POLICY GUIDELINES FOR FORTIFICATION OF FOOD IN SRI LANKA

Ministry of Healthcare and Nutrition,
385, Baddegama Wimalawansa Mawatha,
Colombo 10
Sri Lanka

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Ministry of Healthcare
and Nutrition

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Preface

Micronutrient malnutrition is a wide spread problem throughout the world. Overcoming micronutrient malnutrition is a precondition for insuring rapid and appropriate national development. The achievement and maintenance of desirable level of nutritional quality in the national food supply is an important public health objective.

Food fortification is one of the most popular nutritional interventions for improving the nutrient security of the population. Food fortification is cost effective and reaching a greater proportion of population at-risk than any other feasible interventions and there by important in promotion of optimal health. However random fortification of foods could result in over or under fortification in consumer diets and create nutrient imbalance in the food supply.

The main objective of this document is to establish a set of guidelines that will serve as a model for food fortification in Sri Lanka

This publication is a useful guide to support the industries, decision makers, policy planners and food legislators in relation to the need, benefits, implementation, monitoring and regulation of food fortification.

I am sure these guide lines will be of great use and relevance for both government and private sector in their participation on food fortification.

Dr. Ajith Mendis
Chief Food Authority
Director General of Health Services,
1st August 2008

Acknowledgments

The Food Advisory Committee would like to acknowledge Dr. Ajith Mendis, Chief Food Authority (Director General of Health Services) for steering the committee to formulate and taking action to implement this policy guidelines for fortification of foods.

Many thanks to Dr. D. G. Maheepala, Deputy Director General (Public Health Services) who contributed whole hearted support, without which the policy guidelines not have been successfully completed.

The special thanks due to all round support and guidance given by Dr. C.K. Shaunmugarajah, Director, Environmental and Occupational Health and Food Safety.

Appreciation is also due to the members of the Technical Sub Committee for their valuable expertise contribution in the process of developing this document.

Special mention must be made of Mr.P. Madarasinghe, Assistant Director, Food Control Administration Unit, Ministry of Health. Ackowledgement is also due to Ms Rasitha Perera for secretarial assistance and modifying, revising and formatting the report.

The financial assistance of World Health Organization towards the process of publishing this document is greatly acknowledged.

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Contents

1.0 Introduction

Fortification of food with micronutrients has been practiced for several years particularly by industrial countries as a means of restoring the micronutrients lost during the processing of food.

Fortification as defined by the Codex Alimentarius Commission is the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups (1).

Therefore, fortification of food with micronutrients has been identified as a valid technology for adoption as part of a food-based approach when and where existing food supplies and limited access fail to provide adequate levels of the respective nutrients in the diet. It becomes a valuable method to start and continue an ongoing nutrition improvement programme.

Interest in the addition of micro-nutrient has greatly increased over the last few years. The Governments have studied the problems of malnutrition due to the non-availability of particular nutrients in the food and have started nutrition improvement programmes.

Under free market conditions and advances in food technology, many types of processed foods are produced and offered to consumers. There is a tendency for the food processor to add micronutrients, whether required or not, and use the addition of the micronutrient to claim the superiority of their product.

The increase in the availability of fortified processed foods in the market has given rise to a number of concerns to the authorities. The authorities or the government would like to exercise a degree of control over voluntary fortification of food by industries through food laws or other cooperative arrangements such as codes of practice.

The Chief Food Authority has decided to bring out these guidelines to assist the industries and other government organizations in the design and implementation of appropriate food fortification programmes.

The guidelines provide information relating to the need, benefits, implementation, monitoring and regulating of food fortification. The guidelines are intended to be a resource for government and other agencies that are currently implementing or considering starting a food fortification programme.

2.0 Rationale for Fortification

Micronutrient malnutrition is a widespread problem throughout the world and has both health and economic consequences. The outcome includes blindness, poor cognitive development, reduced growth, lower worker productivity, higher morbidity and mortality and adverse pregnancy consequence.

The Micronutrient interventions, particularly fortifications, have been identified by the World Bank as among the most cost-effective of all health interventions (2).

