

3 Indicators of the salt iodization process

3.1 Factors that determine salt iodine content

Appropriate legislation and supportive regulations constitute the point of departure, or cornerstone, of the salt iodization programme within a country, providing the framework within which the salt iodization programme functions. Regulations specify the iodine content that should be in salt at the point of production for both human and animal consumption. Ideally, they should also outline specific activities for internal and external monitoring of the iodine in salt at the production or iodization sites, and encourage the use of the titration method, or an equivalent method, in order to provide precise measurements of the iodine content in salt. Ultimately, the regulatory environment represents the primary factor determining the iodine content of salt in any country.

Iodization of salt may take place inside the country at the main production or packing sites, or outside the country for those countries importing salt which has already been iodized. Salt is iodized by the addition of fixed amounts of potassium iodate (KIO_3) or potassium iodide (KI), as either a dry solid in a powder form or an aqueous solution, at the point of production. The amount of iodine added to salt should be in accordance with the regulation of the specific country where it will be used.

Iodate is recommended as fortificant in preference to iodide because it is much more stable (15,16).¹ The stability of iodine in salt and levels of iodization are issues of crucial importance to national health authorities and salt producers, as they have implications for programme effectiveness, safety, and cost.

The actual availability of iodine from iodized salt at the consumer level can vary over a wide range as a result of:

¹ Potassium iodate and potassium iodide have a long-standing and widespread history of use for fortifying salt without apparent adverse health effects. Potassium iodate has been shown to be a more suitable substance for fortifying salt than potassium iodide because of its greater stability, particularly in warm, damp, or tropical climates. In addition, no data are available indicating toxicological hazard from the ingestion of these salts below the level of Provisional Maximum Tolerable Daily Intake or PMTDI (15).

- Variability in the amount of iodine added during the iodization process;
- Uneven distribution of iodine in the iodized salt, within batches and individual bags, due to insufficient mixing of salt after the salt iodization process and/or variation in particle size of salt crystals in a batch or bag;
- The extent of loss of iodine due to salt impurities, packaging (for instance, 1kg versus 20 or 50kg), and environmental conditions during storage and distribution;
- Loss of iodine due to food processing, and washing and cooking processes in the household;
- The availability of non-iodized salt from unconventional marketing sources.

In order to determine appropriate levels of iodization, an accurate estimate within countries is required of the losses of iodine occurring under local conditions between the time of iodization and the time of consumption. Control of moisture content in iodized salt throughout manufacturing and distribution, by improved processing, packaging and storage, is critical to the stability of the added iodine. Earlier estimates of losses have proven to be too high. With adequate packaging, losses are minimal under most conditions.

Iodized salt is usually distributed from the producer to the repackager, wholesaler, or retailer either in 50 kg bulk bags, or in consumer packages usually in 500 g or 1 kg polyethylene bags, although smaller or bigger sized packaging may also be used in some countries. Considerable losses of iodine (30–80%) resulting from high humidity and porous 50 kg packaging can be significantly reduced by the use of woven high-density polyethylene bags, with a continuous film insert, or laminate of low-density polyethylene bags, which provides a good moisture barrier.

The loss of iodine in salt from 500 g or 1 kg good quality polyethylene packaging appears to be less than previously thought. There is some evidence that the loss of iodine from salt packaged in good quality small polyethylene bags of about 75 to 80 micron thickness and containing 500 g salt, is generally less than 10% over an 18-month period, regardless of climatic conditions, fine or coarse texture, or whether the packaging had been opened or not.¹

Recommendations

WHO/UNICEF/ICCIDD (19) recommend that, in typical circumstances, where the iodine lost from salt is 20% from production site to

¹ P Joost, personal communication, December 2006.

household, another 20% is lost during cooking before consumption, and average salt intake is 10 g per person per day, *iodine concentration in salt at the point of production should be within the range of 20–40 mg of iodine per kg of salt* (i.e., 20–40 ppm of iodine) in order to provide 150 µg of iodine per person per day (17). In countries where iodized salt is used in processed foods, the iodine content in salt should be closer to the lower end of this range and *vice versa*. The iodine should preferably be added as potassium iodate. Under these circumstances, median urinary iodine levels are expected to vary from 100–199 µg/l.

