Expert Consultation On Nutrient Risk Assessment For Determination Of Safe Upper Levels For Nutrients

4 December 2015
New Delhi

Expert Consultation Report

International Life Sciences Institute-India

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CONTENTS

PREFACE

ILSI-India has almost from its inception in 1999 endeavored to disseminate information about micronutrient malnutrition and encouraged food fortification to make up micronutrient deficiencies. While the Government has initiated several measures to make up this deficiency there is still a long way to go particularly in the rural areas.

A number of food products have also been fortified with different nutrients by Industry in recent years with appropriate labeling to help consumers make more informed choices. There are also a variety of food supplements and nutraceuticals in the market which are yet to be regulated and are indiscriminately consumed. It is possible that some sections of population, judged by the RDAs prescribed by National Institute of Nutrition, may have been using the micronutrients in excess leading to toxicity.

ILSI-India therefore considered it necessary to hold a Scientific Consultation with experts to initiate action to develop Safe Upper Levels for nutrients. Many countries have already adopted Safe Upper levels based on nutrient risk assessment. The Scientific Consultation had the benefit of participation of experts from USA, Europe and Korea and understands the methodology to arrive at Safe Upper levels.

The first draft of the Report was prepared by Dr. K. Bhaskarachary and Dr. Pulkit Mathur. This draft was circulated among the speakers for their comments. ILSI-India appreciates the contribution made by Dr. Oran Kwon, Mr. Basil Mathioudakis, Dr. Madhavan Nair, Dr. V Prakash, Dr. B Sesikeran, and Dr. Allison Yates.

This Report, it is hoped, will be useful in understanding the need to develop Safe Upper Levels for nutrients, the importance of nutrient risk assessment, the methodology to be adopted, and the way to communicate with the general public.

D H Pai Panandiker
Chairman
ILSI-India

ABBREVIATIONS

AIIMS	All India Institute Of Medical Sciences
ARS	Agricultural Research Service
BCC	Behaviour Change Communication
CCFL	Codex Alimentarius Committees On Food Labelling
CCNFSDU	Codex Alimentarius Committees On Nutrition And Foods For Special Dietary Uses
CSIR	Council Of Scientific And Industrial Research
DG	Director General
EFSA	European Food Safety Authority
FAO	Food And Agriculture Organization
FSSAI	Food Safety And Standards Authority Of India
FNB	Food And Nutrition Board
ICDS	Integrated Child Development Services
ICMR	Indian Council Of Medical Research
ILSI	International Life Sciences Institute
INSA	Indian National Science Academy
IOM	Institute Of Medicine, USA
IUFoST	International Union Of Food Science And Technology
IUNS	International Union Of Nutrition Sciences
KFDA	Korean Food And Drug Administration
LOAEL	Lowest-Observed-Adverse-Effect Level
MSSLs	Maximum Safe Supplementation Levels
NCDs	Non-Communicable Diseases
NNMB	National Nutrition Monitoring Bureau
NRVs	Nutrient Reference Values
NIH	National Institutes Of Health, US
NIN	National Institute Of Nutrition
NOAEL	No-Observed Adverse Effect Level
RDA	Recommended Dietary Allowances
RCGM	Review Committee On Genetic Manipulation
SUL	Safe Upper Limits/ Levels
UL	Upper Limits/ Levels
WHO	World Health Organization
WWEIA	What We Eat In America

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RECOMMENDATIONS

Following recommendations were made by the experts:

- A scientific committee be constituted by Indian Council of Medical Research to review the available data, literature and resources from other countries to establish safe upper limits for nutrients.

- Sub-committees be constituted for defining SUL for various nutrients.

- The committees and sub-committees should have representatives from concerned stakeholders including Government, Academia and Industry .

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INTRODUCTION

Background

Numerous advances have occurred in the field of nutrition science in the last few decades in India. These include advances in agriculture and post-harvest technology, food production, food processing and food fortification. Nutrition research also expanded considerably from management of nutritional deficiencies to prevention practices. With the advent of nutritional supplements, fortification and functional foods, the problems of excess intakes and toxicity, as also nutrient interaction are coming into focus increasingly. Priority areas of research are mainly in the field of a) Dietetics and nutrition education (b) Macro and micronutrient deficiency diseases, (c) Diet related chronic diseases (d) Functional foods for optimal health (e) and Nutrition policy research. Consumer awareness is also increasing in all fields including diet and disease. In view of varied cultural practices and changing dietary practices as well as perceptions about the additives, and contaminants there is an important role for the regulators to define food safety aspects as well as labeling. These advances in nutrition science necessitate the need for establishing NRVs, / RDAs as well as setting safe upper limits for regulatory purposes.

Against the background of expansion in the market for functional foods, nutraceuticals, fortified foods, dietary supplements as well as imports from other countries, ILSI-India considered it important and timely to review the available data in India as well as the data available from other countries / sources by organizing an **Expert Consultation on Nutrient Risk Assessment for Determination of Safe Upper Levels for Nutrients.** It was held on 4 December 2015, at Hotel Le Meridien, New Delhi. The Expert Consultation was attended by 23 experts on the invitation of ILSI-India.

Objectives

The main objective of this Expert Consultation was to identify best practices in arriving at safe upper limits for micronutrients for Indian population using the data available through different sources in India based on the risk assessment approach.

Agenda

The consultation was aimed at deliberating on extent of micronutrient deficiencies and the strategies to contain them and to explore the methods for defining ULs , using the data sources available based on the methods of risk assessment as outlined by WHO/ FAO.

