

# Regulation of Fortified Foods to Address Micronutrient Malnutrition: Legislation, Regulations, and Enforcement

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## *Author's Note on This Revised Edition*

This manual was first published with UNICEF support, in 1994 as the *Food Fortification Legislation and Regulations Manual*. This second edition incorporates comments from reviewers and is the culmination of further field application, not only with respect to salt iodization but also includes sugar fortification with vitamin A and fortification of wheat flour with iron. This edition also addresses enforcement issues and is made possible with the support of the Micronutrient Initiative (MI).

The manual has progressed to address these new topics as they have become increasingly more relevant to micronutrient programming. In doing so, it reflects the issues national programs now critically face as they have matured over the decade dedicated to the elimination of micronutrient malnutrition. Most nations are positioned to meet the end decade goal of universal salt iodization (USI) but still face raw salt leakage and salt with inconsistent iodine content in the market. National programs, thus, are concentrating their efforts on quality assurance and enforcement so that they may fine tune the programmatic achievements gained in order to reach and sustain the end decade goals for iodine deficiency elimination. Programs also are turning more attention to the regulatory and programmatic challenges associated with vitamin A and iron fortification.

Finally, lessons learned from salt iodization are contained in the following pages to assist governments with planning and implementing comprehensive regulation for all future fortification activities. These activities are likely to continue well into the next millennium. Many of the lessons learned from salt iodization come from participation in the March 1998 East African Workshop on Quality Assurance, Monitoring, and Enforcement. Experiences of individuals intimately involved in inspection and enforcement functions in some 9 different countries (and less intimately involved in another 6 countries) were shared, and problems and suggestions for regulatory enhancement were explored, along with overall programming issues.

# *Foreword*

This manual uses a model approach for the creation of food fortification legislation and regulations. This approach is based on the idea that principles of general applicability can be implemented when establishing or amending the regulatory framework to provide for food fortification and related activities. It recognizes, however, that different countries have different legal systems and different requirements for law-making, with the result that laws and regulations take different forms in different countries. Nonetheless, there tends to be a remarkable similarity among the food laws of many countries, even those with different legal systems. The manual's contents are based on composite provisions of the food control laws and regulations of many developing countries. It contains principles and provisions that most countries should be able to apply to varying degrees to their own situations.

The manual concentrates on laws in the form of legislation. Governments may be able to enact laws in the more expedient form of executive orders, decrees, or other enactments. These other forms will allow them to avoid the more cumbersome legislative process. However, legislation tends to be more permanent and may be more widely applicable. The underlying principles and provisions provided should be useful for whatever form the legal enactment takes.

## **Taking a General Fortification Approach and Strengthening Regulatory Provisions**

Where a law change is necessary to mandate or allow fortification of particular foods, the manual suggests that governments follow a general approach that authorizes the Ministry to set forth in regulations the requirements and standards for food fortification. This approach is in contrast to amending the food law in a piecemeal fashion to address fortification of a particular food vehicle with a particular nutrient. It is recommended because it is more flexible and efficient.

During the early- to mid-1990s, most governments enacted separate legislation for salt iodization without addressing iron, vitamin A, or other nutrient fortification of foods. This was done, in part, because the political will clearly existed for creating salt iodization legislation but not necessarily for a broader legislative change to encompass fortification generally. Some of those governments that now wish to address fortification with other nutrients are faced with the prospect of enacting additional legislation to cover those nutrients. Where a law change is required, this should be used as an opportunity not only to address additional nutrients but also to strengthen general provisions related to ensuring safe and quality fortified food products. For example, many governments report weak inspection and enforcement systems and some do not require the food industry to routinely practice quality assurance during production or at other points in the food distribution chain. In such cases, it would be beneficial to strengthen the entire regulatory framework as a measure to support current and future fortification programming.

## **Legislation and Regulations as One Component of a Fortification Program**

Establishing legislation and/or regulations should be one of the first steps in a fortification program. Legislation and regulations provide the government with the legal authority to carry out fortification as an integral component of its micronutrient deficiency elimination program. At its most basic function, provisions in the law (and regulations) allow the government to compel or allow the food industry to supply fortified foods as appropriate.

Advocacy also plays a crucial role. Convincing high level officials of the importance of eliminating micronutrient deficiencies is necessary to gain enactment or amendment of the law itself as well as an economic commitment for the fortification program that follows. Developing legislation and regulations and advocating for the overall program go hand in hand. In fact, the process of drafting and enacting legislation can be an important form of advocacy, as discussed in Chapter 1.

It also is critical to advocate to and work with the food industry to gain its acceptance of fortification and make it a full partner in the program. This, along with creating awareness and stimulating demand on the part of consumers for appropriate fortified foods should encourage the industry to want to comply with the law. There are numerous other components of an effective and sustainable food fortification program, such as the existence of an adequate infrastructure for quality control and regulation, technological capability, human capacity, and monitoring and evaluation of the program's efficacy and sustainability. While regulatory provisions and systems are critical, they alone will not ensure a successful fortification program without accompanying efforts in these other sectors.

### **Use of This Manual**

This manual is designed to serve as a guide for governments wishing to ensure that their food laws and regulations contain adequate provisions for food fortification and related (e.g, enforcement) activities. It proceeds under the assumption that most countries already have in existence some type of food control law and regulations. It further assumes that most governments also have enacted separate salt iodization laws and regulations, but that neither the general food control law nor the salt iodization law provides for fortification with iron, vitamin A, or other nutrients.

The manual is designed to help program managers understand the purposes and critical contents of regulatory provisions. It also is designed to provide some programmatic information to legislative drafters who might not be otherwise associated with the national micronutrient program. Ideally, a trained legislative drafter will work with program staff to create the appropriate legal authority for fortification. Where there is no such local draftsman available, the manual may be useful for the program staff charged with drafting the regulatory provisions.

In cases where non-lawyers will be drafting the regulatory provisions, they are encouraged to seek some legal assistance, externally if necessary, prior to finalizing their drafts. Legal consultation is available from PAMM and MI. FAO, the European Union, and other agencies and organizations also may be able to provide such assistance. Additionally, the author recommends that the FAO and WHO publications in the bibliography be consulted for the basic tenants and principles for food control programs and food laws in general.

## I. Introduction

### A Micronutrient Malnutrition: An Overview of the Problem

The preventable or controllable disorders resulting from insufficient dietary intake of essential micronutrients such as iodine, vitamin A, and iron are unacceptably prevalent in much of the world. Reduced intellectual capacity, cretinism, deaf-mutism, physical deformity, blindness, increased morbidity and mortality associated with certain infections, severe anemia, developmental delay, and attention deficits are some of the manifestations of micronutrient malnutrition causing needless suffering and lost potential for billions of individuals throughout the world. (Maberly, 1994).

#### *Iodine Deficiency*

Iodine deficiency disorders (IDD) have been acknowledged as the leading cause of intellectual impairment throughout the world. (Hetzel, 1986). In 1990, when Heads of State declared their commitment to eliminating IDD, an estimated one billion people throughout 95 countries, or over 20 percent of the world's population, were at risk for IDD. (WHO, 1991). At risk populations include those living in cities as well as in rural and mountainous areas. With the global push for universal salt iodization, most countries have reported decreases in the prevalence, although no comprehensive data are yet available.

#### *Vitamin A Deficiency*

Deficiencies in vitamin A are the leading cause of preventable blindness throughout the world. (West, 1989). Forty million pre-school aged children are believed to be vitamin A deficient, with 13 million believed to have resulting eye damage to varying degrees. An estimated half million people go blind annually as a result of severe vitamin A deficiency. (Sommer, 1981).

In addition to vision impairment, vitamin A deficiency is responsible for increased morbidity and mortality from measles and infections of the respiratory and gastrointestinal tract. (Keaton, 1992; WHO, 1992). On a global level, WHO reported the population at risk of vitamin A deficiency (women of child-bearing age, infants, and young children) to be about 800 million. (WHO, 1992).

#### *Iron Deficiency*

Iron deficiency primarily affects young children and women, especially pregnant women. Twenty percent of all maternal deaths occur as the result of severe anemia during pregnancy. (Levin, 1990). In milder cases, anemia decreases physical capacity and productivity. Approximately 50 percent of women and 20 percent of men in developing countries suffer from iron deficiency anemia. (Ramalingaswami, 1992).

In addition to the effects of micronutrient malnutrition on individuals, the socio-economic consequences for entire populations and the development potential of nations must be considered. Increased morbidity and mortality, along



with decreased cognitive and physical abilities, result in substantially diminished productivity within the work force as well as decreased capacity to learn. This diversion of human resources, along with the accompanying diversion of financial and medical resources, significantly interferes with global and individual nations' social and economic development goals.

## **B Food Fortification as One Means of Addressing the Problem**

National governments and the world community, by and through the World Summit for Children (New York, 1990) and the International Conference on Nutrition (ICN) (Rome, 1992), and other fora, have recognized the role of food fortification as an important and sustainable strategy for eliminating or substantially reducing micronutrient malnutrition. Specifically, the ICN Plan of Action for Nutrition calls on governments, international agencies, non-governmental organizations (NGOs), industry, academia, other expert groups, and the community to collaborate, among other things, to ensure and legislate for the fortification of foods or water with necessary micronutrients, where feasible, when existing food supplies fail to provide adequate levels in the diet. Where iodine deficiency is a significant public health problem, the iodization of all salt for both human and livestock consumption is required, recognizing that this is the most effective long range measure for correcting iodine deficiency.

— *International Conference on Nutrition Final Report of the Conference* (FAO, WHO: Rome, December 1992), pp. 43–44.

## **C The Need for Adequate Legislation and Regulations**

In order for governments to undertake effective food fortification activities, it is necessary that they first ensure their laws and regulations provide legal authority and an adequate regulatory framework. Effective regulatory controls protect consumers against the risk of purchasing and consuming nutritionally inadequate, deceptively mislabeled or misbranded, impure, or unsafe foods. With a strong law and regulations that are enforced, noncompliant manufacturers and sellers will not be able to profit by supplying inferior products that do not comply with established standards. Thus, regulation creates a “level playing field” for food manufacturers and sellers.

## **II. The Role of Law in Furthering Public Health Goals**

Law is a means for planning and directing social change. It is an instrument for regulating human conduct by compelling compliance with standards established by the government to protect and promote the well being of its people. Dr. Kwame Nkrumah, First President of the Republic of Ghana, captured the lofty role of law when he said, “The law should be a legal expression of the political, economic, and social condition of the people and of their aims for progress.” (Hutchinson, 1968).

In addition to the very practical benefit of gaining the authority for food fortification as a means of enhancing the population's nutritional and health status, fortification provisions in the law also can be viewed as an advocacy tool. By adopting or amending a law specifically to address food fortification, the government helps establish efforts to combat micronutrient malnutrition as a priority for the nation. In doing so, the government shows its commitment to its citizens, to international and donor agencies, and to the world community.

## **III. Principles Underlying Effective Legislation and Regulations**

### **A A Country's laws should reflect the will and interests of its people.**

The legitimacy of a law that does not genuinely represent the will and the interests of the people probably will (and should) be questioned. People are more likely to comply with a law that they believe to be in their best interest. Equally important, they are more likely to insist that others also comply with the law.

Many national governments and the international community already have determined fortification to be in the best interest of populations who cannot otherwise obtain adequate nutrition from existing food supplies. If their citizens do not already share this determination, governments should undertake efforts to communicate the devastating effects of micronutrient malnutrition and the important health and developmental benefits of appropriate fortified foods to address micronutrient deficiencies.

**B****There should be a way for interested parties to have input into the development of the law and regulations.**

Because fortification of food is a multi-sectoral activity dealing with matters of science, technology, industry, nutrition, health, and the like, the law and regulations will benefit from the input of expertise by representatives in each of these areas. Since food is produced and traded by the food industry in most cases, not the government, it is absolutely critical that industry representatives be involved from the beginning of programmatic and regulatory planning and drafting. Input from all involved sectors will help ensure a realistic approach that recognizes both capabilities and limitations. Finally, input from a broadly-based group of interested persons should prevent the exertion of undue influence by any one powerful interest.

Many countries have established multi-sectoral food boards or commissions to serve in some capacity with respect to setting food standards and overseeing general aspects of the food law. Although many countries have mandated food advisory boards as part of the law, it probably is better to establish such boards as a matter of policy rather than of law. If the board becomes stuck or dominated by one or two strong interests, it will be difficult to move forward.

**C****The provisions of the law should allow flexibility.**

Legislation can contain broad, enabling provisions establishing the purpose and boundaries of the law and vesting the appropriate ministry with the authority and discretion to promulgate implementing regulations to administer the law. This is the approach taken in this manual.

Alternatively, the law can specify most or all aspects of its execution, leaving little discretion for the ministry in charge. This method is inherently less flexible because legal requirements can be changed only by going through the entire legislative process again. With the former method, the Ministry can amend the regulations setting forth the legal requirements through the established process for promulgating and amending regulations. It generally is easier and quicker to amend regulations than to amend a law.

However, there may be legal, political, or customary reasons for establishing detailed legislation rather than broad, enabling legislation. For example, if the ministry charged with administering the law is subject to political influence by powerful interests, it may not be advisable for the law to vest it with a great deal of discretion. If there is no compelling reason to the contrary, a more flexible law generally is advisable.

**D****The law should set a framework for addressing future needs.**

As discussed in the foreword, the law can address not only one particular aspect of fortification, such as salt iodization, but also can provide broader provisions for fortification of foods in general. In such a case, the law would vest the appropriate ministry with discretion to establish fortification requirements (or set food compositional requirements) through regulations. That way, as technology advances or the assessment of populations' nutritional needs changes, the law will not have to be amended to address new nutrient fortification. Rather, regulations can be established or amended to require or permit other fortification activities.

**E****The law should state clearly what is required or prohibited so that people will know how to act.**

If people do not understand what the law and the regulations require, they will not be able to comply, even if they have the desire to do so. It also is important that the law and regulations be clear so that government officials will know what is expected of them when called upon for enforcement, including being able to tell whether or not a violation has occurred.

**F****The law should provide a device for enforcement.**

Many countries' laws require food manufacturers, sellers, and others in the industry to have a licence or be registered to operate. The licence or registration then can be restricted, suspended, or revoked if the licensee does not meet requirements embodied in the law and regulations. This creates a powerful enforcement device. Furthermore, licensing or registration can serve an important information tracking function for program monitoring.

## **G** The law should provide for quality assurance.

The law should require the food industry to test and inspect products and processes routinely to be sure they meet the standards specified in the law and regulations before selling, trading, or otherwise distributing the food. The law can set out the general requirement of practicing quality assurance and the regulations can set out the quality assurance procedures and activities that must be followed.

## **H** The law should vest the government with adequate inspection and investigative powers.

To enable the government to check on compliance, it must be able to inspect the premises, processes, products, and records of any manufacturer, seller, or other commercial holder of food. It also must be able to take and analyze food samples. It is critical for inspections to go beyond mere physical inspections of premises — inspectors should examine processes and procedures during production to be sure that the product is quality assured to meet standards. Reviewing the company's QA records will allow the inspector to get more than a snapshot view. These records will reflect the company's QA processes and its ability to identify and correct problems promptly over time. Verification of the company's implementation of an effective QA system should give inspectors confidence of the company's ability and likelihood of complying with legal requirements.

## **I** The law should provide both incentives and penalties to encourage and compel compliance.

The government's ability to enforce the law and regulations is crucial to the success of food fortification programs. Effective enforcement is supported by having and implementing both incentives and penalties that are well balanced and promptly applied.

## **J** The law should treat everyone equally and fairly.

The law and regulations should contain provisions to ensure fair and equal treatment of those subject to regulation. Similar enforcement actions must be taken for similar violations, so that everyone will be treated equally and fairly. Before taking an enforcement action for failure to comply with the legal requirements, the government should allow the person accused of violating legal requirements an opportunity to contest the charges.

## **K** The law can authorize citizens' suits and private rights of legal action.

As an adjunct to government enforcement, the law can allow consumers to take legal action against the manufacturers and sellers of food who do not comply with legal requirements. This will enable private citizens to take legal action if government enforcement is weak. Even if the legal system currently is not set up for individuals to have easy access to the courts, setting a framework for such activities can be an important consideration for future capabilities.

## **L** Regulatory requirements may need to be phased in over time.

If the food industry is not yet prepared to meet new stringent standards that might be required for any particular fortification activity, the government might want to phase in more stringent production and packaging requirements over time. This can provide a realistic approach and give industry time to gear up to meet the new requirements.

## **IV. Some Policy Considerations**

Before a government undertakes to develop legislation, it must make certain policy decisions, such as:

- whether new legislation is necessary or desirable, or whether the existing law and regulations are adequate to regulate food fortification;
- if a law change is called for, whether to amend the existing food control law or to enact a separate law to provide for fortification;

- whether to limit the legislation to a particular food fortification activity (e.g. salt iodization) only or to enact a more general food fortification law;
- whether the existing regulatory infrastructure is adequate for proper enforcement or whether it needs to be improved;
- whether to introduce legislation at the national or provincial level, taking into consideration issues of consistency with standards in effect in neighboring countries and trading partners so as not to create impediments to the importation of adequately fortified foods; and
- whether to make fortification with a specific nutrient mandatory or permissive.

