# Monitoring Universal Salt Iodization Programmes

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ICCIDD

PROGRAM AGAINST MICRONUTRIENT MALNUTRITION
PAMM
TOWARDS THE ELIMINATION OF HIDDEN HUNGER

WORLD HEALTH ORGANIZATION

The Micronutrient Initiative
L'initiative pour les micronutriments
Iniciativa para los micronutrientes

# Monitoring UNIVERSAL *Salt Iodization* PROGRAMMES

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PROGRAM AGAINST MICRONUTRIENT MALNUTRITION

PAMM

TOWARDS THE ELIMINATION OF HIDDEN HUNGER

The Programme Against Micronutrient Malnutrition (PAMM)

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Readers' suggestions and information about examples of monitoring salt iodization programmes, and problems encountered when monitoring, would be most welcome.

**PAMM** is a collaboration among the Rollins School of Public Health of Emory University, the Centers for Disease Control and Prevention, and the Carter Center Task Force for Child Survival and Development. PAMM receives support from the United States Agency for International Development (USAID), UNICEF, MI, and the World Bank. PAMM supports the global goal of eliminating micronutrient malnutrition through collaboration with: the International Agricultural Center and Wageningen Agricultural University, the Netherlands; countries that have participated in PAMM training or workshops (36 countries as of 1994); and multilateral, bilateral, and non-governmental agencies.

The **MI** was established in 1992 as an international secretariat within the International Development Research Centre (IDRC) in Canada by its principal sponsors: Canadian International Development Agency (CIDA), IDRC, UNICEF, UNDP and the World Bank. The mission of the MI is to facilitate the achievement of the goals of the World Summit for Children that relate to the alleviation or elimination of micronutrient deficiencies. The work of the MI focuses on advocacy and alliance building, the development of sustainable interventions, support for effective programmatic actions, capacity building and the resolution of key operational issues.

Established in 1985, the **ICCIDD** has as its goal the rapid and sustained elimination of global iodine deficiency. Its membership of over 350 persons in more than 70 countries includes scientists, physicians, public health specialists, salt producers, economists, communicators, managers, representatives from UNICEF, WHO, Kiwanis International, and others. CIDA, the Australian International Development Bureau (AIDAB), UNICEF, the World Bank, and USAID are major financial supporters. ICCIDD's activities at the country, regional, and global levels focus on advocacy, coordination, information sharing, applied research, and monitoring.

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# FOREWORD

The world is on the threshold of a major breakthrough in the elimination of iodine deficiency. Efforts over the past decade to create a global awareness of the severity of iodine deficiency, its ramifications, and the simple means to eliminate it through iodization of salt have led to a concerted effort in over 100 countries to regulate and implement universal iodization of all salt for human and animal consumption. Once the effective iodization of salt is established as a permanent measure in a country, iodine deficiency will be eliminated through the provision of daily iodine needs to each individual.

The goal set by the World Summit for Children 1990 and reemphasised at the International Conference on Nutrition 1992 is the virtual elimination of iodine deficiency by the year 2000. A crucial milestone in achieving this goal is to ensure universal iodization of all food grade and animal salt in countries at risk by the end of 1995. Operationally, this translates into the development of a mechanism that delivers iodine in the required quantities to the population at large on a continuous and self-sustaining basis. National governments have recognised that this is an attainable goal with important benefits for the population. The challenge before them is to translate available knowledge into effective programmes with minimum external support. The development of a sustainable system for iodine delivery involves a systematic study of the salt industry, production, distribution patterns, quality, packaging, economics, and consumer preferences. This information is used to plan and implement multi-sectoral efforts that combine the technical action of salt iodization with a host of support measures, including social advocacy, demand creation, regulation, enforcement, programme administration and coordination, quality control, and monitoring. The objective is the total integration of iodization into the prevailing salt production and distribution system in a country with costs fully absorbed within such a framework.

Continuous monitoring of iodine levels in salt is one of the best and simplest ways of monitoring and sustaining a salt iodization programme. Successful programmes test iodine levels in salt at iodization plants and periodically at intermediate points in the distribution network, retail outlets, and at the household level.

This manual has been prepared in response to a strong need in the field for a systematic procedure to establish a permanent iodized salt monitoring system within a country and monitor progress towards the achievement of the mid-decade goal of universal iodization of salt. It is designed for country programme managers who require guidelines and reference material in order to design and implement iodine deficiency disorder (IDD) monitoring programmes. The most feasible system will be determined by a combination of local factors, industry and health infrastructure. It will therefore be up to a country programme manager to select those elements that are most appropriate for a specific country situation. The goal is to permanently integrate and institutionalise salt monitoring and quality assurance into the daily activity of salt producers with periodic monitoring by the government to ensure adequate iodization of all salt for human and animal consumption.

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# PREFACE

The virtual elimination of iodine deficiency disorders (IDD) worldwide will be a monumental achievement by mankind. For the majority of populations, elimination will be achieved through the iodization of all salt intended for human and animal consumption. A stimulus for the development of this manual has been the lack of a single resource that provides specific guidelines for a successful national salt iodization programme. The focus is on monitoring salt iodization programs and we hope the information in this manual will be useful for those involved in developing or improving monitoring systems.

This manual was developed through a grant to the Programme Against Micronutrient Malnutrition (PAMM) from the Micronutrient Initiative (MI). Some of the materials for this manual are based on training courses at the Program Against Micronutrient Malnutrition (PAMM), Atlanta, USA. Many of the ideas and examples are based on country experiences and on consultations with individuals in a number of countries worldwide. Because of the differences in culture, economics, infrastructure, geology, and many other factors, each countries' plan to eliminate IDD will be unique and require selection of appropriate activities. We encourage individuals to provide the editors with "case studies" on what worked and what did not work in their national programmes, and how practical the information provided in this manual proved to be. Any case studies and suggestions for improvement will be considered for use in updated versions of this manual.

In a second version of this manual we plan to include information on how to assess the magnitude and distribution of IDD within the population. This information was purposely left out of this first version to keep the primary focus on salt iodization and monitoring. However, as we approach the year 2000, information on the prevalence of IDD will become increasingly important. We also hope to present more illustrations from developing countries of the approaches and tools being used to monitor iodized salt programs and to deal in greater depth with the special needs and constraints facing small-scale salt producers and others in resource-poor situations. Social marketing is another important component of any intervention strategy to be discussed in the next edition. Any suggestions or comments on how to improve this manual would be greatly appreciated as well as feedback about how the manual has been used.

Contributors to this manual come from a variety of disciplines, including laboratory science, engineering, medicine, public health, law, nutrition, management, and epidemiology. This variety of backgrounds shows the diversity required in national programmes to address IDD.

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# Overview of Monitoring Universal Salt Iodization Programmes

1

## INTRODUCTION

### MONITORING IN CONTEXT

Prevention of the detrimental effects of inadequate intake of three micronutrients—iodine, vitamin A and iron—is of immense importance to global development. It could be the most important achievable international health goal of the decade, exceeding even the impact of global eradication of smallpox in the 1970s.[1]

Of the three micronutrients, correction of iodine deficiency is arguably the most immediately achievable goal. Only in the last decade has it been recognised that iodine deficiency is the leading cause of intellectual impairment. Investments in economic development and education will not achieve their desired outcomes unless this problem is addressed.

Iodization of salt, a common food used by the vast majority of the population, is a proven intervention. Any national iodine deficiency disorders (IDD) elimination programme must ensure that all salt for human and animal consumption, both imported and locally produced, is adequately iodized.

> This iodized salt monitoring manual provides guidelines for managers of national IDD elimination programs and others involved with salt iodization on how to organise a salt monitoring system with particular reference to:
>
> - Key process indicators from importation and production to the household
> - Criteria by which to determine if programme activities are working and identify constraints
> - Procedures for data collection and analysis and use to improve programme performance.

However, salt iodization is not simply a matter of passing legislation or persuading certain salt producers to iodize their salt. Iodine is volatile in all forms, with potassium iodide (KI) the most volatile, and potassium iodate ($KIO_3$) the least. Poor quality control during production and losses following production can prevent adequately iodized salt from reaching the consumer. It is equally important to create a high demand and preference for iodized salt to be used in households. There have been a number of cases where salt iodization was initiated but not sustained, resulting in a return to previous levels of IDD endemicity.

The major components of a national programme to eliminate IDD include: 1) advocacy, education and marketing; 2) intervention design and implementation; and 3) an overall system of quality assurance. Underlying all three components is a sustainable monitoring process.

### ADVOCACY, EDUCATION AND MARKETING

A national IDD elimination programme must operate in a supportive political climate with advocacy efforts creating awareness that all populations, urban and rural, rich and poor, are likely to be affected with IDD. Politicians and policymakers must understand the impact of the deficiency on the next generation, and the adverse consequences for national development if iodized salt is not widely available and used exclusively. This understanding must go beyond recognising goitre as the only manifestation of deficiency, but also to include awareness of the impact of any iodine deficiency on the developing brain. The potential economic impact of an iodized salt programme for livestock should also be emphasised, such as increased yields of meat, milk and wool, as well as improved reproduction.

Education efforts should mobilise all sectors in government and industry. Activities include assuring that everyone demands and uses iodized salt, and testing it for adequate iodine. In some situations, testing of salt can be included in school curricula, with test results brought to the attention of local government officials.

Marketing strategies must build consumer demand for iodized salt, with a willingness to absorb any minor cost differentials. Consumers must support the concept of quality assurance by demanding that iodized salt contain an adequate amount of iodine.

## INTERVENTION DESIGN AND IMPLEMENTATION

In most populations, the use of iodized salt will be the primary intervention for eliminating IDD. For universal (i. e. nationwide) salt iodization to be effective, the salt reaching households must have adequate iodine and the entire population must consume the salt. In some populations other strategies may be needed, such as use of iodized capsules or fortification of other food items. This manual focuses on salt iodization.

In developing a successful and sustainable salt iodization programme, the government must create an environment that facilitates the transition to production and importation of only iodized salt for human and animal consumption. The government must work in collaboration with the private sector to establish working relationships among business (producers and importers), government agencies, and non–government groups, that can be expanded to other fortification efforts as appropriate. This collaborative effort should address a number of issues, including:

- Formulation of legislation that will enable only salt with a specified iodine content (set out in regulations) to be imported or produced, thereby guaranteeing that only this salt is available in the marketplace.
- Regulatory mechanisms phased in over time, to ensure that the appropriate level of iodine in the form of iodate/iodide is added, labelling and packaging procedures are carried out correctly, warehouse storage procedures are followed, and monitoring and enforcement activities are understood and acceptable to all involved.
- Incentives provided to importers and producers, such as supplies, equipment, technical support, training, product endorsement and cooperative marketing, as well as tax, capitalisation and other more direct financial incentives to facilitate compliance.

Each country will have a unique solution to the sustained elimination of IDD through salt iodization, based on its particular size, economic resources, cultural and political context and market structure. National salt iodization programmes in different countries will be at different stages of implementation, but they will generally follow a common pattern:

*Assessment Phase:*

- Complete a situational analysis.
- Establish an understanding of the nature of the problem: brain development instead of goitre; its geographic distribution (urban and everywhere instead of just rural); and its magnitude (loss of cognitive capacity in all developing brains, not just causing cretinism and severe mental retardation).
- Attain high level multi–sectoral sponsorship for the programme.
- Prepare or update legislation and regulation.
- Collect key information for an advocacy and marketing campaign.
- Mobilise the salt importers, producers and traders, and strengthen public/private cooperation.

*Attack Phase:*

- Establish the legal mandate and regulatory environment to ensure implementation.
- Establish the capacity of producers and distributors to begin iodization of all salt.
- Implement a marketing plan.
- Phase in monitoring activities to ensure that adequately iodized salt is being produced and reaches households.
- Use action teams to find problem areas and implement solutions to these problems.

*Consolidation Phase:*

- Amend regulations to phase in quality standards for iodized salt.
- Move to more routine monitoring with a greater reliance on established government inspection to ensure high compliance with legal requirements.
- Undertake periodic assessment at the community level to ensure that IDD elimination has been reached and is maintained.
- Ensure that the programme elements are incorporated as routine activities in both government and business.

## QUALITY ASSURANCE THROUGHOUT THE PROGRAM

Sustained consumption of adequately iodized salt by all segments of the population requires continuous efforts to maintain quality, starting from production through use in the household. This total quality assurance of all programme elements will be done differently in each country, but will have a number of important common elements:

- Establishment with industry of "Best Practices" standards and quality assurance procedures for importation, production, distribution, and marketing of salt to ensure the appropriate iodine level is maintained.
- Establishment of a government inspection system and infrastructure with power to ensure that standards are being met, and corrective actions taken when they are not.
- Establishment of a monitoring system that can identify problems, provide solutions and determine that the corrective measures are taken. A rapid action response team could be established to assist in monitoring activities.
- Establishment of a strategy to verify the extent and nature of the IDD problem and document the impact of the programme on the population.

These quality assurance measures will require cooperation across many sectors at all levels of the government infrastructure and within the salt industry. Once a broadly shared vision of the elimination of iodine deficiency has been achieved, a number of approaches are likely to be common to all national programmes:

- There should be continuous dialogue among all involved, including government ministries and agencies, the private sector, and consumer groups.
- Iodization should be universal (i.e., nationwide) rather than targeted.
- Advocacy efforts should build continuous high level sponsorship and popular support.
- Regulatory requirements should be phased in gradually and cooperatively with the private sector.
- National development strategies and specific department workplans should provide sufficient manpower and resources to meet the targets.
- Monitoring activities should be included in each step of the salt iodization process.

> Responsibility for the provision of a quality product containing the regulated amount of iodine rests with the private sector in most countries. The role of government is to develop the guidelines and the regulatory environment in which the private sector operates.

## SALT MONITORING SYSTEMS

Monitoring provides the necessary information from which to make decisions about programme activities, such as adjustments in iodine levels and changes in storage procedures. While clinical and biological indicators such as goitre grading, thyroid stimulating hormone (TSH) and urinary iodine can be used to measure the impact of programme activities, proper monitoring of the salt iodization process followed by appropriate decisions to remedy problems will guarantee a positive impact.

Monitoring will be done at a number of levels and should be integrated with other activities. Regardless of the stage of the programme or the political and cultural factors affecting its implementation, monitoring of activities is critical to assure quality, success and sustainability. Some countries will have well established monitoring systems for other public health programmes, and salt monitoring can easily be incorporated. Others will have baseline information on iodine deficiency but limited development of an ongoing programme to monitor salt. In developing a monitoring plan, it may be helpful to consider different stages of programme development and phase in monitoring activities over time.

For each step in the monitoring process, it should be clear what the information collected is to be used for and whose responsibility it is to collect, analyse and report that information. Monitoring ensures that regulations are being met and corrective steps are taken when required. A monitoring system is not complete unless the full cycle of assessment, analysis and action is included. Table 1–1 provides a general framework for a salt monitoring system outlining the responsibilities of the private sector, government, and households/communities.

Table 1–1

## General framework for a salt monitoring system

| Decision level | What information is needed | Who manages the information | What monitoring activities are done |
|---|---|---|---|
| **PRIVATE SECTOR RESPONSIBILITIES** | | | |
| Factory | • Is the iodine content in salt adequate when produced and packaged?<br>• Are factory standards being met?<br>• Does the label reflect the salt iodine content in bags? | • Factory owners<br>• Plant manager<br>• Plant foreman<br>• Plant operator | • Internal quality assurance<br>• Facilitate external inspection by regulatory agency<br>• Visual inspection of equipment, salt processing and final product |
| Wholesaler/ Traders | • Is iodized salt being procured?<br>• Is the iodine content at the level claimed? | • Traders<br>• Salt wholesalers | • Inspection of bags<br>• Rapid testing of iodine levels in salt<br>• Review storage and transport practices |
| Retailer | • Is iodized salt being supplied?<br>• Is the iodine content at the level claimed?<br>• Is iodized salt affordable?<br>• Is iodized salt being purchased by all sections of the community?<br>• Is iodized salt stored properly? | • Shopkeepers | • Rapid testing of iodine levels in the salt<br>• Visual checks on salt quality (moisture, contamination) |
| **GOVERNMENT RESPONSIBILITIES** | | | |
| National | • Is iodized salt available to all areas of the country ?<br>• Is the iodine level in salt adequate upon import and production ? | • National IDD Committee<br>• Minister of Health<br>• Salt Commissioner<br>• Programme Manager | • External quality control of imported and domestic salt<br>• Inspection of internal quality assurance records<br>• Monitor proportion of households using adequately iodized salt.<br>• Price of iodized salt. |
| Province | • Is iodized salt available to all consumers?<br>• Is the iodine level in salt adequate at wholesale, retail and household level? | • Provincial Health Superintendent<br>• Food inspector | • Test salt at wholesale and retail level<br>• Assist with rapid testing of salt at household level |
| District | • Is iodized salt preferred by consumers?<br>• Is iodized salt available to households?<br>• Are there particular villages/ areas with low access to adequately iodized salt? | • District health workers<br>• Food inspectors<br>• Peripheral health workers<br>• Community health officers. | • Monitor salt iodine levels with rapid test kit<br>• Price of iodized salt: no excessive increase |
| **COMMUNITY/HOUSEHOLD RESPONSIBILITIES** | | | |
| Community/ Household/ Schools | • Is the iodine level adequate in salt being purchased and consumed?<br>• Is iodized salt more expensive than non–iodized salt?<br>• Is iodized salt labelling adequate? | • Community groups<br>• Household members<br>• School teachers | • Inspect packet label<br>• Rapid testing of salt with kits |

| What responses may be needed |
| --- |
| |
| • Make adjustments to iodization process<br>• Modify packaging, labelling, storage or procurement procedures |
| • Ensure that traders only transport iodized salt and do not accept non– iodized salt from factories.<br>• Improve storage practices at wholesale site; ensure first in first out |
| • Demand that only iodized salt be supplied from wholesalers<br>• Ensure fair pricing so that there will be minimal difference between iodized and non–iodized salt<br>• Improve storage practices at retail level |
| |
| • Develop legislation and enforcement procedures<br>• Demand that all imported and domestic salt meets government standards<br>• Provide technical support for production and monitoring of iodized salt<br>• Support communication efforts to increase awareness of salt producers, traders, retailers and consumers, including exclusive use of iodized salt and how to minimise losses<br>• Appropriate packaging: indication of weight, ppm, expiration date, etc. |
| • Promote use of iodized salt<br>• Enforce legislation |
| • Develop and impose local quality control procedures<br>• Promote use of iodized salt<br>• Inform retailers that only iodized salt should be sold for human and animal consumption<br>• Information, education, communication (IEC) on how to minimise losses of iodine, proper storage, etc |
| |
| • Demand retailer to stock only iodized salt<br>• Involve community leaders/ community groups in efforts to ensure availability and quality of iodized salt<br>• IEC on how to minimise losses of iodine |

What follows is a brief description of elements in a salt monitoring system. A more complete description, with sample forms, technical information and reference materials, is provided in subsequent chapters.

## SALT SITUATION ANALYSIS

At the outset, a situation analysis should be made of salt in the country starting from production and/or importation and following it through distribution channels until it reaches the household. A salt situation analysis helps understand the salt system and identify where monitoring may be needed. Loss of iodine at any point in the distribution may limit the success of the programme. This analysis should include a list of major producers or importers, production/import/export statistics, salt purity, packaging, transport and storage, retail prices and the proportion of households with iodized salt. These data need to be updated periodically according to the country situation, perhaps annually or biannually. More information on salt situation analysis is presented in Chapter 2. Essentially, the analysis should cover the major areas outlined in Table 1–2.

**Table 1–2**

## Major components of a salt situation analysis

### Production and Importation

- List major salt producers and/or importers in the country.
- Tabulate information on quantity of salt imported or produced, status of processing and iodization facilities, quality assurance mechanisms, packaging procedures, overall salt purity and level of iodization, and cost considerations.
- Note procurement costs for potassium iodide (KI) and potassium iodate ($KIO_3$).
- Describe capacity of the current producers (or importers) to meet national needs for iodized salt and the input necessary to ensure this capacity .

### Wholesale / Retail / Distribution Practices

- Follow the distribution of salt from the point of production or importation to the point at which it is available to consumers.
- Provide information on traders and transport (including cooperatives or transport associations); major warehouses and warehouse storage practices; packaging or repackaging issues; and retail outlet practices (storage and sales).
- Describe pricing issues, including government incentive and subsidy programmes, constraints to free market pricing, and marketing activities, both private and public.

### Salt Consumption

- Describe salt consumption patterns, including a general estimate of daily per capita consumption; consumer preferences for different types of salt; cultural practices with respect to purchase of salt; and factors affecting the stability of iodine in salt in households.
- Review previous consumer education efforts, and the capacity of the government and the private sector to influence consumer purchase of iodized salt.

### Legislation and Political Climate

- Review current legislation and regulations affecting salt iodization.
- List agencies responsible for enforcing regulations and procedures used to ensure corrective action is taken.
- Describe political climate in which monitoring activities are being developed, including past advocacy efforts; the level of commitment within various sectors and by various senior political leaders; and the support of key influential groups, such as medical associations and consumer groups.

## LEGISLATION AND REGULATION – IMPLICATIONS FOR SALT MONITORING

As salt iodization proceeds, legislation and regulations should be developed which specify that all salt intended for human or livestock consumption is to be iodized, and that enforcement mechanisms exist to ensure that government standards are met.[2] Regulatory bodies must be provided with the legal authority to inspect and to take corrective actions when inadequacies are identified.

In the formulation of salt legislation, the national food control authority or another standards agency is often given the legal responsibility and authority to test and inspect salt at different points of distribution, including importation, production, and wholesale. In addition, the Ministry of Health or another agency is often mandated to monitor availability and iodine content of salt at the household level, and perhaps in retail markets. There are several enforcement mechanisms to ensure that salt producers, traders and retailers comply with salt legislation, such as making registration and licensing contingent upon satisfactory compliance with the production, distribution and sale of iodized salt. These will vary from country to country. Effective enforcement will depend upon whether incentives and penalties have been clearly stated and whether the regulatory bodies have the authority to exercise them.

Salt producers are usually also required to make regular checks on the adequacy of salt iodine levels in every batch ("internal monitoring"); frequently by rapid test kit or by titration methods on a number of samples. The producers are also required to facilitate regular external checking of their findings by the appropriate government authority.

Chapter 3 provides more specific details and case studies concerning salt legislation, including some illustrations of what actions may be taken when iodized salt does not comply with government regulations at different distribution points.

## GENERAL FRAMEWORK FOR SALT MONITORING FROM PRODUCTION TO THE HOUSEHOLD

Once the legislation and necessary infrastructure are in place for salt iodization, a series of operational guidelines can be developed for ongoing monitoring of the availability and adequacy of iodized salt at any of five distribution points: importation, production, wholesale, retail and the household. The frequency and procedures required for collecting data at each of these points will differ.

Each country needs to evaluate its programmatic needs, institutional capabilities and resources when developing a salt monitoring system that will be efficient, sustainable, and provide timely information to facilitate the decision–making process.

There are several factors which could lead to loss of iodine from salt, including; 1) the purity of the salt, 2) the iodine compound used and amount added at the time of fortification, 3) packaging, 4) transportation and storage conditions, 5) length of time in distribution, and 6) climate. In addition, cultural practices, such as washing salt prior to cooking, may reduce the iodine content.

The overall responsibility for quality control at each monitoring point lies with the appropriate ministries (for example; Ministry of Trade for importation, Ministry of Industry for production and Ministry of Health for consumption).

The following information should be considered at each monitoring point along the salt distribution channel:

- Information needs
- Key indicators
- Data collection, analysis and reporting
- Responses and actions to be taken from data collected
- Sectors involved.

Monitoring production or importation should focus on ensuring that salt meets government standards, and this will primarily be the responsibility of the private sector. Once salt has left the production facility (or point of importation) monitoring becomes more complex. It is important to understand whether losses are occurring during distribution, and this may require monitoring at the wholesale or retail level. Finally, coverage surveys can monitor whether salt reaching households is adequately iodized. The amount of monitoring at each level will depend on the national situation. The closer these monitoring efforts get to the consumer, the more useful the measurement, but the higher the cost. Regardless of the monitoring priorities, ultimately the impact of iodization efforts will have to be demonstrated using biologic indicators.

As the situation improves in certain areas, it should be possible to modify the monitoring plan and collect data less frequently. A general overview of the procedures for monitoring iodine levels in salt from importation and production to the household are presented below.

## MONITORING AT THE POINT OF IMPORTATION

Monitoring imported salt depends upon national legislation and regulations, and guidelines for importers should be developed. Some countries will require imported salt to contain a certain level of iodine, whereas in others noniodized salt may be imported and then iodized within the country. In both situations it will be important to monitor points of entry. Although in some countries trade is informal and passes across borders which are not controlled, in most cases salt is imported by rail, ship or road. Importers must ensure that all salt meets the criteria stipulated in purchase orders.

The Ministry of Health or Ministry of Industry should authorise an agency to check all imported salt to determine if incoming shipments meet government standards. Once verified by appropriate authorities, the shipment is granted a "clean bill of findings" and is cleared for distribution into the country. If noniodized salt intended for human and livestock consumption is allowed into the country, steps should be taken to ensure that it is shipped to an iodization plant and that the same quality control procedures are followed as are used for iodizing domestic salt.

Producers, importers and regulatory agencies should jointly develop requirements to cover such situations where imported salt fails to meet government specifications. When a shipment is found to be of inadequate quality, any one of a number of actions may be taken, including:

- Attempting to have the problem corrected at the expense of the shipper.
- Publishing information on products (salt brands) with unfavorable inspections.
- Restricting or revoking import licenses.
- Imposing civil fines as designated in national regulations.
- Confiscating salt which is of poor quality (and perhaps arranging for re–iodization).
- Imposing criminal penalties.

Chapter 3 deals with issues in legislation and regulations (including penalties and actions) and Chapter 4 covers monitoring of imported salt in greater depth.

## MONITORING AT THE POINT OF PRODUCTION

Monitoring salt at the point of production is the most important step in a monitoring plan, and is undertaken through a combination of internal quality assurance measures and external inspection. The manufacturer should conduct its own monitoring, and moderate to large salt producers should be urged to hire a person specifically for internal quality assurance. If a batch of salt is not adequately iodized at production level, it should be re–iodized prior to distribution.

External monitoring of production level quality assurance should be done by government inspectors, e.g., Ministry of Health or Standards Bureau. External monitoring should be done through unannounced, random visits. All brands which have been approved as properly iodized by the external inspection could be allowed to use a "seal" or "logo" documenting that the salt is of good quality and meets the approval of the National Bureau of Standards, or some other regulatory commission which has the authority and is respected by consumers.

The government, in collaboration with producers, should develop requirements that spell out the steps to be taken in the event that standards are not met. Guidelines should specify exactly what authority has been granted to the inspectors from the government agency responsible for external inspection. Reference should be made to regulations and enforcement procedures that may be called into play to ensure timely corrective action. This might include fines, loss of tax incentives, loss of license, or other penalties. Chapter 5 provides more details on internal and external monitoring.

## MONITORING INTERMEDIATE DISTRIBUTION POINTS: WHOLESALE AND RETAIL LEVEL

The major wholesale distributors should be informed of any legislation or regulations concerning iodized salt and should be provided with rapid test kits to check for the presence and concentration of iodine in salt before it is released for retail sale. It is frequently difficult to monitor retail products. Monitoring at this level may be critical only if the iodine level of salt in households is found to be inadequate, when salt is known to be leaving factories with sufficient iodine concentrations. If there are deficiencies noted at the wholesale level, the factories supplying the wholesalers should be notified to take necessary corrective action. Monitoring retail shops may be useful for identifying villages with inadequate supplies of iodized salt. The issue of monitoring intermediate distribution points is covered in Chapter 6.

## MONITORING AT THE HOUSEHOLD LEVEL

When production monitoring reveals that adequately iodized salt is being produced in sufficient quantities, it will be essential to ascertain whether the product is reaching households with enough iodine. There are essentially two methods and purposes for monitoring household salt:

- **Coverage surveys** are used to determine the proportion of households with adequately iodized salt; these surveys are most often performed at the provincial or national levels.
- **Ongoing process monitoring** is used to identify high risk communities (e.g., "hot spots") where too few households have adequately iodized salt; this monitoring is most often done at the district level to obtain information on individual villages.

In order to track progress towards the mid-decade goal, information is needed to determine the proportion of households with adequately iodized salt. This will require a representative coverage survey of households, either at the national level, or in larger countries, at the provincial level. This is commonly achieved through cluster surveys which are discussed in Chapter 8. Representative household surveys need to be undertaken only once every two to three years, and can be undertaken as an addition to other national sample surveys, such as those on household budget and food consumption or Demographic Health Surveys.

If the primary purpose of household monitoring is to identify villages or small geographic areas where a high proportion of households are not using or do not have access to adequately iodized salt, then alternative sampling methods, such as lot quality assurance sampling (LQAS), may be useful. More details on monitoring using LQAS are presented in Chapter 9. Unlike representative household surveys, ongoing monitoring of household salt may be done more frequently to ensure that the salt iodization program is proceeding well and reaching all areas of the country. In particular, ongoing process monitoring should identify specific villages where the iodized salt supply is inadequate and corrective action is required. Ongoing monitoring may involve communities and could be linked to supplementary monitoring of retail outlets or wholesalers to determine why adequately iodized salt is not reaching households.

Where possible, salt monitoring should also enhance community awareness of IDD and its control. An educated community will demand iodized salt and the salt industry will have to comply. A well–informed community will also apply pressure on the government agencies to plan and implement the IDD control strategy effectively. There are many community groups which could become engaged in this process and provide leadership in such activities, including:

- Women's organisations
- Local Non–Governmental Organisations (NGOs)
- Youth groups
- Schoolteachers.

## SALT IODINE LEVELS

There is general agreement that a desirable daily adult intake of iodine varies from 100 to 300 μg.[4] To visualise this quantity, a particle less than the size of a pinhead is sufficient for one person for one month. There is no universal specification for the level of iodine to be added to salt to achieve this recommended iodine intake. The World Health Organization has recently published a statement on the safety of iodized salt.[4] Numerous factors influence the selection of an appropriate level for a given population, including:

- per capita consumption of salt in the region
- the degree of iodine deficiency in the region
- type of packaging
- transit losses due to heat and humidity
- shelf life required.

Per capita consumption of salt in different countries is usually from 5 to 15 gms per day for children and adults. Table 1–3 offers a sample calculation for fixing the level of iodization of salt.

Since levels of salt consumption vary and the amount of iodine lost will depend on climate, packaging material and storage time, it is not possible to establish a global standard for the quantity of potassium iodate which should be added to salt. Current levels of iodization in different countries vary from 20 parts of iodine per 1 million parts of salt, which corresponds to 34 grams of potassium iodate per tonne (which is possible where salt quality and packing is very good and where there is a high intake of salt), to 100 ppm iodine which is equal to 170 grams of potassium iodate per tonne (where there is poor salt quality, poor packaging, or low salt intake).

Most countries have fixed levels of 50 ppm iodine at the time of production (which corresponds to 85 ppm potassium iodate). WHO/UNICEF/ICCIDD has recommended levels of iodine for salt at different salt consumption levels, environmental and packing conditions. These are summarised in Table 1–4.[3–5]

National authorities should establish suitable iodine fortification levels in consultation with the salt industry. Regulations should stipulate a minimum and maximum level of iodine at the point of salt production and a lower level at the household to allow for storage and transit losses. For example, a population consuming 5 grams of salt per day in a warm, dry climate would require a minimum permitted level at production of 80 ppm for salt packaged in bulk and a minimum level at the household of 45 ppm.

Regulations must also clearly specify whether iodine levels refer to total content of iodine alone or to content of iodine compound ($KIO_3$ or KI). From the example above, 40 ppm of iodine is the same as 65 ppm as $KIO_3$, offering a ready source of confusion unless the chemical form is clearly identified. In general, it is recommended that the level be expressed as content of iodine alone, which emphasises the physiologically important component (iodine) and facilitates comparison of its different forms.

**Table 1–3**

### Sample calculation for fixing the level of iodization in salt

- Assume that the per capita daily requirement of iodine is 200 μg.
- Assume that the per capita salt consumption is 10 g per day.
- Level of iodine required is:*

$$(200/10)\ \mu g \text{ per gm}$$
$$= 20 \text{ parts per million (ppm)}$$

- Add compensation for transit and storage losses (additional 20 ppm).
- Level of iodization required

$$= 40 \text{ ppm iodine}$$
$$= 40 \times 1.685\ KIO_3$$
$$= 65 \text{ ppm } KIO_3$$

* 1 μg/g = 1 ppm

Table 1–4

## WHO/UNICEF/ICCIDD recommended levels of iodine in salt*

**Parts of iodine per million (ppm) of salt, (i.e. µg/g, mg/kg, g/tonne)**

| Climate and average per capita salt intake (g/head) | Required at factory outside the country | | Required at factory inside of country | | Required at retail sale (shop/market) | | Required at household |
|---|---|---|---|---|---|---|---|
| **Packaging** | Bulk sacks | Retail pack (< 2 kg) | Bulk sacks | Retail pack (< 2 kg) | Bulk sacks | Retail pack (< 2 kg) | |
| Warm moist | | | | | | | |
| 5 g | 100 | 80 | 90 | 70 | 80 | 60 | 50 |
| 10 g | 50 | 40 | 45 | 35 | 40 | 30 | 25 |
| Warm dry or Cool moist | | | | | | | |
| 5 g | 90 | 70 | 80 | 60 | 70 | 50 | 45 |
| 10 g | 45 | 35 | 40 | 30 | 35 | 25 | 22.5 |
| Cool dry | | | | | | | |
| 5 g | 80 | 60 | 70 | 50 | 60 | 45 | 40 |
| 10 g | 40 | 30 | 35 | 25 | 30 | 22.5 | 20 |

N. B. These are indicative initial levels that should be adjusted in accordance to urinary iodine measurement.

* Source: *Iodine and Health: eliminating iodine deficiency disorders safely through salt iodization.* WHO/NUT/94.4. WHO, Geneva, 1994.

Table 1–5

## Indicators for salt monitoring and criteria for adequacy†

| Process Indicator | Criterion of Adequacy |
|---|---|
| **A. Factory or importer level** | |
| A1. Percent of food grade salt claimed to be iodized | 100% |
| A2. Percent of food grade salt effectively iodized | 90% or more |
| A3. Adequacy of internal monitoring process | 90% or more |
| A4. Adequacy of external monitoring process* | 10–12 monthly checks per producer/importer, per year |
| **B. Consumer and district level** | |
| B1. Percent of monitoring sites with adequately iodized salt: • households (or schools) • district headquarters (including major markets) | Adequate in 90% of samples |
| B2. Adequacy of monitoring process** | 90% or more |

* Corrective action systematically taken within three hours in 90% of cases, following the lot quality assurance methodology.

