

## Meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia



27–29 September 2011  
Manila, Philippines



**REPORT**

**MEETING ON REGULATORY MONITORING OF SALT AND FLOUR  
FORTIFICATION PROGRAMMES IN ASIA**

Convened by:

WORLD HEALTH ORGANIZATION  
REGIONAL OFFICE FOR THE WESTERN PACIFIC

In collaboration with:

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## NOTE

The views expressed in this report are those of the participants in the Meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia and do not necessarily reflect the policies of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the Meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia, which was held in Manila, Philippines from 27 to 29 September 2011.

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### Keywords:

Food, Fortified – Standard utilization / Micronutrients – Therapeutic use / Sodium chloride, Dietary – Therapeutic use / Flour / Nutritional requirements

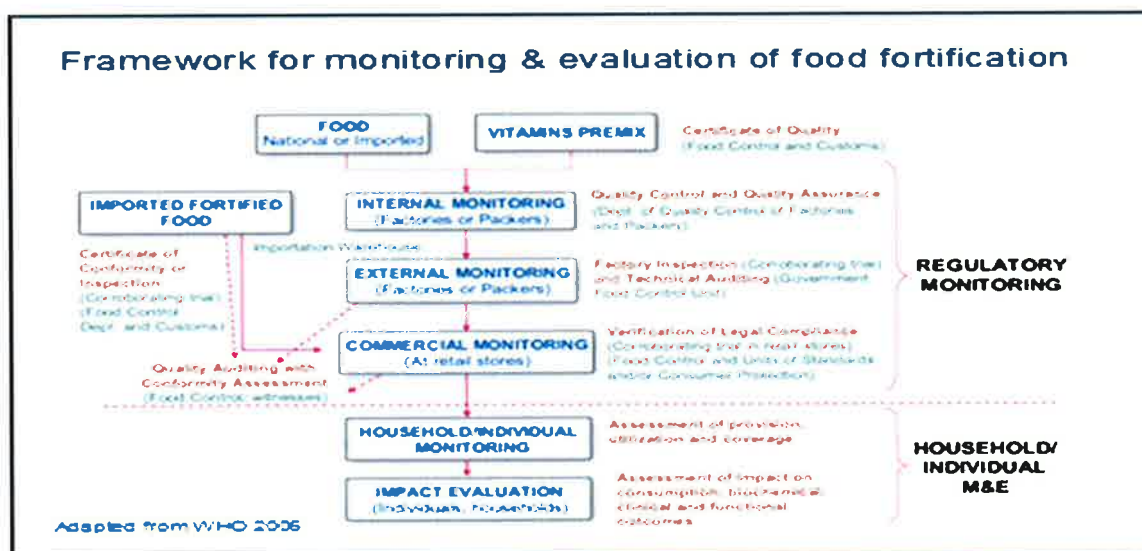
## Acronyms

Codex – Codex Alimentarius  
FAO – Food and Agricultural Organization  
FDA – Food and Drug Administration  
FFI – Flour Fortification Initiative  
GAIN – Global Alliance for Improved Nutrition  
GDP – Gross Domestic Product  
GMP – Good Manufacturing Practices  
HACCP – Hazard Analysis and Critical Control Points  
HPLC – high performance liquid chromatography  
IEC – information, education and communication  
ISO – International Organization for Standardization  
MI – Micronutrient Initiative  
ppm – parts per million  
QA – quality assurance  
QC – quality control  
SOP – standard operating procedures  
SQP – standard quality control procedures  
UNICEF – United Nations Children’s Fund  
WHO – World Health Organization  
WTO – World Trade Organization

## Executive Summary

Vitamin and mineral deficiencies, in particular deficiencies of iron, iodine, vitamin A and folic acid, cause significant economic losses through excess morbidity and mortality of women and children, reduced cognitive development in children, reduced work productivity of adults, and increased disabilities. Food fortification is recognized as a highly cost-effective way to improve the micronutrient intake of populations. Many countries in South-East Asia and the Western Pacific regions are implementing mandatory salt fortification with iodine. Mandatory flour fortification is also being implemented or is being considered in some of these countries. A key component of successful food fortification programmes is the regulatory monitoring of collaboration between the private and public sectors to produce quality fortified food.

Available information on regulatory monitoring systems for iodized salt and fortified wheat flour in countries in the South-East Asia and the Western Pacific regions indicate problems and weaknesses. These include the lack of clarity on roles and responsibilities between different government agencies in external monitoring, a lack of resources for regulatory monitoring, poorly established or badly designed protocols and systems for regulatory monitoring, and insufficient qualified laboratory resources and expertise to test product samples. As these problems are undermining existing and possible future salt iodization and wheat flour fortification programmes, World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the Flour Fortification Initiative (FFI), Global Alliance for Improved Nutrition (GAIN), Micronutrient Initiative (MI) and the World Bank collaborated on a meeting to discuss regulatory monitoring of salt and flour fortification programmes in selected countries in the two regions. The meeting took place on 27 to 29 September 2011 in Manila, Philippines. Representatives from salt and wheat flour industries, as well as representatives from ministries of health, food and drugs, industry, trade and customs, and academia from Bangladesh, China, Indonesia, Malaysia, Mongolia, Nepal, Philippines, Sri Lanka and Viet Nam and the organising agencies met to share guidance and global experiences on regulatory monitoring of salt iodization and flour fortification. The aim of the meeting was for country teams to strengthen existing regulatory monitoring systems in order to increase the cost effectiveness and sustainability of salt and flour fortification programmes.



WHO and Food and Agriculture Organization of the United Nations (FAO)<sup>1</sup> *Guidelines on food fortification with micronutrients (2006)* provide a schematic representation of a model monitoring and evaluation system for fortification programmes. It distinguishes two main categories of monitoring, namely, regulatory monitoring and household/individual monitoring. Regulatory monitoring, the topic of the meeting, also frequently referred to as food control, encompasses all monitoring activities conducted at the production level (i.e. factories and packers), as well as monitoring at customs warehouses and at retail stores, by concerned regulatory authorities as well as by producers themselves, as part of quality control/assurance programmes. The primary aim of regulatory monitoring is to ensure that the fortified foods meet the nutrient, quality and safety standards set prior to programme implementation. Household and individual monitoring, not discussed

<sup>1</sup> <http://www.who.int/nutrition/publications/micronutrients/9241594012/en/>

at the meeting, pertains to coverage of the fortified food and impact assessments. Regulatory monitoring systems for fortified foods are based on national legislation, regulations and standards which establish requirements for foods, and the expected roles and responsibilities of various stakeholders.

The objectives of any **food legislation** are protection of health, protection of consumers' rights and facilitation of trade in safe and healthy food. The development of food legislation should be based on risk analysis, including risk assessment, risk management and risk communication. Legislation should be developed, evaluated and revised in an open and transparent manner, involving public consultation and trading partners. The legal framework should be underpinned by a food law which is, ideally, brief but lays out general principles. This legislation should then be supported by technical regulations and standards that are based on the latest available scientific and/or accepted international norms. National governments should consider Codex standards when developing their own national standards to ensure they are based on the best available science and trade is facilitated internationally.

**Internal monitoring** refers to the quality control and quality assurance (QC/QA) practices conducted by producers, importers and packers. Internal monitoring may be defined as "a system to control all parts of the milling/salt production process to ensure the consistent production of flour/salt that meets both regulatory and commercial requirements." As such, internal monitoring does not involve only one test or one check but is made up of a variety of components and mechanisms, including premix procurement and storage controls, feeder/dosifier installation, feeder calibration, feed rate calculations, process controls (such as check weighting of premix addition), recordkeeping and laboratory analysis or quantitative tests for vitamins and minerals in wheat flour and iodine in salt (as per regulations).

**External monitoring** refers to the inspection and auditing activities carried out at production centres (factories and packers) and importation custom sites. Government authorities are responsible for external monitoring, which is implemented to assure that the production facility is able to produce a quality and safe product that meets national regulations. Thus, external monitoring must assess whether the production facility has adequate raw materials, equipment, systems and procedures in place. The objective of a monitoring visit is to ensure that samples continually conform to national regulations, and not at just one point in time. A typical external monitoring system is comprised of the following: (i) mill/factory inspections, including review of records, (ii) sampling policies and procedures, (iii) laboratory analysis and (iv) enforcement procedures.

**Commercial monitoring**, similar to external monitoring, is generally the responsibility of government and serves to verify that the fortified products comply with standards. However, commercial monitoring is conducted at the level of retail stores. Since fortification does not take place at the commercial level, problems in the fortification process can only be addressed at the food processor. Furthermore there are far fewer mills and salt factories than markets and retail outlets. Resources for monitoring, especially when limited, should thus focus on ensuring that all domestically-produced food meets national regulations *before* it leaves the production facility and all imported food meets national regulations *before* leaving the point of importation. This is more efficient and easier than trying to identify sub-standard foods in the market and tracing them back to the production/import source. Commercial monitoring, therefore, is most helpful when foods come from unknown and unmonitored sources, such as illegal imports or non-registered producers.

Laboratory analysis plays an important role in regulatory monitoring, both internal and external. However the results of laboratory analysis are subject to variation and do not provide conclusive evidence of compliance or non-compliance. Over-reliance on laboratory results can therefore be very misleading and counter-productive in ensuring high-quality fortified food. Laboratory analysis results should instead be considered by food producers and inspectors **in combination** with additional critical information, including information obtained through the mill/factory inspection.

In preparation for the meeting, reviews of the regulatory monitoring systems in Indonesia, the Philippines, Nepal and Viet Nam were undertaken. The reviews covered descriptions, strengths and weaknesses of existing regulatory monitoring systems. Results of the reviews suggest that existing legislation on food fortification do not cover roles and responsibilities of different regulating agencies and guidelines for collaboration among the agencies. Existing legislation also do not sufficiently detail the responsibilities of the industry. The country reviews also suggested that the focus of both regulators and the industry tends to end at product testing and does not continue to process control and internal quality assurance systems. Regulatory monitoring also only



tends to cover registered or licensed facilities and importers and not all food available to consumers. In many countries, in addition to not recognizing and monitoring non-registered producers, legislation may also not require shutting down such facilities. The reviews also indicate that in several countries, commercial monitoring is given more or less equal emphasis as internal/external monitoring, which may be due to the mandates for food inspectors to monitor food where consumers access it, and to monitor food only from registered facilities. As mentioned previously, heavy focus on commercial monitoring has limited effectiveness and can be inefficient especially if it is based on poorly designed regulatory monitoring systems and the related legislative framework. It is therefore necessary in many countries to refocus regulatory monitoring systems on the production level and to monitor all food that can be accessed by consumers, not just foods from registered facilities or legal importers.

At the meeting, participants in country teams came to similar conclusions on their own country's regulatory monitoring systems. For most countries, while flour mills tended to have good internal monitoring systems, there is a need to strengthen internal monitoring in many salt production/iodization facilities, which are generally much smaller and more numerous than flour mills. Several countries identified weaknesses in existing legislation and formulated action plans to include amendments to current standards and greater clarification on roles and responsibilities. Weakness in external monitoring for most countries included lack of manpower and routine systems, limited or no mechanisms to monitor facilities that are not registered, and over-reliance on and problems with laboratory analysis. Many also realized the need to delegate the responsibility for external monitoring to provincial or district authorities. This will provide for additional resources but requires oversight and coordination to ensure that external monitoring is undertaken comprehensively, appropriately and fairly throughout the country.

In some countries, a large number of small salt producers or wheat mills exist. These small facilities often serve the most remote communities and most disadvantaged populations. Because of small size and low capacity, internal monitoring systems are often non-existent or very rudimentary. External monitoring would require significant resources to cover the many facilities. There is, therefore, a challenge to develop ways to support food fortification in these small but important facilities outside of routine government regulatory monitoring.

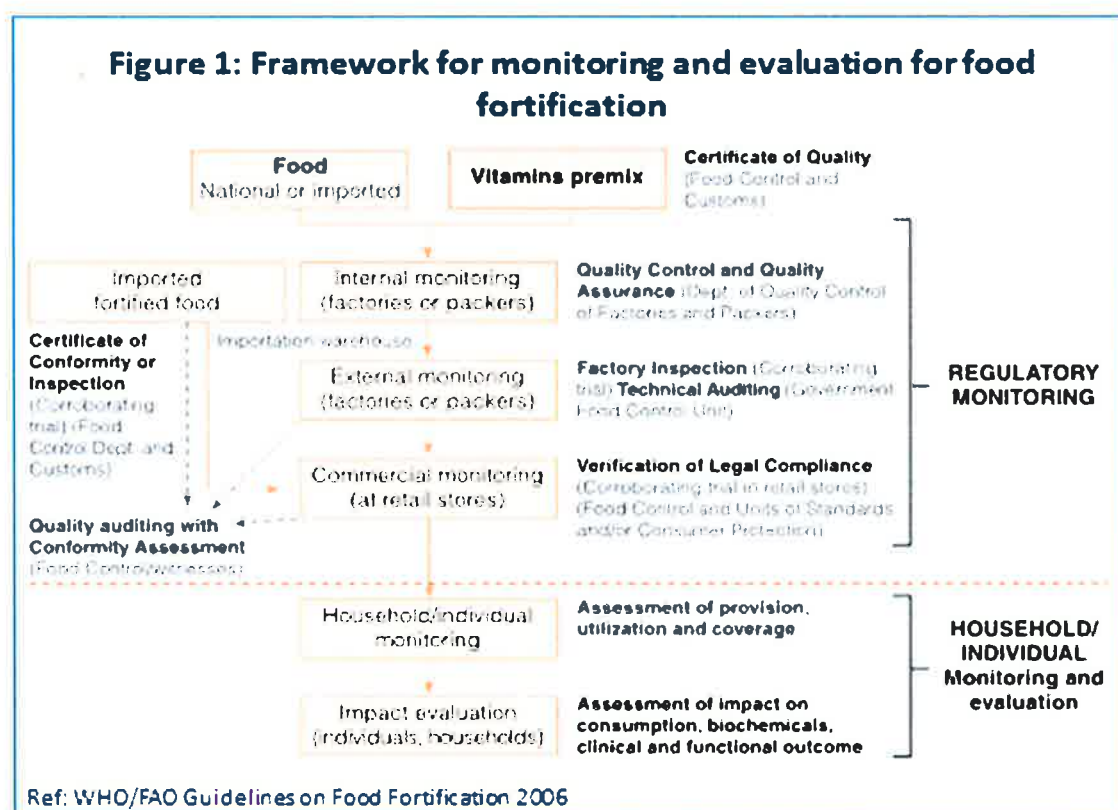
## Introduction

### Background

Many countries in South-East Asia and the Western Pacific regions are implementing mandatory salt fortification with iodine. Programme reviews in these countries indicate that there are often problems with the regulatory monitoring system (China is an exception). In addition, while significant efforts have been made to strengthen programme components such as advocacy and communication, and supply and production of iodized salt and assessments of coverage and impact, relatively little attention has been paid to addressing weaknesses in regulatory monitoring.

New global recommendations<sup>2</sup> on wheat flour fortification were issued by WHO, in collaboration with several international partners, in December 2009. These recommendations have contributed to the momentum by countries to either update existing voluntary standards (China), adopt mandatory flour fortification (Malaysia, Nepal, Viet Nam, Mongolia) or strengthen existing mandatory programmes, including updating existing standards (Indonesia, Philippines). Several states in India have started fortification of wheat flour available for public distribution. This environment of review and change has therefore created an opportunity for countries to improve existing monitoring and evaluation of wheat flour fortification programmes.

WHO and Food and Agriculture Organization of the United Nations (FAO)<sup>3</sup> *Guidelines on food fortification with micronutrient (2006)* provides the schematic representation of a model monitoring and evaluation system for fortification programmes.



The schematic distinguishes two main categories of monitoring; regulatory monitoring and household/individual monitoring. The former encompasses all monitoring activities conducted at the production level (i.e. factories and packers) and at customs warehouses and at retail stores by concerned regulatory authorities and producers themselves, as part of quality control/assurance programmes. The primary aim of regulatory

<sup>2</sup> [http://www.who.int/nutrition/publications/micronutrients/wheat\\_maize\\_fortification/en/](http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fortification/en/)

<sup>3</sup> <http://www.who.int/nutrition/publications/micronutrients/9241594012/en/>

monitoring is to ensure that the fortified foods meet the nutrient, quality and safety standards set prior to programme implementation. Regulatory monitoring systems for fortified foods are based on national legislation, regulations and standards which define the requirements for foods and expected roles and responsibilities of various stakeholders.

Available information on regulatory monitoring systems for iodized salt and fortified wheat flour in many countries in the two regions indicate problems and weaknesses. In the case of salt, the problems are generally in all components of regulatory monitoring (i.e. internal, external and commercial) whereas for flour milling, the problems are related to external monitoring, i.e. inspecting and auditing activities at production centres and importation sites, and commercial monitoring, both of which are undertaken by government authorities.

Common problems in internal monitoring in salt iodization facilities are generally poor quality production/fortification systems (especially in the smaller production facilities), lack of internal monitoring systems and over-reliance on semi-quantitative test kits. Internal monitoring in flour mills is generally better, since these facilities tend to be larger and well-managed, but some also suffer from inadequate internal monitoring systems. External and commercial monitoring for both salt iodization and flour fortification facilities tended to have the same weaknesses. These include insufficient government resources or personnel to undertake required or adequate number of monitoring visits, over-reliance on test results and insufficient consideration of internal quality assurance systems, inconsistent sanctions and punishment, long delays and discrepancies in laboratory test results, lack of follow up on the results of monitoring visits, and unequal monitoring of domestic and imported foods. Reasons for these problems include:

- poorly developed and unclear existing legislation, regulations and standards;
- lack of clarity on roles and responsibilities between different government agencies in external monitoring;
- lack of resources for regulatory monitoring;
- poorly established or designed protocols and systems for regulatory monitoring; and
- insufficient qualified laboratory resources and expertise to test product samples

These problems are undermining existing salt iodization and wheat flour fortification programmes. In addition, countries that are considering mandatory wheat flour fortification have raised concerns about their capacity to effectively monitor implementation.