However, in some instances the quality of iodized salt is poor, or the salt is incorrectly packaged, or the salt deteriorates due to excessive long-term exposure to moisture, heat, and contaminants. Iodine losses from point of production to consumption can then be well in excess of 50%. In addition, salt consumption is sometimes much less than 10 g per person per day. As a result, actual iodine consumption may fall well below recommended levels, leading to low urinary iodine values for the population.

Regular surveys of median urinary iodine levels should therefore be carried out in a nationally representative sample, along with measurements of the iodine content in salt and other sources of iodine in the diet to ensure that those levels are within the recommended range (100–199 µg/l). If not, the level of iodization of salt, and factors affecting the utilization of iodized salt, should be reassessed focusing on:

- The percentage of households using adequately iodized salt, i.e. salt containing 15 to 40 ppm of iodine at the household level;
- Production-level quality assurance;
- Factors affecting the iodine content of salt such as packaging, transport, and storage;
- Food habits in relation to salt intake and cooking practices.

National authorities should establish initial levels for iodization in consultation with the salt industry, taking into account expected losses and local salt consumption. Once iodization has commenced, regular surveys of salt iodine content and urinary iodine levels should be carried out to determine if the programme is having the desired effect.

Discussions and regulations about iodine levels in salt must clearly specify whether they refer to total content of iodine alone or to content of iodine compound (KIO₃ or KI).

It is recommended that the level be expressed as content of iodine alone. This approach emphasizes the physiologically important component (iodine) and facilitates comparison of its different forms.

Managing the iodized salt program in a country

For optimal management and functioning of the salt iodization programme in a country, a governmental health official, a national multisectoral coalition including all the partners involved in IDD control should take responsibility for coordinating and driving IDD-related activities in a country. Ideally, salt producers should be integral members of such commissions to jointly manage the various components of the salt iodization programme along with other role players such as government officials, international health agencies, consumer representatives, researchers, academics, etc. (See Section 2.4 and Figure 1.)

3.2 Determining salt iodine levels

The iodine content of salt can be determined quantitatively with the titration method, and qualitatively using rapid test kits. In addition to the titration method, technology has advanced the possibilities of analysing the iodine content of salt quantitatively using potentiometry or spectrophotometry. A simple and portable single wavelength spectrophotometer has recently been developed. These methods should yield similar quantitative results and should therefore be seen as equivalent methods.

All of these methods have certain advantages and disadvantages which generally influence the choice of method in specific circumstances. However, the titration method, which is by far the most commonly used quantitative method, still remains the reference method for determining the iodine concentration in salt. When other methods are used, it should be standardized against the titration method.

Facilities for titration are usually available in public health or food standards laboratories. In addition, ideally it should be standard practice for salt producers to use the titration method to routinely check the accuracy of their salt iodization at the site where salt is iodized. Titration should preferably be carried out on-site.

Titration method

The titration method requires the use of a small laboratory equipped with some basic instruments, such as a precision scale, a burette, glassware, and pipettes. Additional equipment, such as a magnetic stirrer and dispensers, will save time and optimize the analytical procedure.

Basically, iodine analysis by titration involves the preparation of four solutions and a standard solution which will last for variable periods of time, and then determining the iodine concentration in a salt solution by adding the pre-made reagents/solutions followed by the titration step. The iodine content of salt is determined by liberating iodine from salt and titrating the iodine with sodium thiosulfate using starch as an external

indicator. The method of liberating iodine from salt varies depending on whether salt is iodized with iodate or iodide. Details of the method are given in Annex 1. The procedure requires some training and laboratory skills, which can be conveyed to salt producers during a training course.

Titration, or an equivalent method, is preferred for accurate testing of salt batches produced in factories or upon their arrival in a country, and in cases of doubt, contestation, etc. This method is recommended for determining the concentration of iodine in salt at various levels of the distribution system where such accurate testing is required, and for testing when there are legal enforcement issues. Once the method is established, it is necessary to adhere to proper internal and external quality control measures.