** Monitoring undertaken in 90% of districts in each province, at household and retail level.

† Source: *Indicators for assessing iodine deficiency disorders and their control programs.* Review version, WHO/NUT/93.1. WHO, Geneva, 1994.

## CRITERIA FOR ASSESSING THE ADEQUACY OF SALT IODIZATION PROGRAMMES

Table 1–5 outlines indicators and criteria to track the progress of salt iodization programmes as recommended by the 1993 report of the WHO/UNICEF/ICCIDD Consultation on IDD Indicators.[4] For all of these indicators, more specific guidelines are provided in subsequent chapters of this manual.

For indicators A1 and A2, information should be provided by salt producers who will report to a central agency, e.g., Ministry of Industry, on the amount of salt distributed which meets national standards for iodization. In addition, external inspection will be used to verify the accuracy of factory reporting.

For indicators A3 and A4, adequate monitoring is defined through two processes:

- Requiring all salt producers/refiners to establish an internal system of monitoring and record keeping which can be examined by government inspectors (Chapter 5).
- Instructing government inspectors to take a minimum number of salt samples from each factory on a monthly basis and subject these to standard laboratory analysis (Chapters 10 and 11).

For indicators B1 and B2, adequate monitoring may be undertaken through the implementation of household or school–based surveys in which representative information is collected on the proportion of all households consuming adequately iodized salt. This may be done through sample surveys which provide precise prevalence (coverage) rates (Chapter 6 and Chapter 8), or through alternative sampling methods such as lot quality assurance sampling which indicate whether or not a certain threshold of coverage has been reached, without specifying the degree to which the threshold has been surpassed (Chapter 9).

## METHODS FOR MEASURING IODINE IN SALT

Two techniques available for measuring iodine levels in salt are described in Chapters 10 and 11, and are reviewed here briefly:

• **Rapid test kits** – These kits include small bottles which contain a stabilised starch–based solution, one drop of which is placed on the salt. The intensity of the colour which develops gives a semi–quantitative estimate of the iodine level, up to 50 ppm. A single bottle of reagent (10 ml) will allow about 80–100 tests, and a box of three bottles costs only US$0.40. More details on the composition, precision and procurement of rapid test kits are provided in Chapter 10.

Rapid test kits can be used routinely at each district or other sub–national unit headquarters. This testing would normally fall under the responsibility of health inspectors whose duties include testing the quality of foodstuffs. Salt samples found to be sub–standard should stimulate corrective action, with selected samples sent to a central laboratory for confirmation by titration. Rapid testing could be carried out on salt as it is iodized and before it is packed. It could also be used to check salt at the entry points into a country.

• **Standard titration method** – The titration of salt can be conducted in moderate to large factories, district health offices or hospitals with minimal laboratory equipment and trained technicians. There are slightly different standard methods used depending on whether iodine is in the form of potassium iodate, potassium iodide or if the test is to measure iodine in either form. Facilities are normally available somewhere at the national level, e.g., in a public health or food standards laboratory, but other laboratories at the provincial or district (or other sub–national unit) level and in some salt factories which may need to be equipped and personnel trained. The equipment for iodine titration is not elaborate and it is understood that UNICEF Copenhagen is developing a standard laboratory kit for establishing salt iodine testing which will cost less than US$1,000. This method is preferred for accurate checking of salt batches produced in factories or on arrival in a country, and in cases of doubt or contestation. Titration is recommended to determine the exact concentration of iodine in salt at various levels of the distribution system where accurate testing is required. However, this testing is too time–consuming and expensive for routine monitoring purposes throughout the country. There are further details in Chapter 11.

## RESPONSES AND FOLLOW–UP ACTIONS

Information generated from salt monitoring activities must reach those in a position to make decisions for corrective action. Several steps may be taken to reduce losses of the iodine content in salt, including:

- improving quality control at factories
- improving procurement practices to ensure constant supply of $KIO_3$ or KI
- reducing exposure to heat, light, moisture and contamination
- reducing transport time
- improving packaging
- improving storage practices
- altering cultural practices related to the use of salt that may affect iodine levels
- raising the iodization level required by law.

Salt monitoring should be under the general management of the National IDD Technical Committee or an equivalent body. The salt industry and the environmental service of the Ministry of Health should be represented in the National IDD Committee.
That committee should also take into account findings of any biological assessments, especially urinary iodine analysis from representative populations, when considering changes in the level of iodization.

Because of the important role of salt industry personnel for salt monitoring at the production level and of health inspectors for salt monitoring in the periphery, it is advisable to ensure adequate training and motivation for these key players in monitoring and follow–up procedures.

## SUMMARY

This iodized salt monitoring manual complements the "Technical Guidelines for Monitoring Mid-Decade Goals" already distributed to UNICEF field offices by UNICEF headquarters.[2] The manual deals with basic generic aspects of monitoring and quality assurance, and has been designed for several different users, who have various roles and responsibilities in the salt monitoring process. How monitoring activities are phased into each national programme and what specific activities are undertaken at each administrative level will be unique for each country. Monitoring activities do not replace the need to determine the impact of programme activities, as measured by biologic indicators. Impact assessment is not addressed in this version of the manual, but will be covered in the next version. While no manual can substitute for appropriate training, the concepts presented may also be useful for developing training curricula for monitoring activities. It is hoped that this manual will provide a reasonable set of tools which will enhance salt monitoring, serve to further strengthen existing systems and facilitate the design of new monitoring activities that support efforts toward universal salt iodization.

## REFERENCES

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3. World Health Organisation. Iodine and Health: Eliminating Iodine Deficiency Disorders Safely through Salt Iodization. WHO, Geneva, 1994.

4. Report of a joint WHO/UNICEF/ICCIDD Consultation. Indicators for Assessing Iodine Deficiency Disorders and their Control Programs. Review version, WHO/NUT/93.1, WHO, Geneva, 1993.

5. Venkatesh Mannar MG, Dunn JT. Technical Manual on Iodization of Salt. WHO/UNICEF/ICCIDD (in press), 1995.

# Chapter 2

# Salt Situation Analysis

## INTRODUCTION AND PURPOSE

Every country has its own unique pattern of salt supply, distribution and consumption. A successful salt iodization program must enter this system with minimum disruption in order to deliver the required quantity of iodine to the population at large. All countries with an iodine deficiency problem should first complete a situation analysis of salt from production and/or importation points through distribution channels to the household. This must be done carefully by a knowledgeable group, so the data compiled is useful and distributed widely to those involved in salt iodization. A full situation analysis may take several months to complete and, since salt is a food commodity, should involve representatives from a number of sectors, in addition to the Ministry of Health.

Several steps are required for a situation analysis and these may include:

- listing the major producers or importers
- compiling production/import/export statistics
- collecting information regarding salt quality, packaging, package sizes, transport and storage, retail marketing practices and prices
- reviewing information on household consumption
- reviewing the legislation, regulation and enforcement procedures and environment.

These data need to be updated periodically according to the country situation, e.g., every two years. The analysis will allow a better understanding of all the factors involved in the salt sector, clarify the logical monitoring points, and help identify constraints and challenges in achieving universal salt iodization.

Salt is produced by solar evaporation of sea water, underground or saline lake brines, or is extracted from natural underground deposits by dry mining or solution mining (dissolving the salt with fresh water and evaporating the brine). The salt may be sold directly in crude lump form or refined/dried/powdered before it is packed. Iodization is normally integrated at some stage in the salt production/refining system, preferably just prior to final packing for retail sale.

Distribution patterns vary from country to country. Salt passes from production to wholesale to the retail level before it is sold to the consumer. Often salt in bulk bags (50 or 75 kg) is repackaged in smaller packs for the retail market. Salt may also be dispensed in loose form from bulk bags.

The methodology and specific objectives for a salt situation analysis will depend upon the status of the iodization program in the country. Various stages of planning and implementing salt iodization programmes can be characterized as follows:

- non-existent
- exists but needing substantial modifications
- exists but needing strengthening
- exists and is effective.

The steps to be taken for different situations are summarised in Table 2.1.

**Table 2–1**

### Recommended action for different salt iodization situations

| STATUS OF SALT IODIZATION PROGRAMME | RECOMMENDED ACTION |
|---|---|
| Non-existent | Analysis should include a survey of the extent and severity of IDD by region, analysis of salt production and distribution patterns, and identification of the best point for iodization. Based on these data an implementation programme can be developed. |
| Exists but is in need of substantial modification | Salt importation, production, distribution and consumption patterns should be reviewed to identify the bottle necks that hamper successful implementation of the salt iodization programme. Analysis should include review of effective support measures such as quality control, social marketing, industry incentives, legislation and enforcement. |
| Exists but needing strengthening | Analysis should include an overview of current iodization procedures and the population reached, including those areas where iodization is not an integral part of salt production/ distribution, and discussion of factors inhibiting sustained universal salt iodization. |
| Exists and is effective | Analysis should include discussion of the key elements leading to success, estimates of programme costs and staff patterns, and possible points of stress for long term sustainability, including monitoring. |

## COMPONENTS OF A SALT SITUATION ANALYSIS

### Historic Context

Available information should be reviewed to understand the progression of activities in IDD elimination and salt iodization. This might include a brief discussion of efforts to establish iodization, estimated changes in IDD prevalence from the historic baseline, discussion of the general nature of public/private sector relationships, and a brief history of the IDD programme's evolution.

### IDD Prevalence

A brief description should be prepared of each of the most recent studies on IDD prevalence in different regions of the country, indicating date of study, population group, type of sampling and its representativeness, the clinical classification method used, and the clinical and laboratory results.

### Current Salt Production, Importation, And Refining

Salt is produced from a variety of **sources** of the total edible salt supply, both domestic and foreign (see below). A quantitative summary of sources is the first step in making a country assessment. Overall status of annual salt production, importation/exportation and refining in the country could be presented in the following format:

| Origin | Availability | Rock salt | Lake salt | Sea salt | Other | Total |
|---|---|---|---|---|---|---|
| From within country | | | | | | |
| Imported | | | | | | |
| Exported | | | | | | |

In countries with a limited number of **producers,** a listing of major salt producers and/or importers in the country and quantities handled annually should be made. Where there are several hundred or thousands of producers, the listing should include the major production centres, grades of salt produced, package size of individual units, and number of producers in each category, as illustrated below:

| Name and location of production centre | Grades by salt types and quantities | Package size of individual units | Number of producers in each category |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

Where applicable, details of **imports** should be provided. Who makes the orders for salt to be imported? How are decisions made regarding suppliers? Is this through open competitive tendering? What government agencies need to approve or certify the orders (such as Treasury, Customs and Excise, or Trade)? Standards for and types of controls, if any, should be included in the discussion. Tabulation of importers might be done as follows:

| Point of import | Names of major importers | Sources (country) and quantities (tonne/annum) | Grades of salt imported and quantities (tonne/annum) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

What standard inspection procedures exist for imports into the country? Does the government routinely use a third party (including private foreign agencies) to certify the quality of shipments?

Where applicable, similar information on the quantities of salt (iodized and non–iodized) exported yearly to each foreign country should be provided.

Current **use of salt available** (Production + Imports – Exports) should be presented:

| Use | Iodized | Non–iodized | Total |
|---|---|---|---|
| Human | | | |
| Animal | | | |
| Industrial | | | |

## Salt Refining and Iodization

The analysis of **salt refining and iodization**, should include information on:

- location and capacities of refineries and a description of the refining process
- the processes by which salt is iodized in the country wet or dry method
- the iodine compound used (iodide or iodate)
- the stabiliser (if any) added to the iodine compound
- the type of machine used
- the required level of iodization and the actual level reached in each plant
- control procedures in the plant and intervals at which carried out
- the packaging procedures and estimated proportion of households using iodized salt
- a list of all iodization factories, location, capacities and actual production (for most recent year), as shown in the table below:
- an estimate of the cost of iodization per ton of iodized salt
- details of procurement and distribution of potassium iodate, quantity and prices
- licensing system for salt producers, refiners and iodizations plants; name of state licensing authority.

| Name of iodization factory | Location | Ownership* | Iodized salt production capacity (tonne/annum) | Iodized salt produced (tonne/annum) |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

* State whether private, large or small company, company with other interests, government enterprise or parastatal, access to foreign exchange, and links to multinationals if any. For small producers state whether individual artisans or part of a cooperative.

### Distribution and Marketing of Salt

The analysis should include a review of:

- the major distribution channels for salt within the country from production/importation points through wholesale centres to retail outlets, the marketing channels and systems, selling units and current prices
- transport mechanisms, location of major wholesale and warehousing centres, quantities handled at each centre, storage and handling practices (including conditions and duration of storage and inventory control), packaging or repackaging practices
- prices for different grades and packing at production, wholesale and retail levels
- government incentives and subsidy programmes, if any
- constraints to free market pricing and marketing activities
- countries of export and/or importation
- knowledge, attitudes and practices of producers, wholesalers and retailers with regard to the importance of salt iodization, and their role in universal salt iodization.

### Salt Pricing

This analysis should address the following issues:

- How is the price that the consumer pays for salt determined? Possible options are listed below:
  - free market based on supply and demand; suppliers compete openly.
  - monopoly pricing; one large producer sets price.
  - some government intervention in pricing; establishment of maximum retail price for certain grades of salt.
  - total government price control; suppliers and distributers are required to charge prices established by government at different levels of distribution.

- Where government price control exists:
  - Which ministry and department determine these controls?
  - What information system is used to make this determination?
  - How often are prices reviewed?
  - What are the implications of price controls for the profitability, investment opportunity and development of the salt industry?

- Prices of salt, trends over recent years, highest and lowest prices (for different grades of salt).
- Comment on how much variation (elasticity) is possible for both price and consumer purchasing capacity.
- Compare salt price with the general consumer price index.

### Salt Consumption

A brief review of salt consumption practices including an estimate of daily consumption rates, consumer preferences for different types of salt, cultural practices with regard to purchase, storage and utilisation; and factors affecting stability of iodine in the salt in households should be included.

### Advocacy and Consumer Education

This should include information on:

- the level of political commitment at different levels, including support of key influential groups such as medical associations or consumer associations
- programmes and activities for informing and motivating the general public (or professionals or other specific groups) on IDD and the use of iodized salt
- consumer education efforts and the capacity of government and the private sector to influence consumer purchase of iodized salt
- level of sophistication of mass media efforts
- understanding on the part of political leaders of the importance of a national approach rather than limiting treatment of iodine deficiency to endemic regions. A review of research such as TSH levels in newborns in urban (lowest risk) areas may be helpful for use in advocacy efforts.

### Administration

This should include a review of the administrative infrastructure, including:

- the administrative structure for overseeing and monitoring the programme
- the staffing pattern both centrally and at the provincial and district levels
- budget issues and mechanisms for securing programme support.

**Monitoring and Regulation**
(see also Chapter 3, Issues in Legislation and Regulation)

This should include review of:

- current legislation and regulations affecting salt iodization including current standards
- standards for iodine content in salt at factory, retail stores and households
- mechanisms for monitoring iodine levels in salt at different levels, including discussion of laboratory capacity at different levels
- intervals at which these monitoring activities are practised, the procedures used (sampling location, collection methods, laboratory techniques), the coverage of the control programme (countrywide or limited to certain provinces/states)
- the number of samples analysed by place at which taken and iodine levels found (frequencies of classes of levels in ppm if the analyses are quantitative)
- enforcement mechanisms and procedures, agencies authorised to monitor laws and regulations at the production, wholesale and retail levels, and measures taken if insufficient iodization levels are detected
- problems faced in the systematic control of iodization at the national level, the measures taken to solve them, and recommendations regarding actions that should be taken.

## ACKNOWLEDGEMENTS

Parts of this chapter were adapted from the following publications.

Proceedings of the Fifth Meeting of the PAHO/WHO Technical Group on Endemic Goiter, Cretinism and Iodine Deficiency, Scientific Publication No. 502, PAHO, Washington DC, 1986.

Venkatesh Mannar, VM and Dunn, JT, Technical Manual on Iodization of Salt, ICCIDD/MI/UNICEF, (In press), 1995.

**APPENDIX 2.1**

## Checklist for Performing a Salt Situation Analysis

- ❑ Status of salt iodization programme
- ❑ Historic context
- ❑ Review of IDD prevalence
- ❑ Production, importation and refining
  - quantities by source, and current use
  - major producers/importers
  - import/export figures and standards
- ❑ Salt refining and iodization
  - refining sites and capacity
  - refining practices
  - iodization factories
  - costs
  - details on potassium iodate
- ❑ Distribution and marketing
  - distribution channels (wholesale to retail)
  - transport and storage
  - pricing at various levels
  - government incentives
  - free market issues
- ❑ Salt pricing
- ❑ Consumption
  - daily consumption rates and cultural practices
  - level of awareness as a consequence of advocacy
- ❑ Advocacy and consumer education
  - political commitment
  - consumer motivation/education
  - level of community participation
  - mass media
- ❑ Administration
  - infrastructure
  - staffing
  - budget
- ❑ Monitoring and regulation
  - legislation and regulation
  - standards
  - monitoring activities
  - laboratory issues
  - enforcement

# CHAPTER 3

# ISSUES IN LEGISLATION AND REGULATION

## INTRODUCTION

When programme managers understand the role of legislation and regulations in supporting an effective monitoring programme, their input into the establishment or amendment of such laws and regulations can support crucial activities related to salt iodization. A comprehensive, well-drafted salt iodization or food fortification law with implementing regulations includes monitoring activities which, in turn, support effective enforcement of legal requirements for iodized salt. Without effective enforcement, the government cannot ensure the universal availability of properly iodized salt.

Legal provisions on monitoring should cover two forms of monitoring:

- **Internal,** or **self-monitoring,** by the industry referred to as "Quality Assurance" (QA). With internal monitoring, the industry routinely examines its own processes and procedures to identify and correct any problem areas found.
- **External monitoring** by the government pursuant to its inspection and investigation powers. External monitoring provides the government with the information necessary to enforce the law whenever noncompliance with legal requirements is found.

Current abilities of the industry to produce high quality iodized salt and of the government food control authorities to inspect, sample, or analyse salt are often limited. This manual presents the ideal while recognising that many countries are not yet in a position to achieve all that is outlined in this chapter. It is hoped that this information will stimulate the reader to examine the current monitoring system and capabilities, and take steps to improve them within the constraints and possibilities existing in the country.

## ANALYSIS OF THE LEGAL ENVIRONMENT

Because of the integral role of legislation and regulations in a salt iodization program, there should be coordination and integration of programme requirements and legal requirements. As a first step, existing food legislation and regulations should be assessed for their ability to compel the adequate iodization of salt.

It may be necessary to engage local legal experts with knowledge of food fortification and legislative and regulatory drafting, because laws, legal systems, and customs vary from country to country. If the local expert is unfamiliar with food fortification issues, outside resources should be used as well.

A local legal expert might be found within the government, at the Ministry of Health or Justice, and/or in the country's legislative body. If there is a law school in the country, it may be able to provide appropriate expertise or referral to such an expert. PAMM, FAO, UNICEF and other international agencies may be able to help with an outside expert in food fortification and food regulation.

The FAO publication entitled *An Outline of Food Law* provides model legislation for a comprehensive food control law. A manual from PAMM and UNICEF entitled *Food Fortification Legislation and Regulations* and the publications referenced in its bibliography contain guidelines and models specifically for food fortification and salt iodization provisions for legislation and regulations, as well as background information. Appendix 3–1 contains a checklist for assessing the adequacy of the food law with respect to food fortification.

## LEGISLATIVE AND REGULATORY ACTIVITIES FOR PROGRAMME MANAGERS

Once the review of the existing law and regulations is completed, shortcomings discovered should be communicated to those with the political power to influence legislation and regulations. Any experts assisting with drafting amendments to the law and/or regulations also should be informed. If possible, the programme manager should seek input from the programme perspective to be incorporated into legal provisions governing salt iodization (see case study on the Philippines below).

If it is necessary to amend the existing law, sponsors must be found to introduce new legislation. Once introduced, the legislation might need lobbying for its passage. Additionally, monitoring is necessary to watch for any amendments proposed by others that might weaken the law and thus make the programme difficult to administer.

If the law is adequate but the implementing regulations need amending, programme managers should alert the appropriate person within the ministry charged with enforcing and administering the existing law. Programme managers then should become involved in establishing the standards and requirements that will be contained in the regulations.

Once the law and regulations are in place, programme managers should assist in the development of clear guidelines that will help the industry understand and comply with the quality assurance requirements of the law and regulations. These guidelines should be developed in collaboration with industry, NGOs, other Ministries, and other potentially affected groups.

Finally, if the proportion of properly iodized salt is low, the programme manager can provide input into the legal process if further legislative or regulatory changes are needed, such as increasing the level of iodine in production.

## Philippines

In the Philippines, the programme manager, with the assistance of UNICEF, has been monitoring proposed legislation for salt iodization and has been able to provide programmatic input to the senators and representatives who introduced the legislation. The legislative sponsors were receptive to concerns expressed by the programme manager and UNICEF about initial drafts of the legislation and even invited them to testify before the house subcommittee sponsoring the salt iodization bill. It appears that the concerns expressed by the programme manager and UNICEF will be addressed to some degree in the final version of the legislation.

### LEGAL PROVISIONS FOR MONITORING

Provisions in the law and regulations directly related to monitoring should involve the areas of:

- Quality assurance and recordkeeping.
- Government inspections and investigations.
- Enforcement of legislation and regulations.

Provisions indirectly related to monitoring should involve:

- Standards for iodized salt, including level of iodization and other constituents.
- Requirements for packaging, labelling, transport, and storage.
- Licensing or registration of manufacturers, importers, and sellers, if applicable.

#### What Provisions Should Go in Legislation and Regulations?

The law should be flexible so that as needs change, new legislation does not have to be enacted to amend the existing law. Introducing and passing legislation can be a very political and time- consuming process. To prevent undue constraints, the law should set out general requirements and place the details in the implementing regulations which may be more easily enacted and amended by the ministry charged with overseeing and administering the law. For instance, the law would generally require that all salt intended for human or animal consumption be iodized with potassium iodate, whereas specific levels of potassium iodate for iodizing salt would be found in the regulations for implementing that law.

The law should require salt manufacturers, importers, transporters, distributors, and sellers to undertake periodic quality assurance activities as required by the regulations. In addition, the law must give the ministry (or other appropriate body) broad authority to inspect and investigate the premises of any place where salt is manufactured, received for sale or distribution, sold or otherwise found, or where it is suspected that salt is manufactured, received, sold, or found. The regulations can specify the procedures for inspections. Finally, the law should specify the penalties and incentives available to the government for enforcement as well as certain enforcement procedures and protections. The regulations can provide the mechanisms and procedures for assessing penalties. Table 2–1 summarizes matters that can be appropriately included in the law versus in the regulations.

## India

In India, the law itself sets out the level of potassium iodate required in salt. This level of iodine has been found to be too low. However, since the law establishes the level of $KIO_3$, the government cannot require a higher level of $KIO_3$ and manufacturers and others cannot on their own increase the level of $KIO_3$ without violating the law. A law change through the legislative process is required to increase the level of $KIO_3$ in iodized salt. In the meantime, the government's IDD programme is hampered by its inability to change permissible iodine levels for salt. If the $KIO_3$ level were set out in the regulations rather than in the law, the MOH could change the level through its rule-making process.

**Table 2-1**

## Matters appropriately included in the law versus in the regulations.

| Law | Regulations |
|---|---|
| Requirements for compulsory iodization of all salt intended for human or animal consumption with $KIO_3$ in compliance with all regulatory requirements | Potassium iodate levels at manufacture, import, wholesale, and retail levels |
| Requirement that manufacturers, importers, wholesalers, retailers, and transporters must undertake periodic QA activities | QA activities to be undertaken, such as routine equipment and instrument calibration, and sample testing of iodine content |
| Authority of the government to inspect or investigate any premises where salt is manufactured, imported, received, held, stored, or found, or where it reasonably is believed this is the case | When the government may inspect or investigate, what the government may look at, or how the government may test salt samples |
| Penalties for non-compliance, including fines, license suspension or revocation, adverse publicity, or confiscation | The circumstances under which each penalty or incentive may be applied, the amounts of fines and periods of suspension, and the procedural steps for imposing penalties |
| Incentives for compliance, including transport and display priority for iodized salt, exclusive use of logo, and favorable tax treatment | |

### Phasing in More Stringent Requirements for Iodized Salt Over Time

Ultimately, iodized salt should meet rather stringent quality standards, such as low moisture content, small particle size, and high purity, so that the level of iodine added to the salt will be retained for as long as possible. Moreover, proper packaging is important to protect iodine content against environmental conditions that might cause diminution . However, in many countries, the salt industry is not financially or technically equipped for a full scale improvement of production and packaging activities. Thus, industry might resist iodizing salt if initial standards are too stringent.

If the salt industry is not yet prepared to meet new stringent standards, the government might want initially to require that all salt be iodized with high concentrations of iodine rather than simultaneously requiring wholesale improvements in salt production and packaging. For example, the law could require universal salt iodization by December 31, 1995, while granting the ministry administering the law the authority to phase in more stringent production and packaging requirements over time. This approach will get iodized salt out to the population relatively quickly so that IDD can begin to be addressed immediately. Once the new requirements to increase quality and purity of salt are phased in, the required iodine levels can be lowered.

## MECHANICS OF QUALITY ASSURANCE

Regulations should require that specific QA activities examine:

- **Level of potassium iodate:** to ensure the appropriate level of $KIO_3$ in the salt at manufacture, import, wholesale and retail, and the overall quality of the iodized salt.
- **Packaging:** to ensure the salt is properly packaged in bags made of non-porous material with a lining of high density polypropylene or retail packs of the proper size.
- **Labelling:** to ensure the label contains the legally mandated information, such as:

– Iodine level (expressed in ppm) and other principal ingredients
  – Lot or batch number
  – Manufacture and expiration date of the salt
  – Net weight
  – Price

- **Identification and license number** of the manufacturer, importer, wholesaler and retailer so that noncompliant salt can be traced
- **Authorized use of logo**
- **Storage instructions**

• **Storage, transport, and display of salt:** to minimise losses of iodine by avoidance of direct or strong light, excessive heat, humidity or water, contamination, mixture with noniodized salt, inadequate ventilation, excessive storage time, hooks or other sharp instruments, or stacking on any surface less than four inches above floor level.

The law also should authorise the appropriate ministry to specify regulations for reporting QA, such as a log of sample tests. In addition, it should authorise the ministry to regulate what should be done with improperly stored salt to keep it out of the human and animal consumption market.

Specific activities for QA could be set out in guidelines developed by the government in collaboration with industry. Initially, the law might merely require the industry to monitor its production, packaging, labelling, and storage activities, without specifying what these activities must be. Then, after industry and government have had time to adjust technically and financially, more stringent QA requirements could be set out in legally binding regulations. Input from industry will ensure that QA requirements are feasible and effective.

## EXTERNAL MONITORING: GOVERNMENT INSPECTIONS AND INVESTIGATIONS

The government must have legal authority to conduct periodic inspections of salt manufacturers, wholesalers, retailers, and others in the salt manufacture/distribution chain. It also must have authority to investigate complaints and reasonable suspicions of noncompliance with legal requirements.

Village health workers, consumer groups, and other nongovernmental entities may be able to carry out salt monitoring activities, such as simple tests with permission from households or stores. They also can determine the origin of defective salt and pass this information on to the government. The government then would verify noncompliance before taking any enforcement action.

Inspection and investigation authority should be vested in the most competent government ministry or agency and at the level (local, provincial, district, national) least likely to be dominated by political influence or corruption. If political influence is likely to interfere with external monitoring, some extra-governmental oversight of the whole process might be called for.

## ENFORCEMENT

Enforcement should also be vested in the government ministry or agency and at the level most competent and least likely to be dominated by political influence or corruption. Political interference with enforcement seems to be a universal problem that must be anticipated and dealt with in legislation and regulations.

## WORKING TOGETHER: COLLABORATING TO ENSURE EFFECTIVE MONITORING

Programme managers, government enforcers, legislative and regulatory drafters, NGOs, and industry and consumer representatives can and should work together, both formally and informally, on the following activities:

- Establishing effective and realistic QA activities
- Developing guidelines for industry
- Sharing monitoring information
- Applauding or rewarding good performance by businesses
- Developing a logo for iodized salt
- Training

A working group should be established to link government, industry, NGOs, and agencies as a mechanism for continuous dialogue, drawing upon the expertise of each to ensure fair and feasible inputs into the system.

**APPENDIX 3-1**

# RESOURCES

Useful publications include:

Food Fortification Legislation and Regulations (Draft). Atlanta: PAMM, UNICEF, 1994.

Gerard. An Outline of Food Law. Rome: FAO, 1983.

Guidelines for Developing an Effective National Food Control System. Rome: FAO, WHO, 1979.

International Conference on Nutrition: Final Report of the Conference. Rome: FAO, WHO, 1993.

Management of Food Control Programmes. Rome: FAO, UNDP, 1989.

**APPENDIX 3–2**

# Checklist for Assessing the Adequacy of the Country's Existing Food Law

An adequate food law should meet at least the following criteria:

- ❑ Definition of "food" or "salt" is broad enough to cover salt intended for human or animal consumption
- ❑ Definition of "adulturation" does not preclude adding fortifying agents to food
- ❑ All terms are clear and unambiguous
- ❑ The law covers all persons in the salt manufacture-distribution chain
- ❑ The Ministry administering the law is vested with broad powers to develop implementing regulations
- ❑ The law requires the food industry to engage in routine quality assurance activities
- ❑ The law authorizes the regulations to prescribe requirements for packaging, storage, and transport of iodized salt
- ❑ The Ministry administering the law is vested with broad investigation powers
- ❑ The Ministry is vested with meaningful enforcement authority, including a range of penalties and incentives
- ❑ The law contains adequate legal protections for persons accused of violating the law

# CHAPTER 4

# MONITORING IMPORTED SALT

4

## In monitoring imported salt, it is essential to know:

- Where does imported salt enter the country?
- How much salt is imported into the country each year?
- How much of the imported salt is coarse, crushed (fine), or refined?
- How much of the imported salt is reported to be iodized?
- Which compound is used to iodize the salt, potassium iodate or potassium iodide?
- What proportion of the imported "iodized" salt meets government standards?
- The contribution imported salt makes toward meeting national iodized salt requirements

### KEY INDICATORS

- The amount of iodized salt imported
- Proportion of imported salt meeting government standards
- Adequacy of external monitoring process (number of monthly checks per importer per year)

### DATA COLLECTION, ANALYSIS AND REPORTING

- Routine verification and monitoring of all salt upon importation

### RESPONSES AND ACTIONS

Actions in response to shipments found to be inadequately iodized could include:

- Correct the problem at the expense of the producer, importer, or shipper.
- Publish information on products with unfavorable inspections.
- Restrict or revoke import licenses.
- Impose civil fines.
- Confiscate inadequately iodized salt and destroy it.
- Re–iodize inadequately iodized salt.
- Allow inadequately iodized salt to be used as industrial grade salt only.
- Impose criminal penalties.

## INTRODUCTION

Monitoring imported salt is an important component of national IDD elimination programs. Some countries import no salt while others import all of their salt; most countries fall somewhere between these two extremes. For example, about half the countries in Africa import all or nearly all of their salt. The specifics of monitoring imported salt will depend upon national legislation and regulations. Some countries may require imported salt to contain a certain level of iodine whereas others may allow noniodized salt to be imported and iodized within the country. Legislation and regulations which apply to labelling and packaging are also important. Points to be considered when salt is imported are described in Table 4–1.

Table 4–1

## Possible actions on imported salt based on national legislation/regulations and the availability of iodization equipment.

| | | Legislation/regulations require all imported salt for human and animal consumption to be adequately iodized prior to entry into the country? | |
|---|---|---|---|
| | | **Yes** | **No** |
| Salt iodization equipment readily available in-country? | **Yes** | If salt passes inspection, no action necessary. If salt fails inspection, potential actions include:<br>1. Require iodization of salt.<br>2. Allow salt to be sold but apply warnings or fines to importer, producer, and/or shipper.<br>3. Allow salt to be used as industrial grade only.<br>4. Confiscate and destroy salt. | If salt is adequately iodized, no action is necessary. If salt is not iodized or inadequately iodized, salt should be shipped to an iodization plant for iodization. (This salt should then fall under legislation and regulations applied to domestically produced salt). |
| | **No** | If salt passes inspection, no action is necessary. If salt fails inspection, potential actions include:<br>1. Allow salt to be sold but apply warnings or fines to importer, producer, and/or shipper.<br>2. Allow salt to be used as industrial grade only.<br>3. Obtain salt iodization equipment for iodizing/reiodizing salt.<br>4. Confiscate and destroy salt.<br>5. Do not allow salt to be unloaded within the country | If salt is adequately iodized, no action is necessary. If salt is not iodized or inadequately iodized:<br>1. Obtain salt iodization equipment and iodize salt.<br>2. Develop appropriate legislation and regulations to assure imported salt either be iodized prior to arrival or iodized within the country. |

## LEGISLATION AND REGULATIONS FOR IMPORTED SALT

Government and importers should work collaboratively to develop or modify appropriate legislation and regulations for imported salt. Decisions need to be made concerning where the salt should be iodized (i.e., prior to arrival or within the country), how much iodine the salt should contain, who is responsible for inspecting the salt, and what the penalties are for not meeting acceptable standards. (See Chapter 3 for more details.) It is in the importers' interest to assure that legislation and regulations are fair and evenly applied to all importers.

The regulations should specify the level of iodization required at the point of importation. Salt importers and their producers must take into account the loss of iodine from the point of production to the point of importation. This may require some judgment and experience by the producer and may be a matter of trial and error. Research into losses of iodine during shipment may be useful. Dramatic losses in iodine may occur if storage conditions are wet or dirty.

Legislation and regulations should identify the agencies responsible for sampling and enforcement, and should include clearly defined actions and responses to be taken when imported salt does not meet specifications. All of these controls may need to be stricter and more frequently applied in the early stages of a monitoring program. Once the system is operating smoothly, the frequency of sampling could be reduced.

It is important to assure that salt imported for industrial use is labeled "not for human or animal consumption" and that it is delivered to industrial users only. Some may be tempted to declare their salt for industrial use, but then to distribute it for human or animal use.

## IDENTIFY POINTS OF ENTRY

There are often many points through which salt crosses into countries. Salt may be brought in by ships, boats, trains, trucks, or animals. At the larger points of entry it should be relatively easy to identify the key importers. Where importation of salt is less formal, such as by camels between Djibouti and Ethiopia or dhows (small boats) between small ports, monitoring is more difficult.

## IDENTIFY RESPONSIBLE GOVERNMENT AGENCIES AND INTERNATIONAL AGENTS

Imported salt is commonly managed by the private sector under the control of the government, e.g., Ministry of Trade or Ministry of Commerce. Regulations and standards may be developed and supervised by another body, e.g., a Standards Board. The Ministry of Health may not be involved in monitoring at borders unless it has specifically been mandated as the responsible agency. Health inspectors from the Ministry of Health, who routinely check food quality, or customs officers who are usually under the Ministry of Finance or the Ministry of Trade, could be trained to perform inspections.