An inter-agency, biregional meeting was proposed to discuss regulatory monitoring of salt iodization and wheat flour fortification programmes, particularly internal monitoring by salt and wheat flour producers and external and commercial monitoring by government authorities.<sup>4</sup> The rationale for covering internal, external and commercial monitoring in the same meeting is described below.

- While internal quality assurance is primarily the responsibility of the food industry, the main purpose of external monitoring is to ensure that internal quality assurance systems are established, implemented adequate and effective.
- Meanwhile, when the government's system for regulatory and commercial monitoring is perceived to be fair and transparent, the food industry is more likely to comply with national regulations and produce quality products.
- There is therefore an advantage in bringing industry representatives and regulatory authorities together to discuss improvements to both industry internal quality assurance systems and government regulatory and commercial monitoring systems. By sharing information and improving awareness on roles, responsibilities and criteria for assessment, this meeting may help improve the quality, feasibility and sustainability of regulatory monitoring systems.
- Since the meeting would only be able to include two to three representatives from each industry per country, it would be necessary for country participants and industry associations to develop follow up activities at national level to share conclusions and agreements with other members of the salt and flour milling industries, especially in relation to strategies for improving internal monitoring.

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<sup>4</sup> The meeting did not cover household/individual monitoring and evaluation (including impact assessment) as the relevant stakeholders for these activities are not the same as those involved in regulatory monitoring.

## Objective of the meeting

The overall objective of the meeting was to provide guidance and share global experiences on regulatory monitoring of salt iodization and flour fortification programmes between countries and national stakeholders. This would enable producers and regulatory authorities to strengthen existing regulatory monitoring systems in order to increase the cost-effectiveness and sustainability of salt and flour fortification programmes.

## Expected output

1. Salt and wheat flour producers increase their capacity and commitment to implement adequate quality control and quality assurance systems to consistently produce safe and high-quality products.
2. Regulatory authorities increase their capacity and commitment to monitor fortified food production in an effective, efficient and sustainable way. For most countries, this includes a greater emphasis on monitoring the quality and safety of premix/fortificant, production/fortification and internal quality assurance systems and the fortified food at the production level as opposed to the retail level.
3. Improved dialogue between salt and flour producers and government authorities and an improved understanding of requirements, roles and responsibilities.
4. Documentation of existing national regulatory monitoring systems and practices, and proposals for improvement from selected countries.

## Meeting format

The format of the meeting followed the schematic for regulatory monitoring and was divided into three sessions: (i) food fortification legislation, regulations and standards, (ii) internal monitoring, and (iii) external and commercial monitoring. Each session featured presentations by technical experts and by country representatives on the particular component of the national regulatory monitoring system. There was also group work designed to enable sharing of experiences with different countries and stakeholders on the session topic. A special session was organized on regulatory monitoring in small-scale fortification.

In preparation for the meeting, reviews of the regulatory monitoring system in four countries (Indonesia, the Philippines, Nepal and Viet Nam) were undertaken by four different consultants. The reviews described and explained the existing regulatory monitoring system and discussed strengths and weaknesses.<sup>5</sup> These reviews were summarized and shared with all meeting participants as case studies. The full reports were available only to the four countries, to be used as a resource document for their own discussions. Country presentations during the three sessions were based on these reviews.

Field visits were also organized. One group visited a large flour milling company in Manila, Philippines, and the second group visited the Food and Drug Administration (FDA) to obtain additional information on how the Philippines conducts external monitoring and to visit the FDA laboratories. A salt producer in the Philippines also presented on how internal monitoring is conducted in the Philippines by large and small salt producers.

On the third and final day of the meeting, country teams consisting of representatives from government and the salt and flour milling industries<sup>6</sup> identified strengths and weaknesses in their own regulatory monitoring systems in three categories: (i) food fortification legislation, regulations and standards, (ii) internal monitoring, and (iii) external and commercial monitoring. Action plans were developed to address the weaknesses. Each country team presented their analysis and action plan on the third day. An evaluation of the meeting revealed that 71% of participants felt the country presentations on the last day were the best part of the meeting, participants were generally pleased with the quality of their next steps, and were positive that these steps would be implemented and would improve regulatory monitoring.<sup>7</sup>

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<sup>5</sup> The Nepal review has since been published by the World Bank; "Review of regulatory monitoring system for fortified food in Nepal, World Bank 2012" and is available at <http://documents.worldbank.org/curated/en/2012/02/16259406/review-regulatory-monitoring-system-fortified-foods-nepal>

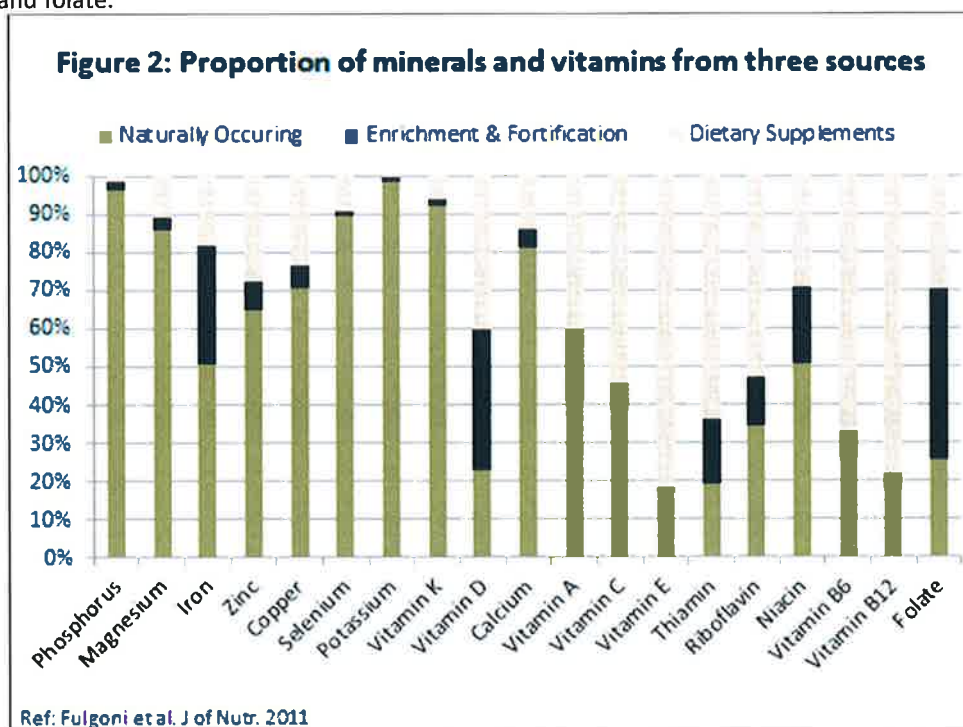
<sup>6</sup> Unfortunately representatives of flour and salt industries were not able to attend from all countries and overall industry representation was lower than expected and hoped for due to poor communication during the invitation process.

<sup>7</sup> Meeting Evaluation – Results – report prepared by meeting organizers.

## Proceedings

### The cost effectiveness of food fortification

Vitamin and mineral deficiencies, in particular deficiencies of iron, iodine, vitamin A and folic acid, cause significant economic losses through excess morbidity and mortality of women and children, reduced cognitive development in children and work productivity of adults, and increased disabilities. In total, the World Bank estimates that micronutrient deficiencies result in the loss of 2-3% of gross domestic product (GDP). Food fortification is one strategy to reduce vitamin and mineral deficiencies, ideally implemented as part of a comprehensive approach which includes dietary diversification and supplementation in high-risk groups. Food fortification is the preferred approach for some nutrients, for example iodine for the general population and folic acid for women during early pregnancy. An important advantage of food fortification is that it does not require significant behaviour change in the consumer. A recent study<sup>8</sup> has demonstrated that even in developed countries, such as the United States of America, food fortification is an important source of iron, vitamin D and folate.



Food fortification is a very low-cost intervention. Horton et al.<sup>9</sup> quote the following figures for reaching 80% of the population with iodine and 70% with iron:

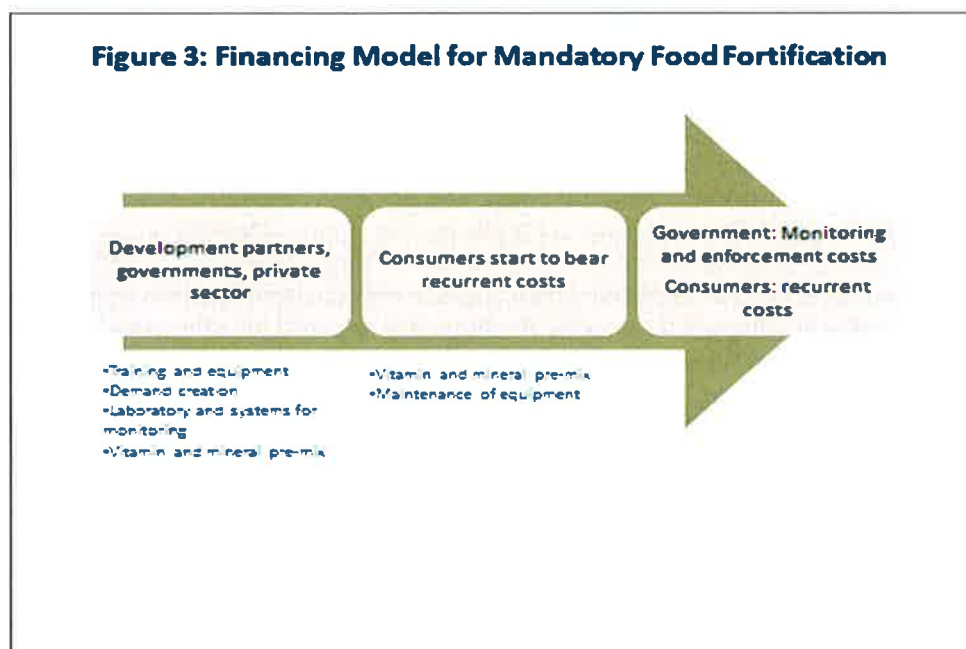
- Iodine: US\$ 0.05/person/year
- Iron: US\$ 0.10-0.12/person/year (depending on iron compound)
- Folic acid: US\$ 0.01/person/year

The cost of fortification, as a proportion of the cost of production of the food vehicle, is low and can be passed on to the consumer, market forces permitting. However, mass fortification invariably involves high-volume, low-profit food vehicles and a high absolute cost of premix; combined with weak enforcement and/or penalties there will likely be non-compliance by food producers on economic grounds. A possible model for mandatory fortification (below) indicates how the consumer gradually carries the cost of fortification.

<sup>8</sup> Fulgoni et al. Food, Fortificants, and Supplements: Where Do Americans Get Their Nutrients? Journal of Nutrition. 141:1847-1854, 2011

<sup>9</sup> Horton et al. Copenhagen Consensus Working Paper, 2008





The benefit-cost of fortification<sup>10</sup> is high compared to that of other nutrition interventions as shown below. This is because it is a relatively low cost intervention and because it is quite effective:

**Table 1: Benefit: cost ratio of nutrition interventions**

INTERVENTION		Benefit: Cost
<b>Micronutrient Supplementation</b>	Vitamin A capsules <2 year old children	100:1
	Therapeutic zinc for infants	14:1
<b>Micronutrient Fortification</b>	Salt iodisation	30:1
	Iron in staple foods	8:1
<b>Biofortification</b>	Plant breeding (iron, zinc, vitamin A)	18:1
<b>Deworming preschoolers</b>		6:1
<b>Behaviour change</b>	Community nutrition programmes	13:1
<b>Community treatment of severely malnourished children</b>		25:1

The Copenhagen Consensus 2008,<sup>11</sup> which brought together economic experts to identify the best solutions for the world's ten biggest challenges, identified micronutrient fortification as the third most important intervention, as indicated below. More detail is available on the Copenhagen Consensus Center website.

<sup>10</sup> Horton et al. Scaling Up Nutrition: What Will it Cost. World Bank 2010  
<http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/Peer-Reviewed-Publications/ScalingUpNutrition.pdf> (click OK on safety warning)

<sup>11</sup> <http://www.copenhagenconsensus.com/Default.aspx?ID=953>

### **Box 1: Conclusions of the Copenhagen Consensuses 2008**

- 1. Micronutrient supplements (vitamin A and zinc) [malnutrition]**
- 2. The Doha development agenda [trade]**
- 3. Micronutrient fortification (iron and salt iodization) [malnutrition]**
- 4. Expanded immunization coverage for children [disease]**
- 5. Agricultural R&D on micronutrients [malnutrition]**
- 6. Deworming and nutrition programs at school [malnutrition]**
- 7. Lowering the price of schooling [education]**
- 8. Increase and improve girls' schooling [women]**
- 9. Community-based nutrition promotion [malnutrition]**
- 10. Provide support for women's reproductive role [women]**

Fortification is not only a good investment but it is also highly feasible. Sixty-eight countries currently require flour to be fortified with at least iron or folic acid<sup>12</sup> and 125 countries are now implementing and reporting on salt iodization programmes. Globally, some 71% of households in all developing countries (74% in Asia) now consume adequately iodized salt.<sup>13</sup>

While progress on food fortification has been impressive, results are preliminary and sustained success and optimal impact requires well-functioning regulatory systems. Additionally, feasibility (and cost) is highly dependent on the complexity of the food processing sector i.e. the number and size of processing units. For most countries, the coverage gap is due to the abundance of smaller-size processors, often in the informal economy. Developing regulatory monitoring systems that can support and enable quality fortification in small-scale enterprises will be necessary for achieving universal and sustainable mandatory food fortification.

<sup>12</sup> Flour Fortification Initiative, May 2012 <http://www.sph.emory.edu/wheatflour/>

<sup>13</sup> UNICEF. State of the World's Children 2012. February 2012

## Overview of regulatory monitoring systems

Regulatory monitoring systems, previously known as food control systems, are a critical component in the success of any food fortification programme. The purpose of regulatory monitoring systems is to ensure that fortified foods meet nutrient quality and safety standards from the time food is produced in the factory until it reaches the retail store. The FAO publication *Strengthening National Food Control Systems (2006)*<sup>14</sup> identifies five components of food control systems and discusses the responsibilities and objectives of food control. The below is an extract from this publication.

**Box 2: Food control** encompasses a number of activities to provide consumer protection and ensure that all foods provided for human consumption are safe, wholesome, conform to safety and quality requirements, and are honestly and accurately labelled as prescribed by law. Most countries have some sort of food control system in place and generally they include the following five components

1. Food Control Management
2. Food Legislation
3. Food Inspection
4. Food Control Laboratories
5. Information, Education and Communication

The capacity of a national food control system relates to its ability to perform appropriate functions effectively, efficiently and sustainably in order to provide safe and quality food for domestic consumption and export. Achieving food safety is a shared responsibility and different types of stakeholders – including government, the food industry, consumers and their organizations, academic and scientific institutions etc – contribute to this capacity. In particular:

1. Government agencies (at central and lower levels) are responsible for establishing and managing an enabling institutional, policy and regulatory framework for food safety, and carrying out food control activities that protect consumers from risks arising from unsafe food and fraudulent practices.
2. Food producers, processors, handlers, manufacturers, traders, retailers and caterers (the food industry) have the primary responsibility for delivering safe food to consumers. This includes responsibility for developing and managing systems that ensure the food supplied and/or served is safe and complies with official food safety requirements
3. Consumers and their organizations are responsible for ensuring that food is handled, stored and prepared in accordance with good hygienic practices and for requesting appropriate standards of food safety.

While these stakeholders each have distinct responsibilities and accountabilities, the multi-dimensional nature of food safety and quality means that their roles are highly inter-connected and interdependent. Active collaboration among stakeholders involved in the food chain from farm to table is therefore essential to ensure the effectiveness and sustainability of the results achieved.

Ref: FAO. *Strengthening national food control systems. A quick guide to assess capacity building needs. Introduction.* FAO, Rome 2007

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<sup>14</sup> <ftp://ftp.fao.org/docrep/fao/010/a1142e/a1142e00.pdf> (click OK on safety warning) and [www.fao.org/righttofood/kc/downloads/vl/docs/AH433.pdf](http://www.fao.org/righttofood/kc/downloads/vl/docs/AH433.pdf) (click OK on safety warning) for the full version



## Food control management

**Box 3: Food control management** is the continuous process of planning, organizing, monitoring, coordinating and communicating, in an integrated way, a broad range of risk-based decisions and actions to ensure the safety and quality of domestically produced, imported and exported food for national consumers and export markets as appropriate. Food control management covers the various policy and operational responsibilities of competent government authorities responsible for food control. These include the development and implementation of food control policies, strategies and plans that reflect the government's commitment to food safety and quality and provide a sound framework for food control activities.

Food control management should be based on risk analysis and an integrated farm-to table approach. Definitions and working principles for risk analysis have been developed for use by the Codex Alimentarius Commission. These principles highlight the need for a structured approach for risk analysis comprised of three separate but closely linked and integral components: i) risk assessment; ii) risk management; and iii) risk communication. In particular, risk management provides a process (distinct from risk assessment) for weighing policy alternatives in consultation with all the interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

*Ref: FAO. Strengthening national food control systems. Guidelines to assess capacity building needs. Part 2 Module 1: Assessing capacity building needs in food control management. FAO, Rome 2006. (2<sup>nd</sup> link in footnote 14)*

There are three common approaches to food control management:

1. Multiple agency: responsibilities for food control are shared between various government ministries (eg. health, agriculture, commerce, trade, industry etc.) or across government agencies at different levels (central, regional, local).
2. Single agency: all responsibility for protecting public health and food safety falls on a single food control agency with clearly defined terms of reference.
3. Integrated agency: policy, risk assessment and management, standards and regulations development, and coordinating functions are assumed by a food control agency at the national level, while responsibilities for food inspection and enforcement, education and training etc. remain with existing agencies at the national, regional and local levels.

### Food legislation

Food legislation normally involves a multilevel legal framework:

- Food legislation (or food law) is the complete body of legal texts (laws, regulations and standards) that establish the broad principles for food control.
- Food regulations are subsidiary legal instruments (usually issued by a minister rather than parliament) which prescribe mandatory requirements that apply to various aspects of food production, handling, marketing and trade, and provide supplementary details that are left open in the main parliamentary-level legislation.
- Food standards are nationally or internationally-accepted procedures and guidelines (voluntary or mandatory) that apply to various aspects of food production, handling, marketing and trade to enhance and/or guarantee safety and quality of food.