## **A** Whether Legislation is Necessary or Desirable

A country's existing food control law might be adequate to allow or mandate fortification without even mentioning the word "fortification". This might be the case if, for example, the law authorizes the ministry to establish food standards in regulations and does not define any term in a way that might preclude fortification. (See discussion under Section 2: Definitions.) In such a case, it might not be *necessary* to enact legislation to amend existing law. Rather, regulations can be amended to compel or allow certain foods to be fortified.

If amendment of the law is not necessary, it still might be *desirable* to introduce legislation for advocacy purposes (to declare efforts to combat micronutrient malnutrition a priority, as discussed in the Foreword and in Chapter 1). More significantly, it might be desirable to amend the law to strengthen its provisions on enforcement and other similar matters if they are not especially strong or inclusive. The desire to *improve* a law that is basically adequate to fulfill the government's purpose with respect to fortification will have to be balanced against political and time constraints, competing priorities, etc.

## **B** Whether to Amend the Existing Food Control Law or Enact Separate Legislation for Food Fortification

If the government decides that legislation is necessary or desirable, the decision then becomes whether to introduce legislation to amend the existing food control law or to enact a new, separate law for food fortification. An advantage to amending the existing law is that all applicable legal provisions governing food are found in one law rather than in numerous laws. This makes it easier to find the relevant provisions for the industry that must comply with them, for the regulators charged with enforcing them, and for members of the public interested in knowing what protections exist. If the existing law requires substantial amendments, however, it probably will be easier and less confusing to enact a separate, new law to address fortification.

## **C** Whether to Limit the Legislation to a Particular Fortification Activity Only or to Enact a More General Food Fortification Law

As we progress through the decade, governments are enacting regulatory provisions for vitamin A, iron, and other nutrient fortification in addition to salt iodization. Rather than enacting separate laws for vitamin A fortification, for iron fortification, and for other nutrient fortification, one law change can be made to vest the appropriate Ministry with authority to set food standards, including those for nutritional goals, in implementing regulations. This will achieve maximum efficiency and reduce the need for new legislation in the future.

## **D** Whether to Improve the Regulatory Infrastructure

A law is only as effective as the government's ability and willingness to enforce it. Governments considering legislation for food fortification should use the prospect of new legislation as an opportunity to examine whether the regulatory infrastructure under the existing food control law is effective and efficient. The government should improve it if it is not.

To determine whether the regulatory infrastructure is sufficient, it is necessary to take a hard look at the authorities charged with inspecting and compelling compliance with legal requirements. Do they have the resources, training, knowledge and political will to enforce the law? Do they do so in an evenhanded manner? Do they need additional supervision

by an outside authority? Are there such serious problems with inspection and enforcement that these powers should be vested elsewhere? Are there innovative ways to enhance the government's ability to enforce in light of limited resources?

For example, a requirement in the law and regulations that the industry practice QA and make QA records available for inspection will help with the inspection and enforcement process. It will do this in three ways:

- food quality will improve with the food companies' routine practice of QA;
- reviewing QA records can serve as a means of overseeing the food production *process*, which is critical to ensuring food quality in a systematic way; and
- review of QA records may even be possible off-site, enhancing the inspection process and increasing its efficiency.

Thus, if there is no regulation for industry to practice QA, this should be addressed in any amendments to the law and/or regulations. If the government is not able to enforce its existing food control law, there is no reason to believe that it will be able to enforce new food fortification requirements. If it cannot, any law for food fortification will be meaningless. The government should be forward thinking, yet realistic, in framing inspection and enforcement provisions. It should set high standards and rigorous legal requirements, phasing them in over time if the full capacity for meeting the requirements presently is lacking. At the same time, however, the government must begin the process of providing additional resources, training, and supervision necessary to ensure that any new legal requirements can be met. As mentioned earlier, delayed implementation dates for provisions that cannot be met at present are one way to address this situation.

This process calls for a careful balance, for if either the industry or the inspecting and enforcing authorities cannot meet newly established requirements, the law will not be taken seriously. A message will be sent that the legal requirements are meaningless and can be ignored. In such a case, more rigorous legal provisions will do more harm than good.

## **E** Whether to Introduce Legislation at the National or Provincial Level

As a general rule, standards for fortification should apply nationwide and not just in "endemic" areas or particular provinces. If different provinces have different standards for foods or manufacturing processes, it will be virtually impossible to administer or enforce the law since food is manufactured, sold, and consumed across provincial borders.

Therefore, it will be desirable to enact legislation at the national level rather than at the provincial level. This will ensure consistency of legal requirements and facilitate administration and enforcement of the law. However, there may exist constitutional, customary, or political constraints that make it necessary to enact legislation at the provincial level (such as in countries operating under a decentralized governance system). In such cases, there still will need to be some centralized policy guidance to encourage the development of consistent provisions among the provinces.

## **F** Whether to Make Fortification Mandatory or Permissive

### **1. Salt Iodization**

General consensus arising out of the WSC and ICN was that governments should make salt iodization mandatory (i.e. endorse the concept of Universal Salt Iodization (USI) prohibiting non-iodized salt from entering the consumption marketplace. Some governments, however, believe that consumers must have the option of choosing either iodized salt or non-iodized salt. Where there is a strong ideological belief that consumers must be given the right to choose the type of salt they consume, it may be politically impossible to mandate USI.<sup>1</sup>

1 Regulation, by its very nature, restricts individuals' choices, however, balanced against the restriction on individual liberty to choose non-iodized salt are the health and safety protections gained for the entire population by making salt iodization mandatory. By way of analogy, many countries have mandatory seat belt laws for vehicle drivers and passengers. Such laws have been challenged by some individuals claiming an undue restriction on personal freedom. Most governments, nonetheless, have found that the potential health and safety benefits for the entire population far outweigh those individual restrictions. Other examples are compulsory vaccination and compulsory primary education. An argument for USI can follow these lines. Additionally, almost all countries have ratified the International Convention on the Rights of the Child. This international instrument can be used as an argument in favor of USI. Signatories have committed to protecting the rights of developing and young children, the population most at risk for iodine deficiency, to achieve their maximum health and development potential. These rights, balanced against an adult's right to choose non-iodized salt merely on the basis of preference, clearly should prevail.

Where salt iodization will not be mandated, enforcement becomes more of a challenge. Additionally, programming efforts must pay particular attention to communications and social marketing activities to stimulate consumer demand for iodized salt over non-iodized salt. While such activities are important whether or not salt iodization is mandated, they are even more critical when it is not. Careful attention also must be paid to understanding demand elasticity based on price. The price of iodized salt must not exceed the price of non-iodized salt to the extent that consumers will choose non-iodized salt because it is significantly cheaper. Consumer preferences for packaging and other characteristics of salt must be known as well to ensure that consumers will choose iodized salt over non-iodized salt where both are available in the market. An understanding of all these factors will be necessary before attempting to establish regulatory requirements. This will allow the design of appropriate requirements that will support the program's objectives.

USI is much more preferable where it is politically and legally feasible to mandate that all salt for human or animal consumption be iodized. Where this is not the case, permissive iodization is a viable alternative, but one that requires additional efforts by the government. It also will require additional enforcement resources since inspecting will become much more of a challenge with both types of salt allowed in the market.

## **2. Fortification With Other Nutrients: Iron and Vitamin A**

Fortification with iron and vitamin A may call for a strategy that promotes fortification of carefully chosen food vehicles but that does not necessarily make it mandatory. In part, this is because multiple food vehicles may be appropriate for iron, vitamin A and other nutrient fortification. Also, other natural dietary sources of these nutrients exist, unlike the case with iodine. If the fortificant is to be carried in only one vehicle, (e.g., iron fortification of wheat, vitamin A fortification of sugar), mandatory fortification likely will be administratively more efficient. If more than one vehicle will be fortified, the population's dietary habits and potential sources and intake amounts of the particular nutrient will have to be well understood in deciding whether to make fortification mandatory or permissive.

Standards for fortified foods specifying nutrient levels and other properties for the fortified vehicle will need to be carefully set out in regulations. The food and populations' nutrient levels will need to be monitored in either mandatory or permissive fortification schemes, but this is especially critical where fortification of more than one vehicle with the same nutrient will be allowed and/or where other sources in the diet for the nutrient are available. Monitoring should be handled as a programmatic requirement and does not require legal provision for it.

## **V. Some Lessons Learned from Salt Iodization**

### **1. Advocacy is a critical component of any micronutrient program.**

In those countries where there have been extensive advocacy activities targeted at both government policy makers and the food industry, policy makers have undertaken the legal mandate and industry has provided significant input into the laws and regulations enacted. As a result, there tends to be greater ownership and acceptance of regulatory requirements. This should result in greater compliance.

Likewise, funds for micronutrient activities have been allocated to the nutrition budget in many countries in greater proportion than in prior years as a result of commitment on the part of policy makers. Additionally, inter-sectoral collaboration among the implementing government ministries has been fostered, making inspection and enforcement more feasible. In some cases, industry-targeted advocacy has even resulted in the food industry assuming an educational and awareness creation role with other industry partners/purchasers. It is this type of involvement and commitment that likely will bring about both programmatic success and sustainability.

### **2. Program monitoring is essential.**

Periodic monitoring of program components is essential for two reasons: 1) it will help determine whether program objectives are being met and 2) monitoring the product will ensure that it is safe and effective. In a few cases, monitoring revealed that iodine levels were too high, resulting in isolated cases of thyrotoxicosis.<sup>2</sup> Prompt corrective action taken on periodic monitoring results can ensure a safe and efficacious program.

Likewise, shelf-life of fortified products may need to be monitored, as recommendations for packaging and nutrient levels are based on general conditions that may not be the precise conditions in any particular country. Thus, the recommendations and legal provisions based on them may need to be fine-tuned over time to meet local conditions.

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2 Findings From 7-Country Study in Africa on Levels of Salt Iodization in Relation to Iodine Deficiency Disorders, Including Iodine-Induced Hyperthyroidism. WHO/UNICEF/ICCIDD Consultation (1997).

It is preferable for governments to set requirements as precisely as possible based on existing recommendations and monitor results rather than to wait to begin fortification until all conditions are known completely. There will always be some degree of the unknown until actual experience is gained, but monitoring will ameliorate potential risks.

There is a good deal of overlap between regulatory inspections and program monitoring data. Thus, monitoring and inspection information should be coordinated and shared with all decision-makers in the micronutrient program. Program monitoring, as that term is used in this manual, is meant to evaluate the status of the program to ensure that program goals and objectives are being met. Regulatory inspections, on the other hand, are an exercise of government power to ensure that regulatory requirements are being met. Inspection results provide the basis for taking enforcement action in cases where noncompliance is found.

By way of illustration, program objectives might include access by all households to iodized salt. If households are found to be consuming non-iodized salt in a particular region, this alerts program staff that they need to determine the reasons and possibly adjust program activities to address the situation (such as increasing consumer awareness activities). No regulatory action would be taken against the households. If it were found from interviewing household members that they purchased the salt from a particular retailer or retailers selling non-iodized salt in violation of regulatory requirements, remedial action would then be taken against the responsible parties in the industry providing the non-iodized salt.

**3. *Regional coordination will enhance national efforts to eliminate micronutrient malnutrition.***

Salt importers are dependent on their trading partners to supply them with appropriately fortified products that meet standards in their own countries. Given that the populations of trading partner countries are likely to share micronutrient problems (and also possibly climatic and other conditions), it makes sense for trading partner governments to collaborate in standards setting (assuming consumption patterns also are similar). Cooperation also in setting QA requirements and verification methods will be beneficial. Governments that are members of the Codex Alimentarius Commission and World Trade Organization (WTO) have pledged to create uniform standards to the extent practicable in order to facilitate trade. Against this background, regional collaboration will both enhance programmatic objectives and facilitate trade.

**4. *The most effective way to draft legal requirements is to use combined expertise in a way that links technical drafting, programmatic knowledge, and industry capability.***

Although not absolutely necessary, it is best for a lawyer to draft the provisions of the law and regulations. However, the lawyer should work *closely* with someone who can give the necessary programmatic input. It also is essential to get input from industry, consumers, and other stakeholders from the very beginning of the process. This will help create a sense of commitment to the program and the process and acceptance of the resulting requirements. Some countries have called groups of stakeholders together to draft regulatory provisions for food fortification during a workshop or retreat. Others have come up with draft provisions as a starting point for discussions and called the stakeholders together to review them and make appropriate changes prior to sending them through the legal process for enactment. Whatever form it takes, broad stakeholder input must be solicited and obtained in formulating regulatory requirements for food fortification.

### I. Key Provisions for Legislation to Authorize or Mandate the Fortification of Food

As discussed in the foreword, this manual assumes that most countries already have a food control law. It further assumes that the existing law does not specifically address fortification. Nonetheless, the existing law may contain similar provisions to some or all of the provisions described below, especially those that are central to any food control law (e.g., provisions related to inspection and investigative powers, enforcement, etc.) Thus, many of the provisions described below may already be a part of any particular country's food law.

This chapter *describes* provisions for inclusion in a food law to encompass fortification, along with the rationale behind the provisions. Governments can adopt the principles underlying the provisions in whatever form or manner and to whatever extent they deem appropriate.

#### ***Section on Purpose and Scope***

There usually is a section that includes a description of the provisions of the legislation and a statement describing the purpose of the act (i.e., the legislation). For example, in the case of fortification, the purpose would be to amend the existing food law to authorize and/or mandate fortification of certain foods to address and alleviate nutritional deficiencies (and to otherwise promote the nutritional status and health of the people). This section also should recognize that effective fortification efforts depend upon an effective overall regulatory system. Thus, a further stated purpose of the act should be to strengthen existing enforcement and related provisions in the food law to ensure the effective regulation of foods.

It also can include a statement recognizing the preventable effects micronutrient malnutrition has on the health of individuals, on the productivity of the population (and on livestock), and on the potential development of the nation. It should mention the effectiveness (medical and cost-effectiveness) of undertaking fortification activities to combat micronutrient malnutrition.

This section further might provide that a specified ministry is given power to determine what foods are required to be or may be fortified. The ministry also should be given power and discretion to set appropriate standards for foods and to regulate food quality and safety.

***Rationale:*** *These paragraphs will serve an advocacy function, making fortification a government priority and setting out the reasons for the law. They also empower the appropriate ministry with the discretion to work out the broad enabling provisions of the law (which will provide the flexibility described earlier).*

#### ***Section on Definitions***

This section should define all key terms used in the law. For example, "adulteration" must be defined in such a way that it does not preclude the addition of fortifying agents to food. "Food" should be defined as being intended for human, or, as specified in regulations, animal consumption.

***Rationale:*** *If key terms are not defined, people may have to guess what they mean. This may affect the interpretation of the law and lead to unintended results.*



### ***Section on Applicability and Exemptions***

This section should provide that the law applies to all food imported, manufactured, distributed, traded, or sold for human or, as specified in the implementing regulations, animal consumption in the country, or for export.<sup>3</sup>

This section further should provide for limited, carefully tailored exemptions if the law makes the addition of particular nutrients to food mandatory. Exemptions should be allowed for people with possible medical contraindications or other legitimate objections to the fortified food. The law or regulations will have to specify how exempt foods are handled.

***Rationale:*** *By listing all of these stages in the food production–distribution chain in delineating its application, the law seeks to cover all food and hold each person in the food chain responsible for compliance with the law. If the law does not allow for controlled exemptions, compliance might become a problem. Also, the law should recognize that there may be instances where the law should not apply. Without appropriate exemptions, the law may be considered unreasonable and may be challenged legally.*

The section covers food intended for animal consumption as well as for human consumption so that there will be no loophole through which noncompliant food eventually enters the market for humans. Also, undernourished livestock will benefit from fortified foods in some cases, making them more productive.

### ***Section on Administration***

There should be a section giving the ministry authority to carry out the administration and enforcement of the law, including making rules and regulations to implement the law.

It should empower the ministry to issue regulations that include provisions for the following:

- (a) specifying which foods may or must be fortified and to what specifications, including nutrient levels to ensure the appropriate level of nutrients in foods at the time of consumption;
- (b) standards for composition, nutritive properties, strength, potency, purity, quality, hygiene, safety, and other properties of food;
- (c) methods of manufacturing, packaging, storing, transporting, and distributing foods;
- (d) labeling and advertising of foods;
- (e) quality assurance, including record-keeping requirements, for food industry;
- (f) procedures for ministry inspections, investigation, sampling and testing;
- (g) enforcement, including legal proceedings; and
- (h) any other matter necessary or desirable for the efficient and effective administration and implementation of the law.

***Rationale:*** *This section gives the ministry broad discretion, within the boundaries of the law, to establish specific requirements that must be followed to comply with the law.*

### ***Sections Containing General Provisions***

These sections should set out the main requirements of the law governing the food industry. The provisions of this section should cover the following:

- (a) ***General Requirements.*** There should be a section that requires all persons involved in the importation, manufacture, packaging, labeling, advertising, storage, display, delivery, distribution, trade, sale, or exportation of food to comply with the requirements specified. The section should specify that violators are subject to penalties for substantial noncompliance as specified in the provisions governing enforcement.

***Rationale:*** *This section is intended to broadly cover every person involved in the food industry so that no loopholes exist through which food not meeting the requirements of the law can enter the market.*

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<sup>3</sup> Substances that would constitute food if intended for consumption but instead are intended for industrial purposes and other non-consumption purposes, by definition, are not covered by law. An example is salt used for tanning leather.

- (b) **Warranties.** This section can provide that every person who deals with food commercially is deemed to warrant to the immediate purchaser that the food conforms to all legal requirements and to the specifications on its label.

