study implementation and data collection. ***C*** 4.4 Data analysis and resort. ***C*** Study of fluoride supplements and toothpaste 5.1. Study design and methodology. ***C*** 5.2. Personnel trained and calibration of examiners. ***C*** 5.3 Survey implementation and data collection ***C*** 5.4.Data analysis and report. ***C*** Salt Industry technology development 6.1. Workshop conducted. ***C*** 6.2. Salt industry personnel trained. ***C*** Study of fluoride excretion in urine 7.1. Procurement and elements and supplies. ***C*** 7.2. Survey design. ***C*** Surveillance systems **8.1** Task force meeting to review current recommendations on fluoride concentration in salt. ***C***

ANNEX 2

PROTOCOL SUMMARY FOR INSTITUTIONAL ANALYSIS AND COST-BENEFIT STUDY OF SALT FLUORIDATION PROGRAMS

AIMS

These studies provide information on the feasibility of developing a salt fluoridation program in a country, and estimate program costs as well as the anticipated benefits. The program also aims to establish a cost-benefit ratio.

METHODS

The information to be collected for these studies focus on four main categories:

1. Dental caries prevalence, incidence and severity, and prevalence of dental fluorosis.

2. Scope of dental public health programs and feasibility of controlling disease with existing resources.

3. General information on the local salt industry, quantity of salts imported and countries of origin. Salt distribution network.

4. Existence of iodination programs. Nutrition information, especially as it relates to consumption and ingestion of salt by the population. Institutions that might cooperate on developing a salt fluoridation program. Existence of a legal framework that would permit inclusion or would facilitate development of specific standards for regulating quality and requirements for fluoride content of salt for human consumption.

Estimated costs of operating a salt fluoridation program may include cost of equipment acquisition, additional personnel that might be needed by the processing plants, cost of baseline studies, monitoring and quality control. Costs are influenced by scope of program particularly as it relates to the number and technological status of the processing plants that would participate in the program and fluoridation techniques to be used.

Benefits are estimated on the anticipated number of dental caries that would be prevented. Calculations are based on existing data, or estimates on dental caries incidence, anticipated program scope, population coverage, etc. A monetary value is assigned to the cost of treatment that would not need to be performed as result of the salt fluoridation program. Savings are calculated based on cost of dental curative services at the public health clinics as well as in the private sector. Net savings are estimated for a period of five years plus one year considered essential for program initiation. Calculations include discounted savings based on depreciation of currency at an internationally accepted rate. For practical purposes, the US dollar is currently being used for this purpose.

ANNEX 3

STANDARIZATION FOR RESEARCH PROTOCOL
Fluoride Concentration in Drinking Water

Important information for the collection of water and general instructions; and information pertaining to the specific meter and electrode for determination of fluoride.

1. WATER SAMPLES

Some of these data are related to identification and location of the water sources and are required for obvious reasons.

1.1 ***Sequential number.*** This information is of vital importance for follow up or in case on need for verification of the sample. The sequence number can be assigned according to the geographical zone taking into account the different physiographic zones of the country.

1.2 ***Source name.*** Equally indispensable for identifying the origin of the water sample, to be able to do later tracking and/or collect water in case of discrepancies.

1.3 ***Location.*** In order to easily locate the origin of the water source, it is important to obtain the name of the district, city, and community.

1.4 ***Zone.*** If it is urban, peri-urban or rural.

1.5 ***Coverage.*** Important to determine the approximate number of inhabitants that benefit from this source. Some sources supply water to various communities.

1.6 ***Soil.*** The type of soil where the source is located can influence the amount of fluoride in the water. Please identify if the soil is rocky, has clay, is sandy, volcanic, etc.

1.7 ***Altitude above sea level.*** It is necessary to register the height because the individual metabolism (retention and excretion of fluoride) varies depending of the altitude above sea level of the area where the person lives.

1.8 ***Reservoir systems.*** The material used in the reservoir system could influence the concentration of fluoride. The material of the collection tanks has to be taken into account whether they are made of concrete, clay, aluminum, and fiberglass or clay fiber. Equally important is to find out the type of viaduct (piping) used to transport the water, if it was soil, clay, cooper, galvanized steel, etc. since fluoride could complex with several of these elements. This is a reason to collect water samples at the source and on the people's place of residence.

1.9 ***Temperature.*** The environmental temperature is important because the range recommended for optimal concentration of fluoride in a given population may vary

according to the ambient temperature. People drink larger quantities of water in hot climates.

1.10 ***Type of sources.*** There may be several types of sources for a same community. It is also possible to find various types of concentrations. So it is very important to specify the type of source, if it is a river, lake, creek, well, spring etc.

1.11 ***Date.*** It is very important to register for identification purposes of the baseline study. The concentration of fluoride in water may vary according to the weather, if it is the rainy or dry season.

1.12 ***Name of responsible party.*** This is the person responsible of collecting the samples and in getting correctly filled all the indispensable data.

2. TECHNIQUE FOR RECOLLECTION OF SAMPLES

2.1 Plastic bottles of 125 ml. or plastic cylinders of 50 ml.

2.2 Wash the recipient 3 or 4 times with the same water that is to be collected.

2.3 Leave the water running up to the edge of the recipient.

2.4 After the sample is taken, close the bottle tightly.

2.5 Immediately, identify the bottle with a pre-made label. This label should have the necessary information that enables one to know its origin, number, and name of source, geographical origin, date, and name of responsible party.

2.6 The samples will be safe in an adequate container for transportation to the analysis site.

ANNEX 4

STANDARDIZATION FOR RESEARCH PROTOCOL FOR SURVEY ON DENTAL CARIES AND DENTAL FLUOROSIS

EXAMINATION PROCEDURES AND CODING FOR VISUAL-TACTILE ORAL HEALTH SURVEYS

Modified version of WHO Oral Health Surveys Basic Methods For use in Epidemiological Evaluations Sponsored

INTRODUCTION

The diagnosis of populations using epidemiologic methods parallels closely those methods used in any clinical setting. However, besides the size of the population examined they differ in important ways.

The clinician follows diagnostic criteria and procedures intended to determine the oral health needs of the **patient**. With that in mind, the practitioner compiles an entire inventory of signs and symptoms. Furthermore, he/she use radiographs and other auxiliary diagnostic tools to supplement the information obtained by direct observation.

In contrast, an oral epidemiologist is concerned with descriptors of oral conditions in the **population**. The idea is to obtain an objective and reliable quantification of the degree of presence of the condition in the population and its changes over time. For that purpose, oral epidemiology studies --such as open-mouth surveys-- require the examination of a large number of subjects and, usually, several examiners. Consequently, the diagnostic criteria and methods used need to emphasize the reproducibility of results rather than the meticulous detection of the earliest sign of disease. In general, to maximize reproducibility epidemiologic methods use conservative diagnostic criteria, relying mainly on unambiguous visual evidence of pathology, rather than on the more sensitive clinical or radiographic diagnostic aids used in clinical practice. The process by which these criteria and methods are internalized by examiners and their recorders is called standardization and quantifying the level of standardization is called calibration.

Why standardization and calibration of examiners and recorders is so important in epidemiologic studies?

Two important issues arise when data are collected: how **valid** and how **reliable** are these data. Bias is the main threat against the **validity** of the data. We all carry our own biases; they affect our capacity of being objective even after professional training. In order to diminish bias, we need to establish strict diagnostic criteria for each condition we intend to examine (standardization); we need to review these criteria, and make their application conscious at the time of examination.

However, having a strict standard criteria is not the only requirement to obtain high quality data. We know that physical and psychological factors such as fatigue, fluctuations in interest, difficulty in making decisions, and variations in visual acuity and tactile sense, affect the judgement of examiners from time to time and to different degrees. Obviously, we need to make efforts to reduce these factors

and to implement, during examination, a system to check how **reliable** the examiners and recorders are in the application of the diagnostic criteria. In other words, we need to have a good (**valid**) criteria and check if we use it correctly (**reliable**). We approach the issue of reliability in two dimensions: between examiners (inter-examiner reliability) and within each examiner (intra-examiner reliability).

The standardization/calibration process has two phases. First, we need that you study and memorize the diagnostic criteria and procedures described in this document. Second, we need to expose you to a calibration exercise in which you will be asked to apply the criteria and methods in a setting similar to the one you will find during field data collection. After the exercise we will assured that all examiners and recorders apply diagnostic criteria and coding correctly and consistently.

Summarizing the objectives of calibration for epidemiologic studies are [1]:

1. To ensure uniform interpretation, understanding, and application of the criteria for the various diseases and conditions to be observed and recorded.
2. To ensure that each examiner can examine to a "uniform" standard, and
3. To minimize variations within and between examiners.

This document is divided into two main sections. In the first section I provide a general explanation of the procedures immediately before the oral examinations. The second section provides the coding for the different conditions to be included in this survey. Each coding scheme is followed with nots and special considerations printed in *italics*. These notes are very important and I expect that you will come to a good understanding of when and why these are applicable before the calibration exercise.

I have included a copy of the latest version of the data entry form for your review and familiarization.

GENERAL INSTRUCTIONS AND PROCEDURE FOR EXAMINATION

As an examiner you will receive a list of schools you will visit and a procedure guide to select children from the school. It is very important that you follow these instructions as the validity of the survey will depend on your ability to select by random children from every school selected.

Also, you will receive equipment and materials. The equipment should be assembled appropriately in a room within the school premises. This room should have some requirements, mainly access to power outlets, appropriate ventilation/cooling, a waiting area with chairs, proximity to a water faucet for washing hands and instruments and access to a garbage bin to dispose used material. You will receive an infection control protocol you must adhere to during the entire process.

The day of the examination you will arrive to the school and contact the principal, who has been notified ahead of time on the day and time of your visit. You will coordinate the classrooms selected and the most appropriate order to avoid conflict with classroom and outdoors activities. You will select a person from the school staff who will coordinate the movement of children from the classroom to the

[1] Moller IJ, Eklund SA. Calibration of Examiners for the International Collaborative Study of Oral Health (ICS II). World Health Organization (limited distribution). 1991.

examination area. If your survey include a consent form, each children should bring them to the examination area.

You will have one or more chairs do carry out the examination. Each chair should have a person who will write down your diagnosis (codes) during examination. This person will be identified as the "recorder." These codes will be written in a paper form (see appendix 1) or in a computer data entry file. Before the child is seat in the chair or examination table, the recorder will collect the consent form and transfer the information (id number, sex, birth date, age) to the data entry form or data entry program. (Appendix 2 explains the codes and procedures to assign an ID number to each person). Once gloved and before starting the examination you will ask for a final agreement in conducting the exam with the child. At this time, you are ready to collect data on the following conditions:

- Dental Fluorosis: children 12, 15, and adults 35-44
- Coronal Caries/sealants & Treatment needs: children 5, 12, 15, and adults 35-44
- Prosthetic status: adults 35-44
- Prosthetic needs: adults 35-44
- Urgency of treatment: all

Once you have collected all the information, the recorder will transfer the value you have assigned in the variable "urgency of treatment" (the last one in the examination process) to a form containing the name of the person examined. This form will be return to the teacher for distribution or will be handed to the child or adult.