Some governments may contract with an agency to check the quality of imported commodities at the point of manufacture. For example, the Swiss company Société Général de Surveillance (SGS) performs quality checks for a number of governments. Similar organisations include Bureau Véritas and Lloyd's Inspection Agency. These companies are increasingly contracted to verify the quality and quantity of imports shipped, and to assure reasonable pricing.

Another method is to make the importers responsible for testing the salt as it enters the country, with government agencies providing external quality assurance (similar to the concept of internal quality assurance undertaken by salt producers described in Chapter 5). Importers would be required to test salt and keep records of all tests performed. These records would be available for review by the designated government agency which would also perform periodic tests on salt samples. This arrangement is particularly appropriate after imported salt has been monitored for some years.

Some precautions may have to be built into the systems against bribing salt monitoring officers to assure shipments pass inspection. One long-term solution is to ensure that other officers are present during testing. If the public at large is aware of the IDD problem, they will demand that, for their own protection, the salt monitoring be correctly done. To avoid potential problems, the monitoring of imported salt could be a shared responsibility between two government services, e.g., Health and Commerce.

## SENSITIZE SALT IMPORTERS ABOUT IDD AND ITS PREVENTION

When discussing with importers the purpose of IDD elimination and the importance adequately iodizing salt, the proper storage of iodized salt by avoiding exposure to light, heat, moisture, dust and other contamination, should be emphasised.

## DEVELOP STANDARD PROCEDURES FOR MONITORING IMPORTED SALT

It is difficult to develop specific requirements for monitoring imported salt which applies to all countries due to the differences in salt trade practices and infrastructure. However, some common considerations have been outlined above. Each country will need to develop and implement standard procedures for monitoring imported salt. The following possible steps can be adapted to any country.

### Steps in Monitoring Imported Salt

- ❑ Review all shipping documents for imported salt.
- ❑ Ensure that the initial tender document correctly states legislative and regulatory requirements for imported salt.
- ❑ Prior to import into country, designate regulatory authorities to check for proper specifications for salt quality and iodine levels before approving the purchase order.
- ❑ Upon import, define what constitutes a "lot" for testing.
- ❑ Determine the minimum number of samples to be drawn for testing and threshold levels to assess whether a lot passes or fails based on lot quality assurance sampling (LQAS) procedures (see Chapter 9).
- ❑ Undertake testing of salt samples to determine if lot is acceptable.
- ❑ If lot passes, grant "seal" or other certification.
- ❑ If lot fails, initiate corrective or punitive responses.

## DEFINE WHAT CONSTITUTES A "LOT"

When monitoring imported salt, it is first necessary to determine what constitutes a "lot." A standard policy should be established on a country–by–country basis. This may be difficult due to the wide variations in transport and quantities ordered. Some importers may order only a few hundred kilograms while others order several hundred or thousands of tonnes at a time.

For a particular order, designate whether the order as a whole or some well–defined segment constitutes a lot for testing. In the case of a large shipment consisting of more than a single boxcar, each boxcar may be considered as a separate lot. Making the definition too small could lead to prohibitive monitoring costs and logistics, while too large a definition could lead to an incorrect assessment if the potassium iodate is not uniformly distributed throughout the salt shipment.

## DETERMINE CRITERIA AND MINIMUM SAMPLE SIZE FOR ADEQUACY

Sample size considerations for monitoring imported salt along with an example are provided in Chapter 9.

## TITRATION VERSUS RAPID TESTING OF SALT

The decision as to whether to use the titration method, the rapid test kits, or a combination of the two will depend on the quantity of salt imported and the capacity to undertake titration methods. (The methods for testing salt are described in further detail in Chapters 10 and 11.) In ports where large quantities of salt are imported, it would be reasonable to require the titration method or a combination of rapid test kits and titration. At sites where salt is imported in small quantities, the rapid test kit could be used with occasional verification by the titration method. Countries will need to decide on a cut–off amount above which titration methods must be used and below which rapid test kits are acceptable. In addition, a decision would have to be made on the frequency of titration testing in the smaller ports, e.g., once a month.

## RESPONSES

If a salt shipment passes inspection, there should be some method of certification, such as a seal from the Department of Customs. If the shipment fails inspection, the corrective actions need to be carried out consistently. Three responses which can be taken are:

- The salt is sent back to the manufacturer. This is costly and in many situations may not be a practical option.
- The salt may be re–iodized. The importing country may not have a facility to iodize salt, but in the long run it may be desirable to set up at least one small capacity plant.
- The salt is accepted in spite of its inadequate iodine, but a warning is given to the importer. In such cases the salt may be used for food in spite of the low levels of iodine or used for industrial (non–food) purposes only.

### Checklist for establishing imported salt monitoring

- ❑ Develop legislation and regulations to include imported salt and stipulate a minimum iodine concentration OR require imported salt to be iodized/re–iodized within the country.
- ❑ Identify the sites where salt enters the country.
- ❑ Identify organisations responsible for monitoring imported salt.
- ❑ Sensitise importers about IDD and the importance of iodizing all salt.
- ❑ Develop standard procedures for government regulatory authorities to assure that purchase documents are properly specified before approving orders.
- ❑ Develop standard procedures for authorities to inspect imported iodized salt to ensure that it meets requirements.

# CHAPTER 5

# INTERNAL AND EXTERNAL QUALITY ASSURANCE

## INTRODUCTION

The most critical component of a national universal salt iodization programme is to ensure that all salt produced or imported for human or animal consumption is adequately iodized. This section provides information on monitoring at the level of production. **Internal quality assurance** refers to the procedures used by the salt producer or processor to ensure that their product consistently meets internal requirements and government and industry standards. This internal process should be complemented by periodic inspection by a government regulatory body, a process called **external quality assurance**, to confirm that products and procedures meet government standards. The principles of internal and external quality assurance outlined in this chapter also apply to imported salt requiring iodization or re-iodization.

A comprehensive salt situation analysis is important for identifying producers and importers, and for understanding the broader context in which monitoring is to be done (see Chapter 2). The development of internal and external monitoring activities and requirements will also be affected by national legislation and regulations (see Chapter 3).

Quality assurance verifies that the manufacturing process is consistent and that the level of iodization is adequate and uniform in products released for shipping. Uniformity is particularly important since large sacks of iodized salt are often repackaged into smaller units, and daily consumption of iodized salt is small. The data collected at the production level can be used by the government to monitor the quantity, quality, production costs, and distribution of iodized salt.

The capacity of producers to undertake quality assurance will depend greatly on trained staff available to perform the procedures. The smallest producers may only be able to check their equipment, and perform semi-quantitative salt analysis periodically. Large producers may establish a separate quality assurance department. All producers should validate their mixing processes and perform quantitative salt analyses in a titration laboratory.

Concepts and sample log sheets presented in this chapter can be applied to small, medium, and large producers. While there are no exact guidelines classifying producers, a suggested classification based on production in tonnes of salt per year is as follows:

| Production facility | Annual production (tonnes/year) |
|---|---|
| Small | Less than 1,000 tonnes |
| Medium | 1,000–4,999 tonnes |
| Large | 5,000 tonnes or greater |

The major differences in quality control between small and large producers are the frequency of measurement and the sophistication of the laboratory and testing methods.

### DIFFERENCE BETWEEN QUALITY ASSURANCE AND QUALITY CONTROL*

**Quality assurance** is a wide-ranging concept which covers all matters which individually or collectively influence the quality of a product. It applies to equipment, product design, supplies and logistics, management and human resource development, and all elements designed to ensure that products are of the quality required for their intended use.

"**Quality control**" is the part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organisation, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations, but must be involved in all decisions which may concern the quality of the product.

* According to World Health Organization Good Manufacturing Practice for Pharmaceutical Products (PHARM/90.129/Rev.3a).

## THE IODIZATION OF SALT

Both the process and the end product of salt iodization need monitoring. In order to develop a comprehensive monitoring plan, it is important to understand the basic procedures used in the iodization process, and the differences in procedures used by small, medium and large producers. The basic process of fortifying salt with iodine is relatively simple, but a number of steps should be taken to ensure consistent quality production.

### Salt Iodization Techniques

Salt can be fortified by adding a liquid solution of potassium iodate to salt (wet method) or by adding dry potassium iodate powder (dry method). In the wet method, potassium iodate is first dissolved in water to make a 4% solution (by weight), that is, 4 kg of potassium iodate mixed with 96 kg (or litres) of water to give a final 100 kg (or litres) of solution. This solution is sprayed on the salt at a uniform rate.

The success of iodization using the wet method depends on a steady and uninterrupted flow of salt and a uniform spray of solution. Evaporation of the iodate solution and obstruction from crusting in the spray nozzle may impair the mixing process.

In the dry method, potassium iodate is first mixed with salt and an anti–caking agent like magnesium carbonate to form a "pre–mix." The pre–mix is then combined with salt in a continuous mixer at a constant rate, usually for 10–15 minutes. The pre–mix frequently has the following formula:

| | |
|---|---|
| Salt | 90% |
| Anti–caking agent | 9% |
| Potassium iodate | 1% |
| | 100% |

The success of the dry method depends on the uniformity of the pre–mix and on the consistency of mixing.

### Level of Iodization

WHO recommends a minimum daily intake of iodine between 100 and 300 micrograms per day. There is no universal specification for the level of iodization in salt. Numerous factors must be considered to determine the recommended level at production and the practical amounts used should be decided upon by the appropriate national authorities. WHO\UNICEF\ICCIDD guidelines estimate these levels according to climate and daily per capita salt consumption:

**Table 5–1**

**WHO/UNICEF/ICCIDD recommended levels of iodine in salt***

**NOTE:**

Parts per million (ppm) = microgrammes per gramme, milligrammes per kilogramme, grammes per tonne

168.6 mg potassium iodate* = 100 mg of iodine

*The quality specifications of potassium iodate are given in Appendix 5–2.

| | Parts of iodine per million (ppm) of salt, (i.e. µg/g, mg/kg, g/tonne) | | | |
|---|---|---|---|---|
| | Required at factory outside the country | | Required at factory inside of country | |
| | Packaging | | | |
| Climate and average per capita salt intake (g/head) | Bulk sacks | Retail pack (< 2 kg) | Bulk sacks | Retail pack (< 2 kg) |
| Warm moist | | | | |
| 5 g | 100 | 80 | 90 | 70 |
| 10 g | 50 | 40 | 45 | 35 |
| Warm dry or Cool moist | | | | |
| 5 g | 90 | 70 | 80 | 60 |
| 10 g | 45 | 35 | 40 | 30 |
| Cool dry | | | | |
| 5 g | 80 | 60 | 70 | 50 |
| 10 g | 40 | 30 | 35 | 25 |

* from *Iodine and Health: eliminating iodine deficiency disorders safely through salt iodization*, (WHO/NUT/94.4) WHO, Geneva, 1994.

## INTERNAL QUALITY ASSURANCE

### From internal monitoring, it is essential to know:

- Whether internal quality control measures ensure that industry standards are being met, and whether the process of salt iodization is proceeding effectively
- Whether adjustments in the iodization process are required
- Whether production is adequate to ensure that needs for iodized salt are being met in the aggregate, overall population.

### KEY INDICATORS

- Number of tonnes of salt produced
- Number of tonnes of iodized salt produced
- Monetary sales of iodized salt
- Percent of food grade salt claimed to be iodized
- Percent of food grade salt effectively iodized (meeting industry standards in terms of iodine content, packaging and labelling)
- Adequacy of internal monitoring process

### DATA COLLECTION, ANALYSIS AND REPORTING

- Routine reporting: ongoing quality control
- Records available for government inspection

### RESPONSES AND ACTIONS

- Development of guidelines for internal monitoring procedures
- Assigning staff for quality control duties
- Development of guidelines for corrective measures
- Improvement in production procedures, including iodization methods, packaging and labelling

### SECTORS INVOLVED

- Private sector: In most instances individual producers take this responsibility. Small producers could form cooperatives and contract services for monitoring their salt.

### Collaboration Between Public and Private Sectors

Together, the government and iodized salt producers should establish a system that provides continuous feedback for quality improvement. This system should be designed to:

- Assist iodized salt and intermediary component (raw material and pre–mix) producers to refine their processes to reduce the chances of iodine degradation and improper mixing, and to improve product uniformity.
- Create a technical forum to bring together the salt industry, regulatory agencies, and distributors to discuss continuous quality improvement of food fortification.
- Serve as a regulatory tool for enforcement of food fortification standards.

## INTERNAL QUALITY ASSURANCE FOR MEDIUM AND LARGE-SCALE SALT PRODUCERS

With proper packaging and reasonable shipping times, salt leaving the production site properly iodized to meet government and industry standards will usually reach the consumer with adequate amounts of iodine. Thus quality control procedures during production are critical. Producing a quality product requires careful attention to many details at all levels, from purchase of equipment and supplies to ensuring consistency during all steps in production.

### Salt Refining and Iodization Processes

Medium and large producers generally use a **continuous** process for salt iodization because maximising output demands complex equipment. In this process, salt moves on a conveyor belt or helicoidal transfer system and potassium iodate solution is sprayed on the salt continuously. Potassium iodate is most commonly added in a liquid form, but solid to solid mixing is also used by some producers. If salt is lumpy, crushing and further refinement is needed prior to mixing.

A description and approximate costs of the equipment needed for continuous processing are shown in Table 5–2.

UNICEF Supply Division, Copenhagen, has issued a supply newsletter containing prices of equipment. Further information is available through UNICEF country offices from UNICEF Supply Division: Procurement Officer, Water and Sanitation Supply Division, UNICEF, UNICEF Platz, Freeport, DK–2100 Copenhagen, Denmark, tel: +45 35 273025, Fax: +45 35 269421.

Table 5–2

## Equipment used for continuous processing

| Equipment/activity | Description | Cost (US$) |
|---|---|---|
| Mixer | Conveyor to move a given quantity of salt over time, provided with devices to turn the salt, mixing the fortifying agent with the salt. Although the mixers are not portable, smaller mobile units may be purchased through UNICEF. | $10,000–100,000 |
| Fortifier | Receptacle to hold and deliver a given quantity of fortifying agent regulated over time, which may or may not be synchronised with the conveyor. The fortifying agent is provided in regulated doses to incorporate it homogeneously into the salt. | $500–5,000 |
| Balance | Device to weigh the fortifying agent; mechanical balances are preferred over electronic. | $200–500 |
| Calibrated containers (as alternative to balance) | Alternatively, calibrated measuring containers can be used to measure the fortifying agent. | $20–50 |
| Preventive maintenance | Staff time, replacement parts (such as spray nozzles) | 10% of initial cost/year |

### MONITORING THE PRODUCTION PROCESS

Quality control of salt iodization is challenging. The continuous mixing process must be validated, there must be monitoring of iodine content during production (in– process monitoring), and samples must be taken periodically at the end of the processing line to monitor iodine levels in the final product. All steps require quality assurance. A detailed explanation of each step in this process follows.

Table 5–3

## Steps in internal quality assurance for the medium and large producer

| Step | Who does it | Frequency |
|---|---|---|
| 1. Purchase quality equipment and supplies. | Owner | Routine |
| 2. Inspect equipment. | Production manager | Twice daily |
| 3. Validate mixing process. | Staff responsible for quality control | Annually |
| 4. Monitor during production. | Production staff | Every hour by rapid test kit, less frequently by titration |
| 5. Check final product. | Staff responsible for quality control | Daily, by lots |
| 6. Record data. | All | Daily control charts; weekly summary |

### Step 1. Purchase quality equipment and supplies.

Producers should ensure that equipment purchased for iodization is of high enough quality to perform consistently. This will avoid mechanical problems contributing to variation in the iodine content of salt produced. Purchased supplies should include salt of specified purity, packaging adhering to producer specifications, and quality assured iodate. Supplies should be stored properly to avoid contamination or abnormal losses of iodine before mixing. This is particularly important when the supplies are purchased in large quantities.

### Step 2. Routinely inspect processing equipment.

When large amounts of iodized salt are produced quickly, both the frequency and precision of monitoring during production are critical to ensure adequate iodine levels. For the spray procedure in particular, it is critical to have an adequate supply of spare nozzles and to inspect nozzles daily to ensure consistent spraying.

### Step 3. Validate the continuous mixing process to ensure constant, consistent mixing.

The continuous mixing process should ensure that the salt is iodized uniformly—that is, whether any given sample of salt has the same iodine content. To validate a continuous mixing process, three to ten batches should be monitored, selecting one batch every 15 minutes, while maintaining a fixed speed for the conveyor or helicoidal shaft and a constant addition of the iodine fortifying agent. In this way the ideal speed for the conveyor and rate of addition of iodate can be determined.

The amount of acceptable variation will depend on the mechanical ability of the mixer; variations of up to 5% may reflect the limitations of the machinery. A spread in values of plus or minus 10% should be acceptable. Immediate action such as calibration is required if the iodine content found in samples differs much more than 10% from the target value. Under ideal conditions, the validation of the best operating conditions is considered complete when the average value during a given day does not differ by more than 2% from the target value and the relative standard deviation (RSD) is 3% or less. (Relative standard deviation is the quotient of the standard deviation of the sample divided by the mean value of the sample.)

If this process is not validated at its optimum level, variations will result and salt will be produced with a wide range in iodine content. This may be problematic later when determining whether the low levels found in household samples are due to decomposition, improper packaging material, or variations at the time of processing.

### Step 4. Monitor iodine levels during production.

In order to avoid production of large quantities of sub–standard salt, large producers should continuously monitor the iodine content of the salt as it is being produced, with routine collection of samples from the production line at regular intervals. Spot testing can be done at least hourly, with confirmation by titration every two hours, depending on the size of the producer.

A control chart such as the one shown in Figure 5–1 below can be used to record this in–process monitoring data. Upper and lower control limits represent the normal variation of the processing system, not the ideal maximum and minimum levels for the product. By knowing the limits of the system, it is easy to identify sample values that are out of these control boundaries and thus act quickly to correct processing errors. The calculations used to create a control chart are given in Appendix 5–3. Note that when a spot test kit is used, the calculations are different from those used for titration. Where titration is not available, the semi–quantitative spot test will only give an estimate of the parts per million (ppm).

Larger producers should have the capacity, and may be required, to establish a titration laboratory (see Chapter 11). Quantitative analysis can be performed on salt samples collected during production, and lot quality assurance sampling (LQAS) can be carried out prior to shipping.

### Step 5. Monitor salt ready for distribution.

Producers control the quality of their final product by sampling “lots” or batches to ensure that each has the correct concentration of iodine. Correct sampling procedures and appropriate determination of the lot size to sample are important. (See also Chapter 9.)

If the final product results are different than those from in–process testing, it either indicates that the sampling plan is inappropriate to identify variations within the process or the testing procedure is not accurate. To verify which factor is the most significant in causing process variations, retained in–process samples can be tested at the laboratory and results compared. Five specimens from the retained samples should be tested by each method (titration and spot testing) in parallel. If results show a variation equal to or greater than 10 mg/kg for the titration method, the mixing process needs improvement. If results show a variation less than 10 mg/kg for the titration method but a difference by more than 10 mg/kg between methods, the testing methods and procedures need improvement.

**Figure 5–1**

## An example of a control chart for in–process monitoring

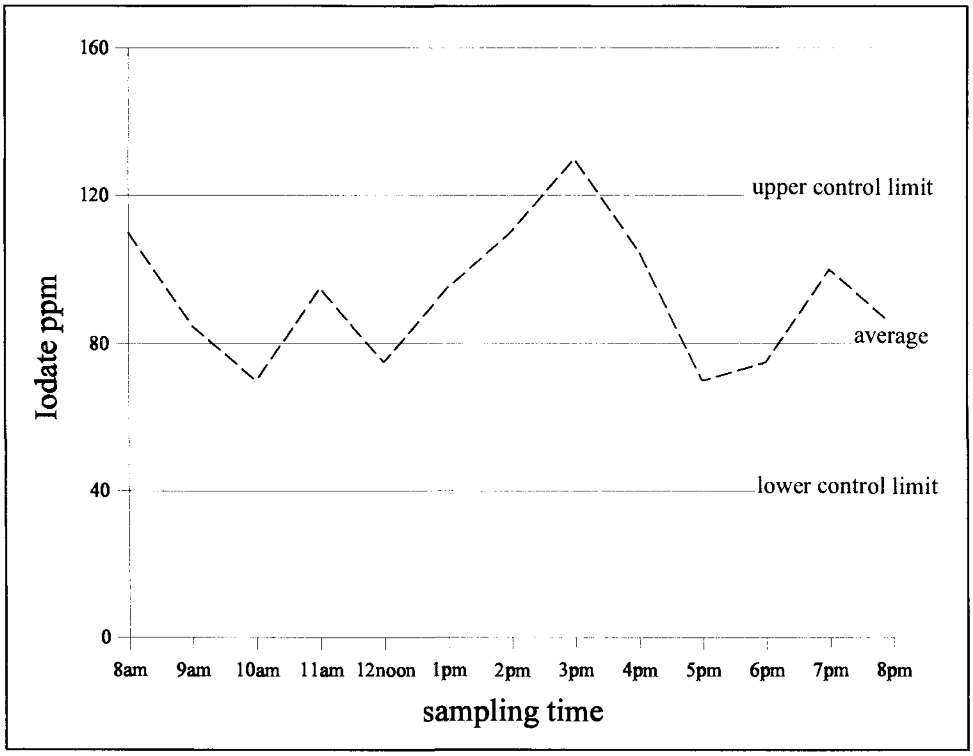



**Table 5–4**

## Equipment for batch processing

| Equipment/ activity | Description | Cost (USD) |
|---|---|---|
| Mixer | Receptacle to hold a given quantity of salt, provided with devices to turn the receptacle or allow the contents to move within the receptacle, evenly mixing the fortifying agent with the salt. Can be either mechanically or manually operated. | $500–1,500 |
| Balance | Device to weigh the salt and fortifying agent; mechanical balances are preferred over electronic. | $200–500 |
| Calibrated container (as alternative to balance) | Alternatively, calibrated measuring containers can be used for this purpose. | $20–50 |
| Preventive maintenance | Staff time, parts | 10% of initial cost /year |

The UNICEF procurement office may be contacted for the current price of various pieces of equipment.

**Step 6. Keep adequate monitoring records.**

Producers may be required to provide government authorities with monthly or bi–annual reports on their quality assurance procedures. Such records should be always available for periodic review. Government inspectors may wish to review:

- maintainence and inspection records, validation reports
- in–process monitoring records and control charts
- final product quality control data.

## INTERNAL QUALITY ASSURANCE FOR THE SMALL-SCALE PRODUCER

### SALT REFINING AND IODIZATION PROCESSES

Establishing quality control procedures is more difficult for small producers. In some instances a small producer may have a very limited operation, with few employees and little profit margin with which to establish a quality control laboratory or assign staff for internal monitoring. The specific quality control procedures will depend on the production capacity and the government regulations for producers of this size. Nevertheless, the iodized salt produced ultimately must meet government standards. The procedures outlined here describe an ideal situation, and should be modified to fit the national context.

Small producers usually use a batch process for salt iodization because equipment costs are lower, the process is simpler, and it is possible to iodize smaller quantities of salt. Daily output using batch processing is limited, but conditions for monitoring and controlling the mixing process are very good. Controlled quantities of salt and potassium iodate are mixed for a preset time in a mixer. After mixing, potassium iodate should be evenly distributed throughout the batch, thus ensuring that any amount taken from the batch will have the specified amount of iodine. The equipment generally required for batch processing is presented in Table 5–4.

**Table 5–5**

**Steps in internal quality assurance for the small producer**

| Step | Who does it | Frequency |
|---|---|---|
| 1. Purchase quality equipment and supplies. | Owner | Routine |
| 2. Inspect equipment | Staff | Daily |
| 3. Validate mixing process. | Staff assigned to QC | Twice a year |
| 4. Monitor production. | Staff assigned to QC | Every 1–2 hours |
| 5. Check product. | Manager | Daily, by lots |
| 6. Record data. | All | Daily control charts; monthly summary |

## MONITORING THE PRODUCTION PROCESS

**Step 1. Purchase quality equipment and supplies.**

Small producers should ensure that equipment purchased for iodization is of good enough quality to perform consistently. Small producers should be aware of the quality of the salt they process and the quality of the packaging material purchased.

**Step 2. Inspect batch mixing equipment, weighing equipment and storage area for potassium iodate.**

Producers should include routine daily inspection of storage areas and iodization equipment in their monitoring plan, and record inspections done and maintainence performed.

**Step 3. Perform validation of the batch mixing process to ensure consistent mixing.**

The procedures described below for validating the mixing procedure may not be realistic for very small producers who do not have adequate laboratory facilities or staff. More careful monitoring of the final product with salt testers will be important in these instances.

Validation procedures ensure that the mixing process remains the same from batch to batch. Since mixers have different shapes and capacities, the mixing time must be validated and maintained for each mixer. The batch process can be validated, i.e., the mixing time determined, by sampling a minimum of three to ten lots. In order to identify whether there are areas which are being poorly mixed, samples are collected from at least five different locations in the mixer/ blender. Adequate and consistent mixing is demonstrated when there is very little variation in iodine content in the samples tested.* Testing should ideally be done by titration, but if this method is not available, rapid test kits will give a semi– quantitative estimate. The mixing time that demonstrates that mixing is adequate can be used for future batches. Validation procedures should be repeated every six months.

* Although most small producers may not have the capacity to determine the magnitude of variability, ideally adequate sampling should be done to determine correct mixing. When the variation of the iodine content of all samples is less than 2% from the target value (e.g., 100 ppm) and the relative standard deviation (RSD) is equal to or less than 3%, it is considered homogeneous, and the parameters used to reach this result can be used consistently for future lots.

**Figure 5–2**

## Example form for validation of dry mixing process

| | | | |
|---|---|---|---|
| Company: | | Location: | |
| Batch number: | | Batch size: | |
| Iodate standard= | ppm | Mixing procedure no.: | |
| Mixing date: | | Mixing time: | |
| Sample no. | Iodate (estimated ppm) | Performed by | Checked by |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| | | | |
| | | ETC. | |
| Conclusion: | ❑ Pass | ❑ Fail | |
| Recommendations: | | | |
| Production manager: | | | |

**Step 4. Monitor salt during production.**

Once the mixing procedure has been validated and iodization becomes routine, samples should be tested regularly during production to ensure that equipment breakdown or human error do not cause production of inadequately iodized salt. The staff assigned to quality control should establish a sampling plan that includes date and time of sampling, grade of salt, frequency of sampling, batch number, sample number, responsible personnel, test to be conducted, standards, and range allowed.

This "in–process" monitoring should be done every one or two hours using semi– quantitative spot testing. Ideally, spot testing should be confirmed periodically, using more quantitative titration methods (see Chapter 11) if laboratory facilities are available, or through the use of government or private laboratories.

Semi–quantitative spot testing is done using a simple field test kit. The current available kit has a sensitivity to estimate iodine concentration of 0, 7.5, 15, and 30 ppm as described in detail in chapter 10.

If a batch of salt is inadequately iodized, the batch should be re–iodized and retested before distribution. The cause of the "out–of–control" situation should be investigated and resolved promptly. As with large producers, a control chart may be helpful to monitor the in–process results.

**Step 5. Monitor salt ready for distribution.**

In addition to monitoring the quality of salt during processing, the final quality of batches prepared for shipping should be checked. The producer should be assured that each batch shipped meets quality standards. Salt that remains at the production facility for more than one month prior to distribution should be retested.

Samples are collected daily from production "lots" or batches and tested to verify that there is no excessive variation among these lots. Producers will need to determine what constitutes a lot for their production facility, but this might include an order for a given wholesaler, a truckload or a specified number of 50–75 kg bags. Depending on the sizeand number of lots to be shipped, lot quality assurance sampling methods (see Chapter 9) may be useful to assure that each lot is adequately iodized. Testing can be done by semi–quantitative methods or titration, although confirmation by titration is preferred.

**Step 6. Keep adequate monitoring records.**

All producers need to keep adequate records of their monitoring activities. It is important therefore, to involve producers in the development of the monitoring plan and in the national committees that oversee the national salt iodization efforts. Being an integral part of the elimination effort is a great incentive to keep better records.

Those responsible for production and quality control should retain all forms and notebooks used for recording the preparation of pre–mix, salt fortification, in–process testing, and final product testing. These documents should be kept in chronological order and maintained for at least 24 months after lot preparation. Control charts graphing the range (in estimated ppm) for both in–process and final product monitoring should be posted and updated as information is collected. These records should be accessible to the authorised government agency responsible for monitoring government product standards (external monitoring). The agency may want to review:

- validation reports and maintenance and equipment inspection records
- in–process spot testing and control charts
- final product testing and any confirmatory titration from other laboratories.

## EXTERNAL QUALITY ASSURANCE

### From external monitoring, it is essential to know:

- Whether internal quality control is being performed correctly
- If records demonstrate continuous satisfaction that validated parameters and government standards are being met
- If independent salt testing confirms producer reports
- If equipment is properly maintained to assure adequate iodization.

#### KEY INDICATORS

- Proportion of salt adequately iodized upon external inspection
- Presence of iodized salt in the marketplace
- Adequacy of external monitoring process

#### DATA COLLECTION, ANALYSIS AND REPORTING

- External inspection of factories
- Evaluation of sales and commercial reports
- Regular review of routine reports from producers
- Periodic analysis of samples from producers

#### RESPONSES AND ACTIONS

- Collaborative development or application of regulations for external quality assurance
- Acknowledgment of adequate quality assurance through seal or logo use
- Enforcement of regulations when standards are not met

#### SECTORS INVOLVED

- Bureau of Standards
- Ministry of Health or Ministry of Agriculture food safety offices
- Ministry of Trade and Commerce

## EXTERNAL QUALITY ASSURANCE

The government agency authorised to perform external monitoring of production facilities should develop a plan for periodic checks of all producers. While external monitoring will focus on large producers, some form of external checking should be done on producers of all sizes. The frequency of these checks depends on the national situation, but should be adequate to ensure that the salt reaching the market meets government standards. External monitoring should increase in frequency when household or retail level monitoring indicates that some products fail to meet standards. Procedures for external monitoring of product quality are similar to industry final product monitoring.

### Step 1. Review legislation and regulations.

Both the guidelines and the authority to enforce these guidelines should be spelled out through legislation and regulation (see Chapter 3).

### Step 2. Develop a monitoring plan.

It is difficult to define a fixed guideline for external monitoring procedures. Depending on the number and size of producers iodizing salt, the government inspection agency should develop an overall plan that describes:

- the frequency of monitoring
- the method of determining which producers to monitor at a given time
- the methods used and the individuals responsible for each step
- the corrective actions to be taken.

Such a plan should be developed in conjunction with the producers so they understand the process and the consequences of failing to meet government standards. Checks and balances should be built in to prevent misuse of the monitoring system.

### Step 3. Establish list of producers to monitor.

Depending on the resources available to the government, the number and distribution of producers, and the agency(s) responsible, centralised monitoring activities will often cover most large producers. For smaller producers, monitoring may be done at the provincial or district level, with central reporting of inadequacies.

### Step 4. Monitor producers.

In situations where there are relatively few large producers (or importers), external monitoring may be as frequent as every month until it is clear that standards are being met. The frequency of external monitoring will be determined by the quality of the salt reaching the market, the number of producers, the availability of government inspectors, and funding. As programmes evolve, the frequency of monitoring should reduce as long as salt with adequate iodine content is reaching the marketplace.

Table 5–6

## Steps in external quality assurance

| Step | Who does it | Frequency |
|---|---|---|
| 1. Review legislation and regulations | National committee | Annually |
| 2. Develop monitoring plan | Regulatory agency staff | Once, update when necessary |
| 3. Establish list of producers to monitor | Regulatory agency staff | Annually (referring to situational analysis) |
| 4. Monitor producers | Central and district inspectors | As needed |
| 5. Record data | Central and district inspectors | Monthly summary |
| 6. Implement enforcement procedures | Enforcement agencies | As needed |

### THE KEY CHARACTERISTICS TO MONITOR MIGHT INCLUDE:

- **quantity of salt produced and sales figures**
- **plant production capacity**
- **in–process and final product quality control records**
- **sampling methods and number of samples used for monitoring**
- **standards and control limits**
- **laboratory techniques used**
- **maintenance records, including spray system**
- **packaging and transport procedures**
- **warehousing practices.**

**Step 5. Record data.**

Clear records should be kept to ensure that external monitoring is being done fairly and accurately. In some instances it may be helpful to make this monitoring process part of the public record so consumers are aware of the quality of the products they purchase.

The results of all external monitoring should be forwarded to the producers. Producers with consistently high quality should be recognised and properly rewarded, perhaps with presentation of a "Manufacturer of the Year" award.

**Step 6. Implement enforcement procedures.**

Enforcement procedures should be defined clearly so producers understand the consequences of producing sub–standard salt. Such procedures may include confiscation of sub–standard salt, loss of incentives, loss of license, or closure of the production facility. Some countries have published the results of external monitoring early in salt iodization programs, so consumers can compare brands.

Figure 5–3

## Sample form used by environmental health inspectors and technicians in Zimbabwe

| District | Type of premise | Type of food | Number of samples | Reasons for sampling | Results of analysis | Action taken | Remarks |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

ETC.

## APPENDIX 5–1

# Standards and Characteristics of Iodized Salt

**1. Description:** The salt must be solid crystals or powder, white in colour, without visible spots of clay, sand, gravel or other foreign matter. A 10% solution in water should be clear, colourless, and without any obvious chemical reaction.

**2. Moisture:** The salt should not contain more than 4% moisture by weight when analysed by desiccation methods recommended by WHO.

**3. Particle size:** For coarse salt, a minimum of 95% of the crude salt should pass through a standard 4 mm sieve.

**4. Water insolubles:** Water insolubles should not exceed 0.2% by weight.

**5. Chloride content:** At least 97% expressed as NaCl on wet basis or "as is" basis.

**6. Soluble impurities:** Magnesium, expressed as magnesium chloride, should not exceed 0.5%.

**7. Iodine content:** The compound used should be potassium iodate ($KIO_3$). Expected range 80–120 ppm at producing location.

**8. Packaging:** The salt should be packaged in woven polypropylene bags or in clean unused jute bags. For retail use, however, the salt should be packaged in polyethylene bags.

**9. Labelling:**

- Name: "IODIZED SALT" (all in letters of the same size)
- Name of manufacturer or packer
- Lot or batch number
- Expiration date or "best used before" date
- Net weight
- Iodine compound used – POTASSIUM IODATE
- Level of potassium iodate, mg/kg or ppm.

**10. Storage and transport:** To minimize avoidable losses of iodine during storage, transport or sale, in bulk or retail, salt should not be exposed to the following conditions:

- strong light or sunlight
- strong heat or high humidity/moisture
- rain
- various forms of contamination like dust and chemicals

mixture with noniodized salt

- bad storage conditions, e.g., lack of aeration; first in/last out.