*Rationale: A warranty, whether written or implied, provides a clear basis for the purchaser to take legal action against the seller if the product does not conform to the warranty. In combination with the defense provisions contained in the law, it also will protect from liability commercial purchasers who, in good faith and without knowledge of defects, then sell nonconforming products to consumers.*

- (c) **Licensure or Registration.** This section should require the ministry in charge of enforcing the law to establish or apply a licensing or registration system for persons who import, manufacture, sell, or export food, if such licensure does not already exist.

*Rationale: This section provides the enforcement device referred to in Chapter 1. Additionally, a licensure/registration system allows the government to keep track of the businesses required to be licenced/registered and can be helpful in program monitoring.*

- (d) **Quality Assurance.** This section should require all manufacturers, importers, packagers, and other commercial holders of food to conduct routine internal checks to ensure that the food is manufactured, packaged, labeled, stored, transported, and maintained in accordance with all legal requirements. It should authorize the ministry to specify quality assurance requirements and procedures in the implementing regulations. Not all intermediaries would be required to test the food in their possession, however.

*Rationale: The industry should conduct self-regulating activities since it ultimately is responsible for complying with legal requirements. Also, such activities will enable the industry to identify any changes in its methods and procedures that need to be made to ensure its compliance with the law.*

- (e) **Packaging.** This section should require the packaging of food in accordance with requirements established by the ministry in regulations to preserve the composition, quality, and purity of food and to minimize dissipation of its nutritive properties from climatic and other conditions.

*Rationale: Without properly taking into account environmental and climatic effects on foods, the beneficial properties of the fortifying agents could be lost as a result of packaging that does not protect against environmental effects. This is especially true in the case of iodized salt. On the other hand, packaging for iron fortified flour is not so important for retaining nutrient content.*

- (f) **Labeling and Advertising.** This section should require that all packaged foods be labeled in a way that is true and accurate and that provides minimum essential information specified by the ministry in regulations. It also should require that any advertisement be true, accurate, and not misleading.

*Rationale: This section is intended to provide essential information about the product and protect the consumer from false or misleading claims. It also will allow the government to trace noncompliant foods back to their sources.*

- (g) **Transport, Storage, and Display.** This section should require that food be transported, stored, and displayed in accordance with requirements established by the ministry in regulations to preserve the composition, quality, hygiene, and safety of food and to minimize dissipation of its nutritive properties from climatic and other conditions.

*Rationale: Without properly taking into account environmental and climatic effects during the transport and storage of foods, the beneficial effects of the fortifying agents may be lost.*

### **Section on Inspections and Investigations**

- (a) **Inspection and Investigative Powers.** This section should provide the appropriate ministry or ministries with power to appoint authorized officers (inspectors) and provide them with the power and resources to inspect and investigate any place or site where food is manufactured, stored, sold, transported, distributed or located anywhere in the country. It should give authorized officers access to the premises and any contents and persons found on the premises. Authorized officers also should be given the authority to observe production processes, examine and copy records and take samples and analyze them or have them analyzed. They also should be authorized to seize food they reasonably suspect does not comply with legal requirements.

This section further should provide authorized officers with the power to stop, search, and detain any means of transport or storage in order to conduct any inspection or investigation. It should require all persons to cooperate with any inspection or investigation and provide true, accurate, and complete information reasonably requested by an authorized officer.

***Rationale:** Inspections and investigations are the primary means by which the ministry can check on compliance. Without adequate powers of inspection and investigation, enforcement becomes impossible and illusory.*

- (b) **Operation of Analyzing Laboratory or Laboratories.** This section should govern laboratories that examine and analyze any food samples taken by the government. It should authorize the ministry to establish procedures for the laboratory's operation, including sample analysis, preservation of evidence, and quality assurance procedures for the laboratory itself.

***Rationale:** This section provides safeguards to ensure accurate analysis results.*

### **Section on Enforcement**

- (a) **Civil and Criminal Enforcement Actions.** This section should provide the ministry with broad enforcement powers. For example, it can authorize the ministry to enforce the requirements of the law and regulations civilly through the imposition of fines, cease and desist orders, licence/registration restrictions, suspension or revocation, adverse publicity, and other appropriate means. It also can make a willful violation of the law or regulations a crime punishable by fine and/or imprisonment upon conviction. In addition, it should authorize the ministry to order the reprocessing or reconditioning, or the seizure and destruction of food determined not to be in compliance with legal requirements.
- (b) **Legal Proceedings.** This section should provide any licensee, or other person or entity accused of violating the law, with the right to a hearing after notice of the charges, before a penalty is imposed and/or before food is destroyed. Most countries' laws provide for a hearing through the court process. However, there may be precedent under other laws in the country for *administrative hearings*, or hearings before the Ministry proposing the enforcement action. If allowed under the country's legal system, an initial administrative hearing before the Ministry charged with enforcing the law may be a more efficient and less costly process for enforcement. Any ministry decision then would be subject to appeal in court. If there will be a system for administrative hearings before the Ministry, this section should authorize the Ministry to establish applicable hearing procedures in compliance with any legal safeguards already established in the country's laws.

This section also can provide the Ministry to recover, when successful, its costs incurred in taking the enforcement action.

- (c) **Defenses.** This subsection should provide a defense for any person in the commercial production-distribution chain whom:
- (1) purchased the food or food product from another providing a *written* warranty;
  - (2) handled the food in a manner in compliance with legal requirements;
  - (3) sold, traded or distributed the food in the same condition it was in at the time of its purchase or reconditioned it to meet legal requirements; *and*
  - (4) could not have discovered, through the exercise of reasonable diligence, that the food did not conform to legal requirements.

The burden of proving the conditions for invoking the defense should rest on the person charged with noncompliance. The issue of speed of hearing for highly perishable commodities should be taken into consideration.

- (d) **Citizens' Suits and Private Rights of Action.** This section can allow individuals who purchased food that does not meet legal requirements to pursue a court action independent of any government enforcement action taken. It can provide for the award of a fixed sum of money as damages for consumers who can show a violation of the law, along with an award of the costs of undertaking any legal action.

***Rationale:** These sections give a variety of enforcement options to hold violators accountable. They also allow the protection of innocent commercial intermediaries who are deceived by the seller despite the exercise of reasonable diligence. Vesting individual consumers with power to enforce independently of the government provides a mechanism for enforcement when the government is unable or unwilling to take comprehensive enforcement action.*

### ***Section on Special Treatment of Fortified Foods***

This section can establish transport priority, favorable tax or tariff treatment, patent rights, or other measures to promote food fortification and to reward those properly engaged in fortification activities. Depending on the legal requirements governing law making, it may be necessary to establish financial incentives under a different law.

***Rationale:*** *Compliance is more likely to be achieved if it is encouraged as well as compelled.*

### ***Section on Standardization***

This section can provide that in establishing standards for food, including fortification, the ministry must consider the standards established by the Codex Alimentarius Commission if the country is a Codex or World Trade Organization (WTO) member.

***Rationale:*** *Consistency with Codex standards draws upon the expertise already established, helps facilitate trade among Codex and WTO member nations, and is required by the Codex and WTO agreements.*

### ***Severability***

This section can provide that if any provision of the law is determined to be illegal or invalid, all remaining provisions are to remain in full force and effect.

***Rationale:*** *This section is intended to save the remainder of the law if only part of it is found invalid, rather than having the whole law thrown out.*

### ***Section on Effective Date and Repeals***

This section should provide the date or event upon which the act becomes effective (if this date is not already established under the country's legal system). It also should provide that inconsistent provisions in existing laws covering the same areas are repealed and superseded by the provisions of this act.

## **II. Trade Considerations: Food Standards and International Trade**

As mentioned above, the Codex Alimentarius provides guidance for setting standards for foods. Codex member countries are required to follow guidelines set by the Commission or explain why deviations from the standards are necessary. In addition, the WTO adopts Codex standards as the governing standards upon which national governments should base their own standards. Countries that are members of the WTO may not set food standards or impose taxes, customs, or tariffs that are trade protectionist in nature, (i.e., that intentionally or unintentionally restrict trade). However, national governments usually may set higher standards so long as they truly are required for health or safety (or environmental protection) and not as a pretext for trade protectionism. It is important to consult all trade agreements to which the standards drafting country is a member to be sure that any standards set are consistent with the terms of applicable agreements.

Even in the absence of the Codex Alimentarius or trade agreements, standards should be set, where possible, to be consistent with trading partner countries' standards. This will eliminate unnecessary barriers resulting in higher costs ultimately borne by the consumer.

### Model Legislative Provisions for Fortification

Many countries will not need to amend the law at all and can concentrate instead on amending the regulations to address fortification and to strengthen provisions on inspections, enforcement, quality assurance, and other critical provisions. For those countries, however, that will need to amend the law, actual language for legislative provisions for food fortification and for enforcement and other crucial activities needs to be developed.

This model takes the approach of mandating salt iodization, since this approach for eliminating IDD has been accepted by most governments. The model addresses fortification with other nutrients by authorizing the Ministry to determine what other foods may or must be fortified in implementing regulations (See Section 6). If a law is passed in this form, it should not be necessary to amend it to provide for fortification of new food vehicles with other nutrients in the future. Rather, the regulations would be amended to provide standards for the new vehicles and nutrients.

The model also assumes that fortification with iron and vitamin A may be permissive rather than mandatory (See Section 9). By presenting the model in this way, the manual recognizes the reality that most governments have not yet fully determined how they will deal with other nutrient fortification. Thus, the model is designed to provide the most flexibility to address various micronutrients.

If legislation is introduced to enact a separate law rather than as an amendment to existing law, similar provisions already in the existing law (e.g., on licensing) can be referenced and incorporated in the new legislation without having to repeat them (as long as the risk of adverse changes to the referenced existing law is low).

### A Integrating the Model Provisions into the Existing Food Control Law

Assuming a food law already exists and will be amended, the model legislation will not be introduced in the format presented in this manual. Parts of it will have to be integrated into appropriate places in the existing law. If, for example, the existing provisions on enforcement contain some but not all of the concepts contained in the model provisions on enforcement, the existing provisions on enforcement can be chosen over the model provisions and retained. Alternatively, they can be deleted in their entirety and replaced with the model provisions in their entirety. Finally, parts of the model provisions on enforcement can be added to the existing provisions on enforcement as appropriate.

For each section of the legislation, there will need to be: 1) introductory language explaining what provisions in the existing law are being deleted altogether, 2) what existing provisions are being replaced and the language that will replace them, and 3) what new provisions are being added. The model provides precise wording for the substantive provisions. However, the actual wording of the sections of the legislation will depend upon the provisions in the existing law that are being amended. It also will depend on the style and form for enactments to amend existing laws in the country.

**Note:** Underlined provisions in the following text signify particularly important provisions to address food fortification comprehensively (they would not be underlined in the actual legislation).

## **B** An Outline of the Model Food Fortification Act

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**Section 1: Purpose and Scope**

**Section 2: Definitions**

**Section 3: Applicability and Exemptions**

(a) Applicability of the Act

(b) Exemptions

**Section 4: Administration**

**Section 5: General Provisions**

(a) Prohibitions

(b) Warranties

(c) Licensing of Food Importers, Manufacturers, Distributors, Sellers, and Exporters

(d) Quality Assurance

(e) Packaging

(f) Labeling and Advertising

(g) Transport, Storage, and Display

**Section 6: Fortified Foods**

**Section 7: Inspection and Investigation Powers of the Ministry**

(a) Inspections and Investigations

(b) Appointment of Authorized Officers

(c) Powers and Duties of Authorized Officers

(d) Operation of Analyzing Laboratories

**Section 8: Enforcement**

(a) Civil Enforcement by the Ministry

(b) Criminal Enforcement

(c) Legal Proceedings

(d) Defenses

(e) Private Right of Action

**Section 9: Special Treatment of Fortified Foods**

**Section 11: Standardization**

**Section 12: Severability**

**Section 13: Effective Date and Repeals**

## **C** Model Food Fortification Act

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**Preamble:** An Act to amend [name of existing food control law, citation to law], to regulate the nutritional properties of food, specifically mandating the iodization of salt and authorizing the fortification of other foods, and for incidental matters, by addressing the law's applicability and exemptions; prohibitions; warranties; licensing of food importers; manufacturers, distributors, sellers, and exporters; quality assurance; packaging, labeling and advertising; transport, storage, and display; fortified foods; inspection and investigation powers of the ministry; inspections and investigations; appointment of authorized officers; powers and duties of authorized officers; operation of analyzing laboratories; enforcement; civil enforcement by the ministry; criminal enforcement; legal proceedings; defenses; private right of action; special treatment of fortified foods; and standardization.

## Section 1: Purpose and Scope

Recognizing the devastating effects of preventable micronutrient malnutrition on the health of individuals, on the productivity of the population and of livestock, and on the development potential of the nation, and in support of the declarations and plans of action from the World Summit for Children (New York, 1990), the International Conference on Nutrition (Rome, 1992), and other fora, the national government undertakes the introduction and passage of this Act.

The entire population is at risk of iodine deficiency disorders, resulting in reduced intellectual capacity even in the case of mild deficiency. Other forms of preventable micronutrient malnutrition lead to blindness, anemia, and other health problems that reduce productivity and human potential. However, relatively simple and inexpensive technology exists for the fortification of certain foods to eliminate or control these problems.

The purpose of this Act, therefore, is to amend the provisions of [name of current food control law], [citation to law], relating to [topic of food act, e.g., food quality and safety] to provide specifically for the mandatory iodization of salt as a means of eliminating iodine deficiency disorders and to authorize the Ministry of [specify ministry to be charged with administering the law] to require or permit the fortification of other foods to address and alleviate other nutritional deficiencies of the people of [name of country] and to otherwise promote their nutritional status and health.

The purpose of this act further is to amend the provisions of [name of food control law] to strengthen and promote the effective regulation of foods.

## Section 2: Definitions

As used in this Act, the following terms shall be given the meanings described below:

- (a) **“additive”** means any substance or mixture of substances intentionally added to food for the purposes of preventing deterioration, affecting aroma, color, or flavor, or modifying or preserving the general physical condition of a food. The addition of essential nutrients to foods shall not be considered additives.
- (b) **“adulterate”** means to add any substance or ingredient to a food in order to give it a false or misleading value or to hide defects; to remove any substance or ingredient that results in diminution of a food’s nutritive or other desirable properties; or to subject food to any process or treatment that injuriously affects its nature, quality, nutritional value, or other properties.
- (c) **“advertisement”** means any representation by any means for the purpose of promoting directly or indirectly the sale, distribution, or consumption of any food.
- (d) **“authorized officer”** means an officer appointed by the ministry or otherwise authorized to carry out duties under the provisions of this Act.
- (e) **“distribute”** with respect to food means to exchange, transmit, convey, consign, supply, deliver, trade, sell, or dispose of, whether or not for remuneration or other consideration.
- (f) **“drug”** means any substance or mixture of substances, other than food, manufactured, sold, or advertised for use in humans or animals in the diagnosis, treatment, mitigation, or prevention of any disease, disorder, or physical or mental impairment, or the signs or symptoms thereof.
- (g) **“essential nutrient”** means any substance, normally ingested, that is necessary for growth, development, and maintenance of health and which is not synthesized in adequate amounts by the body.
- (h) **“export”** with respect to food means to send from this country to another country for distribution in another country.
- (i) **“food”** means any substance or mixture of substances intended in whole or in part for human or, as provided in regulations, animal consumption, including beverages and excluding drugs. All ingredients of such substances, including those used in their manufacture and processing, themselves shall be considered food subject to the provisions of this Act.
- (j) **“fortified food” or “enriched food”** means any food to which one or more essential nutrients, such as vitamins, minerals, proteins, essential amino or fatty acids, or other nutritional substances have been added in order to increase the nutritive value of the food and which are absent from the food in its original state or which are lost during normal manufacturing, storage, or handling. Fortified or enriched foods shall not be considered to be drugs.

- (k) **“import”** with respect to food means to bring into the country from another country for sale or distribution in this or another country.
- (l) **“ingredient”** means any component or substance, including an additive or fortifying agent, used in the manufacture of a food and present in its final product.
- (m) **“iodized salt”** means salt to which iodine has been added for the purpose of fortifying it as a means of combating iodine deficiency disorders resulting from dietary deficiencies in iodine. When intended for human or animal consumption, either alone or as an ingredient in other substances or mixtures of substances, salt shall be considered a food.
- (n) **“label”** means any tag, brand, mark, logo, written or pictorial design, or other descriptive matter on, attached to, included in, belonging to, or accompanying any food.
- (o) **“licence”** means authorization pursuant to the provisions of Section 6(c) of this Act from the Ministry of [ ] to import, manufacture, distribute, sell, or export food.
- (p) **“logo”** means any symbol authorized by the Ministry for use on the packaging or label of certain foods to signify approval by the government.
- (q) **“manufacture”** with respect to food means the making or composing of a food product, including its production, preparation, processing, preservation; combination with other components, substances, ingredients, or products; grading, or other treatment.
- (r) **“minister”** means the Minister of [name of Ministry charged with administering and enforcing the law].
- (s) **“ministry”** means the Ministry of [ ].
- (t) **“package”** means anything in which any food is partially or wholly covered, wrapped, attached, enclosed, contained, or packed.
- (u) **“person”** means any individual, licensee, business, corporation, firm, partnership, proprietorship, organization, agency, association, facility, or other entity.
- (v) **“premises”** means any building, stall, tent, cart, or any other structure, whether fixed, temporary, or mobile, together with the land on which it is situated and any adjoining land used in connection with it, and includes any vehicle, vessel, or aircraft.
- (w) **“regulatory requirements”** means the provisions of all applicable laws, regulations, decrees, and other government enactments relating to food quality and safety, nutrition, hygiene, and any other aspect of food regulation or control.
- (x) **“sell”** with respect to food means to offer, expose, or prepare for sale, trade, or exchange, transmit, convey, consign, supply, deliver, distribute, or dispose of for human or animal consumption for any consideration.