Each examination will take less than five minutes and will require from you a systematic visual/tactile observation and diagnosis of the teeth/surfaces selected. Once you have reached a diagnosis for each tooth/surface you will provide that information to the recorder. Ideally, you do not need to identify the tooth you are providing the code because the examination is carried out sequentially and all boxes in the form or data entry program should be filled out accordingly. However, for matters of consistency we will identify each tooth following the FDI codes:

Upper right quadrant

left quadrant

17	16	15 55 5	14 54	13 53	12 52	11 51	21 61	22 62	23 63	24 64	25 65	26	27
47	46	45 85 5	44 84	43 83	42 82	41 81	31 71	32 72	33 73	34 74	35 75	36	37

Lower right quadrant

Lower left quadrant

For assessing dental fluorosis you will start always on tooth 13 (upper right cuspid), follow towards the midline, and continue to tooth 23 (upper left cuspid). A total of six codes will be provided to the recorder.

For assessing dental caries/sealants and treatment needs you will start with tooth 17 (upper right 2d permanent molar) and continue toward the midline and then end the maxillary jaw with tooth 27 (upper left 2d permanent molar). Then you will continue with tooth 37 (lower left 2d permanent molar) and followed the inverse direction toward tooth 47.

You will provide first the code for each surface caries status, meaning five numbers for molars and premolars and four numbers for incisors and cuspids (no occlusal surface). In providing the surface code for each tooth you always will follow the same order, which is:

MESIAL, OCCLUSAL, DISTAL, BUCCAL, LINGUAL

Once you have finished with the surface data you will provide ONE additional call that will correspond to the treatment need for that entire tooth.

For assessing prosthetic status and needs you will assess the entire mouth following the same pattern as in the assessment of caries and provide two codes, one for status and one for needs. These codes are applicable to the entire person.

Finally, based on your previous observations, you will provide a code to indicate to the child's parents or to the adult been examined about the urgency of need for treatment.

Important Notes:

1. In this survey we will use the FDI codes that correspond to the permanent teeth. The same spaces (boxes) will be used for the primary dentition. Differentiation between a primary and a permanent tooth will be done based on the code used (mostly numbers for permanent teeth, and mostly letters for primary teeth).

2. Third molars are exclude from examination

3. It is important that examination and recording follow the same path in all subjects. Do not skip teeth or surfaces.

4. When providing the codes the recorder should know that the examiner will provide "6" codes for the molars and "5" for anterior teeth (including treatment). Since this is done sequentially, it will be a good idea if the examiner says a key word after he/she have reached the final code for tooth 11, 27, and 31 (e.g., "check" or "midline") so the recorder will check for his/her synchronization. If there is no congruency in the sequence, the examiner should restart in the first tooth of the quadrant.

5. The examiner will provide a total of 169 calls for each individual, regardless of his/her age. These correspond to the 169 available cells in the clinical section of the data entry form.

6. All spaces in the data entry form should be filled before the person leaves the examination area. There are special codes for each variables when the person, because of his/her age, does not qualify for a specific examination.

Your Notes Here:

Coding for Dental Fluorosis
(Tooth-based coding for upper anterior teeth –cuspid to cuspid)

Code	Criteria
0	***No Fluorosis:*** The enamel surface is smooth, glossy and usually a pale creamy-white color.
5	***Questionable:*** The enamel shows slight aberrations from the translucency of normal enamel, which may range from a few white flecks to occasional spots localized most of the time, but not always, on the incisal third of the surface.
1	***Very Mild:*** Opaque, paper-white areas or pencil-mark-thick lines scattered irregularly over the tooth but involving less than 25% of the surface. Many times the hypocalcifications follow the perikimata lines.
2	***Mild.*** The white opacities of the enamel extends to more than 25% but less than 50% of the surface.
3	***Moderate:*** The amount of enamel affected extends to more than 50% of the surface. Sometimes the hypocalcified enamel captures particles and chromogenic bacteria from the environment and saliva changing the color from white to brown.
4	***Severe:*** This code is applicable to any of the previous classifications AND the presence of distinctive unique or confluent pits. Pits correspond to enamel that is lost after eruption. Single pits are diagnosed with an explorer and should have delimitated walls in most of its circumference The bottom of the pit can have normal enamel or fluorotic enamel with or without brown coloration. Brown coloration is not sufficient criteria to code severe.
8	***Not recorded:*** This code is applicable to any partially erupted tooth or any tooth cover with a crown or orthodontic band/bracket.
9	***Excluded.*** Applicable to any primary tooth.

Special diagnostic and clinical situations during examination for dental fluorosis:

Only fully-erupted teeth are scored, using a good source of artificial light. The teeth should NOT be dried before scoring.

A tooth is not evaluated for fluorosis if one-third or more of the visible enamel area is replaced with a restoration or is destroyed by caries or covered with an orthodontic band.

Staining per se in an otherwise intact enamel is not a diagnostic criterion specific to any of the classifications.

Fluorosed teeth do not erupt with pits. Instead, pitting occurs posteruptively when the teeth is subject to masticatory forces. A pit is defined as a discrete, focal loss of outermost enamel. The defect is partly or wholly surrounded by a wall of enamel. Initially, the enamel wall is usually intact. With wear, however, the enamel wall can be abraded away, so that often only part of the enamel can be detected. In contrast to intact enamel on which the explorer tip can be moved easily across the smooth surface, pitted areas demonstrate a definite physical defect in which the base of the defective area may be either carious or sound. If it is sound, the base of the pit is rough and offers resistance to the lateral movement of the explorer tip, and a scratchy sound is detected when the explorer is moved across it. If the base is carious,

it demonstrates softness upon being probed with moderate pressure. The pitted area is usually stained or demonstrates a different color compared with the surrounding enamel.

Coding for Dental Caries (Surface-based coding)

Code for Primary Teeth	Code for Permanent Teeth	Diagnostic Criteria
A		***Sound.*** A sound surface is a surface without any signs of cavitation due to decay, *sequelae* (restorations), or a sealant. If the surface has lost part of its structure due to fracture/trauma it is considered sound. Pit and fissures represent a special situation. Any surface with less than 25% of its entire pit and fissures with coloration will be considered sound, otherwise will be considered as a non-cavitated lesion (see codes L & U)
N	U	***Non cavitated lesion.*** This code is reserved only for surfaces with pit and fissures with more than 25% of the pit showing coloration (brown to black) without clinical signs of decay, i.e., decalcificacion or undermining of surrounding enamel OR demineralized dentin at the bottom of the fossae/fissure.
B	1	***Decayed.*** Three types of lesions can be coded as decayed: 1) Pit and fissure caries lesions: this is defined as the presence of a cavitation OR decalcification or undermining of the surrounding enamel (change of color to dark) or soft dentine at the bottom of the pit or fissure. The explorer should be used ONLY to confirm the presence of soft dentine and ONLY when the naked eye cannot reach a diagnosis. 2) free-surface caries lesions: lesion on any other surface that does not have pit or fissures. (These surfaces include the entire mesial and distal surfaces and the buccal surfaces of anterior teeth –the lingual surfaces of upper anterior teeth and sometimes the lower anterior teeth have pits–). In the buccal surfaces (non-proximal) the diagnosis is reached when there is clear evidence of cavitation. In the anterior proximal surfaces the diagnosis can be reached using the mirror to trans illuminate the proximal area. In the posterior proximal surfaces the examiner need to detect the presence of the cavity with the explorer (changes in color in the marginal reach are not enough the diagnose proximal decay). 3) Secondary caries next to a previous restoration. Diagnosis is reached if you can detect with the explorer the presence of soft dentine. A gap between the restoration and the tooth is not enough criteria to diagnose caries. Any temporary restoration is considered as decayed.
C	2	***Filled.*** A filled surface include any surface restored partially or completely with a restorative material ***as a direct consequence of decay.*** Restorative materials include silver amalgam, crowns (stainless steel or cast), inlays, composite resins, silicates, glass ionomers.
D	3	***Missing due to caries.*** This code applies to any surface from any tooth that has been extracted as a direct consequence of caries. In the primary teeth the code D will be applied to ALL empty spaces in the primary molar area up to age 8 (8 and 11 months). If the child is 9 or older these spaces are coded as unerupted permanent (code 9). Any empty space in the primary anterior area at any age will be coded also as unerupted permanent (code 9). In older cohorts it will be difficult to assess if the tooth has been extracted due to caries, due to periodontal diseases, or because the dental professional decided to extract the tooth for prosthetic reasons. In all these cases the code assigned should be "3".

Code for Primary Teeth	Code for Permanent Teeth	Diagnostic Criteria
E	4	***Missing for other reasons.*** This code applies to any surface from any tooth that has been lost due to reasons not related to caries, i.e., trauma or orthodontic reasons.
F	6	***Sealant Present:*** total or partial sealant present ONLY in occlusal surfaces of permanent or primary teeth. Included here are sealants on parts of the occlusal surface that have been slightly enlarged using a round bur to eliminate suspicious carious tissue. Sealants on fissures from buccal or lingual surfaces of molars or incisors are NOT included. A restoration with a composite resin which required a full preparation is NOT considered a sealant.
H	7	***Bridge abutment.*** We have restricted these code to be applicable only to any tooth prepared as an abutment in both anterior or posterior teeth.
	8	***Implant.*** We have restricted these code to be applicable only to the presence of crowns associated with an implant.
	9	***Unerupted tooth.*** Applicable only to spaces in the arch with absence of primary teeth due to normal shedding AND before any clinical signs of the erupted permanent can be distinguished.
K	T	***Trauma.*** This code is applied to untreated fractures, change in color in the entire crown, restoration involving the incisal edge, and anterior crowns due to trauma.
L	X	***Excluded.*** This code is applicable to all surfaces in very specific situations, including anterior crowns due to cometic reasons. Included teeth that cannot be assessed completely because they are partially cover with orthodontic bands or brackets.

Special Clinical Situations:

Incisal edges of anterior teeth are not considered separate surfaces. If a lesion or restoration is confined solely to the incisal edge its score should be assigned to the nearest adjacent surface.

When a filling or a lesion on a posterior tooth, or a caries lesion on an anterior tooth extends beyond the line angle onto another surface, then the other surface is also scored as affected. However, a proximal filling on an anterior tooth is not considered to involve the adjacent labial or lingual surface unless it extends at least one-third into these surfaces. The reason for this criterion is that tooth structure on adjacent surfaces must often be removed to provide access for the restoration of a proximal lesion on anterior teeth.

In this survey there is no independent code for crowns in either dentition. Therefore, if a posterior tooth has a full crown restoration placed because of caries you should provide code for three surfaces filled due to caries [code 2]. These surfaces are: mesial, occlusal, and distal. If a anterior tooth as a full crown restoration placed because of caries you should provide codes for two surfaces filled: mesial and distal. By convention, all crowns on posterior teeth, excluding abutment teeth for fixed or removable prostheses, are considered to have been placed as a result of caries. On anterior teeth, however, the examiner should make the determination of the reason for crown placement. If the crown was placed for any reason other than caries, such as fracture, malformation, or esthetics, the tooth is coded [X] excluded.

If a tooth has been restored with less than full coverage, all surfaces not involved should be scored in the usual manner.

Some teeth, typically the first bicuspids, are extracted due to orthodontic reasons. You should label these as "missing due to other reasons" [Code 4]. The best hint to identify these patients is to check the status of the contralateral bicuspid and look for evidence of orthodontic treatment. You should be aware that other teeth may also be extracted for orthodontic reasons. In most cases, former or current orthodontic patients recall having extractions if so.