Rapid test kits (RTK)

These are small 10–50 ml bottles containing a stabilized starch-based solution. One drop of the solution dripped on a teaspoon of salt containing iodine produces a blue/purple colour change. Colouration indicates that iodine is present. Different test kits are used depending on whether the salt is iodized with potassium iodate or iodide. In cases where there is suspicion of alkalinity in the salt sample, a ‘recheck solution’ is used. A drop of this solution is applied first, followed by the test solution (see Annex 1 for further details).

Recent evaluations of these kits showed that the colour reaction cannot be used as a quantitative indication of the iodine content (18). These kits should therefore be regarded as qualitative rather than quantitative and are most appropriate to indicate the presence or absence of iodine, but not of the concentration.

An advantage of rapid test kits is that they can be used in the field to give an immediate result. They are therefore useful to health inspectors and others who are involved in carrying out spot checks on food quality or household surveys. They may also play a valuable educational role, in that they provide a visible indication that salt actually is iodized. Accordingly, they can be used for demonstration purposes in schools and other institutions. However, because rapid test kits do not give a reliable estimate of iodine content (19,20), results must be backed up by titration.

There are a large number of test kits available on the market and many countries are currently producing their own. These kits are of variable quality and accuracy. UNICEF, with CDC and WHO, evaluated available test kits, and confirmed that the quality of the kits is quite variable. The evaluation resulted in recommendations for basic qualifications for kits, including instructions in English, recommended sample weight or size, shelf life, and directions for use.

National surveys to estimate the household coverage of adequately iodized salt using rapid test kits alone will only be able to determine the percentage of households using salt containing any iodine. However, in order to make inferences about the household coverage of adequately iodized salt, it is necessary to employ the quantitative titration method for iodine analysis, either on all salt samples or on a sub-sample. For the latter, a sub-sample of salt which has been analysed by the rapid test kit should also be analysed using the titration method for quantification. In this way, more reliable information on the adequacy of salt iodine and its likelihood of providing adequate iodine intake is available for tracking progress.

3.3 Indicators for monitoring at different levels

Ideally, monitoring the iodine content of salt should be conducted internally by the salt producer at the site of iodization, as well as externally by the health authorities. Internal monitoring should be done routinely, and external monitoring intermittently, and where feasible, both these monitoring systems should use the titration method for determining the iodine content of salt. The different steps of the monitoring process are summarized in Figure 2.

Internal monitoring by producers and distributors

A critical indicator of adequate salt iodization is a measure of the quality of iodized salt leaving production facilities. This may be reflected in a proportion of samples meeting government standards, or samples plotted regularly in a control chart to demonstrate that samples fall within the acceptable range.

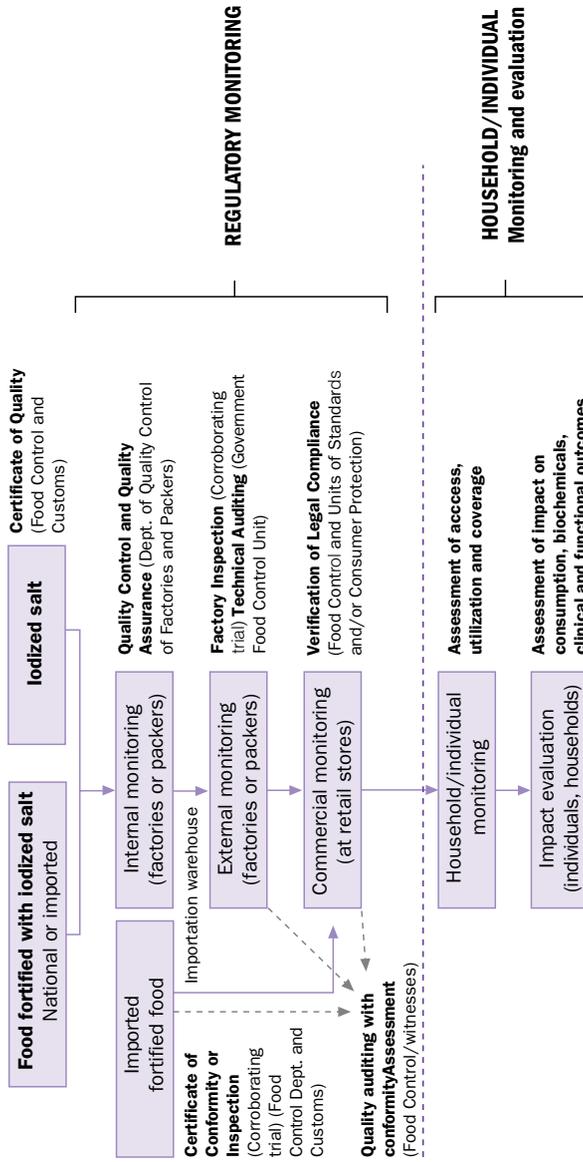
The Ministry of Industry, the Bureau of Standards, or Codex Alimentarius are useful reference sources for guiding producers in the process of iodizing salt. They can also establish the ultimate standards expected in the production of iodized salt.