## APPENDIX 5–2

# Quality Specifications for Potassium Iodate

For salt iodization, potassium iodate should be of food grade quality and conform to the following standards:

**1. Physical appearance:** White to almost white crystalline powder

**2. Particles retained** on100 mesh B.S. sieve: 5% max

**3. Solubility:** Soluble in 30 parts water

**4. Reaction:** A 5% solution in water shall be neutral to litmus

**5. Iodine max:** 0.005%

**6. Sulphate, max:** 0.02%

**7. Heavy metals (as Pb):** Less than 20 mg/kg

**8. Iron:** Less than 10 mg/kg

**9. Bromate, Bromide, Chloride and Chlorate,** max: 0.5%

**10. Insoluble matter, max:** 0.5%

**11. Loss on drying** at 105°C, max: 0.5%

**12. Assay (on dry basis):** 99.0% potassium iodate min

**13. Packing:** Plastic bag or paper drums with closed seal (50 kg)

## APPENDIX 5–3

# Creation of a Control Chart: Calculations for Upper and Lower Control Limits[1]

The routine iodization process will allow some variation in the exact amount of iodine (in ppm) for any given sample. This normal variation is determined by the process itself and will depend on the capability of the machinery, mixing or spraying time, and many other factors. The calculations below provide a method to determine statistically the expected high and low values. By taking a number of samples at different times during normal operation, it is possible to calculate the upper and lower control limits for iodine content that are part of the normal iodization process.

Values that fall outside of the upper and lower control limits indicate that there is something unusual affecting the routine operating procedure, causing it no longer to be in "control". This implies that there is some error in the system that needs correcting. Values fluctuating within the control limits indicate the normal variation that the machinery and operating procedures permit.

These upper and lower control limits are different from the ideal maximum and minimum values which are usually established as government or industry standards or specifications. What the government or industry specifies is the ideal ppm desired. Control limits describe what the equipment and production process can produce consistently.

**When titration methods are used to give an *exact* ppm iodine:**

**Step 1.** Create a sample collection chart.

**Step 2.** Collect 10 samples randomly during normal operation every 1/2 to 1 hour until 20 sub–groups of 10 samples each have been collected. Analyse and record ppm iodine for each sample.

**Step 3.** For each of the 20 sub–groups, calculate the average value for the 10 samples:

$$\bar{X} = \frac{X_1 + X_2 + X_3 \ldots X_{10}}{10}$$

where x is the ppm for a specific sample, and $\bar{x}$ is the mean (in ppm) for the sub-group.

Record the range (R), or the difference between the highest and lowest values within each sub-group.

$$R = \text{highest value} - \text{lowest value}$$

**Step 4.** Calculate the overall average ($\bar{\bar{X}}$) for the 20 sub–groups, using the averages calculated above.

$$\bar{\bar{X}} = \frac{\bar{X}_1 + \bar{X}_2 + \bar{X}_3 \ldots}{20}$$

Calculate the average range using the ranges recorded above.

$$\bar{R} = \frac{R_1 + R_2 + R_3 \ldots}{20}$$

**Step 5.** From these values, calculate the upper (UCL) and lower (LCL) control limits. (The following is based on 10 samples in each sub-group).

$$UCL = \bar{\bar{X}} + 0.308\bar{R}$$

$$LCL = \bar{\bar{X}} - 0.308\bar{R}$$

Note that the factor 0.308 differs for different sample sizes, so if there are only four samples for each sub–group, the average R is multiplied by 0.729.

| | |
|---|---|
| n=4 | factor=0.729 |
| n=8 | factor=0.373 |
| n=10 | factor=0.308 |

## WHEN SPOT TEST METHODS ARE USED TO GIVE AN APPROXIMATION OF THE PPM IODINE:

Most spot test kits give an approximation of the ppm iodine in a given sample by the intensity of the colour change reaction. The kits usually estimate the iodine content as 0, 7.5, 15, or 30 ppm (or up to 50 ppm for some kits). Since this approximation is only a series of estimates and thus not a continuous set of values, a different formula is required to calculate upper and lower control limits.

**Steps 1 and 2.** Same as for titration method described above.

**Step 3.** Decide on the value below which the sample will be considered unacceptable or defective, e.g., < 30 ppm.

**Step 4.** Calculate the proportion of samples (n) from each sub-group that is defective (in this case, n = 10).

$$p = \frac{\text{Number of rejected samples for a given sub-group}}{10}$$

**Step 5.** Calculate the overall proportion of defective samples for all sub-groups.

$$\bar{p} = \frac{\text{Number of rejected samples for all sub-groups}}{\text{total number of samples inspected for all sub-groups}}$$

(For example, if the total number of samples inspected is 10 and the number of sub-groups is 20, then the total number is 10 x 20 = 200.)

**Step 6.** Calculate the upper and lower control limits.

$$UCL = \bar{p} + \frac{3\sqrt{\bar{p}(1-\bar{p})}}{\sqrt{n}}$$

$$LCL = \bar{p} - \frac{3\sqrt{\bar{p}(1-\bar{p})}}{\sqrt{n}}$$

(n = the number of samples in each sub-group, in this case 10.)

1 Adapted from: The Memory Jogger, Goal/QPC, Methuen, Mass USA, 1988.

# CHAPTER 6

# MONITORING AT WHOLESALE AND RETAIL LEVELS

6

## INTRODUCTION

In developing salt monitoring programs, the wholesale and retail levels are two potential distribution points where surveys or monitoring may be useful. The term **"wholesale"** refers to sites such as warehouses where salt is stored prior to distribution to the retail level. **"Retail"** refers to shops or markets where salt is purchased for use in households. In some instances the salt is shipped directly from the producer to the retail level. Reasons for monitoring salt at these levels include:

- When monitoring shows adequate salt iodization during production or importation but the iodine content is found to be inadequate at the household level. An investigation may identify problems at the wholesale and retail levels.
- To assure that wholesalers and retailers store salt properly and sell salt on a "first in/first out" (FIFO) basis.
- To assure that wholesalers and retailers purchase and distribute only iodized salt. Sources of noniodized salt for human or animal consumption should be identified and actions taken to ensure that salt is adequately iodized.
- Villages found to have an inadequate proportion of households using iodized salt may need an assessment to identify reasons for the inadequacy and identify solutions.
- In some settings, monitoring salt in the household may be difficult and therefore monitoring salt in the market may be a proxy.

Lack of adequate infrastructure or resources can be a constraint to monitoring at the wholesale and retail level. In some countries, there may already be an infrastructure for inspections at the retail level. If so, it may be relatively inexpensive to add salt monitoring to the inspection system. It may also be possible to add wholesalers.

Monitoring at the wholesale and retail level can either be performed over the long–term, short–term, or in an episodic manner. A long–term monitoring system would operate for perhaps five to ten years. Short–term monitoring might be instituted to monitor wholesalers or retailers until a certain level of success has been achieved, perhaps over two to five years. Short–term monitoring can act as an educational tool to promote the importance of eliminating IDD. Episodic monitoring is carried out two or more times in areas where specific problems have been identified. The first visit to wholesalers or retailers would be to identify the problems, and subsequent visits would be to assure that efforts to rectify the problems have been successful.

In some countries the focus of monitoring efforts might be to identify and eliminate sources of non-iodized salt. However, the basic concepts of monitoring iodized salt and monitoring to identify sources of non-iodized salt are similar.

Arousing community awareness can be used to create a demand for iodized salt and apply pressure on governmental agencies to implement and sustain salt iodization activities. Groups that can be involved are women's organizations, local non–governmental agencies, youth groups, and schools.

### India

#### EXAMPLE OF NONGOVERNMENTAL ORGANIZATIONS MONITORING SALT IODINE LEVELS

In India, three nongovernmental organizations in the severely iodine deficient state of Uttar Pradesh were involved in monitoring salt at the retail and household level. Each month salt samples were obtained from local retail shops and the results communicated to the community and civic officials. Local politicians were made aware of inadequacies of the iodine content of salt. This resulted in the issue being raised in the Provincial and National Parliament.

The next two sections provide more detailed information on monitoring salt at the wholesale level and at the retail level.

## In monitoring at the wholesale level it is essential to:

- Determine if salt sold by wholesalers meets government standards.
- Determine adequacy of salt storage by wholesalers.
- Review iodine losses during transport and storage.
- Determine whether wholesalers are distributing noniodized salt and identify the sources of noniodized salt.

### KEY INDICATORS

- Proportion of salt distributed by wholesalers that has not been iodized .
- Proportion of iodized salt sold by wholesalers that meets government standards.
- Iodine losses during transport to wholesalers and during storage in warehouses.

### DATA COLLECTION, ANALYSIS AND REPORTING

- Testing of salt in warehouses through use of lot quality assurance sampling (LQAS).

### RESPONSES AND ACTIONS

- If salt from a specific manufacturer is found to be inadequately iodized, a review of the manufacturer's internal and external monitoring records would be indicated. Reviewing how the salt was transported from the manufacturer to the wholesaler may also be useful to identify where iodine losses may have occurred.
- Inform wholesalers of legislation and regulations regarding salt.
- Strengthen social marketing efforts and other educational campaigns to increase the awareness of wholesalers about the importance of iodized salt.
- Encourage wholesalers to promote iodized salt .
- Confiscate noniodized salt from wholesalers.

### SECTORS INVOLVED

- Ministry of Health district (or other sub–national unit) workers or food inspectors .
- Nongovernment organizations (NGOs) working at the community level.
- Ministry of Trade and Industry inspection officers and trade associations.

## MONITORING AT THE WHOLESALE LEVEL

Some district health officers may decide to monitor salt iodine levels in warehouses. Reasons to test salt at this level include:

- Each warehouse may supply salt to a large number of shops and therefore it may be easier and more efficient to monitor warehouses than shops.
- There may be a loss of iodine during transport from the producer to the warehouse which might be detected by monitoring warehouses.
- Warehouses may not be properly storing salt.
- Warehouses may not be using the first in/first out method of rotating salt stocks.

In some warehouses the salt may be repackaged from larger sacks (50 kg) into smaller one kg bags. The adequacy of the producer's packaging and adequacy of packaging performed by the wholesaler may need to be assessed. If important, warehouses could be required to perform routine sampling of salt samples (using the rapid test kit) and to keep internal quality control forms similar to those discussed in Chapter 5. Some issues that need to be decided when monitoring salt iodine levels in warehouses include:

- What constitutes a "lot"? Is this each shipment of salt from a manufacturer? Develop a standard definition that is reasonable for the situation.
- How many samples need to be taken and when should a lot fail? The sample size and "threshold" value would be determined as discussed in Chapter 9.
- How often should warehouses be checked? This depends on the severity of IDD in the area, the adequacy of salt tests performed previously in the warehouses, results of testing salt at the household level, and availability of individuals to test salt. If problems are found at the warehouse level, there may be a need for frequent monitoring, perhaps every month. Once the majority of samples meet standards over a time period, the frequency of testing may be reduced.

## In monitoring at the retail level it is essential to:

- Determine availability of iodized salt in retail markets.
- Determine if "iodized" salt sold in retail outlets meets government standards.
- Review iodine losses during transport and storage.
- Use retailers to promote iodized salt.
- Identify sources of noniodized salt.

### KEY INDICATORS

- Proportion of salt distributed by retailers that has not been iodized.
- Proportion of "iodized" salt sold by retailers that meets government standards.
- Iodine losses during transport to retailers and while at the retailer.

### DATA COLLECTION, ANALYSIS AND REPORTING

- Testing of salt using lot quality assurance sampling (LQAS).

### RESPONSES AND ACTIONS

- If salt from a specific manufacturer is found to be inadequately iodized at the retail level, a review of manufacturer's internal and external monitoring records would be indicated. A review of how the salt was handled, stored, and transported from the manufacturer to the retail shop may identify where iodine losses have occurred.
- Inform retailers of legislation and regulations regarding salt.
- Strengthen social marketing efforts and other educational campaigns to increase retailers' awareness of the importance of iodized salt.
- Encourage retailers to promote iodized salt.
- Confiscate noniodized salt from retailers.

### SECTORS INVOLVED

- Ministry of Health district (or other sub–national unit) health workers or food inspectors.
- Nongovernment organizations (NGOs) working at the community level.
- Ministry of Trade and Industry inspection officers and trade associations.

## MONITORING AT THE RETAIL LEVEL

Retail shops may sell iodized salt, noniodized salt, or both. The primary purposes of monitoring salt at the retail level is to identify areas where:

- An inadequate proportion of shops is selling iodized salt.
- Noniodized salt is available in the market.
- Salt packaged and labeled as iodized is not adequately iodized.

If relatively few shops in a village are selling iodized salt, is there a lack of demand for iodized salt from the consumer? Is there inadequate availability of iodized salt from the wholesalers/traders? Is the iodized salt too expensive? If noniodized salt is available, steps should be taken to remove it from the market (if it is against the legislation and regulations to sell noniodized salt). If packages of salt labeled as iodized contain insufficient levels of iodine, was the salt inadequately iodized at the factory? Has the salt been handled and stored properly since production?

Because of the different possible uses of monitoring salt at the retail level, there may be different goals. For example, one goal might be to assure that 95% of all retail shops sell iodized salt. Another goal might be for 95% of the shops to not sell noniodized salt. The number of shops to sample is described in Chapter 9.

### Frequency of Retail Monitoring/Surveys

The frequency with which the surveys need to be repeated will depend upon many factors such as:

- In general, areas with inadequate availability of iodized salt in the market or too easy access to noniodized salt will need to be surveyed more frequently. Once an area with inadequate availability of iodized salt is identified, efforts need to be made to improve the situation and confirm at a later date that iodized salt availability has improved.
- Areas where IDD is endemic may be a priority for more frequent monitoring than areas where IDD is less of a problem. However, even in areas of mild iodine deficiency there are a number of health consequences of IDD and these areas also need adequate coverage.
- The availability of personnel to perform the survey. Ideally, the sampling should be incorporated into existing health or inspection activities. Testing salt with rapid test kits is simple. Health workers will need training on how to sample retail stores.

### Length of the Survey (Time Frame)

The length of the survey refers to how long it should take to survey retail shops within villages at the district level. As mentioned earlier, village visits should be incorporated into other health activities. If an immunisation team visits each village in a district every six months, they could sample retail shops during each visit and therefore the survey would take six months. If a group of sanitarians inspects the water supply in each village once a year, then the sanitarians could also sample salt and therefore the survey would take one year to complete.

### Long–Term vs. Short–Term Monitoring

When a country has decided that salt at the retail level should be checked periodically, a decision is needed as to whether this will be a long– or short–term process. Many factors will affect this decision, such as the infrastructure and resources available.

### Survey Forms

The forms used at the retail level should be simple and obtain information that would be useful for decision–making. See Figure 6–1 for an example of a form that could be used for monitoring salt at the retail level.

### Villages to Visit

Ideally all villages within a district or subdistrict should be visited. If there are too many villages to visit, one solution is to list all of the villages in a district or subdistrict and randomly select around thirty villages. Selection of the villages can be based on the random number table in Chapter 8 or villages could be systematically selected. Then, over a specified time period (e.g., one year), whenever any health workers either visit or are within the vicinity of the village, they would test salt samples. This would work out to fewer than three villages per month. Note that when a sample village "fails," it is likely to be representative of other villages in the vicinity and further investigation should be undertaken to determine the extent of the problem.

### Selecting Retail Shops in a Village

The primary aim is to select shops that are representative of the village. A method similar to that used for selecting households in the Expanded Programme on Immunisation (EPI) surveys is recommended. This is described in more detail in Chapter 8 in the sections: Selecting Households in a Village, Selecting the First Household, and Selecting Subsequent Households. There will be some differences because generally there are fewer retail shops than households.

### Reporting Information to Higher Administrative Levels

Each country must decide whether the results of testing salt should be reported to higher administrative levels, e.g., from the district to the province. Usually district health officers already have a large number of reports to be completed monthly or annually. The addition of new reporting forms adds to their burden. A new reporting system is justified if it would improve efforts to assure adequate coverage. An alternative is "exception" reporting where only problem areas are reported. A reporting system may be useful over a short time period for advocacy purposes and then phased out.

If a reporting system is considered important, the information reported upward should be kept at a minimum. For example, for a retail–based LQAS system, the information might be reported as shown in Figure 6–2.

**Figure 6–1**

## Example of a retail level salt monitoring form

**RETAIL SHOP SALT MONITORING FORM**

Village/City District Date (dd/mm/yy)_____/_____/_____

| | Noniodized Salt | | Iodized Salt | | | |
|---|---|---|---|---|---|---|
| Shop No. | Available? | Price/kg | Available? | Price/kg | Salt Producer | Test* |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | ETC. | | | |

*0, 7, 15, or 30 ppm

### USE OF RESULTS FROM RETAIL MONITORING

The results from sampling retail shops should be used to improve the availability of iodized salt or to reduce the availability of noniodized salt. For villages that "failed," additional investigation may be needed to determine why the village failed. The district health officer should draw on all resources to address the problem. Possible activities include:

- Assure that stores sell only iodized salt.
- Provide shopkeepers with a listing of iodized salt distributors.
- Encourage iodized salt producers to work with shopkeepers in the health officer's jurisdiction.
- If permissible under legislation and regulations, confiscate noniodized salt.
- Assure that stores sell salt using the first in/first out (FIFO) method.
- Assure that stores do not overprice iodized salt.
- Educate storekeepers about the importance of iodized salt, its handling, and storage.
- Publish in the local newspaper a listing of retail shops selling adequately iodized salt.
- Report problems by specific salt producers to the Ministry of Health.

**Figure 6–2**

## Example of a monthly district retail shop Salt monitoring report form

**MONTHLY DISTRICT RETAIL LEVEL SALT MONITORING REPORT**

**District** Month/Year of Report_____/_____

Number of Villages in District Values used for: $P_0$ $P_a$ n d

How many villages were visited this month? No. of villages that failed based on the number of shops selling iodized salt?

Listing of salt producers from packages marked as iodized and test results:

| Name of Salt Producer | No. Samples Tested | No. Failed |
|---|---|---|
| | | |
| | | |
| | | |
| | ETC. | |

## Checklist for Undertaking Monitoring at Retail Level

- ❑ Determine if salt production or importation information indicates that iodized salt is available in sufficient quantities with adequate iodine levels.
- ❑ Determine if household or school monitoring identifies areas where a high proportion of the population does not consume adequately iodized salt.
- ❑ Decide whether retail monitoring would be advisable.
- ❑ Determine the geographic area to monitor or survey.
- ❑ Determine the type of monitoring, i.e., long–term, short–term, or episodic.
- ❑ Determine the duration of the monitoring/survey effort, from data collection to analysis and use of data results.
- ❑ For monitoring, determine the frequency of the retail shop checks, e.g., every month, every six months, or some other interval.
- ❑ Develop questionnaires.
- ❑ Select villages to visit.
- ❑ Select retail shops within a village.
- ❑ Conduct survey.
- ❑ Analyse data and report results.
- ❑ Take corrective action where necessary.

## Checklist for Undertaking Monitoring at the Wholesale Level

- ❑ Determine if salt production or importation information indicates that iodized salt is available in sufficient quantities with adequate iodine levels.
- ❑ Determine if household or school monitoring has identified areas where a high proportion of the population does not consume adequately iodized salt.
- ❑ Decide whether wholesale monitoring would be advisable.
- ❑ Determine the geographic area to monitor/survey.
- ❑ Determine the location of salt warehouses in the geographic area.
- ❑ Determine the type of monitoring, i.e., long–term, short–term, or episodic.
- ❑ Determine the duration of the monitoring/survey effort, from data collection to analysis and use of data results.
- ❑ For monitoring, determine the frequency of the warehouse checks, e.g., every month, every two months, or some other interval.
- ❑ Develop questionnaires.
- ❑ Conduct survey or institute monitoring.
- ❑ Analyse data and report results.
- ❑ Take corrective action where necessary.

# CHAPTER 7

# MONITORING SALT AT THE HOUSEHOLD LEVEL

## INTRODUCTION

Once salt production and import monitoring determines that iodized salt is being produced and/or imported in sufficient quantities, the next step is to assure that the product is reaching households with enough iodine. There are two distinct purposes for monitoring salt at the household level:

- To determine the proportion of households using adequately iodized salt in a large geographic area. This is often determined through the use of cluster surveys at the provincial or national levels and will be referred to as a "coverage" survey. Coverage surveys are less useful in addressing potential disparities in the distribution of iodized salt within the survey area.
- To identify high risk communities (or "hot spots") where there is an inadequate proportion of households using adequately iodized salt. This will be referred to as "process monitoring" and is usually performed at the district or subdistrict level.

If coverage surveys identify low iodized salt usage or if more specific information on the distribution of iodized salt within the country is needed, additional data collection strategies at the household level may need to be considered. This chapter discusses the two distinct monitoring approaches undertaken at the household level, coverage surveys and process monitoring, and introduces guidelines for their implementation. In Chapters 8 and 9, each approach is discussed in detail.

### Coverage Surveys

**Information needs**

- Whether 90% of households have adequately iodized salt.
- Whether serious losses during distribution are suspected, requiring adjustments in the iodization process or in the distribution of salt.

**Key indicators**

Proportion of households with adequately iodized salt.

**Data collection**

Representative household or school survey usually at the national or provincial level.

**Potential problems to address**

- Whether the proportion of households using salt is unacceptably low.
- Packages of salt labeled as iodized yet when tested contain little or no iodine.
- Noniodized salt is being used in the household.

**Sectors involved**

- Ministry of Health through provincial or district staff.
- Ministry of Health through other program activities such as EPI.
- Other ministries undertaking representative population–based household surveys.
- Ministry of Education

### Process Monitoring

**Information needs**

- Whether serious losses in iodine occur.
- Whether there are specific areas where iodized salt may not be available in sufficient quantities.
- Whether there are specific areas where the population is not using iodized salt.

**Key indicators**

Percentage of communities with an acceptable proportion of households with adequately iodized salt.

**Data collection**

LQAS at the district or subdistrict level, perhaps limited to specific geographic areas.

**Potential problems to address**

- Whether iodized salt is reaching communities throughout the country.
- Packages of salt labeled as iodized yet when tested contain little or no iodine.
- Noniodized salt is being used in the household.

**Sectors involved**

- Ministry of Health through district staff.
- Nongovernmental organizations (NGOs) who can provide staff for data collection and analysis.
- Community organisations such as women's credit organizations.
- Ministry of Education

## POPULATION-BASED COVERAGE SURVEYS

In order to track progress towards the mid-decade goals, information will be needed to determine the proportion of households with adequately iodized salt. This will require a coverage survey of households or schools at the national level, or in larger countries, at the provincial level. Coverage surveys need to be undertaken once every two to three years. Chapter 8 provides detailed information on the design and implementation of coverage surveys using the cluster methodology. The basic steps are as follows:

### Checklist for coverage surveys

- ❑ Review previous surveys and studies that have evaluated iodized salt in households.
- ❑ Determine if an existing or planned survey frame can be used or whether one needs to be developed.
- ❑ Select survey site, e.g. households or schools.
- ❑ Determine the smallest geographic unit for which estimates are needed, e.g., an entire country vs. a province.
- ❑ Calculate sample size requirements. (See Chapter 8)
- ❑ Design survey questionnaire.
- ❑ Select a sample. (See Chapter 8)
- ❑ Recruit survey personnel.
- ❑ Obtain necessary equipment.
- ❑ Train personnel and standardise all data collection procedures.
- ❑ Arrange for transportation, accommodations, etc.
- ❑ Perform survey.
- ❑ Enter data into computerised databases and edit data.(See Chapter 8)
- ❑ Analyse data and prepare a preliminary report of survey results. (See Chapter 8)
- ❑ Finalise reports and disseminate to concerned agencies. (See Chapter 8)
- ❑ Use results to take corrective action where necessary.

The frequency of the coverage surveys will depend upon many factors, including:

- Whether the data collection is integrated into an existing survey and thus tied to its schedule.
- The current status of the salt iodization program. Generally, surveys are performed more frequently during the "attack" phase of the program when there is substantial effort to get all major salt manufacturers and importers to iodize their salt. Once a majority of households are using iodized salt, the surveys can be performed less frequently.
- Areas with a high prevalence of IDD and areas with low iodized salt usage may be surveyed more frequently.
- The resources available to perform the surveys.

The general recommendation is that surveys of household salt be completed before the end of 1995, during 1997–98, and in the year 2000. Ideally, the collection of information on household salt should be incorporated into existing or planned surveys or surveillance systems, such as the Expanded Programme on Immunisation (EPI) surveys, Childhood Diarrheal Diseases (CDD) surveys, and others. The UNICEF Monitoring and Evaluation Unit's multiple-indicator survey for tracking the mid-decade goals includes a module on household salt.[1]

### Issues in Monitoring Coverage of Iodized Salt in Households

#### *Does a Separate Survey Need to be Designed?*

Representative household-based surveys are frequently performed by other ministries to collect information on income, household expenditures, food purchases, or employment, and questions on salt could be incorporated into these surveys. School-based surveys are another way to estimate the proportion of households using iodized salt. The Ministry of Education may survey schools on a routine basis. If it is not possible to utilise an existing or planned survey, then a survey will need to be planned.

#### *Household-based versus School-based Surveys*

Surveys can be made directly by selecting households or, where school attendance rates are high, surveys of schools can act as a proxy. Assessments might also be based on sampling individuals attending health or family planning clinics if a large proportion of the population utilises the clinics.

Household-based surveys are appealing because, when performed correctly, they will be representative of all households in a specified geographic area and the interviewer can see how salt is stored and view the salt packaging. However, household-based surveys are more time consuming than school-based surveys because of the need to go house to house within the village.

School-based surveys are appealing because children can bring salt samples to school and therefore many samples can be tested in a short period of time.

School visits can serve to educate school children on the importance of iodine and of iodized salt. However, there may be the potential for a biased estimate if the proportion of children who attend school is low. Children from the poorer households are usually less likely to attend school. This bias may be minimised by requesting only children in the lowest grades to bring salt as their attendance rates are usually higher than older children.

Another potential problem with school–based surveys is that households with school–aged children may not be representative of all households. However, in many cases where salt reaching villages is from a single source, there is unlikely to be a difference in household salt usage between households with and without school children. Furthermore, iodine benefits school–aged children so it is important to assure that their iodine intake is adequate. In school–based surveys information on the packaging and storage will generally not be available. Children may forget to bring salt or they may share salt. In some countries a letter is sent home with the pupil and the parents are requested to sign the form stating their child was given a salt sample from their home.

### *Determine Geographic Unit for which Coverage Estimates are Needed*

If decisions concerning intervention programmes are made for the country as a whole, one survey sample from the overall population will be sufficient. If comparisons between regions are needed, each region will constitute a "sampling universe" and a separate survey will need to be performed in each region. However, the number of different geographic units to be studied should be kept to a minimum to prevent the collection of unnecessarily large quantities of data. For example, if one wishes to estimate the proportion of households with iodized salt for the country, one sample (300 households or 30 schools) may produce an estimate with the desired precision. (More information on sample sizes is provided in Chapter 8.) However, if one wishes to compare the proportion of households with iodized salt in each of three regions, the total sample size required would be three times as large.

If the purpose of a study is to identify small areas where iodized salt is not available or not being purchased, then the LQAS method should be used.

### *Designing a Survey Questionnaire*

The survey questionnaire should be simple and gather information pertinent to household salt. The questionnaire should be designed so that responses can be easily coded and entered into a computerised database. Questions and codes assigned to variables (e.g., Type of Salt, 1=refined, 2=coarse) should be printed on the questionnaire, or alternatively, on a coding sheet. It is important that the questions be written in the language in which they are to be asked to assure consistency among survey teams. The questionnaire may need to be in more than one language and may require multilingual interviewers. The questionnaire should be field tested on a small sample of subjects with a background similar to the population to be surveyed to make sure that the questions are clear and cover the most common responses.

Data should be entered directly on data collection forms. An example of a line–list form for household–based surveys is depicted in Figure 7–1 and for school–based surveys in Figure 7–2. These forms allow rapid transfer of data to a computer for subsequent analysis as well as the rapid hand tabulation of each variable in the field. If the information is to be incorporated into a larger survey, a questionnaire similar to that shown in Figure 7–3 might be used. Provisions should be made for coding "unknown" or "refused" values.

**Figure 7-1**

## Example line-listing for household-based survey

**SURVEY OF HOUSEHOLD SALT – MINISTRY OF HEALTH, 1995**

Village/City Cluster No. Team No. Date (dd/mm/yy) ____/____/____

Location of Village (urban/rural) Terrain Population size

| HH No. | Type of Salt[a] | Package available?[b] | Brand Name[c] | Labeled as iodized?[b] | Test Results[d] | Storage[e] |
|---|---|---|---|---|---|---|
| 1 | | | | | | |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |
| 5 | | | | | | |

ETC.

a 1=refined, 2=coarse
b 1=yes, 2=no
c 1=Brand X, 2 = Brand Y, 3 = Brand Z, etc., leave blank if no packaging was available
d 0=no iodine, 7=7ppm, 15=15ppm, 30=30ppm
e 1=adequate (stored in plastic bag or closed container away from stove/cooking area)
2=inadequate (not stored in closed container or stored above stove/cooking area)

**Figure 7-2**

## Example line-listing for school-based surveys

**SCHOOL-BASED IODIZED SALT SURVEY – MINISTRY OF HEALTH, 1995**

School School enrollment

Cluster No. Team No. Date (dd/mm/yy)____/____/____

| Child No. | Type of Salt[a] | Test Results[b] | Child No. | Type of Salt[a] | Test Results[b] |
|---|---|---|---|---|---|
| 1 | | | 6 | | |
| 2 | | | 7 | | |
| 3 | | | 8 | | |
| 4 | | | 9 | | |
| 5 | | | 10 | | |

a 1=refined, 2=coarse b 0=no iodine, 7=7ppm, 15=15ppm, 30=30ppm

Figure 7-3

## Example of salt-related questions for household-based survey

**TYPE(S) OF SALT IN HOUSEHOLD:**

1. Refined ❑ Y ❑ N

2. Coarse ❑ Y ❑ N

3. Block ❑ Y ❑ N

**If refined salt was present:**

How much iodate did it contain? (0, 7.5, 15, or 30 ppm) _____

Which best describes the refined salt packaging _____
A. The original packaging was not available
B. The packaging was available and labeled as iodated
C. The packaging was available and not labeled as iodated

If the package was available, which manufacturer? _______________

Was the salt stored in a closed container/plastic bag? ❑ Y ❑ N

Was the salt stored in a dry, enclosed area? ❑ Y ❑ N

The above forms will probably have to be modified for use in different countries. For example, in some countries only refined salt is iodized, whereas in other countries coarse salt may be iodized. To evaluate schools or villages at high risk of having few households with iodized salt, additional questions concerning the village/city might include: population size, availability of electricity, paved road to village/city, terrain (mountain, valley, plateau), altitude, flood plain, and distance to ocean.

Other questions might concern purchasing preference for iodized or noniodized salt, such as costs, taste, or folk beliefs. While these questions may be more appropriate in qualitative research, they may be useful in coverage surveys.

### *Training and Supervision*

The quality of the survey results depends on the efficacy of training and supervision. Training includes: defining the role and task of each member of a survey team, procedures to select households, interviewing techniques, completion and coding of the survey form, and interpretation of salt tests.

**In general, a good training programme consists of three phases:**

**1.** Classroom-based orientation: Demonstration and practice on asking questions and testing salt.

**2.** Field practice session: All survey teams carry out procedures and practice collecting information together in an actual community. A review and discussion after the practice session serves to standardise procedures and activities.

**3.** Start-up phase of the actual survey: Two to three teams survey the first eight to ten individuals together to observe and comment on each other's performance. This phase is deliberately slow to ensure all teams conform to the same practice.

There are usually two levels of supervision, an overall supervisory group and a team leader for each survey team. The supervisory group conducts the training and manages the overall survey and can be viewed as the general managers of the survey. Each survey team should have a designated team leader responsible for the individual or household selection, quality of measurements, and proper completion of survey forms. Individuals from the supervisory group rotate to different teams throughout the survey to monitor progress and help maintain comparability among the teams. The individual from the supervisory group and the team leader should periodically repeat measurements on a separate form and compare results to that obtained by the team members. This repeated measure procedure helps to maintain the quality of data collection.

### *Data Collection, Analysis and Reporting*

The specific details for the design and implementation of a cluster survey, including data collection, analysis and reporting are provided in great detail in Chapter 8.

### *Use of Data*

If packages of salt labeled as iodized contain little or no iodine, it will be important to take corrective actions, including:

- Review manufacturer or importer quality assurance records.
- Review transport and storage of salt from manufacturer or importer to various intermediate points, including wholesalers and retailers.
- Undertake more intensive efforts to encourage shopkeepers and wholesalers to demand that only adequately iodized salt be traded.

On the other hand, if noniodized salt is being used in the household, corrective actions to take may include:

- Determine if iodized salt is available in the market.
- If the sale of noniodized salt for human consumption is not allowed, determine if there is an illegal market for noniodized salt.
- If both iodized and noniodized salt are available, determine consumer preference and investigate price differences between the two types of salt.

## PROCESS MONITORING AT THE HOUSEHOLD LEVEL

If the primary purpose of household monitoring is to identify specific geographic areas where high proportions of households do not have adequately iodized salt, then the use of lot quality assurance sampling (LQAS) is appropriate. Unlike coverage surveys, ongoing process monitoring of households using LQAS may be done more frequently to ensure that the salt iodization programme is proceeding well and reaching all segments of the population. More details, specific technical information and an example of using LQAS are presented in Chapter 9.

The primary purpose of using LQAS at the household level is to identify whether the proportion of the households in a village using iodized salt is adequate. The village will either "pass" or "fail" based on the results of the sampling. If the village passes, it is assumed that the proportion of households using iodized salt is adequate and no additional follow–up is necessary. If the village fails, there may be a need for a larger survey in the village to confirm that too few households are using iodized salt and to determine the reasons for this. A survey at the wholesale and retail level may also be performed at the same time (see Chapter 6).

## Checklist for process monitoring using LQAS at household level

- ❑ Determine the smallest geographic units for which LQAS sampling is needed, usually the district or subdistrict level.
- ❑ Decide on the duration of the survey, from data collection to analysis and use of data results.
- ❑ Select the survey sites, e.g., schools or households.
- ❑ Determine sample size, based on desired thresholds and precision. (see Chapter 9)
- ❑ Design questionnaire.
- ❑ Select households in a village / pupils in a school.
- ❑ Perform survey.
- ❑ Analyse data and report results.
- ❑ Use results to take corrective action where necessary.

