Regulatory monitoring systems of fortified salt and wheat flour in selected ASEAN countries

Annoek van den Wijngaart, France Bégin, Karen Codling, Philip Randall, and Quentin W. Johnson

Abstract

Background. *Considerable efforts have been made over the past decade to address vitamin and mineral deficiencies. An increasing number of countries in the Association of Southeast Asian Nations (ASEAN) are adopting mandatory food fortification as one of the primary strategies to overcome these deficiencies. Experience shows that fortified foods can reach large parts of the population, including the poor, if the fortification is done on a mandatory rather than a voluntary basis and if the food vehicle is widely consumed.*

Objective. *To review the importance of regulatory monitoring as an essential component of food fortification efforts in selected ASEAN countries, with special focus on the available information on regulatory monitoring systems for iodized salt and fortified wheat flour.*

Methods. *The role of regulatory monitoring in strengthening food fortification programs was discussed during a joint regional meeting of the World Health Organization, UNICEF, the Flour Fortification Initiative, the Global Alliance for Improved Nutrition, the Micronutrient Initiative, and the World Bank on regulatory monitoring of salt and wheat flour fortification programs in Asia, which took place in Manila, Philippines, on 27–29 September 2011. This paper reviews the regulatory monitoring systems of selected ASEAN countries that participated in this meeting.*

Results. *Problems and challenges in regulatory monitoring systems for iodized salt and fortified wheat flour in selected ASEAN countries are identified, and a description of the role of regulatory monitoring in strengthening food fortification initiatives, particularly of salt and flour, and highlights of areas for improvement are presented.*

Conclusions. *Regulatory monitoring consists of monitoring activities conducted at the production level, at customs warehouses, and at retail stores by concerned regulatory authorities, and at the production level by producers themselves, as part of quality control and assurance efforts. Unless there are appropriate enforcement and quality assurance mechanisms in place to stimulate compliance by food producers, i.e., regulatory monitoring, having national legislation will not necessarily lead to increased coverage of fortified products and associated outcomes.*

Key words: External and commercial monitoring, flour fortification, food legislation, internal monitoring, monitoring of imported foods, regulatory monitoring systems, salt iodization

Introduction

Global advocacy has increased political awareness of the importance of addressing vitamin and mineral deficiencies. Much progress has been made in recent years to put in place interventions to reduce these deficiencies. Most national nutrition policies include supplementation and fortification as primary strategies to reduce and prevent these deficiencies while stressing the importance of promoting dietary diversification. Food fortification is the practice of increasing the content of vitamins and minerals in a food with the aim of improving the nutritional quality of the food supply and providing a public health benefit with minimal risk to health [1].

Fortification was adopted in Europe and North America in the early part of the twentieth century to combat vitamin and mineral deficiency diseases that were prevalent [2]. Switzerland was one of the

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first countries to fortify salt with iodine to eliminate iodine-deficiency disorders, and addition of vitamin A to margarine was introduced in Denmark in 1930. During the 1930s and 1940s, flour was fortified with iron and B vitamins in a number of countries in Europe and North America. Over time, effective fortification of foods has been responsible for the prevention or correction of a range of micronutrient deficiency diseases, such as iodine-deficiency disorders, iron deficiency, pellagra, beri beri, neural tube defects, etc. Even today in the United States, fortification and/or enrichment (which is synonymous with fortification and refers to the addition of micronutrients to a food that are lost during processing) contributes significantly to intakes of vitamins and minerals such as iron, vitamin D, and folate in the population [1, 3]. In less-developed and middle-income countries, fortification is also recognized as a sustainable strategy to improve the micronutrient status of populations, as indicated in national nutrition strategies from countries such as the Philippines and Vietnam [4, 5].

Currently there are 75 countries with mandatory wheat flour fortification. The fortified flour produced represents 30% of the world's wheat flour from industrial mills. The combined population that is reached through flour fortification is more than 2 billion [6]. Since 1990, households' access to iodized salt in less-developed and middle-income countries has increased from 20% to 72%, and consequently from 2003 to 2012, the number of countries with adequate iodine intake increased from 67 to 107 [7, 8].