Non-vital teeth are scored in the same manner as vital teeth. Therefore, restorations on the lingual surfaces of anterior teeth used as entry for root canal therapy should not be recorded as restorations. This surface should be coded sound.

Hypoplastic teeth are scored in the usual manner. However, if a restoration on such a tooth was placed solely for esthetic reasons, that restoration will not be scored. If a hypoplastic tooth is restored with a full crown, the tooth is coded "excluded" [X].

Malformed teeth are scored in the usual manner except when they have been restored with a full crown for esthetic reasons, in which they are coded "excluded" [X].

When the tooth crown is destroyed by caries and only the roots remain, score all surfaces as carious.

Fractured or missing restorations are scored as if the restorations were intact unless there is caries. If caries is found within or adjacent to the margins of a fractured or missing restorations, caries should be scored only in the surfaces involved.

In the case of supernumerary teeth, only one tooth is called for the tooth space. The examiner must decide which tooth is the "main" occupant of the space.

If both a primary and a permanent tooth occupy the same tooth space, only the permanent tooth is scored. There is a hierarchy in the coding when more than one code is possible. Sound surfaces/teeth are at the bottom. Sealed surfaces/teeth have precedence over sound surfaces/teeth. Restored surfaces/teeth have precedence over sealed surfaces/teeth. And, finally, untreated caries surfaces/teeth have precedence over restorations (See figure 1).

In general, when the same tooth surface is both carious and filled (e.g., upper permanent molar with mesial pit filled and distal pit with caries), caries is coded. When examining a filling for recurrent.

Third molars are not scored. When examining second molars it is important to note that a drifted molar may occupy the space of a missing second molar. In such cases, the diagnosis and call must relate to the status of the missing second molar, not the third molar. If the second molar, for example, was extracted due to caries and the space is now occupied by a sound third molar, the second molar is scored as "missing due to caries" [3] and the third molar is not scored.

A tooth is considered erupted if any of its clinical crown projects through the gum.

Stain and pigmentation alone should not be regarded as evidence of decay since either can occur on sound teeth.

A surface is coded as "sealed" if ANY part of the surface remains covered with the sealant. In most clinical situations, the sealant covers the pit and fissure of the surface. Remember that sealant products varied widely in color and you may need the tactile confirmation of the sealant present.

If you are sure that a composite material has been used as restoration (i.e., it required a preparation using a rotatory instrument) in all or part of the fissure then you should score the surface as filled. In case of doubt and there is composite material present code the surface/tooth as sealed.

A very important note in the coding of caries prevalence ONLY when paper forms are used:

In this survey will be collecting surface data for caries. However, certain codes are applicable to all surfaces. In such cases, the examiner can save time if the code is followed by the word "ALL." The recorder will know that the preceding code is applicable to all surfaces and will write the code for the mesial surface and a horizontal line across the reminding surfaces. Then, The following number will correspond to the code for treatment need to that tooth. *The codes for which this shortcut applies are:*

Coding for Need for Treatment (tooth-based coding)

Code	Criteria
0	***No need for treatment:*** The crown is sound or have a restoration in good stand (no secondary caries).
F	***Fissure Sealant:*** A permanent molar will be eligible for sealant if the following three conditions are present: (1) tooth is within 3 years of eruption; (2) there is a obvious "catch" during examination; and (3) there is at least one additional restoration in any other pit and fissure in the mouth. A primary molar will be eligible for sealants if conditions (2) and (3) are present.
1	The tooth needs one surface restoration
2	The tooth needs a two or three surface restorations OR multiple restorations in combinations of one, two or three surfaces.
3	The tooth needs a crown for any reason.
4	Veneer or laminate for aesthetic reasons (anterior teeth)
5	Pulpar care and post-treatment. The tooth probably needs pulpar care and later a restoration with a filling or a crown. Pulpar care could be need as a consequence of caries or trauma. Pulpar care include treatments in both primary (e.g., pulpotomy, pulpectomy) and permanent teeth.
6	***Extraction.*** A tooth is "indicated for extraction" because caries has destroyed most of the crown, periodontal disease has progressed to a tooth that is highly movable and nonfunctional. We are not including here teeth that need to be extracted due to prosthetic or orthodontic reasons.
7	Reserved code
8	Reserved code
9	Not recorded (excluded). This code should be marked with a code '9' (unerupted tooth) is assigned to the tooth in the diagnosis of caries.

Sound [A, 1], missing (both due to caries and for other reason) [D,E,3 and 4], bridge abutment [7], implant [8], unerupted tooth [9], and excluded [X].

For example for a sound permanent molar which may benefit from sealants, the examiner will say: 1-ALL-F where 1 is the diagnostic code for sound, ALL indicates that the code is applicable to all surfaces, and F indicates that a pit and fissure sealant is indicated for the occlusal surface.

Special Note on Treatment Needed:

A tooth will need a sealant or restoration of any kind (fillings, crowns, etc) for the treatment of primary and secondary caries, restorations lost (i.e., fractured restorations), for the treatment of anomalies in shape and color of the tooth (e.g., when severe fluorosis is present), trauma, and to replace unsatisfactory fillings or sealants. However, the examiner need to be realistic and avoid "ideal" treatment plans. The need for prosthesis will be evaluated separately and ONLY in the cohort of adults (35-44 years). The examiner should use their own criteria and clinical standards to assess the level and complexity of the treatment. However, in general terms, treatment for esthetic reasons should be avoided (the exception will be severe tooth malformation), as well as implants and crowns/veneers over teeth with change in color due to trauma. You will notice that orthodontic treatment is not indicated as well including space maintainer of any removable/fixed appliance.

Coding for Prosthetic Status
(Person-based coding for the 35-44 cohort)

Code	Criteria
0	No prosthesis present
1	One fixed bridge
2	More than one fixed bridge
3	Removable partial denture
4	Both bridge(s) and partial denture(s)
5	Full removable denture
9	Excluded (children)

Coding for Prosthetic Need
(Person-based coding for the 35-44 cohort)

Code	Criteria
0	No prosthesis needed
1	Need prosthesis for one tooth replacement
2	Need for multi-unit prosthesis (fixed or removable)
3	Need for full denture
9	Excluded (children)

Coding for Urgency of Treatment

Code	Criteria
0	No need for current treatment
1	Prophylaxes: Need for tooth cleaning and scaling.
2	Low urgency: Need for restorations and crowns but none of them require attention after a short time (restricted to the most superficial dentine). Include any person in need of prosthesis or crowns.
3	Advanced urgency: Need for restorations and crowns that are deep enough to need assistance after a short time (within 7-14 days) to avoid pulpar involvement or infection. Include any child that will require 5 or more teeth in need of restorations.
4	High urgency: requires urgent care due to pain or infection. Include here any person in need of pulpar treatment or extraction.

Appendix 1: Data Entry Form
Bahamas Oral Health Survey of School Children

Duplicate	Update	Date	Examiner	Recorder
Strata		School	Grade	ID
Gender	Race	Date birth		Age

Fluorosis	13:	12:	11:	21:	22;

	Mesial	Occlusal	Distal	Buccal	LingualBuccal	Treatment
UR17						
UR16						
UR15						
UR14						
UR13						
UR12						
UR11						
UL21						
UL22						
UL23						
UL24						
UL25						
UL26						
UL27						
LL37						
LL36						
LL35						
LL34						
LL33						
LL32						
LL31						
LR41						
LR42						
LR43						
LR44						
LL45						
LR46						
LR47						

Prosthetic status	Prosthetic need	Txurgency

ITEMS TO BE INCLUDED IN REPORTS OF EPIDEMIOLOGICAL SURVEILLANCE ACTIVITIES

Introduction

Most epidemiological surveillance activities associated with water- and salt-fluoridation programs include variations of open-mouth visual/tactile surveys. The methodology and steps in these surveys have been described in two documents published by the PAHO Regional Office for Oral Health <INSERT THE NAME OF THE DOCUMENTS HERE>. This document describe the minimum data items to be reported from any survey associated with surveillance activities for water- and salt-fluoridation programs.

1. Sampling

All surveys include some sort of sampling procedure. During this process a sample of the population is selected to be examined. Generalizability and representativeness are two items closely associated with the type and nature of the sample. Therefore, any survey report should include:

a. Type of sampling: probability or non-probability.

b. If probability sampling was used, the report should explain how the final sample was attained, e.g., stratified sampling, cluster sampling, etc. Also, it is important to include if any weighting or sampling design effect were included in the analysis of the data and the computer software (e.g., SUDAAN) used for this purpose, if any.

c. If non-probability sampling was used, e.g., WHO's "pathfinder," the report should explain how the sample was attained and the criteria used to select geographical sites. Also, many pathfinder-type of surveys had included elements of randomness in the selection of sample units after the geographical sites have been selected, e.g., schools, classrooms, students. The report should describe these selection processes.

2. Calibration

Oral health surveys use examiners who apply specific diagnostic criteria and coding for each oral condition been examined. In order to obtain useful information, the diagnostic criteria and the coding need to be applied accurately and consistently across all examinees. Examiners and recorders learn these criteria during the calibration exercises. Usually, these activities take place immediately before data collection. Calibration of the examiners and recorders includes the discussion of the diagnostic criteria and coding, procedures for examination/recording, and duplicate clinical examinations of patients. Discrepancies in the application of the diagnostic criteria during the clinical examinations are discussed and corrected. In most cases, examiners are considered "calibrated" when they obtain Kappa indicators greater than 0.60 (see below).

Oral health survey reports should include a description of the calibration activities. Among the items to be included are:

a. How the calibration process was carried out
b. How many examiners and recorders were included.
c. The coding for each of the oral conditions been examined.
d. The overall (all examiners) *percent agreement* and *kappa* for intra- and inter-examiner reliability (see *"Reliability,"* below)

3. Reliability

All examiners should demonstrate that have applied the diagnostic criteria accurately and consistently. Reliability has two dimensions, how reliable the examiners are *within* themselves, i.e., intra-examiner reliability, and how reliable the examiners are *between* each other, i.e., inter-examiner reliability. The best technique to measure reliability is to perform duplicate examinations. Duplicate examinations by the same examiner can be used to measure how reliable is that particular examiner (intra-examiner). Duplicate examinations by any two examiners can be used to measure how reliable are between each other (inter-examiner). Two indices of reliability have been used extensively in oral health surveys, i.e., Cohen's *kappa* ( ) and *percent agreement* (PA). (See Appendix A for formulae and an annotated example).

Oral health survey reports should include the following information regarding reliability:

a. Inter- and intra-examiner reliability using both *kappa* **AND** *percent agreement*, for all variables.
b. Inter- and intra-examiner reliability should be calculated for all possible examiners. However, when reporting reliability all duplicate examinations across all examiners should be pooled and an overall measure of inter- and intra-examiner reliability should be reported. See Appendix B for an example.
c. Some surveys do not schedule duplicate examinations during data collection, in that case inter- and intra-examiner reliability should be measured during calibration.
d. The report should acknowledge and explain why duplicate examinations were not scheduled during calibration and/or data collection, if so.