A good example of a multilevel legal framework is present in Canada where the over-arching legislation is the Food and Drugs Act (R.S.C., 1985, c. F-27 latest 2011)<sup>15</sup> which is defined in 37 pages and available in two languages (English and French). The food component is discussed in four paragraphs. The Food and Drugs Act

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<sup>15</sup> <http://laws.justice.gc.ca/eng/acts/F-27/>

is straightforward but undergoes continuous review.<sup>16</sup> Any changes require an Act of Parliament. Under the Food and Drug Act are multiple Food and Drug Regulations<sup>17</sup> which provide details on food regulations and standards. These Regulations are also under constant review but may be changed by an Order of Council. The Food Regulations are defined over 1274 pages.<sup>18</sup>

In many countries, food legislation tends to be a “work in progress”. As gaps in the legislation are encountered, new requirements are created and new language is added to the legal framework. Over time, the legal framework becomes unduly complex. It would be simpler to completely rewrite food legislation but would require high-level government participation and would be time-consuming. Another option is to review existing legislation and ensure new language/amendments are compatible with one another. This should only serve as a temporary measure, as the basis for food law will remain convoluted.

### *Food inspection*

This is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that food products conform to requirements.<sup>19</sup>

Food inspection is not simply restricted to testing; an assessment of the whole system is necessary. In the case of food fortification, reliance on finished product testing alone is problematic.

An optimal model for food inspection involves (i) verification of raw materials, (ii) monitoring of critical steps of the process and, (iii) correct implementation to ensure a proper finished product. Translating this to food fortification, this would involve (i) checking that the premix has the correct composition, (ii) verifying that the process is “fit for purpose” (i.e. the fortificants will remain stable under the conditions in which they will be used), (iii) confirming that premix/fortificants are being added and mixed correctly and (iv) ensuring that premix consumption records reflect correct addition rates against production output from the processor. Compliance can be quickly established as this food inspection system is low-cost and low technology, and provides results in which the inspector can have a high-level of confidence.

### *Food control laboratories*

Laboratories are essential for the analysis of food samples; to assess physical and chemical characteristics, inspect for microbiological contamination, verify the safety and quality of food (whether produced domestically, imported and/or exported), and report necessary results or actions to protect consumers. However, laboratory analysis of finished food products may be questionable, and relying solely on laboratory data may be insufficient. It is recommended that food testing be performed in accredited laboratories, with quality assurance systems conforming to ISO 17025:2005.

### *Information, education and communication*

Information, education and communication (IEC) is the process of developing, packaging and disseminating appropriate messages to specific audiences to increase their knowledge, skills and motivation to make decisions that enhance food safety and quality. Importantly, IEC provides a means for food control systems to

**Box 4: Food inspection**, based on risk analysis, is a vital component of a modern food control system. Food inspection protects consumers by ensuring that domestically-produced or imported food is handled, stored, manufactured, processed, transported, prepared, served and sold in accordance with the requirements of national laws and regulations. In addition, inspection and verification of food exports promotes confidence in the safety and quality of exports, which is essential for international trade.

*Ref: FAO. Strengthening national food control systems. Guidelines to assess capacity building needs. Module 1: Assessing capacity building needs in food inspection. FAO, Rome 2006.*

<sup>16</sup> [http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/blueprint\\_food-plan\\_aliments/reg\\_modernization-modernisation\\_reg-eng.php](http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/blueprint_food-plan_aliments/reg_modernization-modernisation_reg-eng.php)

<sup>17</sup> [http://laws.justice.gc.ca/PDF/C.R.C.,\\_c.\\_870.pdf](http://laws.justice.gc.ca/PDF/C.R.C.,_c._870.pdf) (latest 13 May 2011) (click OK when safety warning pops up)

<sup>18</sup> As of 13 May 2012

<sup>19</sup> Go to <http://www.codexalimentarius.org/standards/list-of-standards/en/> (this takes a little time to download) then scroll down to CAC/GL 20 click for the download page then click on the required language

engage in dialogue along the production process about food safety and quality issues. IEC is critical but frequently overlooked or not considered as part of the mandate of food control systems.

IEC messages may do the following:

- increase awareness and knowledge among participants in the food industry including producers, retailers, and consumers;
- promote adoption of good manufacturing practices (GMP) and food safety systems (e.g. HACCP); and
- enable the collection of information to support decision-making processes, planning and implementation of official food control management activities.

**Box 5:** CODEX defines food fortification as: *“The addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups”.*

IEC is also critical within food production process to ensure that food control inspectors are fully aware of the following:

- Sampling plan, sample size, storage and transportation requirements so that inspectors and the laboratories can plan accordingly.
- Analysis time, sample tracking and interpretation of results against legislation so that inspectors are aware of the time constraints of laboratory analysis, are guided on interpreting the analytical results, and take into account sources of error before making decisions on whether samples are compliant.
- Possible reasons for non-compliance so they can advise industry on how to avoid future problems.
- Media responses to be delivered by authorised knowledgeable spokespersons to ensure accurate information is disseminated to the public.
- Frequently asked questions (FAQs) for consumers, some at varying levels of complexity depending on audience groups, again to ensure dissemination of consistent and accurate information.

In Canada, the United Kingdom of Great Britain and Northern Ireland, Australia and New Zealand, information on issues related to food fortification, legislation and monitoring are publicly available on the Internet, demonstrating that IEC is the responsibility of many participants in the food industry. In some countries, inspection services are directly responsible for IEC, as they often identify the problems and have the ability to determine solutions to be implemented through IEC.

### **Introduction to food fortification legislation and standards**

The objectives of all food legislation are (i) protection of health, (ii) protection of consumers' rights and (iii) facilitation of trade of safe and healthy food. The development of food legislation should be based on risk analysis principles. Thus, food legislation should be based either on Codex<sup>20</sup> standards, codes and guidelines based on thorough risk assessment or on alternative independent, objective and scientific risk assessments. In addition, legislation should be developed, evaluated and revised in an open and transparent manner, and involve consultation with the public and trading partners.

Food control or regulatory monitoring systems have similar objectives. They should be based on risk analysis and developed, reviewed and updated in a transparent, consultative and flexible manner.

As briefly described above, the legal framework for food law consists of multiple levels of legislation, regulations, standards and guidance. Food law can be considered the trunk of a tree, while regulations and standards are the branches, and guidance documents and codes of practice are the leaves.

In terms of fortification, the term “standard” is often misused, and as fortified foods often move across international borders it is useful to review the World Trade Organization (WTO) definitions<sup>21</sup> of fortified foods.

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<sup>20</sup> The *Codex Alimentarius*, or the *Food Code*, is a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to [foods](#), food production and [food safety](#).

<sup>21</sup> World Trade Organization, “The WTO Agreement on Technical Barriers to Trade”, [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbtagr\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbtagr_e.htm)

- i. A “Standard” is a document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.
- ii. A “Technical regulation” is a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Thus, based on WTO terminology, both technical regulations and standards are technical product requirements. The main difference is that compliance with **technical regulations is mandatory, whereas compliance with technical standards is voluntary**. A law that stipulates that a nominated food must contain a minimum amount of a micronutrient (as is the case with mandatory fortification) is an example of a technical regulation. However, countries do not always follow these definitions and use the terms “standard” and “regulation” differently depending on their legislative structure. In some cases, countries will call the requirements “standards” and enforce as mandatory through regulations, despite the WTO definition. In relation to food fortification, the important points are:

1. A standard, as defined by WTO, is voluntary until a country incorporates the standard into a technical regulation which makes it mandatory.
2. Having only a standard for flour and salt fortification without the legal authority of a regulation will mean that fortification will be voluntary.
3. Voluntary fortification will not work as an effective public health intervention. There are many examples of voluntary fortification that have failed to have a public health impact.

The Codex Alimentarius Commission (CAC), established by FAO and WHO, sets international food standards, guidelines and codes of practice to protect the health of consumers and ensure fair practices in the food trade. National governments consider Codex standards when developing their own national standards to ensure they are based on the best available science and that trade is facilitated internationally. Codex has many documents relating to fortification<sup>22</sup> including the following which are most pertinent to flour and salt fortification:

1. Codex General Principles for the Addition of Essential Nutrients to Foods CAC/GL 9 latest 1991
2. Codex Standard for Food Grade Salt Stan 150 latest 2006
3. Codex Standard for Wheat Flour Stan 152 latest 1995
4. Codex General Standard for the Labelling of Prepackaged Foods Stan 1 latest 2010
5. Codex General Standard for the Labelling and Claims for Pre-packaged Foods for Special Dietary Uses Stan 146 latest 1985)
6. Codex General Guidelines on Claims CAC/GL 1 latest 1991
7. Codex Guidelines on Nutritional Labelling CAC/GL 2 latest 2011
8. Recommended International Code of Practice: General Principles of Food Hygiene CAC/RCP 1 latest 2003

The World Trade Organization develops rules and agreements governing trade to ensure free trade between countries. Hence, when developing laws and regulations on food fortification, WTO members must meet WTO

**Box 6: WTO example:** Country A establishes a regulation that all wheat flour must be fortified with electrolytic iron. However this will exclude imports of flour fortified with ferrous fumarate. As this measure does not confirm to Codex standards or global recommendations, and as there is no other scientific or health justification for excluding ferrous fumarate, country A could be accused of establishing a non-technical barrier to trade and being in violation of WTO rules. A possible solution would be to specify electrolytic iron but also add the phrase “or equivalent as per WHO or internationally-accepted practices”.

<sup>22</sup> Codex Alimentarius Commission, List of Standards, <http://www.codexalimentarius.org/standards/list-of-standards/en/> (scroll to the relevant CAC/GL; CAC/RCP or CODEX STAN number, click for the download page, click on the required language)



obligations and adopt or enforce measures necessary to protect human, animal or plant life or health (such as to require food fortification). These sanitary and phytosanitary (SPS) measures must not be applied in a manner that may lead to arbitrary or unjustifiable discrimination between WTO members and/or disguises restrictions on international trade. Countries must therefore base SPS measures and food fortification legislation on international standards and must assess risks to ensure that the measures are necessary to protect health. This will ensure that they do not discriminate against foreign sources of supply.

### *Voluntary and mandatory fortification*

There are two main approaches to fortification. Voluntary fortification *enables* fortification while mandatory fortification *requires* fortification.

Under voluntary fortification, food processors follow certain standards for business reasons or motivations, such as a perceived market advantage. They may, therefore, be operating under standards without scientific basis. Food products may be promoted through advertising and labeling claiming certain health benefits. Depending on the food manufacturer's level of commitment, internal monitoring may not be up to the standard expected in a mandatory programme. There may be little or no verification of label content and nutritional claims, as well as enforcement by government authorities. If this practice is followed by many food processors, fortified products may actually lead to health issues. WHO and FAO guidelines<sup>23</sup> recommend governments to exercise an appropriate degree of control, commensurate with the level of risk, over voluntary fortification, through food laws or industry codes of practice. In addition, governments should ensure that consumers are not misled or deceived by fortification practices.

Mandatory fortification provides a consistent and sustainable source of micronutrients to the general public or a target group consistent with the required minimum and/or maximum levels of micronutrients. Governments tend to institute mandatory fortification where a proportion of the general population exhibits a significant public health need or risk, and nutritional deficiencies can be addressed by food fortification. Governments are responsible for ensuring that the combination of food vehicle and the fortificants will be effective for the target group yet safe for both target and non-target groups. Monitoring and enforcement of mandatory fortification requirements among domestic manufacturers and importers should be carried out by one or more mandated authorities in coordination with the normal surveillance of food contaminants and other food safety issues. This monitoring and enforcement also ensures compliance with international obligations under WTO. Legislation on mandatory food fortification should be clear to consumers, industry participants and regulators, should identify exactly what is required of suppliers, processors, importers and traders, facilitate understanding among consumers and industry participants on the health benefits of fortification, and allow for review and flexibility of the standards and technical regulations based on the latest scientific data.

All the countries represented at this meeting have instituted legislation for mandatory fortification of salt with iodine except for Malaysia, where it is mandatory in only two states, and Viet Nam, where it is voluntary. Indonesia and Nepal also have mandatory fortification of wheat flour. The Philippines mandated fortification of all staple foods including rice, wheat flour, sugar and oil, and implemented a programme of voluntary fortification of any food. Presentations at the meeting confirmed that Mongolia, Viet Nam and Malaysia are in the process of passing legislation for mandatory fortification of wheat flour. Wheat flour fortification is voluntary in most of the remaining countries.

### *Responsibilities of regulators and industry*

Legislation and regulations on food fortification must specify the roles and responsibilities of the government (regulators) and industry. Legislation must also assign a competent body authorized conduct inspections of any food processing facility and review its records to ensure the facility is able to ensure safety and quality of the foods it produces. Thus, the task of regulators is to ensure, through monitoring, that a HACCP<sup>24</sup>/GMP<sup>25</sup>-

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<sup>23</sup> <http://www.who.int/nutrition/publications/micronutrients/9241594012/en/>

<sup>24</sup> HACCP – Hazard Analysis and Critical Control Points is a systematic preventive approach to food safety that addresses physical, chemical, and biological hazards as a means of prevention rather than finished product inspection. <http://www.isacert.com/paginas/index-52.html>

<sup>25</sup> GMP – Good Manufacturing Practices are practices and the systems required to be adapted in pharmaceutical and food manufacturing, quality control, quality system covering the manufacture and testing of pharmaceuticals or drugs including active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs are guidance

based quality assurance system is documented, implemented and maintained in the facility, with objective evidence that the system is effective in controlling the quality and safety issues specific to the foods. Specifically, regulators should be assessing and ensuring the following:

1. Food processing facilities have the infrastructure, as well as qualified and experienced personnel, to produce quality and safe fortified foods that meet regulatory standards.
2. Regular internal audits and management reviews are conducted to ensure adherence to controls and regulations.
3. Food processing facilities have an effective and efficient traceability and recall system in the event of violation of regulations/standards or any food safety concerns.

The legal framework should also consider assessments of regulator performance and any necessary corrective actions.

Food processing facilities should have process standards which are monitored and **maintained**. Standard operating procedures should be developed for manufacturers to identify, monitor and record premix specifications, ensure compliance with process standards and a system of traceability. Manufacturers should also ensure they have qualified and experienced personnel, maintain proper documentation, follow verification procedures and implement internal audit systems to assess compliance with standards and procedures.

The country reviews undertaken in preparation for the meeting suggest that existing legislation on food fortification does not sufficiently address the roles and responsibilities of different regulating agencies, levels of collaboration, and the overall responsibilities of the food industry.

The reviews suggest that regulators and industry focus on end products more than process control and internal quality assurance systems. It is unclear if in the countries reviewed, regulators have the legal right to inspect records. Regulatory monitoring also tends to apply to facilities that are registered, have a licence to operate, or import legally, rather than any facility that produces food available to consumers. Current legislation in many of the countries of concern at the meeting do not cover monitoring of non-registered or licensed food producers, and do not prevent them from operating. Furthermore, it appears that regulators are not assessed or evaluated unlike in Canada, the United Kingdom of Great Britain and Northern Ireland, Australia and New Zealand. Finally, it appears that small salt facilities do not meet the responsibilities outlined above.

#### *Draft Western Pacific Regional Food Safety Strategy 2011 – 2015<sup>26</sup>*

The WHO Regional Office for the Western Pacific developed a draft food safety strategy for the period 2011-2015 to help ensure public health through safe and healthy food. The goal for 2015 is for all countries in the Region to have strengthened national food control systems. WHO will partner with and mentor countries to help them achieve this goal.

#### **Internal monitoring: quality control and quality assurance**

**Quality assurance** is process-oriented and focuses on defect prevention  
**Quality control** is product-oriented and focuses on defect identification<sup>27</sup>

Internal monitoring refers to the quality control and quality assurance (QC/QA) practices conducted by food producers, importers and packers. Internal monitoring may thus be defined as “a system to control all parts of the milling/salt production process to ensure the consistent production of flour/salt that meets both regulatory and commercial requirements.” As such, internal monitoring does not involve only one test or one check; rather it is made up of a variety of components and mechanisms which are explained below. **Process control** of fortification at the mill/factory is therefore a key part of the quality assurance/internal monitoring

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that outline the aspects of production and testing that can impact the quality of a product.

<http://www.flexicose.com/gmp.html>

<sup>26</sup> [www.wpro.who.int/foodsafety/documents/docs/regional\\_food\\_safety\\_strategy2011\\_2015.pdf](http://www.wpro.who.int/foodsafety/documents/docs/regional_food_safety_strategy2011_2015.pdf) (click OK when safety warning pops up – document downloads in a separate window)

<sup>27</sup> [www.diffen.com/difference/quality\\_assurance\\_vs\\_quality\\_control](http://www.diffen.com/difference/quality_assurance_vs_quality_control)

system. Process controls ensure consistent quality and safety of the output, i.e. flour or salt is adequately fortified with required essential minerals and vitamins, and the mill/factory uses mechanisms to monitor activities and take corrective action in a timely manner. A well-implemented process control helps to avoid potential problems such as wastage, product modifications, customer complaints, food recalls and liability issues. A good process control system has more than one measurable parameter.

Maintaining complete records is critical in QA and enables efficient external monitoring in terms of cost and time.

For a large scale food processor, the following are the typical components of a QA system:

- Documented quality plan (covering a full description of the company policy, the manufacturing process and quality assurance system)
- Adherence to an internationally recognized system i.e. HACCP, ISO 22000:2005
- Good Manufacturing Practice (GMP) documents and operating standards
- Standard operating procedures (SOP)
- Standard quality control procedures (SQP)
- Recall system with action plan and traceability system
- Document and record-keeping system
- Quality audit plan

Quality assurance may differ slightly depending on the type of food produced, but generally consists of the following activities:

- Premix procurement and storage
- Feeder/dosifier installation
- Feeder calibration
- Feed rate calculations
- Process controls
  - Check weighing of premix addition, standards and sampling schedule
  - Iron spot test for wheat flour; quantitative iodine testing for salt
- Record-keeping
- Laboratory analysis – quantitative tests for vitamins and minerals in wheat flour and iodine in salt (as per regulations)

### *Optimal and adequate quality and process control mechanisms*

Although the basic activities of quality assurance are the same, the level of sophistication, intensity and accuracy may vary across food producers. An optimal system versus an acceptable system is described below. However, in both systems, all of the mechanisms/activities are measurable and auditable.