Food fortification has several practical advantages over other micronutrient interventions: it can be dovetailed into existing food production and distribution systems, it can increase the nutritional quality of foods or condiments that are widely consumed by the general public (usually referred to as mass fortification), and it does not require changes in eating habits. Mass fortification, when implemented under the right conditions, is recognized as one of the most cost-effective interventions to achieve a measurable impact on micronutrient status and related outcomes, with a cost–benefit ratio of 30:1 for salt iodization and 8:1 for iron fortification [9, 10]. One of the important conditions for implementation is that the government decides to make food fortification mandatory by law, i.e., food manufacturers are legally obliged to fortify particular foods with specified amounts of micronutrients in order to protect public health. Fortification can also be targeted when the food that is fortified is consumed by specific population subgroups, such as complementary foods for young children, supplementary foods for pregnant and lactating women, rations for displaced populations, or subsidized or free food for the poor [1]. Any food fortification effort calls for partnerships between the public and private sectors [11].

In the Association of Southeast Asian Nations (ASEAN), an increasing number of countries are adopting mandatory food fortification as one of the strategies to address vitamin and mineral deficiencies. Salt iodization has been mandatory by law in most countries in ASEAN for the past 10 to 15 years. Malaysia and Vietnam, which currently do not have mandatory salt iodization, are considering changing their policy. Indonesia and the Philippines have implemented mandatory flour fortification for the past decade, and Malaysia and Vietnam are both considering adoption of mandatory flour fortification. Although fortification of oil with vitamin A is mandatory in several Middle Eastern and West African countries, among ASEAN countries only the Philippines has mandatory oil fortification, although Indonesia currently has voluntarily oil fortification (with a plan to make it mandatory in 2013). For many ASEAN countries, rice is the logical food vehicle for fortification, with six ASEAN countries plus China accounting for more than 50% of global rice production and consumption. However, currently only the Philippines has mandatory rice fortification, and this is not being universally implemented. In most Asian countries, mandatory universal rice fortification is constrained by feasibility and cost issues [12] (**table 1**).

Experience from the region reflects lessons learned globally: fortified foods reach more of the population, including the poor, if they are fortified on a mandatory rather than a voluntary basis. This is illustrated by Thailand, which until recently was without mandatory salt iodization and had household coverage rates of iodized salt of around 45%, compared with 88% on average for neighboring countries [13]. Between 1994 and 2005, the proportion of Vietnamese households consuming iodized salt rose steadily from 25% to over 90%, following a decree stipulating the iodization of all salt for direct human consumption and food preparation. However, in 2005, with the belief that iodine-deficiency

TABLE 1. Mandatory food fortification in ASEAN countries

Country	Salt iodization	Staple foods fortified
Brunei	No	—
Cambodia	Yes	—
Indonesia	Yes	Flour, oil[a]
Lao PDR	Yes	—
Malaysia[b]	No (only in 2 states)	—
Myanmar	Yes	—
Philippines	Yes	Flour, oil, rice, sugar
Singapore	No	—
Thailand	Yes	—
Vietnam[b]	No	—

a. Oil is currently fortified on a voluntary basis, but fortification will be made mandatory in 2013.

b. Malaysia and Vietnam are planning to make salt iodization and flour fortification mandatory nationwide.

disorders had been eliminated, the legislation was revised to make salt iodization voluntary. Household use of iodized salt fell dramatically to a current level of just 45% [14]. The situation is similar for flour fortification; in Indonesia and the Philippines, which have mandatory flour fortification, at least 90% of all flour is fortified, whereas in Malaysia, where fortification is voluntary, only about 9% of flour is fortified [6].

However, having mandatory national legislation will not automatically lead to increased coverage of fortified products and associated outcomes. It is of equal importance to have proper enforcement and quality assurance mechanisms in place to stimulate and check compliance by food manufacturers. These mechanisms together are known as regulatory monitoring systems. Available information on regulatory monitoring systems for iodized salt and fortified wheat flour in ASEAN countries indicates problems and challenges, such as a 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. These problems, which undermine existing and possible future salt iodization and wheat flour fortification efforts, were discussed during a regional meeting on regulatory monitoring of salt and flour fortification programs in Asia.*

This paper describes the role of regulatory monitoring in strengthening food fortification programs, particularly of salt and flour, and highlights areas for improvement and the way forward in selected ASEAN countries that participated in the regional meeting.

Role of regulatory monitoring and evaluation in food fortification initiatives

Monitoring and evaluation are essential components of food fortification systems and have to be designed and planned when food fortification is started. They provide an opportunity to assess the quality of food fortification, its impact on households and individuals, and nutritional goals. It is advised that data from monitoring and evaluation be used to improve the way food fortification initiatives are implemented [1, 15].