4. Data

Oral health survey reports should include tables in the following areas:

A. Demographics

1. Distribution (number, percent in sample, and percent in the population,) by sex, race, age, and geographical site/unit (according to sampling). To avoid crowding, these should be self-standing and independent tables. Furthermore, all tables should include totals at the bottom of the table. An example of a table for race is included in Appendix C.

B. Disease Prevalence

2. *Caries Prevalence/Severity:*

   a. Age-specific proportion of persons with untreated decay and caries-free

Percent of caries-free persons in permanent and both dentitions
Percent of persons with untreated decay in permanent and both dentitions

An example is included in Appendix D.

b. Age-specific means and standard deviations (standard errors for probability sample surveys) for the following selected indicators of caries prevalence:

df-T (number of decayed and filled teeth in the primary dentition)
DMF-T (number of decayed, missing, and filled teeth in the permanent dentition)
df-t + DMF-T (Total caries experience in both dentitions)
d-T + D-T (Untreated decay in both dentitions)

If the survey had collected surface-wise information, a second table with the corresponding indicators should be included.

An example is included in Appendix E.

c. Age-specific contribution of each component to DMF-T among those with DMF-T >0

Percent D/DMF-T (Percent of decayed teeth within DMF-T)
Percent M/DMF-T (Percent of missing teeth within DMF-T)
Percent F/DMF-T (Percent of filled teeth within DMF-T)

An example is included in Appendix F.

d. Degree of caries experience in the permanent dentition

Degree of caries experience is obtained by classifying the entire sample into four categories according to the individual DMF-T:

1) DMF-T = 0
2) DMF-T between 1 and 3.0 included
3) DMF-T between 3.1 and 6.0 included
4) DMF-T greater than 6.0

An example is included in Appendix G

Tables in (a), (b), (c), and (d), summarize the data on caries prevalence for the entire sample. In addition, these tables should be re-calculated after stratification by:

- Geographical site
- Sex
- Race
- Sex & Race, if appropriate
- Sex within each geographical site, if appropriate
- Race within each geographical site, if appropriate
- Sex & Race within each geographical site, if appropriate

3. *Other Oral Conditions*

Age-specific tables should be generated for other conditions included in the survey. For example, if the survey had obtained data for presence of fluorosis or sealants, these variables need to be described for each age group and then after stratification by geographical site, sex, and race, if appropriate. It should be stressed that for conditions reported as a dichotomy (yes/no), the sample percentage for either "yes" or "no" category should be included in the table. If the condition is been reported as categorical with more than two levels (polychotomy), e.g., Dean's index of dental fluorosis, then the table should include the number and the percent for each category. Finally, if the condition is measured as a continuous variable, e.g., caries prevalence indices, then the table should include means and standard deviations (standard errors, in case of probability estimates)

Annex H include examples for a dichotomy and a polychotomy variable.

5. Formatting Requirements

The following guidelines are applicable to all tables:

a. All tables should be self-standing and self-explanatory. Therefore, the title should include information on four issues: person (population/sample), place, time (year), and statistic(s) included in the table.

b. The labels in the table should be concise but clear.

c. Make titles consistent across all tables.

d. Use periods (.) and not commas (,) to express decimals. Use commas (,) and not periods (.) To express thousands.

e. For statistics like means, standard deviations, and standard errors, round-up the values to two decimal digits. For percentages use only one decimal digit. Integers should not be reported with decimal digits.

f. Do not calculate statistics for cells that have less than 30 persons. For example, in the tables depicted in Appendices D, E, F, and G, statistics were not calculated for the 18-year-old age-group (N=12). Be aware that some age-groups will end-up with less than 30 persons after stratification by sex, race, etc. The exception to the "30-persons" rule are those cases where the overall statistic have been computed based on more than 30 persons, but the number diminish when the statistic is broken-down (not stratified) by its constituent elements. For example, in Table E, the estimate for each level of the degree of caries experience in the permanent dentition among 17-year-old children was included because the overall number of persons was 55.

g. Include totals and subtotals in each table. Be sure that all subtotals add-up to the total.

h. Any unusual element in the table, such as missing data, should be explained using a footnote. Also, use footnote(s) to explain unusual abbreviations (e.g., "m.d." for "missing data;" "n.c." for "not calculated," or characters such as hyphens)

i. Charts and graphs are excellent media to show differences and trends. In oral health survey reports charts and graphs can be included in addition but not in substitution to the tabulated data.

Appendix A

Calculation of Kappa ( ) and Percent Agreement (PA)

The following table will be used to describe the two most widely used measures of agreement for categorical variables used in oral health surveys. The table displays all possible combinations in a set of paired measurements using a three-level variable.

		First Measurement			
		1	2	3	$p_{i.}$
Second Measurement	1	a_{11}	a_{12}	a_{13}	$a_{1.}$
	2	a_{21}	a_{22}	a_{23}	$a_{2.}$
	3	a_{31}	a_{32}	a_{33}	$a_{3.}$
$p_{.i}$		$a_{.1}$	$a_{.2}$	$a_{.3}$	N

The first index, and the simplest one, is intuitively derived. Since all members of the diagonal of the table (a_{ii}) represent agreement between the two measurements, an index of agreement can be derived calculating their proportion over all possible pairs of measurements (N). This index is called *percent agreement* (Po) which is expressed as:

$$Po = \frac{1}{N} \Sigma a_{ii}$$

Unfortunately, some agreement is expected to occur by chance. The percent agreement expected by chance (Pe) is calculated by adding-up the expected values for each cell in the diagonal of the table. Expected values are calculated using the distribution in the margins of the table (p_{ii}). Therefore:

$$Pe = \frac{1}{N} (\Sigma \frac{a_{i.} a_{.i}}{N})$$

Cohen [1960] included these two terms in a proportion that estimates the agreement beyond chance. Cohen called his index kappa ( ) and defined it as the proportion of the observed excess agreement beyond chance to the maximum possible excess agreement beyond chance:

$$\kappa = \frac{Po \ Pe}{1 \ Pe}$$

The value of kappa ranges from $-1 \leq K \leq +1$. If observed agreement is greater than chance agreement, $K > 1$, if observed agreement is less than chance agreement, $K<1$. The asymptotic large sample variance of kappa may be estimated from:

$$s.e.(\kappa) = \frac{1}{(1\ Pe)\ \sqrt{(N)}} \sqrt{Pe + Pe^2 \quad \sum p_{i.}\ p_{.i}\ (p_{.i} + p_{i.})} \quad ^{1/2}$$

where $p_{i.}$ and $p_{.i}$ represent the row and column marginal proportions respectively.

Landis & Koch have provided an arbitrary guide to qualitatively assess the value of kappa:

Kappa	Strength of Agreement
0	Poor
0.01 - 0.20	Slight
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Substantial
0.81 - 1.00	Almost perfect

The following is an example of the calculations of kappa and percent agreement for intra-examiner reliability. The procedures are equally applicable for calculation of inter-examiner reliability.

During a recent oral health survey data were collected for presence of dental injuries in the front teeth. One examiner performed visual evaluation of the four upper and lower anterior teeth and recorded their injury status using the following coding:

0 = No evidence of injury
1 = Clinical evidence of injury (fracture, decoloration, missing due to injury, etc.)
8 = Not applicable: primary tooth
9 = Not applicable: missing due to causes other than injuries

Six hundred and seventy-two (672) children were examined and in 57 children duplicate examinations were performed. The following table describe the distribution of the 57 pairs of examinations:

Injuries		**First examination**				
	Coding	0	1	8	9	Totals
Second examination	0	359			2	361
	1	1	10		1	12
	8			66		66
	9	1			16	17
	Totals	361	10	66	19	456

The table indicates that a total of 456 (57 x 8) comparisons were made across all duplicate examinations.

According to our formula, Percent Agreement (*Po*) will be:

$$Po = \frac{(359 + 10 + 66 + 16)}{456} = \frac{451}{456} = 0.989$$

and chance agreement (*Pe*) can be calculated using the values at the margins of the table ("totals"):

$$Pe = \frac{\frac{(361 \times 361)}{456} + \frac{(10 \times 12)}{456} + \frac{(66 \times 66)}{456} + \frac{(17 \times 19)}{456}}{456} = 0.6498$$

therefore, kappa will be equal to:

$$\kappa = \frac{0.9890.6498}{1\ 0.6498} = 0.969$$

In consequence, Percent Agreement is 98.9% and kappa is 0.97. (Notice that Percent Agreement is always greater than kappa).

Appendix B

Overall Reliability Estimates

Appendix A has described the different steps to calculate intra-examiner reliability using kappa and percent agreement. In the example used in Appendix A, all possible pairwise comparisons were summarized into a contingency table from where kappa and Po were calculated. These final values were the estimates of reliability for the examiner. When the survey uses more than one examiner it is possible to calculate an overall estimate of *intra-examiner* reliability by pooling the data from each examiner into one contingency table. Also, you can obtain rough estimates by averaging the kappa and Po's values for each examiner but, this requires that all examiners had performed proportionally equal number of duplicate examinations.

Obtaining overall estimates of *inter-examiner* reliability follows the same steps. After constructing contingency tables for each combination of examiners, all data is pooled into an overall table adding the cell values from each table.

As an example, assume that the following sets of 2x2 tables display information on the presence of fluorosis (yes/no) in duplicates examinations carried out by three examiners (each pair of examiners performed exams in six children).

		Examiner 1		
		Yes	No	Total
Examiner 2	Yes	1	1	2
	No	0	4	4
	Total	1	5	6

		Examiner 1		
		Yes	No	Total
Examiner 3	Yes	1	0	1
	No	1	4	5
	Total	1	5	6

		Examiner 2		
		Yes	No	Total
Examiner 3	Yes	1	0	1
	No	0	5	5
	Total	1	5	6

Then you can add the values in each cell of each table and summarize the total into an overall contingency table:

		Examiner		
		Yes	No	Total
Examiner	Yes	3	1	4
	No	1	13	14
	Total	4	14	18

From this overall table you can calculate kappa and Po as described in Appendix A.

Appendix C

El Dorado Oral Health Survey of 5-18 Year-Old School Children, 1999
Distribution of Sample by Race and Population Proportions

Race	Number	Percent	Population Proportion
East Indian	2,938	43.6	43.6
African/American	2,369	35.1	35.1
Native American	594	8.8	8.8
Asian/Pacific Islander	5	0.1	0.1
White/Caucasic	8	0.1	0.1
Mixed Race	814	12.1	12.1
Other	12	0.2	0.2
All	6,740	100.0	100.0

Appendix D

El Dorado Oral Health Survey of 5-18 Year-Old School Children, 1999
Age-Specific Proportion of Caries-Free Persons and with Untreated Decay (d-T + D-T) in the Permanent and Both Dentitions

Age	N	Caries-free Permanent		Caries-Free Both		Untreated Decay Permanent		Untreated Decay Both	
		N	%	N	%	N	%	N	%
5	163	156	95.7	73	44.8	7	4.3	90	55.2
6	692	663	95.8	231	33.4	28	4.0	461	66.6
7	825	734	89.0	204	24.7	85	10.3	618	74.9
8	775	644	83.1	174	22.5	127	16.4	601	77.5
9	806	606	75.2	211	26.2	190	23.6	591	73.3
10	770	528	68.6	268	34.8	220	28.6	487	63.2
11	664	386	58.1	287	43.2	247	37.2	354	53.3
12	547	246	45.0	223	40.8	268	49.0	293	53.6
13	470	185	39.4	176	37.4	257	54.7	266	56.6
14	453	172	38.0	170	37.5	240	53.0	242	53.4
15	339	125	36.9	123	36.3	186	54.9	188	55.5
16	169	43	25.4	43	25.4	108	63.9	108	63.9
17	55	13	23.6	13	23.6	34	61.8	34	61.8
18	12	-- *	-- *	-- *	-- *	-- *	-- *	-- *	-- *
Total	6,740	4,505	66.8	2,200	32.6	2,004	29.7	4,340	64.4

* Statistic was not calculated because there were less than 30 cases.