The criteria used to determine safe UL / NOAEL (No-Observed Adverse Effect Level) internationally were discussed in the meeting (See Appendix 1).

REPORT

The Expert Consultation was attended by 23 experts. The participants included D.G. ICMR, Director NIN, representatives from FSSAI, Ministry of Health and Family Welfare, IUNS, AIIMS, Europe, USA, Korea, and various governmental and nongovernmental organizations. Report of the Conference is given below.

Ms. Rekha Sinha Executive Director, ILSI-India welcomed the Expert Group members and requested the members to introduce themselves. Brief Report of the meeting is given below.

OPENING SESSION

Welcome Address
Mr. D H Pai Panandiker, Chairman, ILSI-India

In his Welcome Address Mr. Panandiker explained the objectives of the Expert Consultation and gave a brief description about ILSI and ILSI-India and its activities since 1996. ILSI has 16 branches and three centers of excellence. He informed about the ILSI-India sponsored research studies as well as capacity building activities in the area of nutrition research. He referred to the current scenario of double burden of malnutrition in India, with some section of the population facing the problem of overweight and obesity and a larger section of population suffering from multiple macronutrient and micronutrient deficiencies. He spoke about the massive burden of iron deficiency along with vitamin A, B12, and D and their public health significance. Vitamin A deficiency in children is still a public health concern so also iron deficiency anemia in adolescents. As regards vitamin B12 about 47-49% of the population and vitamin D 60-80% of the populations is suffering from their deficiencies. Food fortification and supplementation are sustainable solutions. However, Mr. Panandiker cautioned that supplementation may lead to over consumption.

Sale of supplements is growing at the rate 16-18% annually reaching 2 to 2.5 billion US dollars. Two third of urban populations are using supplements. The developed countries are more likely to be exposed to over conservation of nutrients since too many food product are fortified. Institute of Medicine (IOM), USA, European Food Safety Authority (EFSA) and UK Expert Group on Vitamins and Minerals have come up with Safe Tolerable Upper Intake Levels or No-Observed Adverse Effect Level (NOAEL) based on the risk assessment approach recommended by FAO/WHO. However, there is a difference of opinion among the different international bodies on safe UL / NOAEL based on the methodologies used. Mr. Panandiker cited the example of UL for calcium where it varied from 1500 mg to 2500 mg for different countries and mentioned the need to look into these differences. He emphasized that UL is not for recommended level of intakes and regulation is needed for food and Health supplements in India. Thus it is important to discuss these issues and come up with a consensus recommendation for safe upper limits for various nutrients in Indian context.

Mr. Panandiker mentioned that though National Institute of Nutrition, ICMR has published the Recommended Dietary Allowances for Indians, they do not specify the ULs, which are very important for preventing over consumption. Even Food Safety and Standards Authority of India's (FSSAI) draft regulations on different types of functional foods and dietary supplements do not mention about the safe UL.

OVERVIEW SESSION

Chair: Mr. D H Pai Panandiker, Chairman, ILSI-India

Nutrition Status Of Population In India And Disease Burden

Dr B Sesikeran

As per UNICEF (2010), 60% of all deaths, in children below the age of 5 years, in developing countries are attributable to malnutrition. However, there has been a steady decline in infant mortality, maternal mortality, under nutrition, stunting, wasting in under-fives as well as micronutrient deficiencies due to several Government interventions and programs to tackle nutritional anemia, iodine deficiency, vitamin A deficiency through Integrated Child Development Services (ICDS), food fortification and mid-day meal program.

Though there are some improvements in nutritional status as seen by a downward trend in micronutrient deficiencies and nutritional indicators, they still exist and pose a public health problem. Several vulnerable groups like infants and young children, pregnant and lactating women, elderly still suffer from various forms of malnutrition. Faulty infant and young child feeding practices and lack of dietary diversity in complementary foods have contributed to under nutrition and micronutrient deficiencies in preschoolers.

As seen from NNMB data the main reason seems to be very low dietary intakes of most of the nutrients. National Nutrition Monitoring Bureau (NNMB) data show a low intake of most of the protective foods like pulses, milk and milk products, green leafy vegetables, fruits and fats. Time trends from 1975 onwards show that even cereal and millet consumption have dropped significantly from 505 grams per day to 368 grams per day and millets have almost disappeared. This led to a drastic reduction in dietary diversity. Several data show that more than 70% of people consume diets deficient in most of the nutrients specially the essential micronutrients like iron, calcium, vitamin A, B12 and vitamin D as per Indian RDA.

Table 1.

Average Households Intake of foodstuffs (g/per CU/day): Time trends - States* Pooled

STATES	Period of Survey				RDI (Dietary Guidelines 2011)
	1975-79	1988-90	1996-87	2011-12	
Cereals & Millets	505	469	450	368	375
Pulses & Legumes	34	32	27	33	75
Green Leafy Veg.	8	9	15	16	100
Other Veg.	54	49	47	48	200
Roots & Tubers	56	41	44	50	200
Milk & Milk Prod.	116	92	86	95	300
Fats & Oils	14	13	12	16	25
Sugar & Jaggery	23	29	21	14	20

*KER, TN, KAR, AP, MR, GUJ, ORI (7 States)

Souce: NNMB, Tech Rep 26, 2012

The prevalence of iron, vitamin A, folic acid deficiency may be as high as 70% in some of these groups. Recent data has also highlighted the rising prevalence of deficiencies of vitamin B12 and vitamin D. For various reasons the national nutritional supplementation programs have failed to effectively alleviate the micronutrient deficiencies like iron deficiency anemia. The only program which has shown positive results is the fortification of salt with iodine. There has been a remarkable decline in goiter prevalence since the introduction of mandatory salt iodization.