For food fortification to have a health impact, it is essential that the fortified food maintain its expected quality from the time of leaving the factory, during storage, and up to the time of consumption. Thus, the quality of a fortified food needs to be monitored at key points along the distribution system. The aim of this monitoring is to identify points at which the quality of the fortified food is compromised, such as during production due to improper mixing of the food and fortification premix or during distribution due to inappropriate storage [1]. **Figure 1** provides a schematic representation of a model monitoring and evaluation system for fortification schemes. It distinguishes two main categories of monitoring; regulatory monitoring and household and individual monitoring. Household and individual monitoring is concerned with coverage and impact assessments and is not discussed in this article. It is important to note that unless regulatory monitoring is implemented to ensure that a quality product is reaching its consumers, there is limited value in undertaking coverage or impact assessments.

Regulatory monitoring, or food control, includes all monitoring activities at the production level (i.e., factories and packers), as well as monitoring at customs warehouses and retail stores. External and commercial monitoring is carried out by the relevant regulatory authorities at these locations. Internal monitoring refers to monitoring by the producers themselves, as part of quality control and assurance programs. The primary aim of regulatory monitoring in relation to food fortification is to ensure that the fortified foods meet the nutrient standards set prior to implementation [1].

There are three common ways in which regulatory monitoring or food control management systems are organized:

In the *multiple agency* approach, responsibilities for food control are shared between various government ministries (e.g., health, agriculture, commerce, trade, and industry) or across government agencies at different levels (central, regional, local). Involvement of multiple agencies in the food control system might have its challenges, as it takes time to develop and implement regulations, time to make changes, and time to act and coordinate unless there are urgent food safety issues.

In the *single agency* approach, all responsibility for protecting public health and food safety is combined into a single food control agency with clearly defined terms of reference.

In the *integrated agency* approach, policy, risk assessment and management, development of standards and regulations, and coordinating functions are merged in a food safety and control agency at the national level, although responsibilities for food inspection and enforcement, education and training, etc. remain with existing agencies at the national, regional, and local levels [16].

* WHO, UNICEF, Flour Fortification Initiative, GAIN, Micronutrient Initiative and the World Bank organized a regional meeting on the regulatory monitoring of salt and wheat flour fortification programs in Asia. The meeting took place in Manila, Philippines on 27-29 September 2011. Participants included salt and wheat flour producers, as well as representatives from Ministries of Health, Food and Drugs, Industry, Trade and Customs, and academia. The following ASEAN countries attended: Indonesia, Malaysia, Philippines, and Vietnam.

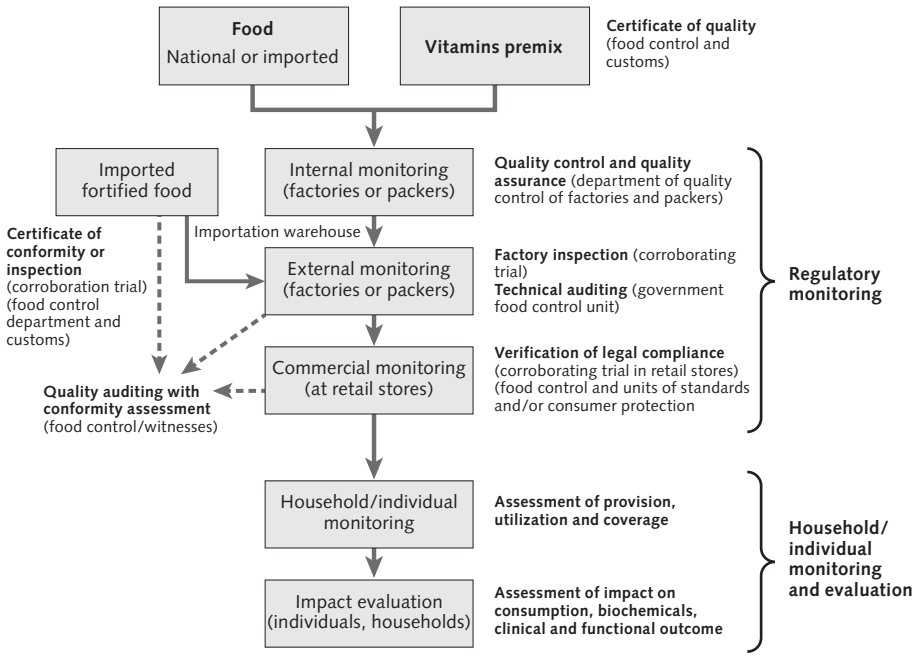

FIG. 1. Monitoring and evaluation system for food fortification. Source: Allen et al. [1]