One out of every four people in the world suffers from micronutrient deficiencies (3). Thus, a quarter of the population does not receive the adequate nutrition to grow up healthy and productive. The need for food fortification in Sri Lanka as a preventive measure to overcome micronutrient deficiencies can be adequately justified based on data available on dietary inadequacy of nutrients and food consumption patterns of populations (Annex 01- % adequacy of nutrient intake according to Sri Lankan RDA).

Several national surveys have shown that there is marked reduction in prevalence of anemia, but iron deficiency continues to be an important problem affecting more than 40% of children, adolescent girls and women of childbearing age, including pregnant women (4). Anemia in infants and children is associated with retardation of physical and intellectual growth, as well as reduced resistance to infections. In adults, anemia adversely affects the immune system, causes fatigue and reduces work capacity. For every 10 percent deficit in hemoglobin concentration, there is a 10-20 percent deficiency in work performance.

In the last national survey on vitamin A status of preschool children (MRI, 1995), prevalence of sub clinical vitamin A deficiency was 35% indicating a public health problem (5). A recent survey (MRI, 2005) to assess the prevalence of Iodine deficiency among children 6-9 years of age, reveals that the total goiter rate was 3.8% (6). The Sri Lankan diet is deficient in iron, iodine, and vitamin A, (zinc and folate, calcium, lysine) Food fortification should be mainly carried out to fill up these inadequacies in Sri Lankan diet.

The Food Act No 26 of 1980 and the Food Labeling and Advertising) Regulations, 2005 made by the Minister in charge of subject of Health in consultation with the Food Advisory Committee, regulates the addition of nutrients to foods and further stipulates mandatory approval of the Chief Food Authority on limits of the food fortification (Gazette notification No 1376/9 dated 19.1.2005[Section 13/ 7 (IV)]).

3.0 The Scope

Fortification can make an important nutritional difference and offer a number of strategic advantages for the large and expanding populations of all socioeconomic classes that regularly purchase and consume commercially processed foods. When superimposed on existing food patterns, fortification may not necessitate changes in the customary diet of the population and does not call for individual compliance; but it can be dovetailed into existing food production and distribution systems. For these reasons, fortification can often be implemented and yield results quickly and be sustained over a long period of time. It can thus be the most cost-effective means of overcoming micronutrient malnutrition.

3.1 Food fortification can take several forms. It is possible to fortify foods

3.1.1. that are widely consumed by the general population (mass fortification or Universal fortification),

3.1.2. designed for specific population subgroups, such as complementary foods for young children or rations for displaced populations (targeted fortification)

3.1.3. on voluntary basis by food manufacturers i.e. foods available in the market place (market driven fortification)

3.2 Mass fortification is essentially a mandatory, targeted fortification however, can be either mandatory or voluntary, depending on the public health significance of the problem it is seeking to address.

3.3 There are other forms of novel fortification such as household and community fortification and bio-fortification of staple foods.

Food fortification is vital where there is a demonstrated need to increase the intake of an essential nutrient by one or more population groups, as manifested in dietary, biochemical or clinical evidence of deficiency. It shall also be considered important to compensate for nutrient losses due to processing and storage.

The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. However, random fortification of foods could result in over or under fortification in consumer diets, creating a nutrient imbalance in the food supply.

Guidelines on food fortification will help food legislators, the government or any manufacturer when implementing food fortification programmes.

4.0 Statement of Policies

4.1 Food fortification shall be recommended for foods that are widely consumed particularly by at- risk population groups.

4.2 Fortification shall be recommended for processed foods that replace or stimulate traditional foods to compensate for nutritional inferiority due to use of substitute ingredients

4.3 Food fortification shall not be encouraged in alcoholic beverages and candies because excessive intake as a result of undue consumption of these fortified products may lead to health problems.

5.0 Objectives

I. To maintain and improve the overall nutritional quality of foods.

II. To avoid nutrient imbalance in the food supply due to over or under fortification

III. To prevent practices that may be deceptive or mislead the consumer.

IV. To provide guidelines for manufacturers who fortify foods to preserve a balance of nutrients in the diet.

6.0 Selection of a food vehicle

Fortification requires the identification of commonly eaten foods that can act as vehicles for one or more micronutrients and lend themselves to centralized processing on an economical scale.