In general, use of LQAS at the household level would be the responsibility of the district or subdistrict health officer. Health officers should assure that at least 90% of the households in every village in their jurisdiction are using iodized salt. Ideally, the testing of salt in villages should be incorporated into other health activities, such as immunisation or maternal and child health visits. Once a sample size is determined there are a number of steps to take in designing an LQAS strategy to identify high risk communities (see Chapter 9).

The frequency of LQAS surveys depends on many factors:

- In general, areas with inadequate coverage are surveyed more frequently. Once an area of inadequate coverage is found, efforts should be made to improve the situation and improvements confirmed at a later date.
- Monitoring households in areas where IDD is endemic may be a priority and performed more frequently than in areas where IDD is less of a problem. However, even mild iodine deficiency has significant health consequences. Therefore, areas with a low prevalence of IDD need adequate coverage with iodized salt.
- The availability of personnel to perform the survey. Ideally, the monitoring should be incorporated into existing health activities. While using the rapid test kits is simple, health workers will need to be trained to sample households or school children.

### General Issues in Process Monitoring of Household Salt using LQAS

*Determine Smallest Geographic Unit to Monitor*

In most cases, representative information will be gathered at the district or subdistrict level. This decision will be a function of four components, including:

- The types of possible responses or interventions and resources available to remedy the situation.
- The expected variation in the availability and distribution of iodized salt.
- Resources available for data collection, processing and reporting.
- Existence of infrastructure used for monitoring other health programs or activities.

Data collection should be tied directly to likely responses and interventions. Cost effectiveness can be maintained by selecting the lowest administrative area that provides meaningful information which can be used by district, provincial, and national IDD control program managers. It is also important to consider other ongoing monitoring and surveillance activities taking place at these levels, the reliability of the information being collected, and the capacity to integrate salt monitoring into existing schemes.

Ideally all villages within a district or subdistrict should be visited. If there are too many villages to visit, one solution is to list all of the villages in a district or subdistrict and randomly select around thirty villages. Selection of the villages can be based on the random number table in Chapter 8 or villages could be systematically selected. Then, over a specified time period (e.g., one year), whenever any health workers either visit or are within the vicinity of the village, they would test salt samples. This would work out to fewer than three villages per month. Note that when a sample village "fails," it is likely to be representative of other villages in the vicinity and further investigation should be undertaken to determine the extent of the problem.

*Length of Time to Perform Monitoring (Time Frame)*

The length of the time to perform one cycle of monitoring refers to the length of time it takes to monitor each site. For example, if there are sixty villages in a district, how long would it take to visit each village and sample households? As mentioned previously, ideally salt monitoring should be incorporated into other health activities. If an immunisation team visits each village every three months, they can sample households for salt at the same time and therefore one monitoring cycle would take three months to complete. If sanitarians inspect the water supply in each village once a year, they could also sample salt and one monitoring cycle would take one year to complete. Reporting a summary of results to the district may be more frequent, perhaps every one to three months.

*Survey Site (Households or Schools)*

To estimate the proportion of households using iodized salt, one can either go directly to households and collect the information or go to schools and request school children to bring in salt samples for testing. The advantages and disadvantages to each approach are the same as for coverage surveys discussed earlier in this chapter.

If there are several schools in the village, one school may be randomly selected for monitoring. There is the potential that salt samples tested in the selected school may not be representative of salt samples within the community.

*Development of Survey Questionnaire Forms*

Examples of forms that could be used in testing salt samples are provided earlier in this chapter and would be similar to those used for coverage surveys.

*Selecting Households in a Village or Pupils in a School*

Once it is determined whether to survey all villages or a sample of the villages, households in the villages will need to be selected. The same method for selecting households in EPI surveys can be used, which is described in more detail in Chapter 8 in the sections: Selecting Households in a Village, Selecting the First Household, and Selecting Subsequent Households.

If schools are the focus of the monitoring, there are two possible ways to select schools: either sample each school in the village or randomly select one school using a random number table (see Chapter 8). Once a school is selected, pupils will need to be selected. See Chapter 8, Selecting Pupils within a School.

*Reporting Information to Higher Administrative Levels*

Specific issues regarding reporting of results from testing salt to higher administrative levels are discussed in Chapter 6 in the section Reporting Information to Higher Administrative Levels.

If it is decided that a reporting system would be important, the information reported upward should be kept at a minimum. For example, for a household-based LQAS system, the information might be as shown in Figure 7–4. In a school-based system an example form is shown in Figure 7–5.

Figure 7-4

## Example of a monthly district household salt monitoring

**MONTHLY HOUSEHOLD SALT MONITORING FORM – MINISTRY OF HEALTH, 1995**

District Month/Year of Report ______/______

Number of Villages in District Values used for[a] : $P_o$ $P_a$ n d

How many villages were visited this month? How many villages failed?

Listing of salt producers on packages marked as iodized and test results:

| Name of Salt Producer | No. of Samples Tested | No. of Samples that Failed |
|---|---|---|
| | | |
| | | |
| | | |
| | ETC. | |

[a] Please see Chapter 9 for further information about these values and their definitions

Figure 7-5

## Example of a monthly district school-based salt monitoring report form

**MONTHLY DISTRICT SCHOOL-BASED SALT MONITORING REPORT**
**MINISTRY OF HEALTH, 1995**

District Month/Year of Report ______/______

Number of Villages in District Values used for[a]: $P_o$ $P_a$ n d

How many schools were visited this month? How many schools failed?

[a] Please see Chapter 9 for further information about these values and their definitions

From the reports shown in Figures 7–4 and 7–5, it will be possible for the district to determine the proportion of villages or schools with pass or fail.

### *Use of Results from LQAS Household Surveys*

From the data collected at the district or subdistrict level, it is possible to "map" the distribution of villages that pass or fail to provide a visual representation of problem areas. Ultimately, the results from sampling villages should be used to improve coverage. For villages that "fail," additional investigation needs to be undertaken to determine why the village failed. First, the village should be revisited and additional households sampled. If a problem is verified, items to investigate include:

- Is iodized salt readily available in the market? (see Chapters 6 and 9)
- Is noniodized salt readily available in the market? (see Chapters 6 and 9)
- Is the failure because salt packages are labelled as iodized, but when tested do not contain adequate levels of iodine?
- Is the salt labelled as iodized stored properly within the household?
- Do consumers prefer noniodized salt? If yes, why?
- If both iodized and noniodized salt are available, what is the price difference?

The district health officers should use their own resources and draw on others as necessary to address the problem. Activities that could be undertaken would include:

- Assure that stores sell only iodized salt.
- Provide shopkeepers with a list of iodized salt distributors.
- Encourage iodized salt producers to distribute iodized salt in their area.
- Depending on the legislation and regulations, confiscate noniodized salt.
- Assure that stores sell salt using the first in/first out (FIFO) method.
- Assure that stores do not overprice iodized salt.
- Provide educational messages concerning the importance of iodized salt.
- Provide educational messages on the proper storage of iodized salt.
- Address consumer preference for noniodized salt.
- Publish in the local newspaper a listing of salt producers that adequately iodize their salt.
- Report to provincial or national Ministry of Health problems by specific producers in adequately iodizing their salt.

## REFERENCES

1. UNICEF Monitoring and Evaluation Unit. Monitoring the Mid–Decade Goals Through Multiple–Indicator Surveys. Draft Methods Paper, 1994. New York: UNICEF.

# CHAPTER 8

# CLUSTER SURVEYS

## INTRODUCTION

The most common method used for monitoring an intervention or measuring the magnitude of a problem is to perform a rapid population-based cluster survey. This chapter will describe methods for assessing the proportion of households using adequately iodized salt, referred to as "coverage" surveys in Chapter 7. If the primary purpose of a survey is to identify small, localised populations without adequate access to iodized salt, then another type of survey design called lot quality assurance sampling, or LQAS, would be more appropriate (see Chapters 7 and 9). There are other surveillance methods, such as the use of sentinel sites, that may also be useful but are not discussed in this document.

Population-based surveys can be used to estimate the proportion of households with adequately iodized salt. They can also help identify subgroups at higher risk of not having adequately iodized salt, for example, those living in villages without electricity. This method is not very useful for screening a large number of villages to identify "problem" areas. If the survey is representative of the population, it can provide a baseline for comparison with subsequent surveys.

Because surveys can be expensive and time-consuming, every attempt should be made to incorporate household salt testing into existing or planned surveys. Surveys routinely performed in many countries include: the Expanded Programme on Immunisation (EPI) surveys, Childhood Diarrheal Diseases (CDD) surveys, Demographic and Health Surveys (DHS), school-based surveys, and labour force, income, expenditure and food purchasing surveys. Check with other ministries within the government to see what types of household-based surveys are being planned and determine whether they would be willing to also collect information on household salt. If salt sampling is going to be incorporated into another survey, the data should be representative of a larger population and available within a reasonable time span. A separate survey should be designed and implemented only if it is not possible to incorporate household salt into other planned surveys. While much of this chapter focusses on the design of new surveys, some aspects will be useful for incorporation of household salt information into an existing survey.

This chapter will discuss the methods for performing surveys and use of the Epi Info program called "Csample" to analyse survey data.

## DESIGN AND IMPLEMENTATION OF A SURVEY

If the collection of salt information is included in an existing or planned survey, then there may be little control over the number of households or schools in the sample. For example, the standard EPI survey collects information from thirty villages, and within each village, households are visited to collect information on seven children within a certain age range. To find the seven eligible children, up to 40 households may be visited. The sampling of salt could be from all households visited whether or not there are children of the appropriate age range for the EPI survey.

If salt sampling cannot be incorporated into an existing survey, a household- or school-based survey can be implemented. In household-based surveys, a "cluster" is commonly designated as a village, community, or city; in school-based surveys, the "cluster" is a school. In either case, the number of villages/cities to select for household-based surveys or the number of schools to select in a school-based survey is recommended to be thirty. (For more information on why thirty clusters should be selected, see the reference by Binkin et al.[1]).

**For household-based surveys, the general steps to follow are:**

**Step 1.** Select villages/cities to survey
**Step 2.** Determine the number of households to survey in each village/city
**Step 3.** Select households in each village/city

**For school-based surveys, the general steps are:**

**Step 1.** Select schools
**Step 2.** Determine the number of salt samples to test in each school
**Step 3.** Select children in each school to bring salt samples to school

The number of households to visit in each village or the number of salt samples to test in each school depends upon resource limitations and desired precision of the estimate.

## Technical Note:

Precision is a term that describes how close the estimated proportion is likely to be to the "true" proportion. Precision is more easily described in terms of how wide the 95% confidence intervals are around the estimated proportion. For example, if we completed a survey and found that 50% of the households had iodized salt and the lower and upper 95% confidence limits were 10% and 90%, respectively, this would be a study with very little precision. The interpretation would be that while we observed 50% of the households in the survey to have iodized salt, we are 95% confident that the "true" proportion is within the 10% to 90% limits, that is, it is consistent with the survey data that the "true" proportion of households with adequately iodized salt may be as low as 10% or as high as 90%. A more precise survey which estimated 50% of households with iodized salt would have narrower confidence limits, for example, 40% and 60%.

Precision in cluster surveys is based primarily on three factors: the sample size, the proportion estimated, and the design effect. In general, as sample size increases, precision improves (i.e., the confidence interval gets narrower). The design effect (DEFF) is a measure of the "clustering" of the outcome. It is beyond the scope of this document to explain further DEFF, but suffice it say that while cluster surveys are extremely useful in minimising the number of villages that need to be surveyed, the penalty is that the variance increases which makes the confidence intervals wider (i.e., there is less precision than if the same number of households had been selected at random from the geographic area of interest). However, the advantages provided by cluster surveys in terms of improved efficiency and lower cost far outweigh this issue of the DEFF.

The minimum recommended sample size, based on thirty clusters, is ten households in each village for household-based surveys or ten children from each school for school-based surveys.[2] This results in a total of 300 salt samples being tested.

If sufficient resources are available, a larger number of samples may be obtained in each cluster. However, obtaining more than thirty samples per cluster results in very little improvement in precision. In schools it adds very little to survey costs or time to increase the number of pupils who bring in salt samples from ten to thirty. For household-based surveys adding more households per cluster can add costs and time to the survey. For additional discussions on sample size calculations, see Appendix 8–1.

## HOUSEHOLD-BASED SURVEYS

### Selecting villages/cities to survey

In household-based surveys, the sample communities are usually selected using a technique called "proportionate to population size" or PPS (sometimes also called "population proportionate sampling"). Using this method, the likelihood of a community being selected is proportional to its population size, i.e., larger cities are more likely to be selected than small villages. The PPS method of selecting survey sites is used for EPI surveys.

The first step is to obtain the "best available" census data for each of the villages and cities in the area of interest. Then make a list with three columns (see Table 8–1). The first column lists the name of each village, town, and city (hereafter referred to as "community"). The second column contains the total population of each community. Finally, the third column contains the cumulative population which is obtained by adding the population of each community to the combined population of all the communities preceding it on the list. The list can reflect the order given in national census data or may be arranged from largest to smallest population or any other order. A sampling interval is obtained by dividing the total population size by the number of clusters desired. A random number between 1 and the sampling interval is chosen (from Appendix 8–2) as the starting point and the sampling interval is added sequentially to the random number until thirty clusters are chosen. (Appendix 8–2 provides instructions on how to use the random number table.) The 30 clusters should be plotted on a map of the area, and a logical sequence for the field work developed for each of the survey teams.

### Example: Village Selection in a Cluster Survey

In the fictitious area of El Saba, there are fifty communities (Table 8-1). In practice there would usually be many more than fifty villages but this number of communities is used for illustrative purposes to describe the method. The first column contains the names of the communities, the second column the population of each community, and the third column the cumulative population. A fourth column is used for identifying which communities will have one or more clusters selected. Follow the four steps to select communities to be included in the survey:

**Step 1:** Calculate the sampling interval by dividing the total population by the number of clusters. In this example, 24,940/30 = 831.
**Step 2:** Choose a random starting point between 1 and the sampling interval (in this example, 831) by using the random number table in Appendix 8-2. For this example, the number 710 is randomly selected.
**Step 3:** The first cluster will be where the 710th individual is found based on the cumulative population column, in this example, Mina.

**Step 4:** Continue to select clusters by adding 831 cumulatively. For example, the second cluster will be in the village where the value 1,541 is located (710 + 831 = 1541), which is Bolama. The third cluster is where the value 2,372 is located (1541 + 831 = 2372), and so on. In communities with large populations, more than one cluster will probably be selected.

If two clusters are selected in a city, divide the city into two sections of approximately equal population size. Perform the survey in each area as described. Similarly, if three or more clusters are in a city, divide the city into three or more sections of approximately equal population size.

**Table 8-1**

## Selection of communities in El Saba using the PPS method

| Communities | Pop. | Cum. | Cluster | Communities | Pop. | Cum. | Cluster |
|---|---|---|---|---|---|---|---|
| Utural | 600 | 600 | | BanVinai | 400 | 10,880 | 13 |
| Mina | 700 | 1,300 | 1 | Puratna | 220 | 11,100 | |
| Bolama | 350 | 1,650 | 2 | Kegalni | 140 | 11,240 | |
| Taluma | 680 | 2,380 | 3 | Hamali-Ura | 80 | 11,320 | |
| War-Yali | 430 | 2,810 | | Kameni | 410 | 11,730 | 14 |
| Galey | 220 | 3,030 | | Kiroya | 280 | 12,010 | |
| Tarum | 40 | 3,070 | | Yanwela | 330 | 12,340 | |
| Hamtato | 150 | 3,220 | 4 | Bagvi | 440 | 12,780 | 15 |
| Nayjaff | 90 | 3,310 | | Atota | 320 | 13,100 | |
| Nuviya | 300 | 3,610 | | Kogouva | 120 | 13,220 | 16 |
| Cattical | 430 | 4,040 | 5 | Ahekpa | 60 | 13,280 | |
| Paralai | 150 | 4,190 | | Yondot | 320 | 13,600 | |
| Egala-Kuru | 380 | 4,570 | | Nozop | 1,780 | 15,380 | 17,18 |
| Uwanarpol | 310 | 4,880 | 6 | Mapazko | 390 | 15,770 | 19 |
| Hilandia | 2,000 | 6,880 | 7,8 | Lotohah | 1,500 | 17,270 | 20 |
| Assosa | 750 | 7,630 | 9 | Voattigan | 960 | 18,230 | 21,22 |
| Dimma | 250 | 7,880 | | Plitok | 420 | 18,650 | |
| Aisha | 420 | 8,300 | 10 | Dopoltan | 270 | 18,900 | |
| Nam Yao | 180 | 8,480 | | Cococopa | 3,500 | 22,400 | 23,24,25,26,27 |
| Mai Jarim | 300 | 8,780 | | Famegzi | 400 | 22,820 | |
| Pua | 100 | 8,880 | | Jigpelay | 210 | 22,840 | |
| Gambela | 710 | 9,590 | 11 | Mewoah | 50¡ | 22,890 | |
| Fugnido | 190 | 9,880 | 12 | Odigla | 350 | 23,240 | 28 |
| Degeh Bur | 150 | 10,030 | | Sanbati | 1,440 | 24,680 | 29 |
| Mezan | 450 | 10,480 | | Andidwa | 260 | 24,940 | 30 |

### Selecting Households in a Village

There are several ways to select households in a village. The method used in EPI surveys, which generally provides a reasonable approach to household selection, will be described.[3] If a household is selected for the sample, every attempt should be made to locate the individuals in that household. Finding residents at home can be facilitated by doing the survey during hours when people are most likely to be at home or by working with local leaders to request that people remain near their houses until the sampling is completed.

Selecting households involves two steps: first, the selection of the first household to visit, and second, the selection of subsequent households to visit. The selection of the first household can be done using different methods depending upon the size of the village and whether a listing or map of households is available. These steps are described in more detail below.

#### *Selecting the First Household*

*Method 1 - Small village where a list or map of the households is available:*
Some villages may have a reasonably complete listing or map of households from census records or tax lists. In small villages it might be feasible to quickly map the village and number the households (if there are fewer than 100). The steps for selecting households are:

**Step 1:** Number all of the households.
**Step 2:** Randomly select a number from 1 to the highest numbered household. The number can be selected using a random number table or from a currency note.
**Step 3:** Go to the selected household and collect the survey information.

*Method 2 - Smaller village where a list or map of households is not available:*
If there are more than 100 households and no list or map, it may not be practical to develop such a list. The steps to take in this situation are:

**Step 1:** Select a central area of the village, such as a market, mosque or church.
**Step 2:** Randomly select a direction to walk towards the outer part of the village. This can be done by spinning a bottle or pen on the ground. Whichever way the bottle or pen points, go in that direction.
**Step 3:** Count all of the households from the central area to the edge of the village.
**Step 4:** Randomly select a number from 1 to the total number of households counted. The number selected will be the first household to visit.

*Method 3 - Urban areas:*
If a survey is to be performed in a large urban area, one approach is to divide the area into smaller sections of approximately equal population size. Then randomly select one of the areas. If the selected area has a list of households available, then use Method 1 described previously to select the first household. If there is no list, then use Method 2 described previously only in Step 2 walk towards the outer part of the smaller section rather than the outer part of the city. Another method that can be used in urban areas is to randomly select a block and randomly select the first household on the block.

#### *Selecting Subsequent Households*

Once the first household is selected, the second household is the one whose front door is closest to the first household (the direction of the second and subsequent households is not important). The third household to visit would be the closest front door of the next household (excluding any households already visited). This is repeated until the appropriate number of households is selected.

In urban areas there may be multi-family dwellings, such as apartment buildings. One approach would be to determine the number of floors in the building, randomly select one floor, go to that floor, number the apartments, randomly select one apartment, then follow the "next closest front door" method to select subsequent apartments. If all the households on that floor have been visited and you need more households to complete the survey, go to the front door of the building and select the nearest front door of the next dwelling and repeat the process.

*Note:* In household-based surveys, using the "next closest household" method for selecting households may result in a sample of households not representative of the village. Results at the cluster level should therefore be interpreted cautiously.

## SCHOOL-BASED SURVEYS

The two main issues in performing school-based surveys are:

1) How to select schools to be in the survey; and
2) how to select pupils within a school.

### Selecting schools

When performing school-based surveys in a geographic area, the first questions that need to be answered are:

1. Is there a list of all schools in the geographic area?
2. If there is a list, is the number of pupils in each school known?

In most areas a list of schools and their enrollment is available. In this case, the selection of schools would be performed using the PPS method described for selecting villages. If there is a list of schools but the enrollments are not known, schools can be selected using systematic selection. Using systematic selection rather than PPS complicates the analysis somewhat, but if enrollment information cannot be obtained easily there may be no alternative. If there are an extremely large number of schools in an area or no list of all of the schools, one of the methods described below can be used.

*Method 1 - Schools and their enrollment are known:*
In this situation, the PPS method described for selecting villages described earlier in this chapter is preferable. First, generate a list of schools similar to that shown in Table 8-2. Second, determine the cumulative enrollment. Finally, the selection of the schools using PPS is the same as described for selecting villages.

**Table 8–2**

## Selection of schools using the PPS method

| Schools | Enrollment | Cumulative | Cluster |
|---|---|---|---|
| Utural | 600 | 600 | |
| Mina | 700 | 1,300 | 1 |
| Bolama | 350 | 1,650 | 2 |
| Taluma | 680 | 2,380 | 3 |
| etc. | | | |

*Method 2 - A list of the schools is available but enrollments are not known:*
When a list of schools is available but the enrollment for each school is not known, then the systematic selection method should be used. The steps are as follows:

**Step 1:** Obtain the list of the schools and number them from 1 to the total number of schools
**Step 2:** Count the number of schools (N).
**Step 3:** Determine the number of schools to sample (n), which is usually thirty.
**Step 4:** Calculate the "sampling interval" (k) by N/n (always round down to the nearest whole integer).
**Step 5:** Using the random number table (Appendix 8–2), select a number between 1 and k. Whichever number is randomly selected, go to the school list and include that school in the survey.
**Step 6:** Select every kth school after the first selected school.

### *Example: Systematic Selection of Schools*

For illustrative purposes, Table 8–3 lists fifty schools. How would eight schools be selected?

**Step 1:** The listing is shown in Table 8–3.
**Step 2:** There are fifty schools, therefore N=50.
**Step 3:** The number of schools to sample is eight, therefore n=8.
**Step 4:** The sampling interval is 50/8 = 6.25; round down to the nearest whole integer which is 6; therefore, k=6.
**Step 5:** Using a random number table, select a number from 1 to (and including) 6. In this example, let's say the number selected was 3. Therefore, the first school to be selected is the third school on the list, which in this example is Bolama.
**Step 6:** Select every sixth school thereafter; in this example, the selected schools would be 3, 9, 15, 21, 27, 33, 39, and 45.

**Table 8-3**

## Selection of schools using the systematic selection method

| School | | Selected? |
|---|---|---|
| 1 | Utural | |
| 2 | Mina | |
| 3 | Bolama | Y |
| 4 | Taluma | |
| 5 | War-Yali | |
| 6 | Galey | |
| 7 | Tarum | |
| 8 | Hamtato | |
| 9 | Nayjaff | Y |
| 10 | Nuviya | |
| 11 | Cattical | |
| 12 | Paralai | |
| 13 | Egala-Kuru | |
| 14 | Uwanarpol | |
| 15 | Hilandia | Y |
| 16 | Assosa | |
| 17 | Dimma | |
| 18 | Aisha | |
| 19 | Nam Yao | |
| 20 | Mai Jarim | |
| 21 | Pua | Y |
| 22 | Gambela | |
| 23 | Fugnido | |
| 24 | Degeh Bur | |
| 25 | Mezan | |
| 26 | BanVinai | |
| 27 | Puratna | Y |
| 28 | Kegalni | |
| 29 | Hamali-Ura | |
| 30 | Kameni | |
| 31 | Kiroya | |
| 32 | Yanwela | |
| 33 | Bagvi | Y |
| 34 | Atota | |
| 35 | Kogouva | |
| 36 | Ahekpa | |
| 37 | Yondot | |
| 38 | Nozop | |
| 39 | Mapazko | Y |
| 40 | Lotohah | |
| 41 | Voattigan | |
| 42 | Plitok | |
| 43 | Dopoltan | |
| 44 | Cococopa | |
| 45 | Famegzi | Y |
| 46 | Jigpelay | |
| 47 | Mewoah | |
| 48 | Odigla | |
| 49 | Sanbati | |
| 50 | Andidwa | |

In some circumstances you might actually select more than the number needed. In the above example, had the random number chosen in Step 5 been 1 or 2, then nine schools would have been selected rather than eight. This is because the value for k was rounded down from 6.25 to 6. To remove one school so that only eight are selected, again go to the random number table, pick a number and the school that corresponds to the random number is eliminated from the survey. To properly analyse the data collected using systematic sampling, additional information to collect would be the number of eligible pupils in each school, from which statistical weights are developed. This is discussed in more detail below in the section on analysis of survey data.

*Method 3 - An extremely large number of schools:* In very large populations it may not be possible or efficient to select schools using the PPS or systematic selection methods. For example, Szechuan Province in China has a population of around 100 million. Even if a list of schools was available at the provincial level, it would take a lot of time and effort to select schools using either the PPS or systematic method. Another approach is to first select districts (which in China are called "counties") using the PPS method. Develop a listing of the districts, their populations, and cumulative populations similar to the PPS selection described earlier. Next, determine the number of schools to survey based on the cumulative population using PPS. For districts with more than one "cluster" to be selected, go to the district and select the schools using a random number table. For example, if a district has 200 schools, take a list of the schools and number them from 1 to 200. Next, go to the random number table and randomly select a number from 1 to 200. If a district is to have two schools selected, then randomly select two numbers. While not technically correct, it would be acceptable to analyse the school-based data as though the schools were selected using the PPS methodology.

### Selecting Pupils Within a School

The simplest way to select students within a school is by systematic selection, similar to that described earlier for selecting schools with some modifications depending on the number of eligible pupils in the school and the number of pupils to be sampled. The steps to follow are presented below:

**Step 1:** Obtain a list of pupils in the grades to be surveyed and sequentially number them from 1 to the total number of eligible pupils.
**Step 2:** Count the number of pupils (N).
**Step 3:** Determine the number of pupils to sample (n), usually between 10 and 40.
**Step 4:** *If N/n is less than 1,* then sample all pupils. *If N/n is greater or equal to 1 and less than 2,* then it is usually easier to select children to exclude from the survey. Calculate the "sampling interval" (k) by N/(N-n), always rounding down to the nearest whole integer. Select a random number from 1 to k. The number selected is the first child to exclude from the survey; exclude every kth child. *If N/n is greater than or equal to 2,* then select pupils to be included in the survey. Calculate the "sampling interval" (k) by N/n, always rounding down to the nearest whole integer. Select a random number between 1 and k. Include every kth child.

*Examples*

1. If a selected school has only 18 eligible children yet 20 are to be selected, all 18 children should bring salt to school. One could go to a higher or lower grade and randomly select two more children, but do not select another school to get additional salt samples.

2. If there are 28 eligible pupils in the school and 20 are to be selected, calculate the sampling interval (k) by N/(N-n) = 28/(28 - 20) = 28/8 = 3.5, which is rounded down to 3 (as described in Step 4 above). Next, randomly select a number from 1 to 3. For example, if the number selected was 2, exclude the second child from the survey and thereafter every third child would be excluded. Therefore, the pupils to **not** survey are 2, 5, 8, 11, 14, 17, 20, 23, and 26.

Now the listing of children to exclude has nine numbers but only eight need to be excluded. Use the random number table to select one of these children to be included in the survey. For this example, say that the number 17 was randomly selected to be included in the survey. Therefore, the following children would be surveyed: 1, 3, 4, 6, 7, 9, 10, 12, 13, 15, 16, 17, 18, 19, 21, 22, 24, 25, 27, and 28.

3. If a school has 143 eligible individuals and ten are needed for the survey, the sampling interval would be k = 143/10 = 14.3 which is rounded down to 14. Therefore, every fourteenth individual is to be included in the survey. Pick a random number from 1 to 14 (inclusive) using a random number table. The child corresponding to the randomly selected number is surveyed. Next, every 14th child is surveyed. For example, if the random number selected is 6, the children corresponding to the following numbers would be selected for the survey: 6, 20, 34, 48, 62, 76, 90, 104, 118, and 132.

### Other Possibilities

In situations where male and female children attend the same school, the selection of schools and pupils would be the same as discussed above. In other situations males and females may attend separate schools, in which case when a school of one sex is selected, the nearest school of the opposite sex is also surveyed. For example, a survey is to be performed in an area where males and females attend separate schools. The survey is to select thirty schools and sample twenty pupils in each. Schools are selected and when an all male school is visited, collect information on ten male pupils; next, go to the closest female school, and collect salt samples from ten female pupils.

## ANALYSIS OF SURVEY DATA

With the increasing availability of microcomputers, data can be entered in a relatively short time and analysed in the field. The calculated proportion of households using adequately iodized salt is an estimate of the larger population. Confidence intervals provide a range of values in which the "true" proportion is likely to be "captured."

Before performing various types of analyses, thought should be given as to what questions will be critical for decision making, such as: Is there a large proportion of households not using iodized salt? If so, what can be done to improve the situation? Which legal or communications strategies are likely to improve the situation? The analyses should give priority to these questions while other analyses can be performed later to address less urgent information needs.

In the interpretation of data, it is important to remember that sampling errors, measurement errors, and the skill of the survey team members influence survey results. Care should be taken to present the survey results not as exact figures, but rather as estimates.

In transmitting the results of analyses to the government and other agencies, the total number of households examined and the percentage of households with iodized salt should be highlighted. Cross-tabulated data may be useful to present in certain circumstances, but such tables should be kept simple, straightforward, and presented with a clear purpose. With cluster surveys, care must be taken to present the data in an aggregate fashion rather than by clusters to avoid having individual clusters inappropriately singled out for intervention at the expense of a broader intervention program. The statistical variability in an individual cluster is too large to draw firm conclusions, and it must be remembered that each cluster is probably representative of tens or hundreds of locations in similar conditions.

There are differences in how data are analysed depending upon whether or not the PPS methodology was used and these are described in the next two sections.

### PPS Surveys

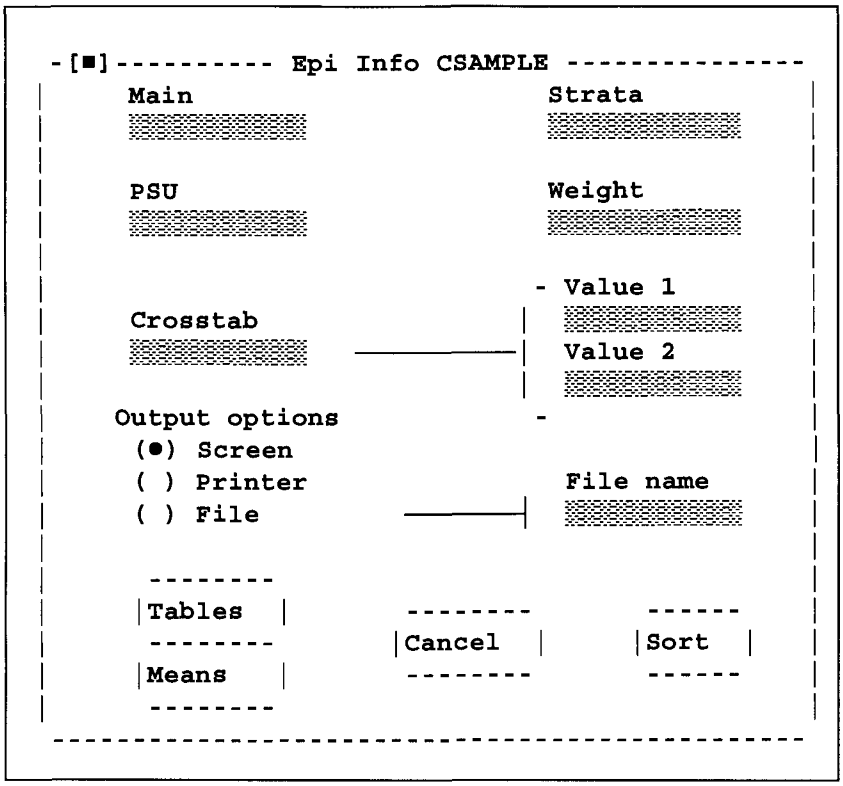
With PPS surveys, it is relatively straightforward to calculate the proportion of households using iodized salt. All that is needed is to count the number of samples that were adequate and divide by the number of samples tested, which can easily be calculated by hand. For example, if 300 households were visited and 157 had adequately iodized salt, then the proportion of households with adequately iodized salt would be 157/300 = 52%. If a school-based PPS survey was performed and 451 children out of 600 had salt with adequate levels of iodine, then the proportion would be 451/600 = 75%. If the data are on a computer, analyses could be performed by software programs like Epi Info.[4]

While the calculation of the proportion for PPS surveys is straightforward, the calculation of the confidence interval is more complex. The confidence interval is an important part of presenting the results because it provides a range that, with 95% confidence, captures the "true" proportion. The width of the confidence intervals provides an idea of the precision of the survey; the narrower the confidence limits, the greater the precision. In comparing one area to another or the results of two surveys performed at different times in the same area, the confidence intervals allow one to determine whether differences between two prevalences are significant. In the calculation of confidence intervals, most software programs, such as the Statistical Package for the Social Sciences (SPSS) and the Statistical Analysis System (SAS), assume that the data were collected using simple random sampling. In general, given equal sample sizes, confidence intervals for PPS surveys are wider than those assuming simple random sampling. This is because there is usually a penalty for the PPS survey because it samples twice, whereas in simple random sampling there is only one sampling. In PPS the first selection is the village or school (i.e., the "clusters"), and the second selection is individuals to be in the survey. It is beyond the scope of this manual to explain this concept further.

Epi Info Version 6.0 has a module for analysing complex survey data called "Csample." This program can calculate correct confidence intervals for survey data which take into account complex designs. Additional information on use of Csample can be found in the Epi Info documentation; an example, using real data from a district in an Asian country, is described next.

**Figure 8–1**

## Screen from Csample software




*Example of Analysing PPS Data using Csample*

In this example, thirty schools were selected by PPS, and within each school, forty salt samples were tested. After reading the Epi Info data file (a ".REC" file), the second Csample screen is shown in Figure 8-1. The "Main" variable is that which identifies whether or not the salt was iodized. In this example, it was called "iodine," and was coded as 0 if there was no iodine and 1 if there was iodine. The other important variable is the PSU (Primary Sampling Unit), which in a cluster survey is the variable which identifies the clusters. In this example, the variable is called "cluster." The other parts of the screen (Strata, Weight and Crosstab) are left blank. The results of the analysis are shown in Figure 8-2. The interpretation of the output is that only 4.1% of the salt samples tested contained iodine and the 95% confidence limits were 2.2%, 6.0%. If the cluster design of the survey had been ignored (i.e., assumed that the data were collected using simple random sampling), the proportion of households with iodized salt would be the same (4.1%), but the confidence intervals would be too narrow (3.1%, 5.4%). The design effect (DEFF) was 2.9 which would indicate that there was variation in the proportion of salt samples with iodine from school to school. In this example, the proportion of salt samples with iodine by school ranged from zero to 20%.