Regulatory monitoring systems in ASEAN

Countries in ASEAN have organized their regulatory monitoring systems in different ways: the Philippines is in the process of moving from a single agency system toward an integrated system, with the Food and Drug Administration (FDA) establishing national policies and local government authorities responsible for at least some of the monitoring and enforcement. Indonesia has a multiple agency system made up of the Ministry of Industry and the Badan Pengawas Obat dan Makanan (BPOM), which is the Indonesian National Agency of Drug and Food Control under the Ministry of Health, plus local government. The Ministry of Industry is responsible for production-level monitoring, although BPOM undertakes retail monitoring. Sometimes the two agencies conduct joint production-level monitoring. As in the Philippines, local government authorities also have some regulatory monitoring responsibilities. Vietnam has a single agency system under the Vietnam Food Administration (VFA) in principle, although food fortification programs to date have been regulated by "program agencies" such as the Hospital of Endocrinology for iodized salt and the National Institute of Nutrition for fish sauce, with subsequent implications for sustainability [16].

Food legislation

Regulatory monitoring systems for fortified foods are based on national legislation, regulations, and standards, which establish requirements for foods and ideally also the expected roles and responsibilities of various stakeholders. The objectives of any food legislation are or should be the protection of health, protection of consumers' rights, and facilitation of trade in safe and healthy food. The development of food legislation has to be based on risk analysis principles. Food standards can be based either on Codex Alimentarius standards or on alternative independent, objective, and scientific risk assessments. Legislation has to be developed, evaluated, and revised in a comprehensive, open, and transparent manner, involving consultation with the public, the scientific community, and trading partners [1].

A legal framework for food fortification has to be underpinned by a Food Law, which is, ideally, brief but lays out the general principles. This legislation then has to be supported by technical regulations and standards that are based on the latest available science and/or accepted international norms. National governments should consider Codex Alimentarius standards when developing their own national food fortification standards so that they will be based on the best available science and so that trade is facilitated internationally. Food fortification standards (technical regulations) have to specify amounts and forms of micronutrients in order to ensure the effectiveness of food fortification; for example, the World Health Organization (WHO) has developed recommendations for wheat flour fortification that specify different levels of fortificants depending on flour consumption levels and also which

iron fortificants will be used, taking into account global evidence of impact and their bioavailability [17].

Unlike the optimal model, Indonesia has a number of decrees and regulations that govern salt and wheat flour fortification, rather than a regulation under the Food Act. However, the standards for the fortified foods are separate from the original decree and can be changed without changing the original decree. Thus, Indonesia has a Food Act (1996), a Law on Food Labeling and Advertising (1999), and a Law on Food Safety, Quality and Nutrition (2004). For mandatory salt iodization, there is then a Presidential Decree mandating that all salt for human and livestock consumption needs to be iodized and a Ministry of Industry Regulation on Processing, Packaging and Labeling of Iodized Salt. There is also a mandatory food standard for "iodized consumption salt" (2010). In the case of mandatory wheat flour fortification, the Ministry of Health in 1998 issued a decree recommending all wheat flour produced and distributed in the country be fortified. In 2000, the Indonesian Bureau of Standards (BSN) issued a national quality standard (SNI) for flour, which included iron, folic acid, zinc, and vitamins B_1 and B_2. In 2001, following a BSN and World Trade Organization (WTO) review, the Ministry of Industry issued a regulation mandating fortification of wheat flour as stipulated by the above-mentioned SNI. Since then, several further regulations have been issued by a variety of government agencies in support of the salt iodization requirement.*

In contrast, Vietnam's legislative framework does follow the model approach. Although Vietnam does not yet have mandatory fortification of salt or wheat flour, a recently passed Food Safety Law (2010) paves the way for mandatory food fortification, and technical regulations are currently being developed that will make salt iodization and flour fortification mandatory. **,***

Malaysia has a Food Act (1983) under which food regulations can be issued. Food Regulation 285 establishes a voluntary standard for iodized table salt or iodized salt. However, in Sabah and Sarawak states, this voluntary standard has been made mandatory.**** If Malaysia does adopt national mandatory salt iodization or mandatory wheat flour fortification, it will likely be through a similar Food Regulation.