Appendix E

El Dorado Oral Health Survey of 5-18 Year-Old School Children, 1999
Age-Specific Means and Standard Deviations for Selected Indices of Dental Caries Prevalence in Both Dentitions

Age	N	df-T		DMF-T		df-T + DMF-T		d-T + D-T	
		Mean	s.d.	Mean	s.d.	Mean	s.d.	Mean	s.d.
5	163	2.31	3.17	0.06	0.33	2.37	3.24	2.37	3.24
6	692	2.85	3.25	0.060.	0.32	2.91	3.30	2.91	3.30
7	825	3.04	2.82	0.15	0.47	3.19	2.91	3.17	2.91
8	775	2.64	2.45	0.26	0.66	2.90	2.62	2.89	2.61
9	806	1.82	1.98	0.41	0.85	2.23	2.20	2.19	2.19
10	770	1.15	1.60	0.56	1.03	1.71	1.88	1.62	1.85
11	664	0.53	1.12	0.90	1.48	1.44	1.83	1.25	1.69
12	547	0.19	0.69	1.33	1.84	1.52	1.95	1.21	1.71
13	470	0.05	0.33	1.64	2.02	1.69	2.03	1.35	1.81
14	453	0.01	0.09	2.00	2.59	2.01	2.60	1.46	2.10
15	339	0.02	0.15	2.172.17	2.53	2.19	2.53	1.69	1.92
16	169	0.01	0.08	2.50	2.52	2.50	2.52	1.44	2.11
17	55	0.00	0.00	2.18	2.25	2.18	2.25	1.92	1.74
18	12	-- *	-- *	-- *	-- *	-- *	-- *	-- *	-- *
Total	6,740	1.45	2.30	0.81	1.61	2.25	2.54	2.07	2.46

* Statistic was not calculated because there were less than 30 cases.

Appendix F

El Dorado Oral Health Survey of 5-18 Year-Old School Children, 1999
Age-Specific Relative Contribution of Each DMF-T Element
Among those with DMF-T > 0 (Permanent Dentition)

Age	N (DMF-T>0)	% D / DMF-T	% M / DMF-T	% F / DMF-T
5	7	100.00	0.00	0.00
6	30	96.67	3.33	0.00
7	91	93.04	5.86	1.10
8	131	96.69	2.54	0.76
9	200	92.54	6.96	0.50
10	242	84.87	14.55	0.58
11	278	80.80	17.76	1.44
12	301	76.87	22.49	0.64
13	285	77.71	20.22	2.07
14	281	71.93	25.27	2.80
15	214	67.26	27.35	5.39
16	126	64.82	31.47	3.61
17	42	68.04	20.55	11.41
18	8	-- *	-- *	-- *
Total	2,236	79.5	18.4	2.1

* Statistic was not calculated because there were less than 30 cases.

Appendix G

El Dorado Survey of 5-18 Year-Old School Children, 1999
Age-Specific Degree of Caries Experience

Age	N	DMF-T = 0		1 < DMF-T 3		3 < DMF-T 6		Dmf-T > 6	
		N	%	N	%	N	%	N	%
5	163	156	95.7	6	3.7	1	0.6	0.00	0.00
6	692	662	95.7	28	4	2	0.3	0.00	0.00
7	825	734	89	85	10.3	6	0.7	0.00	0.00
8	775	644	83.1	112	14.5	19	2.5	0.00	0.00
9	806	606	75.2	172	21.3	26	3.2	2	0.2
10	770	528	68.6	191	24.8	47	6.1	4	0.5
11	664	386	58.1	198	29.8	60	9	20	3
12	547	246	45	192	35.1	84	15.4	25	4.6
13	470	185	39.4	158	33.6	85	18.1	42	8.9
14	453	172	38	146	32.2	77	17	58	12.8
15	339	125	36.9	95	28	65	19.2	54	15.9
16	169	43	25.4	58	34.3	38	22.5	30	17.8
17	55	13	23.6	22	40	12	21.8	8	14.5
18	12	-- *	-- *	-- *	-- *	-- *	-- *	-- *	-- *
Total	6740	4504	66.8	1468	21.8	523	7.8	245	3.6

Statistic was not calculated because there were less than 30 cases.

Appendix H

Middle America Oral Health Survey of School Children, 1997
Age-Specific Distribution of Children with Pit-and-Fissure Sealants in Permanent Molars

Age	N	% With Sealants in Permanent Molars
6	204	13.7
7	400	30.0
8	397	44.1
9	209	57.4
13	269	63.2
14	377	58.4
15	167	56.3
Total	2,023	45.8

Middle America Oral Health Survey of School Children, 1997
Prevalence of Dental Fluorosis in 6-9 and 13-15 Year-Old Children, by Region

		None		Questionable		Very Mild/Mild		Moderate/Severe	
Region	N	n	%	n	%	n	%	n	%
1	451	257	57.0	93	20.6	69	15.3	32	7.1
2	538	328	61.0	118	21.9	62	11.5	30	5.6
3	537	274	51.0	151	28.1	69	12.8	43	8.0
4	497	159	32.0	128	25.8	109	21.9	101	20.3
Total	2,023	1,018	50.3	490	24.1	309	15.4	206	10.3

ANNEX 5

STANDARDIZATION FOR RESEARCH PROTOCOL FOR URINARY FLUORIDE EXCRETION IN CHILDREN

Urine Sampling and Analysis for Determination of Fluoride Intake

Time-controlled urine sampling

Presence of fluoride in one time (spot) sample of urine offers insufficient information on the average daily fluoride intake. This information can best be obtained from samples collected over a 24 hour period. This may be possible with full parent collaboration or from hospitalized children. If it is difficult to obtain parents collaboration for supervised collection of urine during the day period, efforts should be made to collect supervised urinary samples during pre-school/school hours and one overnight collection at home. The following procedure has been adapted from the standard methods for urine sampling and analysis for determination of fluoride intake used in milk fluoridation studies (Marthaler, T.& Phillips P.C.). The procedure permits collection of urine over a period of 14-18 of the 24 hours cycle and provides sufficient information to estimate the total daily fluoride intake in children.

Protocolary requirements

Since 3-5 year old children may be attending kindergarten or elementary school, arrangements for project development should be made with the school (s) administration in the communities where the project is being planned to be conducted. Administration approval is essential. It also facilitates communication with parents of potential participants and will assure teachers and staff collaboration for all required activities prior and during project development.

A short and clear note explaining the purpose of the study should be prepared by the investigators and made it available to the school nurse so that it can be sent to parents inviting them to allow their children to participate. The nurse should be well informed of the purpose, objectives, implications, risks and time that each participant would be involved in the project so the she/he can answer any questions that parents might have prior to allowing their children to participate in the project. Invitations should me sent to the parents at least one week in advance prior to the intended date for initiating the project. Parents should be informed that the consent form would include all pertinent information and that it will be necessary for them to sign it giving permission to their child (children) to participate.

Institutional Review Boards (IRB) oversee the safety and rights of humans that participate as research subjects. The consent form explaining the purpose and activities to be conducted, benefits and risks of subjects, participation time and other implications must be prepared by the investigators using plain language, (easily understood by an individual with limited education i.e.: 7th grade). This consent form must be approved by the local IRB or equivalent agency and must be signed by the parent or guardian of the participating child, the investigator and a witness. Date should be recorded. The project director will keep original signed and the dated consent form with other project records. A copy of the consent form should be given to the parent of the participating child. Parents should also be instructed that it will be necessary for them to provide demographic information on their child and indicate the type of foods ingested by the child the day before and the day of sample collection. Additional information on

use of products containing fluorides such as toothpaste, tablets, drops or topical fluorides will need to be collected by completion of a simple questionnaire.

General Instructions

1. The day before urine collection starts it is advisable to meet with the school nurse to finalize details, identify classrooms and restroom facilities for boys and girls, and agree with the necessary project flow. Any additional information on project specifics can be provided at this time. Parents should be reminded that urine collection will be initiated the following day and that they should record the type of foods (solids and liquids) ingested by the child the day before and the day of the sample collection. Parents should be contacted directly or a note may be sent home with the child.

2. A roster of participating children is made and the corresponding identification number is assigned.

3. When child needs to urinate h/s is asked to empty the bladder. The name and time are recorded. This urine ids not collected. This procedure is followed with each participating child.

   Note: With some 3 year old children it may be necessary to use pediatric urine collectors.

4. When each child returns to urinate, a container of approximately 135 ml capacity is given for him/her to urinate. The time and volume of urine are recorded. The urine is transferred to a larger graduated container. The procedure is repeated at each urination during the pre-set collection period i.e.: morning (A).

5. At the end of the first supervised pre-set collection period, the process is repeated. The time should be recorded for each child. If the child is unable to urinate, the time at his/her last urination is recorded as the end of his/her collection period.

6. For each child, the time and volume of urine collected are recorded on the label and the following information transferred onto the recording form:

   a. Time of initial voiding of the bladder
   b. Time of last urine collection into the large container
   c. Total volume of urine collected between the initial voiding and the end of collection period.

7. Thirty (30 ml) of urine are placed into a plastic tube and a small crystal of Thymol added. The cap is secured and the sample stored in a cool place. If a refrigerator is not available, a portable Styrofoam cooler with ice cubes or dry ice may be used to maintain samples cool and to transfer them to the laboratory for analysis.

The procedure is repeated in the afternoon hours (B). If parents have agreed to collaborate on supervised collection at home during remainder of afternoon and evening, the procedure should be carefully explained to them. A container with label indicating period C should be made available for entering necessary information. If a third period is not to be conducted, an overnight collection should be arranged. A separate container should be provided to parents for this collection The container should have a label on which parents are to record the time of last urination before the child goes to bed and the time of first urination in the morning.

If it is suspected that the child may urinate during the night without notifying the parent, it may be necessary to fit him/her with a pediatric collectors such as the one described in section 1.3. Parents should be instructed on their method of use and should be reminded that these collectors are for single sample collections. The collected urine needs to be emptied into a larger container and the volume recorded. If the child is old enough to urinate in the large container, he/should be asked to do so if he/she needs to urinate during the night. The total volume of urine since the last urination before going to bed is recorded on the label for period D.

The concentration of fluoride is determined in each sample collected from each child for each period. The recorded volume and concentration of each sample for each period are used to calculate urinary flow and fluoride excretion rates per hour, per period and for 24 hours.

