ANNEXES

ANNEX A

Indicators for assessing progress towards the sustainable elimination of iodine deficiency disorders

The international community has endorsed the goal of the sustainable elimination of iodine deficiency as a public health problem. In order to measure progress made towards this goal, various indicators have been developed (*1*). These indicators can be conveniently grouped into three categories, namely indicators related to salt iodization itself, those that reflect the population's iodine status and thirdly, those that provide a measure of the sustainability of the salt iodization programme. Success criteria for each of these sets of indicators have also been established; these can to be used to assess whether the sustainable elimination of iodine deficiency as a public health problem has been achieved (see **Table A.1**).

TABLE A.1

Indicators for monitoring progress towards the sustainable elimination of iodine deficiency as a public health problem

Indicator	Success criteria/goals
Salt iodization	
Proportion of households using adequately iodized salt[a]	>90%
Urinary iodine[b]	
Proportion of the population having urinary iodine below 100 µg/l	<50%
Proportion of the population having urinary iodine below 50 µg/l	<20%
Programmatic indicators	
An effective, functional national multidisciplinary body responsible to the government for the national programme for the elimination of iodine deficiency disorders, with a chairman appointed by the ministry of health.	At least 8 of the 10 programmatic indicators listed should exist
Evidence of political commitment to universal salt iodization and the elimination of iodine deficiency disorders.	
Appointment of a responsible executive officer for the iodine deficiency disorders elimination programme.	
Legislation or regulations on universal salt iodization (ideally regulations should cover both human and agricultural salt).	
Commitment to assessment and reassessment of progress in the elimination of iodine deficiency disorders, with access to laboratories able to provide accurate data on salt and urinary iodine.	

TABLE A.1 *Continued*

Indicator	Success criteria/goals
Programme of public education and social mobilization on the importance of iodine deficiency disorders and the consumption of iodized salt.	
Regular monitoring of salt iodine at the factory, retail and household levels.	
Regular monitoring of urinary iodine in school-aged children, with appropriate sampling for higher risk areas.	
Cooperation from the salt industry in maintenance of quality control.	
A system for the recording of results or regular monitoring procedures, particularly for salt iodine, urinary iodine and, if available, neonatal thyroid stimulating hormone, with mandatory public reporting.	

[a] Adequately iodized salt is salt that contains at least 15 ppm iodine. Additional conditions for the use of salt as a vehicle for eliminating iodine deficiency disorders are:
- Local production and/or importation of iodized salt in a quantity that is sufficient to satisfy the potential human demand (about 4–5 kg per person per year).
- At the point of production (or importation), 95% of salt destined for human consumption must be iodized according to government standards for iodine content.
- Salt iodine concentrations at the point of production or importation, and at the wholesale and retail levels, must be determined by titration; at the household level, it may be determined by either titration or certified kits.

[b] Data (national or regional) should have been collected within the last 2 years.

Source: adapted from reference (*1*).

Reference

1. *Assessment of iodine deficiency disorders and monitoring their elimination. A guide for programme managers*. 2nd ed. Geneva, World Health Organization, 2001 (WHO/NHD/01.1).

ANNEX B

The international resource laboratory for iodine network

The International Resource Laboratory for Iodine network (IRLI), launched in 2001, is sponsored by the Centers for Disease Control and Prevention (CDC), the International Council for Control of Iodine Deficiency Disorders (ICCIDD), the Micronutrient Initiative (MI), the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO). Its purpose is to support the national public health and industry monitoring that contributes to sustaining progress towards achieving universal salt iodization and the elimination of iodine deficiency[1].

The global IRLI network works to strengthen the capacity of participating laboratories to accurately measure iodine in urine and salt. Its main activities include:

(i) training and technology transfer to national laboratories;

(ii) formation of regional iodine networks;

(iii) development of technical standards and external quality assurance/proficiency testing programmes;

(iv) collaboration with the salt industry and other sectors when appropriate;

(v) information sharing among regional networks and communications with the IRLI Coordinating Committee and other interested parties;

(vi) seeking necessary resources to sustain the operation of regional networks.

As of 2004?? membership of the International Resource Laboratory for Iodine network extended to 12 countries, as follows:

Australia

Institute of Clinical Pathology and Medical Research
Westmead Hospital
Darcy Road

[1] More information on the IRLI network can be obtained by e-mailing: **iodinelab@cdc.gov.**

Westmead
New South Wales 2145
http://www.wsahs.nsw.gov.au/icpmr

Belgium

Centre Hospitalier Universitaire Saint-Pierre
322 Rue Haute
1000 Brussels
e-mail: Daniella_GNAT@stpierre-bru.be

Bulgaria

National Center of Hygiene, Medical Ecology and Nutrition
15 Dimiter Nestorov Street
Floor 6, Laboratory 5–6
Sofia 1431
http://www.nchmen.government.bg

Cameroon

Faculty of Medicine and Biomedical Sciences
BP 1364
Sciences – FMBS
Yaounde
e-mail: WHO.YAO@camnet.cm

China

National Reference Laboratory for Iodine Deficiency Disorders
Disease Control Department
Ministry of Health
PO Box No 5
Changping
Beijing 102206
e-mail: nrl@cnidd.org

Guatemala

Food Safety and Fortification Area
Instituto de Nutrición de Centro América y Panamá (INCAP)
Calzada Roosevelt, Zona 11
Apartado Postal 1188
Guatemala City
http://www.incap.ops-oms.org

India

All India Institute of Medical Sciences
Centre for Community Medicine
Room 28
New Delhi – 110 029
e-mail: cpandav@now-india.net.in

Indonesia

Laboratorium Biotehnologi Kedokteran/GAKY
Diponegoro Medical Faculty
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Kazakhstan

The Kazakh Nutrition Institute
Klochkov Str. 66
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Peru

Unidad de Endocrinologia y Metabolismo
Instituto de Investigaciones de la Altura
Universidad Peruana Cayetano Heredia
Av. Honorio Delgado 430
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Lima 1
e-mail: epretell@terra.com.pe

Russia

Institute of Endocrinology
Dm Ulyanova, 11
Moscow
e-mail: iod@endocrincentr.ru

South Africa

Nutritional Intervention Research Unit
Medical Research Council
PO Box 19070
Tygerberg 7505
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e-mail: pieter.jooste@mrc.ac.za

ANNEX C

Conversion factors for calculating Estimated Average Requirements (EARs) from FAO/WHO Recommended Nutrient Intakes (RNIs)

The recommended method for setting fortificant levels in foods is the Estimated Average Requirement cut-point method (*1*). Estimated Average Requirements (EARs) for use in such computations can be derived from published Recommended Nutrient Intakes (RNIs), by the application of the conversion factors listed in the table below. The EAR is obtained by dividing the RNI (or an equivalent dietary reference value) for a given population subgroup by the corresponding conversion factor (**Table C.1**).

The conversion is equivalent to subtracting 2 standard deviations of the average nutrient requirement for a population subgroup. The conversion factors listed here are based on standard deviations derived by the United States Food and Nutrition Board of the Institute of Medicine (FNB/IOM) and which are used by the Board to calculate its Recommended Dietary Allowances (RDAs).

TABLE C.1

Conversion factors for calculating Estimated Average Requirements (EARs) from FAO/WHO Recommended Nutrient Intakes (RNIs)

Nutrient	Children			Males			Females					
	1–3 years	4–6 years	7–9 years	10–18 years	19–65 years	>65 years	10–18 years	19–50 years	51–65 years	>65 years	Pregnant	Lactating
Vitamin A	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Vitamin D[a]	–	–	–	–	–	–	–	–	–	–	–	–
Vitamin E	1.25	1.25	1.25	1.25	1.3	1.3	1.25	1.2	1.2	1.2	1.2	1.2
Vitamin C	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.2	1.2	1.2
Thiamine (vitamin B_1)	1.25	1.25	1.25	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Ribiflavin (vitamin B_2)	1.25	1.25	1.25	1.2	1.2	1.2	1.1	1.2	1.2	1.2	1.2	1.2
Niacin	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
Vitamin B_6	1.25	1.25	1.25	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Folate	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Vitamin B_{12}	1.3	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Iron[b]	–	–	–	1.4	1.3	1.3	1.6	–	1.6	1.6	1.2	1.4
Zinc	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Calcium[c]	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Selenium	1.2	1.3	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Iodine	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Fluoride[a]	–	–	–	–	–	–	–	–	–	–	–	–

[a] Conversion factors are not given for vitamin D and fluoride because there is insufficient information to support the derivation of an EAR for these micronutrients. The recommended intakes are usually expressed as Adequate Intakes (AIs), or represented by the usual intake of healthy people.

[b] Conversion factors are not provided for children ≤9 years or for menstruating women aged 19–50 years, and should not be used for women aged 14–18 years who are menstruating, due to the high variability and the skewed nature of the distribution of the requirements for iron in these population groups.

[c] Conversion factors to be applied to calcium requirements set by the United Kingdom Department of Health (i.e. Reference Nutrient Intakes), which are conceptually similar to the FAO/WHO RNIs. (*2*)

Source: reference (*1*).

References

1. Food and Nutrition Board, Institute of Medicine. *Dietary reference intakes: applications in dietary planning*. Washington, DC, National Academy Press, 2003
2. Department of Health. *Dietary Reference Values of food energy and nutrients for the United Kingdom*. London, Her Majesty's Stationery Office, 1991.

