

# **“Establishing Internal Quality Assurance/Quality Control Systems in Salt Iodization Factories” Project: The Global Alliance for Improved Nutrition (GAIN) Experience in the Philippines**

## **Background**

The 2008 National Nutrition Survey reported low levels and high variation in iodine content of household salt. This was linked to the poor quality of iodization as verified in field observations and reports by UNICEF and partners indicating the absence of QA/QC in salt iodization factories. The general state of QA/QC in factories in the Philippines may be characterized as follows:

1. Inadequate knowledge of factory owners and/or officers about iodine deficiency, iodized salt and the salt iodization program
2. Lack of/inadequate knowledge of Food and Drug Administration (FDA) standards, iodine concentration to target, computation of iodate solution mixing concentration and proper solution preparation, importance of and procedure in calibrating iodization machine and sprayer and the necessary tools
3. Absence of quantitative tool to measure iodine levels and dependence on Rapid Test Kit (tester for presence or absence of iodine with indication of low or high concentration). Consequently, there is absence of data analysis, problem solving and taking of proper corrective actions.

The state of the factories developed because of the following reasons:

1. The mandate for salt iodization training based on the ASIN Law is assigned to the Department of Health. Lacking the technology transfer function and capacity, the DOH was not able to sustain the provision of trainings and technical assistance. The government agency with such function and capacity, the Department of Science and Technology (DOST), was tapped by the DOH only for salt iodization machine design.
2. The salt factories are mostly family enterprises which are profit driven. They intended to keep operations very simple and cut as much costs as possible. Machines are locally fabricated without engineering design input causing poor mixing capacity. Machines and equipment are not well maintained and lead to poor production control. Production personnel are mostly contractual and work in difficult working conditions, resulting to poor motivation and commitment to work. The factories suffer from quick turn-over of people or they may practice frequent rotation of personnel. They lack basic knowledge about iodine, iodized salt and salt iodization.
3. The Food and Drug Administration (FDA) is mandated to regulate the salt industry. It is to register and issue Licenses to Operate (LTO) to salt iodization factories. The LTO is issued when a factory meets the requirements set including Good Manufacturing Practice (GMP) and the presence of an internal QA/QC system (where the use of Rapid Test Kit for iodized salt testing is allowed). Owing to the ineffectiveness of the FDA, the issuance of an LTO did and does not guarantee the presence of an internal QA/QC system. The issuance of an LTO only means that the facility has met the minimum of the GMP requirements, uses RTK for quality control and is monitored once a year (at least for the initial issuance or the renewal of the LTO).

## **GOOD PRACTICES IN PROJECT DESIGN AND IMPLEMENTATION**

1. Implementation of the QAQC Project through a government agency, the Department of Science and Technology (DOST)
  - a. While GAIN, on its' own, could have developed the internal QAQC systems of salt iodization factories much faster, it chose to implement the project through a government agency to ensure that salt industry support is sustained even after the GAIN-UNICEF USI Project ends. Also, instead of partnering with the DOH, the DOST was tapped to implement the project because it is the main government agency mandated for technology research, development and transfer. The Industrial Technology Development Institute (ITDI) of the DOST at the national level led project planning and implementation while regional DOST offices implemented trainings, conducted monitoring visits and gave needed technical assistance. The regional DOST provided local presence and are accessible for immediate assistance to factories. To emphasize the role of the DOST in USI, GAIN, as it participated in the review of the USI law, suggested the rewording of the Revised Implementing Rules and Regulations to specifically identify DOST (instead of the DOH) as main agency responsible for salt iodization technology transfer.
  - b. To ensure that all DOST officers involved have the same basic knowledge of the principles and concepts of the project, a national training of trainers on the envisioned internal QAQC system was given. Annual national technical meetings were also conducted to update on project status, challenges, actions needed and new knowledge/technology.
2. Signing of partnership agreements for QAQC trainings with major iodized salt producers
  - a. Because the government was mistrusted and has poor regulatory capacity, it was not easy for GAIN to offer the QAQC trainings to the salt industry who initially saw the trainings as unnecessary and inconvenient. GAIN met with salt factory owners and explained the benefits of undergoing the training such as: a) contribution to social development as part of Corporate Social Responsibility (CSR) b) compliance to the Law in anticipation of the FDA strengthening and c) as a business strategy to attract customers who require quality system implementation among its suppliers. To appease the major concern of the owners on information confidentiality and to ensure that they fulfill their responsibilities during the training and monitoring period, agreements were signed with them. The agreements made the implementation smoother. GAIN also gained the further trust of the producers as it honored the confidentiality clauses in the signed agreements.
3. Meeting with production workers to explain the USI program and QAQC project relevance
  - a. GAIN anticipated difficulty in working with the factory personnel because of their dire situation (as discussed in the Background). To win their support, the USI program and the benefits of using adequately iodized salt was explained to them. They understood the importance of their work which improved self-worth perception. This eased our entry into their factories.