In the Philippines, the legislation for food fortification is the result of two separate laws, which are not under a general food act. Republic Act No. 8172 mandates national salt iodization, and Republic Act No. 8976 mandates fortification of the staple foods rice, sugar, oil, and wheat flour. The standards for these fortified foods are included in these acts, which are supported by Implementing Rules and Regulations. However, for salt there has been already an amendment to the standard by way of an Administrative Order, and revised Implementing Rules and Regulations have also been issued. The way these acts are being implemented is currently being reviewed.*****

Having a national food and nutrition policy that indicates a role for food fortification is an optimal first step in the implementation of food fortification legislation. Food legislation has a tendency to be "work in progress," the Indonesian situation being a case in point. As gaps in the legislation are found, new requirements are created and small pieces of legislation are added to the legal framework. Over time, this convolution of the legal framework often makes managing the legislation unduly complex for regulatory monitoring authorities. The easiest option would be to totally rewrite food legislation, but this requires high-level government participation, which may not be forthcoming due to other priorities and would be very time-consuming. The other option is to systematically review existing legislation and make necessary amendments to ensure they are compatible with one another. Although this process can be implemented more quickly, as it uses lower-level officials, it is only a temporary measure, and the food fortification legislation still remains convoluted [16].

Internal monitoring

Internal monitoring refers to quality control and quality assurance practices as conducted by industry, i.e., producers, importers, and packers. Quality control is product-oriented and focuses on defect identification, whereas quality assurance is process-oriented and focuses on defect prevention. 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, but is made up of a variety of components and mechanisms, including premix procurement and storage controls, feeder and dosifier installation, feeder calibration, feed rate calculations, process controls (such as check weighing of premix addition), record keeping, and laboratory analysis. It also includes quantitative tests for vitamins and minerals in wheat flour and iodine in salt [16].

* Jack Bagriansky. 2011. Review of legal and regulatory framework for food fortification in Indonesia. Submitted to GAIN.

** Tran Khanh Van. 2011. Report on review of legal and regulatory monitoring system for fortified food in Vietnam. Submitted to GAIN.

*** Personal communication UNICEF Vietnam.

**** Karen Codling for UNICEF EAPRO. Review of National Legislation for Universal Salt Iodization, South Asia and East Asia and the Pacific. March 2013 (draft).

***** Philip Randall. 2010. Review of regulatory monitoring system for fortified foods in the Philippines. Submitted to UNICEF.

Internal monitoring systems tend to be better in larger production facilities that have the capacity and resources to establish strong procedures and qualified personnel to undertake them.

In Indonesia, approximately 60% of total salt is produced in large-scale facilities that have good process control procedures, laboratories, and qualified laboratory staff. The remaining 40% of salt is produced by small- and medium-scale processors that do not have the laboratory facilities to make regular quantitative measurements of iodine levels in produced salt and often do not have any process checks or controls. In contrast, all flour in Indonesia is milled in large, sophisticated domestic mills or is imported. The Indonesian mills purchase premix from reputable companies and have strong process control systems with laboratories on site. In addition to regular testing of representative samples in their own laboratory, most mills periodically send samples for verification analysis by external, accredited laboratories. Through these multiple processes, Indonesian mills have a relatively strong internal monitoring system. The situation is very similar in the Philippines, where internal monitoring systems are strong in large salt factories and all the flour mills, whereas internal monitoring is weak or nonexistent in the numerous small- and medium-scale salt production and iodization facilities, which tend to be the primary source of non-iodized or inadequately iodized salt. In Malaysia too, all flour mills are large-scale, with good internal monitoring systems, which will enable good quality assurance of fortification if it becomes mandatory. The Vietnam salt industry is similar to that in Indonesia and the Philippines, with a large number of small and medium producers with limited or no internal monitoring systems. The majority of flour is milled in large mills with good capacity for internal monitoring [16].*,**

External and commercial monitoring

External monitoring refers to the inspection, testing, and auditing activities carried out at production centers, factories and packers, and importation 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 facility has adequate raw materials, equipment, systems, and procedures in place to do this on a continuous basis. Contrary to popular perception, the objective of a monitoring visit is not to see if a sample collected on that day conforms to national regulations.

Rather, as noted above, external monitoring would aim to verify that internal monitoring is adequate and ongoing. Thus, a typical external monitoring system has the following components: mill or factory inspections (including review of records), sampling policies and procedures, laboratory analysis, and enforcement procedures. A common problem in and also outside ASEAN, especially related to salt iodization, is that often smaller salt producers are not legally registered and hence are not officially known to the government, so that inspection and testing of production facilities does not take place [16].