### Non-PPS Surveys

It may not always be possible to perform a PPS survey. For example, if schools were selected using a systematic sampling methodology, the enrollment of each sampled school is required to correctly analyse the data which must be "weighted." The concept behind "weighting" is that each child surveyed represents a larger number of children. Therefore, in surveys where a fixed number of children are selected from each school (for example, twenty pupils per school), children selected from a large school represent more children than pupils from a small school. This is illustrated in Table 8-4. If the size of the school is ignored, the proportion of salt samples estimated to contain iodine is the total number of "positive" tests divided by the number of samples tested, which in Table 8-4 is 20 / 60 = 33.3%. Another way to perform the calculation is to add the percent of positive samples and divide by the number of schools, which in this example would be (50% + 40% + 10%) / 3 = 33.3%. This later method demonstrates that there is an assumption that each school is weighted the same, i.e., one-third of the total. However, the enrollments differ: School A is much larger than the other two schools and therefore should be given more "weight" in the analysis.

**Figure 8–2**

## Example of output from Csample software

```
CTABLES COMPLEX SAMPLE DESIGN ANALYSIS

 Analysis of IODINE
IODINE                              <- The variable name for whether the salt had iodine
 ------------------------
|            |Total      |
|------------|-----------|
|0           |           |
| Obs        |       1151|
| Percent   V|     95.917|
| SE%        |      0.977|
| LCL%       |     94.001|
| UCL%       |     97.832|
|------------|-----------|
|1           |           |    <- Coding for iodine in salt, 1= yes, 0=no
| Obs        |         49|    <- The number of children with iodized salt
| Percent   V|      4.083|    <- The percent of children with iodized salt
| SE%        |      0.977|    <- Standard Error
| LCL%       |      2.168|    <- LCL% is the lower 95% confidence limit
| UCL%       |      5.999|    <- UCL% is the upper 95% confidence limit
|------------|-----------|
|Total Obs   |       1200|    <- Total number of children surveyed
|------------|-----------|
|Design eff. |      2.927|    <- The design effect (DEFF)
 ------------------------

  Sample Design Included:
  -----------------------
  Sampling Weights--None
  Primary Sampling Units from CLUSTER
  Stratification--None

  0 records with missing values
```

**Table 8–4**

## Example of weighted data

| School | Salt Tested No. | Positive % | No. Sampled (n) | Enrollment (N) | Weight (w) |
|---|---|---|---|---|---|
| A | 10 | 50 | 20 | 100 | 5.0 |
| B | 8 | 40 | 20 | 30 | 1.5 |
| C | 2 | 10 | 20 | 20 | 1.0 |
| | 20 | | 60 | 150 | |

**Ignoring weights**

Proportion = 20 / 60 = 33.3% or (50 + 40 + 10) / 3 = 33.3%

**Weighted**

$$\text{Proportion} = \frac{(50 * 100) + (40 * 30) + (10 * 20)}{150} = 42.7\%$$

(Note: the asterisk symbol * means multiplication)

One method of calculating weight is to add a new variable that divides the size of the school by the number of pupils surveyed in the school. For example, in Table 8–4, each pupil surveyed in School A should be given a weight of 100/20 = 5, i.e., each pupil surveyed in school A represents five pupils. In School B the weight would be 1.5, and School C, 1.0.

### *Example of Analysing Non-PPS Data using Csample*

Using the data from Figure 8-2, the "weight" variable described above was calculated. The weight variable must be entered into the second screen of Csample (see Figure 8–1), which in this example was called "weight." The results of the weighted analyses are shown in Figure 8-3. The "weights" affect both the proportion of households with salt and the design effect, which in turn affect the width of the confidence interval.

**Figure 8–3**

## Example of weighted data output from Csample software

```
                         CTABLES COMPLEX SAMPLE DESIGN ANALYSIS

  Analysis of IODINE
 IODINE
 |            |Total      |
 |------------|-----------|
 |0           |           |
 | Obs        |       1151|
 | Percent    V     95.277|
 | SE%        |      1.259|
 | LCL%       |     92.810|
 | UCL%       |     97.744|
 |------------|-----------|
 |1           |           |
 | Obs        |         49|
 | Percent    V      4.723|
 | SE%        |      1.259|
 | LCL%       |      2.256|
 | UCL%       |      7.190|
 |------------|-----------|
 |Total Obs   |       1200|
 |------------|-----------|
 |Design eff. |      4.225|
 |------------|-----------|

   Sample Design Included:
   -----------------------
   Sampling Weights from WEIGHT field      <-    Name of WEIGHT field
    Primary Sampling Units from CLUSTER
   Stratification--None

   0 records with missing values
```

### Other Analyses

The most important analysis is the proportion and 95% confidence intervals of households with adequately iodized salt. Other useful analyses are common characteristics of clusters with low coverage, such as the size of the village, whether the village is urban or rural, or whether there is a paved road to the village or electricity. These analyses would help focus efforts to improve coverage in areas in greatest need. Targeting efforts would not be directed towards only the individual clusters with low coverage but towards all villages with similar characteristics. However, as mentioned previously, interpretation of data at the cluster level must be done with caution.

For more detailed information on survey design and analysis, a recommended textbook is Scheaffer et al., *Elementary Survey Sampling*.[5]

**Software**

As mentioned, Epi Info Version 6.0 can be used for data entry and analysis. The cost of the English versions of the manual and software are:

| | Description | Stock No. | Inside Continental U.S. | Outside Continental U.S. |
|---|---|---|---|---|
| **Epi Info Version 6.0** | Manual and Disks | USD-E6S | $50.00 | $65.00 |
| | Manual only | USD-E6M | $35.00 | $50.00 |
| | Disks only | USD-E6D | $16.00 | $19.00 |

Volume discounts are available. Epi Info 6.0 can be ordered from:

USD, Incorporated
2075-A West Park Place
Stone Mountain, GA 30087, USA
Phone number: 404-469-4098
Fax number: 404-469-0681

For users with full access to the Internet, the Epi Info Version 6.0 software is available via an anonymous ftp (file transfer protocol) at: ftp.cdc.gov in the directory transaftp/pub/epi/epiinfo. For information on how to obtain other language versions of Epi Info (Arabic, Chinese, French, Portuguese, Russian, and Spanish), contact:

The Division of Surveillance and Epidemiologic Studies
Epidemiology Program Office
Centers for Disease Control and Prevention
Atlanta, GA 30333, USA
Phone number: 404-639-1326
Fax number: 404-639-1546
E-mail address: agd1@epo.em.cdc.gov

## ACKNOWLEDGMENTS

Parts of this chapter were adapted from the Centers for Disease Control and Prevention *Nutrition Assessment Manual*[7] and from the *EPI Coverage Survey*[3] manual.

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**APPENDIX 8–1**

# Sample Size Calculations for Cluster Surveys

To determine a sample size for a proportion, estimates for the expected proportion (p), desired level of certainty (Z), and level of absolute precision (d) must be determined. If the estimated proportion is not known, 0.5 (or 50%) is used because it produces the largest sample size (for given values of Z and d). If the proportion is expected to be between two values, select the value closest to 50%. For example, if the proportion is thought to be between 15% and 30%, use 30% for the sample size calculation.

The desired level of certainty (Z) refers to the level of confidence desired. Standard Z values are 1.96 for 95% confidence intervals and 1.65 for 90% confidence intervals. The concept of "certainty" is based on sampling a population to estimate a population proportion. The proportion calculated from survey data is an estimate of the population proportion. Generally a confidence interval is calculated to present the range of proportions within which the "true" proportion is likely to be captured. For example, if the proportion is 40% and the 95% confidence interval is (30%, 50%), the interpretation would be: We are 95% confident that the true proportion in the population lies somewhere between 30% and 50%. This would mean that it would be very unlikely (e.g., less than 5 times out of 100) for the true population proportion to be below 30% and or for it to be greater than 50%.

The level of absolute precision (d) specifies the width of the confidence interval: do you want the confidence interval to be ±5%? ±10%? For example, if the proportion is estimated to be 40%, would you be content with a confidence interval of (30%, 50%), which would be ±10%, or would you like a narrower confidence interval, (35%, 45%), i.e., ±5%? Values for d (the desired absolute precision) depend on the expected proportion and the purpose of the study. In general, if there is to be a comparison between different studies, then a relatively smaller d value may be needed to detect differences between studies. In estimating the proportion for only one study, common values for d are 0.025, 0.05, and 0.10 (i.e., 2.5%, 5.0% and 10%).

The sample size required for a cluster survey is almost always larger than that required for a random or stratified sample because of a phenomenon known as the design effect (DEFF). If the proportion of a condition is approximately the same in each sampled cluster, the DEFF will be around the null value of one. The greater the clusters differ from one another, the larger the DEFF. As the DEFF increases (which increases the variance around the proportion estimate), the sample size must be increased to maintain a desired level of precision.

The formula used for calculating sample size in cluster surveys which take into account the cluster design is:

$$n = \frac{Z^2 pq(DEFF)}{d^2}$$

Where DEFF = design effect and q = (1 – p)

There is not much experience in estimating what the DEFF is in household salt surveys, but in most nutrition and immunisation surveys, the DEFF is usually around two. However, if there is a large difference in the proportion of households that have iodized salt from one cluster to another, say 90% in some clusters and 10% in others, then the DEFF will probably be larger than two. In the example in Figure 8–2 using real data, the DEFF was 2.9.

Sample sizes for different values of the proportion, design effect, confidence level, and width of the confidence interval are in Table 8–5. A worksheet for use with this table is:

| | |
|---|---|
| Best estimate of the proportion of households using salt | ______% |
| Level of confidence (95% or 90%) | ______% |
| How wide do you want the confidence interval ( ±5% or ±10%) | ______% |
| Best estimate/guess of the design effect (usually between 2 to 4) | ______ |

In EPI surveys, the sample size traditionally used is 210 (30 clusters of 7 children each). This size is based on an assumed prevalence (p) of 50% (the value which gives the largest sample size), a desired level of confidence of 95% (Z = 1.96), confidence interval width of ±10% (d), and a design effect (DEFF) of 2. From Table 8–5, the sample size would be 193. When 193 is divided by 30 (the number of clusters), the value is 6.43 which is rounded up to 7 for seven children in each cluster.

In nutritional anthropometry surveys, the sample size traditionally used is 900 (30 clusters of 30 children each). This size is based on an assumed prevalence (p) of 50%, a level of confidence of 95% (Z = 1.96), confidence interval width of ±5% (d), and a design effect (DEFF) of 2. The actual calculated sample size is 768 (which, after to rounding up to a whole number for each cluster, would be 26 children per cluster in a 30 cluster survey or a total of 780 children); however, generally 900 (30 clusters of 30 children) are surveyed to provide an extra margin of protection for the precision, because the true design effect may be slightly greater than 2, and for convenience because 30 children in each cluster represents the number of children who can readily be weighed and measured by a single team in a day. If less precision is needed, a smaller sample size within each cluster may be used.

In a cluster sample survey, approximately thirty clusters should be surveyed.[1] Selecting substantially fewer than 30 clusters may provide an inaccurate picture of the true proportion of households with iodized salt within the population being surveyed, whereas the potential benefit of selecting substantially more than thirty clusters is minimal.

For additional information on sample size calculations, see Lwanga and Lemeshow.[6]

**Table 8–5**

## Sample sizes

**for various levels of proportions, design effects, confidence levels, and confidence interval width for cluster surveys**

**Total sample size required for 95% confidence level with a width of ±5%.**

| | Design Effect | | | | | |
|---|---|---|---|---|---|---|
| Proportion (%) | 1* | 2 | 3 | 4 | 5 | 6 |
| 10 or 90 | 139 | 277 | 415 | 554 | 692 | 830 |
| 20 or 80 | 246 | 492 | 738 | 984 | 1230 | 1476 |
| 30 or 70 | 323 | 646 | 969 | 1291 | 1614 | 1937 |
| 40 or 60 | 369 | 738 | 1107 | 1476 | 1844 | 2213 |
| 50 | 385 | 769 | 1153 | 1537 | 1921 | 2305 |

**Total sample size required for 95% confidence level with a width of ±10%.**

| | Design Effect | | | | | |
|---|---|---|---|---|---|---|
| Proportion (%) | 1* | 2 | 3 | 4 | 5 | 6 |
| 10 or 90 | 35 | 70 | 104 | 139 | 173 | 208 |
| 20 or 80 | 62 | 123 | 185 | 246 | 308 | 369 |
| 30 or 70 | 81 | 162 | 242 | 323 | 404 | 485 |
| 40 or 60 | 93 | 185 | 277 | 369 | 461 | 554 |
| 50 | 97 | 193 | 289 | 385 | 481 | 577 |

**Total sample size required for 90% confidence level with a width of ±5%.**

| | Design Effect | | | | | |
|---|---|---|---|---|---|---|
| Proportion (%) | 1* | 2 | 3 | 4 | 5 | 6 |
| 10 or 90 | 98 | 195 | 293 | 390 | 488 | 585 |
| 20 or 80 | 174 | 347 | 520 | 693 | 866 | 1040 |
| 30 or 70 | 228 | 455 | 682 | 910 | 1137 | 1364 |
| 40 or 60 | 260 | 520 | 780 | 1040 | 1299 | 1559 |
| 50 | 271 | 542 | 812 | 1083 | 1354 | 1624 |

**Total sample size required for 90% confidence level with a width of ±10%.**

| | Design Effect | | | | | |
|---|---|---|---|---|---|---|
| Proportion (%) | 1* | 2 | 3 | 4 | 5 | 6 |
| 10 or 90 | 25 | 49 | 74 | 98 | 122 | 147 |
| 20 or 80 | 44 | 87 | 130 | 174 | 217 | 260 |
| 30 or 70 | 57 | 114 | 171 | 228 | 285 | 341 |
| 40 or 60 | 65 | 130 | 195 | 260 | 325 | 390 |
| 50 | 68 | 136 | 203 | 271 | 339 | 406 |

*A design effect (DEFF) of 1 has the same sample size as random sampling from a large population. The confidence interval (CI) is based on the Z value (1.96 for 95% CI, 1.645 for 90% CI). The width is the absolute precision (d) around the proportion. To use the table, take the total sample size required and divide by the number of clusters to determine the number of children per cluster to be surveyed.

## APPENDIX 8–2

# RANDOM NUMBER TABLES

To use the random number table in Table 8–6, first choose a direction in which numbers will be read (down, up, left, or right). Next, close your eyes and point to a place on the random number table. The number closest to the point touched on the table is the starting point. Read the numbers in the direction decided upon ahead of time using the number of digits required.

**Example:** In the selection of households, it was determined that every 26th household should be included in the survey. To select the first house, a random number is selected from 1 to (and including) 26. For this example, it was decided to read the numbers downward from the starting point, and the starting point is in the third column and the eleventh row (8921). In this example, we only need to use the first two digits, 89.

Reading down the column, the next number is 52, then 50, 39, 69, and finally 21. The value 21 is between 1 to 26 and therefore the first house to be sampled is the 21st household, and after that, every 26th household is selected.

If more than four digits are needed for the selection process, the numbers in the next column can be used. For example, say a five digit number is needed for selecting villages and cities from a cumulative population listing to be included in a cluster survey. The first number in the upper left-hand corner of the random number table could be read as 20,570, and, reading downward, the next number as 64,352, etc.

If a random number table is not available for making selections, another method to obtain a number is to use the local currency. Usually there is a unique serial number on paper money. From a group of paper money, randomly pull one bill out and use the serial number on the bill.

Table 8-6

# Random number table

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2057 | 0762 | 1429 | 8535 | 9029 | 9745 | 3458 | 5023 | 3502 | 2436 |
| 6435 | 2646 | 0295 | 6177 | 2755 | 3080 | 3275 | 0521 | 6623 | 1133 |
| 3278 | 0500 | 7573 | 7426 | 3188 | 0187 | 7707 | 3047 | 4901 | 3519 |
| 7888 | 6411 | 1631 | 6981 | 1972 | 4269 | 0022 | 3860 | 1580 | 6751 |
| 4022 | 6540 | 7804 | 5528 | 4690 | 3586 | 9839 | 6641 | 0404 | 0735 |
| 0888 | 3504 | 2651 | 9051 | 5764 | 7155 | 6489 | 2660 | 3341 | 8784 |
| 0605 | 4640 | 8692 | 7712 | 9832 | 6607 | 0480 | 2557 | 3461 | 9755 |
| 4398 | 8857 | 0221 | 3844 | 1823 | 4407 | 5914 | 7545 | 2362 | 2428 |
| 7899 | 2623 | 9965 | 7366 | 0486 | 8185 | 5896 | 3985 | 3105 | 7210 |
| 5375 | 2213 | 8481 | 0919 | 2350 | 7310 | 7106 | 0046 | 1683 | 6269 |
| 1120 | 5436 | 8921 | 6457 | 8361 | 9849 | 9902 | 4244 | 2377 | 9213 |
| 4625 | 5978 | 5266 | 7521 | 8488 | 6854 | 9203 | 2598 | 2673 | 2399 |
| 5112 | 4318 | 5003 | 3532 | 6430 | 5679 | 5041 | 2108 | 1813 | 4235 |
| 3915 | 9380 | 3918 | 5957 | 3603 | 6553 | 6247 | 8907 | 5282 | 1106 |
| 9223 | 5629 | 6982 | 4138 | 2901 | 7592 | 1650 | 2580 | 5676 | 6470 |
| 0122 | 0620 | 2140 | 5291 | 8499 | 3653 | 1727 | 0453 | 3032 | 2902 |
| 4114 | 2462 | 2820 | 0414 | 7197 | 3854 | 2940 | 3500 | 8685 | 6131 |
| 0774 | 7788 | 5011 | 4971 | 0848 | 0748 | 7103 | 3262 | 5182 | 1185 |
| 1493 | 3425 | 0114 | 4662 | 0802 | 1125 | 8745 | 5513 | 9750 | 0695 |
| 5727 | 7577 | 8631 | 0759 | 5430 | 9953 | 1426 | 0405 | 2109 | 2304 |
| 5329 | 2475 | 8555 | 8172 | 1376 | 3459 | 6778 | 6917 | 0159 | 9635 |
| 7058 | 4886 | 2373 | 5937 | 9383 | 5763 | 8004 | 8602 | 2457 | 9134 |
| 0099 | 2200 | 2369 | 8140 | 4865 | 4874 | 4867 | 5206 | 0434 | 3845 |
| 0659 | 0499 | 3671 | 2771 | 2104 | 9275 | 2118 | 8024 | 1033 | 0529 |
| 1596 | 6230 | 3551 | 3506 | 5255 | 9108 | 0356 | 1225 | 1590 | 4395 |
| 0545 | 4817 | 9267 | 0371 | 5284 | 2221 | 0196 | 1096 | 4899 | 5525 |
| 6166 | 0733 | 6128 | 5076 | 1275 | 0830 | 7068 | 3991 | 3074 | 2971 |
| 4117 | 9128 | 4402 | 2038 | 5331 | 7530 | 7453 | 0957 | 1607 | 6088 |
| 8288 | 2958 | 3952 | 3918 | 5441 | 9365 | 9416 | 4897 | 7032 | 2475 |
| 1577 | 9415 | 2710 | 8305 | 6371 | 6065 | 0247 | 1365 | 8204 | 0017 |
| 9777 | 9879 | 4107 | 4685 | 8972 | 9948 | 4715 | 7049 | 0376 | 0882 |
| 7306 | 1399 | 4910 | 0074 | 9746 | 3203 | 9962 | 6041 | 4534 | 0062 |
| 8830 | 8623 | 7382 | 3570 | 5267 | 2355 | 7382 | 0171 | 7830 | 7416 |
| 0649 | 6675 | 6679 | 6681 | 7699 | 0805 | 5125 | 3177 | 7846 | 6891 |
| 4000 | 0001 | 3982 | 6805 | 6783 | 4715 | 6524 | 8615 | 3841 | 5508 |
| 2282 | 5183 | 4865 | 6339 | 8762 | 8930 | 4058 | 0575 | 1083 | 2992 |
| 8197 | 8865 | 0619 | 5693 | 4251 | 1158 | 1801 | 2006 | 1051 | 6518 |
| 4222 | 6138 | 0639 | 6599 | 0124 | 6559 | 4921 | 5162 | 7018 | 2384 |
| 1331 | 1221 | 3024 | 3839 | 2581 | 0017 | 4060 | 4781 | 6342 | 2808 |
| 9245 | 8353 | 5373 | 1085 | 2086 | 3356 | 3530 | 7662 | 7278 | 7993 |
| 9405 | 7493 | 9184 | 0309 | 0636 | 7980 | 3496 | 8936 | 4313 | 6417 |
| 2824 | 0568 | 0885 | 9270 | 4830 | 5958 | 2679 | 5622 | 3936 | 8687 |
| 1421 | 7905 | 1374 | 5079 | 5885 | 4803 | 4167 | 2356 | 0106 | 6433 |
| 8862 | 5634 | 9431 | 1435 | 3847 | 1364 | 7439 | 1254 | 3347 | 7625 |
| 0633 | 2973 | 0255 | 8997 | 5394 | 6188 | 2572 | 3427 | 4085 | 4168 |

# CHAPTER 9

# LOT QUALITY ASSURANCE SAMPLING (LQAS) FOR MONITORING SALT

9

## INTRODUCTION

Testing salt for iodine content may be performed for different purposes and in different settings. This chapter focusses on a specific method that can be useful for monitoring salt at:

- Importation
- Production
- Warehouses
- Retail shops
- Households

More information on the purpose and issues involved in monitoring salt at these various levels can be found in Chapters 4–7. Another issue not covered in this chapter is whether the rapid test kit or titration methods should be used for measuring the iodine content of salt nor appropriate cutoff (in terms of iodine parts per million). This chapter focusses on the application of a method called lot quality assurance sampling (LQAS) for monitoring salt.[1-3] LQAS can be used to determine whether or not a minimum standard for adequately iodized salt has been met.

## WHAT IS LQAS?

LQAS has its origins in industry where it is used to determine whether a "batch" or "lot" of items meets some quality assurance standards. For example, a manufacturer of light bulbs may produce light bulbs in lots of 2,000. For every lot, they may want to assure that at least a certain minimum number of light bulbs work, or inversely, that only a small number will fail. It would be inefficient to test every single light bulb prior to shipping. In general, LQAS is used when there is a need to test "lots" as efficiently as possible (i.e., the fewest number of light bulbs) to determine whether or not the lot meets a predetermined standard for quality. LQAS has been used in immunisation programmes to identify clinics where children are inadequately immunised. Within every clinic, a small sample of immunisation records are checked and the adequacy of each child's immunisations determined. If records reveal too many children not properly immunised, the clinic "fails" and further investigation is made to confirm whether a problem truly exists. If enough children are properly immunised, the clinic should "pass" and no corrective action is needed. In this way, it is possible to focus efforts where programmatic support is needed.

This chapter presents an overview of LQAS and provides the technical details with examples of how to determine appropriate sample sizes. Those who desire a more in depth review of LQAS can refer to Appendix 9–1.

## SAMPLE SIZE FOR LQAS

The sample size selected is designed to inform whether a "lot" (e.g., a population or a batch of salt) meets a specific standard. This standard is usually established at the national or provincial level. Operationally, two important values that need to be determined are the number of items to take (n) and the "threshold value" d* (the number of the items in a single sample that fail to meet the standard) which will indicate whether a lot "passes" or "fails." The actual number of items that fail are referred to as d. The selection of n and d* need to take into account the following:

- The program goal, e.g., the proportion of salt samples in a lot that should contain sufficient iodine (referred to as "$P_a$")
- The proportion of samples of salt in a lot that contain iodine below which would be designated a "failure" (referred to as "$P_0$").

**Technical Note:** Two other values that need to be determined for sample sizes are the desired level of significance and power. Discussion of these values is beyond the scope of this document and one set of values is used at the import, production, and warehouse monitoring and another set of values for monitoring at the retail and household level.

Reasonable values for $P_a$ and $P_0$ depend on the specific situation to which they are applied. The next section deals with sample sizes for monitoring salt at the import, production, and warehouse level, and the following section considers sample sizes at the retail and household level. An important assumption is that samples of salt are randomly selected throughout the "lot."

**Note:** This chapter describes only single-sampling plans. A similar method called double-sampling is described in Lemeshow and Taber.[4]

### Sample Sizes for Import, Production, and Warehouses

A sample size table for monitoring salt at importation, production, and in warehouses is shown in Table 9-1. The values in Table 9-1 are calculated to assure that adequately iodized salt will have a small probability of failing.

#### *Example of LQAS with Imported Salt*

A ship comes into port carrying salt which is claimed to be iodized. How many samples are needed to determine whether the salt meets government standards? For this example, assume that when salt is imported and claimed to be iodized, under ideal conditions 99% of the salt would truly be adequately iodized (i.e., $P_a$ = 99%). Also assume that by regulations at least 80% of the salt must be adequately iodized when it enters the country ($P_o$=80%). Using Table 9–1, n=16 and d*=1. Sixteen samples would need to be taken. If none or one sample (d=0 or 1) tests negative (i.e., insufficient iodine in the sample), the salt meets government standards and "passes." If two or more samples test negative (d≥2), the shipment "fails" to meet standards.

**Table 9–1**

## LQAS sample sizes at import, production, and warehouse levels for various values of $P_a$ and $P_o$†

| $P_a$ | $P_o$ | n | d* | $P_a$ | $P_o$ | n | d* | $P_a$ | $P_o$ | n | d* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 99% | 95% | 164 | 4 | 90% | 80% | 147 | 23 | 80% | 65% | 106 | 30 |
| | 90% | 47 | 2 | | 75% | 70 | 12 | | 60% | 61 | 19 |
| | 85% | 25 | 1 | | 70% | 42 | 8 | | 55% | 40 | 13 |
| | 80% | 16 | 1 | | 65% | 28 | 6 | | 50% | 28 | 10 |
| | 75% | 11 | 1 | | 60% | 20 | 5 | | 45% | 21 | 8 |
| | 70% | 8 | 0 | | 55% | 15 | 4 | | 40% | 16 | 6 |
| | 65% | 7 | 0 | | 50% | 12 | 3 | | 35% | 12 | 5 |
| | 60% | 5 | 0 | | 45% | 9 | 2 | | 30% | 10 | 4 |
| | | | | | 40% | 7 | 2 | | 25% | 8 | 4 |
| 95% | 85% | 94 | 9 | 85% | 70% | 90 | 21 | 75% | 55% | 68 | 25 |
| | 80% | 47 | 5 | | 65% | 52 | 13 | | 50% | 44 | 17 |
| | 75% | 29 | 3 | | 60% | 34 | 9 | | 45% | 31 | 13 |
| | 70% | 20 | 4 | | 55% | 24 | 7 | | 40% | 22 | 10 |
| | 65% | 14 | 2 | | 50% | 18 | 6 | | 35% | 17 | 8 |
| | 60% | 11 | 2 | | 45% | 14 | 5 | | 30% | 13 | 6 |
| | 55% | 9 | 1 | | 40% | 11 | 4 | | 25% | 10 | 5 |
| | 50% | 7 | 1 | | 35% | 9 | 3 | | | | |

†Level of significance = 10% and power = 99%

*Example of LQAS with Locally Produced Salt*

A government inspector visits a large salt producer. The inspector reviews the internal quality control information (see Chapter 5) and notices a large pile of salt sitting outdoors in an open area. The inspector is told that the salt has been iodated and is waiting to be shipped elsewhere. The inspector decides to test samples of the salt to see if it adequately iodized. According to instructions developed at the national level, any salt that is thought to be improperly stored following iodization should be checked. The current standards are based on $P_a$=99% and $P_0$=70% (assuming the country is in the early stage of their salt iodization program and the regulations are phasing in what is considered "adequately iodized"); therefore n=8 and d*=0. The inspector takes 8 samples (which should be selected randomly from throughout the salt) and uses a rapid test kit to assure at least a minimal level of iodine. If none of the samples fail (d=0), the salt is accepted. If any samples fail, the inspector declares the lot as inadequately iodized and takes appropriate steps as determined by the government.

*Example of LQAS at the Warehouse Level*

An inspector visits a warehouse where salt arrives from salt producers in fifty kilogram sacks. At the warehouse the salt is repackaged into one kilogram plastic bags and distributed to retailers. On one side of the warehouse the inspector counts 185 fifty kilo sacks from one salt producer and on another side of the warehouse are 163 sacks from a different producer. The inspector decides to treat the salt from each of the two salt producers as different "lots." In the current phase of the salt iodization program, government regulations stipulate that 25 samples should be taken from each lot and tested using the rapid test kit. If one or no rapid tests are negative (d=0 or 1), the salt passes inspection. If two or more tests fail (d≥2), the salt fails inspection. (This example is based on $P_a$=99 and $P_0$=85 in Table 9–1.)

### Sample Sizes for Household and Retail Monitoring

For a household- and retail-based survey or monitoring system, a reasonable value for $P_a$ might be 95%, i.e., the ideal situation would be 95% of the households using adequately iodized salt. The lowest acceptable value would differ depending upon the situation within the country, province, or district, but the goal is to pick a value that will identify only the "worst" situations. For example, if fewer than 70% (i.e., $P_0$ = 70%) of the households are using adequately iodized salt, this would trigger action to improve the situation. A table of the sample sizes is shown in Table 9–2.

**Table 9-2**

## LQAS sample sizes at the household and retail levels for various values of $P_a$ and $P_0$†

| $P_a$ | $P_0$ | n | d* | $P_a$ | $P_0$ | n | d* | $P_a$ | $P_0$ | n | d* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 99% | 95% | 123 | 2 | 90% | 80% | 83 | 10 | 80% | 65% | 56 | 13 |
| | 90% | 42 | 1 | | 75% | 42 | 5 | | 60% | 33 | 8 |
| | 85% | 23 | 0 | | 70% | 26 | 3 | | 55% | 22 | 5 |
| | 80% | 16 | 0 | | 65% | 18 | 2 | | 50% | 15 | 4 |
| | 75% | 11 | 0 | | 60% | 13 | 2 | | 45% | 11 | 3 |
| | 70% | 8 | 0 | | 55% | 10 | 1 | | 40% | 9 | 2 |
| | 65% | 7 | 0 | | 50% | 8 | 1 | | 35% | 7 | 2 |
| | 60% | 5 | 0 | | 45% | 6 | 1 | | 30% | 5 | 1 |
| | | | | | 40% | 5 | 1 | | 25% | 4 | 1 |
| 95% | 85% | 60 | 4 | 85% | 70% | 50 | 9 | 75% | 55% | 61 | 18 |
| | 80% | 32 | 2 | | 65% | 30 | 6 | | 50% | 35 | 10 |
| | 75% | 21 | 1 | | 60% | 20 | 4 | | 45% | 23 | 7 |
| | 70% | 15 | 1 | | 55% | 14 | 3 | | 40% | 16 | 5 |
| | 65% | 11 | 1 | | 50% | 11 | 2 | | 35% | 12 | 4 |
| | 60% | 8 | 0 | | 45% | 8 | 2 | | 30% | 9 | 3 |
| | 55% | 7 | 0 | | 40% | 6 | 1 | | 25% | 7 | 2 |
| | 50% | 5 | 0 | | 35% | 5 | 1 | | | | |

†Level of significance = 5% and power = 80%

*Example of LQAS at the Household Level*

The long-term goal of a government is for 95% of households to have iodized salt and the government wants to identify villages that have fewer than 50% of the households using iodized salt. Therefore, $P_a$ = 95% and $P_0$ = 50%. In Table 9–2, the number of households to sample (n) would be 5. If any household is found not to have adequately iodized salt ($d \geq 1$), the village would "fail." If all of the samples are adequate, the village would "pass."

As the iodized salt situation improves and fewer villages fail at the current $P_0$ level, the $P_0$ value might be increased. For example, the $P_0$ value might be increased to 70% which would correspond to n=15 and d*=1. If the $P_0$ value is initially set too high, the majority of villages would fail, which would defeat the purpose of focussing intervention efforts on areas with the biggest problems.

*Example of the LQAS at the Retail Level*

A district health officer would like to identify villages where there is inadequate access to iodized salt. The goal is for 95% of all shops that sell salt to offer iodized salt. Initially, the district health officer would like to identify villages where fewer than 75% of the retail shops selling salt also sell iodized salt. How many shops need to be visited in each village? $P_a$ = 95% (the goal of the proportion of shops to sell iodized salt) and $P_0$ = 75% (the threshold limit). Using Table 9–2, the following values would be used: n = total number of samples = 21; d* = acceptance number = 1.

The interpretation of the n and d* values are that in each village, 21 shops that sell salt are visited. If none or only one shop is not selling iodized salt (d=0 or 1), the village passes. If two or more shops are not selling iodized salt ($d \geq 2$), then the village would fail.

## ADDITIONAL COMMENTS

Specific significance and power values are provided in Tables 9–1 and 9–2. If one wants to specify different values for these parameters, see Lwanga and Lemeshow for additional tables and formulae.[2] The possibility of combining information from LQAS has not been discussed. For example, in using LQAS at the household level to "pass" or "fail" villages, the information from all villages (or a sample of villages) in a district could be combined to estimate the proportion of households with iodized salt in the district. This would be the same as performing a "stratified" survey. The information needed from each village would be an estimate of the number of households in the village, the number of households sampled (n), and the number of households without iodized salt (d). For more information on how to combine these data see Scheaffer et al.[5]

## REFERENCES

1. Lanata CF, Black RE. Lot quality assurance sampling techniques in health surveys in developing countries: advantages and current constraints. Wld Hlth Statist Q 1991;44:133-139.

2. Lwanga SK, Lemeshow S. Sample size determination in health studies: a practical manual. World Health Organization, Geneva, 1991.

3. Lemeshow S, Stroh G Jr. Sampling techniques for evaluating health parameters in developing countries: a working paper. National Academy Press, Washington DC, 1988.

4. Lemeshow S, Taber S. Lot quality assurance sampling: single- and double-sampling plans. Wld Hlth Statist Q 1991;44:115-132.

5. Scheaffer R, Mendenhall W, Ott L. Elementary Survey Sampling (Fourth Edition). Duxbury Press, Belmont, 1990.

**APPENDIX 9–1**

# BASIC CONCEPTS IN LQAS

When using LQAS, a decision will be made to accept a lot (i.e., the lot "passes") or to not accept a lot (i.e., the lot "fails"). Because this decision is based on a sample, sometimes the decisions will be incorrect. Table 9-3 depicts the "truth," which is not known with certainty for any one sample, across the top of the table and the "decision" down the left side of the table. In the upper left and lower right cells the correct decisions are made. In the upper right and lower left cells incorrect decisions are made. The two possible errors are:

- To "pass" the lot when in truth the lot is inadequate, called the consumer risk because the consumer is getting a "bad" product, also called an "alpha" ($\alpha$) error.
- To "fail" a lot when in truth the lot is adequate, called the "provider risk" because the provider thinks the lot is "bad" when in fact it is acceptable, also called a "beta" ($\beta$) error.