Recording Form for Collection of Urinary Samples

					School:			**Locality:** **Mean temperature:**			**Date:**		
Children Data:						**Period A (Morning)**		**Period B (Noon and Afternoon)**		**Period C (Afternoon & evening)**		**Period D (Nocturnal)**	
No	ID	Age	Sex	Weight		Start	End	Start	End	Start	End	Start	End
					Time								
					Vol.								
					Time								
					Vol.								
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*Adapted from WHO Form No. 96391

ANNEX 6 *(Presented in Spanish)*

STANDARDIZATION FOR RESEARCH PROTOCOL FOR USE OF FLUORIDE CONTAINING PRODUCTS

(ESTANDARIZACIÓN DE LOS PROTOLOS DE INVESTIGACIÓN PARA USO DE LOS PRODUCTOS QUE CONTIENEN FLUORUROS)

OBJETIVOS

1. Determinar el uso de pasta dental y la frecuencia de cepillado dental, en niños de tres a cinco años de edad.

2. Determinar el porcentaje de niños de tres a cinco años de edad, que según su madre ingieren pasta dental durante el cepillado.

3. Identificar qué pastas dentales son las más utilizadas y si éstas están o no fluoruradas.

4. Conocer la prevalencia de consumo de suplementos fluorurados en niños de 3 a 5 años de edad (gotas, tabletas, suplementos vitamínicos, etc.).

5. Determinar frecuencia del consumo de suplementos fluorurados y si el uso es por prescripción médico-odontológica o automedicación.

Hipótesis

a. La mayoría de los niños de tres a cinco años de edad se cepillan los dientes con pasta de adultos, es decir, que contienen concentraciones de 1.000 a 1.500 ppm de flúor; independientemente si se hallan en zona de riesgo de fluorosis o no.

b. El uso (frecuencia y cantidad) de pastas dentales y suplementos fluorurados, en los niños de tres a cinco años de edad, no es mayor en poblaciones que reportan alta prevalencia de fluorosis.

c. En los niños de 3 a 5 años de edad, los suplementos fluorurados son utilizados con baja frecuencia y la mayoría de los niños que los usan, es por prescripción médico-odontológica.

d. El uso de pasta dental y suplementos fluorurados en los niños de 3 a 5 años, es diferente según el nivel de instrucción de la madre y tipo de ocupación del padre o responsable económico de la familia.

MATERIALES Y MÉTODOS

El presente es un estudio de observación, de corte transversal, con base a una muestra representativa que considera a las zonas de riesgo y sin riesgo de fluorosis dental de las principales ciudades de cada país. La unidad de observación de estudio estuvo constituido por niños de tres a cinco años de edad, de sexo femenino y masculino, que asistían a las guarderías o jardines de infantes públicos o privados de las ciudades.

Para la selección de la muestra, se obtuvo las poblaciones universos de los niños de 3 a 5 años de edad, de las localidades seleccionadas con más de 2.000 habitantes, de acuerdo con los datos de los departamentos de estadística de las entidades estatales.

cabe resaltar que se consideraron los datos socioeconómicos de los padres o responsables de las familias tales como: nivel de educación de la madre y tipo de ocupación del padre o responsable económico de la familia, por la importancia que tienen en la situación de salud bucal de los niños.

Diseño muestral

La muestra del estudio correspondió a un diseño estratificado (zonas de riesgo y sin riesgo de fluorosis) aleatorio. La selección de los estratos se hizo con base en los resultados de los estudios de línea basal de concentración de flúor en el agua de consumo humano, así como de caries y fluorosis dental.

Es decir, en el caso del primer estrato o zona con riesgo se tomaron en cuenta aquellas localidades que presentaron niveles de fluoruro superiores a 0.5 ppm de flúor en el agua y en donde se habían reportado casos de fluorosis dental. El segundo estrato se tomaron en cuenta a aquellas localidades con ausencia de fluorosis dental y donde la concentración de flúor era menor a 0.5 ppm..

La selección de las localidades en cada estrato se realizó en forma propositiva, tomando en cuenta los criterios señalados anteriormente. La selección de las unidades de observación (niños) se realizó en forma aleatoria; para ello se construyeron listados de las instituciones educativas tanto públicas como privadas, con la finalidad de realizar el sorteo de los niños de las localidades seleccionadas.

La muestra calculada (en el paquete estadístico epi info) para cada zona, fue de 120 niños de 3 a 5 años de edad, que asistían a guarderías o jardines de infantes públicas y privadas. Se trato de que exista igual número de hombres y de mujeres.

Para el cálculo de la muestra se tomaron en cuenta los siguientes criterios:

- Nivel de confianza al 95%
- Prevalencia de uso de pastas y suplementos fluorurados 50%
- Precisión (error absoluto) 10%
- Población universo de cada zona

Levantamiento de datos

Para el levantamiento de datos se utilizó un formulario previamente elaborado, el mismo que sirvió para la entrevista a las madres o responsables de los niños. Se preguntó tanto sobre el uso de pastas dentales como sobre el consumo de suplementos fluorurados, su frecuencia y edad de inicio del uso, etc. La entrevista se realizó por encuestadores que recibieron criterios estandarizados sobre su uso. (Formulario, ver anexo)

Antes de la entrevista a los padres de los niños seleccionados, el equipo de encuestadores había obtenido información sobre el nombre y presentación de la pasta dentales y suplementos fluorurados que existían en el mercado de cada país.

Capacitación

La capacitación del equipo de trabajo: "Asistentes de Investigación Odontológica" (AIOS) en cada país, se realizó sobre los aspectos técnicos del manejo de la encuesta del estudio, codificación de las preguntas del formulario, correcto llenado de los datos, recomendación de no inducir las respuestas etc.; de tal manera que todos los profesionales odontólogos estuvieron familiarizados con el procedimiento a seguirse.

Prueba piloto

Se realizó una prueba piloto utilizando el formulario elaborado para el estudio en cada país. Se seleccionó una guardería infantil o jardín de infantes. Se escogió al azar un grupo mínimo de 25 niños del grupo edad indicado. A los responsables de la institución educativa se les explicó claramente de lo que se iba realizar, pidiéndo su colaboración. Igualmente se indicó a los encuestadores que la información debería de ser dada de preferencia por la madre y en su defecto por algún familiar adulto.

El uso previo del formulario permitió verificar la confiabilidad, operatividad y validez de las preguntas.

Recolección de los datos

La recolección de los datos para el estudio siguió una programación previamente elaborada para cada país. Se recomendó la necesidad de identificar previamente la guardería o institución sorteada, donde se haría la encuesta, así como el número de encuestas diarias que cada encuestador debía realizar, a fin de calcular el tiempo de cada entrevista y la frecuencia de las actividades de cada día, de esta manera se estandarizaron los procedimientos y se evitó desfases en los cronogramas establecidos.

Procesamiento de la información

Los formularios de la encuesta una vez revisados y realizado el control de calidad, fueron entregados al responsable nacional para enviar al centro de procesamiento de los datos del estudio, en donde fueron ingresados en una base de datos del paquete epi info.

Plan de análisis

Para el análisis de la información, se seleccionaron las variables de acuerdo a los objetivos e hipótesis del estudio. El procesamiento de los datos se realizó en el paquete estadístico epi info versión 6. El análisis fue de tipo descriptivo, a través de frecuencias, proporciones o porcentajes y promedios, así como cruces de variables y análisis inferencial en el caso de las hipótesis del estudio.

ANNEX 7 *(Presented in Spanish)*

*RECOMMENDATIONS, LEGISLATION AND REGULATION FOR SALT FLUORIDIATION**

(RECOMENDACIONES, LEGISLACIÓN Y REGULACIÓN DE LA SAL FLUORURADA)

Con base en los datos recogidos a través de OPS y la consulta de las legislaciones sobre fortificación de la sal en los países de América Latina y el Caribe, se elaboró un análisis de la legislación que establece la yodación de la sal en la Región.

Esta información sirvió de base para diseñar lineamientos generales que puedan servir como guía o modelo de Marco Jurídico para los países que requieran o deseen actualizar o elaborar sus legislaciones bien sea con respecto a la yodación de la sal o a la yodación y fluoruración de la sal.

Los resultados son los siguientes:

Argentina: En 1978 se promulgó la ley y el reglamento que obligan a la yodación de la sal para consumo humano y animal en todo el país y luego se inició un programa de yodación de la sal con un nivel de yodación de 30 ppm. Dicha cobertura es nacional e incluye la sal importada. Argentina actualmente no fluorura la sal y en cuanto a la exportación comercializa con los países del Mercosur.

Bolivia: En 1968 se emite la ley y los reglamentos para la yodación de la sal para consumo humano y animal en todo el país. En el año de 1977 se inicia un programa de yodación de la sal con un nivel de yodación de 50 ppm. La cobertura de la ley es nacional e incluye la sal importada. Bolivia tiene un programa de fluoruración de la sal y el Marco Legal contempla el yodo y el Flúor. Actualmente la industria se desarrolla en pequeña escala y no existe importación ni exportación del producto final. En 1996 se lo designa país libre de DDY como problema de salud pública.

Brasil: En 1953 se legisla sobre la yodación de la sal y en 1953 y 1977 se reglamenta para exigir el cumplimiento de la yodación de la sal para consumo humano en todo el territorio nacional. Dicha cobertura es nacional y se inicia la yodación en 1957, incluye la sal importada pero no la sal para consumo animal. Los niveles de yodación de la sal son de 15 a 30 ppm. Este país importa sal desde Venezuela y exporta a los países del Mercosur.

Chile: En 1982 se elaboró un reglamento nuevo cuya cobertura es nacional y solo contempla el ion Yodo. Se agrega Yodo del 88% al 90% de la sal. Actualmente, se encuentra pendiente de aprobación una modificación al Reglamento del Código Sanitario para reducir los niveles de yodación de la sal. Chile no posee programa de fluoruración de la sal.

Colombia: En 1947 se decreta la ley de yodación de la sal y es reglamentada en 1955. Se inicia un programa de yodación de la sal con un nivel de yodación de 70 a 100 ppm. Tiene cobertura nacional y solo incluye la sal de consumo humano. Colombia posee programa de fluoruración de la

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* Documento preparado por el Dr. Gabriel Da Cunda, Consultor para UNICEF Colombia, Diciembre 1999.

sal y el Marco Legal contempla el ion Yodo y Flúor. Desde 1998 Colombia es designado como país sin DDY como problema de salud pública.

Costa Rica: En 1941 se emite la ley de yodación de la sal y es reglamentada en 1970. Se inicia un programa de yodación de la sal con un nivel de yodación de 30 a 50 ppm. Incluye sal para consumo humano y tiene carácter nacional. Costa Rica posee un programa de fluoruración de la sal y está en estudio la inclusión del flúor dentro del Marco Legal. En referencia al comercio exterior, este país exporta e importa sal.

Cuba: *No* dispone de leyes que obliguen a la yodación de la sal. Existe sin embargo yodación de la sal en la actualidad y está en inicio la ejecución de un programa de fluoruración de la sal. En cuanto al Marco Legal, se está proponiendo un modelo para la adición de flúor. Se ha producido cierto volumen de sal yodada entre 1995 y 1997 pero la falta de recursos ha limitado la continuidad y la aplicación de cobertura de yodación de la sal.