Table 2.

Median Households Intake of Nutrients (per CU/day): Time trends - States* Pooled

STATES	Period of Survey				RDA (2011)
	1975-79	1988-90	1996-87	2011-12	
Proteins (g)	61.5	58.4	53.7	49.0↓	60
Energy(Kcal)	2349	2283	2108	1852↓	2320
Calcium (mg)	606	565	521	433 ↓	600
Iron (mg)	17.2	15.5	14.2	13.4↓	25
Vitamin A (μg)	246	282	300	296	600
Thiamin (mg)	1.46	1.33	1.20	1.20↓	1.20
Riboflavin (mg)	0.81	0.87	0.90	0.80	1.40
Niacin (mg)	14.7	14.2	12.7	13.7	16
Vitamin C (mg)	39	37	40	46	40
Dietary Folate (μg)	-	-	153	127↓	200

*KER, TN, KAR, AP, MR, GUJ, ORI (7 States)

Souce: NNMB, Tech Rep 26, 2012

There has been a rapid increase in the incidence of diet related lifestyle disorders like obesity, Type 2 diabetes, hypertension, cardiovascular diseases, and cancer. Lifestyle diseases are now contributing to almost 60% of all-cause mortality. India now suffers from a ''Double Burden" of malnutrition with both under nutrition and over nutrition co-existing. What makes it worse is that these diseases seem to have fetal origins and populations which were once undernourished seem to be more at risk of developing these diseases. To prevent the generation -to-generation propagation of these nutrition related disorders, there is an urgent need to intervene as early as the fetal or embryonic stages.

WHO has recommended reduction in saturated fat, free sugars and salt and total elimination of trans fat to prevent these diet related non-communicable disorders (DR-NCDs). Increase in physical activity levels, which have generally declined over time as a result of mechanization and changing lifestyles, are also being recommended to combat these NCDs.

Short term strategies to combat under nutrition and micronutrient deficiencies include food as well as specific nutrient supplementation. These strategies have been operational in India for several decades now. Lacunae in the implementation have resulted in poor coverage especially for specific nutrient supplementation programs. There are several long term strategies like dietary diversification, health and nutrition education, bio fortification and genetic modification to improve the nutrient content and bioavailability of micronutrients in commonly eaten foods. In addition, reducing the burden of communicable diseases through better environmental hygiene and sanitation and improving the availability and access to better food and health care facilities is crucial for achieving the target of reducing malnutrition. These strategies are the most desirable and sustainable, however they are difficult to achieve, and take a long time to show results.

Food fortification is a viable medium term strategy to tackle micronutrient deficiencies. Fortifying commonly consumed foods like salt, cooking oil, milk, wheat and rice with iron, vitamin A, D, folic acid etc. is being done in several countries. It is a cost effective approach which doesn't require a major change in the food habits of a population and hence is likely to have better compliance. However, there is hesitation at the regulatory level in permitting fortification for a large number of foods due to the fear of exceeding tolerable safe upper levels of intake. No adverse effects due to excess intake of micronutrients have been reported in countries where almost all the processed foods are fortified with one or more nutrients and consumed by most of the population. Compared to these in India as of now only a limited number of foods are fortified.

Table 3.

Advantages & Disadvantages of Various Strategies

STRATEGY	ADVANTAGES	LIMITATIONS
Short Term (Nutrient Supplementation	Immediate Benefit Very Effective, if property implemented	Expensive, Needs Manpower, Inadequate/Irregular Supplies, Inadequate/irregular Coverage, Non-compliance, Not Sustainable.
Long Term (Nutrition Education/ Dietary Diversification)	Desirable, Sustainable, No cost involved	Difficult to achieve, Time Consuming
Medium Term (Food Fortification)	Easy, Cost effective Good compliance, Sustainable, Easy to Regulate.	Risk due to severel foods being fortified

Key Discussion Points:

1. There is a big gap between policy and implementation.
2. There is a need to strengthen NNMB and generate region/district wise data continuously on dietary intakes, nutritional status and diet related diseases.
3. There is an urgent need to develop effective monitoring system of all national nutritional programs.
4. There is a need to relook at the data to find out energy intake levels in different sectors of population and their relation to overweight and obesity. Though there is reduction in energy intakes on the whole, simple carbohydrate consumption is increasing which is of concern and may have adverse effects on the population.
5. Food consumption, lifestyle and disease patterns differ between rural and urban India, with consumption of more energy dense foods meat and egg consumption with reduced physical activity in urban areas.
6. There is a need to increase physical activity, dietary diversity and decrease consumption of income elastic foods to prevent lifestyle diseases.
7. Though dietary consumption patterns show intakes less than RDA across India there is still need for establishing upper limits for nutrients to prevent excessive consumption through fortification or supplementation.

Mr. Panandiker summed up the session and remarked that an urgent need has been felt to generate data on nutritional status of population along with dietary intakes of all nutrients for formulating policies and programs. ILSI-India proposes to conduct a Total Diet Survey to add to the database. The design and other parameters of the survey will be discussed in a meeting to be held on 24th December 2015.