Specific criteria should be met when choosing the appropriate food vehicle to introduce the fortificant.

- According to WHO, FAO Guidelines on Food Fortification with Micronutrients, 2006 (7) the following types of foods have some or all of the following characteristics,

Foods that are:

- Consumed by a large proportion of the population, including (or especially) the population groups at greatest risk of deficiency.
- Consumed on a regular basis, in adequate and relatively consistent amounts.
- centrally processed (central processing is preferable for a number of reasons, but primarily because the fewer the number of locations where fortificants are added, the easier it is to implement quality control measures; monitoring and enforcement procedures are also likely to be more effective).
- Containing a nutrient premix to be added relatively easily using low-cost technology and in such a way so as to ensure an even distribution within batches of the product.
- Used relatively soon after production and purchase. Foods that are purchased and used within a short period of time of processing

tend to have better vitamin retention and fewer sensorial changes due to the need for only a small over dosage.

7.0 Choice of Fortificant Compound

When selecting the most appropriate chemical form of a given micronutrient, the main considerations of concern are thus:

- *Sensory problems.* Fortificants must not cause unacceptable sensory problems (e.g. colour, flavour, odour or texture) at the level of intended fortification, or segregate out from the food matrix and they must be stable within given limits. If additional packaging is needed to improve stability of the added fortificant, it is helpful if this does not add significantly to the cost of the product and make it unfavourable to the consumer.
- *Interactions.* The likelihood or potential for interactions between the added micronutrient and the food vehicle and with other nutrients (either added or naturally present), in particular, any interactions that might interfere with the metabolic utilization of the fortificant, needs to be assessed and checked prior to the implementation of a fortification programme.
- *Cost.* The cost of fortification must not affect the affordability of the food nor its competitivity with the unfortified alternative.
- *Bioavailabitity.* The fortificant must be sufficiently well absorbed from the food vehicle and be able to improve the micronutrient status of the target population.

8.0 Mandatory and Voluntary Fortification

8.1 Mandatory Fortification

8.1.1 Key Characteristics

Mandatory fortification occurs when governments legally require food producers to fortify particular foods or categories of foods with specified micronutrients (Example –iodisation of salt in Sri Lanka).

Mandatory fortification, especially when supported by a properly resourced enforcement and information dissemination system, delivers a high level of certainty that the selected food(s) will be appropriately fortified and in constant supply.

Governments are responsible for ensuring that the combination of the food vehicle and the fortificants will be efficacious and effective for the target group, yet safe for target and non-target groups alike. Food vehicles range from basic commodities, such as various types of flour, sugar and salt which are available on the retail market for use by consumers as well as ingredients of processed foods, to processed foods that are fortified at the point of manufacture. Given their widespread and regular consumption, basic commodities are more suited to mass fortification, whereas certain processed formulated foods are usually the better vehicle for targeted fortification initiatives.

8.1.2 Mandatory Fortification In Relation To Public Health

Governments tend to institute mandatory fortification in situations where a proportion of the general population, either the majority (mass fortification) or an identified population group (target fortification) has a significant public health need or risk that can be ameliorated or minimized by a sustained supply and regular consumption of fortified food(s) containing those micronutrients.

Mandatory fortification is usually prompted by evidence that a given population is deficient or inadequately nourished, such as clinical or biochemical signs of deficiency and /or unacceptably low levels of micronutrient intake. In some circumstançes, a demonstrated public health benefit of an increased consumption of a given micronutrient might be considered sufficient grounds to warrant mandatory fortification even if the population is not considered to be seriously at risk according to conventional biochemical or dietary intake criteria.

8.2 Voluntary Fortification

Fortification is described as voluntary when a food manufacturer freely chooses to fortify particular foods in response to permission given under the Food Law, or under special circumstances, is encouraged to do so.

This should be permitted only

- Where there is valid, scientific evidence that an increase in the intake of a essential nutrients is likely to benefit population groups where food habit changes cause deficiencies **or**
- To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing **or**
- To enable the nutritional profile of specific substitute foods to be aligned with the primary food.