ANNEX D

A procedure for estimating feasible fortification levels for a mass fortification programme

1. Introduction

Mass fortification is the term used to describe the addition of micronutrients to foods that are widely consumed, such as staples, condiments and several other commodities. This can be a very efficient way of supplying micronutrients to a large proportion of the target population for a number of reasons. Firstly, mass fortification does not require changes in dietary habits and secondly, programmes can be based on existing food distribution networks. In addition, staples and condiments tend to be consumed throughout the year, and when fortified on an industrial scale, the increase in the cost of the product due to fortification is usually relatively small. On the downside, because staples and condiments are also consumed in large amounts by non-target groups, when fortified, some individuals could be put at risk of increasing their nutrient intakes to levels that are close to, or exceed, the Tolerable Upper Intake Level (UL). This can be a potential problem for nutrients such as vitamin A, vitamin D, vitamin C, niacin (when using nicotinic acid as the fortificant), folic acid, iron, zinc, calcium, iodine and fluoride.

In practice, the amount of fortificant micronutrient that can be added to a food is often dictated by safety concerns for those at the top end of consumption of the chosen food vehicle. In addition, some micronutrients, including β-carotene, vitamin C, riboflavin (vitamin B_2), iron, zinc, calcium and iodine, can only be added in amounts up to a certain threshold, beyond which the sensory properties of the food vehicle are negatively affected. Fortification levels can also be restricted by the cost of the added micronutrients; high fortificant costs might mean that programmes are unaffordable or at risk of not being implemented as planned. Vitamin A (non-oily), vitamin D, vitamin C, niacin and some compounds of iron and calcium are among those nutrients whose addition to food are most likely to be limited by cost constraints. In sum, such limitations on the magnitude of micronutrient additions need to be balanced against the desire to achieve a particular nutritional goal.

For this reason, when planning a mass fortification programme, or more specifically, when deciding on the level of fortification, it is advisable to first

determine the probable safety, technological and cost constraints on the amount of micronutrient that can be added to a given food vehicle. Having established a limiting level for each of these factors, the "lowest" value of the three then becomes what is referred to as the *Feasible Fortification Level* (FFL). A methodology for determining the FFL is described in section 2 below, and its application illustrated by means of a worked example in section 3.

The **Feasible Fortification Level (FFL)** is that which is determined, subject to cost and technological constraints, as the level that will provide the greatest number of at-risk individual with an adequate micronutrient intake without causing an unacceptable risk of excess intake in the whole population.

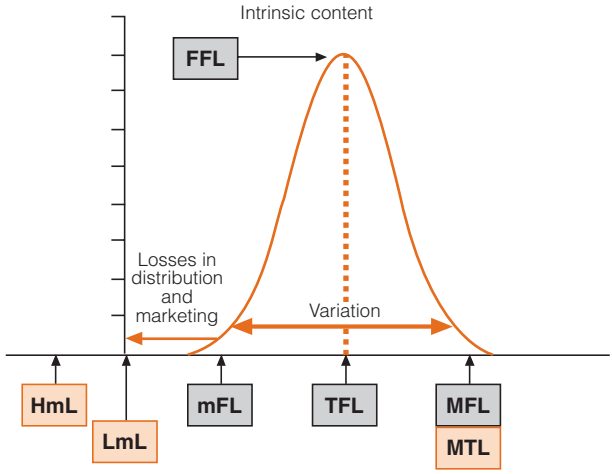
The FFL is a useful concept in that it can be used to estimate the additional intake that would result from the consumption of a given amount of a fortified food, to decide the final formulation of a micronutrient premix, and to estimate the cost of fortification for each micronutrient added. The FFL is used as the basis for various production and regulatory parameters that are commonly associated with food fortification. Production parameters are applied at food processing factories, and include the *Target Fortification Level* (TFL), the *Maximum Fortification Level* (MFL), and the *Minimum Fortification Level* (mFL). The latter is used in national food regulation to establish the *Legal Minimum Level* (LmL). Another important regulatory parameter is the *Maximum Tolerable Level* (MTL), which is invoked in food law for those nutrients whose intake might approach the UL as a result of fortification (see section 2.4). **Figure D1** illustrates the relationship between the production and regulatory parameters defined here.

The **Target Fortification Level (TFL)** is the average micronutrient concentration of a fortified food product measured at the factory. Food factories should aim to produce products that contain this target level. It is calculated by adding the natural intrinsic concentration of each micronutrient in the unfortified food vehicle to the FFL.

The **Minimum Fortification Level (mFL)** is given by reducing the TFL by an amount equivalent to two coefficients of variation in the measured micronutrient content of a fortified food at the factory. This level represents the lower limit of the micronutrient content to be achieved by the fortification process.

FIGURE D1

Relationship between the various production and regulatory parameters associated with mass fortification



FFL = Feasible Fortification Level; mFL = Minimum Fortification Level (a production parameter); TFL = Target Fortification Level (a production parameter); MFL = Maximum Fortification Level (a production parameter); LmL = Legal Minimum Level (a regulatory parameter), MTL = Maximum Tolerable Level (a regulatory parameter).

The graph also shows the Household Minimum Level (HmL), which may be lower than the LmL, on account of losses during storage in the home (i.e. before the food is consumed). This parameter is sometimes used to monitor the utilization, coverage and consumption of fortified foods by consumers.

The **Maximum Fortification Level (MFL)** is given by increasing the TFL by an amount equivalent to two coefficients of variation of the measured micronutrient content of a fortified food at the factory. This level represents the upper limit of the micronutrient content to be achieved by the fortification process.

The **Legal Minimum Level (LmL)** is the minimum micronutrient content of a fortified food as defined in regulations and standards; it is the amount that should appear on the label of a fortified food. The LmL is obtained by reducing the mFL by an amount equivalent to the average loss of micronutrient during distribution and storage, within the stated shelf-life of the product.

The **Maximum Tolerable Level** (**MTL**) is the maximum micronutrient content that a fortified food can present as it is established in food law; its purpose is to minimize the risk of excess intake of certain micronutrients. The MTL should coincide with the MFL for those micronutrients for which there is a risk of excess intake.

2. Selecting fortification levels on the basis of safety, technological and cost constraints

2.1 Limits to micronutrient additions

2.1.1 The safety limit

Micronutrient intake is a function of the amount of food consumed and also the micronutrient content of the food. Since adult males tend to have the highest food consumption rates of staple foods (and thus the highest micronutrient intakes if a staple were to be mass fortified), this group has the greatest risk of excessive micronutrient intakes. In order to assess the risk of excessive intakes, it is necessary to determine the 95th percentile of consumption of the food to be fortified, as well as the usual nutrient intake from all dietary sources (including dietary supplements if they supply nutrient forms that are of concern from a safety point of view) for those individuals most at risk – in this case, adult males.

Based on these assumptions, the safety limit for a micronutrient addition can be calculated using Equation 1. Note that if more than one food is being considered for mass fortification, the safety limit should be divided among all of them. If the food vehicles to be fortified are interchangeable in the diet (e.g. wheat flour and maize flour, cereals and pastas) the usual intake of the interchangeable foods can be combined in order to estimate a common safety limit, and in turn, a common Feasible Fortification Level.

Equation 1

$$\text{Safety limit}^{1}(\text{mg/kg}) = \frac{[\text{UL(mg)} - \text{amount of micronutrient from diet (mg) and any supplements (mg)}]}{[\text{95th percentile of consumption (kg)}]}$$

2.1.2 The technological limit

A food can only be fortified up to a level that does not change its organoleptic (i.e. colour, flavour, odour) and physical properties, measured just after fortifi-

[1] A more accurate calculation may consider losses during distribution and storage, as well as losses during food preparation. However, because losses vary hugely according to conditions and situations, and because allowance is often made to compensate for these losses (i.e. an overage), it is usually acceptable to use this simplified approach.

cation and over the shelf-life of the food. This level should be determined experimentally both for the food and for products for which the fortified food is an important ingredient. Ideally, a range of micronutrient levels – and, if more than one micronutrient is involved, combinations of micronutrient levels – should be tested by individuals with expertise in the sensory analysis of foods in order to determine what amount of each nutrient is technically compatible with a given food matrix. Each combination of micronutrient(s) and food matrix will have its own set of technological maxima. Technological limits are not necessarily fixed; as a result of technological innovation (e.g. the development of new fortificants that have fewer colour, odour and reactive problems), it may well be possible to raise the technological maximum at a future date.

2.1.3 The cost limit

Of the three, the cost limit is generally the more flexible and adjustable parameter, being dependent on value judgements about what is an acceptable price increase for fortified food products. Most ongoing food fortification programmes operate with price increases in the range 0.25–2.0%.

It is recommended that fortification programme managers discuss with industry at an early stage of programme development what an acceptable increment in production costs and product price would be, i.e. one that would make any mass fortification programme both feasible and sustainable. If more than one micronutrient is to be added, then their combined cost should fall within this predefined permitted increment.

When conducted on a relatively large-scale industrial basis, by far the largest share of the incremental cost of fortification (90% or more) can be attributed to the cost of the fortificant itself. This being the case, the cost limit can be calculated according to Equation 2, where the cost of the fortificant micronutrient(s) is used to substitute for the cost of the entire fortification programme. This approximation does not apply to some rice fortification processes, which rely on the use of rice premixes in low dilution rates (1:100 or 1:200). In this case, the cost of manufacturing of the premix exceeds that of the fortificant compounds.