SESSION ONE

Strategies To Address Nutrition Deficiencies In India

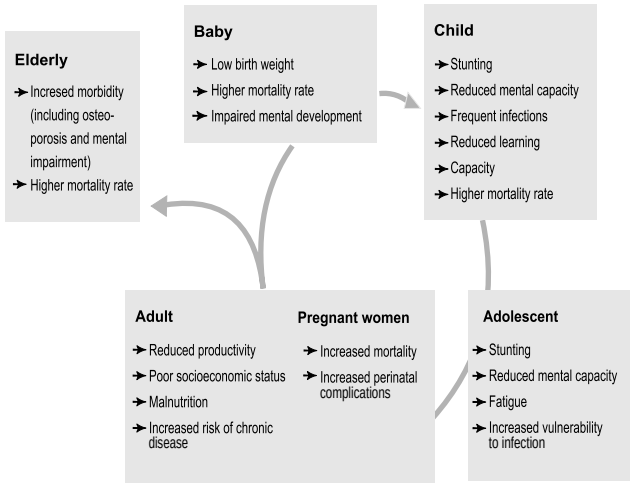
Chair: Dr. B Sesikeran, Former Director, National Institute of Nutrition

Food Fortification: Benefits & Challenges

Dr. K. Madhavan Nair

Micronutrient deficiencies can have very serious consequences at each stage of the lifecycle. Nutrients like iron, folic acid and iodine play an important role in brain and cognitive development. Micronutrients are also important for immunity and hence influence morbidity and mortality at all life stages.

Figure 1.
Consequences of Micronutrient Deficiency



Tackling micronutrient deficiencies needs implementation of evidence based simple, cost effective, sustainable and scalable strategies. Food fortification has had a long history of safe use and it has proved to be a very cost effective public health intervention strategy to control micronutrient deficiency. Several countries have successfully demonstrated how fortifying foods can lead to control and prevention of adverse effects of deficiencies of vitamins A, D, several B vitamins, iodine and iron. Food fortification to prevent deficiencies of micronutrients is considered as one of the best global welfare investments.

International bodies like, Codex Alimentarius Commission and WHO have given guidelines to be followed for fortification. Over the years many countries have focussed on iodization of salt and wheat flour fortification with iron and folic acid. In fact, wheat flour fortification has been widely advocated in developing countries. A recent systematic analysis of research data has however shown limited evidence of the effectiveness of wheat flour fortification in reducing anaemia. There is insufficient evidence to evaluate whether programs that followed WHO iron recommendations for flour fortification have better outcomes. Several beneficial effects of fortification have been reported in literature like decreased incidence of neural tube defects due to folic acid fortification and decreased prevalence of goitre and iodine deficiency related disorders due to fortification of salt with iodine. Efficacy trials of foods fortified with iron and those on fortification with vitamin D have yielded positive beneficial results. It is also important to note that no adverse effect of toxicity has been reported at fortification levels.

Implementation of fortification strategies in India requires a clear understanding of the context of population dynamics. India has a large diverse and growing population, a background of poor nutrition and environment and a high prevalence of micronutrient deficiencies, in spite of national nutrient supplementation programs. The biggest challenge lies in

assessing the determinants of micronutrient deficiency, and in identifying region and culture specific food vehicles for fortification, as well as available platforms for its implementation.

It is also important to ensure food synergy as nutrients interact with each other and hence improving bioavailability of nutrients like iron from traditional diets involves increasing the vitamin C content of the diet. So for instance the bioavailability of iron from the habitual Indian diet can be improved by eating foods like papaya, guava, pineapple or lemon which are rich in vitamin C.

Fortification of food at the point of use for example, use of multiple micronutrient powders for infants is a strategy with a strong evidence base. There are many challenges for micronutrient fortification in India. As a policy, fortification needs to be mandatory in certain foods for it to benefit the population at large. The policy should also ensure that this is integrated with the different national programs in existence. The major challenges to this policy approach are the involvement of the unorganised sectors in the food processing industry, technological challenges in setting standards, creating mandated legislation and regulations, partnering with industry and then the mammoth task of monitoring. There needs to be a behaviour change communication (BCC) program for all stakeholders and capacity building of producers as well as enforcers. The regulatory authorities need to continuously monitor the intake levels of the population - not just to look at nutrients which are deficient in the diet but also to ensure that nutrients are not consumed at levels beyond the tolerable upper intake levels.

National level scale up of multiple strategies could be envisioned in the coming years leading to effective control of multiple micronutrient deficiencies in India. Food fortification, universal use of salt fortified with iron and iodine and improving iron bioavailability from Indian diets are mentioned as priority areas in nutrition in the 12th Five Year Plan goals.

Key Discussion Points:

1. Large scale studies are needed to generate data on micronutrient deficiencies and the effectiveness of fortification in India to influence Government policy regarding fortification.
2. With the available data worldwide and also from India, fortification with some micronutrients can be initiated and simultaneously the effectiveness can be studied.
3. Developing spot test for determining the level of fortification is very important.
4. There is an urgent need for fixing the level of fortification, which should be decided on priority basis by FSSAI.
5. Regulatory bodies like FSSAI should have strategies for effective monitoring and quality control of fortified foods.
6. There is a problem in deciding the specific food vehicles in India for target population as under the programs like PDS, staple cereals mainly like rice or wheat are provided and their fortification is very difficult and not cost effective to be included in national programs.
7. The possibility of multiple micronutrient fortification should be explored.
8. FSSAI should also look into labelling requirements for fortified foods so that the consumer can make informed choices and voluntary fortification of foods like milk, oil, and processed foods should be permitted and should be accessible to all.
9. It is important for regulatory bodies like FSSAI to give a range between which the fortified nutrient should be present in the different foods, based on Indian RDAs as they are slightly different from those prescribed by WHO/FAO.