When instituting voluntary fortification arrangements, the government has a duty to ensure that the consumers are not misled or deceived by fortification practices and also wish to be satisfied that market promotion of fortified foods is not in conflict with, or compromise, any national food and nutrition policies on healthy eating.

It is important that the government should exercise an appropriate degree of control over voluntary fortification through food laws or other cooperative arrangements. The degree of control should at least be commensurate with the inherent of risk.

8.2.1 Approval Of Chief Food Authority

Food manufacturers wishing to fortify their products should submit a written request to the Chief Food Authority giving details of their planned fortification.

Provided, however the written request to the Chief Food Authority is not necessary

(a) if the nutrient is to be added to maintain the nutritional profile at preprocessing level after processing

(b) if the nutrient added to food does not exceed 1/3 of the Tolerable Upper Intake levels given in Table 1.

9.0 Quality Assurance

The maintenance of a well-functioning quality assurance programme is essential to developing an effective, practical and economical fortification program. Quality assurance refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards.

Quality assurance for food fortification consists of establishing the following procedures (8):

- obtain from the provider, a certificate of quality[1] for any micronutrient mixes used;
- request, receive and store in a systematic, programmed and timely manner the ingredients and supplies for the preparation of a preblend[2];

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[1] The micronutrient mixes must be accompanied by a certificate obtained from an accredited laboratory certifying the nutrient content. This is usually the case for products shipped by international companies dedicated to this task.

[2] A preblend is the combination of micronutrient mix with another ingredient, often the same food that is to be fortified; with the purpose of reducing the dilution proportion and improving the distribution of the micronutrient mix in the food and guaranteeing that there will be not be separation (segregation) between the food and the micronutrient particles.

- produce the preblend according to a schedule that is adjusted to the rate of food manufacturing and fortification;
- control the adequate performance of the preblend equipment;
- appropriately label and deliver the preblend;
- use the preblend in the same order of production (i.e. first in, first out);
- verify appropriate functioning of the feeder machines and the mixers in a continuous and systematic manner;
- ensure that the product is adequately packaged, labeled, stored and shipped.

It is possible that other process variables, such as pH and temperature/time exposure, could affect the stability of added micronutrients and should also be considered in the design of quality assurance programmes.

The quality control procedures will typically consists of taking samples of the fortified food, either by batch or in a continuous manner depending on the system of production and determining their micronutrient content (9). Irrespective of the sampling method, the number of samples required will be governed by the consistency and reliability of the fortification process.

Food-control systems based on HACCP principles, risk-based inspection procedures, and internationally accepted analytical methods should be developed in support of fortification. Fortificants must meet quality criteria specifications explicitly established for each application, including chemical stability, appearance, bioavailabitity and homogeneity.

Goals of food fortification programmes must be clearly stated at the outset of the programme and a proper monitoring and evaluation process incorporated as part of the fortification.

The standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission should be considered, when required.

10.0 Fortification Levels

The approach recommended in these guidelines for setting fortificant levels in food is the *Estimated Average Requirement* (EAR)[3] *cut-point method* given by the WHO/FAO Guidelines on Food Fortification with Micronutrients, 2006 (7).

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[3] Estimated Average Requirement (EAR) for micronutrient is defined as the average daily intake that is estimated to meet the requirement of half of the healthy individuals in a particular life stage & gender subgroup.

The EAR cut-point approach is different from the past practice of using Recommended Nutrient Intake (or Recommended Dietary Allowance) of a nutrient as the desirable or "target" intake. The latter approach is valid for deriving the desired nutritional intake of an individual, but not that of a population.

The main aim of regulating the levels of fortificants in processed foods is preserving the nutritional balance and safety of the diet for the population at large. Minimum levels need to be set to ensure that reasonable amounts of micronutrients are added to food products; this must be stated on the product label, and may be referred to when advertising the product. It is important to fix maximum levels so as to reduce the risk of an excessive nutrient intake through the consumption of fortified foods, especially for those micronutrients with well-established **Tolerable Upper Intake Level (UL)** values.

The market-driven fortified processed foods are usually marketed to all family members, rather than to specific or physiological groups, presents difficulties in setting maximum limits on the permitted levels of fortificants in such foods.