Equation 2

$$\text{Cost limit}^{1}(\text{mg/kg}) = \frac{\begin{array}{c}[\text{Food price (US\$ per kg)} \times \text{price increment} \\ (\%100) \times \text{proportion of micronutrient} \\ \text{in fortificant } (\%100) \times 10^{6}]\end{array}}{[\text{Fortificant price (US\$ per kg)}]}$$

[1] A more accurate calculation may consider losses during distribution and storage, as well as losses during food preparation. However, because losses vary hugely according to conditions and situations, and because allowance is often made to compensate for these losses (i.e. an overage), it is usually acceptable to use this simplified approach.

2.2 Estimating the Feasible Fortification Level (FFL)

As stated in the introduction, whichever one of the three limits defined and calculated as above, i.e. the safety, the technological and the cost limit is the lowest becomes the FFL. Each micronutrient in a given food matrix will have its own FFL.

Once the FFL has been defined, it is possible to estimate for each micronutrient the additional intake that would be supplied to the target population, as well as the probable cost of the fortification process (based on the cost of the fortificants), and the final formulation of the premix (by multiplying the FFL by the dilution factor).

2.3 Estimating production parameters: the Target Fortification Level (TFL), the Minimum Fortification Level (mFL) and the Maximum Fortification Level (MFL)

The TFL is given by the sum of the calculated FFL and the natural intrinsic content of the micronutrient in the unfortified food. The value of the TFL should be used at the factory level as the target average micronutrient content of a fortified food, and thus as the reference value for quality control specifications.

The mFL is derived from the TFL according to Equation 3, that is to say, the TFL is reduced by an amount that is proportional to two times the coefficient of variation (CV) of the measured nutrient content of a food that has been fortified by a given process (when that process is performing adequately). The variability in the micronutrient content of a fortified food depends on the nature of the food vehicle and the amount of micronutrient added. Generally speaking, the inherent variability in the fortification process is lowest for liquids and greatest for coarse solids. For liquids, a CV of 10% is typical; for fine solids, such as cereal flours, the addition of niacin, iron, zinc and calcium has a CV of 15%, which rises to 25% for most other micronutrients. The variability for coarse solids, such as sugar and unrefined salt, is higher still, generally speaking around 30–50%.

Equation 3

$$\text{mFL (mg/kg)} = \text{TFL} \times [1 - (2 \times \text{CV in the nutrient content of the fortification process (\%/100)}]$$

The MFL is calculated in a similar way, the only difference being that twice the CV of the micronutrient content achieved by the fortification process when performing adequately is *added* to the TFL (Equation 4):

Equation 4

$$\text{MFL (mg/kg)} = \text{TFL} \times [1 + (2 \times \text{CV in the nutrient content during the fortification process (\%/100)})]$$

2.4 Estimating regulatory parameters: the Legal Minimum Level (LmL) and the Maximum Tolerable Level (MTL)

Irrespective of whether mass fortification is mandatory or voluntary, from a public health perspective, fortification levels should be prescribed in national standards and regulations. Such regulations may mention the technological parameters described in section 2.3, but it is essential that they refer to those levels that should feature on food labels and which should be used for inspection and enforcement purposes, i.e. the LmL and the MTL.

The LmL is calculated by subtracting from the mFL the expected losses of micronutrients during the distribution and storage of fortified products. Equation 5 summarizes the calculation:

Equation 5

$$\text{LmL (mg/kg)} = [\text{mFL (mg/kg)} \ (1 - \text{proportion of losses during storage and distribution})]$$

It may be necessary to specify a time frame after fortification, during which time nutritional claims must be upheld. In general, most mineral contents, with the exception of iodine in raw salt, should remain more or less constant, but vitamin contents are more liable to change with time, depending on the product. However, such losses rarely exceed 50%, even for the most sensitive nutrients (e.g. vitamin A, folic acid) during the shelf-life of the fortified food.

The MTL is simply the legal expression of the MFL for those nutrients for which there may be a safety concern, for example, vitamin A, vitamin D, folic acid, niacin (as nicotinic acid) iron, zinc, calcium and iodine. For other nutrients it may not be necessary to specify this parameter in regulations, something which reduces the complexity of the enforcement system required.

3. Selecting a fortification level based on the FFL: an example calculation

A government of a country is aware that most of its population has a diet rich in cereals but poor in foods of animal origin. Consequently, the general population is at risk of deficiencies in vitamin A, riboflavin (vitamin B_2), folate, vitamin B_{12}, iron and zinc. The government is considering introducing a mass fortification programme to counteract the risk of multiple micronutrient deficiencies and to this end has requested its public health nutritionists to

investigate the feasibility of supplying 70% of the Estimated Average Requirements (EARs) of these micronutrients via fortified foods and to recommend suitable fortification levels for achieving this nutritional goal.

3.1 Selecting appropriate food vehicles and determining the significance of food fortification in public health terms

Data on the level of consumption among the target population of four widely consumed staples, sugar, oil, wheat flour and rice, are summarized in **Table D.1**.

On the grounds that they are consumed by at least 50% of the population, sugar, oil and wheat flour were singled out as being the most appropriate vehicles for mass fortification. Although rice is also consumed in large amounts by the population, much of the supply is produced at small-scale, local mills, and thus much more difficult to fortify.

Although reasonable coverage can be achieved by the fortification of the three nominated food vehicles, there was nevertheless some concern that up to 30% of the target population might not benefit from the planned fortification programme. The sector of the population falling into this category is that which resides in rural areas and whose accessibility to industrially-processed foods is likely to be limited. Since it is technically possible to add vitamin A to all three vehicles, coverage is likely to be the greatest for this vitamin. However, for some of the other nutrients under consideration, which can only be easily added to one of the three proposed vehicles (i.e. wheat flour), coverage is likely to be significantly lower. It was concluded that the potential coverage made vitamin A fortification of all three products worthwhile, but that it would be necessary to provide micronutrient supplements in various forms (e.g. tablets, powders, beverages) to ensure an adequate micronutrient intake by that fraction of the population not covered by mass fortification (in particular those living in rural areas). It was recommended that supplements be distributed both commercially and through social programmes, and that they should provide the equivalent of 70% of the EAR for the micronutrients of concern. The proposed composition

TABLE D.1

Consumption profile of selected industrially-produced staples

Food	Consumers (% of population)	Consumption[a] (g/day)		
		P-5th	P-50th	P-95th
Sugar	70	10	20	60
Oil	60	5	10	25
Wheat flour	50	100	200	600
Rice[b]	10	100	250	700

[a] Expressed as percentiles of consumption.
[b] Refers to rice produced at larger-scale industrial facilities only.

TABLE D.2

Recommended composition of dietary supplements to complement fortified foods

Micronutrient	Daily equivalent dose[a]
Vitamin A	300 µg
vitamin B_2 (riboflavin)	0.8 mg
Folic acid	200 µg[b]
Vitamin B_{12}	1.4 µg[c]
Iron	10 mg
Zinc	4 mg

[a] These doses are given as equivalent doses so that they can be used to formulate a daily as well as a discontinuous dose (e.g. a weekly dose). The aim is to supply at least 70% EAR for adult males, which is used as the reference average for the family.

[b] 200 µg folic acid is equivalent to 340 µg Dietary Folate Equivalents (200 × 1.7), which means that a dietary supplement containing this dose would contribute 106% of the Estimated Average Requirement (EAR) for this particular nutrient.

[c] This dosage could provide up to 140% of the Estimated Average Requirement (EAR) of vitamin B_{12} in view of the higher bioavailability of the synthetic form relative to natural dietary sources.

of the dietary supplements (expressed as daily equivalent doses) are presented in **Table D.2**.

3.2 Analysing the safety, technological and cost limits to vitamin A fortification

The calculation of a safety limit for vitamin A fortification needs to take account of the fact that this micronutrient is to be added to more than one food (in this case three). Thus as a first step in the calculation, it is necessary to adjust the UL that will be used for the estimation of the safety limit for each food as follows:

$$\text{UL per food} = [\text{UL} - (\text{diet and supplement intake})]/3$$

The intake of vitamin A (in the retinol form) from dietary sources by the target population was estimated to be around 600 µg per day. This value represents the high end of consumption (i.e. the 95th percentile of intakes). Given that the UL for vitamin A is 3 000 µg and assuming a further daily intake of vitamin from supplements of 300 µg (see **Table D.2**), then:

$$\text{UL per food} = [3\,000 - (600 + 300)]/3,$$

that is:

TABLE D.3
Safety limits for vitamin A

Food	95th percentile of consumption (g/day)	Safety limit (mg/kg)
Sugar	60	12
Oil	25	28
Wheat flour	300	1.2

$$\text{UL per food} = 700\,\mu g.$$

Then, using Equation 1, it is possible to calculate a safety limit for each food. The results are given in **Table D.3**.

The question then arises whether or not it is technologically feasible to add these levels of vitamin A to the chosen food vehicles. According to the country's food technologists it is, and thus it was concluded that vitamin A fortification is unlikely to be limited by technological considerations in this scenario.

As food technologists warned that price increases in food products due to fortification in excess of 2% for sugar and oil, and 0.3% for wheat flour, might meet with opposition from the food industry, it was considered instructive at this point to estimate the increase in price that would result from fortification of the three products at the safety limits of vitamin A addition. **Table D.4** summarizes the results of such calculations.