Management Of Micronutrients Through Food Fortification And Food Based Approach On The Platform Of Bioactives And Food Safety

Dr V. Prakash

The problem of multiple micronutrient deficiencies in developing countries is as a long standing issue mainly in the poorer sections of the society. Though many policies and intervention programs are aimed to alleviate the same, these issues still continue to be major public health concern. Micronutrient fortification is one such strategy which has proved to be effective in many developed countries. But, most of the affected population groups in countries like India often do not have access to fortified foods because of low purchasing power and undeveloped distribution channels.

The technology for fortifying various foods has not been fully established as regards nutrient levels, stability and physical property characteristics; nor has acceptability by consumers in terms of cooking properties and taste been determined. Insufficient scientific knowledge regarding nutrient interaction complicates the decision regarding levels of a nutrient to be added to food. Nevertheless, fortified foods as part of food aid are of unquestionable value to protect the nutritional status of vulnerable groups and victims of emergencies.

With voluntary fortification of food by the industry, many such foods may reach the markets which are fortified with the same nutrient. The consumer may unknowingly consume multiple doses of the micronutrient which causes alarm from the safety point of view as excess intake of a nutrient can lead to toxicity. Therefore, the issue of the maximum amount of micronutrients that a person can consume per day from various food sources (both fortified and non-fortified) is an important aspect that needs the attention of all stakeholders. Awareness of the consumer is very crucial to ensuring that the right amount of micronutrients is included in the family diet.

A very scientific basis needs to be adopted for determining the level of fortification in foods. A risk analysis approach needs to be adopted for fixing minimum and maximum limits for fortification. For this purpose, looking at dietary patterns of different geographical and cultural regions of India becomes extremely important rather than looking according to political divisions of the country. Issues such as improving bioavailability and bioaccessibility of nutrients also need to be addressed for strategies to contain micronutrient deficiencies. Various technologies are now available for the processing of food in a manner to conserve most nutrients, as well as for the effective fortification of most foods. Current problems can be addressed by learning from past experiences. It is also very important to link the food industry/ food producing centre to the nutrient delivery centres.

Functional foods can be a good vehicle for supplying micronutrients. Along with food, nutraceuticals can also play a vital role in addressing the problem of malnutrition. For food based strategies to succeed it is very important that the consumer be educated about ways of improving nutrient bioavailability from the diet. The 3Ns of Nutrients, Nutraceuticals and Nutritionals are important for the holistic functioning of physical health, cognitive health and wellness altogether. Perhaps they may also delay the onset of certain diseases. Nutrigenetics and epigenetics are emerging disciplines which need to be explored in this regard.

Translational-Innovation models in the food chain need to be integrated and a firm science based approach of Sustainable Nutrition with micronutrients be used to reach rural and urban, as well as rich and poor in the country. Separately the need of special children like those with severe acute malnutrition (SAM) or those with celiac disease should also be addressed. Food losses due to wastage need to be dealt with to improve micronutrient availability. Co-operatives greatly improved the availability of milk in the country but it still remains inaccessible to poor children. Small innovative actions at the household level can lead to big differences in nutrition. The food processing industry needs to have stringent quality control measures in place to ensure micronutrients are not lost from foods. Richness of traditional knowledge also should be tapped. Capacity building needs to be done at all levels in order to effectively tackle the issue of micronutrient malnutrition. This is especially important because of the social and economic impact of good nutrition. Long term policies and sustainable interventions are needed throughout the lifecycle from "paediatrics to geriatrics".

While fortifying with micronutrients it is important to clearly look at bioavailability, the upper limits of use, the toxic cumulative effects if taken in high amounts and the influence of food-food interaction on bioavailability. The current Expert Consultation organized by ILSI-India would possibly come out with a declaration on management of micronutrient malnutrition as well as their safe upper limits of intakes.

Table 4.
Life Cycle Approach For Nutrition

Nutrition throughout the Life Cycle is vital of course MN is needed till last breath not just in Nutrition Programmes?! The chain of Pediatrics to Geriatrics! Prakesh / CSIR-India	Products containing nutritional substitutes, nutritional supplements are here to stay, having reached a worldwide consumer demand for a safe Healthy diet with a clean mandate of minimum MN content assured. ***No easy way out?!*** Prakesh / CSIR-India

Key Discussion Points:

1. Though agricultural production has increased in recent decades, it has not translated into dietary adequacy in the population. The main constraint being lack of adequate technology innovation in the area of food processing and storage, supply.
2. When fortifying the various foods the bio accessibility as well as bio availability of various nutrients and nutrient interactions should be looked into taking into consideration the intake of functional foods.
3. Instead of fortifying vanaspati with vitamin A or D milk, oil can be fortified which will help in containing the adverse effects of consuming transfats.
4. Akshayapatra should be commended for using soy dal analogue for providing cheap and good source of protein in mid-day meal in some states.
5. Political will and commitment is very essential as seen in some countries like Thailand for effective policy implementation.