The difficulties are compounded by the fact that the same serving size of the fortified food is common to all members of the family and unnecessarily large amounts of micronutrients may be delivered to children by fortified foods.

Establishing maximum levels for nutrient additions that take into account the above safety concerns thus requires adopting some form of risk assessment appraisal. Such approaches base the calculation of a safe maximum limit on accepted values of the UL for the most vulnerable groups, which in this case are children in the age group 4-8 years (7).

10.1 Keeping The Nutritional Balance

Some micronutrients were internationally omitted from the discussion, because, either they do not have a recognized UL (health risks have not, as yet, been identified), or their UL is high to not to raise serious concerns about the safety of high intakes from fortified foods.

However, to maintain an adequate balance in the diet, it is recommended that these other nutrients be added to process fortified foods in roughly the same proportion as those for micronutrients for which large intakes are undesirable.

The recommendations should be according to the Codex Guidelines on Nutrition Claims (10).

10.2 Legal Minimum and Maximum Levels

The legal minimum and maximum levels apply to the amount of both naturally occurring and fortificant micronutrient present in the food, not just to the amount of fortificant that is added.

In cases where only a minimum requirement is set and providing that the cost of the fortificant is not prohibitive, manufactures can ignore a food's natural content of a given micronutrient content, thus risking exceeding the legal minimum by at least the natural content.

If total maximum levels of micronutrients are also prescribed, the food's natural content must be taken into account to ensure the total does not exceed the maximum permissible limit.In cases where the natural content is likely to be negligible, the legal minimum and maximum levels approximate to the range of permitted micronutrient addition.

Procedures for determining the legal minimum and maximum total micronutrient content of fortified food should be set according to the Chapter 7 of WHO/FAO Guidelines for Food Fortification with Micro-nutrients (7). The most appropriate value given by the guidelines for micronutrient is the tolerable upper intake level (UL). ULs for the range of micronutrients given in the above reference are given in Tables 1 and 2.

Manufacturers whenever need to add extra amounts of micronutrient (an overage) to account for any subsequent losses of fortificants during production, storage and distribution, thereby ensuring that the food need at least legal minimum at the relevant distribution point. When calculating overages, manufacturers should bear in mind any maximum level that may also be applied to the food at that same distribution point.

The regulatory limits (i.e. the minimum and maximum levels) represents extremes of the total permitted micronutrients content of the fortified foods at the point(s) in the distribution chain to which the regulation applies. Generally this is taken to be at the point(s) of retail sale. Theoretically, no individual food sample taken for testing from a retail outlet should have micronutrient contents outside of these boundaries.

Tables 1

Tolerable Upper Intake Levels (ULs)

Nutrient (unit)[a]	1–3 years	4–8 years	9–13 years	19–70 years
Vitamin A (μg RE)[b]	600	900	1700	3000
Vitamin D (μg)[c]	50	50	50	50
Vitamin E (mg α-tocopherol)	200	300	600	1000
Vitamin C (mg)	400	650	1200	1000[d]
Niacin (vitamin B_3)(mg NE)[e]	10	15	20	35
Vitamin B_6 (mg)	30	40	60	100
Folic acid (μg DFE)[f]	300	400	600	1000
Choline (mg)	1000	1000	2000	3500
Iron (mg)	40	40	40	45
Zinc (mg)	7	12	23	45[g]
Copper (mg)	1	3	5	10
Calcium (mg)	2500	2500	2500	3000[h]
Phosphorus (mg)	3000	3000	4000	4000
Manganese (mg)	2	3	6	11
Molybdenum (μg)	300	600	1100	2000
Selenium (μg)	90	150	280	400
Iodine (μg)	200	300	600	1100
Fluoride (μg)	1300	2200	10000	10000

[a] Although no UL is specified for arsenic, silicon and vanadium, there is no justification for adding these substances to foods.
[b] Refers to preformed vitamin A only (i.e. esters of retinol). 1 μg RE = 3.33 IU vitamin A.
[c] As calciferol, where 1 μg calciferol = 40 IU vitamin D.
[d] The United States Food and Nutrition Board of the Institute of Medicine recommends a UL of 2000 mg vitamin C/day for adults.
[e] Based on the flushing effects of nicotinic acid. If niacinamide is used as the fortificant, the UL would be much higher. A UL for adults of 900 mg niacinamide/day has been recommended by the European Commission (*319*).
[f] Refers to folic acid derived from fortified foods, or supplemental folic acid.
[g] The United States Food and Nutrition Board of the Institute of Medicine recommends a UL of 40 mg zinc/day for adults (*91*).
[h] The United States Food and Nutrition Board of the Institute of Medicine recommends a UL of 2500 mg calcium/day for adults (*193*).