Commercial monitoring is also the responsibility of government and is conducted at the level of retail stores and markets. The purpose is to verify that the fortified products, or any foods, comply with national standards at the point where consumers access them. It is important to keep in mind that fortification takes place at the food processor, not at the markets or retail outlets. Thus, problems in the fortification process can only be addressed at the level of the food processor. Furthermore, there are far fewer mills and salt factories than markets and retail outlets. Thus, limited resources for monitoring would ideally focus on ensuring that all domestically produced food meets national regulations before it leaves the production facility or that all imported food meets national regulations before leaving the point of importation. This is more efficient and easier than trying to identify substandard foods in the market and then tracing them back to the production or import source. Commercial monitoring is mainly helpful when foods are coming from unknown sources (which cannot be monitored), such as illegal imports or from nonregistered producers [16].

In the Philippines, the external monitoring system for iodized salt and fortified flour suffers from a general lack of resources and ongoing reorganization of the newly formed Food and Drug Administration. The Philippines also has many non-licensed salt producers that are not monitored. These producers are often not licensed because they do not meet Good Manufacturing Practices (GMP). Yet there are limited efforts to help them improve their operating standards, and there is no political will to close them down. External monitoring of flour fortification is less problematic, but problems exist with the quality of laboratory analysis and the time taken to get laboratory results; yet these results are relied upon to hold imports in port and administer penalties to mills for noncompliance.***

In Vietnam, external monitoring of salt iodization is not systematic and there appear to be no updated

* Tran Khanh Van. 2011. Report on review of legal and regulatory monitoring system for fortified food in Vietnam. Submitted to GAIN.

** Philip Randall. 2010. Review of regulatory monitoring system for fortified foods in the Philippines. Submitted to UNICEF.

*** Philip Randall. 2010. Review of regulatory monitoring system for fortified foods in the Philippines. Submitted to UNICEF.

guidelines on monitoring at the industry or market level. Moreover, the current guidelines have not been properly implemented*. Clearer roles will hopefully be identified in a new decree on production and marketing of food-grade salt under the new 2010 Vietnam Food Safety Law.**

Flour mills in Indonesia are inspected to check whether their production is in compliance with 16 SNI parameters, including 5 related to fortification. For salt producers, iodine content is one component of a comprehensive set of quality parameters outlined in the SNI. Production-level monitoring is primarily undertaken by the Ministry of Industry, which sees its role as supporting industry. Thus the results of these inspections are often kept confidential and used to improve performance rather than impose sanctions. BPOM, on the other hand, is an enforcement agency and will bring action against producers found in noncompliance with the SNI. The problem is, however, that BPOM's activities tend to focus on the retail level, as their mandate is to ensure food standards and safety for the consumer, whereas the solution to any problems found will usually lie at the production or import level.***

Monitoring of imported foods

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

Monitoring of imports must include review of all available documentation, including a certificate of analysis from the exporting country if available, to assess whether the imported food complies with national regulations. A certificate of analysis is an authenticated document, issued by an appropriate authority, that certifies the quality and purity of pharmaceuticals, foods, or animal and plant products being exported [18].

In addition, laboratory or quantitative testing will have to be applied, especially if there is no certificate of analysis. For example, it is advised to test all incoming salt quantitatively to verify if it is adequately iodized. Imports of flour can usually be assessed on the basis of a certificate of analysis. Care is needed to ensure that all sampling and testing or collaborative protocols meet Codex Alimentarius and WTO standards, since imports that do not meet national regulations in principle will have to be rejected, which is then an international trade issue [19].

Malaysia has no domestic salt production, so all salt is monitored, and salt iodization is mandatory only in the states of Sabah and Sarawak. However, monitoring at the point of entry or retail level is not routine practice. It is not clear if the limited manpower of the responsible agency within the Ministry of Health for external monitoring is the only reason for this [16].

About two-thirds of all salt in the Philippines is imported, usually in a non-iodized form. It is then supposed to be iodized in country. Control of imports in the Philippines is therefore about trying to ensure that incoming non-iodized salt that will flow into the food system is iodized in a domestic salt processing facility. As already noted, however, many of these are not registered. In contrast, samples of imported flour are collected at the importer's warehouse prior to clearance for release. This process is coordinated closely in the Philippines between the Bureau of Customs and the FDA.****

In Indonesia, the Customs Office of the Ministry of Finance monitors imported foods for compliance with their respective SNIs. Monitoring of imports is based on a certificate of analysis. Often the inspections are implemented in collaboration with BPOM. The infrastructure of both organizations is strong at major port facilities in Indonesia, but it is difficult to monitor shipments at small ports of entry throughout the country.*****

Laboratory analysis

Laboratory analysis plays an important role in regulatory monitoring, both internal and external. However, the results of laboratory analysis are subject to several sources of variation and do not provide conclusive evidence of compliance or noncompliance. Over-reliance on laboratory results can therefore be very misleading and counterproductive to ensuring high-quality fortified food. Food inspectors will have to consider laboratory analysis in combination with additional critical information, including information obtained from mill or factory inspections [16].