All words and terms not defined herein shall be given their plain and customary meanings and shall be interpreted in accordance with the context in which they appear.

### **Section 3: Applicability and Exemptions**

- (a) **Applicability of the Act.** The provisions of this Act shall apply to all food imported, manufactured, packaged, labeled, stored, transported, displayed for sale or distribution, distributed, or sold in the country, or exported from the country. The provisions of this Act shall not apply to any food that is grown or cultivated and consumed solely by an individual or his or her own family or animals.
- (b) **Exemptions.** In cases where this Act or its implementing regulations mandate the fortification of any particular food, the Ministry may authorize that there be made available for restricted distribution and sale, limited quantities of that food in its original state. Such food shall be labeled, stored, distributed, transported, and made available for sale only at specified locations and under conditions prescribed by the Ministry in regulations.



## Section 4: Administration

The Ministry shall establish and amend, as appropriate, implementing regulations which include provisions for the following:

- (1) specifying which foods are required to be fortified and which foods may be fortified;
- (2) standards for composition, nutritive properties, including fortification, strength, potency, purity, quality, safety, hygiene, and any other properties of food;
- (3) licensing procedures and requirements;
- (4) conditions and requirements for the import and export of food;
- (5) conditions and requirements for the manufacture of food;
- (6) conditions and requirements for the storage and transport of food;
- (7) requirements for packaging, labeling, and advertising of food;
- (8) conditions and requirements for the distribution, display, and sale of food;
- (9) quality assurance procedures and requirements to be followed by food manufacturers, importers, packagers, wholesalers, and retailers, including record-keeping requirements;
- (10) procedures and requirements for Ministry inspections and investigations;
- (11) procedures and requirements for sample taking and analysis, including preservation of evidence and certification of analysis results;
- (12) procedures and requirements for seizing, detaining, condemning and destroying or otherwise disposing of food that does not meet regulatory requirements;
- (13) procedures and requirements for enforcement, including cost recovery to the government;
- (14) legal proceedings;
- (15) prescribing anything which is to be or which may be prescribed under this Act;
- (16) exempting food from provisions of this Act;
- (17) any other matter necessary or desirable for the efficient and effective administration and implementation of this Act.

*(The above provisions represent a composite taken from provisions in the laws from the Bahamas, Botswana, Nigeria, Zambia, Zimbabwe, as well as from the author's own experience with regulation and legislative drafting).*

## Section 5: General Provisions

- (a) **General Requirements.** Subject to the provisions of subsections 1 and 2 and any exemption authorized by the Ministry, all persons who import, manufacture, package, label, advertise, store, transport, display for sale or distribution, deliver, distribute, sell, or export food shall carry out their activities in a manner that complies with all applicable regulatory requirements. Any person found to have substantially violated any applicable regulatory requirement shall be subject to the enforcement provisions of Section 8.
  - (1) Where food that does not meet the regulatory requirements of this country is imported into the country, it shall be subject to confiscation. As an alternative, it may be reconditioned, re-labeled, repackaged or otherwise treated as necessary to cure any area of noncompliance with regulatory requirements. While undergoing any curing process, it shall be identified clearly and stored separately from all other food. If not cured within an appropriate period from the date of entry into the country, as established in regulations, such food shall be subject to forfeiture and destruction as well as any other penalty under Section 8.
  - (2) Food intended for export that does not meet the regulatory requirements of this country but that does meet the regulatory requirements of the importing country may remain in this country for an appropriate period established in regulations. Any such food shall be clearly labeled as intended for export only and shall contain a warning that it is not authorized for sale or consumption in this country. Additionally, it shall be stored separately from all other foods. Strict record keeping as required by the Ministry and in regulations shall be followed for export food under this subsection.

- (3) If any commercial seller or distributor discovers that any food in his/her possession or control does not meet regulatory requirements, he/she shall: a) return it to the seller from whom it was purchased, who shall be responsible for reconditioning it or replacing it with food that meets regulatory requirements and/or compensating the purchaser for any loss incurred; b) recondition it so that it meets all regulatory requirements or re-label it for non-consumption purposes; or c) destroy it.
- (b) **Warranties.** Every person who imports, manufactures, displays, distributes, sells, or exports any food is deemed to warrant to the immediate purchaser that it handled the food in conformity with all regulatory requirements and that the food meets the specifications on its label and in any advertisement. If no written warranty is provided to the ultimate consumer, a warranty nonetheless shall be implied.
- (c) **Licensing of Food Importers, Manufacturers, Distributors, Sellers, and Exporters.** No importer, manufacturer, distributor, seller, or exporter of food shall operate or advertise its business without having a licence as provided in this section [or as provided in [cite to law governing licensure of businesses]].
- (1) An application for an initial licence shall be made to the Ministry on forms and in a manner prescribed by the Ministry and shall be accompanied by any prescribed fees.
  - (2) The Ministry shall grant a licence only after receiving a complete and accurate application and upon a showing at an inspection that the applicant will be operating in substantial compliance with regulatory requirements. Where an inspection reveals any area(s) of noncompliance with regulatory requirements, such area(s) of noncompliance shall be corrected by the applicant within the period specified by the Ministry.
  - (3) A licence is not transferable to any other person or location. Unless restricted, suspended, or revoked, a licence shall remain fully valid for a period of [ ] months and be subject to renewal.
  - (4) A licence is subject to renewal in accordance with requirements established by the Ministry, including the payment of any prescribed fees and a showing at an inspection of substantial compliance with regulatory requirements. Where an inspection reveals any area(s) of noncompliance with regulatory requirements, such area(s) of noncompliance shall be corrected by the applicant.
  - (5) Any licensee:
    - (i) who substantially fails to meet regulatory requirements,
    - (ii) who has had a licence restricted, suspended, or revoked within the previous twenty-four (24) months [or the appropriate period], or
    - (iii) who has had a history of repeated noncompliance with regulatory requirements, may be denied a licence upon initial application or renewal or may be issued a restricted licence; provided, however, that any applicant denied a licence or issued a restricted licence, within [ ] days of notification of the denial or restriction, may request an administrative hearing or appeal to a court of competent jurisdiction. If no such request [appeal] is made, the denial or restriction shall be final.
- (d) **Quality Assurance.** All persons who import, manufacture, package or repackage, label, sell, or export food shall establish procedures and carry out activities for quality assurance in accordance with requirements prescribed in regulations to ensure that their activities and the food in their possession or under their control meets applicable regulatory requirements.
- (e) **Packaging.** All packaged food shall be packaged in a manner that protects and preserves its composition, quality, purity, hygiene, and safety; protects it from harmful or contaminating substances, agents, or effects; and protects its nutritive properties from excessive heat, moisture, and other conditions that may cause diminution. Food shall be packaged in accordance with prescribed requirements established in regulations.
- (f) **Labeling and Advertising.** All packaged food shall be labeled and advertised in a manner that is true and accurate and that is not likely to mislead the consumer. All food shall be labeled in accordance with requirements prescribed in regulations.
- (g) **Transport, Storage, and Display.** All food shall be stored and transported in a manner that protects and preserves its composition, quality, purity, hygiene, and safety; protects it from harmful or contaminating substances, agents, or effects; protects its nutritive properties, and that is in conformance with any requirements established in regulations. Foods fortified in compliance with regulatory requirements shall be given priority in storage, display, and transport over non-fortified foods of the same class or category.  
(Bahamas, Botswana, Zambia)

## Section 6: Fortified Foods

Effective [date], all salt intended for human or animal consumption, unless exempted, shall be iodized in accordance with all specifications and standards established by the Ministry in regulations. Other foods shall or may be fortified as required or authorized by the Ministry in regulations.

## Section 7: Inspection and Investigative Powers of the Ministry

Authorized officers shall have the authority to conduct inspections and investigations to determine compliance with regulatory requirements.

### (a) Inspections and Investigations

- (1) **Inspections.** The premises and operations of all licencees shall be subject to periodic inspection, including for licence renewal, after the initial inspection.
- (2) **Investigations.** Any premises where food is received, held, manufactured, packaged, labeled, stored, displayed, distributed, or sold by any person, whether or not that person is required to hold a licence, shall be subject to an investigation whenever an authorized officer has a reasonable basis to question compliance with regulatory requirements of activities, operations, or of food therein.

(b) **Appointment or Designation of Authorized Officers.** The Minister may appoint or designate such persons to act as authorized officers as he or she deems appropriate for the proper enforcement of this Act. All persons so appointed shall be qualified, as determined by the Minister, by technical training, competent knowledge, skill, and experience. No authorized officer shall be engaged directly or indirectly in any commercial activity in the food industry.

(c) **Powers and Duties of Authorized Officers.** Subject to the provisions of subsection (a), authorized officers shall have the power to:

- (1) enter the premises to conduct inspections or investigations at any time during business or operating hours or at any other reasonable or necessary time;
- (2) examine, open, and test any equipment, utensils, tools, packages or anything the authorized officer reasonably believes is used or capable of being used for the manufacture, packaging, labeling, storage, or distribution of food;
- (3) take samples of any food and analyze them or have them analyzed;
- (4) examine any operation or process carried out in or upon the premises;
- (5) examine and make copies of or from any books, documents, notes, or other records the authorized officer reasonably believes might contain information relevant to determining compliance with regulatory requirements;
- (6) interview or question any licensee, owner of the premises, or any person using the premises, and their employees, agents, contractors and workers, all of whom shall cooperate fully and truthfully with any inspection or investigation;
- (7) stop, search, and detain any aircraft, ship, vehicle or other means of transport or storage in which the authorized officer reasonably believes food is contained or conveyed and examine, open, take samples of and analyze or have analyzed any food or materials found therein; and
- (8) seize and detain any food the authorized officer reasonably believes does not comply with regulatory requirements, upon providing the licensee or owner of the food, or if they are unavailable, any other person on the premises where the food is located, written notice of the seizure and detention and the grounds for it. If any food so seized and detained is determined to meet regulatory requirements, it shall be returned immediately to the premises from which it was seized. If any food is determined not to meet regulatory requirements, it may be destroyed or otherwise disposed of pursuant to the provisions of Section 7.

(d) **Identification of Authorized Officers.** Authorized officers must present proof of their appointment or their identity as authorized officers if requested by the person being inspected or investigated. (*Bahamas, Botswana, Zimbabwe*)

(e) **Operation of Analyzing Laboratories.** The Ministry shall establish procedures for analyzing laboratories' operation, including qualifications of its personnel, procedures and methods for sample analysis, preservation of evidence, quality assurance for the laboratory, and other matters necessary or desirable to ensure the proper operation of the laboratory.

## Section 8: Enforcement

- (a) **Civil Enforcement.** The Ministry may take a civil administrative enforcement action [or may commence a civil action in a court of competent jurisdiction]<sup>4</sup> against any licensee or person responsible for the importation, manufacture, packaging, labeling, storage, display, advertisement, distribution, sale, or exportation of food found, pursuant to the provisions of subsection (c), not to be or have been in substantial compliance with all provisions of applicable regulatory requirements. Penalties authorized by this section may be imposed for each substantial violation of regulatory requirements and may be imposed singly or in combination, as follows:
- (i) imposition of a civil fine of no less than [ ] and no greater than [ ], in accordance with criteria established in regulations, taking into account the seriousness of the violation(s), whether the same or similar violations have occurred previously, and such other factors as the Ministry deems appropriate;
  - (ii) issuance of an order to cease and desist from any activity that does not comply with regulatory requirements;
  - (iii) confiscation and destruction or other disposition of food that does not meet regulatory requirements;
  - (iv) adverse publicity of unfavorable inspection, investigation of analysis results; and
  - (v) licence restriction, suspension or revocation.
- (b) **Legal Proceedings.** Prior to imposing any penalty pursuant to subparagraph (a), the Ministry first shall provide the licensee or person accused of violating any regulatory requirement with written notice of the alleged violation(s), the intended enforcement action to be taken, and of the right to contest the charges in an administrative hearing [or in a court of competent jurisdiction]. If no such hearing is requested by the accused in writing within the time specified by the Ministry [or by law], the accused shall be deemed to agree to any enforcement action or actions proposed in the notice. If a hearing is requested, it shall be held in accordance with all applicable requirements of the [title of law governing the conduct of administrative enforcement actions, or civil court proceedings, as applicable, citation]. In any hearing under this section, the following shall apply:
- (1) an affidavit or certification under oath by an analyst from the analyzing laboratory regarding any food which is the subject of the proceedings shall be admissible on its mere production as *prima facie* proof of the violations shown by the examination or analysis of the food; provided, however, that the accused shall be notified in advance of the intent to produce such an affidavit or certification and shall be advised of the right to compel the live testimony of the analyst in any proceeding in which the affidavit is sought to be used;
  - (2) copies from any record, book, or document certified as true and correct copies by the authorized officer who obtained them shall be deemed admissible into evidence as authentic;
  - (3) where food is found in or on any premises used for the manufacture, distribution, or sale of food, such food shall be presumed to be food intended for manufacture, distribution, or sale;
  - (4) where it is proven that a substance or mixture of substances normally is used for human or animal consumption, it shall be presumed that it was intended for human or animal consumption as food;
  - (5) where it is proven that a substance is capable of entry into or being used in the composition or preparation of, or as a vehicle for the preparation of food, it shall be presumed that it was intended for such entry or use;
  - (6) any quantity of food found in or on any premises at the time a sample thereof was taken shall be presumed to possess the same properties as such sample; and
  - (7) the person identified on the label or packaging of any food as the manufacturer, importer, exporter, packager, or seller shall be presumed to have manufactured, imported, exported, or packaged or sold the food, as applicable.
- (c) **Criminal Enforcement.** It shall constitute a crime to willfully contravene any provision of this Act or applicable regulations. Any person convicted by a court of competent jurisdiction of so doing may be criminally fined in an amount no less than [ ] and no greater than [ ] and/or imprisoned for a period of no less than [ ] months and no greater than [ ] months. Civil and criminal action may be taken singly or in combination for any violation. Any criminal action shall be taken in accordance with the requirements of [title of law governing criminal proceedings], [cite the law].

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<sup>4</sup> This provision will depend upon whether there is a procedure for taking administrative actions within the ministry responsible for enforcement (or within another ministry, such as the Ministry of Justice), or whether all actions must be initiated in court. The model assumes that enforcement actions may be taken administratively.

(d) **Defenses.** It shall be a defense for any food seller or distributor charged with violating any regulatory requirement to prove that he or she:

- (1) purchased or received food from another providing a written warranty,
- (2) handled the food in a manner in compliance with regulatory requirements,
- (3) sold or distributed the food in the same condition it was in at the time of its purchase or receipt or reconditioned it to meet regulatory requirements, and
- (4) could not have discovered at the time of purchase or receipt, or thereafter, through the exercise of reasonable diligence, that the food did not conform to regulatory requirements.

The burden of proving each element of the defense shall lie with the person charged with noncompliance.

(e) **Private Right of Action.** Any consumer who has purchased food that does not comply with regulatory requirements shall have a private right of action against any person in the food manufacture-distribution chain who failed to comply with regulatory requirements. Any consumer who prevails in any such action shall be entitled to damages in the amount of [ ] and recovery of the costs of taking the action, without the necessity of a showing that he or she suffered actual damages. (*Bahamas, Botswana, Nigeria, Zambia*)

### **Section 9: Special Treatment of Fortified Foods**

Foods that are fortified in compliance with regulatory requirements shall enjoy priority over non-fortified foods of the same class and category with respect to transport, storage, and display, including retail shelf space; shall be entitled to carry a logo authorized by the Ministry; and shall be entitled to any other favored treatment established by the government.

### **Section 10: Standardization**

In establishing standards for food, the Ministry shall take into account fully the recommended international standards of the Codex Alimentarius Commission, including those related to fortification of foods.

### **Section 11: Severability**

In the event that any provision, sentence, clause, or phrase of this Act may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining provisions. The remaining provisions shall remain in full force and effect.

### **Section 12: Effective Date and Repeal of Prior Laws**

This Act shall become effective [ ] and shall repeal all prior inconsistent provisions of other enactments in force on the effective date.

## I. The Role of Regulations

Once legislation or other statutory enactment is passed, implementing regulations typically need to be developed by the Ministry charged with administering the law. It is through the regulations that the government lays down the specific requirements (food composition standards, quality assurance procedures, etc.) that the food industry and others must follow in order to comply with legal requirements. The regulations may expand upon the legislative provisions but they may not conflict with them or exceed the authority granted in the law.

It also is through the regulations that the government sets out the specifics of its authority (derived from the legislation) for administering the law and regulations, including its enforcement power. In delineating this authority, the government should set out checks and balances for making sure that its own administration of the law and regulations is fair and protective of the rights of those obliged to comply with regulatory requirements.