Sources: adapted from references (*91,93*). FAO/WHO have only recommended ULs for vitamins A, B_3 (niacin), B_6, C, D and E, calcium, selenium and zinc for adults. The remaining values are those recommended by the United States Food and Nutrition Board of the Institute of Medicine.

11.0 Permitted Micronutrient Compounds

Commercially available fortificant compound vary in their chemical composition and bioavailabitity, not all compounds being appropriate for use in all foods.

A list of all the permitted micronutrient fortificant compounds is given in Annex 2.

Permitted vitamin formulations and mineral substances, which may be added to foods is given in Annex 03.

Purity criteria for these compounds will also be required and it should be set according to the Food Chemical Codex (11) and British Pharmacopoeia (12).

Table 2

Calculated maximum micronutrient content[a] per 40 kcal-sized serving, assuming no other sources of micronutrient in the diet

Nutrient[b]	UL (children aged 4–8 years)	Maximum amount	
		Per 40 kcal serving	As a % of the RNI[c]
Vitamin A (as retinol) (μg RE)	900 μg	60 μg	10
Niacin (as nicotinic acid[d]) (mg)	15 mg	1.0 mg	6
Folic acid (mg)	400 μg	27 μg	7
Iron (mg)	40 mg	3 mg	22
Zinc (mg)	12 mg	0.6 mg	4
Calcium (mg)	2500 mg	167 mg	17
Iodine (μg)	300 μg	20 μg	13

UL, Tolerable Upper Intake Limit; RNI, Recommended Nutrient Intake.

[a] Maximum levels listed here should be reduced by an amount proportional to the amount of nutrient supplied by the diet (including though mandatory mass fortification programmes).

[b] There are other micronutrients with UL values, but they are not included here because it would be very difficult to approach the UL through the consumption of fortified foods.

[c] As a percentage of the RNI for adult males.

[d] Niacinamide can be used without this restriction.

12.0 Coverage

These guidelines shall apply to all fortified foods except dietary supplements and foods for which established standards include specifications for nutrient composition or levels of fortification, e.g. breast milk substitutes, follow-up formula are available.

Annex 01:

Percentage adequacy of Nutrient Intake According to Sri Lankan RDA

Overall energy adequacy was 87.3%, whereas iron adequacy was 77.5% and vitamin A adequacy was 68.4%. Intake of iron was adequate only in the fishing sector.

There were 35.7% of families who were unable to achieve 80% of energy adequacy and the urban sector recorded the highest proportion of 45.4%. Fishing community recorded the lowest percentage of inadequacy of proteins. Vitamin A intake was less than 80% in majority of families (83.8%) in the Estate community. Adequacy of the comparative intake of Vitamin A, iron and calcium by different communities is illustrated in Figure 1.

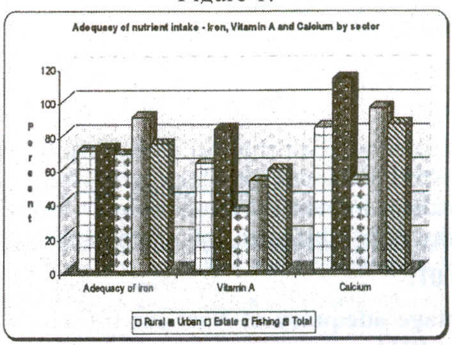
Table 1

Nutrient Adequacy Ratio

Sector	Calorie	Protein	Iron	Vitamin A	Vitamin C
Rural	89.2	109.5	73.1	73	183
Urban	89.7	118.4	73.6	95.5	129
Estate	82.4	99.4	69	40.5	117
Fishing	85.4	127.8	98.6	60.1	105
All	**87.3**	**112.9**	**77.5**	**68.4**	**142**
Nutrient Adequacy <80%					
Rural	33.9	24.8	67.3	66.8	30
Urban	45.4	20.2	63.3	63.3	43.1
Estate	33.6	24.5	63.5	83.8	41.5
Fishing	30	7	30	63.5	53
All	**35.7**	**19.1**	**56**	**69.3**	**41.9**