SESSION TWO

Nutrient Risk Assessment & Upper Levels: Country / Regional Experiences

Chair: Dr. V Prakash, Vice President, International Union of Nutritional Sciences

Nutrient Risk Assessment and Upper Levels - USA Perspective

Dr Allison A. Yates

The Food and Nutrition Board (FNB) of the Institute of Medicine, U.S. National Academy of Sciences provides guidance to the nation in areas of nutrition especially on the recommended levels of nutrient intakes. Expert committees appointed by the FNB periodically review, revise and expand the nutrients included. With growing interest in fortifying foods, and in potential consumption of nutrients in amounts greater than that recommended, in 1994 the FNB initiated a process to establish multiple reference values for nutrients that included levels of intake above that recommended but which were considered within the tolerable limits of consumption. This collection of multiple reference values is termed Dietary Reference Intakes (DRIs) and continues to include RDAs and for many nutrients, upper reference values, termed Tolerable Upper Intake Levels (ULs). Quantitative dietary reference values address multiple users and meet multiple needs like those for regulations regarding labelling, limits for fortification and for assessing adequacy of diets of population groups. A sub-committee consisting of nutrition science experts and toxicologists was formed to develop the process for establishing ULs, developing a risk assessment model for nutrients in 1997 modifying the one used to establish tolerances for environmental contaminants and toxicants.

The risk assessment model for nutrients included five steps: identifying adverse effects (hazards) associated with intake in humans, evaluating the levels of intakes associated with the effects noted (dose-response), assessing the expected amounts that could be consumed, characterizing the uncertainty associated with the available data and the seriousness of the adverse effect, and then deriving a reference value, the UL, which is defined as "the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase." The UL is not a recommended level of intake and is not a level that is desirable to attain.

Key issues in the development and application of a model for ULs of nutrients include the consideration of quantifiable risk as opposed to societal constructs of 'safety', limitations of traditional models which depend on animal toxicity data, unique characteristics of nutrients which area required for health compared to contaminants, sparse documentation of human adverse effects of chronic overconsumption, and coordination of the work of multiple-nutrient review panels with focused subcommittees. What is considered 'safe' is actually a point on the continuum defined by social mores. A variety of toxicological studies are needed to evaluate the risk posed by nutrients if eaten in excess.

Unique characteristics of available data on overconsumption of nutrients include absence of dose-response data, few available human or animal chronic studies, few surveillance studies to establish the no-observed adverse effect level (NOAEL) and significant differences in bioavailability, particularly for trace elements. Available databases have concentrated on supplement intake, but not total intake.

Aspects important to consider when applying the steps of risk assessment to nutrients are that limited data are available due to few human studies. Depending on clinical significance of observed adverse effects, the uncertainty factor used varies and also that observed effects may vary depending on form of intake. Risk assessment models for estimating ULs for nutrients like folic acid, vitamin A and iron were discussed.

Critical points in establishing useful ULs include integrating nutrient requirements analysis with evaluation of adverse effects. These can't be isolated activities—and must involve both nutritionists and toxicologists. There is a need to also evaluate existence of food and supplement intake data to assure that adequate exposure (intake) estimates exist for relevant sub-population groups. Dietary guidelines need to reflect varied population needs as well as potential adverse effects—depending on the seriousness of the adverse effects. Risk managers determine how to incorporate risk assessment into policy and use it in developing final Dietary Guidelines and determining label values, etc. What We Eat in America (WWEIA) intake surveys now include nutrient intake estimates from supplements as well as foods to allow comparison with established ULs.

Table 5.

Critical Points in Establishing Useful ULs

- Integrate nutrient requirements analysis with evaluation of adverse effects-can't be isolated activities-and must involve both nutritionists and toxicologists
- Evaluate existence of food and supplement intake data to assure that adequate exposure (intake) estimates exist for relevant sub-population groups
- Dietary guidance needs to reflect varied population needs as well as potential adverse effects -depends on the seriousness of the adverse effects.
- Risk managers determine how to incorporate risk assessment into policy-Final Dietary Guidelines label values, etc.

Nutrient Risk Assessment and Upper Levels- European Perspective

Mr Basil Mathioudakis

Mr Basil Mathioudakis gave European perspectives on nutrient risk assessment and Upper levels. He started his presentation with history of food regulation in Europe. The regulation of foods, food supplements and nutrients started in 1991 with foods for infants and young children and foods for Special Medical Purposes. Regulations on supplements were introduced in 2002 and finally in 2006 the directives for regulation on the use of vitamins and minerals in foods were introduced. The aim of these specific rules is to ensure safe food for the consumers. They ensure an adequate composition of products which provide at least minimum amounts of micronutrients while ensuring that consumption of products do not pose a risk to health by specifying the maximum amounts for micronutrients that can be present.

The European Food Safety Authority (EFSA) is the risk assessor in Europe and the European Commission has mandated EFSA to review the upper levels of daily intakes of individual vitamins and minerals that are unlikely to pose a risk of adverse

health effects. EFSA was also to provide the basis for the establishment of safety factors, where necessary, for individual vitamins and minerals which would ensure the safety of fortified foods and food supplements containing these nutrients.

Nutrient risk analysis addresses the risks of deficiency and excess, and follows the same principles and guidelines as those for traditional food safety risk analysis to consideration of excessive intakes of nutrients and other chemical substances. Principles of nutrient risk assessment are used in determining Tolerable upper intake level (UL), one of the important criteria for setting of maximum amounts for use of vitamins and minerals. UL is defined as the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans. 'Tolerable intake' in this context connotes what is physiologically tolerable and is a scientific judgement as determined by assessment of risk, i.e. the probability of an adverse effect occurring at some specified level of exposure. ULs may be derived for various life-stage groups in the population.