In Indonesia, the task of laboratory analysis of fortified flour facing the authorities has been complicated

* Tran Khanh Van. 2011. Report on review of legal and regulatory monitoring system for fortified food in Vietnam. Submitted to GAIN.

** Personal communication UNICEF Vietnam.

*** Jack Bagriansky. 2011. Review of legal and regulatory framework for food fortification in Indonesia. Submitted to GAIN.

**** Philip Randall. 2010. Review of regulatory monitoring system for fortified foods in the Philippines. Submitted to UNICEF.

***** Jack Bagriansky. 2011. Review of legal and regulatory framework for food fortification in Indonesia. Submitted to GAIN.

by a regulatory approach specifying that all five micronutrients listed in the SNI be analyzed in each and every sample. As a consequence, investment of laboratory resources per sample is high. Moreover, considerable energy and resources are devoted to micronutrients that are exceedingly difficult to measure in flour because they are labile (such as the B vitamins) or added in minute quantities (such as folic acid), or because the margin of error in laboratory tests is exceedingly wide. Therefore, these results may not be reliable. More importantly, because these results are official—and potentially associated with legal action and damage to company image — industry must respond.*

A technical solution, which is applied in South Africa [20] and other countries, would be to focus quantitative analysis on "marker" micronutrients such as iron that are easier to measure because they are added to flour at a higher level. If the vitamins and minerals are found in proper proportions in the premix, then the easier, less expensive, and more accurate analysis for iron can serve as a marker for the adequacy of other micronutrients. This recommended approach implies greater regulatory effort and focus on quality assurance of the premix and the associated certificate of analysis from the premix supplier [16].

Non-laboratory testing methods and technologies

In general, the gold standard for food testing, including testing for vitamin and mineral content, is a quantitative test in a laboratory. However, there are a number of non-laboratory methods of qualitative testing that determine the presence or absence of a vitamin or mineral (spot tests), or semi-quantitative measurement, which provides an approximation of vitamin or mineral content within a range.

Two examples of a spot test are the iodine spot test (usually referred to as the rapid test kit or RTK) and the red spot test for iron. With the RTK, a blue color indicates the presence of iodine. Due to differences in salt texture, purity, and color and inter-observer variation, it is unreliable to use the test kit to assess whether a representative salt sample has exceeded a minimum iodine level, although RTKs are often marketed as semi-quantitative methods. Certainly in regulatory monitoring, the test kit cannot be used both by producers for internal monitoring and by regulators for external monitoring. At best, the test kit can indicate if a certain batch of salt has been iodized, for example, as a screening step in retail monitoring.

In the red spot test for flour, dark red spots indicate the presence of added iron (the test does not identify intrinsic iron). This test can detect the presence of all of the common iron fortificants in flour. Similar to the iodine spot test, it cannot indicate the level of iron. However, it does indicate that iron fortificant was added, and if this is premixed with other fortificants it indicates that the flour has been mixed with the fortification premix. If factory documents indicate that premix has been added in the right amounts, these records, together with the certificate of analysis of the premix and the results of the iron spot test, can be used together to confirm that the flour has probably been correctly fortified.

Spot tests have the advantage of being cheap and very fast, giving a yes or no answer in a matter of seconds. They can also be used by regulators to identify obvious representative non-compliant samples for further investigation.

Non-laboratory equipment also exists for quantitative measurement of iodine in salt that uses a low-cost spectrophotometer, such as the WYD Checker or the iCheck Iodine, to measure the intensity of the color created by the reaction of reagents with the iodine [21, 22]. Semi-quantitative and quantitative equipment also exists for measuring vitamin A in flour, oil, and sugar.

An increasing number of these new technologies can provide qualitative, semi-quantitative, and quantitative assessments without the need for sophisticated laboratories or highly trained laboratory staff. These new technologies make vitamin and mineral assessment cheaper, easier, and quicker but have disadvantages in terms of accuracy. Nevertheless, an important contribution of these non-laboratory techniques is that they make final product testing available to all, even small- and medium-scale producers. Some of the technologies that provide high-quality quantitative assessments could potentially also be endorsed for legal enforcement, which requires validated quantitative techniques [16].