On the basis of these computations, it is evident that the addition of vitamin A to sugar at a level of 12 mg/kg is barely cost compatible. On the other hand, of the three food vehicles, sugar has the best penetration (see **Table D.1**). On balance, it was decided to proceed with the fortification of sugar, despite the fact that the relative high cost might make the implementation of this intervention much more difficult.

3.2.1 Assessing the nutritional implications of the fortification with vitamin A at the Feasible Fortification Levels

The probable additional intakes of vitamin A due to fortification at the safety limits calculated above, at the 5th, 50th and 95th percentiles of consumption of each food, are shown in **Table D.5**. In each case, the additional intake is expressed as a percentage of the EAR, which for adult males is 429 µg per day.

According to the figures given in **Table D.5**, use of a three-food strategy would provide an additional intake somewhere between 28%[1] and 499% of the

[1] This value corresponds to the additional intake of vitamin A at the 5th percentile consumption of fortified sugar, which is the food with the widest consumption (70% of the population).

TABLE D.4

Cost analysis of fortification with vitamin A at the estimated safety limits for sugar, oil and wheat flour

Food	Level of vitamin A addition (mg/kg)	Cost analysis		
		Cost of fortification (US$ per MT[a])	Product price (US$/kg)	Price increment (%)
Sugar	12	11.00	0.50	2.0
Oil	28	6.00	0.70	0.9
Wheat flour	1.2	0.67	0.45	0.15

[a] MT stands for metric ton or 1 000 kg.

TABLE D.5

Additional intake of vitamin A at various levels of consumption of fortified foods

Food	Level of vitamin A addition (mg/kg)	Additional intake (as a % of the EAR[a])		
		P-5th	P-50th	P-95th
Sugar	12	28	56	168
Oil	28	33	65	163
Wheat flour	1.2	28	56	168
TOTAL		89	177	499

EAR, Estimated Average Requirement.
[a] Based on the EAR of vitamin A for adult males (429 µg/day). This value is used to represent the "average" intake for the family.

EAR for adult males (i.e. the extreme values of this combined strategy). This finding provides justification for the decision to proceed with the vitamin A fortification of sugar (despite the cost) as without it, the programme is unlikely to attain its nutritional goal of supplying 70% of the EAR to most individuals in the population.

The above analysis also demonstrates the benefits of fortifying three vehicles with lower amounts of vitamin A rather than just one with a relatively high amount. Adopting the latter approach would not only result in an unacceptably high cost increment, but also increases the risk of those individuals at the high end of consumption of the single vehicle reaching the UL without significantly improving the intake of those individuals at the low end of consumption. Furthermore, the coverage of the intervention would be limited to those consuming the single chosen food vehicle.

Taking into account all of the above considerations, it was decided to select the safety limits of vitamin A fortification as the FFLs, i.e. for sugar, 12 mg/kg, for oil, 28 mg/kg and for wheat flour: 1.2 mg/kg.

TABLE D.6

Production parameters for vitamin A fortification

Food	FFL (mg/kg)	Intrinsic vitamin A content (mg/kg)	TFL[a] (mg/kg)	CV[b] (%)	mFL[c] (mg/kg)	MFL[d] (mg/kg)
Sugar	12	0.0	12	33	4	20
Oil	28	0.0	28	10	22	34
Wheat flour	1.2	0.0	1.2	25	0.6	1.8

FFL, Feasible Fortification Level; TFL, Target Fortification Level; CV, coefficient of variation; mFL, Minimum Fortification Level; MFL, Maximum Fortification Level.

[a] The Target Fortification Level is given by adding the intrinsic vitamin A content of the food vehicles to the FFL.

[b] The coefficient of variation (CV) is a measure of the reproducibility of the fortification process.

[c] Calculated using Equation 3.

[d] Calculated using Equation 4.

TABLE D.7

Regulatory parameters for vitamin A fortification

Food	FFL (mg/kg)	Losses during distribution and storage (%)	LmL[a] (mg/kg)	MTL[b] (mg/kg)
Sugar	12	30	3	20
Oil	28	30	15	34
Wheat flour	1.2	25	0.5	1.8

FFL, Feasible Fortification Level; LmL, Legal minimum Level; MTL, Maximum Tolerable Level.

[a] Calculated using Equation 5.

[b] In this case, this is the same as the Maximum Fortification Level (MFL) given in **Table D.6**.

3.2.2 Establishing the production parameters

Having selected the FFLs, and using the definitions and equations given in section 2.3, the next task is to establish the production parameters for vitamin A additions at the factory level. These parameters are given in **Table D.6**.

3.2.3 Establishing the regulatory parameters

Regulatory parameters, the LmL and the MTL, for vitamin A fortification are summarized in **Table D.7**. These will form the basis of label claims and government enforcement activities. In the case of vitamin A fortification, it is necessary to set a MTL because of the need to make sure that individuals within the population (i.e. those at the high end of consumption) would not be at risk of excessive intakes of vitamin A.

3.3 Analysing the safety, technological and cost limits to wheat flour fortification

Having assessed the feasibility of vitamin A additions, the same procedure can be repeated to address the question of the incorporation of folic acid, vitamin

B_{12}, riboflavin (vitamin B_2), iron and zinc to wheat flour. Table D.8 provides a summary of the main features of this analysis, which reveals that folic acid addition is limited by safety concerns, vitamin B_{12} addition by cost, and vitamin B_2, iron and zinc additions by the risk of organoleptic changes in the sensorial and physical properties of the wheat flour.

3.3.1 Assessing the nutritional implications of the fortification of wheat flour, and adjusting the Feasible Fortification Levels

The nutritional implications of fortifying wheat flour at the FFLs calculated in **Table D.8** (i.e. as determined by safety, technological and cost constraints) are summarized in **Table D.9**. This is expressed in terms of the additional intakes that will result from the consumption of fortified wheat flour at three levels of consumption, the 5th percentile (i.e.100 g per day), the 50th percentile (i.e. 200 g per day) and the 95 percentile (i.e. 600 g per day). Intakes are given as absolute amounts and as a percentage of the EAR for adult males. Please note that this consumption pattern is high, and although it is typical of the Middle East and Central Asian countries, it may not be the case for other countries of the world. Each region or country should make their own calculations based on their own conditions in order to select the most appropriate fortification levels.

The calculations show that addition of folic acid to wheat flour would achieve the goal of supplying 70% of the EAR to nearly all consumers of wheat flour (that is to say, to 50% of the population). The case of vitamin B_{12} is also favourable, in fact, particularly so. Its level can be reduced to 0.010 mg/kg (from 0.040 mg/kg), which will help to reduce overall cost of the programme while still satisfying the nutritional target (i.e. an additional intake of 100% of the biological requirements (EAR) of this nutrient for almost all individuals who consume wheat flour).

In contrast, the addition of vitamin B_2 at a level of 4.5 mg per kg is not sufficient to meet nutritional goals, and therefore other sources of this nutrient (e.g. dietary supplements) would have to be supplied to the target population. The same is true of iron, and, in the case of reproductive-age women the deficit is likely to be even worse, since their iron requirements are greater than those used in the present calculation.

Although fortification with zinc at a level of 40 mg/kg would be expected to attain the EAR goal, in the interests of avoiding possible problems with iron absorption (zinc additions at these levels could inhibit the absorption of iron), it was considered prudent to reduce the level to 20 mg/kg. This would maintain a suitable balance with the additional iron intake. Any future interventions should pair zinc and iron additions in a way that complements the impact of wheat flour fortification.

TABLE D.8

Safety, technological and cost limits for wheat flour fortification[a]

Nutrient	Fortificant	Cost of fortificant (US$/kg)	Proportion of nutrient in fortificant	UL (mg/day)[b]	Intake from the diet and supplements (mg/day)[c]	Limits (mg/kg)			FFL[g] (mg/kg)
						Safety[d]	Technological[e]	Cost[f]	
Folate	Folic acid	90.00	0.90	1	0.2	1.3	NA	13.5	1.3
Vitamin B_{12}	Vitamin B_{12}, 0.1% water soluble	38.00	0.001	NA	NA	NA	NA	0.040	0.040
Vitamin B_2	Riboflavin	38.00	1.00	NA	NA	NA	4.5	36	4.5
Iron	Ferrous sulphate, dried	2.52	0.32	45	10	58	30	171	30
Zinc	Zinc oxide	3.35	0.80	45	4	68	40	322	40

UL, Tolerable Upper Intake Level; FFL, Feasible Fortification Level; NA, not applicable.

[a] Assumes that the per capita consumption of wheat flour is 100–600 g/day, and that the price of wheat flour is US$ 0.45/kg. This high level of consumption is typical of countries in the Middle East and Central Asia. Other countries should calculate their safety values according to their own consumption figures.

[b] Values are for adult males; this group is considered to be at greatest risk of reaching the UL through the consumption of fortified wheat flour.

[c] Intakes are specified only for those micronutrients for which there may be a safety concern (the main source of which, in this case, will be dietary supplements).

[d] Calculated using Equation 1.

[e] Technological compatibility is determined experimentally to confirm the absence of undesirable changes in the food vehicle due to the addition of fortificants.

[f] Calculated using Equation 2. It was predetermined that each nutrient should not increase the price of wheat flour by more than 0.3%.

[g] The Feasible Fortification Level (FFL) is the lowest of the three limits.