When determining sample sizes for LQAS, the frequency of incorrect decisions must be taken into account, based on the consequences of the two types of error.

At the import or production level, failing lots which are truly adequately iodized can have severe economic and other consequences for the importer and producer. Therefore, the sampling scheme must assure that the beta errors are minimised. (Table 9–1 allows for this type of error in only 1% of the adequately iodized lots.) On the other hand, the decision to "pass" a lot which is truly inadequate means some of the population may continue to receive an inadequate level of iodine. (Table 9–1 allows for this type of error to occur 10% of the time for inadequately iodized salt.)

For household and retail level monitoring, failing villages when in truth they are adequate usually means that the government may intervene unnecessarily. The consequences are minimal and Table 9–2 allows for 20% of the adequate villages to "fail." If an area "passes" when in truth there are inadequate iodine levels in salt, IDD will continue to occur. This is usually the error that one would like to minimise and Table 9–2 allows this error to occur in only 5% of the villages that have inadequate coverage.

**Table 9-3**

## Basic Concepts in LQAS

| | | Truth<br>Lot is adequate | Lot is not adequate |
|---|---|---|---|
| **Decision** | Lot "passes" | Correct decision to pass lot | **Error:** Lot passes when it is really inadequate ("consumer risk" or alpha error). |
| | Lot "fails" | **Error:** Lot fails when it is really adequate ("producer risk" or beta error). | Correct decision to fail lot. |

# CHAPTER 10

# RAPID SALT TESTING KITS

## INTRODUCTION

The quality control of salt iodization through testing is critical to the overall success of any iodine deficiency disorders (IDD) elimination program. Rapid "spot" tests are highly sensitive tests that can be performed rapidly to detect levels of iodine in salt, and play an important role in salt monitoring programs. This chapter provides technical information about the intended use, availability, training requirements, and quality control issues pertinent to these spot tests. General comments about commonly available commercial test kits are also provided. Procedural notes for those wishing to prepare "in-house" salt test reagents themselves are given. Because these tests are specific for the form of iodine, details are given for tests for both potassium iodate ($KIO_3$) and potassium iodide (KI) in salt. More precise, quantitative measurement of the content of iodine in salt by factory and government laboratories is discussed in Chapter 11 – Titration Methods for Salt Iodine Analysis.

### Definition of Salt Iodine Spot Tests

Spot tests are technically simple, rapid check methods for detecting salt iodine, and can be readily performed outside the laboratory. The tests can be classified into two main categories:

- **Qualitative tests:** These indicate only the presence or absence of iodine over a broad range, e.g., a positive test result may simply indicate a salt sample with an iodine of content somewhere between 5 to 100 parts per million [ppm].
- **Semi-quantitative tests:** These give an approximate concentration of the iodine content in salt. These tests generally use some form of colour chart by which the iodine levels in a salt sample are estimated, e.g., <10 ppm, 10–24 ppm, 25–40 ppm.

Various spot test methods basically use the same general reaction mechanism: a starch-based reagent solution which produces a blue colour when iodine is present in the salt sample (Figure 10–1). More information about the chemical reaction is given later, in the section on "In-house" Salt Iodine Spot Test Method.

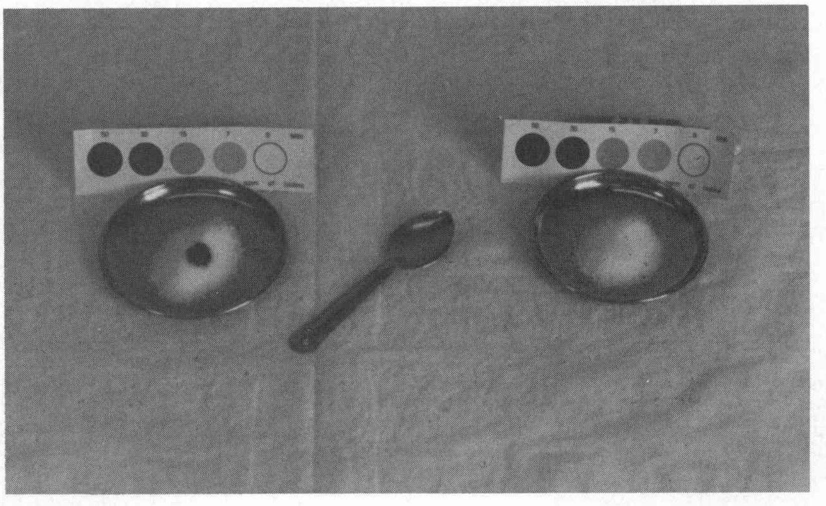


**Figure 10–1** *Photo showing a positive and negative spot test result for salt iodine.*

### Purpose of Salt Iodine Spot Tests

Because spot tests are simple, rapid, and are easily applied in field settings, individuals without specific chemistry training can easily verify whether a salt sample has been iodized. Spot tests can be used at the production, distribution, retail, and household levels. They are particularly appropriate for small scale salt producers who may not be able to achieve the level of sophistication needed to establish more quantitative laboratory titration methods.

In many countries spot testing kits are used by salt producers, health workers, child development organisations, urban services organisations, community leaders, school children and teachers, and retailers. They provide valuable information for the monitoring of salt iodine quality, as well as creating awareness and demand within the community to consume only iodized salt.

## TYPES OF SALT TEST KITS

### Commercial Spot Test Kits

A number of rapid spot test kits capable of detecting the levels of potassium iodate ($KIO_3$) in salt samples are now commercially available (see Appendix 10.1 for additional information on commercial kits). Most of these kits give semi-quantitative results and provide sufficient material to test approximately 100 salt samples per kit.

These commercial spot kits come ready to use and provide all the necessary materials needed for the test, including the test solutions (in dropper bottles), plate or dish for sample testing, measuring spoon, color comparison chart, and kit bag or container. Test kits are usually very portable and small, easily fitting into a pocket. Figure 10–2 shows some examples of typical field test kits.

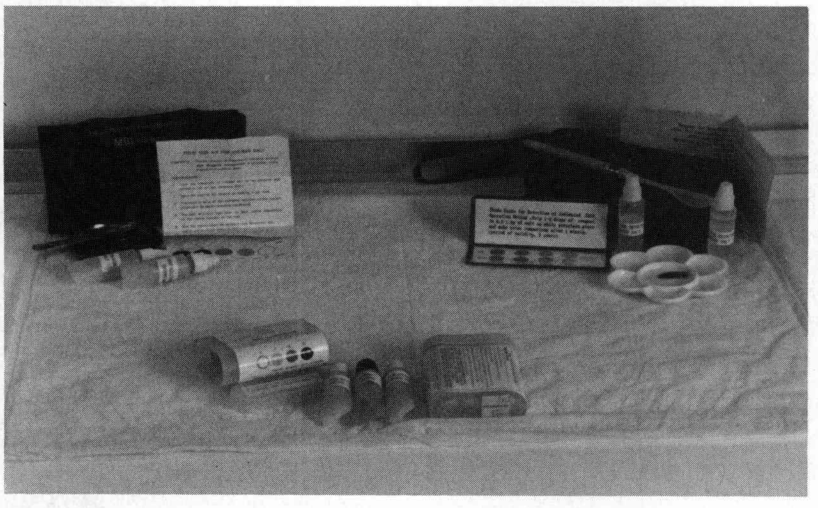


**Figure 10–2.** *Photo showing 3 different spot test kits and their typical components*

#### *General use of commercial kits*

Most commercial kits contain written instructions for the test procedure, usually in English. These should be followed carefully. Generally however, carrying out spot tests with these kits involves using a teaspoon to place one or two spoonfuls of salt onto the test plate, and adding one to two drops of test solution onto the salt sample. Addition of more than a few drops of test solution will not alter the test result, but simply wastes the solution.

Results should be determined immediately by comparing the intensity of the blue colour obtained on the test sample with the calibrated colour chart provided. If the result is not interpreted straight away, colour fading may occur over time and lead to incorrect results.

Some test kits will provide an additional "neutralising solution" for use with alkaline salt samples. In some cases, the alkalinity of the salt will lead to a negative test result even if iodine is actually present in the sample. Such kits recommend retesting a negative sample by first applying one drop of the neutralizing solution to the salt, and then two drops of test solution.

#### *Training for use of commercial kits*

While the kits are reasonably simple and can be used by non-technical persons, some form of preliminary training is advisable. The first concern should be the provision of clear, easily understood instructions. If the language of the instructions provided by the kit manufacturer is not appropriate, a clear translation that can be incorporated into the kits for field use should be made. It may also be helpful to run simple training sessions with prospective kit users, to practice using the kits and compare the interpretation of test results among users. One good method to achieve this is to have all participants carry out spot tests on a number of common salt samples and compare individual results. Potential problems that may be encountered in the field could also be discussed at this time.

#### *Precautions*

• Contamination may occur if the measuring spoon and test plate are not washed and/or wiped clean between each sample testing.

• The kits do not provide result forms or control samples, so thought will need to be given to how these can best be provided. Please see Quality Control section below.

• Because spot test kits are generally specific for iodate, not iodide, incorrect conclusions can be drawn if the test is applied to samples containing potassium iodide. Case Study 1 describes a situation in which this problem arose. If the form of iodine in a salt sample is unknown, a test for both iodate and iodide can be performed. (See "In-house" Salt Spot Method Section Below.)

• The kits should show an expected shelf life, usually 12–18 months. Kits which have outlasted their shelf life should not be used. Some commercial kits do not state the specific production date of that kit. Efforts should be made by purchasers to insist that producers/suppliers provide both production and expiration dates on all kits.

• In addition to the expiration date of the kit as a whole, the test solution also has a limited shelf life once the dropper bottle has been opened and used. This is generally three to six months. It is important therefore to make sure that the date on which the kit is first used is recorded on the test bottles.

• The kit solutions often contain dilute acid, so care should be taken not to spill solutions on clothing or to give them to young children.

*Quality control aspects*

While spot tests and kits are relatively simple, it is still important that routine testing of a "control" salt sample be performed whenever other samples are being checked. This control can be a salt sample known to have a positive iodine content, which is taken into the field with each kit and tested along with the unknown samples at each site. Should this known positive sample give a negative or lower than expected result, then one may suspect reagent deterioration or expiry of kit.

Because of the pivotal role spot kits often play in national salt iodine monitoring programmes, it is a good policy to undertake occasional cross-checking of results obtained with spot tests compared with more quantitative laboratory-based methods, e.g., titration. This will add confidence that the field spot tests are performing properly.

While there are no hard and fast rules concerning the frequency of such cross-checking, it should at least be done whenever new batches of field test kits are obtained and/or introduced. However, perhaps the best mechanism is to have a small number of salt samples continuously submitted to a central laboratory from various field settings along with the appropriate spot test results obtained, for quantitative cross-checking. Case Studies 1 and 2 provide descriptions of how cross-checking of spot test results from actual situations in two countries raised questions about the quality of salt iodization, and the usefulness of the salt iodine monitoring system.

**CASE STUDY 1**
**Samples giving negative spot test results while salt company claims salt was fortified.**

UNICEF salt kits detected iodate only, so when a major salt company changed to the use of potassium iodide, the spot tests began to give negative results. Independent laboratory investigation revealed that the samples were indeed fortified with potassium iodide, and the company was requested to change back to the use of potassium iodate in accordance with national regulations.

Conclusion — The form of iodine in salt should always be confirmed when using spot test results.

## "IN-HOUSE" SALT IODINE SPOT TEST METHOD

Spot tests are specific for the form of iodine; only the relevant form of iodine will react with visible colour development. Thus a sample fortified with potassium iodide (KI) will yield a negative result when an iodate ($KIO_3$) spot test is performed, and vice versa.

The following method published by Dustin and Ecoffey (1978) can be used in the laboratory or prepared as a kit for field use to verify the presence and form of iodine (iodate or iodide) in salt. Other spot test methods have also been published for both iodate and iodide (Narasinga and Ranganathan, 1985).

### Reagents

**Solution A:** 0.5% weight/volume (w/v) starch solution, made by boiling 0.5g soluble starch (or rice starch) in 100ml deionized water.
**Alternate Solution A:** Mix 10g wheat starch with 15g $H_2O$ and 90g glycerol, warm to 90°C in a water bath until mixture becomes uniformly translucent.

**Solution B:** 1%(w/v) sodium nitrite (0.25g in 25ml $H_2O$).

**Solution C:** 20% volume/volume (v/v) $H_2SO_4$ solution (2ml +8ml $H_2O$).

**Solution D:** 12%(w/v) potassium iodide (3g in 25ml $H_2O$).

**Solution E:** 5N hydrochloric acid solution, made by mixing 10ml concentrated HCl (12N) with 15ml deionized water.

**CASE STUDY 2**
**Conflict in test results**

In a donor agency country office a salt sample was tested using the UNICEF spot test kit for detection of iodate ($KIO_3$), with a result of >30 ppm. However, when cross-checked in an independent laboratory using the same type of kit, a result of <15 ppm was found, and the corresponding iodometric titration method result was 7 ppm.

Further investigation of the sample in the laboratory, using the spot test, yielded results <30 ppm, while additional results from quantitative methods ranged from 3 to 125 ppm.

The remaining sample was sent from the donor agency office to the laboratory for further analysis. The spot test gave results varied from >30 to >50 ppm, and titrations gave results ranging from 11 to greater than 104 ppm.

Conclusion — The salt was being inconsistently iodized during the manufacturing process.

In tropical climates, Solution A (both forms) is the least stable of the reagents, and should be prepared fresh if a known positive test sample fails. Mold growth in this mixture can be a problem, and thiomersal can be added as a preservative (5g added to each 25g starch, to give a final concentration of 0.1% thiomersal in solution).

The other solutions are generally usable as long as they remain colorless.

### Spot Test for Iodide

This test will detect the presence of iodide in salt at levels of 5–100 ppm. Mix 50ml solution A, ten drops (0.5ml) solution B and ten drops (0.5ml) solution C. If being used in a field setting, the "drops" referred to are those delivered by a regular medicine dropper, approximately 0.05ml each. This is the test reagent, which is stable for two to three days in temperate climates.

Place a small amount of the salt to be tested onto a saucer, and moisten with two drops of test reagent. If iodide is present, the salt should immediately turn blue, and remain blue for several minutes before fading.

**NOTE**: The relative degree of iodization **cannot** be measured using this test, as a uniform blue color is obtained over much of the range.

Reaction mechanism for the iodide spot test: Free iodine is liberated from salt iodide by oxidation with an acidic solution of sodium nitrite. The free iodine will turn starch a dark blue colour.

$$2NaNO_2 + H_2SO4 \rightarrow 2HNO_2 + NaSO_4$$

$$2HNO_2 + 2I^- \rightarrow I_2 + 2NO + H_2O$$

$$I_2 + STARCH \rightarrow \text{Blue Colour}$$

### Spot Test for Iodate

This test will detect the presence of iodate in salt at levels of 6–130 ppm. Mix 25ml solution A, 25ml solution D and 12 drops (0.6ml) solution E. This is the test reagent, which is stable for two to three days in temperate climates.

Place a small amount of the salt to be tested onto a saucer, and moisten with two drops of test reagent. If iodate is present, the salt should immediately turn grey/blue, and remain this colour for several minutes before turning brown.

**NOTE:** The relative degree of iodization can be roughly measured because this test will produce various shades of grey-blue over the range of iodate levels.

Reaction mechanism for iodate spot test: Iodate from salt, in the presence of free hydrogen ion, oxidizes added iodide to give free iodine; this then turns starch blue.

$$IO_3^- + 5I^- + 6H^+ \rightarrow 3I_2 + 3H_2O$$

$$I_2 + STARCH \rightarrow \text{Blue Colour}$$

*Cost of Reagents*

It costs approximately US$1.00 to prepare one set of Solutions A – E. This set of working solutions can be kept for testing salt samples for two to three days, and the volume is sufficient for testing approximately 500 samples.

## REFERENCES


1. Dustin JP, and Ecoffey JP. A field test for detecting iodine-enriched salt. Bulletin of the World Health Organization, 56(4):657-658, 1978.

2. Narasinga R, Ranganathan S. A simple field kit for testing iodine in salt. Food and Nutrition Bulletin, 7(4):70-72, 1985.

APPENDIX 10-1

# COMMERCIAL FIELD TEST KITS FOR IODIZED SALT

Commercial field spot test kits manufactured by MBI Chemicals, Madras, India, are available for procurement through UNICEF:

UNICEF Supply Division
UNICEF Plads, Freeport
DK-2100, Copenhagen, Denmark
Phone: (45) 3 527 3527
Fax: (45) 3 526 9421

**Ordering Information:**

Field Test Kits for the determination of potassium IODATE in iodized salt samples:

UNICEF STOCK No.: 05-860-00
(NOTE: For range 0-50 ppm)

UNICEF STOCK No.: 05-860-01
(NOTE: For range 0-100 ppm)

Field Test Kit for the determination of potassium IODIDE in iodized salt samples:

UNICEF STOCK No.: 05-860-02

**NOTES:**

1. There are two types of kits available for salt fortified with potassium iodate or potassium iodide. The type needed must be specified when ordering.

2. The standard kit is designed to check the presence of iodine in salt (fortified with potassium iodate) over the range of 0–50 ppm and consists of two ampoules of the test solution (10 ml in each ampoule, sufficient for 40–50 tests), packed in a cloth pouch along with a stainless steel spoon and plate, color chart and instruction notes.

3. For countries setting iodine dosage in salt at 100 ppm, MBI offers an alternate test kit. The test solutions show color contrast for iodine content up to 100 ppm.

4. The solutions have a shelf life of more than eighteen months if unopened and six months after opening the ampoule.

5. Refill ampoules (10) are available in cardboard boxes along with a colour chart and manual.

6. ALKALINE SALT: Some salts are alkaline due to the presence of carbonates, or certain free flow agents in the salt. In such circumstances the test solution may not give a blue colour indicating the presence of iodine in the salt. To avoid this problem a recheck solution has been developed. In cases where there is suspicion of possible salt alkalinity, or where the normal test solution does not indicate an expected colour change, a drop of the recheck solution may be placed on the salt before adding a drop of the normal test solution to detect the presence of iodine. If the recheck solution is used with a non-alkaline salt sample followed by addition of the normal solution, the correct iodine level will still be indicated. The recheck solution is provided in the test kit if the buyer indicates this need. Two recheck solution ampoules can also be provided in the refill ampoule carton if requested. The recheck solution ampoules can be recognized by the red cap and the label on the ampoules.

7. BULK QUANTITIES: Usually a box of ten ampoules (each with 10 ml of test solution) is sufficient for one user for a whole year during which he/she can conduct around 400 spot tests. Hence a box of ampoules may be planned for each user. MBI may offer the test solution in bulk packs of one litre (sufficient to fill 10 boxes, each with ampoules). For every ten users one litre of test solution may be ordered as reserve. This may be used to refill the ampoules of the ten users. Care will need to be taken during refilling to clean the ampoules with boiled double distilled water so that the solution is not contaminated with the earlier stock. The bulk packing may be reordered as and when the stock depletes.

8. PRICE DETAILS: The following prices (in US$) have been given for these kits at the time of writing (1994). Please contact UNICEF Copenhagen for the most current prices.

| **Standard kits** | |
|---|---|
| Pouch containing two test ampoules, plate and spoon, colour chart and instructions | US$ 1.80 |
| Cardboard box containing ten refill ampoules, one color chart, one instructional manual | US$ 1.30 |
| Plastic box containing two ampoules of test solution & one ampoule of recheck solution | US$ 0.40 |

9. DELIVERY TIME: MBI advises that a delivery lead time of four weeks may be assumed from the time an order is placed.

# CHAPTER 11

# TITRATION METHODS FOR SALT IODINE ANALYSIS

## INTRODUCTION

There are a number of methods for testing the iodine content of salt, ranging from qualitative "spot" tests which are useful in field settings (see Chapter 10, Rapid Salt Testing Kits, for details), to more quantitative methods, such as iodometric titrations performed in laboratories for validation purposes.

The technical information on salt iodine titration provided in this chapter should assist those wishing to establish laboratories for salt monitoring purposes. While iodine titration methods are reasonably simple, they are still quantitative chemical tests, and therefore demand a certain degree of analytical skill, as well adequate funds to setup and maintain a modest laboratory. In addition, the analyst will need some expertise in order to maintain quality assurance records for method and result validation.

For the above reasons, these guidelines on salt iodometric titration will primarily be aimed at:

- Medium to large scale salt producers (e.g.> 1,000 tonnes per year), as part of their factory quality control.
- Government agencies responsible for quantifying the iodine content of salt obtained from producers, and perhaps other sites, such as households, markets, warehouses and importers.

The technical requirements of iodine titration analysis may limit its use for some, such as small scale producers or field workers who also need to verify salt iodine content. In these situations, use of simpler semi-quantitative, or qualitative spot tests, as described in Chapter 10, would be much more appropriate.

A person with experience in laboratory chemistry techniques would be preferable for performing these tests and maintaining adequate quality assurance records. Such a person could be trained in less than a week. Less experienced persons could be considered to perform the actual titration procedure, but would require a longer training period and greater levels of routine supervision.

Different salt iodine test methods need to be used depending on the form of iodine (iodate or iodide) used in fortification. The iodometric method for iodate will not detect the iodine content of a salt sample fortified with potassium iodide, and vice versa. If the form of iodine in the salt sample is unknown, a simple spot check method can be employed for verification (see Chapter 10 for relevant details).

Information regarding the testing of salt fortified with potassium iodate ($KIO_3$), which is recommended in developing countries due to its greater stability than potassium iodide (KI), is detailed below. Information includes the chemical basis for the titration method, reagent preparation and stability, step by step procedure and precautions, and cost details.

The second part of this chapter provide details regarding quality control practices necessary for laboratories to ensure that reliable data are generated. This includes steps required for the initial method validation, with worked examples, as well as more general routine quality control and quality assurance issues.

Appendices are also provided with information about laboratory water requirements, a listing of all necessary equipment, and information about an alternative titration method which can be used if salt is known to be fortified with potassium iodide instead of potassium iodate.

## TITRATION METHOD FOR IODATE CONTENT

### Description of Reaction

The iodine content of iodated salt samples is measured using an iodometric titration, as described by DeMaeyer, Lowenstein, and Thilly, (1979). The reaction mechanism can be considered in two steps (See Box 1):

### Reaction 1: Liberation of free iodine from salt

- Addition of $H_2SO_4$ liberates free iodine from the iodate in the salt sample.
- Excess KI is added to help solubilise the free iodine, which is quite insoluble in pure water under normal conditions.

### Reaction 2: Titration of free iodine with thiosulfate.

- Free iodine is consumed by sodium thiosulfate in the titration step. The amount of thiosulfate used is proportional to the amount of free iodine liberated from the salt.

• Starch is added as an external (indirect) indicator of this reaction, and reacts with free iodine to produce a blue colour. When added towards the end of the titration (that is, when only a trace amount of free iodine is left) the loss of blue colour, or endpoint, which occurs with further titration, indicates that all remaining free iodine has been consumed by thiosulfate.

**Box 1:**

## Reaction Steps for Iodometric Titration of Iodate

1. $IO_3^- + 5I^- + 6H^+ \rightarrow 3I_2 + 3H_2O$

(from salt) (from KI) (from $H_2SO_4$)

2. $2Na_2S_2O_3 + I_2 \rightarrow 2NaI + Na_2S_4O_6$

Sodium thiosulfate, Iodine, Sodium iodide, Sodium terathionate

## REAGENT PREPARATION

### Water Requirements for Reagent Preparation

Water required for this method should be boiled, distilled water, which requires provision of a distillation unit. As a simpler alternative, regular tap water treated with a mixed bed deionizing resin can be used, thus avoiding the need for an expensive distillation unit. (See Appendix 11–2 for further details on preparation of this water.

• **0.005M Sodium thiosulfate ($Na_2S_2O_3$):** Dissolve 1.24g $Na_2S_2O_3.5H_2O$ in 1000mL water.
Store in a cool, dark place. This volume is sufficient for 100–200 samples, depending on the iodine content of samples. The solution is stable at least 1 month, if stored properly.

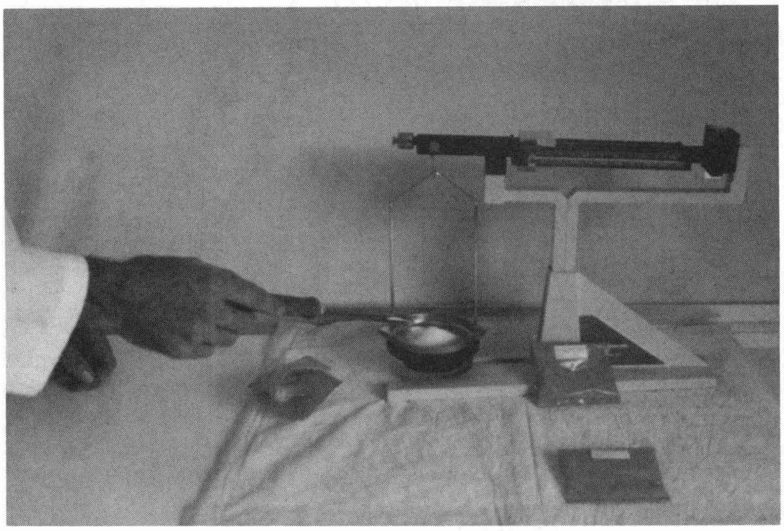
• **2N Sulfuric acid ($H_2SO_4$:** Slowly add 6mL concentrated H2SO4 to 90mL water. Make to 100mL with water. This volume is sufficient for 100 samples. The solution is stable indefinitely.

**Note:** Always add acid to water, **not** water to acid, to avoid excess heat formation and spitting of acid. Stir solution while adding acid.

• **10% Potassium iodide (KI)**: Dissolve 100g KI in 1000mL water. Store in a cool, dark place. This volume is sufficient for 200 samples. Properly stored the solution is stable for six months.

• **Starch indicator solution:** Make 100mL of a saturated NaCl solution, by adding NaCl to approximately 80mL water in a beaker, with stirring and/or heating, until no further solid will dissolve. This solution is stable for at least one year. Weigh 1g soluble starch into a 100mL beaker, add 10mL water, heat to dissolve. Add saturated NaCl solution to the hot starch solution to make up to 100mL. Store in a cool, dark place. This volume is sufficient for 50 samples. The solution is stable for up to one month, and should be heated (not boiled) each day it is used to re-suspend any solids.

**Figure 11–1:** *Weighing salt sample*



**Procedural Steps**

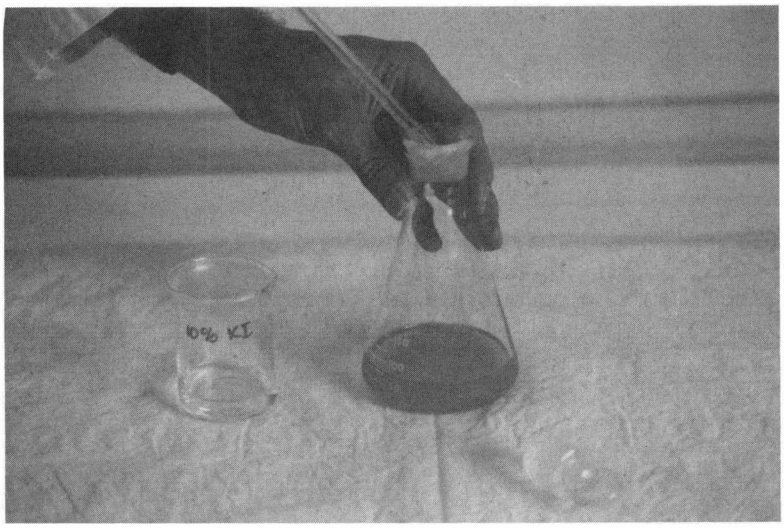
**Step 1.** Weigh 10g of the salt sample into a 250mL Erlenmeyer flask with a stopper.
**Step 2.** Add approximately 30mL water, swirl to dissolve salt sample.

**Step 3.** Add water to make volume up to 50mL.

**Step 4.** Add 1mL 2N $H_2SO_4$.
**CAUTION – Do not pipette by mouth.**

**Step 5.** Add 5mL 10% KI. The solution should turn yellow if iodine is present.
**CAUTION – Do not pipette by mouth.**

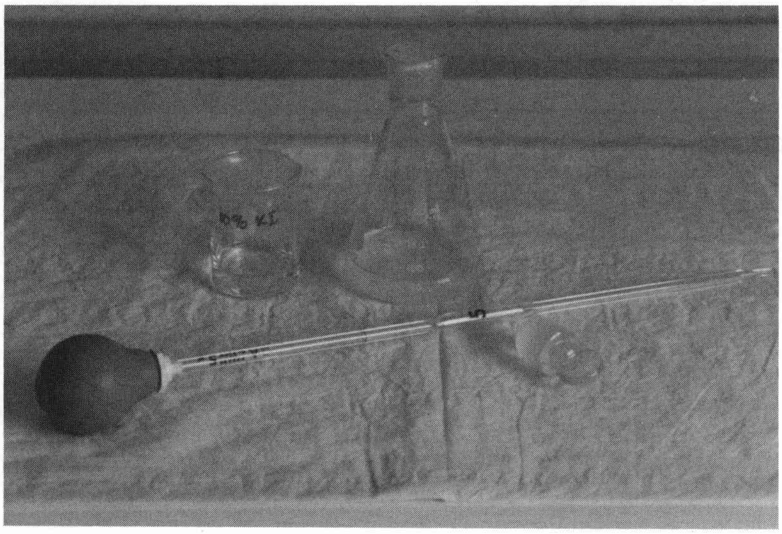
**Figure 11–2:** *Addition of 10% potassium iodide solution*



**Step 6.** Stopper the flask and put in the dark (cupboard or drawer) for 10 minutes.

**Step 7.** Rinse and fill burette with 0.005M $Na_2S_2O_3$, and adjust level to zero.

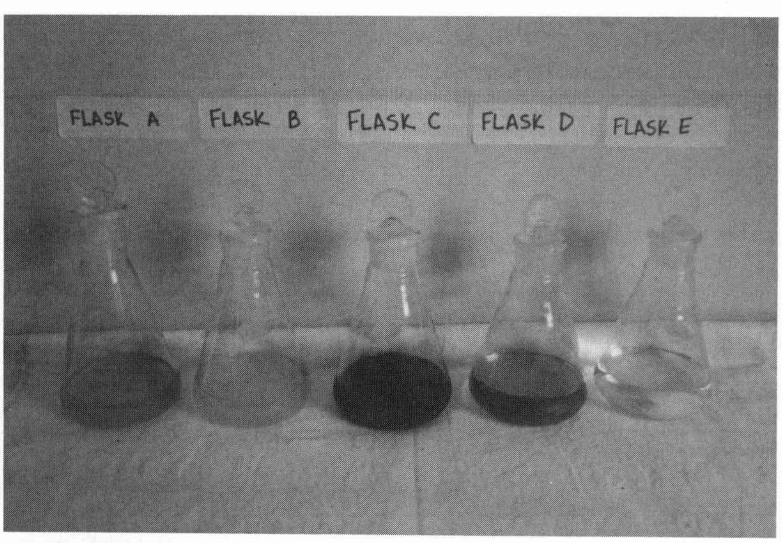
**Figure 11–3:** *Filling the burette with sodium thiosulfate solution*



**Step 8.** Remove flask from drawer, and add some $Na_2S_2O_3$ from the titration burette until the solution turns pale yellow (Flask B shown in Figure 11.4).

**Step 9.** Add approximately 2mL of starch indicator solution (the solution should turn dark purple) and continue titrating until the solution becomes pink, and finally colourless. (Colour sequence of titration is shown in flasks C, D and E, figure 11.4)

**Figure 11–4:** *This photo shows the various color changes that will be seen during the titration.*
*Flask A - after addition of KI (Step 5);*
*Flask B - just prior to addition of starch (Step 8);*
*Flask C - after starch has been added (Step 9);*
*Flask D - just prior to titration end-point (Step 9);*
*Flask E - titration end-point (step 9).*




**Step 10.** Record the level of thiosulfate in the burette and convert to parts per million (ppm) using the conversion table in Appendix 11–3.

**NOTE:** Analysis time is approximately 20 minutes per sample.

### Precautions

- The reaction mixture should be kept in the dark before titration because a side reaction can occur when the solution is exposed to light that causes iodide ions to be oxidized to iodine.
- Inaccurate results may occur if starch solution is used while still warm.
- If starch indicator is added too early, a strong iodine-starch complex is formed, which reacts slowly, and gives falsely elevated results.
- The reaction should be performed at mild room temperature (<30°C), since the iodine is volatile, and the indicator solution loses sensitivity when exposed to high temperatures.

**Box 2**

## Salt Iodine Laboratory Costs

Note — A complete laboratory equipment and reagent list is given in Appendix 11–1.

The equipment required to set up the salt iodine titration method described would cost approximately the following, based on US scientific company prices:

US $3,280
if distilled water is to be used

US $2,005
if tap water treated with deionizing resin is to be used

Reagents sufficient for at least 1,000 samples would cost: US$ 330

## SALT IODINE METHOD VALIDATION AND QUALITY ASSURANCE

It is of the utmost importance that salt iodine test results be reliable, accurate and timely. This is especially the case if the salt iodine test data is to be used for iodine deficiency programme evaluation and monitoring.

Establishing a salt iodine monitoring system that gives information about how well the salt is fortified is the "first level" in salt iodine quality assurance. However, we must also be sure that the information derived from the monitoring system (i.e., the actual salt iodine test results) is also of good quality. This can be considered the "second level" of salt iodine quality assurance.

### Laboratory Quality Assurance and Quality Control

Quality "assurance" typically takes a broader approach, and deals with certain management and organisation concepts that influence the operation of the entire laboratory. The minimum requirements needed to assure the quality of all laboratory salt iodine testing are discussed in detail below, and practical working examples are provided. Figure 11–5 details some of the key elements of salt iodine laboratory quality assurance.

**Figure 11–5**

## Key elements of Total Laboratory Quality Assurance for Salt Iodine

- Salt Sample Recording
- Reagent inventory/batch Checks
- Equipment checks
- Method validation
  - Sensitivity, recovery, cross-checks
- Internal Quality Control
  - Establish QC materials
  - Routine QC testing
  - Monitor test Precision
- External Quality Control
  - Establish laboratory network
  - Link industry and Government labs

## VALIDATION

During the initial se-up phase of salt iodine titration methods, these four performance characteristics should be thoroughly validated: precision, sensitivity, recovery, and comparison and cross-checking. Each is briefly described below.

### Precision

Calculate the percentage Coefficient of Variation (%CV) for repeat analysis of the same sample (at least ten separate estimates). If possible, this should be done on a number of different salt samples that have a range of iodine concentrations, e.g., 25, 50 and 100 ppm. With good technique, and reliable methodology, the precision should be < 15% CV.