## II. Addressing Iron and Vitamin A Fortification in Regulations

By the time of the writing of this 2<sup>nd</sup> edition, most governments already have enacted legislation that deals with salt iodization, but without addressing fortification with other micronutrients. In cases where the government enacted USI legislation but its general food control law also is broad enough to allow for fortification of other foods, it will not be necessary to enact new legislation; rather fortification with iron and vitamin A can be handled in implementing regulations.

Likewise, for those governments that, in addressing salt iodization also provided the Ministry general fortification authority, as in the model Legislative Provisions for Food fortification (Section 1), specific provisions for iron and vitamin A fortification can be dealt with in implementing regulations. In cases where the general food control law is not broad enough to authorize fortification and where USI legislation was enacted without addressing other micronutrient fortification, it will be necessary to go through the legislative process again to provide appropriate legal authority for additional fortification activities.

This can be done by amending either the general food control law or the USI law. Rather than amending the law to address only iron and vitamin A, however, the provisions suggested under the model legislation for food fortification can be used in amending the law. This way, if the government decides to address folate, zinc, or other nutritional deficiencies through fortification in the future, it will not be necessary to continue enacting piecemeal legislation. Rather, implementing regulations will be the vehicle through which the government can accomplish its comprehensive fortification program.

## III. Model Regulations for Food Fortification

The following pages provide model regulations to implement the model legislation provided in Chapter 3. It must be noted, however, that regulations do not lend themselves fully to a model approach. This is because it is through the regulations, as discussed above, that the government fills in the more general requirements of the law with specifics to meet its

particular needs. Thus, the model regulations are intended to provide an idea of some of the provisions that implementing regulations might contain. While they are not intended to be all-inclusive, the model regulations contain specific provisions for fortification and provisions related to the main points of the model legislation.

As with the model legislation, it is assumed that there will be in effect some type of food control regulations implementing the existing food control law. Therefore, for each section, there will need to be 1) introductory language explaining what provisions in the existing regulations are being deleted altogether, 2) an explanation of what existing provisions are being replaced and the language that will replace them, and 3) an explanation of what new provisions are being added. The model provides only substantive provisions and does not provide the language for introducing them.

The model assumes that the government will mandate the fortification of one staple food with iron (e.g., iron fortified wheat flour) and that it will allow vitamin A fortification of more than one vehicle (e.g., sugar and another vehicle). In any event, the regulations should set forth standards for each fortified vehicle mandated or permitted. This may require amending the regulations from time to time to address all appropriate food vehicles and fortificants the government decides to include in its fortification program. Model standards for iodized salt, iron-fortified flour, and vitamin A fortified sugar are provided in Regulations' Schedules 1-3.

## **A** An Outline of the Regulations for Food Fortification

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- 1.0 Purpose
- 2.0 Definitions
- 3.0 Applicability of the Regulations
- 4.0 Exemptions
- 5.0 Food Standards
  - 5.1 General Requirements
  - 5.2 Conformance with Codex Alimentarius Commission Standards
  - 5.3 Imported Foods
  - 5.4 Exported Foods
  - 5.5 Foods That Do Not Comply With Regulatory Requirements
- 6.0 Fortified Foods
  - 6.1 Foods Required To Be Fortified
  - 6.2 Permissive Fortification Activities
- 7.0 Licensing Requirements
  - 7.1 Initial Licence
  - 7.2 Licence Renewal
  - 7.3 Licence Restriction, Suspension, or Revocation
  - 7.4 Correction of Noncompliance
- 8.0 Quality Assurance
  - 8.1 Quality Assurance Activities
  - 8.2 Record Keeping
- 9.0 Packaging
- 10.0 Labeling
- 11.0 Transport, Storage, and Display

- 11.1 Transport, Storage, and Display of Fortified Foods
- 11.2 Transport, Storage, and Display of Exempted Foods
- 11.3 Transport and Storage of Non-Food Items
- 12.0 Inspections and Investigations
  - 12.1 Authorized Officers
  - 12.2 Inspection and Investigative Powers
  - 12.3 Analyzing Laboratories
- 13.0 Enforcement
  - 13.1 Civil Enforcement
  - 13.2 Civil Penalties
  - 13.3 Criminal Penalties
  - 13.4 Legal Proceedings
- 14.0 Special Treatment of Fortified Foods
- 15.0 Severability
- 16.0 Effective Date and Repeal of Prior Regulations

## **B** Model Regulations for Food Fortification

These regulations are promulgated by [name of Ministry] pursuant to [name of food control law or USI law], as amended, [citation] to amend [title of existing food control or USI regulations].

### **1.0 PURPOSE**

The purpose of these regulations is to ensure the nutritional properties, quality, and safety of foods, specifically providing for the proper fortification of foods and to amend the procedures and standards for regulating the import, manufacture, packaging, labeling, advertising, storage, transport, display, distribution, sale, and export of fortified foods.

### **2.0 DEFINITIONS**

As used in these regulations, the following terms shall be given the meanings described below:

[repeat definitions contained in the legislation, refining them to the extent appropriate, and add other necessary definitions].<sup>5</sup>

### **3.0 APPLICABILITY OF THE REGULATIONS**

Subject to the provisions of Rule 4.0, these regulations shall apply to all food imported, manufactured, packaged, labeled, stored, transported, displayed, distributed, or sold in this country or exported from this country. The provisions of these regulations shall not apply to food that is grown, or cultivated and consumed solely by an individual or his or her own family or animals.

### **4.0 EXEMPTIONS**

Foods shall be exempt from the provisions of these regulations and the Act under the following circumstances and conditions:

- (a) Where, pursuant to the provisions of these regulations any particular food is required to be fortified, a licensee may be granted authorization upon application to the Ministry to import, manufacture, distribute, sell, or export, as is applicable, food that is not fortified. Any authorization so granted shall be specified on the licence. The authorization for exemption shall follow the food and shall constitute an exemption for all other persons handling the food. Non-fortified foods and foods exempt from meeting particular requirements under this subsection shall be clearly labeled as non-fortified or not meeting specified requirements and shall be stored and transported separately from other foods of the same class and category that are fortified.

<sup>5</sup> As mentioned earlier, the regulations may expand upon or refine the provisions, including definitions, contained in the legislation; however, any expansions or refinements cannot conflict with the definitions in the legislation.



- (b) In the case of non-fortified foods or other foods exempt from meeting particular requirements under the provisions of subsection (a), such foods, if held for retail sale, shall not be displayed in open view or accessible to the consumer without the assistance of a [sales clerk, pharmacist, etc.]

## 5.0 FOOD STANDARDS

**5.1 General Requirements.** Unless exempted by the provisions of the Act or these regulations, all food imported, manufactured, packaged, labeled, advertised, stored, displayed, distributed, sold, or exported shall meet the standards of composition, nutrition, strength, purity, safety, [etc.], and all other requirements set forth in these and other applicable regulations.

**5.2 Imported Foods.** Food imported into the country that is subject to exemption under 4.0 and that does not meet regulatory requirements shall be subject to confiscation unless reconditioned, re-labeled, repackaged, or otherwise cured within [ ] days from the date of its entry into the country. Records shall be kept that show the date of entry into the country, name and address of exporter, date(s) and types of reconditioning activities, name and address of purchaser(s), and date(s) of purchase(s).

**5.3 Exported Foods.** Food intended for export that does not meet regulatory requirements of this country but that does meet the requirements of the importing country may remain in this country for a period of no longer than [ ] days from the date of entry into this country or the date of manufacture in this country, as the case may be. Records shall be kept that show the date of entry or manufacture, lot numbers, name, address, and licence number of manufacturer, intended destination, date of export, and name(s) and address(es) of purchaser(s).

**5.4 Foods That Do Not Comply With Regulatory Requirements.** Any commercial seller or distributor of food who finds upon exercising reasonable diligence that any food within its custody or control fails to meet regulatory requirements shall: (1) return it to the preceding seller who shall be responsible for compensating the purchaser for any loss incurred; (2) recondition it to meet regulatory requirements prior to selling or distributing it further; or (3) destroy it. Any food found not to meet regulatory requirements shall be segregated from all other food until such time as it is returned, reconditioned, or destroyed and a record shall be kept of any actions taken with respect to food found not to meet regulatory requirements.

## 6.0 FORTIFIED FOODS

Because dietary deficiencies in certain essential nutrients, including iodine, iron, vitamin A, [etc.], cause a host of preventable physical and mental impairments, including reduced intellectual capacity and cretinism, physical deformity, blindness, severe anemia, [etc.], and because relatively simple and inexpensive technology exists for fortifying common foods with these micronutrients, these regulations provide for the fortification activities described below.

**6.1 Foods Required to be Fortified.** The following foods shall be fortified and otherwise shall meet all requirements of these regulations.

- (a) SALT Effective [date], all salt in this country intended for human or animal consumption, unless exempted, shall be iodized and shall conform to the specifications set forth in Schedule 1. In particular, such salt shall comply with specified iodine levels and all other regulatory requirements at entry into the country or after repackaging, or at the end of the manufacturing process, as applicable, and at all points of sale or distribution;
- (b) FLOUR. All flour in this country intended for human or animal consumption, unless exempted, shall be fortified with the iron source or sources specified and shall conform to the specifications set forth in Schedule 2 and all other regulatory requirements. In particular, such flour shall comply on entry into the country or after repackaging, or after the manufacturing process, as applicable, and at all points of sale or distribution.

## 7.0 LICENSING REQUIREMENTS

**7.1 Initial Licence.** No importer, manufacturer, distributor, seller, or exporter of food shall operate or advertise without having a valid licence issued by the Ministry. Prior to beginning operation, all persons required to have a licence shall apply to the Ministry on the forms prescribed and shall submit the prescribed licensing fee. The licence shall be granted if, following an inspection, the applicant is found to be in substantial compliance with applicable regulatory requirements, appears likely to be able to sustain compliance, and has not had a licence revoked or suspended within the previous [ ] months. Any licence granted shall be prominently displayed on the premises. If found not to be in substantial compliance with regulatory requirements, the applicant shall be informed of the specific areas of noncompliance, given a reasonable time to correct these areas, and reinspected without having to reapply for a licence. If found not to be in substantial compliance at reinspection, the application shall be denied.

**7.2 Licence Renewal.** A licence shall be subject to renewal every [ ] months. At least [ ] days to expiration of its licence, the licensee shall submit a renewal application to the Ministry on the forms prescribed along with any applicable fee. The licence shall be renewed if, following an inspection, the licensee is found to be in substantial compliance with regulatory requirements and the licensee has exhibited a satisfactory history of compliance during the period it has held a licence. If the licensee is found not to be in substantial compliance with regulatory requirements at the renewal inspection or has exhibited a history of substantial or repeated noncompliance during the period he or she has held a licence, his or her renewal application shall be denied.

**7.3 Licence Restriction, Suspension, or Revocation.** If a licensee is found during any inspection or investigation not to be in substantial compliance with regulatory requirements, the Ministry may restrict, suspend, or revoke the licence in accordance with the provisions of the Act [or reference to other applicable regulations or statutes].

**7.4 Correction of Noncompliance.** If, at any time, a licensee is found to be in substantial but not full compliance with regulatory requirements, the Ministry shall provide written notice to the licensee of any such area(s). Within a reasonable time after such notice, as specified in the notice, the licensee shall correct the area(s) of noncompliance.

## 8.0 QUALITY ASSURANCE

**8.1 Quality Assurance Procedures.** All manufacturers shall develop and routinely follow, as applicable, a procedure for quality assurance that has checks throughout the manufacturing process to ensure that the finished product complies with specified standards.

The procedure shall conform, at a minimum, to the following principles.

- (a) identification of areas where deviation from standards are likely to occur;
- (b) determination of critical points in the manufacturing process to control the potential areas of deviation;
- (c) establishment of critical limits that must be met at each critical point;
- (d) appropriate monitoring procedures for each critical point;
- (e) establishment of deviation procedures at each control point;
- (f) procedures for verification that the QA plan is working successfully;
- (g)
  - (1) As part of their quality assurance activities, food manufacturers, importers, re-packagers, and exporters shall be required to randomly test raw materials and final product samples, as applicable, to ensure that the final product meets standards prior to distribution.
  - (2) Wholesalers and retailers who do not repackage food shall not be required to test samples of food in their possession or under their control unless notified by the local authority or Ministry following a determination that there is a problem of actual or potential noncompliance with standards.
  - (3) Wholesalers and retailers shall be required to routinely inspect packages, labels and storage conditions for compliance with regulations.
- (h) In addition to any general requirements in the regulations related to quality assurance, specific requirements contained in standards for specific foods shall be followed.
- (i) All quality assurance activities, findings, and corrective action shall be documented and made available to authorized officers for inspection and copying upon reasonable request. QA records shall be kept for a minimum of two years.

**8.2 Quality Assurance Activities.** Quality assurance activities shall be followed as specified for particular foods in addition to any general requirements contained in this section. Proof of meaningful quality assurance activities shall be deemed to meet the requirement of reasonable diligence for invoking defenses under the Act and regulations.

## 9.0 PACKAGING

Food may be packaged only in suitable materials that protect the food and preserve its composition, quality, purity, hygiene, and safety; protect it from harmful or contaminating substances, agents, or effects; and protect its nutritive properties from excessive heat, moisture, and other conditions that may cause diminution. Specifically, [additional requirements, if any].

## 10.0 LABELING

All packaged food shall be labeled in a manner that is true and accurate as to identity, character, nature, composition, quality, strength, safety, purity, nutritive value, and other properties, and in accordance with standards for the particular food.

- 10.1 Only foods fortified in compliance with regulatory requirements may use or carry any government-authorized logo [or: Use of such a logo is allowed only upon written authorization of the Minister].
- 10.2 Where a particular food otherwise is required by regulatory requirements to be fortified or meet particular standards but is allowed an exemption from those requirements, its label shall contain a conspicuous warning that it is not fortified or does not meet all government standards as authorized by special exemption [and is available only by (prescription or other controlled means)].
- 10.3 No label or advertisement shall contain any unauthorized logo or any statement, claim, design, device, name, abbreviation or other signification which is false, misleading, deceptive, or likely to create an erroneous impression with respect to any particular concerning the food contained in the package or concerning the quality of its nutritive value.
- 10.4 The label on any packaged substances, mixtures of substances, or ingredients which, if intended for human or animal consumption, would meet the definition of food but which instead are intended for non-consumption uses shall carry a conspicuous warning that they are not intended or authorized for human or animal consumption.
- 10.5 All information printed on labels shall be verifiable.
- 10.6 Minimum information appearing on the labels of packaged food shall include at least the following:
  - (a) name of the food;
  - (b) licence number, name, and address of importer, manufacturer, distributor, seller, and exporter, as is applicable;
  - (c) lot or batch number;
  - (d) weight;
  - (e) proportions of the principal ingredients of the product;
  - (f) presence of fortifying agents, including the name and function of each such agent;
  - (g) presence of additives, including the name and function of each additive;
  - (h) volume;
  - (i) [etc].

## 11.0 TRANSPORT, STORAGE, AND DISPLAY.

All food shall be transported, stored and displayed in a manner that protects and preserves its composition, quality, purity, hygiene, and safety; protects it from harmful or contaminating substances, agents or effects; and protects its nutritive properties from the effects of excessive heat, moisture, and other conditions that might cause diminution.

- 11.1 **Transport, Storage, and Display of Fortified Foods.** Fortified foods shall be given priority in transport, storage, and display for distribution or sale over non-fortified foods.
- 11.2 **Storage, and Display of Exempted Foods.** Foods exempted from fortification or otherwise meeting any particular standard contained in regulatory requirements shall be stored separately from foods of the same class or category that meet all regulatory requirements. Separate storage and transport may be accomplished by demarcating areas of discreet physical space without the necessity of storing or transporting in separate buildings, rooms or vehicles. Exempted foods shall be displayed at retail in a manner that requires the assistance of a [pharmacist, sales clerk] to obtain access to it.
- 11.3 **Storage of Non-Food Items.** All food shall be stored separately from any packaged substances, mixtures of substances, or ingredients which, if intended for human or animal consumption, would meet the definition of food, but which instead are intended for non-consumption uses. Separate storage shall be accomplished by utilizing separate buildings, rooms, or vehicles.

## 12.0 INSPECTIONS AND INVESTIGATIONS

- 12.1 **Authorized Officers.** In addition to those authorized officers appointed by the Minister, every medical or health officer of the Ministry automatically shall be deemed an authorized officer for the purposes of this Act. Any officer of the Department of [title for the customs agency and/or Ministry of Industry and/or

standards bureau, etc.] appointed by the [head of customs agency/MOI/standards bureau] also may act as an authorized officer. While carrying out official duties, authorized officers shall present proof of identity and/or of their appointment if requested by the person being inspected.

**12.2 Inspection and Investigative Powers.** In addition to the general inspection and investigative activities authorized by [name of food act], authorized officers may take samples of food from manufacturers, distributors, and retail sellers periodically and analyze them or have them analyzed for content and composition.