TABLE D.9

Nutritional implications of wheat flour fortification[a]

Nutrient	Fortificant	FFL (mg/kg)	EAR[b] (mg/day)	Absolute additional intakes (mg/day)			Additional intakes (as a % of the EAR)		
				P-5th	P-50th	P-95th	P-5th	P-50th	P-95th
Folate[c]	Folic acid	1.3	0.32	0.130	0.260	0.780	69	138	414
Vitamin B_{12}[d]	Vitamin B_{12}, 0.1% water soluble	0.040	0.002	0.0040	0.0080	0.0240	400	800	2400
	Vitamin B_{12}, 0.1% water soluble	0.010[e]	0.002	0.001	0.002	0.006	100	200	600
Vitamin B_2	Riboflavin	4.5	1.1	0.45	0.9	2.7	41	82	245
Iron[f]	Ferrous sulphate, dried	30	10	3	6	18	28	56	167
Zinc	Zinc oxide	40	5.8	4	8	24	69	138	414
	Zinc oxide	20[g]	5.8	2	4	8	34	69	207

FFL, Feasible Fortification Level; EAR, Estimated Average Requirement.

[a] Assumes that the per capita consumption of wheat flour is 100 g/day at the 5th percentile of consumption, 200 g/day at the 50th percentile and 600 g/day at the 95th percentile.

[b] Based on the values for the EAR for adult males. These values are used to represent the "average" intake for the family.

[c] The calculation of the additional intake as a percentage of the EAR takes account of the higher bioavailability of folic acid as compared with dietary folate (1 µg folic acid = 1.7 Dietary Folate Equivalents (DFEs) or 1.7 µg food folate).

[d] The calculation of the additional intake as a percentage of the EAR takes account of the higher bioavailability of the synthetic form of vitamin B_{12} as compared with dietary sources (% EAR multiplied by 2).

[e] The FFL has been adjusted downwards because the original value provided much more than was necessary to attain the nutritional goal of an additional intake of 70% of the EAR.

[f] If the average consumption of wheat flour is less than 150 g/day, ferrous fumarate may be used in place of ferrous sulfate as the fortificant in order to achieve the nutritional goal of an additional intake intake of around 50% EAR. However, it is important to note that this change increases iron fortification costs four-fold.

[g] The FFL has been adjusted downwards because it was important to keep the nutritional balance of the diet.

TABLE D.10

Production and regulatory parameters for wheat flour fortification

Nutrient	Fortificant	Accepted FFL[a] (mg/kg)	Intrinsic content (mg/kg)	CV[b] (%)	Production parameters			Regulatory parameters	
					MFL[c] (mg/kg)	TFL[d] (mg/kg)	mFL[e] (mg/kg)	LmL[f] (mg/kg)	MTL[g] (mg/kg)
Folate	Folic acid	1.3	0.2	25	0.8	1.5	2.3	0.6	2.3
Vitamin B_{12}	Vitamin B_{12}, 0.1% water soluble	0.010	0.000	25	0.005	0.010	0.015	0.005	NA
Vitamin B_2	Riboflavin	4.5	0.5	25	2.5	5.0	7.5	2.3	NA
Iron	Ferrous sulphate, dried	30	10	15	28	40	52	28	52
Zinc	Zinc oxide	20	10	15	21	30	39	21	39
Vitamin A	250-SD	1.2	0	25	0.6	1.2	1.8	0.5	1.8

FFL, Feasible Fortification Level; CV, coefficient of variation; mFL, Minimum Fortification Level; TFL, Target Fortification Level; MFL, Maximum Fortification Level; LmL, Legal minimum Level; MTL, Maximum Tolerable Level; NA, not applicable.

[a] The level of fortification that was finally selected, having adjusted the original FFLs for some micronutrients. The composition of a fortification premix for use with wheat flours is obtained by multiplying the FFL by the dilution factor.
[b] The coefficient of variation (CV) is a measure of the reproducibility of the fortification process.
[c] Calculated using Equation 3.
[d] The Target Fortification Level is given by summing the intrinsic micronutrient content of the unfortified wheat flour and the FFL. Factories should aim to produce foods that, on average, contain this amount of micronutrient.
[e] Calculated using Equation 4.
[f] Calculated using Equation 5.
[g] Relevant only for those micronutrients with safety concerns; equivalent, in this case, to the MFL.

3.3.2 Establishing production and regulatory parameters

Based on the slightly revised FFLs, production and regulatory parameters for the fortification of wheat flour with folate, vitamins B_2 and B_{12}, iron and zinc are calculated in the same way as for vitamin A (see section 3.2.2 and 3.2.3). These are given in Table D.10. For completeness, **Table D.10** also includes the corresponding parameters for vitamin A, calculated earlier (**Tables D.6** and **D.7**).

3.4 Concluding comments and recommendations

The above analysis establishes that fortification of wheat flour at the levels proposed (the "accepted" FFLs) would provide appropriate amounts of essential micronutrients to the majority of consumers. Moreover, the cost of the addition

TABLE D.11

Final formulation for the fortification of refined wheat flour and estimated associated costs for a hypothetical country[a]

Nutrient	Fortificant	Accepted FFL (mg/kg)	Regulatory parameters		Estimated costs of fortification	
			LmL[b]	MTL[c]	(US$ per MT[d])	(% of total cost)
Folate	Folic acid	1.3	0.6	2.3	0.13	5.6
Vitamin B_{12}	Vitamin B_{12}, 0.1% water soluble	0.010	0.005	NA	0.38	16.2
Vitamin B_2	Riboflavin	4.5	2.3	NA	0.17	7.3
Iron	Ferrous sulphate, dried	30	28	52	0.24	10.1
Zinc	Zinc oxide	20	21	39	0.08	3.6
Vitamin A	250-SD	1.2	0.5	1.8	0.67	28.7
Vitamin B_1	Thiamine mononitrate	6	2.8	NA	0.18	7.6
Vitamin B_6	Pyridoxin	5	2.4	NA	0.17	7.3
Niacin	Niacinamide	50	40	NA	0.45	13.6
Total					2.34	100.0
Price increment due to fortification (%)					0.5	

FFL, Feasible Fortification Level; LmL, Legal minimum Level; MTL, Maximum Tolerable Level; NA, not applicable.

[a] Assumes an average per capita consumption of wheat flour of 200 g/day (the 95th percentile of consumption is 600 g/day), and that the price of wheat flour is US$ 0.45 per kg. This high level of consumption is typical of countries in the Middle East and Central Asia. Other countries should calculate their fortification formulas according to their own consumption figures.

[b] The Legal Minimum Level (LmL) is the level of fortificant which should appear on the label and is the level to be enforced. It includes the intrinsic nutrient content of the unfortified wheat flour.

[c] The Maximum Tolerable Level is specified for those micronutrients for which there is safety concern; its purpose in food law is to assure that almost all wheat flour consumers do not reach the Upper Tolerable Intake Level for the nutrients for which this parameter is specified.

[d] MT stands for metric ton or 1 000 kg.

TABLE D.12

Estimating the overall cost of the proposed fortification programme and the annual investment required

Food vehicle	Consumer base (% of the population)	Cost of fortification (US$ per MT[g])	Annual demand (MT[g])	Per capita consumption[a] (kg/year)	Per capita consumption[b] (g/day)	Consumption per consumer[c] (g/day)	Total cost[d] (Million of US$ per year)	Annual investment per person[e] (US$)	Annual investment per consumer[f] (US$)
Sugar	70	11.00	100 000	10	27	39	1.10	0.110	0.157
Oil	60	6.00	30 000	3	8	13	0.18	0.018	0.030
Wheat flour	50	2.34	500 000	50	137	274	1.17	0.117	0.234
Total							2.45	0.245	0.421

[a] The annual per capita consumption (in kg) is calculated by dividing the annual demand by the total population, which for the purposes of this example is assumed to be 10 million persons (i.e. annual demand (in MT) × 1 000/10 000 000).

[b] The daily per capita consumption (in g) is calculated by dividing the annual per capita consumption by the number of days in the year (i.e. annual per capita consumption (in kg) × 1 000/365).

[c] The daily consumption per consumer is calculated by dividing the daily per capita consumption (in g) by the proportion of population that consumes the food. Ideally the daily consumption per consumer calculated in this way should equate to between the 50th and 95th percentile of daily consumption as determined by dietary surveys.

[d] The total annual cost of fortification is calculated as the product of the fortification cost per MT (in US$) and the annual total demand (in MT).

[e] The annual investment per person (in US$) is calculated as the annual total cost (in US$) divided by the total population (in this example, 10 million persons).

[f] The annual investment per consumer (in US$) is calculated as the annual investment per person (in US$) divided by the proportion of the population that consumes the food.

[g] MT stands for metric ton or 1 000 kg.

of vitamin A, vitamin B_2 (riboflavin), folate (folic acid), vitamin B_{12}, iron and zinc, was within acceptable limts.

Given that the process of milling eliminates many of the B vitamins that are necessary for the metabolic transformation of starch and protein, and that the costs associated with the addition of these vitamins are relatively small, it was decided to include some of the other the B vitamins in the nutrient premix. **Table D.11** thus shows the final formulation of the fortified wheat flour, as well as an estimate of the associated costs.

Estimates of the overall cost of the fortification programme to the country, as well as the annual investment required per person and per consumer, are given in **Table D.12**. These figures indicate that the health benefits that can be expected from the proposal to fortify selected foods make the investment an excellent option for the country.