The following gives a worked example:

**SALT IODINE TITRATION (PPM)**

| | SALT SAMPLE NUMBER | | |
|---|---|---|---|
| **RESULT No.** | **#1** | **#2** | **#3** |
| 1 | 18 | 48 | 75 |
| 2 | 20 | 52 | 68 |
| 3 | 19 | 50 | 73 |
| 4 | 16 | 47 | 67 |
| 5 | 22 | 55 | 70 |
| 6 | 17 | 48 | 72 |
| 7 | 21 | 43 | 75 |
| 8 | 23 | 51 | 66 |
| 9 | 19 | 55 | 72 |
| 10 | 20 | 49 | 78 |
| **MEAN** | 19.5 | 49.8 | 71.6 |
| **STD DEV.** | 2.17 | 3.68 | 3.86 |
| **%CV*** | 11.1 | 7.4 | 5.4 |

$* \% CV = \frac{\text{Standard deviation}}{\text{mean}}$

### Sensitivity

Establish an estimate of the lowest iodine level that can be reasonably detected by the test method used (i.e., its operational sensitivity). An example of the criterion that might be used to calculate this is the point at which the mean salt iodine concentration (ppm) of samples consistently yields results with a CV >20%.

### Recovery

An initial percent recovery should be made to ensure that the test system is capable of detecting all iodine present. This can be done by analysing a series of salt solutions to which known concentrations of iodine have been added. The following is a worked example:

**IODINE (PPM)**

| ADDED | OBSERVED | MEASURED* | %RECOVERY** |
|---|---|---|---|
| NONE | 15 | | |
| 20 | 32 | 17 | 85 |
| 40 | 53 | 38 | 95 |
| 60 | 77 | 62 | 103 |
| AVERAGE | | | 94* |

MEASURED = OBSERVED value corrected for BASELINE (i.e., value obtained with NO iodine added)

** % Recovery = (MEASURED ppm / ADDED ppm) * 100%

As a guideline, the average recovery, allowing for expected test imprecision, should be between 85 and 115 percent.

### Comparison & cross-checking

If possible, an initial sample cross-check should be performed with others as a means of assessing method bias. This could be done either with a laboratory using the same method or compared to alternative techniques e.g., correlation between titration method and spectrophotometric method.

**NOTE:** PAMM (Program Against Micronutrient Malnutrition) provides a service for those laboratories wishing to cross-check samples for their initial validation. For further information, please contact:

PAMM Laboratory
Centers for Disease Control
Mailstop F20
4770 Buford Highway Ne
Atlanta, Ga, 30341-3724, USA
Phone: 1 404 488 4088
Fax: 1 404 488 4609

## ROUTINE QUALITY CONTROL

Once the laboratory method has been validated as above, it must establish and maintain ongoing quality control (QC) data, both internally (or "in-house") and externally (inter-laboratory), as described below.

### Internal or "In-house" Quality Control

Known positive iodized salt sample(s) should be obtained by the laboratory and stored in sufficient quantity for analysis **every** time salt titrations on unknown samples are run e.g., daily or weekly. By performing multiple analyses on these positive salt samples, a concentration range can be established and used for operational quality control purposes. The following provides a description and worked example of how to calculate and establish a quality control range and a quality control chart.

*Establishing and Interpreting a Quality Control Range:*

Multiple salt iodine analyses on a known positive salt sample should be performed until approximately 15 to 20 titration results have been obtained. To establish the control range, it is best if these results are obtained over a period of time (e.g., three to four tests per day), rather than all at once (eg. twenty tests in one day), as this will give a more realistic estimate of true day-to-day and analytic variability.

Once a sufficient number of these test results have been obtained, use a hand calculator or standard statistical formulae to calculate the sample mean concentration (X) in ppm, and standard deviation (SD). The 95% confidence interval can then be calculated and used as the operating control range, as follows:

$$\text{Sample Mean } (\bar{X}) \pm 2 \times \text{SD}$$

The $\bar{X} - 2(\text{SD})$ = the lower confidence limit (L), and $\bar{X} + 2(\text{SD})$ = the upper confidence limit (U). The operating control range is (L, U).

Unless serious technical or performance errors occur during these initial analyses, the above range should reasonably reflect the normal amount of variation expected when using this method over time. Therefore, any future analysis of the same sample should produce a result between the lower and upper limits (i.e., the L – U range), for 95% of test results. Values falling within this range are considered to be "in control." Only 5% of subsequent test values for this sample should fall outside the established range, provided the method (and technician) is operating normally. Results falling outside the established range are considered potentially suspicious and therefore classed as "out-of-control."

Example: A known iodized salt sample was analysed by titration twenty times. For the 20 result values obtained, the calculated sample mean was 32 ppm, and the standard deviation was 2.5. The operating control range (OCR) for this example can be established as:

$$\begin{aligned} \text{OCR} &= 32 \pm 2\ (2.5) \\ &\quad 32 \pm 5 \\ &\quad (27,\ 37) \end{aligned}$$

Therefore, the lower control limit is set at 27 ppm, the upper control limit is 37 ppm, and the control range is 27 to 37 ppm. Subsequent test results falling between 27 and 37 ppm are to be considered in control, while any results <27, or >37 ppm are outside the control range, and therefore out-of-control.

*Quality Control Charts*

Once the above operating control range has been established, standard quality control charts and rules should be used to interpret these control values, decide acceptability of test results, and be kept as a permanent record to verify all unknown sample results.

The quality control chart is prepared as follows:

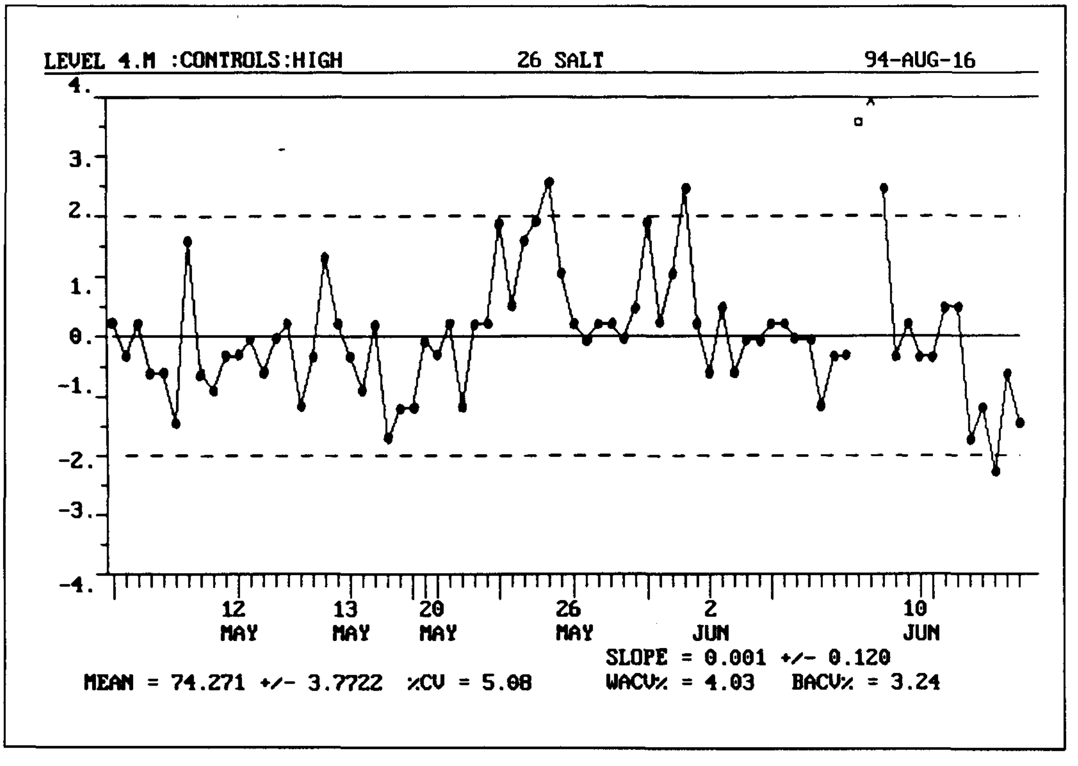
- Use regular linear graph paper to prepare these plots.
- Enter the salt iodine concentration (in ppm) scale for the control on the Y-axis. Make sure the concentration range plotted on this axis extends from less than the lower limit (i.e., <L), to above the upper limit (i.e., >U). For the example given above, which has a calculated range of 27 to 37 ppm, the Y-axis could be scaled from 20 to40 ppm.
- Find the sample mean concentration value (i.e., ) on the Y-axis scale, and draw a continuous horizontal line across the entire graph paper at this point. For the example this would be at 32 ppm.
- Find the lower limit concentration value (i.e., L) on the Y-axis scale, and draw a continuous horizontal line across the entire graph paper at this point. For the example this would be 27 ppm.
- Find the upper limit concentration value (i.e., U) on the Y-axis scale, and draw a continuous horizontal line across the entire graph paper at this point. For the example this would be 37 ppm.
- The X-axis is used to plot time, i.e., the date on which the control sample is analysed.

Once prepared, this chart is used to plot the specific analysis date, and salt iodine concentration obtained for the control every time it is tested. If the control point obtained is between the two limit lines, then the test is deemed in control, and all results are accepted. Any control values that are plotted outside the two limit lines should be considered as out-of-control, and the results of any corresponding unknown salt samples tested at the same time should also be rejected as unacceptable due to possible method error.

When an out-of-control value is obtained, steps should be taken to identify the possible reason for this event (e.g., use of old reagent, incorrect procedure used or reagent mix-up), and correct the problem. Once resolved, and control values have returned to normal, repeat the previously rejected unknown salt samples to obtain acceptable results.

Figure 11–6 gives a real example of a typical salt iodine quality control chart for a control with a mean salt iodine concentration of 74 ppm, a standard deviation of 3.8, and an operating control range of 66.4 to 81.6 ppm. (Note: The computer software used to generate this chart plots the y-axis in units of standard deviation, as opposed to ppm units, but this will not change the general overall shape of the chart.) As can be seen, such charts are very useful in identifying when problems occur within the test system, and allow corrective action to be taken. In Figure 11–6 the extremely high values above the upper limit (called outliers) were due to a deterioration in the sodium thiosulfate solution which give falsely elevated test results.

**Figure 11–6:** *Example of a Salt Iodine QC Chart*

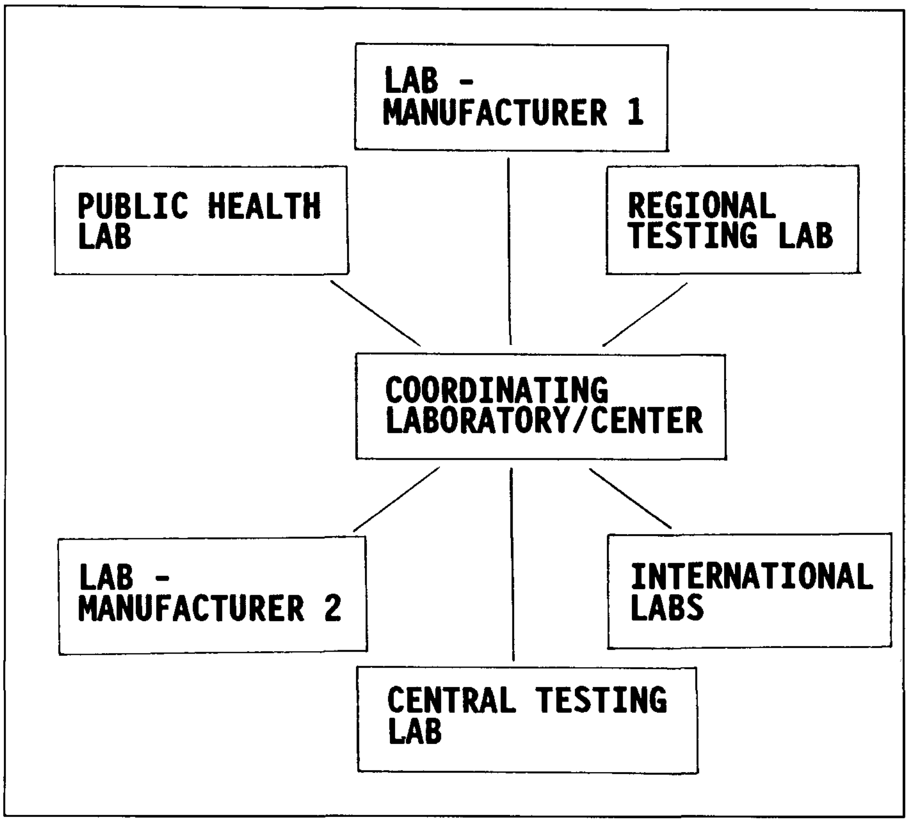


### External or Inter-laboratory Quality Control

External cross-checking of samples is the best way for each laboratory to assess its own performance compared to other laboratories, and detect potential method bias or inaccuracy. This type of inter-laboratory exchange should be seen as a supplement to internal QC, not as its replacement! Each salt iodine testing laboratory (government and industry) should be encouraged to form or participate with others in an on-going salt sample exchange network (see Figure 11–7).

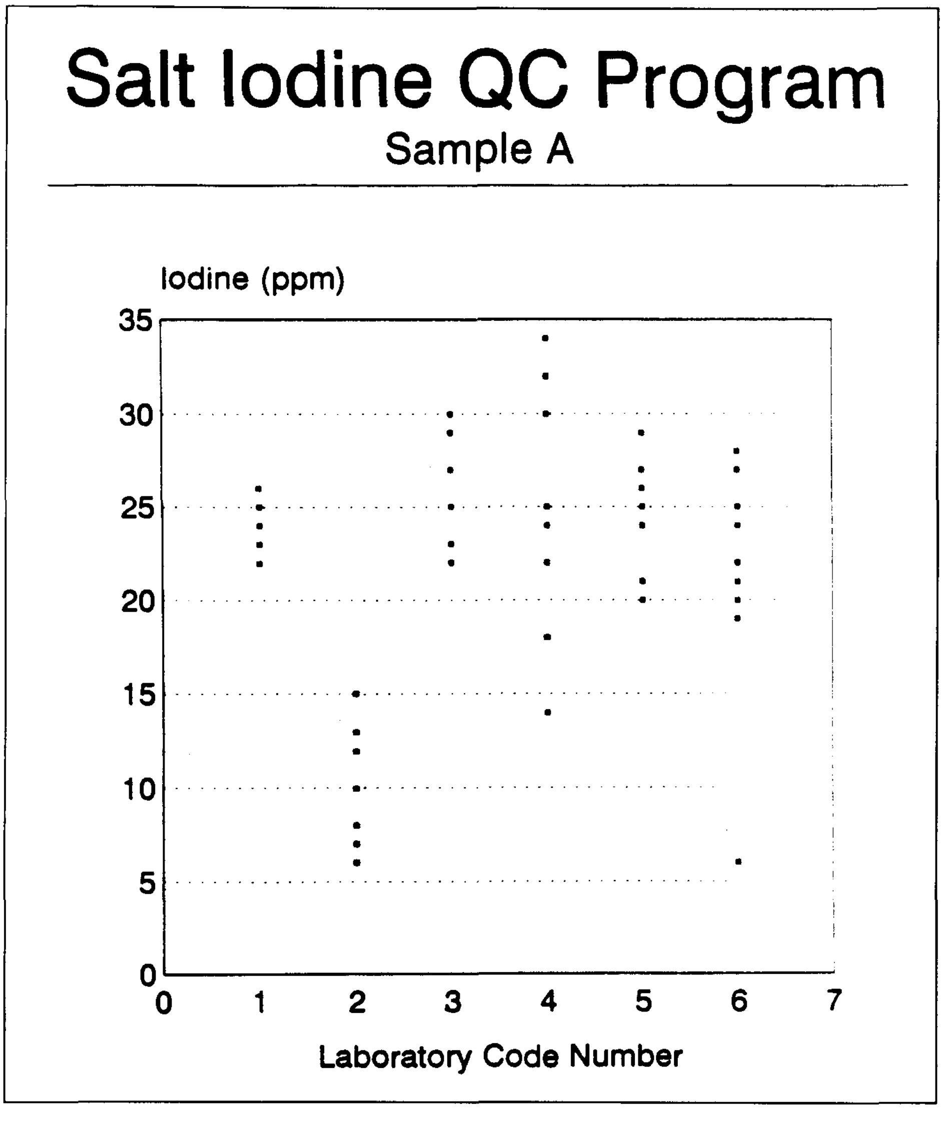
These "external" comparisons should occur at regular intervals (e.g., two to three times per year). Each time participants in the QC programme are sent unknown salt samples for analysis, and test results should be returned to the QC programme coordinator by a specified date, collated, reviewed, and reported to each participant as soon as possible. Feedback should show how results from each laboratory compare to all others participating in the same programme. However, it is most important that the results be presented anonymously. This is easily achieved by giving all laboratories a special code number known only by the coordinator and participating laboratory.

**Figure 11–7:** *External Salt Iodine QC Network*



The reported results are best presented graphically, as shown in figure 11–8. The value of external comparisons can be seen in this example. While most laboratories yielded similar salt iodine results (20 to 30 ppm), Laboratory 2 showed consistently lower values, while Laboratory 4 had greater imprecision compared to the other laboratories. Also note that Laboratory 6 had generally satisfactory results, except for one obvious outlier.

**Figure 11–8:** *Example of Salt Iodine External QC Chart*




An alternative approach is to have all participating laboratories send salt samples along with their test results to some central coordinating laboratory for analysis and comparison. However this approach will increase the work load at the coordinating laboratory.

Coordination of the external QC programme is probably best done by an independent agency (e.g., Government), and every effort should be made to encourage voluntary participation by all salt testing laboratories, especially industry and producers. Use of awards or certificates sent to regular participants in the programme can be a helpful motivational tool.

## OTHER ELEMENTS OF QUALITY ASSURANCE

### Salt Sample Recording

Each laboratory must maintain a logbook with sample details recorded in ink, such as:

- Date/time collected
- Date/time received
- Sample specific details (code #, brand, batch, expiry date)
- Date analysed
- Technician performing test
- Test result
- Supervisor's signature
- Date result is reported

An example of a format that could be used in a salt sample analysis logbook is given at the end of the chapter, which could be copied and adapted for use as a "master" form.

### Reagent Inventory Details

The laboratory supervisor should ensure all relevant details regarding test chemicals are recorded:

- Chemical brand, quantity, grade and batch/lot number
- Date ordered and received
- Date each "working" reagent is prepared, and by whom
- Give each working reagent an "in-house" lot number

An example of a salt iodine reagent inventory form is given at the end of the chapter, which could be copied and adapted for use as a "master" form.

### Instrument Calibration

The exact details depend on the type of test method used, but these should be performed in some routine fashion (e.g., calibrate balance every month). For each calibration keep a record of the following details:

- Instrument tested
- Date calibrated
- Calibrated by whom?
- Outcome (pass/fail, specific reading.)

## REFERENCES

1. De Maeyer EM, Lowenstein FW, Thilly CH. "The control of endemic goitre". World Health Organization, Geneva, 1979.

## SALT SAMPLE ANALYSIS LOGBOOK

| SAMPLE ID** | DATE SAMPLE COLLECTED | DATE SAMPLE RECEIVED | DATE OF ANALYSIS | TECHNICIAN | RESULT (ppm) | SUPERVISOR'S SIGNATURE* |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

ETC.

** Sample ID = code number, brand, batch, expiry date etc.

## SALT IODINE REAGENT INVENTORY

CHEMICAL:__________________________________

| *DATE ORDERED | DATE RECEIVED | BRAND, QUANTITY | BATCH/LOT NUMBER | DATE WORKING REAGENT PREPARED | TECHNICIAN | WORKING SOLUTION LOT No. |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

ETC.

**APPENDIX 11–1**

# Equipment and Reagents Required to Establish a Salt Iodine Laboratory

Many items on the following list of equipment and reagents can be procured through UNICEF Copenhagen Supply Division, or various scientific supply companies.

| QUANTITY | | UNICEF CODE |
|---|---|---|
| 1 | Balance, Four-beam pan<br>Sensitivity = 0.01g,<br>Capacity = 410g<br>(e.g., Fisher Scientific Cat. No. 02-020-411)** | |
| 1 | Set of weights for above<br>(e.g., Fisher Scientific Cat. No. 02-314) | |
| 4 | Flask, volumetric, 1000mL<br>(e.g., Fisher Scientific Cat. No. 10-210G) | |
| 2 | Flask, volumetric, 100mL<br>(e.g., Fisher Scientific Cat. No. 10-119-10D) | |
| 2 | Measuring cylinder, 10mL<br>(e.g., Fisher Scientific Cat. No. 08-552-4H) | |
| 12 | Measuring cylinder with stopper, 100mL | 09 374 30 |
| 12 | Beakers, Pyrex | 09 160 00 |
| | Flasks, Erlenmeyer (conical) with stopper, 250mL<br>(e.g., Fisher Scientific Cat. No. 10-098E) | |
| 4 | Pipette, volumetric, 1mL | 09 676 00 |
| 4 | Pipette, volumetric, 5mL | 09 679 05 |
| 4 | Burette w/straight stopcock 10mL | 09 239 00 |
| 4 | Burette stand | 09 767 00 |
| 2 | Laboratory safety glasses<br>(e.g., Fisher Scientific Cat. No. 17-286-1C) | |
| 1 | Parafilm, for covering beakers<br>(e.g., Fisher Scientific Cat. No. 13-374-12) | |
| 12 | Glass bottles with stoppers,<br>for reagents, 250mL | 09 194 50 |
| 4 | Funnel, lab, plain, diam. 65mm | 09 450 00 |
| 4 | Watch glass, 75mm diam. | 09 888 00 |
| 6 | Spatula Lab single blade 150mm<br>SS length | 09 699 10 |
| 4 | Dropper bottle, glass 25-60mL | 09 190 00 |
| 1 | Desiccator plain Scheibler 150x150mm | 09 374 60 |

| QUANTITY | | UNICEF CODE |
|---|---|---|
| | NOTE: If distilled water is to be used, the following equipment is required: | |
| 1 | Water Still 4L/day electric 220V | 01 676 00 |
| 1 | Hot plate 220V | 20 004 02 |
| 1 | Rod, stirring, flint glass assorted pkt | 09 686 00 |
| | **OR** | |
| | NOTE: If tap water treated with deionizing resin is to be used (see Appendix 11.2), the following equip ment replaces the 3 previously listed items: | |
| 2 | Flask, Erlenmeyer, 4L<br>(e.g., Fisher Scientific Cat. No. 10-040P) | |
| 1 | Whatman Filter Paper, 15cm diameter<br>(e.g., Fisher Scientific Cat. No. 09-805G) | |
| 1 | 4L Polyethylene carboy for water storage<br>(e.g., Fisher Scientific Cat. No. 02-963AA) | |
| 1 kg | Mixed bed deionizing resin<br>1.5meq/mL, 300-1,180μm, mesh size 20-50<br>(e.g., Fisher Scientific Cat. No. 31038, 0.1 cubic feet – this should be enough to provide sufficient water for at least one year). | |
| 1 | Hotplate/stirrer, 220V<br>(e.g., Fisher Scientific Cat. No. 11-501-7SH) | |
| 3 | Magnetic stirring bars<br>(e.g., Fisher Scientific Cat. No. 14-511-70) | |

### REAGENTS REQUIRED

Sodium Thiosulfate Pentahydrate, ANALAR, 500g
(e.g., Fisher Scientific Cat. No. S445-500)
(Sufficient for 50,000 samples)

Sulfuric Acid, concentrated, 2.5L
(e.g., Fisher Scientific Cat. No. A298-212)
(Sufficient for 40,000 samples)

Potassium Iodide, 500g

Sodium Chloride, 3kg
(eg. Fisher Scientific Cat. No. S271-3)
(Sufficient for 3,000 samples)

Soluble starch, 500g
(eg. Fisher Scientific Cat. No. S516-500)
(Sufficient for 25,000 samples)

** Fisher Scientific, 50 Fadem Road, Springfield, NJ, 07081, USA Fax: 201-379-7415, ATTENTION: Jackie Dubeau

APPENDIX 11–2

# USE OF TREATED TAP WATER WITH DEIONIZING RESIN AS AN ALTERNATIVE TO DISTILLED WATER

The resin required (as per Appendix 11–1) is a mixed bed resin, containing cation and anion exchange beads. Deionization occurs by exchanging cations with hydrogen, and anions with hydroxyl on the resin. In this way, all ionic species are removed from the water.

e.g., Resin-H + Resin-OH + NaCl $\rightarrow$ Resin-Na + Resin-Cl + $H_2O$

The resin contains a colored dye (eg. purple) irreversibly bound to the anion exchange resin, which turns from purple to gold when the exchange capacity is exhausted.

To deionize water for use in the laboratory, follow these steps:

**Step 1.** Add resin to a conical flask or beaker, covering the base with approximately 1.5cm of resin. Usually a 2 – 5 L flask is used; the bigger the flask, the more resin needed.

**Step 2.** Fill the flask with good quality tap water (distilled water can also be used if available) and mix on laboratory stirrer for approximately one to three hours. Alternatively, water can simply be left in the flask with the resin for a longer period of time (24 hours), with occasional stirring and then let resin settle.

**Step 3.** Decant the water from the resin, making sure not to leave the resin dry. ALWAYS LEAVE AT LEAST 1cm OF WATER ON THE RESIN. If the resin is allowed to dry out it must be discarded, since the ion exchange capability may be greatly reduced.

**Step 4.** To ensure complete removal of resin particles that may float on the surface, simply pass resin-treated water through standard laboratory-grade filter paper.

Mixed bed resins are not normally regenerated after exhaustion because of the difficulty of separating the two resin components, and proper re-mixing. However, if you wish to regenerate the resin after it has changed colour, you must separate the anion and cation exchange resin beads. Shake the resin in twice its volume of water, let it settle, and decant the top layer containing the less dense anion exchanger. Repeat until separation is complete.

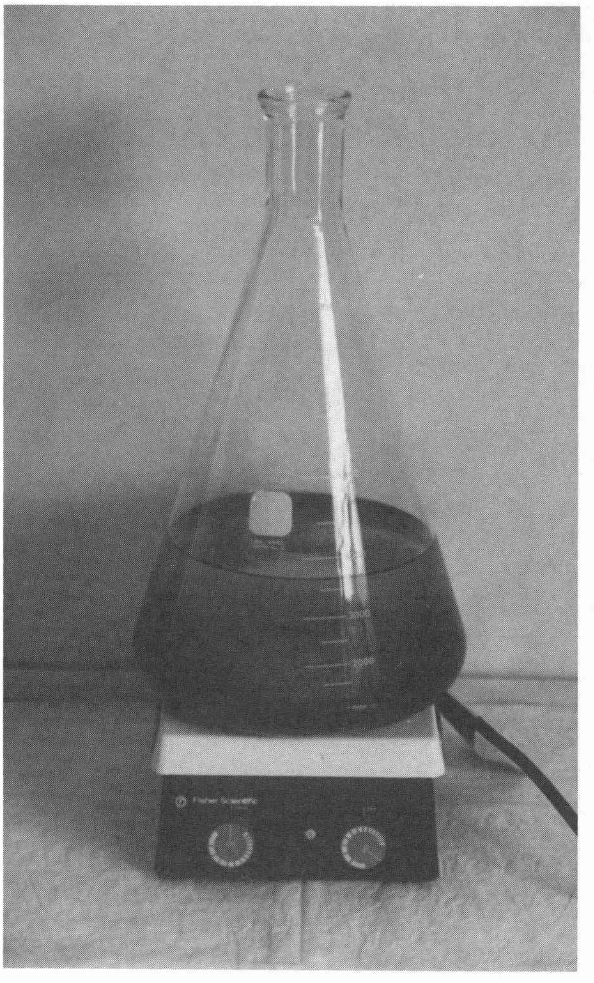


**Figure 11–9** *Mixing resin procedure*

Regenerate the cation exchanger using three times the volume of 3N HCl and rinse with four volumes of deionized water. Check that the pH is <5. Regenerate the anion exchanger with at least ten volumes of 3N NaOH and rinse with deionized water until the pH <9. Mix the resins thoroughly by agitating with a stirring rod.

The mixed bed resin has a shelf life of two years at room temperature. This shelf life may be extended by storing in the refrigerator.

**APPENDIX 11-3**

## CONVERSION TABLE : IODINE CONTENT IN PARTS PER MILLION

| BURETTE READING | PARTS PER MILLION (ppm) | BURETTE READING | PARTS PER MILLION (ppm) |
|---|---|---|---|
| 0.0 | 0.0 | 5.0 | 52.9 |
| 0.1 | 1.1 | 5.1 | 54.0 |
| 0.2 | 2.1 | 5.2 | 55.0 |
| 0.3 | 3.2 | 5.3 | 56.1 |
| 0.4 | 4.2 | 5.4 | 57.1 |
| 0.5 | 5.3 | 5.5 | 58.2 |
| 0.6 | 6.3 | 5.6 | 59.2 |
| 0.7 | 7.4 | 5.7 | 60.3 |
| 0.8 | 8.5 | 5.8 | 61.4 |
| 0.9 | 9.5 | 5.9 | 62.4 |
| 1.0 | 10.6 | 6.0 | 63.5 |
| 1.1 | 11.6 | 6.1 | 64.5 |
| 1.2 | 12.7 | 6.2 | 65.6 |
| 1.3 | 13.8 | 6.3 | 66.7 |
| 1.4 | 14.8 | 6.4 | 67.7 |
| 1.5 | 15.9 | 6.5 | 68.8 |
| 1.6 | 16.9 | 6.6 | 69.8 |
| 1.7 | 18.0 | 6.7 | 70.9 |
| 1.8 | 19.0 | 6.8 | 71.9 |
| 1.9 | 20.1 | 6.9 | 73.0 |
| 2.0 | 21.2 | 7.0 | 74.1 |
| 2.1 | 22.2 | 7.1 | 75.1 |
| 2.2 | 23.3 | 7.2 | 76.2 |
| 2.3 | 24.3 | 7.3 | 77.2 |
| 2.4 | 25.4 | 7.4 | 78.3 |
| 2.5 | 26.5 | 7.5 | 79.4 |
| 2.6 | 27.5 | 7.6 | 80.4 |
| 2.7 | 28.6 | 7.7 | 81.5 |
| 2.8 | 29.6 | 7.8 | 82.5 |
| 2.9 | 30.7 | 7.9 | 83.6 |
| 3.0 | 31.7 | 8.0 | 84.6 |
| 3.1 | 32.8 | 8.1 | 85.7 |
| 3.2 | 33.9 | 8.2 | 86.8 |
| 3.3 | 34.9 | 8.3 | 87.8 |
| 3.4 | 36.0 | 8.4 | 88.9 |
| 3.5 | 37.0 | 8.5 | 89.9 |
| 3.6 | 38.1 | 8.6 | 91.0 |
| 3.7 | 39.1 | 8.7 | 92.0 |
| 3.8 | 40.2 | 8.8 | 93.1 |
| 3.9 | 41.3 | 8.9 | 94.2 |
| 4.0 | 42.3 | 9.0 | 95.2 |
| 4.1 | 43.4 | 9.1 | 96.3 |
| 4.2 | 44.4 | 9.2 | 97.3 |
| 4.3 | 45.5 | 9.3 | 98.4 |
| 4.4 | 46.6 | 9.4 | 99.5 |
| 4.5 | 47.6 | 9.5 | 100.5 |
| 4.6 | 48.7 | 9.6 | 101.6 |
| 4.7 | 49.7 | 9.7 | 102.6 |
| 4.8 | 50.8 | 9.8 | 103.7 |
| 4.9 | 51.9 | 9.9 | 104.7 |

## APPENDIX 11-4:

## ALTERNATIVE TITRATION FOR IODIDE CONTENT

### Description of Reaction

While use of potassium iodide (KI) is not common in many developing countries for salt fortification, basic details of a titration method (De Maeyer EM, Lowenstein FW, Thilly CH, 1979) suitable for analysing salt iodized with KI are provided here.

The reaction mechanism for this iodometric titration is as follows:

**Reaction 1:** Potassium **iodide** is dissolved from the salt.

**Reaction 2: Bromine water** oxidizes iodide ions to free iodine. Sodium sulfite and phenol are added to destroy excess bromine so that no further oxidation of $I^-$ can occur before KI solution is added.

**Reaction 3:** The titration reaction with thiosulfate is the same as that described in the iodate method earlier.

**Box 3**

### Reaction steps for Iodometric Titration of Iodide

1. $KI \rightarrow K^+ + I^-$
2. $Br_2 + 2I^- \rightarrow 2Br^- + I_2$
3. $I_2 + 2S_2O_3^{2-} \rightarrow 2I^- + S_4O_6^{2-}$

## REAGENT PREPARATION

Water preparation is the same as for procedures described in section on "Titration Method for Iodate content," page 86.

1. *Methyl Orange Indicator* – Dissolve 0.01g methyl orange in 100mL water.

2. *2 N Sulfuric Acid* – Add 5.56mL concentrated $H_2SO_4$ to 90mL water, make to 100mL with water.

3. *Bromine Water* – Place 5mL in a small flask, (keep in fume hood due to dangerous fumes)

4. *Sodium Sulfite Solution* – Dissolve 1g sodium sulfite in 100mL water

5. *Phenol Solution* – Dissolve 5g phenol in 100mL water

6. *Potassium Iodide Solution* – Dissolve 10g potassium iodide in 100mL water

7. *Sodium Thiosulfate Solution (0.005N)* – Dissolve 0.124g sodium thiosulfate pentahydrate in 100mL water

8. *Starch Solution* – Dissolve 1g soluble starch in 100mL water, with heating

(All the above need stoppered flasks and should be stored in the dark)

### Procedure

**Step 1.** In a 250mL Erlenmeyer flask place 10g of salt sample and 50mL water. Swirl to dissolve.

**Step 2.** Add 6 drops of methyl orange indicator (solution turns pale orange). Add 2N $H_2SO_4$ dropwise (1 drop or until a pink colour change). This is done to neutralise the reaction mixture.

**Step 3.** Add 0.5mL bromine water (solution changes to yellow).

**Step 4.** Add sodium sulfite solution, dropwise, until solution turns pale yellow. Wash down the flask sides with $H_2O$.

**Step 5.** Add 3 drops phenol solution (solution turns clear).

**Step 6.** Add 1mL 2N $H_2SO_4$.

**Step 7.** Add 5mL potassium iodide solution. (Turns yellow).

**Step 8.** Add sodium thiosulfate solution from the titration burette until solution turns pale yellow. Add 1mL starch solution, leading to a dark purple colour. Continue titration until solution becomes colourless.

**Step 9.** Note the burette reading and convert to ppm using the table in Appendix 11-3.

**Precautions** – Please refer to precautions listed in the iodate method described earlier.