Adherence to these manufacturing standards is perhaps the most important issue in the elimination of IDD. Therefore, the producer plays a pivotal role both in improving the accuracy of the iodization process and in reducing the considerable variations observed in iodine concentration in many countries.

Among the areas of greatest concern is the very important mixing or spraying step (21). This area not only includes the actual iodization method chosen by a production or packaging facility, but also the assurance that the producer closely adheres to the amount of time for mixing.

Salt samples taken from the production line should be regularly analysed by titration. The iodine concentration of each batch should be

Figure 2 A monitoring and evaluation system for salt iodization



Adapted from L. Allen (17).

checked at least once. Rapid test kits can be used more frequently to check that the addition of iodine has not been interrupted.

It is recommended that wherever possible adequate staff at a production plant should be trained and their skills standardized to determine the iodine concentration accurately using the titration method. Furthermore, key persons at each production site, including the managers, should be aware of the detrimental consequences of iodine deficiency and excess, as well as the health benefits of correctly iodized salt.

Results should be recorded and plotted in a quality assurance chart. When levels are not satisfactory, immediate corrective action should be taken and that action entered into the record book.

Because production methods and factory sizes vary so widely, it is beyond the scope of this manual to define this process in any greater detail. Whatever the method adopted, the process, combined with external quality assurance measures, should result in salt that has an iodate level within the upper and lower range established by regulations. In other words, internal and external quality control should ensure that the level of iodine is in the range stipulated by national regulations, that is both effective to control iodine deficiency and safe with regard to excessive iodine intake.

When importers and distributors procure salt, they have the responsibility to either ensure that it meets specifications as stipulated in the requirements, or to ensure that these are met before salt goes out to the wholesale or retail market. This implies that they should have a quality assurance system that includes salt iodine titration measurements.

If the salt they receive is not up to standard, they will need to have their own iodization facility. All salt should be distributed in polyethylene bags with appropriate labels.

External monitoring by governments

Legislation and regulations establish the authority of the government to ensure that iodized salt meets government standards, and external monitoring by the government is done under the guidance of relevant regulations.

Governments must have some method of periodically checking that salt producers are maintaining adequate quality assurance measures, and that salt leaving production facilities meets government standards. The main indicator for this level of monitoring is the proportion of samples taken that fall within the accepted range for iodine content. In addition, there may be a need for monitoring at the retail level to assess the presence of counterfeit salt or salt not meeting standards in the marketplace. Capacity for retail monitoring varies, and the purpose may be

for checking the availability of different types of salt in the market or for advocacy, rather than providing a robust proportion as is done with household sampling.

External monitoring is based upon the establishment of a law which mandates that all salt for human and – in many countries, animal – consumption is iodized. Details of implementation, inspection, and enforcement are usually set out in the regulations. Guidelines for developing regulations are available (22). It is crucial to state in the regulations the amount of potassium iodate to be added at the point of production.

Other legal requirements covered in regulations should include packaging in polyethylene bags, labelling to identify the iodine level, and the name and address of the company packaging the salt. The regulation also needs to designate a government agency or department which will be responsible for a system of licensing producers, importers, and distributors, and inspecting their facilities.

That agency must also be responsible for periodically checking the quality assurance records that must be kept, and for spot-checking the salt for iodate content. Several monitoring and inspection systems have emerged in different countries.

Often this monitoring becomes a function of the Food and Drugs Bureau of the Health Ministry. In other countries, the Ministry of Industry, or Mines, or Agriculture has this responsibility. In the case of importation of salt, the Customs Authority is often in charge of checking the specifications in the importation document, and in some circumstances taking samples to check the iodate level in the salt.