Source: Dietary survey- MRI, 2000

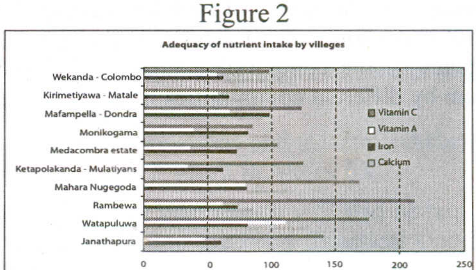
Figure 1.



Estate community has shown very low intake of all three nutrients compared to other three sectors namely rural, fishing and urban. Intake of calcium was above 80% of RNI for all sectors other than the estate group.

The percentage adequacy of the nutrients calcium, iron, vitamin A and vitamin C intakes by 10 villages studied is shown in Figure2.

Figure 2



A wide variation in nutrient adequacy is seen and a majority of villages had less than adequate levels of intake of vitamin A and iron. The highest adequacy of iron intake is observed in the fishing communities in villages Madampella and Monachogama.

Annex 02:

List of permitted vitamins, minerals, fatty acids & amino acids which may be added to foods.

1._Vitamins

Vitamin A
Vitamin D
Vitamin E
Vitamin K
Vitamin B1
Vitamin B2
Niacin
Pantothenic acid
Vitamin B6
Folic Acid
Vitamin B12
Biotin
Vitamin C
Choline
Inositol

2._Minerals

Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium
Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus

3. Amino acids

Isoleucine
Leucine
Lysine
Methionine
Phenylalanine
Threonine
Tryptophan
Valine
Histidine
Arganine

4._Fatty acids

Alpha-linolenic acid
Arachidonic acid
Docosahexaenoic acid
Eicosapentanoic acid
Linoleic acid
Linolenic acid

Annex 03:

Permitted vitamin formulations and mineral substances, which may be added to foods

1._Vitamin formulations

VITAMIN A
retinol
retinyl acetate
retinyl palmitate
beta-carotene

VITAMIN D
cholecalciferol
ergocalciferol

VITAMIN E
D-alpha-tocopherol
DL-alpha- tocopherol
D-alpha-tocopheryl acetate
DL-alpha-tocopheryl acetate
D-alpha-tocopheryl acid succinate

VITAMIN K
phylloquinone (phytomenadione)
B1,B2, Niaan
Pantothemic acid
Bb, Folic acid, Biotien, B12
VITAMIN B1
thiamin hydrochloride
thiamin mononitrate

VITAMIN B2
riboflavin
riboflavin 5'-phosphate-sodium

NIACIN
nicotinic acid
nicotinamidenicotinamide

PANTOTHENIC ACID
D-pantothenate, calcium
D-pantothenate, sodium
Dexapanthenol

VITAMIN B6
pyridoxine hydrochloride
pyridoxine 5'-phosphate
pyridoxine dipalmitate

FOLIC ACID
Pteroylmonoglutamic
acid

VITAMIN B12
cyanocobalamin
hydroxocobalamin

BIOTIN
D-biotin

VITAMIN C
L-ascorbic acid
sodium-L-ascorbate
calcium-L-ascorbate
potassium-L-ascorbate
L-ascorbyl 6-palmitate