Ecuador: En 1968 se emite la ley de yodación de la sal y se reglamenta en 1969. Tiene carácter nacional y no incluye la sal para consumo animal. En 1973 se inicia un programa de yodación de la sal usando Yoduro de Potasio a un nivel de 50 ppm. Este país posee un programa de fluoruración de la sal y el Marco Legal contempla ambos iones. Ecuador acaba de recibir la nominación de país libre de DDY como problema de salud pública. En cuanto a su comercio exterior, existe exportación hacia Colombia pero no se importa sal.

Guatemala: En 1954 se emite la ley de yodación de la sal, la cual es reglamentada en 1955. Tiene cobertura nacional e incluye toda la sal para consumo humano y animal. Se inicia un programa de yodación de la sal en 1959 usando Yodato de Potasio a un nivel de 60 ppm. a 100 ppm. Recientemente Guatemala comenzó a ejecutar un programa de fluoruración de la sal y está en proceso la inclusión del flúor dentro del Marco Legal ya existente.

El Salvador: En 1961 se promulga la ley que obliga a la yodación de la sal para consumo humano y animal en todo el territorio nacional. Se reglamenta en 1967 y en 1972 se inicia un programa de yodación de la sal utilizando Yodato de Potasio a un nivel de 60 a 100 ppm. Recientemente comenzó a ejecutarse un programa de fluoruración cuyo Marco Legal está en proceso.

Honduras: En 1960 se decreta obligatoria la yodación de la sal para consumo humano y animal en todo el territorio nacional. Es reglamentada en 1961. En 1971 se inició un programa de yodación de la sal utilizando Yodato de Potasio a un nivel de 60 a 100 ppm. Honduras tiene en proceso un programa de fluoruración de la sal cuyo Marco Legal está en revisión. En cuanto al comercio exterior importa sal de Nicaragua, México y El Salvador y no hay exportación de sal.

México: En 1963 se decreta la yodación de la sal y se reglamenta en el período 1963-1974. Tiene cobertura nacional e incluye tanto la sal para consumo humano como la de consumo animal. Se inicia un programa de yodación de la sal con un nivel de yodación de 34 a 68 ppm. Está en ejecución un programa de fluoruración de la sal.

Nicaragua: En 1969 se decreta obligatoria la yodación de la sal y se reglamenta en 1977. Las disposiciones legales obligan a la yodación de la sal para consumo humano y animal que se distribuye en todo el país. En 1978 se inicia un programa de yodación de la sal utilizando Yodato de Potasio con un nivel de 30 a 50 ppm. Nicaragua posee un programa de fluoruración de la sal en inicio y se empieza a

estudiar el Marco Legal para el flúor. En referencia al comercio exterior, se exporta sal a Honduras y Costa Rica y se importa desde Costa Rica.

Panamá: En 1965 se promulga la ley de yodación de la sal y es reglamentada en 1969. Tiene cobertura nacional y no incluye la sal para consumo animal e industrial. Se inicia un programa de yodación de la sal con un nivel de yodación de 66 a 100 ppm. Panamá tiene proyectado un programa de fluoruración de la sal así como también la incorporación del flúor a su Marco Legal.

Paraguay: En 1958 se promulga la ley de yodación de la sal, la cual es reglamentada en el periodo 1966-1980. Tiene cobertura nacional e incluye la sal para consumo humano y animal. En 1966 se inicia un programa de yodación de la sal usando Yodato de Potasio a un nivel de 60 a 80 ppm. Este país no posee un programa de fluoruración de la sal.

Perú: En 1969 se decreta la ley de yodación de la sal y su reglamento es aprobado en 1971. Tiene obligatoriedad nacional y afecta tanto la sal para consumo humano coma la sal para consumo animal. En 1972 se inicia un programa de yodación de la sal usando Yodato de Potasio a un nivel de 30 a 40 ppm. Existe un programa de fluoruración de la sal. Perú fue designado país libre de DDY en 1998. Perú exporta sal hacia Colombia; no importa sal.

Uruguay: En 1961 se decreta la ley de yodación de la sal y se reglamenta en el período 1963-1974. Incluye la sal para consumo humano y animal y es de cobertura nacional. Desde 1963 existe un programa de yodación de la sal usando Yodato de Potasio a un nivel de 30 ppm. Uruguay tiene un programa de fluoruración de la sal y el flúor está contemplado en el Marco Legal. Exporta e importa sal a los países del Mercosur.

Venezuela: En 1966 se emite la ley de yodación de la sal y se reglamenta en 1968. Tiene cobertura nacional y obliga a la yodación de la sal para consumo humano y animal. Venezuela cuenta con un programa de yodación de la sal desde 1968 usando Yodato de Potasio a un nivel de 20 a 30 ppm: y el flúor esta contemplado en el Marco Legal. Acaba de ser declarado país libre de DDY coma problema de salud pública. Exporta sal hacia República Dominicana, Colombia y Brasil e importa desde Colombia y Bonaire.

Belice: Actualmente existe la yodación de la sal con un nivel de yodación de 30 a 100 ppm. y se proyecta un programa de fluoruración de la sal. No existe producción interna de sal y la totalidad de la sal es importada. No existe Marco Legal que contemple los iones Yodo ni Flúor. Se está trabajando desde el punto de vista legal dada la necesidad de regulación de la importación de sal.

República Dominicana: La sal en este país presenta yodo y tiene proyectado un programa de fluoruración de la sal. El Marco Legal contempla el yodo, y el flúor esta en estudio. En 1995 por Decreto Presidencial se declaró la obligatoriedad de la yodación de la sal en todo el país. En 1996 se pone en marcha el programa de yodación de la sal. República Dominicana importa sal desde Venezuela, Ecuador, Colombia y Jamaica.

Guyana: Carece de industrias salineras y la totalidad de la sal que se consume es importada. Posee sal yodada y no yodada y no existe adición de Flúor en la misma. Desde el punto de vista legal no hay un marco establecido.

Haití: En este país existe yodación de la sal y aun no existe Marco Legal que regule el Yodo en la sal. No hay programas de fluoruración de la sal.

Jamaica: Existe yodación de la sal desde 1962 para sal de consumo humano y animal (60 a 100 ppm) y además un programa de fluoruración bien establecido. Desde el punto de vista legal, su marco contempla la presencia del ion Yodo y Flúor. Jamaica no reporta tener problemas de salud pública relacionados con DDY.

Caribe (12 países de habla inglesa): Aquí se realiza la yodación de la sal y está en proyecto un programa de fluoruración de la sal para los 12 países, aunque no existe legislación reportada sobre el Yodo o el Flúor en la sal. Estos países no reportan tener problemas de salud pública relacionados con los DDY.

LINEAMIENTOS GENERALES PARA LA ELABORACIÓN DE UN MARCO JURÍDICO PARA LA YODACIÓN Y FLUORACIÓN OBLIGATORIA DE SAL PARA CONSUMO HUMANO

Consideraciones Generales

Corno primer punto, se enumeran antecedente, leyes, decretos y reglamentaciones generales de fluoruración y yodación de sal en el momento actual en el país en curso.

Considerando:

I. Que la carencia de yodo y flúor significa un serio problema sanitario para el país, tanto por su incidencia en la salud como por sus repercusiones económicas;

II. Que su incremento causa un importante deterioro principalmente en la población de escasos recursos económicos;

III. Que una de las medidas preventivas más eficaces contra los DDY y la caries dental consiste en el aporte de Yodo y Flúor a la sal destinada al consumo humano;

IV. Que el éxito obtenido en cuanto a la erradicación del bocio endémico en cada país a través del consumo masivo de sal yodada indica que la sal sería también el vehículo apropiado para la ingesta de Flúor.

Decreta:

Reglamento unificado de la ley de yodación obligatoria de la sal para consumo humano y del programa nacional de fluoración.

CAPITULO I

DEFINICIONES

Art. 1 Desígnase con el nombre de sal para consumo humano sin otro agregado, al producto comercialmente puro o purificado que químicamente se identifica con el nombre Cloruro de Sodio, extraído de las fuentes naturales. Se presenta en forma de cristales incoloros, soluble en agua y de sabor salado franco; su consumo es autorizado por la autoridad sanitaria. Exclúyese de este concepto, la sal empleada con fines industriales no alimenticios.

Art. 2 La sal para consumo humano atendiendo a su destino, se considera tanto a la de consumo directo coma indirecto.

Art. 3 Entiéndase como sal para consumo humano directo aquella que se emplea en la cocina y en la mesa para confección y aderezo de los alimentos.

Art. 4. Se designa con el nombre de sal para consumo humano indirecto aquella que se utiliza en la industria alimenticia como agente conservador, saborizante y en general como aditivo en el procesamiento de la materia alimenticia.

Art. 5 Desígnase sal para consumo animal al producto constituido por Cloruro de Sodio, se utiliza únicamente en la alimentación de animales.

CAPITULO II

NORMAS SANITARIAS GENERALES

Art. 6. El control periódico de la sal de consumo humano es función privativa del Ministerio de Salud Pública a través de la Dirección correspondiente.

Art. 7. Toda la sal que se produzca en el país para consumo humano directo, es decir, sal de mesa y cocina, debe ser yodada y yodada fluorurada previo a su expendio.

Art. 8. La sal de consumo humano, en orden a sus características, a su pureza y granulación determinadas en este reglamento, clasifícase en tres grupos:

1. Sal molida
2. Sal refinada
3. Sal de mesa

Art. 9 La sal de consumo humano, deberá presentarse bajo la forma de cristales blancos, de forma cúbica, agrupados y unidos de manera que constituyen pequeñas pirámides de base cuadrangular.

Los diferentes tipos de sal granulada deberán ser de aspecto uniforme dentro de cada tipo, además deberán estar exentas de nitritos, impurezas y microorganismos que indiquen

manipulación defectuosa del producto, esto es, ausencia de coliformes, microorganismos patógenos y cromogénicos. El recuento de gérmenes banales no podrá ser mayor a 20,000.

Art. 10 La sal molida y refinada es el producto beneficiado con eliminación de sales higroscópicas de magnesio y calcio, impurezas orgánicas, arena y fragmentos de concha, los cristales deberán pasar por el tamiz malla No. 20 y el 25% por lo menos deberá pasar por el tamiz malla No. 60. Además sus características fisicoquímicas deben satisfacer los límites señalados en la norma NTN-INEN 57 y los siguientes límites:

- Humedad a 150°C. No mayor de 2%
- Residuo insoluble en agua. No mayor del 0.3%
- Cloruro de Sodio (sobre sustancia seca y deducida del antihumectante). No menor del 98%
- Grado de turbiedad. No mayor del 25%

Art. ll. La sal de mesa corresponde en sus características de granulación, constantes físicas y químicas a las que se establecen para la sal refinada, excepto que no debe presentar una humedad mayor del 0.5%, límite que requiere la adición de antihumectantes en un máximo que no exceda el 2%, proporción que permitirá que el porcentaje del Cloruro de Sodio pueda descender hasta un 96%.

Art. 12. La Sal de Consumo Humano Directo debe ser yodada y yodada fluorurada, debiendo reunir las especificaciones y normas sanitarias correspondientes a cada tipo consignadas en este Capítulo, debiendo contener:

Sal Yodada, producto constituido básicamente por el Cloruro de Sodio (NaCl), adicionado de Yodato de Potasio o Sodio (KlO o NalO respectivamente), o Yoduro de Potasio (Kl) dentro de los límites de Yodo libre en concentración de 75mg. Por Kg. de sal, permitiéndole una tolerancia de 25 mg. Por Kg. de sal de mas o de menos.