- (a) For any food sample taken, the authorized officer shall take a sample in duplicate and place the samples in sealed containers or packages and mark them to record or otherwise shall record:
  - (1) the name of the person from whom they were taken;
  - (2) the address of the premises from which the sample was taken;
  - (3) the identity of the food or food product and the quantity of the sample;
  - (4) the date and time the sample was taken; and
  - (5) the name of the officer who took the sample. If not tested on the premises, the authorized officer shall submit the sample for analysis to an authorized laboratory within [ ] hours of taking it. The authorized officer shall keep the other sample for counter-analysis.
- (b) If the person who owns the food or his/her agent so requests, the authorized officer shall take a third sample, which shall be sealed and marked as above, and left with the person concerned.
- (c) The laboratory shall analyze samples submitted to it. The laboratory official breaking the seal on the container of the sample shall sign his or her name and the date next to the seal or on a certification affixed to the container. Following analysis, the sample shall be placed in its original container if possible and resealed or in a new container and sealed with a new seal. The date, time, and results of the analysis shall be recorded on the container or on a certificate affixed to the container, along with the signature of the analyst attesting to the analysis results. The sample and results then shall be returned to the authorized officer who took the sample within [ ] days of its analysis. The authorized officer shall notify the owner within [ ] days of his or her receipt of the sample results if the sample is found not to comply with regulatory requirements by sending a copy of the analysis report to the owner. The authorized officer shall place the sample in a secured space if intended to be used as evidence in any legal proceeding.

**12.3 Analyzing Laboratories.** [Specify procedures for operation of the laboratory, qualifications of personnel, procedures and methods for sample analysis, etc.]

## 13.0 ENFORCEMENT

**13.1 Civil Enforcement.** The Ministry shall have the authority to impose a penalty or penalties against any licensee or other person responsible for the importation, manufacture, packaging, labeling, storage, display, advertisement, delivery, distribution, sale, or exportation of any food whose activities are found not to have met regulatory requirements, including:

- (a) knowingly making any written or oral statement that is false or misleading in connection with an application for a licence, including renewal, or on documents submitted pursuant to any inspection or investigation;
- (b) failing or refusing to provide any authorized officer with meaningful access to the premises, agents or employees, equipment, materials, food, or records, including allowing authorized officers to make photocopies of records, or information pertinent to making a compliance determination, or
- (c) otherwise failing to comply with regulatory requirements, including standards for fortified foods.

**13.2 Civil Penalties.** When the Ministry finds that any licensee or other person has done any of the things enumerated in subparagraph 13.1, the Ministry, subject to providing notice and the opportunity for a hearing in accordance with the provisions of [name of law governing hearings], may impose any one or more of the following penalties:

- (a) publish the results of any unfavorable inspection, investigation, or food sample analysis;
- (b) restrict a licence, if applicable, to prohibit certain activities which the licensee has shown an inability to conduct in compliance with regulatory requirements;

- (c) suspend a licence for a definite period or for an indefinite period in connection with any condition which may be attached to full restoration of the licence;
- (d) revoke a licence in cases of substantial noncompliance with licensing requirements, if the licensee has been found on at least one other occasion within the past twenty-four (24) months [or other appropriate period] to have failed substantially to meet regulatory requirements, or if the noncompliance poses a direct and substantial threat to the health or safety of potential consumers;
- (e) impose a civil fine of up to [ ] for the first such offense, a fine of [ ] for the second such offense, a fine of up to [ ] for the third or more such offense; provided, however, that if the noncompliance with regulatory requirements poses a direct threat to the health or safety of potential consumers, the fine may be in any amount up to [ ] or as determined by the Ministry at its discretion;
- (f) order that the person refrain from any particular activity that does not comply with regulatory requirements; and
- (g) confiscate and destroy or otherwise dispose of food and materials that do not substantially meet regulatory requirements or, alternatively, order it to be reconditioned and re-labeled to meet regulatory requirements.

**13.3 Criminal Penalties.** Any person who willfully contravenes any provision of applicable regulatory requirements, upon conviction in a court of competent jurisdiction, shall be guilty of a crime and shall be subject to imprisonment and/or a fine.

**13.4 Legal Proceedings.** For any enforcement action taken, the Ministry shall notify the person charged with violating regulatory requirements in writing of the provisions allegedly violated, the factual bases for each allegation, and the proposed penalty or penalties. The notice also shall advise the person so charged of the right to request an administrative hearing [or an appeal in court] within [ ] days of the date of the notice to contest the charges. Failure by the accused to request a hearing [or an appeal in court] shall constitute agreement with the findings and consent to the proposed enforcement action(s).

Any administrative action shall be taken in accordance with the provisions of [title of law governing administrative or court hearings], [citation], subject to the provisions of [name of food act] related to legal proceedings and defenses.

**13.5 Private Right of Action.** Any consumer who has purchased or received food that does not comply with regulatory requirements may pursue a legal action against any person(s) in the food manufacture-distribution chain shown to have violated regulatory requirements. If successful, the consumer shall be awarded a statutory amount in accordance with the enforcement provisions of [name of food act], along with the costs of bringing the action.

## **14. SPECIAL TREATMENT OF FORTIFIED FOODS**

Foods fortified in compliance with regulatory requirements shall enjoy priority over non-fortified foods of the same class and category with respect to transport, storage, and retail display. Equipment used to fortify foods shall be [description of favorable tax treatment for such equipment], [etc.].

### **15.0 SEVERABILITY**

In the event that any provision, sentence, clause, or phrase of these regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination shall not affect the remaining provisions. The remaining provisions shall remain in full force and effect.

### **16.0 EFFECTIVE DATE AND REPEAL OF PRIOR REGULATIONS.**

These regulations shall become effective [ ] and shall repeal all prior inconsistent regulations in force on the effective date.

### Inspections and Enforcement

#### Introduction: Time to Enforce

Most national salt iodization programs around the globe have attained a certain maturity, reaching the point where the majority of the salt in the market is iodized. This salt is not always of consistent quality that meets standards. Governments, as a result, are turning their attention more to the inspection and enforcement aspects of programming to achieve the final programmatic advancement necessary to reach and move beyond the year 2000 goals. The predominant strategy at this point for most governments is to stop leakage of non-iodized salt into the consumer (human and animal) market and to ensure that the iodine content of the salt is in accordance with standards to prevent both too much iodine (potentially resulting in hyperthyroidism) and too little iodine (resulting in lack of protection of the population).

While many governments report leakage of non-iodized salt and inconsistent/inferior quality salt as the major remaining barriers to their salt iodization programs, most also report, at this point, little or no enforcement action. At the same time, some salt producers report that they are counting on government monitoring and enforcement to make them comply with standards. Thus, inspection and enforcement hold the key to the final success and sustainability of salt iodization programs in many countries (along with continued advocacy, communications, and other critical activities). As more governments also concentrate their efforts on vitamin A and iron fortification, they will find similar issues related to inspection and enforcement needs. Concentration on these activities with respect to iodized salt will set the regulatory stage for the inspection and enforcement function related to other fortified foods.

#### I Legislative and Regulatory Framework for Inspections and Enforcement

The previous chapters provide the legislative and regulatory framework — the enabling legal authority — for the government's inspection and enforcement functions. The most critical legislative /regulatory provisions that support the government's ability to inspect and enforce effectively include those on: quality assurance, licensure/registration of food producers/importers, wholesalers (and possibly retailers), penalties and incentives, inspections, and legal proceedings.

##### *Quality Assurance*

As discussed earlier, routine QA practice by food companies, primarily producers and importers, will help ensure a product that meets standards. It follows, then, that with routine industry QA practice, there should be greater compliance and less need to take enforcement actions. Once the government is satisfied that particular producers/importers have set up effective QA procedures and routinely and successfully follow them, this may allow for fewer or less extensive inspections. Additionally, reviewing QA records can provide important information to inspectors that also may lessen the inspection burden. Finally, it may even be possible to establish a mechanism for self-reporting using QA and other records that can help inspectors make limited or targeted inspections based on the information obtained.

##### *Licensure or Registration*

Licensure or registration of producers, importers, and retailers will provide the legal hook for taking enforcement actions referenced in Chapter 1. If a licence is required to do business and is subject to sanction for failure to comply substantially

with regulatory requirements, this can be a very effective way to compel compliance. Most countries already licence businesses. Since it is not desirable to require a number of different licences for the same business, the existing licensure system should be expanded, if possible, to cover food quality issues rather than imposing an entirely new licensing scheme in addition to any that already exists.

### ***Penalties and Incentives***

Penalties available to the government to address noncompliance should be broad, extending beyond the power merely to revoke a licence. Government officials may be reluctant to cancel a licence altogether and put a company out of business. Licensure revocation also may be difficult to do politically, not only because of the economic consequences to the business forced to close but to the community in which the business' employees live and whose residents patronize it. That is why less drastic licensure action, such as licensure limitation and suspension, also are recommended as sanction options, along with others.

Common penalties found in countries' laws and regulations often include small fines and imprisonment, in addition to licensure revocation. Government officials, understandably, can be reluctant to jail industry officials absent egregious circumstances. Small fines do not tend to be a meaningful deterrent- they often are just considered a cost of doing business and do not encourage meaningful changes in practice. Therefore, there generally is a need for additional sanction options. For example, a sanction of adverse publicity such as publishing a list of noncompliant companies in the local paper, can be a very effective deterrent, yet not very difficult or costly to impose.

Likewise, publishing a list of good corporate citizens can provide an effective incentive for compliance. Financial (such as tax or tariff reductions) and other incentives can provide the financial breaks that will enable the industry to comply with regulatory requirements (e.g., financial ability to buy the necessary equipment or fortificant) and to encourage them to want to comply (e.g., good publicity, transport priority). A balanced mix and range of meaningful incentives and penalties will facilitate enforcement.

### ***Inspections***

Broad inspection authority for the government is important. The most critical points here include being able to observe production processes and review and copy records, in addition to being able to take and analyze samples.

Most countries' regulatory provisions provide sufficiently broad inspection authority; however, many inspectors tend to limit their inspections to looking at the condition (hygiene and safety) of the physical premises and taking samples, without investigating the *systems*, processes and procedures in place to ensure compliance with regulatory requirements. If effective systems are in place and being followed, this gives a good idea of how likely it is that compliance with requirements is being attained and is likely to continue.

A law or regulation change will not be necessary for strengthening inspection functions in many countries. Rather, developing and following internal inspection protocols and procedures that include reviewing systems, processes, and procedures may help invigorate the inspection function, provide guidance to inspectors, and make the process more efficient.

In addition, it probably will be necessary to advocate to inspectors to be sure they understand the importance of properly fortified foods in combating micronutrient deficiencies. Overcoming the lack of motivation and political will that plagues many countries' inspection and enforcement systems will be necessary.

### ***Legal Procedures and Proceedings***

Many countries have cumbersome, time-consuming procedures that government officials must follow in order to take enforcement action. These procedures may be required by law, but in some cases, governments impose burdensome procedures on themselves simply as a matter of practice. An example is providing endless warnings before imposing a penalty. It is important to provide notice of violations and allow an opportunity to correct them and/or defend against them. However, companies that continuously violate the same or similar requirements and who never take significant corrective action should not be allowed to continue in this manner. Once given an opportunity or two to take corrective action, swift and definite action should follow. As discussed above, a protocol that establishes a procedure for notice, correction, and imposing penalties based on history of noncompliance and seriousness of the violations can help make the enforcement system more efficient and consistent.

If it is possible to take administrative enforcement action before the Ministry rather than having to institute an action in court, this also can make the enforcement system more efficient and expedient. Administrative hearings also tend to allow for a less intimidating environment for the government officials prosecuting the case, especially if they are not lawyers, as well as for the persons against whom the action is taken. Providing for administrative hearings may require a change to the law, absent authority elsewhere under the country's legal system and various laws. Seeking a legal opinion from the Ministry of Justice on this issue is recommended.

## II Inspections and Enforcement in Practice: Establishing Protocols and Procedures to Facilitate Action

As mentioned above, many governments report little inspection and enforcement activity despite an awareness of substantial noncompliance with standards on the part of some companies. Typically, this is the result of inadequate resources but many officials also acknowledge a lack of motivation on the part of inspectors. Thus, it is necessary to enhance the inspection and enforcement systems by making the job of inspectors easier and maximizing limited resources. Developing and using protocols and procedures should facilitate the inspector's job. The planning that goes into their development should take account of the resource constraints and seek innovative ways to maximize available resources. Some suggestions on both follow.

### Steps for Developing Inspection/Enforcement Protocols and Procedures

1. Conduct or review fortified food situation analysis (discussed on next page).
2. Identify priority areas for inspections based on resources available and the information obtained from step 1.
3. Develop and use written protocols/procedures for carrying out the inspection function, covering such things as frequency of inspections, coverage of inspections, sample taking and analysis, etc.
4. Develop and use inspection checklists or forms for inspectors to record their findings in a consistent manner.
5. Develop and use form notices to businesses to inform them of inspection results.
6. Develop and use written protocols/procedures for carrying out the enforcement function, covering such things as the criteria for imposing the various penalty and incentive options, handling repeat noncompliance, etc.

Written protocols for government inspectors to use when inspecting for compliance will help them do their jobs and at the same time will ensure consistency. This will allow businesses to feel confident that they are not being singled out or treated unfairly. It also will help the government, if challenged, prove that by following its established protocols and procedures, it is acting consistently in carrying out its inspection and enforcement duties.

An inspection and enforcement protocol might address the following areas: priority areas for concentrating inspection resources, frequency of inspections, what is examined during inspections, steps for taking and methods for analyzing samples, notice requirements, procedures and criteria for allowing corrective action by the alleged violator, follow-up or verification inspections, and imposing penalties and offering incentives.

#### ***Inspection Priorities and Frequency of Inspections***

In deciding on inspection priorities and the frequency of inspections, the government will have to balance the number of businesses/sites subject to inspection against the resources (staff, vehicles, etc.) available to carry out inspections and investigations. In doing so, it will have to set certain priorities. For example, where should inspection resources be concentrated: at the level of production, points of import, wholesale, and/or retail?

If the food is produced in compliance with standards, it is likely to meet standards at the time of consumption, absent improper packaging, unduly long storage time or transport or storage under improper conditions. Thus, it may make sense to concentrate resources at the level of production and major points of entry into the country for imports. Program monitoring information should be useful in making these prioritization decisions. This information should include a *situation analysis* which identifies, among other things, all producers, importers, wholesalers, and retailers of the fortified food in question (to the extent possible), their share of the market or the volume of their production/trade, and whether the product under their control historically has tended to meet regulatory requirements (or is likely to meet requirements because of routine and effective QA practices), along with the distribution chain the food goes through from the point of production/import to the point of retail.

Inspections at the most important level (e.g., production/import) and of those businesses responsible for a large proportion of the food in question may be where the government decides to concentrate its resources. Additionally, it may seek to concentrate on problem areas.



## Steps in Conducting a Situation Analysis

1. Identify and inventory all businesses involved in the production, import, and trade of fortified food products along with their approximate share of the market or the volume of their production/trade.
2. Identify their licence/registration numbers.
3. Identify the producers, importers, wholesalers, and retailers who, together, hold about 80% of the market for the product/trade.
4. Identify those routinely practicing QA (whether or not QA is mandated by the law/regulations).
5. Identify the compliance history of the major producers and traders.
6. Identify the major routes and distribution chain the product follows, from exporting country or internal production to retail points.
7. Identify inspection responsibilities and resources (staff, vehicles, petrol, etc.).

This information should be kept current and shared among government inspectors, customs officials, program managers, and others integrally involved in the fortification program.

The government should establish the *inspection cycle*, that is, the frequency of inspections for businesses at each level to be inspected during a specified period of time (e.g., ideally, at least *twice* per year for producers/importers) based upon the resources available and the number of businesses/sites to be inspected. If it will not be possible to inspect *every* business at the most important levels during the inspection cycle because there are too many of them, those inspected should be chosen randomly (such as by using the list of businesses and a random numbers table) to ensure fairness. Inspections should be unannounced. In addition to routine (or random) inspections, where the government has notice of actual or potential substantial noncompliance by any particular business, it should conduct an investigation and take action at *any* time. Once the fortification program has been under way for some time and the food companies have worked out effective QA systems, it may be possible to reduce the number of inspections during the inspection cycle. A sample inspection protocol is contained in Appendix A.

## Inspection Forms and Records

### *Inspection Checklist*

A checklist of items to cover during inspections should be made, if one does not already exist. Having in mind the compliance history of the entity being inspected may allow for more limited or more targeted inspections of those with a proven track record; however, deviations from the checklist or protocol should be explained. Sample inspection checklists and forms are contained in Appendix B.

### *Protocol Instructions on Sample Taking and Analysis*

The law probably already provides the requirements for taking and analyzing samples. In addition, it would be helpful to develop a sampling methodology that identifies sample size (e.g., 50 g. salt for each sample), the lab method to be used (e.g., rapid test kit followed by titration confirmation of negative or questionable results), and the number of samples to be taken and analyzed. Again, this will guide inspectors and ensure consistency. The Codex Alimentarius Commission, International Standards Organization (ISO), and other standards setting organizations' publications on sampling and verification methodologies should be consulted in establishing these for the foods in question.

### *Protocol Instructions on Notice Requirements, Corrective Action and Follow up Inspections*

Following inspections, the owner of the business should be provided with a copy of the inspection report that outlines both areas of compliance and areas where violations were found, along with a brief description of how the violation was determined.

The person responsible for the business failing to meet requirements should be required to elaborate a plan of correction for fixing the problem(s) identified *and* preventing a recurrence. For example, any product released from production that does not meet standards also indicates a problem with the QA system being used. Thus, the problem with machinery, dosing, mixing, etc. will have to be fixed and the QA system will have to be improved to catch and prevent further instances. Plans of correction should be compared with earlier plans submitted from the same business. They should be rejected if they are not substantially different from those in previous submissions that do not truly solve the problem.