	<b>Optimal</b>	<b>Acceptable</b>
Fortificant addition	Computer-controlled systems: flour/salt flow matched with fortificant addition by computer (computerized feedback systems).	Manual feeder: volumetric feeder for flour, liquid spray for salt. Feeders of flour/salt manually calibrated. Check weighing performed 2-4 times per shift.

### *Premix procurement and storage*

Quality fortification starts with appropriate premix procurement and storage. Premix specifications and standards should comply with food fortification regulations in terms of the levels and types of vitamins and minerals to be added. Standards should also dictate when the premix is "fit for purpose", i.e. in terms of stability (stability is currently the only criteria for measurement). Food processors should follow an approved supplier list with at least two premix suppliers. These suppliers should have met certain criteria in terms of GMP, delivery times, packaging requirements, certificate of analysis, etc. They should be able to demonstrate that their product meets the specifications and is "fit for purpose". Criteria might be set and assessed by the national government or by the food processor. Purchase and storage records should be maintained on when and from where the premix was purchased and on how long and where it has been stored. Premix should be stored in a cool, dry storage room or area; flour premix should be stored in an air-conditioned room. The

system of stock rotation should be "first in, first out". Usage records should be maintained indicating which premix lot numbers were used in which batches of salt or flour. For salt iodization, another key aspect of premix management is correct mixing of the potassium iodate and water solution to ensure the solution is the correct concentration. To ensure the integrity of flour premix, it may undergo testing at an external laboratory once or twice per year.

### *Feeder/dosifier installation*

For flour, the feeder should be placed above the flour collection conveyor approximately two-thirds of the way downstream and at least three metres from the discharge end of the conveyor. Ideally this conveyor should have a mixing component (as opposed to a basic auger) though a pneumatic conveying system that is long enough may provide adequate mixing. Should the flour conveyor be just below the ceiling of the facility, it is recommended that the feeder be placed on the floor above (plansifter floor), feeding into the conveyor. This enables better control and recharging of the feeder than when the feeder is two to three metres in the air amongst a tangle of pipes.

For salt, most of the same basic principles apply, though the process involves the addition of a liquid to a solid. Addition of the potassium iodate solution is usually at the start of the process; there has been debate on whether it is better to add the solution before or after the crusher (if applicable), and whether or not the crushing action aids mixing. Solution should be added using a spray rather than dribbled; the point of addition should be early enough to allow for sufficient blending (i.e. after a sufficient time from the point of discharge). While an automated system is preferred, it is not always feasible. The use of low-level indicator alarm in the iodine solution holding tank is considered essential.

### *Feeder calibration and feed rate calculations*

Feeder calibration is essential and is slightly more complex in the fortification process for flour than for salt. Since a salt sprayer handles a solution of consistent specific gravity, it is only necessary to determine, by weight, how much solution is discharged per unit time at a range of settings on the pump.

Flour premix, however, may exhibit differing specific gravities due to the composition of the premix, including the diluents. Variation in specific gravity is more commonly found between suppliers of the same premix formulation than within one supplier. Every batch of premix should be tested against the calibration curve in case some variations exist. Since the feeder operates under a volumetric principle, it is necessary to monitor for changes in premix specific gravity. Up to 20% differences in specific gravity have been observed between suppliers. By presenting the data graphically it is simple to estimate the required feeder setting for any feed rate, but it is important to note that this estimate needs to be verified by check weighing of premix addition. The calibration curve should be dated and signed off by a competent member of staff and records of all cross checks should be kept, especially between batches of premix.

### *Feeder problems*

For salt, the main problem is blockage of the spray nozzle(s). This should be monitored visually on a regular basis. While more likely to occur on start up, continued blockage due to some insoluble material may occur.

For flour, the situation is again slightly more complex than for salt in that the premix (which is hygroscopic) may bridge or tunnel in the feeder (see pictures below). This is common problem in cheap feeders, as the more expensive feeders have agitators which ensure consistent specific gravity and counter settling due to the vibration in the mill. In a flour mill, it is possible that the mill stops unexpectedly (due to choking, a burst sieve, etc.) and the feeder keeps operating. This can be rectified by ensuring the feeder is linked to the main electronics system in the mill (i.e. to first break or the plansifter) so that if the mill feed stops, the premix feeder stops as well. It is also possible that the feeder runs out of premix (a problem common to cheaper feeders) while the mill is still running. A good feeder has a low-level alarm to alert mill staff to recharge the feeder before it is empty.



**Figure 4: Premix feeding problems**



**Product testing**

Product testing is one of the tools available to the producer and is used in conjunction with other process control tools. For wheat flour, rapid qualitative/semi-quantitative testing for the presence of one micronutrient in the premix as an indicator is common. Iron is usually chosen as the indicator nutrient and is most commonly tested using the iron spot test. For salt, quantitative testing by titration or another measure (e.g. WYD machine) is required because premix feed control systems in salt iodization facilities are less effective at ensuring optimal levels of iodization than premix feed control systems in flour fortification (which use a combination of premix quality and specification, feeder calibration, check weighing, etc.).

Quantitative testing on the full micronutrient content of flour by an external laboratory on a periodic basis is recommended. Such quantitative testing is more important when a fortification process is starting up as it will provide valuable information for fine-tuning calibration. For both flour and salt, a small sample should be retained from every process control test to form a composite sample for that batch/day/week/month. A portion of this composite sample can be sent for quantitative analysis and also be provided to regulatory monitoring authorities to represent the food processor’s production over that period.

**Premix control systems**

Premix controls are critical as they verify that the premix is being added at the correct levels using an inventory control system. These controls serve as a cross check to premix addition rate records and should be calculated on a weekly or monthly basis. They are also important as a QA/QC and HACCP audit tool.

An example of how premix control operates in a large flour mill is indicated below. This low-level technology (based on review of records only) was used successfully to monitor a programme in Afghanistan where the mill had no access to laboratory facilities. The premix control system relied on review of facility records and calculation of the premix used against the flour produced. Based on the premix stock release system tied to flour orders, it was estimated that the premix addition was within 5.0% of target addition rate.

**Table 2: Example of premix control**

	<b>Indicator</b>	<b>Amount</b>
A	Starting premix inventory	2,140kg
B	Amount premix purchased	10,00kg
C	Ending premix inventory	10,040kg
D	Amount used (A+B-C)	2,100kg
E	Fortified flour produced	10,00MT
F	Actual Addition Rate (D/E x 1000)	210g/MT
G	Target Rate*	200g/MT
H	Percent of Target (F/G x 100)	5% above target
* based on supplier specifications		

## Introduction to external and commercial monitoring

External monitoring refers to the inspection and auditing activities carried out at production centres (factories and packers) and importation custom sites. External monitoring is the responsibility of government authorities and is implemented as a mechanism to assure compliance with standards and regulations. Commercial monitoring, conducted at the retail level, is similar to external monitoring in that it is generally the responsibility of government and serves to verify that the fortified products comply with standards.

The basis for external monitoring systems is proper legislation, including food laws, regulations and standards. The system serves to establish whether the requirements and specifications of the legislation are being met. Several government sectors involved as food laws are usually developed by a ministry of justice, parliament or equivalent, with input from the ministries of health, trade, commerce and agriculture. Food regulations are usually developed by ministries of health and trade, and food standards are developed by ministries of health and trade or commerce, and/or a bureau of standards. There may also be sub-laws pertaining to inspections or enforcement systems which are often the responsibility of ministries of health or trade. Meanwhile, actual external or commercial monitoring is the responsibility of ministry of Health, industry or trade and the monitoring of imports and exports is the responsibility of the ministry of trade and/or customs.

Fortified food products should not be treated in the same way as pharmaceuticals, but they do deserve more attention than unfortified, mass consumed food products. It is therefore necessary to apply quality assurance (discussed in Internal Monitoring) and safety principles to food fortification. In many countries, food regulations and standards are not specific to fortified foods. Ideally, food laws establish mandatory fortification and separate food regulations and standards exist that are specific for the required fortified foods.

External and commercial monitoring is usually the responsibility of a department within the ministry of health, industry or trade. Frequently more than one department is involved (as when there is a multiple-agency food control management system). Food inspectors may have overlapping responsibilities and lack background and training. There are limited resources, including travel budget, laboratory facilities, and inspectors themselves. Sub-laws on external monitoring, inspection regulations and standard operating procedures are often lacking and may limit the way inspections are conducted. Country reviews confirmed the need for strengthening and redesigning regulatory monitoring systems, particularly external and commercial monitoring.

The general reasons for external monitoring are to register or license a facility, and meet regulations to ensure the quality of food. Given these different reasons, the focus of the inspections could be different. For example, external monitoring may be conducted to ensure basic licensing criteria are met such as building certification, human resources, GMP, necessary equipment, etc. Alternatively, external monitoring may focus on review of premix, production processes, final product testing, etc. The country reviews indicate that in some countries only inspections that focus on registration and licensing purposes take place. If this is the case, the aspects that should be monitored for regulatory quality assurance monitoring should then be monitored as part of the licensing/registration requirement.

If regulatory monitoring exposes violations at a particular facility, penalties should be applied. These penalties may be (i) fines, (ii) temporary suspension of license to operate while the facility improves their production process and/or (iii) permanent closure of the facility. Penalties should be applied progressively as the objective is to encourage facilities to meet national regulations and standards. Ideally, penalties should be reviewed periodically to ensure fines and/or suspension periods are at levels that encourage compliance to regulations and standards. Technical assistance and/or advice may be provided to help producers to improve their production.

### *External monitoring*

The objective of external monitoring is to assure that the production facility is able to produce a quality and safe product that meets national regulations. Thus external monitoring must assess whether a facility has adequate raw materials, equipment, systems and procedures in place to achieve this objective on a continuous basis, not just at one point in time. A monitoring visit should assess whether samples collected on a particular day are representative of continuous production, and that samples conform to national regulations.

A typical external monitoring system has the following components:

1. Mill/factory inspections, including review of records
2. Sampling policies and procedures

3. Laboratory analysis
4. Enforcement procedures

An assessment checklist should be available for all mill/factory inspections. The checklist should facilitate review of all the mechanisms that food processors use to assure quality and safety. The inspector should look at (i) premix procurement and storage, (ii) feeder location and operation, (iii) process controls, (iv) product testing and laboratory procedures and results, and (v) premix usage reconciliation calculations. Inspections should involve both a physical review of the facility (walking around and examining equipment, etc.) and a review of all relevant records. Food inspectors must have the authority to review all records including orders, delivery receipts, invoices for premix, etc.

Food samples should be collected for quantitative testing. There should be standard guidelines for collection of samples and laboratory testing that are accepted industry-wide. How samples are collected and handled will depend on whether the visit is a routine monitoring visit or if the sample pertains to a legal case against the facility (e.g. penalty for non-compliance). For a routine monitoring visit, one sample is usually sufficient. The specifications for a sample should be agreed upon by industry and regulatory monitoring authorities, and include a minimum weight (e.g. 500 grams for flour) and other guidance to ensure that the sample is representative, similar to that retained by the processor for internal monitoring. Generally, larger samples, collected over a period of time representative of one batch, are preferable so that the sample is representative of the overall food production and not a finite point in time. For legal enforcement, however, sampling must follow internationally accepted sampling protocols, such as CODEX GAC/GL 50 2004.<sup>28</sup>

### *Monitoring of imported foods*

Monitoring of imported fortified foods requires the cooperation of customs officials, as the best inspection location is usually at the point of importation. It is much more difficult to identify and withdraw imported foods once they are in the marketplace. In some countries, limited importation points make it easier to control imports, but more often there are multiple locations between country borders where food may cross. In such cases, identifying imported foods that do not meet national regulations may only be possible in the marketplace.

Monitoring of imports should include a review of all available documentation including certificate of analysis<sup>29</sup> from the exporting country to assess whether the imported foods comply with national regulations. In addition, laboratory or quantitative testing should be applied, especially if there is no certificate of analysis. For example, all imported salt should be tested by titration, WYD machine or similar method to verify if adequately iodized. Imports of flour can usually be assessed by reviewing a certificate of analysis. Sampling and testing must meet Codex and WTO standards. Imports that do not meet national regulations should be rejected, which then becomes an international trade issue.

### *External versus commercial monitoring*

Since fortification takes place at the food processor problems in the fortification process can only be addressed at the production point. Furthermore, since there are far fewer mills and salt factories than markets and retail outlets, as well as limited resources for monitoring, it is best to ensure that all domestically-produced food meets national regulations **before** it leaves the facility and that all imported food meets national regulations **before** leaving the point of importation. Doing so is easier and more efficient than trying to identify sub-standard foods in the market and then trace back to the production/import source. Commercial monitoring is only really helpful when the sources of foods are unknown (and therefore cannot be monitored). Examples are situations involving illegal imports or non-registered producers.

Despite the limitations and difficulties of commercial monitoring, the country reviews suggest that in several countries, government monitoring takes place primarily at retail level or, at best, equally between retail and production level. This seems to be due to the mandates given to food inspectors (to monitor food at the point at which consumers access it) and to a pre-occupation with monitoring packaged food and/or food from

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<sup>28</sup> Go to <http://www.codexalimentarius.org/standards/list-of-standards/en/> (this takes a little time to download) then scroll down to CAC/GL 50 click for the download page then click on the required language

<sup>29</sup> An authenticated [document](#), issued by an appropriate [authority](#), that certifies the [quality](#) and purity of pharmaceuticals, foods, and animal and [plant products](#) being exported. Ref: <http://www.businessdictionary.com/definition/certificate-of-analysis.html>

registered facilities only. Such a focus on commercial monitoring is ineffective and inefficient and stems ultimately from poorly designed regulatory monitoring systems and the related legislative framework. In many countries it is necessary to refocus regulatory monitoring systems to support quality production and to monitor all food that can be accessed by consumers, and not just foods produced by registered facilities or imported legally.

### Laboratory requirements for external monitoring

Laboratory analysis is **just one component** of a complete external monitoring system and should not be solely relied upon to ensure compliance with food legislation. There are weaknesses and limitations of laboratory analysis:

1. While laboratory analysis for food fortification measures vitamin and mineral content of the final food product, it is not possible to distinguish the vitamin and mineral content intrinsic to the food vehicle (which can be highly variable) from the nutrients achieved through fortification (which can be somewhat variable).
2. There is significant variation in results of micronutrient levels from different laboratories due to differences in analysis methodology, storage and management of the sample, and observer variation. In order to address this many food control laboratories operate using ISO 17025<sup>30</sup> 2005 *General requirements for the competence of testing and calibration laboratories*. Despite this practice, variation continues to exist. For example, the American Association of Cereal Chemists (AACC) run a Vitamin, Mineral and Proximate (VMP) worldwide ring trial<sup>31</sup> which clearly indicates the level of variability that can be expected amongst food laboratories considered competent in micronutrient analysis. Using the 2010 data in which approximately 14 laboratories analysed six samples of fortified wheat flour, the statistics indicated an average coefficient of variation at 95% confidence level of 21.8% for iron (maximum variation 55.6% and minimum 11.6%); for folic acid 44.4% (81.9 and 30.2%) and for vitamin A, a staggering 141.0% (370% and 62.4%). Variation in results between laboratories also exists because testing for micronutrient content of fortified foods requires measurement of a small amount of micronutrient in a large amount of food. In South Africa, laboratories used for fortification analysis exhibited a very high degree of conformity when analysing micronutrient premix, but those same laboratories provided widely divergent results when analysing fortified food products because of the high level of dilution of the micronutrients.
3. There is also variation in the level of nutrients (and other additives) added through fortification. Producers use internal monitoring and process controls to try to limit this variation as much as possible but some amount of variation will always exist. The more sophisticated the production and fortification facilities and the better internal monitoring is implemented, the level of variation will be less. Depending on the method of sample collection, there may also be variation in nutrition content of food samples. Codex document CX/MAS 1 1987 states “...in particular, the estimate of the value **may** be dependent upon the method of analysis used, but it is **always** dependent on the type of sampling plan and the lot acceptance procedure used.” Conforming to internationally acceptable sampling protocols, such as *Codex Methods of Analysis and Sampling*<sup>32</sup> is, therefore, critical to the perceived performance of any food control laboratory and to regulatory monitoring operational effectiveness in general.

### Box 7: Intrinsic vitamin and mineral content of food vehicles

Wheat kernels naturally contain some amounts of all of the following vitamins and minerals: iron, zinc, thiamine, riboflavin, niacin and folate. The amounts of these nutrients in wheat flour vary based on the different types of wheat, where they are grown, the growing season and milling practices, particularly the extraction level.

Salt, in particular sea salt, contains some amount of iodine. The level varies depending on the source of the salt.

In both wheat flour and salt the variation in nutrient content may be significant and it is not efficient or possible to know in advance the nutrient content in order to be able to distinguish between the intrinsic levels and those achieved through fortification.

<sup>30</sup> [http://www.iso.org/iso/catalogue\\_detail.htm?csnumber=39883](http://www.iso.org/iso/catalogue_detail.htm?csnumber=39883)

<sup>31</sup> <http://www.aaccnet.org/resources/checksample/Pages/default.aspx>

<sup>32</sup> CAC. 1987. *Instructions on Codex sampling procedures*. Joint FAO/WHO Food Standards Programme, CX/MAS 1-1987. Rome, FAO. [http://search.yahoo.com/search?fr=chr-greentree\\_ie&ei=utf-](http://search.yahoo.com/search?fr=chr-greentree_ie&ei=utf-)



Given these three sources of variation and lack of indication of the level of confidence or variation, laboratory results are still used by food inspectors and regulatory monitoring officers to determine if a certain facility complies with national regulations.