4. Conduct of assessments to determine baseline QA/QC practices and quality level of each factory
  - a. Because each factory and its resources are unique, assessments were conducted to understand the situation which the training team will encounter. Recommendations were made to improve equipment and tools in preparation for the training. Generally, some modifications of the salt iodization machine and spraying system were needed. Minor adjustments, as needed, were made in the training plan. Because of these, the training sessions become less difficult.
5. Trainings of factories consisted of theory, hands-on practice and coaching and Conduct of follow-up visits were conducted
  - a. Because the project dealt with simple factories and non-technical and poorly motivated personnel, GAIN combined theory, hands-on practice and coaching to ensure that the necessary knowledge and skills were imparted. To lessen the tendency to go back to old practices which are very convenient, follow-up visits were conducted.
6. Phase out of the use of RTK and introduction of the WYD Iodine Checker as the main tool for the quantitative testing of iodine
  - a. The QAQC system implemented did not use the RTK in any way. In all factories covered by the project, their historical use of the RTK misled production officers and management that they were iodizing properly. It was a useless tool inside the factory.
  - b. The WYD Iodine Checker is a convenient tool- it was easily operated and maintained even by production personnel without college education. It proved to be reliable and withstood dusty and corrosive environment in salt factories. The WYD Iodine Checker had an empowering effect on production personnel who worked in humble and difficult environment. They found it interesting to measure iodine levels and use the knowledge to take appropriate corrective measures.
7. Production of WYD Reagents by the DOST
  - a. Only one salt iodization company had the ability to produce the WYD reagents. The DOST employees association offered to include WYD reagent production in their livelihood initiatives. Production was undertaken by retired DOST employees with extensive laboratory experience, using the laboratory facilities of DOST. This ensured the good quality of the chemicals.
8. Data Recording using the QAQC Software
  - a. The factory officers found the QAQC software convenient to use. It allowed for automatic data consolidation and generation of reports. However, it is proving a challenge in some areas where internet connection is slow and internet use for the factory is budgeted.

## **LESSONS LEARNED and CHALLENGES**

9. Implementation of the QAQC Project through DOST
  - a. The QAQC project competed with the many other project of the DOST region. Constant follow-up and monitoring was needed to keep the project in line.
10. Commitment to the project by the owners of salt iodization factories

- a. The commitment of the owners is strongly tied to profit and potential profit. The effort to iodize adequately is mainly driven by the demand of selected large food processors and some salt repackers for large operators while medium and small operators have no motivation to comply with standards. When there is an opportunity to beat competition through lower cost, the first to be targeted is lower iodization levels. The need for stronger FDA regulations is wanting.
11. Labor issues pose a constant threat to QAQC implementation
- a. The poor condition of many workers is not being addressed by the owners. The distraction caused by it occupies the higher agenda in the minds of the workers. Workers can miss following the processes for adequate iodization.
12. Salt Iodization Machine Design
- a. The condition of the salt iodization machines and sprayers are major determinants of proper iodization. Most of the salt iodization machines in the Philippines are locally fabricated. Since the design phase was not guided by engineers, critical design considerations were not considered. The simple addition of agitators to the screw mixers have helped but in some cases, the screw mixer is just too short to allow adequate mixing
13. WYD Iodine Checker
- a. While the WYD is a good equipment, it needs a support system to ensure that it is properly used and maintained. The factories still need reminders when the reagents are exhausted. There were cases where the WYD Iodine Checker is not cleaned at the end of the day and left unpacked and exposed to dust and other elements. All of these issues are continually being addressed.
14. Dosing Pumps
- a. This is a robust equipment which is supposed to last for years in salt iodization operations. However, one fourth of the units procured broke down because of very poor handling and maintenance. This is despite all reminders and instructions. The units had been repaired and the issue discussed with the owners of the factories.
15. Factory Capacity for Iodization Control
- a. Despite their limitations and shortcomings, factory workers, given the proper tools, when motivated and using their experience, can address issues on inadequate iodization on their own.

## **FUTURE PLANS**

16. Implementation of the QAQC Project through DOST
- a. GAIN has gained verbal approval of action plans to ensure the DOST sustains the QAQC project achievements. GAIN will work with the ITDI to institutionalize these initiatives which will include yearly renewal of training certification, WYD calibration and testing of FDA collected samples.

17. Commitment to the project by the owners of salt iodization factories
  - a. Once the GAIN-funded survey of food processors and salt repackers is completed by April 2014, GAIN and UNICEF will coordinate advocacy to these groups that they will demand from the salt factories adequately iodized salt. It is estimated that half of the iodized salt production is for processed foods. This demand when generated will create a lot of pressure on the big factories to sustain QAQC implementation
  - b. GAIN is currently working with some DOH regional offices and Local Government Units in using the WYD for monitoring and excluding non-iodized and inadequately iodized salt from the markets. This pressure will be upon many medium and small scale factories which is difficult for FDA to monitor. The project is being done in coordination with the FDA region.
  - c. GAIN is also working with FDA to strengthen its food database, especially the salt industry component. The project is being finalized in March 2014. GAIN is also working with UNICEF to help FDA strengthen its salt monitoring capacity
18. Salt Iodization Machine Design
  - a. DOST has committed to tie-up the availment of its incentives to the procurement of properly designed salt iodization machines

## **RESULTS BEING ACHIEVED**

Most factories which were assisted had less than 1/3 of the samples tested passing the FDA standard and the average iodization is below the minimum. After completing the training and monitoring visits, the factory collected samples achieved at least 80% passing rate, with many above 90%, and the average iodization rates are within standard. However, we have noticed a strong tendency to lower iodization levels in the smaller factories to match up with competitive pressure (and also due to weak FDA monitoring).