It is critical to follow-up with a new inspection whenever serious noncompliance has been found. Failure to follow-up sends a clear message that enforcement is illusory. This likely will only encourage future noncompliance. Follow-up inspections, like initial inspections and investigations, should be unannounced.

#### ***Sharing Inspection Information With Other Involved Sectors***

For the inspection and enforcement system to work efficiently, it is necessary to have an established and ongoing mechanism for *routine* information sharing. Again, a protocol, with forms, for this will be helpful to ensure integration of program monitoring data with product/business inspection information. All ministries or agencies/departments responsible for the inspection and monitoring functions (e.g., MOH, MOT, Customs, Standards Bureau, program manager, trade organizations, etc.) and all levels, from central to local or provincial/district, should share critical information useful for decision-making *regularly*. This will allow action to be taken to modify the program, including enhancing enforcement activities, as needed. Once information has been analyzed, reports should be made available to policy makers and industry and consumer groups. This will serve an important advocacy function.

### **III Putting the Protocols and Procedures into Practice**

#### ***Maximizing Limited Resources***

The government clearly has the legal responsibility and should predominantly be the one to carry out the inspection role. However, it can encourage others to be involved in the inspection function to a lesser and less formal degree. For example, there are numerous international and local certification or accreditation agencies, such as the ISO, national multi-sectoral standards bureaus and the like. Under certification or accreditation schemes of these organizations, companies usually pay a fee to become accredited or to have their products certified. This type of certification or accreditation may give government inspectors some comfort that products are being produced or imported according to the accrediting agency's standards. If so, government inspectors may be able to concentrate less on the companies accredited or certified by legitimate and trustworthy organizations.

Likewise, industry trade organizations can be encouraged to play a self-policing role. Again, this cannot replace government inspections, but it may lessen the burden if self-policing seems to be working well. Finally, consumer organizations and NGOs can be encouraged to use test kits in the market to see if the salt (for now; possibly sugar and flour later) being sold is fortified. If they find it is not, they can report this to the local government authority, which then can conduct an official investigation or inspection.

Companies also can be made to send in samples and production records for review every so often. Based on a review of these records, inspectors can then verify compliance, either routinely or randomly, by unannounced inspections. If it is found that the test results or records were falsified in any way, swift and severe penalties should be imposed. Of course, even absent falsification, samples sent in probably are likely to have been produced with the greatest of care, knowing that they would be tested externally. Thus, they may not truly reflect the typical situation. In any event, the government, in collaboration with industry and NGOs, might experiment with a number of different ideas to see what could work to make the inspection system more efficient and workable in light of limited resources.

#### ***Taking Meaningful Enforcement Action***

As suggested above, it would be ideal for the government to have available to it a wide range of both penalties and incentives. Then, the government should determine through practice which ones seem to be most effective in bringing about compliance and deterring future noncompliance. The development and use of protocols outlining the penalties and incentives available and the circumstances under which they are to be applied will help the process along and ensure consistency. Repeat violations should be subject to progressively more severe penalties. Taking sure and consistent enforcement action will signal the government's seriousness about its fortification program.

Information on enforcement actions should be shared among all those involved in the government's micronutrient program, including the consuming public. It will be important for companies and consumers, as well as policy makers, to know that the government is serious about compliance by imposing penalties and providing incentives as appropriate.

## Summary Suggestions for Enhancing the Inspection and Enforcement Function

1. Review legal authority (legislation, regulations, and food standards) and strengthen if necessary. Harmonize standards and verification/certification methods with trading partner countries to the extent possible.
2. Create a database of all fortified food producers, importers/exporters, wholesalers, and retailers.
3. Ensure a licencing/registration system that allows tracking of food distribution channels and company compliance status.
4. Identify inspection priorities and develop and follow protocols and procedures for inspections, enforcement actions, and sharing information on monitoring and inspections/enforcement results.
5. Ensure that industry routinely practices QA and promote QA training for both industry representatives and inspectors as necessary.
6. Encourage industry, consumer, and NGO involvement in the monitoring processes.
7. Empower inspectors, consumers, and industry personnel to combat micronutrient deficiencies by increasing their knowledge base through communications and advocacy on the importance of properly fortified foods, publication of good and bad inspection results' providing and encouraging the use of, rapid test kits
8. Take swift and sure enforcement action for noncompliance when criteria under established protocols are met. Ensure consistency.

## Schedule 1

### Standards for Iodized Salt and Related Matters

1. **Crude salt.** Salt to be iodized shall be in the form of solid crystals or powder, white in color, and without visible impurities.
2. **Particle size.** Ninety-five percent (95%) of the cured salt shall pass a standard millimeter sieve.
3. **Constituent levels of iodized salt.**

#### Constituent Levels of Iodized Salt

Constituent	Weight (%)
Sodium Chloride (NaCl)	97.0 minimum (on a dry matter basis)
Magnesium (Mg)	0.5 maximum
Water insolubles	0.2 maximum
Moisture	0.4 maximum
Potassium iodate (KIO <sub>3</sub> ) at the point of production: 30+ 10ppm as iodine <sup>6</sup>	

#### 4. Potassium iodate.

Physical appearance:	white to almost white crystalline powder
particles retained on 100-mesh BS sieve:	5% max. w/w
solubility:	soluble in 30 parts water
reaction:	a 5% solution in water shall be neutral to litmus
iodine (I <sub>2</sub> ) max. w/w:	0.005%
sulphate max. w/w:	0.02%
heavy metals (as Pb):	<20 ppm
iron:	<10 ppm
bromate, bromide, chloride & chlorate max. % w/w:	0.5
insoluble matter max. w/w:	0.5
loss on drying @ 105 C max. % w/w:	0.5
assay (on dry basis):	99.0% KIO <sub>3</sub> min.
Packing seal:	Paper drums closed 50 kg plastic bag

6 Each national authority must set the appropriate level of iodine based on its population's consumption patterns, climatic conditions, distribution patterns, and similar data. This figure represents the recommendation of WHO/UNICEF/ICCIDD for the African countries involved in the 1997 Seven African Country Study on the relationship between salt iodization and iodine status. It may not be applicable to the situation in any given country.

Rather than expressing the iodine content in ranges, it is expressed as a single value with some allowance for reasonable deviation. This is because if a range is expressed, producers are likely to concentrate on the bottom figure of the range.

5. **Packaging.** Effective [date], all iodized salt shall be packed in unused, nonporous material made of or with a lining of high density polyethylene, such as woven polypropylene bags, jute bags, or other to ensure retention of the appropriate iodine level at the time of consumption.
6. **Labeling.** Salt may not carry a logo authorized by the Ministry unless it is iodized in accordance with standards. Any logo authorized shall be displayed as specified by the Minister. In addition to any other labeling requirements, labels on packages of iodized salt shall contain the following information and the salt in the package shall confirm to the specifications on its label:

IODIZED SALT

Name & address of manufacturer/importer:

Manufacturer's/importer's licence no.:

Lot/batch no.:

Potassium iodate (KIO<sub>3</sub>): \_\_\_\_ppm (or mg/kg)

Net weight:

In addition, information showing the date of production or expiry date shall accompany the package.

7. **Transport, storage, and display.** During transport, storage, and display, in order to minimize avoidable losses of iodine, iodized salt shall not be exposed to any of the following:
  - (a) direct sunlight
  - (b) excessive heat
  - (c) water or excessive humidity
  - (d) contamination with other particles or substances
  - (e) mixture with non-iodized salt
  - (f) inadequate ventilation or aeration
  - (g) hooks or other sharp instruments
  - (h) storage in uncovered areas
  - (I) stacking on any surface less than two inches above floor level
  - (j) [other]
8. **Distribution and sale.** Iodized salt shall be dispatched, distributed, and sold according to the principle of first in, first out.
9. **Quality assurance activities.** All manufacturers, importers, packers, wholesalers, and retailers shall conduct routine quality assurance activities to ensure the quality of salt under their control in accordance with the provisions of Section [ ] of the regulations.
  - (a) **QA at manufacture.** At a minimum, manufacturers shall undertake the following QA activities:
    - i. **iodine levels:** at regular intervals on each day of manufacture, samples of iodized salt shall be collected from the production line and tested for iodine content. Semi-quantitative tests may be used provided they are confirmed by titration as necessary.
    - ii. **equipment:** equipment shall be maintained and inspected routinely to ensure its proper operation.
    - iii. **mixing:** the mixing process shall be monitored regularly to ensure constant and consistent mixing.
    - iv. **salt ready for distribution.** For salt stored at the place of manufacture for a period of [ ] or more months, random samples from lots/batches shall be sampled to ensure the correct concentration of iodine.
    - v. **packaging and labeling:** the packages and labels of iodized salt shall be routinely inspected to ensure they comply with regulatory requirements.
  - (b) **QA at import, wholesale and upon repackaging.** At a minimum, importers, re-packagers, and wholesalers shall undertake the following activities:
    - i. **iodine levels:** upon receipt at import or wholesale or on repackaging, as the case may be, and periodically thereafter if stored for more than [ ] months, routine samples of salt by batch/lot shall be analyzed to ensure the correct concentration of iodine.
    - ii. **storage and display:** storage and display areas shall be routinely inspected to ensure that salt is being stored and displayed properly and that it is being distributed on a first in, first out basis.

- (c) **Corrective action.** Whenever problems are found, they shall be communicated to the person responsible and corrective action shall be taken immediately and prior to further manufacture or distribution, as the case may be.
- (d) **Record keeping.** At manufacture, daily control charts and weekly summaries of activities shall be made. At all other levels, documentation of QA activities, including corrective action, shall be made as appropriate to demonstrate compliance. QA records shall be maintained for a period of at least [ ] months and shall be made available to authorized officers or upon reasonable request.

**10. Other requirements.** [Include other Codex requirements to the extent applicable].

## Schedule 2 Standards for Iron Fortified Flour and Related Matters

### 1. Fortification Specifications by Flour Type:

#### Wheat Flour

Nutrient	Nutrient Level	Flour Type by Extraction Rate (ash content)	Period Between Production and Utilization (recommended)
ferrous sulfate	30 ± 5 mg/100 kg	<82% extraction (ash<8)	<3 months
elemental iron	60 ± 5 mg/100 kg	<82% extraction (ash<8)	<6 months
EDTA	1 ± 5 mg/100 kg	>82% extraction (ash>8)	<3 months

#### Maize Flour

Nutrient	Nutrient Level added/total Nutrient Level	Period Between Production and Utilization (recommended)
ferrous fumarate	30 ± 5 mg/100 kg	<3 months
reduced iron mix	60 ± 5 mg/100 kg	<3 months

#### Semolina Flour

Nutrient	Nutrient Level added/total Nutrient Level
ferrous sulfate	30 ± 5 mg/100 kg

**2. Other nutrients that may be added. In addition to iron, the following nutrients may be added to flour:**

Nutrient	Source	Concentration
calcium	calcium carbonate	40
	calcium sulfate, dehydrate	23
	tri calcium phosphate	39
folacin	folic acid	83
iodine	calcium iodate	62
	potassium iodate	59
magnesium	magnesium oxide	60
	magnesium sulphate	14
niacin	niacinamide	100
	nicotinic acid	100
vitamin A	vitamin A palmitate, 250SD	250IU/mg
vitamin B1	thiamin hydrochloride	100
	thiamin mononitrate	103
vitamin B12	1% cyanocobalamin	1
vitamin B2	riboflavin	100
vitamin B6	pyridoxin HCl	83
zinc	zinc oxide	80
	zinc sulfate	36

**3. Packaging of fortified flour.** Packaging shall be unused and shall be of multiwall paper or woven polypropylene to restrict exposure of the fortified flour to air and light.

**4. Labeling of fortified flour.** Only flour fortified in compliance with standards may carry a logo authorized by the Ministry, which shall be displayed as specified by the Minister. In addition to any other labeling requirements of these regulations, labels on bags or packages of fortified flour shall contain the following information and the flour in the bag or package shall conform to the specifications on its label:

**IRON FORTIFIED FLOUR**

Name & address of manufacturer/importer:

Manufacturer's/importer's licence no.:

Type and level of iron: (e.g., \_\_\_\_ ppm ferrous sulfate)

Net weight: \_\_\_\_\_ kg

In addition, information showing the date of processing or expiry date shall accompany the package.

**5. Transport, storage, and display of fortified flour.** Fortified flour shall be dispatched, distributed, and sold according to the principle of first in, first out.

**6. Fortificant specifications.**

(a) **Specifications for iron sources used as fortificants.** Iron to be added to flour shall meet the following specifications:

i. **reduced iron.** If reduced iron is used for fortification, it shall be a USP/FCC grade, of very fine particle size, produced by a hydrogen reduction or electrolytic process, black in color, magnetic, and dissolvable in dilute mineral acids. In addition, it shall conform to the following:

Assay	96.0% Fe min.
Hydrogen loss	1.75% max.
Acid-insoluble substances	1.00% max.
Arsenic (As)	8 ppm max.
Lead (Pb)	25 ppm max
Mercury (Hg)	5 ppm max.
Particle size	(Fisher subsieve analyzer or equivalent)
Through 200 mesh	99% min.
Through 325 mesh	95% min.

- ii. **Ferrous sulfate.** If ferrous sulfate is used, it shall be a USP/FCC grade, light tan, dried form, and of fine particle size. In addition, it shall conform to the following:

Assay: as FeSO <sub>4</sub>	86.0% -89.0%
Iron (Fe)	31.6%-32.6%
Insoluble substances	0.05% max.
Arsenic (As)	3 ppm max.
Lead (Pb)	10 ppm max
Mercury (Hg)	3 ppm max.
Particle size	(Fisher subsieve analyzer or equivalent)
Through 200 mesh	99.5% min.
Through 325 mesh	90.5% min.
Bulk density:	loose            30 lbs/cu foot typical
packed	45 lbs/cu foot typical

- iii. **EDTA.** If EDTA is used, it shall meet the USP or equivalent.
- iv. **packaging.** Pre-mixes shall be packaged in polyethylene-lined drums or boxes.
- v. **premix storage and handling.** Pre-mixes shall be kept in well-sealed containers in a cool dry place. Exposure to light and air shall be minimized to prevent nutrient degradation. Pre-mixes shall be kept from any other flour additives and other additive feeders. Fortificants shall not be blended with other flour additives. Upon receipt, the lot numbers shall be recorded. A first-in, first-out system of stock rotation shall be employed

**7. Quality Assurance Activities.** All manufacturers, importers, wholesalers, and retailers shall conduct routine quality assurance activities to ensure the quality of the fortified flour under their control.

- (a) **Quality assurance at manufacture (milling):** At a minimum, manufacturers shall undertake quality assurance activities to address the following:
  - i. **iron levels:** routine semi-quantitative spot tests shall be conducted throughout the production process and during packaging, along with quantitative testing using calorimetric or atomic absorption methods at least once per month.
  - ii. **check weighing:** a check weighing procedure to measure the quantity of pre-mix added per minute shall be instituted.
  - iii. **equipment:** routine calibration, maintenance, and cleaning of flour mixing conveyors and regular feeder adjustment checks by weighing flour coming out of the feeder shall be undertaken. A check weighing test shall be run at the start of the production run, every 4 hours, and at the end of the production run.
  - iv. **packaging and labeling:** the packages and labels of fortified flour shall be routinely inspected to ensure they comply with regulatory requirements.
  - v. **record keeping:** documentation of adherence to maintenance and repair schedules, and spot check and quantitative test results shall be made and maintained for a period of at least 12 months. Records shall be made available to authorized officers upon reasonable request.
- (b) **Quality assurance at import, wholesale, and retail.** At a minimum, importers, wholesalers, and retailers shall undertake quality assurance activities to address the following:
  - i. **Iron levels:** upon receipt at import or wholesale, as the case may be, and periodically thereafter, random samples of flour shall be analyzed to ensure the correct concentration of iron. Spot tests may be used for this purpose with random verification of spot test results using an official quantitative method, AOAC or equivalent, by an accredited laboratory.
  - ii. **Record keeping:** documentation of spot tests and corrective action shall be made and maintained for a period of 12 months. Records shall be made available to authorized officers upon reasonable request.
- (c) **corrective action.** Whenever problems are found, they shall be communicated to the person responsible and corrective action shall be taken immediately and prior to further manufacture or distribution, as the case may be.



1. **Composition standards for fortified refined and white sugar.** Sugar for human or animal consumption may be fortified with retinol palmitate. If fortified, sugar shall meet the following composition characteristics.

- a. **Contaminant levels.** Refined and white sugar shall be clean and free of foreign substances. Contaminant levels shall not exceed the following values:

arsenic	1 mg/kg
copper	2 mg/kg
lead	1 mg/kg

- b. **Vitamin A content.** Fortified sugar shall contain 15 mg/kg retinol palmitate.