It is therefore not unusual to receive different laboratory analysis results from a fortified food. For example, the results of a certificate of analysis from the exporting country may be different from a laboratory analysis undertaken by the importing country. Differences in results arise from variations in laboratory procedures, sampling methods and time (in the case of exported and imported food). For many micronutrients, stability over time is not an issue, but may be so for vitamin A, which is known to be unstable under UV light and in humid environments. Such a problem needs to be resolved by improving the quality of the premix, ensuring that it is "fit for purpose", and improving storage conditions. Codex provides the following guidance in the event of variations in laboratory results<sup>33</sup>:

1. CAC/GL 20 1995 Principles for Food Import and Export Inspection and Certification
2. CAC/GL 25 1997 Guidelines for the Exchange of Information between Countries on Rejection of Imported Food
3. CAC/GL 27 1997 Rev 2006 Guidelines for Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food
4. CAC/GL 34 1999 Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspections and Certification
5. CAC/GL 47 2003 Rev 1 2006 Guidelines for Food Import Control Systems
6. CAC/GL 50 2004 General Guidelines on Sampling
7. CAC GL 70 2009 Guidelines for Settling Disputes over Analytical (test) Results

Food laboratories may also be involved in assessing if a particular micronutrient premix "conforms to specification", meaning that it meets, or exceeds the claims indicated in the certificate of analysis and/or product label. Non-compliance is extremely rare in terms of premix quality for wheat flour fortification. However, laboratories are rarely asked to determine if the premix is "fit for purpose". This involves determining if the premix will perform as expected in the final fortified product and is as important, if not more important, than verifying that a premix meets specifications. A limited number of countries include laboratory analysis of premix in regulatory monitoring activities as a way of ensuring the quality of the starting point of fortification. This is a worthwhile activity and contributes significantly to internal quality assurance by the industry, which is then able to assume that all permitted premix imports are suitable for use. Even if non-compliance of premix according to specifications may be rare, it is probably quite common that premix may not be "fit for purpose". A study in South Africa assessed the stability of premix (vitamin A, vitamin B complex, folic acid, iron and zinc) by subjecting it to accelerated storage at 40°C and 75% relative humidity. The results showed that some samples had retained approximately 80% of vitamin A after 30 days, while other samples lost 80% over the same period. The samples that experienced losses were considerably cheaper, and while they conformed to specifications, they were determined not to be "fit for purpose".

While laboratory analysis plays an important role in regulatory monitoring, both internal and external, the results are subject to much variation and do not provide conclusive evidence of compliance or non-compliance. Over-reliance on laboratory results can therefore be very misleading and counter-productive to ensuring high-quality fortified food. Laboratory analysis results should instead be considered by food inspectors **in combination** with critical information, including those obtained through mill/factory inspection, such as premix usage rate, sample source and collection method, and expected variation in laboratory analysis results. Laboratory analysis results alone are not sufficient to assess compliance with national regulations.

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[8&type=642886&p=CAC.+1987.+Instructions+on+Codex+sampling+procedures.+Joint+FAO%2FWHO+Food+Standards+Programme%2C+CX%2FMAS+1-1987.+Rome%2C+FAO](http://www.codexalimentarius.org/standards/list-of-standards/en/). Download "ALINORM 09/32/23" file name is al32\_23e.pdf

<sup>33</sup> Go to <http://www.codexalimentarius.org/standards/list-of-standards/en/> (this takes a little time to download) then scroll down to the relevant CAC/GL Number under "Reference" and click for the download page then click on the required language

### Non-laboratory testing methodologies and technologies

In general, the gold standard for food testing, including testing vitamin and mineral content, is quantitative testing in a laboratory. However, there are many non-laboratory methodologies that enable **qualitative** testing, which measures presence or absence of a component (commonly through a spot test) or semi-quantitative measurement which provides a range of approximation. Semi-quantitative non-laboratory methods are extremely valuable in food fortification but must be applied carefully, as they do not provide the accuracy of laboratory testing (which, previously discussed, is susceptible to extensive variation).

Two examples of a spot test are the iodine spot test and the red spot test for iron (AACC 40-40). In the iodine spot test, a blue coloration indicates the presence of iodine. Note that there are separate tests for potassium iodate (illustrated) and potassium iodide; false negatives can arise if the wrong test is used. Several iodine test kits claim to be suitable for use as semi-quantitative tests to identify when the iodine content is above or below a certain level (usually 15ppm). In this test kit, it is true that the blue colour is darker when there is more iodine, and that the level of darkness could suggest presence over a certain level. In reality, due to differences in texture, purity and colour and inter-observer variation, it is unreliable to use the test to assess whether a salt sample has exceeded a minimum salt sample. Certainly in regulatory monitoring, the test kit should not be used either by producers for internal monitoring or by regulators for external monitoring. At best, the test kit can be used to indicate if a certain batch of salt has been iodized.

**Figure 5: Blue colour created by salt test kit**



**Source: Philip Randall**

In the red spot test for flour, dark red spots indicate the presence of added iron. The test does not identify intrinsic iron. The three samples shown below contain 0 ppm, 30 ppm and 50 ppm of added electrolytic iron but, as with the iodine spot test, this test is not considered suitable for semi-quantitative use. This test can be used to indicate the presence of all the common iron sources in flour fortification (i.e. electrolytic, ferrous fumarate, ferrous sulphate and NaFeEDTA). For the latter it is important to note that the iron is already a ferric salt so the addition of hydrogen peroxide is not required (if added the spots disappear).

**Figure 6: Red Spot Test for flour**



**Source: AACCI Method 40-40.01 Iron -- Qualitative Method**  
[<http://methods.aacnet.org/summaries/40-40-01.aspx>]

Spot tests are cost-effective and provide quick results ("yes" or "no"). They can also be used by the regulator to identify obvious non-compliance samples for further investigation.

Non-laboratory quantitative equipment to test for iodine in salt rely on measuring the intensity of the colour using a low-cost spectrophotometer such as the WYD Iodine Checker and the iCheck IODINE. The WYD Iodine Checker, which is produced in China, requires the user to make up some reagents and then add a sample of salt dissolved in water in order to create a colour reaction. The iCheck IODINE comes with prepared vials of solution to which the salt water sample is added. Both machines use a similar spectrophotometer to measure the colour intensity and level of iodine in the salt.

**Figure 7: ICheck iodine**



**Figure 8: WYD Checker machine**



**Source:**

**Jonathan Gorstein**

**Source: BioAnalyt.**

[<http://www.bioanalyt.com/products/icheck-and-iex-iodine>]

These and similar machines, are generally considered quantitative-grade equipment<sup>34</sup> but are more user-friendly than the official titration method. These machines are therefore often recommended for internal quality assurance, particularly in small-scale enterprises where quantitative testing by titration, considered the gold standard, may not be practical. Limitations in using the WYD Iodine Checker include difficulty in sourcing the necessary chemicals and reagents needed for the analysis (as it is often small- to medium-scale salt factories that source the chemicals) and inaccuracy at very low and very high levels of iodization. Since the iCheck IODINE uses prepared vials of reagent, there is no need to source chemicals; however the current cost per test of the iCheck IODINE appears to be higher than that for the WYD Iodine Checker.

<sup>34</sup> All machines claiming to be able to measure iodine using a spectrophotometer should be verified before wide scale or official use. The WYD has been validated by US CDC (<http://www.ncbi.nlm.nih.gov/pubmed/15214258>) and the iCheck iodine is currently being validated through a process funded by GAIN



Semi-quantitative and quantitative equipment also exist for measuring vitamin A in flours, oils and sugar including the BASF model<sup>35</sup> below and the iCheck CHROMA.

**Figure 9: Quantitative and semi-quantitative equipment for measuring vitamin A**

1 HPLC	2 BASF Test kit	3 iCheck test kit
		
<ul style="list-style-type: none"> <li>• Lab equipment needed</li> <li>• Technically highly trained staff               <ul style="list-style-type: none"> <li>• High-Priced</li> <li>• Quantitative</li> </ul> </li> <li>• Golden Standard</li> </ul>	<ul style="list-style-type: none"> <li>• Applicable in the field</li> <li>• Technically trained staff               <ul style="list-style-type: none"> <li>• Low-Priced</li> <li>• Semi-quantitative</li> </ul> </li> <li>• Screening tool</li> </ul>	<ul style="list-style-type: none"> <li>• Applicable in the field</li> <li>• Low trained staff               <ul style="list-style-type: none"> <li>• Middle-Priced</li> <li>• Quantitative</li> </ul> </li> <li>• Precise easy-to-use test kit</li> </ul>

**Source:** Acknowledgements are given to Dr Andreas Blüthner of BASF for permission to use extracts from a power point presentation on the subject.

The BASF test kit extracts the vitamin A from the relevant matrix and then uses chromogenic reagents to develop a colour which can be compared against a supplied colour chart or set of copper sulphate solutions the user can prepare by the tester. This test kit provides a semi-quantitative assessment of vitamin A content. The iCheck CHROMA uses similar chemical theory and a spectrophotometer to measure the colour which indicates vitamin A concentration. The results are a quantitative assessment of the vitamin A content, theoretically comparable to a quantitative result that could be achieved through HPLC analysis in a laboratory. The technique is currently undergoing independent validation against HPLC for vitamin A in different flours, oils, etc. Recent advances in electronics will enable multiple components such as iron and folic acid to be measured using the same instrument after individual extractions. This will be an important development as there is currently no non-laboratory quantitative assessment for iron in flour and other food products. In summary, an increasing number of new technologies exist to provide qualitative, semi-quantitative and quantitative assessments of vitamin and mineral content without the need for sophisticated laboratories or highly-trained laboratory staff. While these new technologies enable cheaper, easier and quicker assessments, they exhibit disadvantages in terms of accuracy. Careful decision is required in determining when and which method to use. Nevertheless, these non-laboratory techniques make it possible to conduct final product testing, even for small and medium producers. Internal monitoring may primarily consist of frequent qualitative and semi-quantitative checks, with at least one quantitative check performed at intervals determined by the regulator. External monitoring may involve a qualitative or semi-quantitative assessment for screening, and a quantitative assessment to verify vitamin and/or mineral content. Quantitative equipment is also very useful for screening of imports and commercial (retail) monitoring. Validated quantitative laboratory techniques (such as HPLC and titration) should always be required for legal enforcement.

### **Regulatory monitoring in small-scale fortification**

Regulatory monitoring, including internal and external monitoring, is crucial for all forms of food fortification. Although this meeting focused on salt and wheat flour fortification, the same principles apply for other forms of fortification, such as oil or sugar fortification. They apply also to small-scale fortification. However, there are special considerations in small-scale fortification.

<sup>35</sup> Acknowledgements are given to Dr Andreas Blüthner of BASF for permission to use extracts from a PowerPoint presentation on the subject



Small-scale fortification refers to fortification by small-scale food producers. For wheat flour, mills with a daily capacity of less than 20 MT/day are considered small scale.<sup>36</sup> For salt processing, no level of capacity has been defined for small-scale production. Small-scale food producers lack sophisticated technologies and budgets for extra staff or equipment. The owners, managers and workers often have limited education. Facilities may not be registered with authorities nor have a licence to operate. In addition, customers of small-scale facilities may tend to be less concerned with quality than with price. Some facilities may even operate on a barter system, wherein a farmer brings his wheat to the village mill and the flour is returned to him. The mill keeps the bran as payment. Small-scale salt processors are common throughout Asia and number in the thousands in countries such as Indonesia. Small-scale wheat mills tend to be more common in South Asia. In general, small-scale processing facilities exist where the raw material is locally produced; hence small-scale salt processors are present where salt is farmed or mined, and small-scale wheat mills are found in countries that grow wheat on a subsistence basis.

Fortification efforts have tended to focus on large-scale facilities. These facilities are considered more capable of quality fortification as they are able to install the necessary equipment for fortification and apply necessary internal monitoring mechanisms. Large-scale facilities may also produce the majority of the national supply of the food vehicle where both small and large facilities exist; this is especially true for salt. In South Asia however, the majority of wheat flour is still milled in small facilities. In the long term however, in line with industrial development, it is expected that small food processing facilities will eventually be replaced by a smaller number of large facilities. The focus on large-scale food processors is then justified when the objective is mandatory food fortification. However, in many developing countries, communities that would benefit most from fortification are those that source their food from small-scale facilities. Focusing only on large-scale facilities often excludes the most disadvantaged from the benefits of fortification.

The Micronutrient Initiative (MI) is attempting to find ways to implement small-scale fortification. The MI has experience in working with both small-scale wheat mills and salt processors in countries such as Nepal, Indonesia, Bangladesh and Pakistan. The work often entails subsidizing or creating revolving funds for premix, developing and providing appropriate technologies for fortification and providing training and technical support. An area that is particularly difficult is regulatory monitoring because the small-scale facilities do not have the capacity to implement even basic internal monitoring beyond ensuring the right amount of premix to the right amount of salt or flour. Furthermore, food inspectors are not able to monitor the small-scale facilities because they are too numerous, are located in rural and remote areas, and are usually not registered. There are also minimum barriers to entry and exit, enabling small-scale facilities to open and close frequently, sometimes following the seasonality of salt production and wheat flour milling.

In salt iodization, MI has had success in improving salt testing by (i) ensuring access to laboratories, (ii) providing "mobile laboratories" to groups of salt processors or (iii) providing the WYD Iodine Checker machine to processors. However, the WYD Iodine Checker machine needs a continuous supply of the chemicals needed to make up the reagents and high turn-over of personnel in the salt factories means staff have to be repeatedly trained on salt testing. Salt test kits, which are very simple to use and preferred by small-scale facilities, are only able to differentiate between iodized and non-iodized salt. Thus MI is trying to establish systems that use a quantitative methodology as an alternative to the salt test kit.

In a small-scale wheat flour milling project in Nepal, funded by the Asian Development Bank and technically supported by MI, a process was established with "monitoring assistants" visiting the small-scale mills on a weekly basis to inspect the facility, check the premix and the premix addition, manage supplies of premix, conduct spot tests on the flour and collect flour samples for semi-quantitative analysis. The monitoring assistants also visit households to test the flour and collect samples for analysis. Data collected and reports are sent to district-level coordinators who compile the data, organize monthly meetings with all monitoring assistants and conduct semi-quantitative analysis on the samples collected. This project provided a cadre of to facilitate both internal and external regulatory monitoring and provide supervisory and technical support to the small-scale facilities. The cadre of monitors are paid for by MI.

MI's experience demonstrates that small-scale fortification is possible, but with limitations. Sample collection is not cost-effective, there is no true internal monitoring, revolving funds, subsidies and support are needed,

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<sup>36</sup> [http://www.who.int/nutrition/publications/micronutrients/wheat\\_maize\\_fortification/en/](http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fortification/en/)

and awareness of consumers and processors needs to be enhanced. Given these, small-scale fortification may be difficult to sustain and scale up.

## Country analysis of existing regulatory monitoring systems and action plans to address weaknesses

### Bangladesh salt iodization

Salt iodization has been mandatory in Bangladesh since 1989. Majority of edible salt sold in Bangladesh is "washed and crushed", which is partially refined and iodized salt. A portion of salt sold is "open" salt which is taken from large sacks and sold loose, and "packet" salt which is packaged and sold in 500g or 1kg plastic bags. In an IDD and USI survey during 2004–2005, only 51.2% of households were found to be consuming adequately iodized salt (down from 55% in 1999 and 54.4% in 1996). However, median urinary iodine in children and women was above 100ug/L suggesting adequate iodine intake.

**Table 3**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
<p>Universal Salt Iodization Act passed by Parliament in 1989.</p> <p>Law for salt iodization specifies definite range from production to consumption level (45-50ppm at production, &gt;20ppm at retail and &gt;15ppm at HH).</p> <p>National salt policy</p> <p>Institutional network exists.</p> <p>High awareness level among the consumers exists.</p> <p>High political commitment exists.</p>	<p>Iodization not mandatory for processed and animal foods.</p> <p>No provision for major penalties for repeated offenses.</p> <p>Arrangement of testing facilities/laboratory is not mandated by law.</p> <p>Recently declared policy is not widely known by stakeholders.</p> <p>Inconsistencies in standards of iodine level</p> <p>Inadequate supply of properly mixed iodized salt.</p> <p>Insufficient magistracy related to manpower and logistics for legal enforcement.</p>	<p>Amend/update law to include revised rules and regulation.</p> <p>Establish laboratories at individual mills.</p> <p>Facilitate wide circulation as well as implementation.</p> <p>Initiate harmonization between different standards.</p> <p>Strong enforce monitoring and legislation.</p> <p>Increase involvement of magistrate.</p>
<b>Internal Monitoring System</b>		
<p>Large factories have modern plants and monitoring mechanisms with labs for quantitative analysis.</p> <p>Periodic government orders and instructions to the mills for regular monitoring exist.</p>	<p>Small factories do not have sufficient testing facilities.</p> <p>Orders are not properly carried out due to lack of enabling environment at production level.</p> <p>Rapid turn-over of trained manpower.</p> <p>Lack of commitment by salt factories.</p>	<p>Strengthen testing facilities at modern mills.</p> <p>Enforce establishment of testing facilities at small mills.</p> <p>Government and millers will take initiative to create enabling environment.</p> <p>Continuous skill development training will be arranged.</p> <p>Strengthen awareness of production of quality crude salt among the farmers.</p>

		Motivational initiative will be taken
<b>External Monitoring System</b>		
Strong legislative and policy support exists.	Insufficient legal enforcement.	Increase involvement of local government and local administration in legal enforcement.
Modern lab facilities at regional and zonal level exist.	Inadequate utilization of lab facilities.	Upgrade CIDD laboratories for quantitative analysis of more samples.  Conduct training to enhance laboratory personnel skills.
	Lack of coordination and communication among concerned organizations.	Ensure rapid and effective communication and strengthened coordination among concerned organizations.
Local government units (LGUs) and NGOs are involved.	LGUs are not sufficiently equipped for this type of monitoring.	Equip LGUs with logistics for salt monitoring.

### Bangladesh: flour fortification

Though some feasibility and acceptability studies on wheat flour fortification have been conducted and WFP is currently supporting fortification at a limited number of mills, there are no specific plans or efforts for wheat flour fortification in Bangladesh. Consumption of wheat flour is very low – about 20-30g/capita/day, but is reportedly increasing as a result of increased consumption of instant noodles. Industry sources report that there are about 300 roller mills in Bangladesh and production by chakki mills is minimal. An analysis of the regulatory monitoring system for flour was not therefore completed for Bangladesh.