ANNEX E

A quality control monitoring system for fortified vegetable oils: an example from Morocco

1. Background

In 2002, the Moroccan Ministry of Health launched a programme to fortify vegetable oils with vitamins A and D. Prior to its implementation, a National Food Fortification Committee (NFFC), hosted by the Ministry of Health, was established to serve as a forum for the supervision, follow up and evaluation of the oil fortification programme in Morocco. This Committee comprised food industry representatives, university researchers, staff members of government technical standards and inspection units, and representatives from each of the sponsoring agencies.

The Committee's first task was to conduct a feasibility study of soybean oil fortification. One of the objectives of this study was to determine an appropriate level of fortification, bearing in mind the overages that would be required to compensate for losses of vitamins A and D_3 during storage and culinary treatment (i.e. cooking and frying). Fortificant levels for vitamins A and D_3 were subsequently set at 30 IU/g and 3.0 IU/g, respectively, with tolerances at the product distribution stage in the range of 70–150% of these levels. It was also established that fortified vegetable oils would need to be commercialized in opaque containers.

2. Design of the QC/QA system

Having completed its feasibility study, the Committee reviewed and subsequently approved the proposed quality control and quality assurance (QC/QA) procedures for the oil fortification programme. These procedures, which were based on good manufacturing practice (GMP), were set out in the form of a technical manual. The technical manual provides comprehensive guidance on a full range of monitoring, inspection and auditing activities but places particular emphasis on quality control, recognizing this as being a key component of the fortification programme. In a measure designed to encourage compliance among producers, fortified oils that had been produced according to the prescribed internal quality control procedures were identified as having been done so by means of a Ministry of Health logo.

2.1 Hazard analysis and critical control point

The hazard analysis and critical control point (HACCP) approach was used as the basis of the system that was developed for monitoring the quality of fortified oils produced in Morocco. The usefulness of this approach for ensuring the safety of processed foods is acknowledged by both the Codex Alimentarius Commission and the World Health Organization (WHO). It can also be applied to the management of the quality of food products as this relates to the manufacturing process; this makes the HACCP approach complementary to other quality control systems such as the ISO 9001:2000[1].

HACCP analysis is a tool that is used to identify specific hazards (i.e. biological, chemical or physical hazards), as well as preventive measures for eliminating or controlling those hazards. In the case of fortified vegetable oils, microbiological hazards are unlikely to be a major concern, largely because of the absence of water in such products. The potential hazards are more likely to be chemical in nature, for example, contamination by polyaromatic hydrocarbons or by migration products from the packaging materials. Quality hazards may arise due to problems with the refined vegetable oil used as the vehicle for fortification (e.g. high rates of peroxidation, defects in the flavour characteristics) or with the fortificant compounds that are added (e.g. lumping, colour, odour).

The seven principles of HACCP, as adopted by Codex (*1*), establish a framework for developing a HACCP-based system that is specific to a given combination of food product and production line. Such a system identifies hazards at a series of critical control points (CCP), and then for each CCP, identifies critical limits and appropriate monitoring and control measures. The system is managed through daily review and analysis of the records for each CCP.

It is generally recommended that a HACCP system is periodically evaluated by an external auditor. In addition, the system should be revised whenever a modification is made to the production process, for example, in the wake of customer complaints or customer surveys that report a product defect.

2.2 Critical control points in the production of fortified vegetable oils

Application of the HACCP methodology to the production of fortified oils in Morocco identified the following CCPs; in each case, the appropriate preventive measure or action is described:

[1] ISO 9001:2000 is a norm of the International Standards Organization for the certification of quality management systems in the food industry. It signifies adherence to effective quality systems to ensure compliance with statutory and regulatory requirements applicable to products, and the existence of management reviews, quality objectives and process management focused on continuous improvement.

1. Receiving of the refined vegetable oils (the food vehicle)

   Action. Each lot should be tested using approved methods to confirm compliance with Moroccan specifications.

2. Quality of the fortificant premix

   Action. A quality assurance certificate should be obtained from the provider of the premix, and periodic analyses should be conducted to verify the vitamin content as well as the organoleptic properties of the premix (e.g. colour, texture, odour).

3. Storage of the fortificant premix

   Action. The premix should be re-assayed periodically for vitamin content to ensure that it continues to meet the required concentrations until the end of its shelf-life.

4. Addition of the fortificant premix

   Action. The premix use inventory should be assessed, that is to say, the amount of premix used should be compared with the amount of fortified vegetable oil produced (this is the simplest method). Alternatively, the metering pump should be calibrated by weekly testing and its in-line accuracy recorded.

2.3 Quality control and feedback systems for implementing corrective actions

The following quality control procedures and feedback mechanisms were established as part of the quality control monitoring system developed for the oil fortification process:

1. Product sampling and frequency

   Procedure: Three to five samples of fortified vegetable oil (collected after packaging) should be taken daily from each production line and the levels of vitamins A and D_3 measured. Levels should be within 95–150% of the declared content. One "composite sample" should be prepared daily from each production line and kept in an opaque airtight container for up to 3 months. These composite samples may be tested for their vitamin contents by government inspectors. Four samples should be analysed monthly by an external laboratory, and the results obtained used to verify the quality of the process.

- Labelling of fortified vegetable oils
  Procedure: Fortified vegetable oils must be identified with a label, which should specify, as a mimimum, the product brand, the batch number, the address of the responsible entity, the date of production and durability, as well as the declared levels of vitamins A and D_3. Fortified vegetable oils should be designated using the product's usual name followed by the words "vitamins A & D_3 fortified", or "vitamins A & D_3 enriched". Any expression of a therapeutic nature of the product on the labels is not allowed, but functional nutritional allegations for the vitamins A and D_3 are permitted.

- Distribution of fortified vegetable oils
  Procedure: Producers should be required to keep detailed records about the quantities of fortified oils they distribute to wholesalers and retailers. This is to facilitate the monitoring of the turnover of fortified oils and the assurance of the declared levels of vitamins A and D_3. Every 3 months, about 10 samples should be taken from retailers and households for testing. Whenever deviations from the admitted tolerances in vitamin A and D_3 contents are observed (–30% to +50%), an internal technical audit should be carried out to determine the cause(s) of such deviations.

- Documentation
  Procedure: All results of quality assurance activities should be recorded and made available to government inspectors upon request. A recall procedure should be established to deal with cases of overdosed vegetable oils (i.e. those containing high amounts of vitamins A and D_3) that might pose a threat to consumer health.

- Inspection and technical audits
  Procedure: Technical auditing, rather than sample testing, forms the mainstay of the inspection activities. At the factory level government inspection activities should concentrate on the internal quality control and assurance procedures adopted by individual manufacturers of fortified vegetable oils. Due vigilance must be given to corrective measures taken by producers to solve any limitations or errors. Attention should also be paid to the production equipment, conditions of the premix storage and addition, analysis and labelling of fortified vegetable oils, and product storage conditions. Warnings must be issued to manufacturers in cases of negligence and deviations from the established procedures. If no corrective measures are taken by manufacturers to ensure compliance, an external technical audit should then be carried out.

  — During each visit, between three and five samples of packaged product should be taken and sent to the Official Laboratory of Analysis and

Chemical Research (OLACR) in Casablanca for analysis. Vitamin A and D_3 contents should lie between 95% and 150% of the declared levels.

At the level of the wholesaler and retailer, inspection activities are mainly concerned with labelling, turnover of fortified oils according to the "FIFO" (first in-first out) principle, and the conditions of storage and handling of these products.

- Training activities
  Procedure: One-day training sessions should be scheduled for fortified oil production managers and government inspectors. The areas that should be covered during these sessions are as follows: techniques of vegetable oil refining; methods for vitamin A and D_3 analysis; techniques of vegetable oil sampling; factors affecting the stability of vitamins A and D_3 in vegetable oils; and the principles of the HACCP approach and its application to fortified vegetable oils.

Reference

1. Hazard analysis and critical control point (HACCP) system and guidelines for its application. *Codex Alimentarius -Food hygiene- Basis texts- Second editions*. Rome, Food and Agriculture Organization of the United Nations, 1997: Annex.

ANNEX F

The Codex Alimentarius and the World Trade Organization Agreements

1. The Codex Alimentarius

The Codex Alimentarius, which means "food law" or "code" in Latin, is a comprehensive collection of internationally adopted and uniformly presented food standards and related texts (including guidelines) that are commonly referred to as the "Codex texts". The Codex texts address a wide range of general matters that apply to all processed, semi-processed and raw foods distributed to consumers, such as food hygiene, food additives, pesticide residues, contaminants, labelling and presentation, and methods of analysis and sampling. The texts also deal with various matters that are specific to individual commodities; for instance, commodity standards, guidelines and related texts have been developed for commodity groups such as milk, meat, cereals, and foods for special dietary uses. The complete Codex Alimentarius is available via the Codex web site[1].

The ongoing revision and development of the Codex Alimentarius is the responsibility of the Codex Alimentarius Commission, which was established in the early 1963 as an intergovernmental body by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). Membership is open to all Member countries of FAO and/or WHO.

The Codex texts are developed or revised though 29 subsidiary bodies comprising regional, commodity and general committees, all of which are intergovernmental in nature and most of which are currently active. The committees of most relevance to fortification and related issues are the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), which is hosted by Germany, and the Codex Committee on Food Labelling (CCFL), hosted by Canada. The terms of reference for the CCNFSDU is to advise on general nutrition issues and to draft general provisions concerning the nutritional aspects of all foods, develop standards, guidelines and related texts for foods for special dietary uses (*1*). The remit of the Codex Committee on Food Labelling is to study problems related to the labelling and advertising of foods, to draft provisions on labelling that are applicable to all foods and to endorse draft provisions on labelling prepared by other Codex Committees.