The ULs are based on the maximum physiologically tolerable intakes of a nutrient which do not produce any adverse effects even on chronic consumption. It is critical to select the best quality data available. NOAEL (highest intake of a nutrient at which no adverse effects have been observed) or LOAEL (lowest intake at which an adverse effect has been demonstrated) has been used for deriving ULs for different nutrients. Selection of the appropriate uncertainty factor is also very critical and requires expert judgement. For exposure assessment, intakes from all sources need to be considered including water, fortified foods and food/nutrient supplements. Quality of the nutrient intake data is very important.

The EFSA evaluations are very similar to the nutritional risk analysis principles and guidelines adopted by the Codex Commission in 2010. EFSA also takes into account the work of other international bodies like FAO/WHO, FNB (USA) and Institute of Medicine (IOM) of USA. Uncertainty factors used in the derivation of ULs are determined by the data available, the population group studied and the severity of adverse effects observed, etc.

The work of EFSA related to deriving ULs was carried out between 2000-2005 and included 34 vitamins and minerals. Lack of data did not allow the establishment of ULs for all the micronutrients. However, a lot of useful information was made available for risk managers. This included a list of nutrients for which no adverse effects could be identified even at intakes that by far exceeded the intakes from all sources.

The basic principle on which food related legislation is based in Europe is safety, based on risk analysis. Based on risk assessment by EFSA, the European Commission and the EU member states act as the risk managers. They have been discussing potential models for setting maximum amounts for vitamins and minerals in foods, including supplements which are regulated as foods in the EU. The criteria for setting these maximum amounts are laid down in the relevant legislation and are the ULs and the intake of vitamins and minerals from all sources. Reference intakes of vitamins and minerals for the population need to be taken into account and the basic principle of food safety needs to be kept in mind. This is especially important for foods for special nutritional uses.

Risk managers need to carefully look at the margin between the RDA and UL levels of each nutrient. Where UL cannot be established, an indication should be given on the highest level of intake where there is reasonable confidence in data on the

absence of adverse effects. ULs are not thresholds for adverse effects. Maximum amounts of nutrients which can be added to foods are decided by risk managers using the above mentioned criteria. In the risk management context, nutrients can be divided into 3 categories – those which pose no risk even if eaten in large amounts, those which pose low risk and those which pose a potentially high risk. Accordingly, their maximum amounts in foods, including food supplements, in foods can be derived.

Table 6.

Upper Levels By SCF /EFSA

BM

Vitamins	Adult Upper Level
Vitamin A	3000 µg
B Carotene	not est.
Vitamin D	100 µg
Vitamin E	300 mg
Vitamin K	not est.
Vitamin C	not est.
Thiamin	not est.
Riboflavin	not est.
Niacin	10 mg free nicotinic acid / 900 mg nicotinamide
Vitamin B6	25 mg
Folacin	1000 mg
Vitamin B 12	not est.
Biotin	not est.
Pantothenic acid	not est.

(not est. = not established

Table 7.

Upper Levels By SCF/EFSA

BM

Minerals	Adult Upper Level
Boron	10mg
Calcium	2500 mg
Chromium	not est.
Copper	5 mg
Fluoride	7 mg
Magnesium	250 mg
Iodine	600 µg
Iron	not est.
Selenium	300µg
Molybdenum	600µg

(not est. = not established
* Supplemental readily dissociable salts

Upper Levels By SCF/EFSA

BM

Minerals	Adult Upper Level
Potassium	not est.
Phosphorus	not est.
Manganese	not est.
Zinc	25 mg
Silicon	not est.
Vanadium	not est.
Tin	not est.
Chloride	not est.
Nickle	not est.

(not est. = not established

Table 8.

Characteristics of Upper levels (Uls)

BM

Uls are:

- Based on Scientific risk assessment's assumptions and uncertainties
- Not only safe, but safe by a comfortable margin
- Defined and identified to reflect safety of chronic intakes
- Values that take account of identified sensitive population

Uls are not:

- Thresholds for adverse effects
- "Safety limits"
- Applicable to temporarily elevated intakes

Nutrient Risk Assessment & Upper Levels- Asian Perspective

Dr Oran Kwon

Dr Oran Kwon gave Asian perspective on the risk assessment for tolerable upper intake levels (ULs) and the risk management for maximum safe supplementation levels (MSSLs) of vitamins and minerals. She presented the Korean experience in defining UL as an example of Asian perspective. Three major ways of delivering micronutrients to the population are through nutrient dense foods, through food supplements and foods fortified with nutrients. Dr Kwon remarked that a number of health conscious people were now regularly taking nutrient/food supplements causing concern about potential adverse effects on their health. Some nutrients have a relatively low safety margin between adequate intake levels and

maximum safe intake levels. Toxicological end points have been identified for most vitamins and minerals. Therefore, it is necessary that regulations are established to ensure consumer safety and public health protection from unacceptably high intakes of nutrients.

In 2005 the Codex Alimentarius Commission finalized the guidelines for vitamin and mineral food supplements and highlighted that the maximum levels in supplements should not be set solely based on the recommended nutrient intake, but also take into account both ULs and daily intakes from other dietary sources. In parallel with the Codex guideline, two risk management models were proposed by European Responsible Nutrition Alliance and BfR Wissenschaft. The Korea Food and Drug Administration (KFDA) laid down regulations on the MSSLs for vitamins and minerals in 2006. Previously the RDAs had been applied as the basis of MSSLs for vitamins and minerals. The key data for setting MSSLs include qualitative risk characterization of each nutrient or specific numerical ULs and estimation of potential intakes of nutrients from food supplements and other dietary sources. The Korean Nutrition Society provided these data. Then, possible problems that could be faced when the MSSLs are changed were critically elaborated with taking into account the opinions from academia and the industry.