### Indonesia: salt iodization

Salt iodization is mandatory in Indonesia. Indonesia produces about one million tons of salt for human consumption, including for food processing and fish curing. The salt is produced by about 17,000-20,000 large- and small-scale farmers, primarily in nine provinces of Indonesia. Depending on the weather, about 200,000 tons of high-quality salt is imported from Australia, India or China mainly for food processing. Domestic salt is processed by numerous large and small salt processors. Although there were 571 registered producers in 2008, the industry appears to be made up of 10 large companies, about 360 medium processors and many small-scale processors. A national health survey (Riskesmas) undertaken in 2007 found that for household salt 57% was adequately iodized, 36% was inadequately iodized, and 8% was not iodized. This was determined by titration using 18ppm iodine, which is the national standard). FDA/BPOM monitoring data from the last five years shows that the adequately iodized salt comes primarily from the large salt processors while the inadequately iodized comes primarily from the medium- and small-scale processors. The majority of non-iodized salt is believed to be raw, unprocessed salt coming direct from salt farms and freely distributed in market places especially in areas near the salt farms or salt boilers (i.e. this salt does not pass through a processor).

**Table 4:**

<b>Strengths</b>	<b>Weaknesses</b>	<b>Action Plans (2011/12)</b>
<b>Legislation and Standards</b>		
Sufficient legislation and standards including Food Act (1996), Law on Food Labelling and Advertising (1999) and Law on Food Safety, Quality and Nutrition (2004).	90% of small processors (± 360) cannot register for SNI because they cannot meet all criteria required by the SNI. Neither can they register as a small scale or home industry (PIRT) because they	Small salt processors will required to obtain a home industry license (PIRT), in place of the SNI. They will thus be registered and can be monitored. This will need to be done in collaboration with the FDA

<p>Presidential Decree 69 (1994) mandates that all salt intended for consumption by humans or livestock must be iodized. Ministry of Industry is designated as the Coordinator for controlling the processing, packaging and labelling of iodized salt.</p> <p>Ministry of Industry Decree No.42/M-IND/PER/11/2005 on Processing, Packaging and Labelling of Iodized Salt</p> <p>Indonesian National Standard (SNI) for iodized edible salt began in 1992 with updates in 1999, 2000 and 2010. This standard is mandatory.</p> <p>Ministry of Home Affairs Decree No. 63/2010 that all governors, mayors and <i>bupati</i> must coordinate and fund the IDD Control Programme (GAKY) and define coordinating bodies from provincial to sub-village levels to assure that “all the community consume iodized salt with SNI standard”.</p>	<p>produce a product for which there is a mandatory SNI. Thus they have no registration and do not follow the requirement for salt iodization.</p>	<p>(BPOM) as normally PIRT is not applicable for products that should fall under the SNI.</p>
<b>Internal Monitoring System</b>		
<p>Large-scale facilities, which produce about 60% of total salt, have good process control procedures, laboratories and qualified laboratory analysts. They use regular titration to ensure that the salt produced is adequately iodized.</p>	<p>60% of small-scale processors (approximately 360) do not have a laboratory and/or ability to conduct regular qualitative measurement of iodine level due to lack of trained human resources, mini laboratory for titration or reagent supply.</p>	<p>Small-scale processors will be provided with rapid test kits and clusters of small-scale processes with mini-labs (MI-UNICEF model).</p> <p>Strengthen processor associations/cooperatives.</p> <p>Provide support for periodic re-training on iodization systems (dosage) and internal monitoring by district industry office.</p> <p>Develop “Iodine Bank” in the clusters/groups of salt processors.</p>
<b>External Monitoring System</b>		
<p>Large-scale processors are monitored externally by MOI and BPOM (FDA)</p> <p>Ministry of Home Affairs Decree No. 63/2010 authorizes local government to monitor and enforce universal salt iodization –</p>	<p>Small and unregistered processors are not monitored.</p> <p>Unpackaged/unprocessed salt find their way to markets and consumers.</p> <p>Many district laws, including</p>	<p>Clarify roles/responsibilities of local government in terms of external monitoring of salt iodization and develop their capacity to undertake this task, including providing a dedicated mini-lab, developing standard operating procedures (SOPs) for</p>

<p>this can include undertaking external monitoring and registering small-scale salt processors who are not able to obtain SNI registration</p>	<p>Decree No. 63, are not implemented because there has been no funding source established by district/city government.</p>	<p>joint sampling, etc.</p> <p>Discuss with FDA (BPOM) and Ministry of Health to modifications to criteria to temporarily allow small salt processors to obtain PIRT.</p> <p>Ensure the sustainability of the external monitoring by advocating to relevant stakeholders for allocation of proper resources.</p> <p>Engage local law enforcement to prevent raw/un-packaged salt at markets by developing local government legislation (<i>perda</i>) and SOPs.</p> <p>Mobilize communities, chief of villages and local women's groups to actively control and drive out non-iodized salt from local markets/kiosks.</p>
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### Indonesia: flour fortification

Flour fortification is mandatory in Indonesia. Based on household expenditure data from 2008 collected through the Social Economic Survey, Indonesians consume about 52g of flour per person per day.

Consumption levels are similar in urban and rural areas. Consumption of wheat flour and wheat flour products appear to be increasing, driven largely by increasing demand for instant noodles. All of Indonesia's wheat is imported. It is milled by 15 large, sophisticated mills; the largest mill in the world is in Indonesia. Currently, about 10-15% of national demand is imported as flour from Turkey and Sri Lanka. All domestically-produced flour is believed to be adequately fortified according to the national standard (SNI). It is not known if all the imports are fortified.

**Table 5:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
<p>Sufficient legislation and standards including Food Act (1996), Law on Food Labelling and Advertising (1999) and Law on Food Safety, Quality and Nutrition (2004).</p> <p>A Ministry of Health Decree in 2000 (updated in 2010) recommended all wheat flour produced and distributed in Indonesia be fortified and a national standard (SNI) requires the addition of iron, folic acid, zinc, vitamin B1 and B2.</p>	<p>SNI mandates the monitoring of five flour fortificants. However the detection of small doses of vitamins, especially folic acid, is difficult for most laboratories. As a result the mills add an overage of fortificant to ensure that the folic acid can be detected.</p> <p>SNI does not meet WHO recommendations for iron level and compound, folic acid and zinc levels (assuming per capita flour consumption of less than 75g/day).</p>	<p>Revise SNI requirement to analyse the amount of premix added, and measure amount of iron in the fortified flour as a "marker" of the entire premix.</p> <p>Conduct study on impact of fortified flour in improving nutrition status of the community.</p> <p>Revise the SNI to be in line with WHO recommendations.</p>
<b>Internal Monitoring System</b>		
<p>Indonesian mills purchase premix from reputable companies and have strong process control</p>		

systems (most mills are fully automated).		
The mills also have laboratories and qualified lab analysts. Samples are frequently sent out to external laboratories for full assessments.		
<b>External Monitoring System</b>		
All mills are monitored annually by MOI and BPOM. Process control is reviewed and samples are analysed by government laboratories.	The detection of folic acid in flour is difficult due to the very low levels. Samples of fortified flour may thus not appear to meet the SNI. To avoid this, mills routinely add more folic acid in order to ensure it can be detected.	Revise the analysis method of the SNI to consider analysis of the premix and the amount added; use iron as a marker of premix added.  Strengthen laboratory and human resource capacity in external monitoring.

#### Malaysia: salt iodization

Salt iodization is mandatory only in the states of Sabah and Sarawak. All salt is imported into Malaysia, and salt imported into Sabah and Sarawak is already iodized. A national IDD survey among school children in 2008 indicated borderline urinary iodine levels among people in Peninsular Malaysia, especially among rural children. People in six states exhibited urinary iodine levels less than the WHO cut-off for adequate iodine nutrition, indicating mild deficiency. National consumption of iodized salt was low; 28.2% of people consumed salt with iodine, 17.6% consumed salt with more than 15ppm iodine (WHO recommendation) and 6.8% consumed salt with between 20–30ppm of iodine (required by the Food Act 1983). Urinary iodine levels and consumption of iodized salt were higher in people in Sabah, indicating successful mandatory iodization. Even in Sabah however, only 25% of the population consumed salt iodized at 20-30ppm.

**Table 6:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
Food Regulation 285 (under the Food Act 1983) establishes a standard for iodized table salt or iodized salt at 20–40ppm.	Iodization of salt is only mandatory in Sabah and Sarawak, and is voluntarily in Peninsular Malaysia.  The iodization level specified in the Food Regulation does not differentiate between levels at point of entry (import) or at retail.	Salt iodization will be mandatory for the whole country, pending approval of food regulation by the Minister of Health/Ministry of Health committees. After the approval by MOH Committees, a Food Regulation on mandatory salt iodization will be gazetted with approval of Minister of Health.  Require a pre-shipment certificate at point of entry.  Develop database of salt re-packers to enable monitoring at that level.



<b>Internal Monitoring System</b>		
Not applicable; all salt is imported		
<b>External Monitoring System</b>		
Enforcement is responsibility of Ministry of Health.  Monitoring is supported by testing at accredited food laboratories.	External monitoring at point of entry and retail levels is not routine practice.  Limited manpower for external monitoring.	Develop SOP/mechanism and provide appropriate resources for routine external monitoring at point of entry and retail levels.  Increase information and communication to stakeholders and consumers.

### Malaysia flour fortification

Malaysians consume about 115g of wheat flour per day in the form of bread and noodles. All of Malaysia's flour is milled in 13 large mills or is imported into the country as flour. A Ministry of Health proposal for mandatory flour fortification is currently being finalized, and will be submitted to Cabinet for approval. General purpose flour, which makes up about 27% of total flour, is price-controlled and millers are subsidized by the Government to compensate for high wheat prices. Details on how to implement mandatory flour fortification in the context of these price controls and subsidies are being developed.

**Table 7:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
Food Regulation 43 (under the Food Act 1983) provides a voluntary standard for fortified flour. In the Ministry of Health proposal, flour fortification will become mandatory (2.6ppm folic acid and 60ppm iron as ferrous fumarate).	Legislation for mandatory flour fortification is not yet in place.	Complete Cabinet Memorandum is pending approval to amend Food Regulation and make flour fortification mandatory.
<b>Internal Monitoring System</b>		
Modern facilities have good process control and laboratories on-site.	Flour fortification is voluntary so there is limited experience in internal monitoring, as well as a lack of training of analysts, laboratory equipment etc.	Enforce mandatory flour fortification.  Facilitate training on internal monitoring (focus on process control) by microfeeder/premix suppliers, FFI and GAIN.
<b>External Monitoring System</b>		
Centralized government food laboratory exists.	External monitoring currently focused only on safety and quality of food.  Manpower is limited.	Develop SOP/mechanism for routine external monitoring at mill & retail level with appropriate resources.  Increase information and communication to stakeholders and consumers

### Mongolia: salt iodization

Salt iodization is mandatory in Mongolia. Approximately 8% of Mongolia's salt is domestically produced and the remaining 92% is imported, primarily from China and the Russian Federation. The majority of imports are iodized. Currently about 89.1% of households consume iodized salt and 75.7% consume adequately iodized salt. (Fourth National Survey on Food and Nutrition, 2010)

**Table 8:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12-2015)</i>
<b>Legislation and Standards</b>		
<p>Law on Food (1999) and Law on salt iodization and prevention of IDD (2003). The latter includes roles and responsibilities of government agencies, producers and consumers.</p> <p>Mandatory national standards exist for iodized salt.</p> <p>Guidelines for producers on salt iodization exist.</p> <p>A regulation on control of fortified foods (salt and flour) has been approved by the Minister of Food and Agriculture, Health and Inspections which covers sampling, fortification, testing and storage.</p>	<p>Existing laws and regulations do not mention the need for internal monitoring by producers.</p> <p>The Law on Food indicates that Inspection agency shall exercise the power to build up information database on food safety.</p> <p>The Law on Food has no clear indication on who monitors, how monitoring is conducted, and whether the information is used for planning, is provided to government agencies, communities and producers.</p> <p>Proposed database does not include registration of fortified food including level of iodized salt production and iodine content based on internal monitoring.</p>	<p>For 2012, develop/update necessary regulations or guidelines to include an efficient regular monitoring structure. (Existing regulation indicates quarterly monitoring which is not implemented due to many constraints or unrealistic way of doing business).</p> <p>For 2012, develop regulation on food safety database, information sharing and their use in various planning within the respective ministries and agents.</p> <p>For 2012 through 2015, develop technical standards on characteristics of fortified food and regulations for each fortified food production.</p>
<b>Internal Monitoring System</b>		
<p>Salt manufacturers, including small producers, use the iodine checker and titration.</p> <p>Salt manufacturers receive free potassium iodate in line with memorandum of understanding for 2010-2012 between the Ministry of Food, Agriculture and Light Industry (MOFALI) and the Government of Japan.</p>	<p>Irregular monitoring, particularly at smaller manufacturers.</p> <p>No official protocol on internal monitoring.</p> <p>Smaller manufactures face difficulties, including high turnover of trained staff, and are sometimes reluctant to purchase reagents.</p> <p>Internal processes are interrupted by seasonal operation of salt producers, causing irregular supply of raw material.</p>	<p>Review of internal monitoring operations to be conducted by responsible government agencies in 2012 if funds are available.</p> <p>Conduct training for salt producers based on assessment of needs and current situation of internal monitoring. To be done in 2012 if funds are available.</p> <p>Supply necessary equipment for internal quality control. To be done in 2013 if funds are available.</p>
<b>External Monitoring System</b>		
<p>Officially approved guidelines for planned external monitoring exist.</p> <p>Each province has a chemical laboratory with official accreditation. Iodine content in salt is determined by titration.</p> <p>Custom inspection units at the border have quality control laboratories which are able to check iodine content by WYD and titration.</p>	<p>Lack of government resources (budget and human) for regular monitoring exacerbated by scattered location of salt manufacturers.</p> <p>No central database of information from external monitoring in inspection agencies (State and province).</p>	<p>Standardize external monitoring and update existing regulation external monitoring in 2013.</p> <p>Advocate increasing Government budget allocation for external monitoring in 2012.</p> <p>Improve capacity of provincial laboratories and human resources in 2012.</p>



## Mongolia: flour fortification

A law to mandate fortification of all flour milled domestically (from locally grown and imported wheat) and all imported flour is currently under development. As flour fortification is not yet mandatory, regular monitoring system have some weakness. Previous and current fortification programmes have limited focus on regular monitoring, resources and knowledge on efficient methods of monitoring.

**Table 9:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
<p>A law on mandatory flour fortification is currently being drafted.</p> <p>Standards exist for fortified flour (high and I grade) and premix KAP complex. Formula was developed during implementation of ADB project "Sustainable food fortification JFPR 9052" but needs to be revised to include vitamin D, etc.</p> <p>Guidelines for flour fortification exist for producers.</p> <p>A regulation on control of fortified foods (salt and flour) has been approved by three ministries and covers sampling, fortification, testing and storage.</p>	<p>Flour fortification is not yet mandatory and needs special effort.</p> <p>The premix KAP complex used to date does not meet WHO guidelines nor the Ministry of Health food fortification guideline.</p> <p>Policy- and decision-makers understanding of importance of fortified flour is insufficient.</p>	<p>Advocate to policy- and decision-makers the importance of fortified flour to address common micronutrient deficiencies, such as iron, vitamin D, zinc, and folic acid among Mongolian population.</p> <p>Enforce a law on mandatory fortification on locally-produced and imported flour.</p> <p>Update the standard for fortified flour and premix KAP complex in line with WHO guidelines and the Ministry of Health guidelines on food fortification.</p> <p>Develop regulations to establish a regulatory monitoring system, sharing of information between respective ministries and agents and technical regulations for the fortified flour.</p> <p>Increase public awareness of the importance of food fortification.</p>
<b>Internal Monitoring System</b>		
<p>Large mills have good internal monitoring including process controls.</p> <p>Spot test is currently being conducted by domestic mills.</p> <p>Laboratories are capable of undertaking semi-quantitative analysis with adequate reagent supply.</p>	<p>No regular protocol on operation.</p> <p>Monitoring is irregular particular by smaller mills.</p>	<p>Review of internal monitoring operations in small flour millers by responsible government agencies.</p> <p>Conduct training for small flour millers based on assessment of needs and current situation of internal monitoring.</p> <p>Mandate GMP for large millers between 2012-2015.</p>

<b>External Monitoring System</b>		
<p>Officially-approved guidelines for planned external monitoring exist.</p> <p>Each province has an officially-accredited chemical laboratory to conduct spot test for fortified flour.</p> <p>Quarterly monitoring undertaken for large millers (20 millers).</p>	<p>Lack of government resources (budget and human) for regular monitoring.</p>	<p>Standardize and conduct regular monitoring.</p> <p>Improve capacity of provincial laboratories and training of human resources once the law is approved - beyond 2013 if fund available</p>

### **Nepal: salt iodization**

Salt iodization was mandated in 1999. Almost all salt is imported into Nepal, mainly from India, and is processed and distributed by the Salt Trading Corporation Limited. Salt is imported either already iodized or re-iodized if necessary, mainly at five points of entry, as well as at other branches as per requirements. The Salt Trading Corporation has large, sophisticated facilities capable of quality iodization and packaging. However, a small amount of non-iodized or inadequately iodized salt enters Nepal illegally. The DHS 2011 indicates that 80% of households are consuming adequately iodized salt. This is an increase from 73% in 2010 (Nepal Living Standards Survey 2010-2011) and 58% in 2005. Surveys utilized rapid test kits (semi-quantitative methodologies) for assessing adequately iodized salt.