As indicated above, the salt testing kits that are used by these government agencies should not be used in enforcement at the production level, as they often give both false positive and false negative results and the colour does not always accord well with titration. Government inspection systems need to have access to and use of salt titration in a standardized laboratory on a regular basis.

When countries first began to introduce salt iodization, inspection systems were used largely to guide salt iodization programme managers in identifying problems with salt iodization, and were rarely used for enforcement purposes. As countries increase the coverage to 50%, these systems should be strengthened and used for enforcement against those producers who fail to comply with the law.

It is often the less expensive non-iodized salt in the market that prevents the realization of the elimination of IDD. Indeed, as coverage of iodized salt increases, special efforts need to be made to identify the non-compliant importer, producer and distributor and systematically eliminate that problem. To this end, a national register of all salt pro-

ducers supplying iodized salt to the market and of distributors/traders of iodized salt will enhance the interaction with health authorities and will create the opportunity of efficient external monitoring and mutual exchange of relevant IDD information in an effort to strengthen the salt iodization programme. These measures provide a 'level playing field' for producers complying with the law.

Salt must be iodized indefinitely, or until it is demonstrated that an adequate iodine intake is available from other sources. The infrastructure, together with the annual budget to support the government inspection system, must be permanently established. In order to guarantee this, it is essential that inspection and collection of iodized salt samples be integrated into the existing food inspection system in the country. The contact between the health authority and the salt producers could be used to inform and educate the producer about IDD and the need for optimal iodization of salt. Feedback of salt iodine results are an important component of this interaction.

Monitoring at the household level

Just as knowing whether salt leaving production facilities is adequately iodized, knowing whether consumers are using that salt is critical to a programme's success. The main indicator for assessing household use is the proportion of households using salt with adequate iodine. This indicator must accurately reflect the situation for the population sampled, and the level of iodine in the salt sampled.

In the past, rapid test kits have been used to assess household coverage, whether used in surveys or in other data collection activities. Results were presented as the percentage of households using salt with no iodine and the percentage using 'adequately' iodized salt. However, the ability of the rapid test kits to distinguish 'adequately' iodized salt has since been recognized as limited, and titration is recommended for at least a sub-sample of salt samples used in monitoring at the household level.

Household level monitoring methods are described in Chapter 5. Household monitoring is usually done through surveys or other community-based methods.

For use with cross-sectional surveys, a household questionnaire concerning the use of iodized salt and qualitative testing of that salt using a salt rapid testing kit has been employed successfully to determine overall coverage of iodized salt and to identify geographical gaps in the programme. However, it must be emphasized that were rapid test kits are used alone, it will only be possible to report on the proportion of households using salt with any iodine, and not the proportion using 'adequately' iodized salt, as has been done in the past.

Questions on iodized salt use and salt testing have been included in the UNICEF Multiple Indicator Cluster Surveys (MICS) and in the Demographic and Health Surveys. Some countries have successfully added household salt testing to other national surveys, e.g., to either nutrition surveys or surveys that collect key economic and census data. These surveys provide estimates of the proportion of the population iodized salt coverage, and identify areas where there is low use of iodized salt and/or where all the salt is non-iodized.

National surveys can be costly, and a community-based method may be possible on a more regular basis. This approach may be organized in the community or through the schools, particularly in areas with high rates of school enrolment. Providing salt testing kits to environmental health officers, community midwives, nutrition officers, schoolteachers, mayors, and other government workers responsible for community health, has been helpful in this process. These approaches are very effective communication and awareness tools, particularly when this awareness is linked to action. This action could involve approaching the salt producers or distributors and directly requesting them to supply iodized salt.

Depending on the sampling methods and survey design adopted, it may be possible for monitoring at the household level to provide results that allow for visual representation of variations of coverage and provide a basis for targeting resources and focusing interventions in areas where they are most needed. Monitoring at this level should be followed by specific action to identify further reasons for low iodized salt usage, and should result in a range of actions to correct the problem.

Finally, the occurrence of parallel markets of non-iodized salt has frequently been a barrier to achieving USI. National cross-sectional household surveys and community monitoring have often been useful in identifying such salt and in developing strategies to address the problem.