- c. **Other characteristics.**

1. **refined sugar.** Refined sugar shall conform to the following specifications:

minimum polarization	99.5 degrees
minimum sucrose	99.0%
maximum inverted sugar	0.04% w/w
maximum ash	0.01 w/w
humidity (maximum after 3 hrs @ 105 degrees C)	0.1%
color without retinol	150 ICUMSA units (max.)
color with retinol to the human eye	white

2. **white sugar.** White sugar shall conform to the following specifications:

minimum polarization	99.7 degrees S
minimum sucrose	97.0%
maximum inverted sugar	.06%
maximum ash	0.1%
humidity (maximum after 3 hrs @ 105 degrees C)	0.1
color without retinol	300 ICUMSA units (max)
color with retinol to the human eye	white to yellow

2. **Composition Standards for Vitamin A Fortificant Pre-mix.** The fortificant pre-mix shall consist of sugar of the type in which it will be diluted and vegetable oil with a low proportion of unsaturated fatty acids (e.g., peanut or palm oil). The pre-mix shall be water soluble.

maximum peroxides	5 meq/kg
final average retinol content	16.5 g/kg

3. **Packaging.** Packaging materials shall protect the sugar and fortificant from contamination, degradation of added nutrient levels, and alteration of sensorial properties.

- a. **Sugar.** Sugar for human consumption shall be packed in plastic or paper bags made with non-toxic material. Package sizes of 1–10kg will provide the best protection of the retinol content.
- b. **Fortificant pre-mix.** The pre-mix shall be packaged in polyethylene and covered by a polypropylene bag. Black polyethylene will provide the best protection of the nutrient.

4. **Labelling.** Labels shall be permanently printed on the package surface and shall describe the product in an accurate manner that is in no way likely to mislead the consumer.

a. **Sugar.** In addition to meeting general labeling requirements in the regulations, the labels shall contain at least the following information:

name & address of manufacturer:

licence no:

lot/batch number: \_\_\_\_\_

Product name: SUGAR FORTIFIED WITH VITAMIN A

Vitamin A (Retinol) content: 15 mg/kg

Storage Instruction: Keep out of direct sun/bright light

b. **Fortificant pre-mix.**

VITAMIN A PREMIX-NOT SUITABLE FOR DIRECT HUMAN CONSUMPTION

(in letters at least \_ the type size of the trade name)

Minimum retinol content: 15 g/kg

lot/batch number: \_\_\_\_\_

Date of manufacture: \_\_\_\_\_

5. **Quality Assurance Activities.** In addition to any other quality assurance requirements contained in the regulations, minimal product sampling shall be in accordance with the following:

#### A. Sugar

Type and Frequency	Average	Variability
<i>at production</i> semi-quantitative assays every 25–50 MT	12–18 mg/kg	>60% (15–18 mg/kg) composite samples
<i>at import</i> confidence assays in 5 samples of 50 g randomly selected from equal no. of bags	12–18 mg/kg >80% (>5 mg/kg)	100% (>2 mg/kg) >80% (>5 mg/kg) individual samples

#### B. Fortificant pre-mix

Type and Frequency	Average	Variability
<i>at production</i> 5g sample from each batch	16–17 mg/kg	>80% (15–18 mg/kg) daily composite sample
<i>at distribution/retail</i> Samples are not required. Packaging, labelling, and storage conditions shall be routinely inspected.		

## **Sample Inspection Protocol and Procedure**

The following suggests an outline for developing an inspection protocol and procedure.

### **Protocol for Inspections of Fortified Foods**

Developed by the Ministry of \_\_\_\_\_

Effective date: \_\_\_\_\_

Last revised: \_\_\_\_\_

#### **Purpose**

The purpose of this protocol is to make it clear what should be done during inspections and who is responsible. Following the protocol should make your job easier and should ensure consistency in application. Consistency is important to be sure that all similarly situated businesses are treated similarly and, thus, fairly. Should there be a need to deviate significantly from this protocol, please note in writing a brief explanation of why that deviation was necessary.

#### **The Importance of Inspecting**

Micronutrient deficiencies (inadequate dietary intakes of iodine, vitamin A, and iron) are a critical public health problem in this country. The entire population is at risk for these deficiencies. Even in cases where there are no clinical symptoms, these deficiencies prevent the human (and livestock) brain and body from developing to their full potential, resulting in lower IQ levels, reduced strength and stamina, and increased sickness and death from infections. Severe cases can result in mental retardation (iodine deficiency), increased sickness and death from infections (vitamin A), and during childbirth (iron deficiency).

It is most critical for women of childbearing age and infants to have sufficient micronutrients in their diets. Iodized salt is the sole way iodine is gotten in the diet in this country. Vitamin A and iron are gotten from a variety of sources, but vitamin A fortified sugar [and/or other vehicle] and iron fortified flour [and/or other vehicle] are the principal ways the government seeks to ensure that there is sufficient intake of these micronutrients in the diets. Thus, it is absolutely critical that fortified foods meet the standards elaborated in regulations. This, in turn, will ensure that the foods provide protection against these preventable deficiencies.

#### **Responsibilities for Inspections**

The following Ministries and agencies are charged under the law with inspecting fortified foods to ensure compliance with standards:

- MOH
- MOT
- Customs
- [ ]
- [ ]

The MOH is responsible for inspecting at [specify level(s)]

The MOT is responsible for inspecting at [specify level(s)]

The Bureau of Customs is responsible for inspecting at [specify level(s)] etc.

#### **Frequency of Inspections**

All producers within each province (or district, village, etc.) must be inspected at least \_\_\_ time(s) per each \_\_\_ month period (the inspection cycle).

All importers and re-packagers within each province (or district, village, etc.) must be inspected at least \_\_\_ time(s) per each inspection cycle.

The contents of all containers attempting to cross the border must be tested, selecting random samples by lot/batch.

Wholesalers should be inspected at least \_\_\_ time(s) per each inspection cycle, resources permitting.

Retailers should be inspected at least \_\_\_ time(s) per each inspection cycle, resources permitting.

Where it is not possible, due to resource or other constraints, to inspect all companies in a given category (e.g., producers, importers, wholesalers, retailers) during the inspection cycle, companies to be inspected within that category should be chosen randomly. From a list of all companies in that category in the district, village, etc., use a random numbers table or other method to identify the subset of companies to be chosen for inspection during the inspection cycle. For the cycles following the initial inspection cycle, the inspection list may be limited to those companies not chosen during the previous cycle(s). Companies whose compliance history indicates the need for closer supervision (or that meet some other clear criteria) should be inspected as frequently as necessary to be sure of compliance.

All inspections must be unannounced.

### Scope of Inspections

Inspections at production and repackaging facilities should examine the following:

- the raw products (salt, flour, sugar before fortification, along with the fortificant pre-mix)
- the finished, fortified food product (testing of contents by lot/batch)
- the production process (mixing of fortificant with the food vehicle)
- QA practices and records (production, equipment maintenance, materials, etc.)
- product packaging
- product labeling
- storage areas and practices
- the physical premises (hygiene)

Inspections at points of entry of imported foods should examine the following:

- the finished, fortified food product (testing of contents by lot/batch)
- product packaging
- product labeling

Inspections at wholesale and retail facility should examine the following:

- the finished, fortified food product (random testing)
- product packaging
- product labeling
- storage areas and practices
- the physical premises (hygiene)

### Sample Taking Procedure

A minimum of \_\_\_ samples should be taken from the production line and tested prior to addition of the fortificant.

A minimum of \_\_\_ samples should be taken from the end of the production line, after mixing of the fortificant, and tested.

A minimum of \_\_\_ random samples should be taken from packages of the product at the production facility.

Sample size shall be at least: 5 g for salt  
\_\_\_ g for sugar  
\_\_\_ g for flour

Initial testing of iodized salt may be done using the rapid test kit. Negative or questionable results must be confirmed with a quantitative test at the government laboratory, however prior to testing with either method, validation of the testing method must be done.

Each sample must be taken in duplicate [or as the law requires], placed in a sealed container, and marked in accordance with legal requirements found at [cite the applicable law and attach a copy of the relevant provisions]. If requested by a company representative, a third sample shall be likewise taken, sealed and marked, and given to the representative for the company's own testing.

### Exit Interviews

Initial findings from the inspection should be shared with the designated company representative. Inform the representative that s/he will receive an official copy of the inspection report once it is finalized. Explain that if deficiencies are noted on the report, the company must submit an acceptable plan of correction identifying the actions it will take to correct all problems identified within the time identified by the inspector (usually \_\_\_ days). If the plan of correction is not acceptable, the company will be notified and allowed one more opportunity to submit a revised plan (or will be penalized).

### **Inspection Records and Reports**

An inspection/investigation record form and checklist are attached, outlining the areas to be covered (as above) and should be used during all inspections. Additional findings, if any, should be noted.

Inspection/investigation records should be finalized and filed at [specify location] within \_\_\_ days of the completion of the inspection. Copies should be sent to [specify appropriate government officials] and the company inspected within this same time period. Records must be kept for a minimum of \_\_\_ years.

### **Follow-up Inspections**

Where significant deficiencies are found during an inspection, an unannounced follow-up inspection should be made within \_\_\_ days of receipt of the plan of correction to verify that meaningful corrective action has been taken. Follow-up inspections should be unannounced.

### **Penalties and Incentives**

The following penalties are available: [list penalties available under law]

The following criteria should be used in assessing a sanction or penalties:  
[elaborate criteria violations based on scope and seriousness of violations ]

If a violation is a repeat violation (the same or similar violation of the same regulatory requirement within the past \_\_\_ inspections), a more severe penalty should be applied.

If a company is found to be in substantial compliance with regulatory requirements, it should be sent a congratulatory letter along with the inspection findings.

### **Investigations**

Investigations should be conducted any time there is objective evidence to suggest potential noncompliance. This may come from a complaint from a consumer or other company, from monitoring data, from history of noncompliance by a particular company, etc. Investigations should follow the same basic protocol used for inspections, but may be targeted to the area(s) of suspected noncompliance.

For ease of reference, the following matrix provides summary information on the inspection process.

**Summary Inspection Matrix: Inspections at a Glance**

<b>Responsible Ministry/Agency</b>	<b>Who is inspected/ where</b>	<b>Frequency of Inspections</b>	<b>Inspection Coverage</b>	<b>Sampling Procedure</b>	<b>Inspection Reports</b>	<b>Other</b>
<b>MOIT</b>	e.g. producers and importers in district	every ___ months	<input type="checkbox"/> raw product test <input type="checkbox"/> final product test <input type="checkbox"/> production process <input type="checkbox"/> QA <input type="checkbox"/> product package <input type="checkbox"/> product label <input type="checkbox"/> storage <input type="checkbox"/> physical premises	rapid test of ___ samples, ___ g each, confirmed by quantitative testing @ gov. lab	filed w/in ___ days of completion of inspection  copies sent to company and [gov. agency]	
<b>MOH</b>	e.g., retail outlets	every ___ months	<input type="checkbox"/> final prod. test <input type="checkbox"/> prod. package <input type="checkbox"/> prod. label <input type="checkbox"/> storage <input type="checkbox"/> physical premises			
<b>Customs</b>	points of entry	every shipment of fortified food	<input type="checkbox"/> export certification/docs <input type="checkbox"/> final product test (by lot/batch) <input type="checkbox"/> prod. package <input type="checkbox"/> prod. label			
<b>Standards Bureau</b>						
<b>Other</b>						

**Inspection Record**

Date of inspection: \_\_\_\_\_

Time begun: \_\_\_\_\_ Time ended: \_\_\_\_\_

Name and title of inspector:

\_\_\_\_\_

Address of inspection site:

\_\_\_\_\_

\_\_\_\_\_

**Identifying and Background Information:**

Name of producer, importer, wholesaler, retailer (circle appropriate one):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Address/phone/fax:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Licence No.: \_\_\_\_\_

Tonnes produced/imported/sold annually: \_\_\_\_\_

**If substantial noncompliance is found, answer the following:**

Source(s) of the product (raw or processed) prior to its present location: names and addresses of seller(s) to the company being inspected: \_\_\_\_\_

\_\_\_\_\_

Typical distribution route (s) of the food from point of production to its current location: \_\_\_\_\_

\_\_\_\_\_

Distribution route(s) of the food from its present location to the next purchaser(s): \_\_\_\_\_

\_\_\_\_\_

**Compliance Checklist**

Topic/area Inspected	Compliance status: yes or no If no, give short statement of basis of noncompliance finding	Citation to applicable regulation	Check if repeat violation (same or similar w/in last 2 inspections)	Plan of correction (to be completed by the company) due date: _____
<b>1. PRODUCT — Raw</b> a. raw product (e.g., salt) substantially meets standards b. fortificant premix substantially meets standards c. QA of raw product and fortificant routinely practiced and corrective action taken as indicated	a. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes: b. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes: c. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes:	pre-printed cite to reg. (and summary of requirements)  pre-printed cite to reg.  pre-printed cite to reg.		
<b>2. PRODUCT — Processed</b> a. fortificant level in final product meets standards b. product samples taken by inspector meet standards	a. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes: b. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes:			



Compliance Checklist *Cont'd*

Topic/area Inspected	Compliance status: yes or no If no, give short statement of basis of noncompliance finding	Citation to applicable regulation	Check if repeat violation (same or similar w/in last 2 inspections)	Plan of correction (to be completed by the company) due date: _____
<p><b>3. PRODUCTION PROCESS</b></p> <p>a. equipment routinely validated and regularly maintained (See producer's QA &amp; maintenance records)</p> <p>b. mixing of fortificant during production process properly done (See producer's QA records &amp; observe production if possible)</p> <p>c. QA routinely practiced during production or repackaging, including quantitative (titration) sample tests by lot/batch (See producer's QA records &amp; observe QA procedures if possible)</p> <p>d. QA records demonstrate timely corrective action taken when problems identified</p>	<p>a. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes:</p> <p>a. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes:</p> <p>a. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes:</p> <p>a. yes <input type="checkbox"/> no <input type="checkbox"/> N/A <input type="checkbox"/> notes:</p>			

Compliance Checklist *Cont'd*

Topic/area Inspected	Compliance status: yes or no If no, give short statement of basis of noncompliance finding	Citation to applicable regulation	Check if repeat violation (same or similar w/in last 2 inspections)	Plan of correction (to be completed by the company) due date: _____
<b>5. PRODUCT PACKAGE</b> a. proper materials used b. properly sealed c. appropriate size	a. yes <input type="checkbox"/> no <input type="checkbox"/> notes: a. yes <input type="checkbox"/> no <input type="checkbox"/> notes: a. yes <input type="checkbox"/> no <input type="checkbox"/> notes:			
<b>6. STORAGE</b> a. storage time appropriate b. Storage area and product placement ensure protection	a. yes <input type="checkbox"/> no <input type="checkbox"/> notes: a. yes <input type="checkbox"/> no <input type="checkbox"/> notes:			
<b>7. COOPERATION WITH INSPECTION</b>				
<b>10. OTHER</b>				

**Product Sample Chart**

PRODUCT SAMPLE RESULTS	Fortificant Level (Circle ppm or mg/kg)	Other Constituents (e.g., moisture, particle size, etc.) meet standards (yes or no; if no, describe noncompliance)	Sample Size and date and time taken	Lot/Batch no. (Specify whether taken during production or from package)	Sampling Methods (test kit, quantitative test, or both) and date and time of sample test
<b>Sample 1</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)	___ g. taken on ___/___/___ at ___:___:___m.		
<b>Sample 2</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)			
<b>Sample 3</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)			
<b>Sample 4</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)			
<b>Sample 5</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)			
<b>Sample 6</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)			
<b>Etc.</b>	___ ppm or mg/kg	yes <input type="checkbox"/> no <input type="checkbox"/> (explain)			

\_\_\_\_\_  
Name and Title of Inspector

\_\_\_\_\_  
Signature of Inspector

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and Title of Company Representative

\_\_\_\_\_  
Signature of Company Representative

\_\_\_\_\_  
Date

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**Act:** a written law of the nation; statute.

**Adjudication:** the legal process of resolving a dispute; the formal pronouncement of a judgement or decree; a judgement or decision given by a court of law.

**Adulteration:** the act of mixing something impure or injurious with something pure or genuine; the act of mixing an inferior article with a superior one of the same kind.

**Applicability:** relevance; bearing upon a particular case.

**Codex Alimentarius Commission:** subsidiary body of FAO and WHO responsible for developing standards for food quality, safety, labeling, and standards for analysis and sampling, and for promoting mutual recognition of food inspection systems.

**Compel:** urge forcefully under the authority of the law.

**Court of Competent Jurisdiction:** court which has the legal authority to hear and decide a case.

**Enactment:** a method or process by which a bill in the legislature becomes law; a law.

**Enjoy:** to have, possess and use; to occupy or have benefit of.

**Godown:** storage facility.

**Law:** rule of conduct prescribed by the lawmaking power of the state, which must be obeyed and followed by citizens subject to sanctions or legal consequences; includes statutes and regulations.

**Legislation:** preparation and enactment of laws by the country's legislative body.

**Loophole:** an omission in the text through which the intent of a law may be evaded.

**Prima facie:** on the face of it; a fact presumed to be true unless disproved by some evidence to the contrary.

**Private right of action:** authorization for individuals to initiate legal action in response to the violation of a law of which they are the interested beneficiaries.

**Provision:** legal or formal statement providing for something; clause of this.

**Regulations:** rules issued by governmental ministries or departments to carry out the intent of the law and to guide the activity of those regulated by the ministry, and of their own employees to ensure uniform application of the law. Regulations have the force and effect of law but are subordinate to legislation.

**Severability:** ability to separate a part from the whole without destroying the remaining portions.

**Statute:** an act of the legislature declaring, commanding, or prohibiting something; a law or enactment.

**Statutory damages:** damages specified in a statute as recoverable upon proof of a violation of the statute.

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**Korea:** Food Sanitation Act

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**Pakistan:** Pure Food Ordinance, 1960; Pure Food Rules, 1965

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