**Table 10:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
<p>Iodized Salt (Production, Sale and Distribution) Act in place since 1999.</p> <p>Iodized salt standard is 50ppm at production and 30ppm at retail.</p> <p>Food control is overseen by the Department of Food Technology and Quality Control under the Ministry of Agriculture and Cooperatives (DFTQC). Laboratories to test food fortification exist.</p>	<p>Regulation under the Iodized Salt Act has not been gazetted – as a result salt iodization is not yet mandatory.</p> <p>A standard for common salt (which does not include iodization) exists under food regulation of Food Act.</p>	<p>Mandate salt iodization either by establishing regulations for Iodized Salt Act 1999 or removing standard for common salt from Food Act regulation.</p> <p>Modify and approve SOP for salt iodization.</p> <p>Organize multisectoral meeting for reviewing fortification standard of salt.</p>
<b>Internal Monitoring System</b>		
<p>Well-established laboratory at all entry points and sales depots of salt trading.</p> <p>Internal monitoring system established (QA/QC) with trained human resources.</p>	<p>GMP is not implemented.</p> <p>Inadequate skills of technical personnel.</p>	<p>Update and endorse SOP on internal monitoring.</p> <p>Conduct refresher training for technical personnel.</p> <p>Strengthen laboratory facilities.</p>

<b>External Monitoring System</b>		
<p>Food inspectors from central, regional and custom points monitor market, industry and importation points.</p> <p>Guidelines and format for external regulatory monitoring exists.</p> <p>Laboratory facilities are available at central and regional level.</p> <p>Minimum mandatory food standards exist.</p> <p>Manufacturers are required to have licenses prior to producing food.</p>	<p>Insufficient human resources to cover all industries and retail market throughout Nepal.</p> <p>Inadequate laboratory facilities.</p>	<p>Conduct capacity building of DFTQC staff, with a focus on process monitoring.</p> <p>Strengthen laboratory facilities.</p> <p>Develop and revise guidelines for external monitoring.</p>

### Nepal: flour fortification

Approximately 20%–30% of all flour consumed in Nepal is milled by about 20 large roller mills located primarily in the Terai. The remainder of Nepal’s flour is milled by small chakki and water mills at the village level. In August 2011, the fortification of all roller mill flour was mandated by the Government. Pilot projects are underway to support fortification by the small-scale mills.

**Table 11:**

<b>Strengths</b>	<b>Weaknesses</b>	<b>Action Plans (2011/12)</b>
<b>Legislation and Standards</b>		
<p>Food legislation is in place (Mandatory Fortification Notification under Section 7 of Food Act 2023).</p> <p>The standard for fortification has been set as 60ppm as elemental iron, 1.5ppm of folic acid and 1 ppm of vitamin A.</p> <p>Food control institution (Department of Food Technology and Quality Control under the Ministry of Agriculture and Cooperatives) and laboratory exist.</p>	<p>All commercially-processed wheat flour is not covered by the legislation</p> <p>Good manufacturing practices are not mandatory.</p>	<p>Develop SOP for flour fortification.</p> <p>Organize multisectoral meeting to review fortification standard of flour.</p> <p>Review and revise mandatory flour fortification regulation to include all commercially-processed wheat flour.</p>
<b>Internal Monitoring System</b>		
<p>Process control systems, internal monitoring systems and laboratory facilities with trained staff exist in roller flour mills.</p>	<p>GMP is not implemented.</p> <p>Retention of quality technical human resources is a problem.</p>	<p>Update and endorse SOP on internal monitoring.</p> <p>Explore atomization of feeder.</p> <p>Conduct refresher training for technical personnel including continuation of technical backstopping to roller mills to ensure quality assurance.</p>

		Ensure premix imported from certified suppliers only.  Strengthen laboratory facilities.
<b>External Monitoring System</b>		
<p>Food inspectors from central, regional and custom points monitor market, industry and importation points.</p> <p>Guidelines and format for external regulatory monitoring exists.</p> <p>Laboratory facilities are available at central and regional level.</p> <p>Minimum mandatory food standards exist.</p> <p>Manufacturers are required to have licenses prior to producing food.</p>	<p>Insufficient human resources to cover all industries and retail market throughout Nepal.</p> <p>Inadequate laboratory facilities.</p> <p>Standard does not cover all products at industries.</p> <p>Small-scale industries do not have an operating license.</p>	<p>Conduct capacity building of DFTQC staff, with a focus on process monitoring.</p> <p>Develop and revise guidelines for external monitoring.</p> <p>Strengthen laboratory capacity of DFTQC to analyse vitamin A and folic acid in fortified flour.</p> <p>Promote use of logo developed for fortified wheat flour to facilitate demand (as done for iodized salt).</p>

### Philippines: salt iodization

Salt iodization has been mandatory in the Philippines since 1995 with the ASIN law. Since then household coverage of iodized salt has increased to the current level of 81.1%. However, 18.9% of salt remains un-iodized and 80.4% is below the national standard of 20ppm, implying that 61.5% is inadequately iodized. Roughly 70% of salt for domestic consumption is imported and the remainder is produced in a limited number of areas of the Philippines. Nevertheless, there are multiple importers and many small, medium and large salt farmers and processors. Transport of non-iodized salt within the Philippines is permitted, which complicates monitoring and enforcement of the ASIN law.

**Table 12:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)<sup>37</sup></i>
<b>Legislation and Standards</b>		
<p>Strong legal framework through:</p> <ol style="list-style-type: none"> <li>1. Republic Act No. 8172, otherwise known as "An Act for Salt Iodization Nationwide (ASIN)" which was approved on December 1995 with corresponding Implementing Rules and Regulations (IRR).</li> <li>2. Republic Act No. 9711, otherwise known as "Food and Drug Administration Act of 2009" (August 18, 2009) amending Republic Act No. 3720, otherwise known as "Food, Drug and Cosmetics Act".</li> </ol>	<p>Non-implementation of support from other departments/agencies.</p>	<p>Continue strengthening the Technical Working Group on the National Salt Iodization Program (TWG-NSIP) and the Salt Iodization Advisory Board.</p>
	<p>Value-added tax (VAT) is applied to imports of iodized salt, but not non-iodized salt, thus discouraging imports of iodized salt.</p>	<p>Explore and extend incentives e.g. income tax holiday, lower government fees, soft loans for equipment, etc.</p>
	<p>Many salt manufacturers are unable to meet good manufacturing practice (GMP) standards and so are unable to secure license-to-operate (LTO).</p>	<p>Continue to work for legislation that will declare iodized salt as a zero-VAT product.</p> <p>Formulate GMP standard appropriate to salt industry based on risk analysis to be conducted.</p>

<sup>37</sup> These concerns are covered by the Strategic Plan of the National Salt Iodization Program that includes other action lines that will be pursued to ensure more effective salt iodization and its use

<b>Strengths</b>	<b>Weaknesses</b>	<b>Action Plans (2011/12)<sup>37</sup></b>
<p>3. FDA Administrative Order No. 153 s. 2004 on the "Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking, or Holding Food".</p> <p>4. FDA Administrative Order No. 88-B s. 1984 on "Rules and Regulations Governing the Labelling of Prepackaged Food Products Distributed in the Philippines"</p>		Conduct review of ASIN Law and its IRR.
<b>Internal Monitoring System</b>		
Motivated towards more efficient protocols.	RTK-based monitoring conducted instead of quantitative monitoring.	Support industry to build QA systems by setting standards for salt iodizing machines, developing a scheme for equipment validation, and conducting training and mentoring.
Industry is open to improvement or changes.	Documentation of processes not adequately done.	
	Validation of equipment to check effectiveness in mixing is not performed.	
	Single standard across all levels leads to production of non-adequately iodized salt.	Conduct a review of the ASIN Law and its IRR.
<b>External Monitoring System</b>		
Local government units (LGUs) participation in monitoring (when strong).	Low licensing coverage because of inability to meet GMP requirements.	Provide further guidance and assistance to LGUs to enable them to improve monitoring.
Availability of training records.	<p>LGU monitoring is weak when there is:</p> <ul style="list-style-type: none"> <li>• lack of resources and direction,</li> <li>• insufficient reporting to FDA, and</li> <li>• Poor coordination of results.</li> </ul> <p>Trans-shipment monitoring protocols not being followed due to inadequate resources (e.g. human).</p>	<p>Strengthen the FDA external monitoring system based on the country review done by Dr Randall as is applicable to Philippine context.</p> <p>Review ASIN Law and its IRR.</p> <p>FDA to implement process monitoring of salt iodization plants in addition to collecting samples for testing.</p>
	BOC does not strictly enforce agreed procedure for receiving salt importation (i.e. salt should be in yellow lane and not in green lane).	Conduct re-orientation among BOC officials.

### **Philippines: flour fortification**

Flour fortification was made mandatory in the Philippines on the basis of a Republic Act issued in 2000 establishing a mandatory and voluntary fortified food programme. The mandatory programme included flour fortified with vitamin A and iron, rice fortified with iron, oil fortified with vitamin A and sugar fortified with vitamin A. At the present time, all flour, domestically milled and imported, is believed to be fortified. All oil is



also believed to be fortified. Rice managed by the National Food Authority is fortified. Sugar is not fortified. Approximately 90% of the wheat flour in the Philippines is domestically milled; the rest is imported, particularly from Turkey. Wheat is milled into flour in 12 large and sophisticated mills which are believed to have good process control procedures.

**Table 13:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)<sup>38</sup></i>
<b>Legislation and Standards</b>		
Strong legal framework through:  1. Republic Act No. 8976 – "Philippine Food Fortification Act of 2000" (November 2000) and subsequent IRR and standards.  2. Republic Act and administrative orders noted in Table ??	Recognized laboratories required to report results of testing to FDA, which is not consistent with principle that these laboratories are independent.	FDA to validate weakness regarding reporting; if true, provisions are to be reviewed and revised.
	Standards for fortification need to be updated to comply with WHO recommendations.	Review and revise standards for flour fortification.
	Support from other departments/agencies not implemented.	Strengthen coordination mechanisms to ensure adequate support to industries covered; include revival of commodity-specific technical working groups.
<b>Internal Monitoring System</b>		
Established procedures for monitoring and resources at large scale.	Possibility that the industry is using premix that does not adequately protect the stability of vitamin A which results in loss of vitamin A in the finished product.	Ensure industry retains samples/composite sample of premix for FDA validation.  NNC to present the results of FDA monitoring to the flour industry and to facilitate resolution of the issue related to the stability of vitamin A in the fortificant being used.
<b>External Monitoring System</b>		
Regular monitoring performed since there are few flour millers to monitor.	The same sampling methodology is used for routine monitoring and for enforcement.	Strengthen the external monitoring system of FDA based on the country review done by Dr Randall as applicable in the Philippine context; engage services of an external consultant as necessary.

### **Sri Lanka: salt iodization**

Salt iodization is mandatory in Sri Lanka. All salt is domestically produced and over 80% is processed by just two major producers. However, about 10% of salt is processed by about 250 small-scale producers. Much of this salt is either not iodized or poorly iodized. The third National IDD Survey of 2010 indicated that 68.3% of salt was adequately iodized. Urinary iodine data indicates adequate iodine nutrition among school children but inadequate levels among pregnant women remain.

**Table 14:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
Legislation for mandatory salt fortification was developed in 1995 and revised in 2005. A second revision was made in 2011	Legislation for mandatory salt applies only to salt for human consumption and not salt for animal consumption.	Enforce a maximum level of iodine in production (25-35ppm)  Rephrase vague clauses in the

<sup>38</sup> There are plans to formulate a strategic plan for fortified staples once the policy on mandatory fortification of staples has been adopted

<p>although it has not been gazetted yet.</p> <p>The standard for iodized salt is 30ppm at production level and 15-25 ppm at retail level.</p> <p>Policy guidelines for fortification of food exist as well as a Food Advisory Committee, a Fortification Sub-Committee and an Iodine Steering Committee. The Iodine Steering Committee monitors the USI programme at central level.</p>		<p>current gazette (e.g. clause for table salt).</p> <p>Create a network of regional food laboratories.</p> <p>Quantify maximum tolerance levels of impurities.</p> <p>Facilitate registration of salt producers, re-packers and products.</p> <p>Enforce labelling requirement for processed foods.</p>
<b>Internal Monitoring System</b>		
<p>80% of salt is processed by two large producers with good internal process control systems.</p>	<p>Irregular recordkeeping of premix and laboratory results.</p> <p>Poor feedback mechanism to regulators.</p> <p>Poor or non-existent internal monitoring at small-scale facilities.</p>	<p>Discourage iodization by small-scale facilities, unless they have a laboratory capable of quantitative assessment. Small facilities should be restricted to repacking only.</p> <p>Ensure that salt processing facilities establish internal quality control systems.</p> <p>Develop a uniform internal monitoring checklist.</p> <p>Develop a regular and timely feedback mechanism between industry and regulators.</p>
<b>External Monitoring System</b>		
<p>Regular monitoring at retail and production sites by the Ministry of Health.</p>	<p>Government monitoring does not use internal monitoring results of the salt industry.</p> <p>Poor feedback to producers and inadequate dialogue with producers.</p> <p>No computerized database of external monitoring results for trend analysis.</p>	<p>Develop a checklist for external monitoring.</p> <p>Develop central and regional databases on external monitoring data.</p> <p>Establish regular networking with stakeholders.</p> <p>Request a tax waiver for potassium iodate from the Ministry of Finance and Planning. Establish a system for procurement of KIO<sub>3</sub> by registered companies only in order to ensure good quality of KIO<sub>3</sub>.</p>

### Sri Lanka: flour fortification

Flour in Sri Lanka is milled by only two very large mills. One mill, Serendib, which has approximately 20%–25% of the market share for flour, voluntarily fortifies its flour at levels of 60ppm electrolytic iron and 1.5ppm of folic acid. The Government has a policy of discouraging consumption of wheat and promoting consumption of rice for health reasons and because all wheat is imported whereas rice is domestically grown. Food balance

sheets suggest wheat consumption is falling. For these reasons there is no political will to mandate flour fortification.

**Table 15:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
Policy guidelines for fortification of food in Sri Lanka (2008) exist. These guidelines set out principles of food fortification including principles for establishing standards.	No legislation for mandatory fortification.	Discuss voluntary fortification with millers.
<b>Internal Monitoring System</b>		
Both flour mills are large and sophisticated. Information is not available on their internal monitoring systems, but these mills are likely to have strong process control systems.	No dialogue between millers and the Ministry of Health.	Initiate dialogue with millers to support strong internal monitoring systems.  Develop a uniform internal monitoring check list
<b>External Monitoring System</b>		
Laboratory facilities for monitoring are available.	No external monitoring systems currently exist.	Establish a regular monitoring system for voluntary fortification.  Develop a checklist for external monitoring.

### **Viet Nam: salt iodization**

Viet Nam implemented universal salt iodization since 1999 following a government ordinance (No. 19) on production of iodized salt for human consumption including salt in food processing. By 2005, Viet Nam was thought to have achieved all the goals of the IDD programme: median urinary iodine was above 122ug/L and national coverage of adequately iodized salt was 93.2%. As a result, resources and national efforts for salt iodization were scaled back; primary responsibility for the programme was assigned to provinces, budget was cut, etc. An updated government decree (No. 163) was issued in 2005 but it did not mandate iodization of all salt. A survey conducted during 2008–2009 revealed that coverage with adequately iodized salt had fallen to 69.5% and urinary iodine levels had also fallen to 83ug/L, below the target level of 100ug/L.

From September 2009, under the new decree, local authorities now have a right to allocate budget to provide iodized salt to the citizens of the provinces or to directly provide money for poor people to buy iodized salt. Instead of subsidizing the cost and freight for iodized salt, either iodized salt is directly provided or support in kind is given to the poor, disadvantaged or targeted beneficiaries. Local authorities decide which method is appropriate for their local context. However, there is evidence that the poor in some provinces use the funds provided to buy other products, not iodized salt as intended. In some ethnic minority areas, cash provided was used to buy alcohol instead of iodized salt. Therefore, it is recommended that provinces provide iodized salt instead of cash to the targeted beneficiaries. Viet Nam state enterprise Vinafood 1 was assigned the task of purchasing salt from salt producers, producing iodized salt and providing it to target populations in disadvantaged provinces.

Currently, both refined salt and iodized salt circulate widely in consumer markets. However, insufficient attention has been paid to the iodine levels of iodized salt, leading to a poor IDD control programme.

Up to now, the Government is trying to maintain the supply-demand balance of iodized salt, one of the essential goods in the country. At present, salt is farmed in 20 provinces of Viet Nam and processed by more than 80 medium to large salt processors. However, many processors have stopped producing salt. Salt production of Viet Nam was 1.2 million tons in 2010. According to the Decree No. 61/2010/ND-CP dated 4 June 2011, the enterprises working in the field of salt production, salt exploitation and salt processing have

been categorized for priority investment within the agriculture sector, wherein a small subsidy for salt transportation of up to 500,000 VND per year, per producer is provided.

**Table 16:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
<p>Food Safety Law No. 55/2010/QH12 in effect since July 2011.</p> <p>Technical regulations for iodized salt ratified in 2011.</p>	<p>No existing decree on mandatory salt iodization.</p> <p>No existing regulation for handling violations of compliance with technical regulations on iodized salt.</p> <p>No quality assurance requirements for manufacturers of iodized salt.</p>	<p>Develop or revise decree on mandatory salt iodization (to be done by Ministry of Health in 2011–12).</p> <p>Develop decrees to handle violations of food safety and compliance with technical regulations for fortified foods (to be done by VFA in 2012).</p> <p>Develop circular on guidelines for external monitoring systems (to be done by VFA in 2012).</p> <p>Develop technical regulations on factory conditions including required staff, facilities, procedures, etc. (to be done by MARD in 2012).</p>
<b>Internal Monitoring System</b>		
<p>Sixty-nine per cent of households consume adequately iodized salt.</p> <p>Iodized salt in production since 1999.</p>	<p>Large number of small- and medium-sized industries with little or no quality assurance systems.</p> <p>Lack of or poor facilities and technology for quality assurance.</p>	<p>Ministry of Health provides technical support for internal monitoring, including guidelines.</p> <p>MOARD and MOIT provide support/incentives to small- and medium-sized producers.</p>
<b>External Monitoring System</b>		
<p>External monitoring undertaken by iodine deficiency control programme.</p>	<p>External monitoring by IDDC programme is not systematic; VFA has only recently become involved in administration/management/regulation of iodized salt.</p> <p>No guidelines on monitoring at industry or market level.</p> <p>Roles and responsibilities of government agencies (MOH, MOIT and MOARD) for food safety control are currently being defined (under the Food Law in effect since July 2011).</p>	<p>Develop a monitoring system involving factory inspection (to be done by VFA in 2012).</p> <p>Develop and strengthen laboratories (to be done by VFA in 2012).</p>

### **Viet Nam: flour fortification**

A new food safety law in Viet Nam, approved on 17 June 2010 and in effect since 1 July 2011, allows food fortification as a strategy to improve public health if the vitamin and mineral deficiencies concerned are proven to be public health problems. Under this law, a decree on mandatory flour fortification and standard operating procedures will be developed. Wheat is milled into flour in Viet Nam in 27 mills. There are about

five large scale mills and the remainder are small or medium scale mills in North Viet Nam. Many of these mills already have experience in adding fortificants or additives as requested by their customers. Although wheat flour consumption remains quite low (approximately 40g per person per day according to FAO data), consumption is rising rapidly and wheat flour is consumed mainly in the form of noodles (fresh and instant), bread, baguettes, cookies and other bakery products.