Sin perjuicio de que tales concentraciones sean modificadas por resolución del Ministerio de Salud, acorde con la evaluación de las encuestas nutricionales respectivas, y cuando lo justifiquen los estudios epidemiológicos de salud en relación a la dosificación de Yodo.

Art. 13. La adición de Yodo deberá hacerse solamente mediante el empleo de Yoduro de Potasio o Sodio y el Yodato de Potasio.

La adición de flúor deberá realizarse a través de Fluoruro de Sodio o Potasio (Naf o KF respectivamente), de acuerdo al método de producción (vía seca o vía humedad).

Art. 14. Se exceptúa de fluorurarse la sal para consumo humano que se destina a la industria no alimenticia.

Art. 15. La sal para consumo humano deberá ser acondicionada en envases de primer uso que conserven la integridad del producto, confiriéndole la protección adecuada contra la contaminación y la humedad. El material del envase en contacto con el producto deberá ser resistente a la acción de este, y de tal naturaleza que recíprocamente no altere, ni la composición, ni las características organolépticas del mismo.

Art. 16. Los establecimientos e instalaciones que se ocupen de la producción industrial de la sal para consumo humano, deberán además satisfacer los requisitos generales estipulados por el Código de la Salud y el presente reglamento.

Art. 17. La elaboración y fraccionamiento de la sal yodada de uso indirecto podrá verifcarse exclusivamente en los establecimientos previamente autorizados por la autoridad de salud.

Art. 18. Las personas naturales o jurídicas propietarias de las instalaciones mencionadas en el Art. 17, deberán satisfacer los requisitos establecidos por el Código de la Salud.

Art. 19 Los centros de elaboración, fraccionamiento, envase o reenvase de sal yodada y sal yodada fluorurada o de sal para consumo humano indirecto, deberá satisfacer además los requisitos técnicos estipulados en el Código de la Salud, en la parte pertinente al saneamiento ambiental y al equipo.

Art. 20. A efecto de garantizar la correcta adición y permanencia del yodo y el flúor en la sal, el promotor esta obligado a emplear el procedimiento eficiente y económicamente factible utilizando el método de adición por vía húmeda que garantice la distribución homogénea de los elementos, de tal forma que la muestra tomada de manera aleatoria y ensayada cumpla con el contenido de yodo y de flúor establecido en el presente Reglamento.

Art. 21. La sal para consumo humano directo o indirecto de importación que se comercialice en el país debe cumplir con las especificaciones que marca la Ley, respecto a las características físicas, químicas, microbiológicas y de adición de micronutrientes (yoduro o yodato y fluoruro).

Art. 22. Las plantas para el refinado y purificado de la sal para consumo humano deberán contar con equipos construidos en acero inoxidable en atención al alto grado de corrosión que provoca esta materia prima.

La planta constará de:

a. Un secador rotativo que produzca una cortina contigua de sal, purificándola y elevando su temperatura a 120°C en forma homogénea en toda su masa.

b. Un sistema de turbina y ciclonaje que absorban las impurezas que se van desprendiendo del producto a lo largo de su pasaje por el secador rotativo, mediante una fuerte corriente de aire.

c. Equipos de cribado con mallas de acero inoxidable para no contaminar de oxido el producto.

d. Los transportes de una etapa a otra del proceso deberán ser mecanizados y no tener contacto con operario alguno.

e. Los mezcladores a utilizarse, en función de las bajas dosis de Yodato de Potasio y Fluoruro de Sodio o Potasio a ser incorporadas, deberán ser mezcladores de precisión. Estos equipos son mezcladores cónicos verticales de movimiento epicicloidal de gran

precisión, que constan básicamente de un recipiente tronco cónico que en su interior lleva incorporado un tomillo tipo Arquímedes para obtener la homogeneización de la mezcla exigida por el Ministerio de Salud Publica.

f. Las envasadoras de sal para consumo humano deberán ser totalmente automáticas, cumpliendo de esta forma la totalidad del ciclo sin que el producto, luego de refinado, entre en contacto con la mano del hombre.

Los equipos descritos son el mínimo requerido para estos procesos. El control de calidad de la incorporación de yodo y flúor se efectuará en cada batida del mezclador tomándose dos muestras, las que deberán ser analizadas y rotuladas indicándose fecha y número de tachada, manteniéndose a disposición del Ministerio de Salud Publica por un plazo de cuarenta y cinco días. Los locales donde estén instaladas las plantas refinadoras y purificadoras de sal, así coma el local de envasado de sal apta para consumo humano, deberá contar con la habilitación del Ministerio de Salud Pública.

CAPITULO III

DEL ENVASE Y ROTULACIÓN

Art. 23. El envasado de la sal yodada y yodada fluorurada de consumo directo deberá realizarse observándose el cumplimiento de las condiciones estipuladas en el Art. 16 de este Reglamento.

Art. 24. El envase para el expendio de sal yodada y yodada fulgurada deberá llevar rótulo visible en idioma castellano, con caracteres bien diferenciados, en que se consigue, además del nombre, patente si lo hubiera, lo siguiente:

1. La designación de sal yodada o yodada fluorurada para consumo humano.
2. Contenido neto del producto en el envase expresado en unidades de sistema métrico decimal.
3. Nombre del establecimiento productor, localización, número del Registro Sanitario con la patente concedida y número de lote.
4. La leyenda "Elaborado en su país de origen"
5. Declaración de los aditivos empleados.
6. Advertencia en el caso de la sal yodada fluorurada: "No se consuma o comercialice este producto en las áreas donde exista en el agua de consumo humano, niveles de flúor mayores a 0.7 ppm.

Art. 25 El envase para el expendio de la sal de consume indirecto deberá llevar rotulo visible en castellano en el que conste:

1. La designación de la sal para uso en la industria alimenticia.
2. Contenido neto expresado en unidades del sistema metric0 decimal.
3. Nombre del establecimiento productor y localización.
4. Número del Registro Sanitario.
5. Número de la Patente.

CAPITULO IV

DEL REGIMEN DE CONTROL Y DE LAS SANCIONES

Art. 26. El Ministerio de Salud Público por intermedio de sus dependencias técnicas, llevará un registro de las industrias de sal para consumo humano en que constarán las características técnicas pertinentes al volumen de producción, tipos de productos que elaboran, distribuidores de la sal y demás datos necesarios para efectuar un eficiente control.

Art. 27. Las personas, sociedades, firmas comerciales, etc. que figuren como propietarios de fábricas, establecimientos que elaboren, fiaccionen, envasen o reenvasen sal yodada para la industria alimenticia, sal y sal yodada fluorurada para consumo humano, serán las directamente responsables de todo producto que sea entregado para la venta, con defectos en su elaboración o deficiencias del envase. No admitiéndose excusa alguna tendiente a atenuar o eludir dicha responsabilidad.

Art. 28. Los centros de expendio de sal yodada y sal yodada fluorurada, tales como: supermercados, bodegas, abacerías, etc. que expendan sal que no reúna los requisitos establecidos en el presente Reglamento, serán sancionados de conformidad con las penas establecidas en el Código de la Salud.

Art. 29. Toda planta yodizadora y fluoruradora de sal tendrá que llevar un registro de control de calidad del proceso de producir, el cual deberá estar disponible para las autoridades sanitarias o de comercio que lo soliciten.

Art. 30 Quedan excluidas de los requerimientos precedentes, la partida de sal destinada para fines industriales no alimenticios, la misma que se considera no apta para el consumo humano.

Art. 31 Los establecimientos que se ocupan de la producción de sal para consumo humano directo o indirecto, deberán cumplir las normas sanitarias e higiénicas establecidas en el Código de Salud y este Reglamento.

Art. 32. La tenencia de sal común no yodada y fluorurada está permitida solamente a los concesionarios de yacimientos en explotación, a los industriales que la refinan o que la yodizan y fluoruren y a los que la utilizan para fines industriales no alimenticios.

Art. 33. La comercialización de la sal para consumo directo o indirecto, nacional o importada que no llenen los requisitos exigidos en los artículos precedentes, será considerada como delito contra la salud pública y sus responsables serán sancionados de conformidad con lo dispuesto por el Código Penal.

Art. 34. La dirección General de Salud de cada país hará cumplir todas las disposiciones de higiene, calidad, contenido de yodo, flúor y envase para las sales de consumo humano directo e indirecto, sal de uso en la industria alimenticia, y sal para consumo animal dispuestas en el presente Reglamento.

Art. 35. Los productores de la sal yodada y yodada fluorurada para consumo humano directo, sal para la industria alimenticia, sal para consumo animal y los refinadores, envasadores o reenvasadores que vendan o distribuyan sal que no cumplan con lo establecido en el presente Reglamento, serán sancionados de conformidad con las penas establecidas en el Código de la Salud.

Art. 36. De comprobarse la violación de los requisitos de calidad, yodación o fluoruración, el productor o expendedor serán sancionados de a cuerdo a lo establecido en el Código de la Salud.

Art. 37. El método de prueba para verificación de las especificaciones químicas de flúor que se establece en este Reglamento, es el potenciómetro con electrodo específico y de referencia de flúor.

Art. 38. Los fabricantes de envases para sal yodada y fluorurada solamente podrán fabricarlos para las personas o empresas que tengan Registro Sanitario vigente, y deberán mensualmente enviar al Programa de Fluoruración de la Sal, el listado de los envases fabricados para sal.

DISPOSICIONES TRANSITORIAS

Se enumeran las disposiciones transitorias que harán necesarias.

RECOMENDACIONES

- No se deben considerar barreras arancelarias los criterios básicos de esta normativa sanitaria.
- Las políticas sociales y los criterios sanitarios deben primar sobre los empresariales y/o comerciales. NAFTA, MERCOSUR, C. E. E.
- Los países deben evaluar el marco jurídico legal que existe, para apoyar a los programas de yodación .
- Esto requiere revisar las leyes, decretos y regulaciones para que los programas sean implementados efectivamente.
- La introducción obligatoria de la sal yodada y yodofluorurada (donde sea necesario adicionar Fltior)dentro del c6digo alimentario.

- La regulación sobre el uso adicional de fluoruro debe ser revisada, para disminuir el riesgo de la población a ser expuesta a fluorosis.

- Debe implantarse un estricto control de las industrias salineras. Cuantitativa y cualitativamente.

- Debe existir un estricto control del sector publico.
  - Vigilancia epidemiol6gica.
  - Garantía calidad.

- Se debe determinar un compromiso.
  - Comercio Exterior (Importación y Exportación).

- Se debe asegurar la sostenibilidad de los programas.

A modo de recomendación, se mencionan los países que requieren fortalecer, modificar o elaborar su legislación

Fortalecer	**Modificar**	**Yodo**	**Flúor**	**Elaborar**
Colombia	República Dominicana	No	Si	Caribe *(12 países)*
Chile	Panamá	No	Si	Haití
Brasil	Nicaragua	No	Si	Guyana
Bolivia	Honduras		Si	Belice
Argentina	El Salvador		Si	
Ecuador	Guatemala		Si	
México	Cuba		Si	
Venezuela	Costa Rica		Si	
Canadá				
Jamaica				
Paraguay				
Perú				
Uruguay				