[1] www.codexalimentarius.net.

1.1 Codex texts relevant to food fortification

The part of the Codex Alimentarius of greatest direct relevance to food fortification is the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 07-1987, amended 1989, 1991) (*2*). This section, which covers the addition of essential nutrients for the purposes of restoration, nutritional equivalence of substitute foods as well as fortification, provides guidance to governments with regard to the planning and implementation of national food fortification programmes.

More specifically, the Codex General Principles for the Addition of Essential Nutrients to Foods by:

— providing guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods; and by

— establishing a uniform set of principles for the rational addition of essential nutrients to foods;

seek to:

— maintain or improve the overall nutritional quality of foods;

— prevent the indiscriminate addition of essential nutrients to foods, thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances (this also helps to prevent practices that may mislead or deceive the consumer);

— facilitate acceptance in international trade of foods that contain added essential nutrients.

The General Principles state that the essential nutrient:

- should be present at a level that will not result in an excessive or an insignificant intake of the added nutrient considering the amounts from other sources in the diet;
- should not result in an adverse effect on the metabolism of any other nutrient;
- should be sufficiently stable in the food during packaging, storage, distribution and use;
- should be biologically available from the food;
- should not impart undesirable characteristics to the food, or unduly shorten its shelf-life;

- the additional cost should be reasonable for the intended consumers, and the addition of nutrients should not be used to mislead the consumer concerning the nutritional quality of the food;
- adequate technology and processing facilities should be available, as should methods of measuring and/or enforcing the levels of added nutrients.

A number of other Codex texts provide guidance and recommendations that are of relevance to fortified foods. Advice relating to the nutritional quality of foods for special dietary uses is contained in *Codex Alimentarius, Volume 4 – Foods for special dietary uses* (*3*). Food labelling, nutrition labelling, and claims that can be used by governments to establish their national regulations are covered in *Codex Alimentarius – Food labelling – Complete texts* (*4*).

1.2 Recommended levels of nutrients in foods for special dietary uses

A series of Codex standards propose maximum and minimum levels of selected nutrients, in particular minerals and vitamins, for various foods having special dietary uses, for example, foods for infants and children. Recommended minimum and maximum vitamin and mineral levels for infant formulas are given in the Codex Standard for Infant Formula (CODEX STAN 72-1981, amended 1997) (*5*), and for follow-up formulas in the Codex Standard for Follow-up Formula (CODEX STAN 156-1987, amended 1989) (*6*). Rather than prescribing minimum and maximum nutrient levels, the Codex Standard for Canned Baby Foods (CAC/STAN 73-1981, amended 1989) (*7*) prefers to leave this matter to the national regulations of the country in which the food is sold.

The Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979, amended 1991) (*8*) sets out recommendations regarding the source of any added minerals, their purity requirements, and the type of foods in which they can be used. In the case of the vitamins, the various forms are listed (with purity requirements), together with a number of specially formulated vitamin preparations, where applicable.

The Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991) not only provide recommendations relating to nutritional matters but also address technical aspects of the production of formulated supplementary foods (*9*). These Guidelines include a list of reference daily requirements for those vitamins and minerals "for which deficiency is most frequently found in the diets of older infants and young children", these being the nutrients which should be given primary consideration in the formulation of supplementary foods. However, local conditions, in particular, the nutrient contribution of locally produced staple foods to the diet and the nutritional status of the target population, should be taken into account when deciding which micronutrients to add. The Guidelines make the general

recommendation that when a food is supplemented with one or more of the following nutrients (vitamins A, D, E or C, thiamine (vitamin B_1), riboflavin (vitamin B_2), niacin, B_6, folate, B_{12}, calcium, iron, iodine or zinc), the total amount added per 100 g of dry food should be at least two thirds of the reference daily requirement for that nutrient (*9*).

In the Codex Standard for Processed Cereal-based Foods for Infants and Children (CODEX STAN 74-1981, amended 1991) (*10*) maximum levels of sodium are defined for different types of products covered by the standard. It is also specified that "the addition of vitamins, minerals and iodized salt shall be in conformity with the legislation of the country in which the product is sold".

1.3 Labelling

General labelling requirements are defined in the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 01-1985, amended 2001) (*11*) and the Codex General Guidelines on Claims (CAC/GL 01-1979, revised 1991) (*12*). Nutritional labelling is covered by the Codex Guidelines on Nutrition Labelling (CAC/GL 02-1985, revised 1993) (*13*) and nutritional claims by the Guidelines for Use of Nutrition Claims (CAC/GL 23-1997, amended 2001) (*14*).

The Codex Guidelines on Nutrition Labelling are based on the principle that no food should be described or presented in a manner that is false, misleading or deceptive, and that any claims made should be substantiated (*13*). A nutrient declaration, defined in section 2.3 of the Codex Guidelines as "a standard statement or listing of the nutrient content of a food", is mandatory only when claims are made. The Guidelines include provisions for nutrient declarations, calculation and presentation. Nutrient Reference Values (NRVs) for labelling purposes are defined for 14 vitamins and minerals, as well as for protein.

The Codex Guidelines for Use of Nutrition Claims (*14*) were developed as a supplement to the general provisions of the General Guidelines on Claims (*12*), primarily to provide a basis for the harmonization of nutrition claims. Nutrition claims are widely used as a marketing tool but have the potential to cause confusion for consumers. The Codex Guidelines for Use of Nutrition Claims specify that nutrition claims must be consistent with, and support, national nutrition policy. Nutrition claims that did not support national policy should not be permitted.

The Codex texts recognize the importance of establishing a link between nutrition labelling provisions and nutrition policy as a whole. Thus the Codex texts on nutrition and labelling, by providing guidance to national governments, allow for the development of national regulations and requirements according to the specific needs of the population. Conditions have been defined for foods that are a "source" of, or are "high" in, vitamins and minerals and protein. These

provisions apply to claims that are made about any foods, not just fortified foods. When such claims are made, nutrient declaration should be provided in accordance with the Guidelines on Nutrition Labelling (*13*), as mentioned above. Conditions for the use of health claims are currently under discussion by the Commission.

2. The World Trade Organization Agreements

The World Trade Organization (WTO) is the only international organization in existence that deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and as freely as possible (*15*). By February 2002, 144 countries, which are collectively responsible for more than 90% of world trade, had negotiated their accession to membership of the WTO (*16*). Further information about the work of WTO and its agreements is available via the WTO web site[1].

The two WTO agreements (*17*) of most relevance to food are the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), and the Agreement on Technical Barriers to Trade (the TBT Agreement). Under the terms of both agreements, countries may adopt provisions that limit trade for legitimate reasons; the legitimate reasons can include health considerations, provided that such measures do not unnecessarily restrict trade. However, it is the latter, the TBT Agreement, that usually has the more significant implications for food fortification regulations, whether mandatory and voluntary, and for this reason is the focus of the discussion here[2].

2.1 The Agreement on Technical Barriers to Trade: background and general provisions

In the 1970s, Contracting Parties to the General Agreement on Tariffs and Trade (GATT) expressed their dissatisfaction with the emergence of new non-tariff barriers (NTBs) to trade. A GATT working group was thus established to evaluate the impact of NTBs on international trade, and reached the conclusion that the main form of NTBs that exporters faced were in fact technical barriers. During the Tokyo Round of GATT talks held in 1979 an Agreement on Technical Barriers to Trade (also called the Standards Code) which governed the preparation, adoption and application of technical regulations, standards and conformity assessment procedures was drafted. The final form of the TBT Agreement was negotiated during the Uruguay Round in 1994 and entered into force in 1995, at the same time as the WTO.

[1] www.wto.org.

[2] This part of the Guidelines has been drafted by the WTO's Trade and Environment Division and remains their responsibility.

The TBT Agreement is premised on an acknowledgement of the right of WTO Members to develop technical requirements[1], and to ensure that they are complied with (through what are known as conformity assessment procedures). However, the objective of the TBT Agreement is to ensure that unnecessary obstacles to international trade are not created. This is achieved through a number of principles that govern the preparation, adoption and application of mandatory and voluntary requirements and conformity assessment procedures. These principles include:

- non-discrimination;
- the avoidance of unnecessary obstacles to international trade;
- harmonization;
- the equivalence of technical regulations and of the results of conformity assessment procedures;
- mutual recognition of conformity assessment procedures;
- transparency.

At the international level, the TBT Agreement acts as an important instrument to guard against the improper use of technical requirements and conformity assessment procedures, that is to say, as disguised forms of restrictions on trade. It also guards against the development of inefficient requirements and procedures that create avoidable obstacles to trade. In some settings, it can act as a mechanism for encouraging countries to adopt less trade restrictive approaches to meeting regulatory objectives.

2.2 Coverage and definitions of the TBT Agreement

The TBT Agreement divides technical requirements into three categories, namely technical regulations, standards and conformity assessment procedures, which are defined as follows.

- *A technical regulation:* a "Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

[1] The term "technical requirement" in the context of these Guidelines embraces both voluntary and mandatory product specifications.

- A *standard*: a "Document approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."
- A *conformity assessment procedure:* "Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled."