**Table 17:**

<i>Strengths</i>	<i>Weaknesses</i>	<i>Action Plans (2011/12)</i>
<b>Legislation and Standards</b>		
<p>Food Safety Law No. 55/2010/QH12 in effect since July 2011.</p> <p>Technical regulations for flour fortification ratified in 2011.</p>	<p>No existing decree on mandatory flour fortification.</p> <p>No existing regulation for handling violations of compliance with technical regulations on fortified flour.</p> <p>No quality assurance requirements for manufacturers of fortified flour</p>	<p>Develop a decree on mandatory flour fortification (to be done by Ministry of Health in 2012–2014).</p> <p>Develop decrees for handling violations of food safety and compliance with technical regulations for fortified foods (to be done by VFA in 2012).</p> <p>Develop circular on guidelines for external monitoring systems (to be done by VFA in 2012).</p> <p>Develop technical regulations on factory conditions including staff, facilities, procedures, etc. (to be done by MOIT in 2012)</p>
<b>Internal Monitoring System</b>		
<p>70% of products are manufactured in modern factories certified ISO/HACCP.</p> <p>Consumption of wheat flour is increasing.</p> <p>Flour manufacturers have experience in fortification and adding additives.</p>	<p>Most factories are not yet ready for fortification.</p> <p>Premix, lab facilities and fortification technologies are limited.</p> <p>There is a lack of information on benefits of flour fortification (price and other barriers from a commercial point of view).</p>	<p>Provide technical support for internal monitoring, including guidelines, particularly for small mills. General characteristics of quality control of wheat flour should be guided by MOIT but the quality control of fortified flour should be guided by Ministry of Health (according to food law). MOH and MOIT to provide information on premix suppliers, laboratory assistance and feeders. MOIT to provide government support/incentives to small- and medium-sized mills.</p>
<b>External Monitoring System</b>		
<p>Not applicable; there is no external monitoring system for fortified flour in place.</p>	<p>Not applicable; there are no guidelines on levels for monitoring of fortified flour.</p> <p>Roles and responsibilities of government agencies are currently being defined (under the Food Law in effect since 1 July 2011).</p>	<p>Develop a monitoring system through mill inspection and post-market survey for monitoring both retail and wholesale markets (to be done by MOH and MOIT in 2012).</p> <p>Develop and strengthen laboratories (to be done by VFA in 2012).</p>



## Conclusions and Recommendations

1. Fortification is one of the most cost-effective strategies to address micronutrient deficiencies, which contribute to a loss of gross domestic product (GDP) between 2% and 3%.
2. To ensure cost effectiveness and sustainability, fortification requires an enabling environment which consists of a thoughtful legal framework and effective, auditable, internal and external regulatory monitoring.
3. The legal framework needs to be underpinned by a food law or legislation which should be brief and use general language such as "not containing any harmful substances", "must be fit for human consumption", etc. This legislation should in turn be supported by technical regulations and standards that are based on the latest available scientific evidence and/or accepted international norms.
4. Development of technical regulations and standards ideally involve wide participation of stakeholders such as (but not limited to) government, industry, supply chain operators and the general public. Legal mechanisms are ideally user friendly but still provide clear directives as to the roles, duties and responsibilities of all concerned.
5. It is recommended that internal monitoring be formalized and strive to match the standards of internationally accepted norms such as HACCP, GMP, ISO, etc. Internal monitoring is ideally transparent and adaptable to external regulators' expectations. This includes self-regulation which can be internally and/or externally verified and withstand a comprehensive audit by experts in that field.
6. It is incumbent upon food producers to ensure the fortification premix is fit for purpose and sourced from credible suppliers as quality premix is essential for producing a quality fortified product.
7. It is recommended that external monitoring is based on internationally-accepted risk analysis protocols which can guide the regulator on the level and frequency of inspection required.
8. External monitors are ideally knowledgeable about the systems they are inspecting so they can offer advice and support to industry to prevent non-compliance. They may be proactive and not restrict themselves to enforcement. These monitors are ideally subject to performance review. In many countries there is a need to build the capacity of external regulators and develop guidelines for their roles and responsibilities.
9. External monitoring, while expected to cover everything from quality of input to safety of the consumer, may emphasize monitoring at the point of production as this is where fortification takes place.
10. Under international agreements, imports need to be monitored to the same standard as locally-produced foods. Logistical constraints, such as the need to move the product out of the port facilities expeditiously, require different methodologies for regulatory monitoring of imports, such as greater reliance on certificates of analysis.
11. Monitoring at retail and household level is within the mandate of the external monitoring agency and provides valuable information regarding the quality of fortified foods throughout the food chain. Non-compliance at retail or household level needs to be investigated thoroughly. Since the producer cannot be blamed at this level, given the producer uses a verified internal monitoring system and has a clean history of external inspections of the premises, deficiencies may be due to problems anywhere within the supply chain.
12. Due to the broad mandate of the external regulator, it is often necessary to devolve authority (but not responsibility, which remains with the regulator) to regional or local agencies to conduct

monitoring on the regulator's behalf. If this is the case, it is the responsibility of the regulator to ensure that (a) monitoring is being carried out in a systematic and satisfactory manner and (b) mechanisms are in place to ensure two-way communication with the regulator.

13. External monitoring will always be easier if there is a registration and licensing system observed by food processors and/or handlers. Such registration or licensing may be the mandate of another agency and, if so, good communication is required.
14. IEC plays a key role in any sustainable food fortification programme. Thus, the regulator needs to be an integral part of the effort and ensure industry knows what to do, how and why. Mechanisms to identify and troubleshoot processing errors, and ensure good communication between the regulator and all involved in the food chain are necessary. IEC messages from the regulator need to be developed, and are ideally highly specific and presented in language appropriate to the recipient.
15. Good laboratory facilities with adequately qualified analytical personnel and access to suitable (if not the latest) technologies will enable the regulator to obtain timely analytical support and guidance in interpreting that analysis within the requirements of the technical regulations and/or standards. Screening tools, such as spot test or qualitative techniques, as well as high-level quantitative analyses, are also recommended. The laboratories, ideally, are also able to provide information relating to laboratory error in any analysis and advise if such analysis is suitable as a monitoring tool.
16. In many countries, small-scale fortification is necessary for reaching the most disadvantaged. However, it might not be possible or realistic to ensure routine regulatory monitoring in small-scale fortification enterprises. It may be necessary to establish parallel, externally-funded systems to provide small-scale facilities with the support they need to produce a quality fortified product. Standards for large-scale production may not be applicable or necessary as long as the fortified food produced is safe.
17. Fundamental to regulatory monitoring, whether for large- or small-scale fortification, is identifying the point of production or fortification so that all functioning facilities are monitored - not just those which are licensed, registered or otherwise known to the regulators.

**OPENING REMARKS BY DR SHIN YOUNG-SOO,  
WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC,  
AT THE MEETING ON REGULATORY MONITORING OF  
SALT AND FLOUR FORTIFICATION PROGRAMMES IN ASIA**

**27–29 September 2011**

**WHO Regional Office for the Western Pacific, Manila, Philippines**

DISTINGUISHED PARTICIPANTS, COLLEAGUES, LADIES AND GENTLEMEN.

It is a pleasure to host this meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia. I am especially pleased by our strong partnerships with the organizations whose collaboration, hard work and support have made this meeting possible. In particular, I would like to thank UNICEF, the Flour Fortification Initiative, the Global Alliance for Improved Nutrition — or GAIN, the Micronutrient Initiative and the World Bank for helping plan and fund this meeting. I am honoured to make these opening remarks on behalf of all our partners.

Today marks the second major event focused on Nutrition this year, in South-East Asia and the Western Pacific, following the Biregional Meeting on Scaling-up Nutrition held in Sri Lanka in August.

As you all know, fortification of staple foods is a highly effective way of improving nutritional status and public health because it does not require people to change their eating habits. By adding micronutrients to staple foods, we can help to achieve United Nations Millennium Development Goals — in particular MDGs 1 through 6. Micronutrients make a *macro* impact on development.

More than being effective, micronutrient supplementation and fortification have proven to be among the most cost-effective ways to reduce malnutrition and the resulting health and development issues it creates.

The Copenhagen Consensus is a group of leading economists, including five Nobel laureates, who analysed solutions to global problems on a cost versus benefit basis. The group concluded in 2008 that two of the three most cost-effective solutions to global problems involved adding micronutrients to food. Micronutrient supplementation for children — specifically Vitamin A and zinc — was rated Number 1, while iron and salt iodization was judged the third-most cost-effective way to attack malnutrition.

The conclusions of these top economists serve to provide further support to work that WHO and UNICEF have supported for decades and that was started as far back as 100 years ago.

The success of salt iodization programmes is perhaps the best example of the great strides possible when the food industry works with government to improve public health.

In 1990 the United Nations World Summit for Children set the goal of virtual elimination of iodine deficiency disorders — or IDD. At that time, IDD affected more than 2 billion people all over the world. IDD hurts children's ability to learn and negatively affects workers' productivity. Indeed, IDD can retard development in a country.

Thanks to a worldwide effort, the proportion of people consuming iodized salt increased from about 20% in 1990 to about 70% by 2000. This represents an increase of 350% over 10 years. But even in many countries where salt is iodized, often not enough iodine is used to erase the threat of iodine deficiency for consumers.

These are important concerns to address now, as more than 120 countries are putting salt iodization programmes into effect. Another 34 countries have already eliminated iodine deficiency with such programmes.

The key has been strong partnerships. Former United Nations Secretary-General Kofi Annan singled out the universal salt iodization and iodine deficiency disorders work as a model public-private partnership for development.

Two regions in particular — Latin America and the Caribbean, and East Asia and the Pacific — are now close to achieving the goal of 90% of households consuming adequately iodized salt. This achievement is one of many to celebrate in the Western Pacific Region, even as success has been more elusive in South Asia.

We face similar challenges with iron fortification programmes in the Region. About 2 billion people globally suffer from iron deficiency. More than half of them live in South Asia.

Experts from WHO, the World Bank and Harvard University concur that iron deficiency costs countries more than any other disease, except tuberculosis. Anaemia and even mild to moderate iron deficiency can hamper the work performance of people of all ages. The condition can cripple children's ability to learn and grow, as well as their ability to fight off infections and other illnesses.

While rice is the main staple food in Asia, wheat has proven easier to use in large-scale fortification programmes because most countries, including the Philippines, have large modern wheat mills that can supply entire markets with high-quality fortified flour.

Iron fortification is especially important for pregnant women, nearly half of whom globally suffer from anaemia, considered responsible for 20% of maternal mortality. In fact, adding multiple vitamins and minerals — including folic acid and iron — to the more than 400 million tons of wheat consumed globally each year would substantially improve health and nutrition overall, and help reduce birth defects.

But for these programmes to continue to steadily contribute to achieving the health-related MDGs, we must have strong and efficient regulatory systems in place to make certain that fortified foods meet nutritional, quality and safety standards.

The WHO and FAO Guidelines on Food Fortification with Micronutrients provide a model for monitoring and evaluating fortification programmes.

Even with clear guidelines, however, weaknesses in the regulatory monitoring systems can threaten to undermine the successes in the Region. Specifically, health officials in some countries hesitate to start mandatory wheat flour fortification programmes because of concerns about their capacity to implement and monitor them.

Another concern with salt fortification programmes is overall salt consumption. Iodized salt does not mean increasing total salt consumption. High intake of salt is a major risk factor for high blood pressure and related noncommunicable diseases, such as stroke and cardiovascular diseases.

Estimates of salt consumption in the Western Pacific Region show it is much higher than the recommended limits and is increasing in some countries. WHO encourages closely coordinating salt reduction strategies with salt fortification programmes to ensure good iodine levels while reducing the risk of hypertension and related diseases.

Precisely to help countries work through issues to build such programmes is the reason that so many partners — WHO, UNICEF, FFI, GAIN, the Micronutrient Initiative and the World Bank — have come together to organize this Meeting on Regulatory Monitoring of Salt and Flour Fortification Programmes in Asia.



In addition, we have invited representatives from various government sectors, as well as the salt and wheat flour industries, to bring together all the points of view and experience necessary to conduct successful national fortification programmes.

This mix of partners from all sides of the issue — from the public and private sectors, governments, scientific institutions, national and international nongovernmental organizations, millers and more — is our greatest strength: a good partnership is much more than the sum of its parts, a good partnership produces real and workable solutions.

With that spirit and conviction, I welcome you to Manila and wish you success in your deliberations. I look forward to reviewing your conclusions and recommendations.

But most of all, I look forward to hearing your solutions.

Thank you.



Flour Fortification Initiative  
A Public Private Civic Investment in Each Nation



**MEETING ON REGULATORY  
MONITORING OF SALT AND FLOUR  
FORTIFICATION PROGRAMMES  
IN ASIA**

**WPR/DHP/MCN(01)/2011.1  
26 September 2011**

**Manila, Philippines  
27-29 September 2011**

**ENGLISH ONLY**

**PROGRAMME OF ACTIVITIES**

**Tuesday, 27 September 2011**

08:00 – 08:30 Registration

**Opening**

08:30 – 08:45 Opening  
Dr Shin Young-soo, WHO Regional Director for the Western Pacific

08:45 – 09:10 Introduction of participants and nomination of officers (T. Cavalli-Sforza)  
Administrative announcements

09:10 – 09:20 Group photo

09:20 – 09:50 Coffee break (*Conference Lounge*)

09:50 – 10:00 Review of agenda (K. Codling)

10:00 – 10:15 The cost-effectiveness of food fortification (L. Laviolette)

**Introduction to a food control systems and regulatory monitoring**

10:15 – 10:30 Introduction to food control systems (P. Randall)

10:30 – 11:30 Pre-workshop questionnaire (Q. Johnson)

11:30 – 12:30 Lunch (*Conference Lounge*)

**Introduction to food fortification legislation and standards**

12:30 – 13:00 Food fortification legislation and standards (N. Anandavally)

13:00 – 13:20 Case study: Country experience with food fortification  
(Nepal and Viet Nam)

13:20 – 13:30 Questions and discussion

13:30 – 14:30 Group Work I: Food fortification legislation and standards

- 14:30 – 14:45            Feedback to plenary
- 14:45 – 15:15            Coffee break (*Conference Lounge*)

**Introduction to internal monitoring**

- 15:15 – 15:45            Internal monitoring: Quality control and quality assurance (Q. Johnson)
- 15:45 – 16:00            Case study: Country experience with internal monitoring  
(Salt industry representative from Indonesia)
- 16:00 – 16:15            Questions and discussions
- 16:15 – 17:30            Demonstration on new testing methods for micronutrients in food  
(P. Randall)
- 17:30                      Departure to Pan Pacific Hotel
- 18:00                      Informal reception (*Conference Suite, 7th Floor, Pan Pacific Hotel*)

**Wednesday, 28 September 2011**

**Internal monitoring (continued)**

- 08:30 – 09:30            Group Work II: Internal monitoring of flour fortification and salt  
iodization
- 09:30 – 09:45            Feedback to plenary

**Introduction to external and commercial monitoring**

- 09:45 – 10:15            External and commercial monitoring (Q. Johnson)
- 10:15 – 10:45            Coffee break (*Conference Lounge*)
- 10:45 – 11:05            Laboratory requirements for external monitoring (P. Randall)
- 11:05 – 11:45            Regulatory monitoring for fortified food in the Philippines  
(Philippines Country Team)
- 11:45 – 13:00            Lunch (*Conference Lounge*)

**Field visit**

- 13:00 – 17:00            Field visit to Food and Drug Administration (FDA) offices and flour  
milling factory

**Thursday, 29 September 2011**

**External and commercial monitoring (continuation)**

- |               |  |
|---------------|--|
| 08:30 – 09:00 | Feedback from field visit  |
| 09:00 – 10:00 | Group Work III: External monitoring of flour fortification and salt iodization                     |
| 10:00 – 10:15 | Feedback to plenary  |
| 10:15 – 10:45 | Coffee break ( <i>Conference Lounge</i> )  |
| 10:45 – 11:05 | Regulatory monitoring in small scale fortification (M. Galvin)                                     |
| 11:05 – 12:30 | Group Work IV: Development of next steps for improvements to existing regulatory monitoring system |
| 12:30 – 13:30 | Lunch ( <i>Conference Lounge</i> )   |

**Development of country plans**

- |               |  |
|---------------|--|
| 13:30 – 14:00 | Preparation of presentation                  |
| 14:00 – 15:20 | Country presentations on proposed next steps |
| 15:20 – 15:50 | Coffee break ( <i>Conference Lounge</i> )    |

**Closing**

- |               |  |
|---------------|--|
| 15:50 – 16:00 | Presentation of participants' conclusions of the meeting |
| 16:00         | Closing  |







**MEETING ON REGULATORY MONITORING  
OF SALT AND FLOUR FORTIFICATION  
PROGRAMMES IN ASIA**

**WPR/DHP/MCN(01)/2011/IB/2  
29 September 2011**

**Manila, Philippines  
27-29 September 2011**

**ENGLISH ONLY**

**INFORMATION BULLETIN NO. 2**

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