2. Mineral substances

calcium carbonate
calcium chloride
calcium salts of citric acid
calcium gluconate
calcium glycerophosphate
calcium lactate
calcium salts of orthophosphoric acid
calcium hydroxide
calcium oxide
calcium sulphate
magnesium acetate
magnesium carbonate
magnesium chloride
magnesium salts of citric acid
magnesium gluconate
magnesium glycerophosphate
magneseim salts of orthophosphoric acid
magnesium lactate
magnesium hydroxide
magnesium oxide
magnesium sulphate
ferrous carbonate
ferrous citrate
ferric ammonium citrate
ferrous gluconate
ferrous fumarate
ferric sodium diphosphate
ferrous lactate
ferrous sulphate
ferric diphosphate (ferric pyrophosphate)
ferric saccharate
elemental iron (carbonyl + electrolytic + hydrogen reduced)
cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper lysine complex
sodium iodide
sodium iodate
potassium iodide
potassium iodate
zinc acetate
zinc chloride
zinc citrate
zinc gluconate
zinc lactate
zinc oxide
zinc carbonate
zinc sulphate
manganese carbonate
manganese chloride
manganese citrate
manganese gluconate
manganese glycerophosphate
manganese sulphate
sodium bicarbonate
sodium carbonate
sodium citrate
sodium gluconate
sodium lactate
sodium hydroxide
sodium salts of orthophosphoric acid
sodium selenate
sodium hydrogen selenite
sodium selenite
sodium fluoride
potassium fluoride
potassium bicarbonate
potassium carbonate
potassium chloride
potassium citrate
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium salts of orthophosphoric acid
chromium(III) chloride & its hexahydrate
chromium(III) sulphate & its hexahydrate
ammonium molybdate (molybdenum(VI))
sodium molybdate (molybdenum (VI))

Glossary

Average Intake (AI) is a recommended intake value based on observed or experimentally determined approximations or estimates of nutrient intake by a group or groups of apparently healthy people that are assumed to be adequate.

Enrichment refers to the addition of micronutrients to a food irrespective of whether the nutrients were originally in the food before processing or not.

Essential micronutrient refers to any micronutrient, which is needed for growth and development and the maintenance of healthy life, that is normally consumed as a constituent of food and cannot be synthesized in adequate amounts by the body.

Estimated Average Requirement is the average (median) daily nutrient intake level estimated to meet the needs of half the healthy individuals in a particular age and gender group. The EAR is used to derive the Recommended Dietary Allowance.

Fortification is the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

Fortificant is a substance, in chemical or natural form, added to food to increase its nutrient value.

Legal Minimum Level is the minimum amount of micronutrient that a fortified food must contain according to national regulations & standards. This value is estimated by adding the intrinsic content of a micronutrient in the food to the selected level of fortification.

Market-driven fortification refers to the situation where the food manufacturer takes the initiative to add one or more micronutrients to processed foods, usually within regulatory limits, in order to increase sales & profitability.

Mass fortification refers to the addition of micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk.

Maximum Tolerable Level is the maximum micronutrient content that a fortified food can present as it is established in food low, in order to minimize the risk of excess intake. It should coincide or be lower than the safety limit.

Nutrient requirement refers to the lowest continuing intake level of a nutrient that will maintain a defined level of nutriture in an individual for a given criterion of nutritional adequacy.

Processed foods are those in which food raw materials have been treated industrially so as to preserve them. Some may be formulated by mixing several different ingredients.

A premix is a mixture of a micronutrient(s) and another ingredient, often the same food that is to be fortified, that is added to the food vehicle to improve the distribution of the micronutrient mix within the food matrix and to reduce the separation (segregation) between the food and micronutrient particles.

Quality assurance (QA) refers to the implementation of planned and systematic activities necessary to ensure that products or services meet quality standards. The performance of quality assurance can be expressed numerically as the results of quality control exercises.

Quality control (QC) refers to the techniques and assessments used to document compliance of the product with established technical standards, through the use of objective and measurable indicators.

Restoration is the addition of essential nutrients to foods to restore amounts originally present in the natural product, but unavoidably lost during processing (such as milling), storage or handling.

Recommended Nutrient Intake (RNI) is the daily intake that meets the nutrient requirements of almost all apparently healthy individuals in an age and sex-specific population group. It is set at the Estimated Average Requirement plus 2 standard deviations.

Tolerable Upper Intake Level (UL) is to the highest average daily nutrient intake level unlikely to pose risk of adverse health effects to almost all (97.5%) apparently healthy individuals in an age and sex-specific population group.

Usual intake refers to an individual's average intake over a relatively long period of time.

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