Conclusions

Although progress on food fortification is impressive in some ASEAN countries, the results are still fragile. Reviews of the regulatory monitoring situation in selected ASEAN countries show that there are several weaknesses that are undermining the effectiveness and sustainability of current fortification efforts. In several countries, government monitoring takes place primarily at the retail level, which is ineffective and inefficient. Existing legislation on food fortification often does not contain sufficient information on the roles and responsibilities of different regulatory agencies and how they ideally would collaborate. Nor does it describe fully the responsibilities of the industry. Both regulators and industry focus on end-product testing more than

* Jack Bagriansky. 2011. Review of legal and regulatory framework for food fortification in Indonesia. Submitted to GAIN.

process control and internal quality assurance systems. Another common problem is that regulatory monitoring is focused on facilities that are registered or have a license to operate, or on legal imports, rather than on the producers of all food available to consumers. This is especially relevant with regard to salt from nonregistered processing facilities.

Most countries recognize weaknesses with external monitoring, including lack of manpower and routine systems and over-reliance on and problems with laboratory analysis. Several countries have or are considering transferring some responsibility for external monitoring to provincial or district authorities. Such transfer accesses additional resources but also requires oversight and coordination to ensure that external monitoring is undertaken comprehensively, appropriately, and fairly throughout the country.

Way forward in regulatory monitoring of fortified salt and flour for ASEAN countries

In several ASEAN countries, mandatory fortification programs for salt and flour have been ongoing for many years. Efforts to develop legislation, create public awareness, develop consumer demand, and increase supply are numerous and the same attention and resources should be put towards ensuring strong regulatory monitoring systems. Over the next few years, fortification programs will probably expand to include additional foods and condiments to address micronutrient deficiencies in populations. Strengthening regulatory monitoring systems will be critical to ensure the success of these fortification activities in improving the health and nutrition of the populations and the sustained overall impact of these efforts. Regulatory monitoring systems need to be designed taking into account the nature of the food processing industry as well as the country's legislative framework and the capacities of regulatory government authorities.

External monitoring of both salt and flour fortification remains far from perfect, and streamlining the monitoring closer to the production site, increasing the focus on process monitoring rather than laboratory results only, and providing sufficient resources for laboratories and technical personnel, as well as defining roles and responsibilities of regulatory agencies and the private sector, need to be prioritized. With decentralization already happening in several countries, coordination with subnational authorities (provincial or district) is also essential to ensure comprehensive and adequately resourced monitoring systems.

In light of recommendations coming from the regional workshop, observations from the country reviews, and the authors' own views, key areas for improvement and the way forward are highlighted below for both salt iodization and flour fortification.

Salt iodization

The priority action needed in existing salt iodization systems is to ensure regulatory monitoring, both internal and external, of the facilities that produce the majority of the country's salt, whether they be all facilities in a certain geographic area (e.g., salt-producing area) or a group of facilities that have the majority of the market. In countries in which small- or medium-scale producers produce a large proportion of the salt, such as the Philippines, Indonesia, and Vietnam, the authorities are advised to enable these producers to become licensed so that they can be supported and monitored. In some situations, it may also be necessary to strengthen or set up associations or cooperatives of small processing facilities in order to increase their capacity to produce quality iodized salt. Lessons can be learned from the Cambodia experience, where development of a salt producers' association greatly increased the supply of iodized salt*. Providing training and retraining on iodization systems and internal monitoring for both small-scale and larger salt processing facilities is recommended to build capacity to produce quality iodized salt in countries. In countries where salt is imported, there is a need to ensure the quality of imports through requirement of pre-shipment certificates of analysis and periodic analysis by at least semi-quantitative means.

Flour fortification

Overall, the regulatory monitoring of wheat flour is much better than that of salt. However, the regulatory monitoring of mandatory wheat flour fortification in ASEAN countries could be improved by increasing the focus of monitoring on verification of the quality and addition of premix and other process monitoring instead of relying only on analyzing samples of fortified flour. Where there are problems with laboratory analysis of some micronutrients, it is advised to choose one micronutrient in the premix that can serve as a marker for the entire premix.

In Malaysia and Vietnam, where wheat flour fortification will become mandatory in the near future, it is necessary to plan ahead for proper mechanisms for regulatory monitoring with the relevant government and private sector actors. This will have to include training on internal monitoring with a special focus on process control, development of mechanisms and guidelines for routine external monitoring at the mill and retail levels, and dedication of appropriate resources for adequate and effective regulatory monitoring. Involvement of industry at the planning stage of mandatory flour fortification is also essential.

* Conkle J, Carton T, Un S, Berdaga V. Case study on a decade of universal salt iodization in Cambodia. January 2012 (draft).

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