While both technical regulations and standards are technical product requirements, the main difference between the two is that compliance with technical regulations is mandatory, whereas compliance with standards is voluntary. A law that stipulated that a nominated food must contain a minimum amount of a micronutrient (as is the case with mandatory fortification) is an example of a technical regulation. Voluntary fortification provisions or a labelling permission for voluntary micronutrient content claims are examples of standards.

The TBT Agreement contains provisions which ensure that technical regulations do not act as unnecessary obstacles to trade. These provisions apply to technical regulations developed by central and local governments, as well as those developed by nongovernmental bodies. WTO Members are fully responsible for ensuring the observance of all the provisions of the TBT Agreement as they relate to technical regulations. They must also formulate and implement positive measures and mechanisms in support of the observance of the provisions of the TBT Agreement by local and nongovernmental bodies.

Standards are addressed separately under a "Code of Good Practice", which is contained in Annex 3 of the TBT Agreement. Most of the principles that apply to technical regulations, also apply to standards through the Code. The Code is open to acceptance by central, local and nongovernmental standardizing bodies (at the national level), as well as by regional governmental and nongovernmental bodies. However, the TBT Agreement notes that, "The obligations of Members with respect to compliance of standardizing bodies with the provisions of the Code of Good Practice shall apply irrespective of whether or not a standardizing body has accepted the Code of Good Practice."

Conformity assessment procedures are subject to many of the same principles as those that apply to technical regulations and standards, in order to ensure that they themselves do not constitute unnecessary obstacles to international trade. WTO Members are fully responsible for ensuring observance of all provisions relating to conformity assessment under the terms of the TBT Agreement, and must formulate and implement positive measures and mechanisms in support of the observance of the provisions by local government bodies. They must also ensure that central government bodies rely on conformity assessment

procedures operated by nongovernmental bodies, but only if such bodies are in compliance with the relevant provisions of the TBT Agreement.

2.3 Legitimate objectives

Under the TBT Agreement, technical regulations may be developed for one or more of the objectives considered as legitimate by the TBT Agreement. Legitimate objectives include: "inter alia, national security requirements, the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health, or the environment". Fortification measures are most likely to fall under the protection of human health category. However, the prevention of deceptive practices, which refers to measures that mislead or deceive consumers (e.g. false nutritional information given on food labels), might also constitute a legitimate objective and thus WTO Members would be allowed to adopt technical regulations to guard against such practices.

The risks associated with legitimate objectives are assessed against a number of factors, including: "inter alia, available scientific and technical information, related processing technology or intended end-uses of products". Once again, the inclusion of the words "inter alia", indicates that some flexibility may be exercised in the selection of factors against which risks may be assessed.

2.4 Principles which govern the preparation, adoption and application of mandatory and voluntary requirements and conformity assessment procedures

2.4.1 Non-discrimination

The principle of non-discrimination forms the backbone of the international trading system. The TBT Agreement embraces the GATT principle of non-discrimination, and applies it to technical regulations, standards and conformity assessment procedures. In general, it is the principle that outlaws discrimination between products of WTO Member countries, and between imported and domestically produced products.

With respect to both technical regulations and standards, the TBT Agreement stipulates that the non-discrimination principle be observed throughout the various stages of their preparation, adoption and application. For instance, a WTO Member cannot adopt a technical regulation mandating that all imported food meet certain micronutrient standards, if it does not enforce such standards on its own domestically produced food. Nor can it enforce a technical regulation on one, but not on another, of its trading partners. In short, under the disciplines of the TBT Agreement and the WTO system as a whole, treatment must be no less favourable.

WTO Members must also ensure that conformity assessment procedures are not prepared, adopted or applied in a discriminatory manner. Achieving

non-discrimination with respect to conformity assessment requires, among other things, ensuring suppliers' right to conformity assessment under the rules of procedure, including the option of having conformity assessment activities undertaken in situ and to receive the mark of the system. Conformity assessment systems must not distinguish between the procedures to be followed for products originating from different sources. For instance, systems cannot subject similar products to tests of varying degrees of stringency depending on their source of supply.

2.4.2 Avoidance of unnecessary obstacles to international trade

The avoidance of unnecessary obstacles to international trade is the principal objective of the TBT Agreement. With respect to both technical regulations and standards, the TBT Agreement states that WTO Members must ensure that neither technical regulations nor standards are "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade". With respect to technical regulations, the TBT Agreement elaborates on the meaning of this phrase; it stipulates that technical regulations may not be more trade restrictive than is necessary to fulfil a legitimate objective, taking into account the risks that non-fulfilment would create.

Determining whether or not a technical regulation poses an unnecessary obstacle to international trade involves two steps. Firstly, the regulation must be designed to meet one of the legitimate objectives delineated in the TBT Agreement (see section 2.3). Secondly, the regulation must be the least trade-restrictive option available to a WTO Member that achieves that legitimate objective, taking into account the risks that would be associated with its non-fulfilment.

The TBT Agreement encourages WTO Members to develop technical regulations and standards that are based on product performance requirements, rather than on design requirements. The former creates fewer obstacles to trade, providing exporters greater leeway in terms of fulfilling the objectives of the technical requirements. For instance, it would be preferable for a country to stipulate the minimum amount of a micronutrient that must be present in a specific type of food rather than a specific process for the addition of that micronutrient.

To help avoid unnecessary obstacles to international trade, the TBT Agreement requires WTO Members to revoke technical regulations when the objectives that had given rise to their adoption no longer exist, or if changed circumstances or objectives can be addressed in a less trade-restrictive manner.

WTO Members must also ensure that unnecessary obstacles to international trade are avoided when preparing, adopting and applying conformity assessment procedures for technical regulations and standards. The TBT Agreement states that, "Conformity assessment procedures shall not be more strict or be

applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks that non-conformity would create." In other words, conformity assessment procedures must not be applied more stringently than is necessary to ensure conformity. They must consider the risks of reduced stringency, and decide whether or not the risks outweigh the benefits of having fewer obstacles to international trade.

The TBT Agreement also urges Members to ensure that conformity assessment procedures are undertaken as expeditiously as possible, that information requirements are limited to whatever is necessary, that the confidentiality of information is respected for legitimate commercial interests, and finally that the fees charged domestically are equitable to the fees charged for foreign products.

2.4.3 Harmonization

The TBT Agreement encourages WTO Members to base their technical regulations, standards and conformity assessment procedures on international standards, guidelines and recommendations, when these exist or their completion is imminent, excepting when they are deemed to be inappropriate or ineffective. For example, it allows derogation from technical regulations and standards in the event of climatic or geographic differences, or because of fundamental technological problems. Although not specifically refered to in the TBT Agreement, the Codex Alimentarius is widely interpreted as being the relevant text or "gold standard" with respect to the development of regulations on food products.

The call for harmonization is intended to avoid undue layers of technical requirements and assessment procedures, and to encourage the wider application of those that have already been developed and approved by the international community. To support this endeavour, the TBT Agreement calls upon WTO Members to participate in the work of international standardizing and conformity assessment bodies.

2.4.4 Equivalence and mutual recognition

International harmonization is a time-consuming process, and is sometimes difficult to achieve. The principle of equivalency is thus designed to complement that of harmonization and the TBT Agreement encourages WTO Members to accept each other's regulations as equivalent until international harmonization becomes possible. More specifically, the TBT Agreement stipulates that WTO Members give positive consideration to recognizing other Members' technical regulations as being equivalent to their own, even when they differ, provided that they are satisfied that the regulations adequately fulfil their objective. Through the establishment of equivalency arrangements between countries, products that meet the regulations of the exporting country do not have to

comply with the regulations of the importing country, so long as the same objectives are fulfilled by the two sets of requirements. This significantly reduces barriers to trade.

The TBT Agreement also calls upon WTO Members to ensure, whenever possible, that the results of conformity assessment procedures of other Member Countries are accepted, even when they differ from their own, provided that the procedures give the same level of confidence. The purpose of this provision is to avoid multiple product testing (in both exporting and importing country markets), and its associated costs. However, it is acknowledged that in order to achieve acceptance, negotiations may be needed, primarily to ensure the continued reliability of conformity assessment results (the accreditation of conformity assessment bodies is a factor that can be taken into account in this regard). The TBT Agreement encourages these kinds of mutual recognition agreements between WTO Members.

2.4.5 Transparency

Transparency is a central feature of the TBT Agreement, and is achieved through notification obligations, the establishment of enquiry points, and the creation of the WTO TBT Committee.

Notification obligations require WTO Members to notify their draft technical regulations, standards and conformity assessment procedures and also to allow other Members sufficient time to comment on them. Members are obliged to take comments from other countries into account.[1] Notifications provide a useful means of disseminating information, and can often help to avoid unnecessary obstacles to international trade at an early stage. The advantage of the notification system is that it provides exporters with the opportunity to learn of new requirements prior to their entry into force, to comment on these requirements (and know that their comments will be taken into account), and to prepare themselves for compliance.

The TBT Agreement stipulates that each WTO Member establish an enquiry point for responding to questions on technical regulations, standards and conformity assessment procedures (whether proposed or adopted), and for supplying relevant documents.

A TBT Committee has been established as part of the TBT Agreement to act as a forum for consultation and negotiation on all issues pertaining to the Agreement. Participation in the Committee is open to all WTO Members, and a number of international standardizing bodies are invited to attend meetings as observers.

[1] Draft technical regulations and conformity assessment procedures only have to be notified when an international standard, guide or recommendation, does not exist (or they are not in accordance with existing ones), and if they may a have a significant effect on the trade of other WTO Members.

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