The current and potential intakes of vitamins and minerals from the various dietary sources are critical for assessing MSSLs. The ability to acquire and maintain useful and up-to-date food composition and intake data is a growing challenge because of the changing food supply and the increase of food supplements and nutrient fortified foods. National nutrition surveys are the best sources of information. Korean National Health and Nutrition Examination Survey (KNAHES) in an on-going cross-sectional study based on a single-day 24-hour recalls and dietary frequency. Intake of macronutrients, dietary fiber, calcium, phosphorus, iron, sodium, potassium, vitamin A, carotene, retinol, thiamin, riboflavin, niacin, and vitamin C from food and beverages is estimated. KFDA database for food supplement registration and other survey data for supplement intake are also available. For risk management, the mean highest intake levels (95 percentile intake) are used.

Individual nutrients have been divided into three categories based on relative risk of population intakes exceeding the UL. Group A nutrients are those for which the ULs have not been established because no adverse effects in healthy individuals with high intakes has been documented. No further risk management measures are required for these nutrients. These nutrients include vitamin B1, B2, B12, biotin, pantothenic acid, potassium, and chromium. There is no maximum safe level for these nutrients. For the nutrients with ULs, the relative safety was calculated by the ratio of UL and RDA. Where the ratio is higher than 10, the nutrients are placed in Group B which have a low risk of exceeding the UL. Where the ratio is below 10, the nutrients are placed in Group C which pose a potential risk at excessive intake.

For Group C nutrients, not only the risk of excessive intake but also the risk of insufficient intake needs to be taken into account in risk management. A case-by-case consideration for risk of deficiency, skewed distribution of intake, serious adverse effects, at-risk groups, and repeated intakes should be done before setting MSSLs.

Dr Kwon summarized her presentation by saying that MSSLs are voluntary at present but a necessary measure for safety. To this end, risk assessment provides a systematic means to evaluate the probability of the occurrence of adverse health effects due to

excessive intake of nutrients. The ratio of UL and RDA (or Nutrient Reference Values) provides empirical and objective approaches to help categorize nutrients on the basis of the risk associated with exceeding ULs. Assessment of the current and future intake of vitamins and minerals from all dietary sources is required. Acquiring up-to-date composition and intake data and estimating usual intake remained as the major challenges.

Table 9.

NUMERICAL UL FOR 14 NUTRIENTS

	Toxicologic end points	NOAEL	UF	UL
Vit A (ug RE)	Terotogenic/hepato-toxicity	4,500/14,000	1.5/5.0	3,000/3,000
Vit D (ug)	Hypercalcemia	60	1.0	60
Vit E (mg a-TE)	Bleeding	540	1.0	540
Vit C (mg)	Gastrointestinal intolerance	3,000	1.5	2,000
Niacin (mg NE)	Flushing (nicotinic acid) Hepatotoxicity (nicotinamide)	50/1,525	1.5/1.5	35/1,000
Vit B6 (mg)	Neuropathy	200	2.0	100
Folate (ug DFE)	Neurological injury	5,000	5.0	1,000
Ca (mg)	Milk alkali syndrome	5,000	2.0	2,500
Fe (mg)	Stomach pain	70	1.5	45
Zn (mg)	Copper deficiency	50	1.5	35
Cu (ug)	Damage in the liver	10,000	1.0	10,000
Mn (mg)	Neurological symptoms	11	1.0	11
I (ug)	Increase in TSH level	3, 000	1.0	3, 000
Se (ug)	Selenosis	850	2.0	400

Key Discussion Points:

1. Published data on adverse effects is used to arrive at end points of toxicity that would be used for defining ULs, for instance gastric distress is used to decide the UL for iron.
2. ULs are mostly used by risk assessors and managers especially in regulatory bodies and not so much by the consumer.
3. There is a role of uncertainty factor in defining ULs.
4. ULs are generally worked out for adults without body weight as a consideration as the data on adverse effects is inadequate.
5. Supplements may not require upper limits as they are supposed to be used for shorter duration to correct a specific deficiency. ULs apply to chronic daily intakes and not temporarily elevated intakes.
6. For deriving the ULs the endpoints may vary from country to country and for specific physiological groups like children.

SESSION THREE

Interactive Session With Director General, Indian Council Of Medical Research On Approach Towards Determination Of Upper Levels For Nutrients For Indian Population

Chair: Dr. B Sesikeran, Former Director, National Institute of Nutrition

Dr Soumya Swaminathan, Secretary, Department of Health Research & Director General, Indian Council of Medical Research joined the Panel Discussion. Mr. Panandiker welcomed Dr Soumya Swaminathan, Secretary, Department of Health Research & Director General, and Indian Council of Medical Research to the meeting. He briefed Dr Swaminathan on the purpose of the Expert Group meeting, the sessions which had taken place since morning and on the importance of determining ULs for different nutrients in the context of policy making and food regulations. He then requested Dr Sesikeran and Dr Prakash the Chairpersons for the first two sessions to sum up the presentations and discussions which had taken place during the day.

Brief Review Of Session One

Dr. B Sesikeran

The Overview Session in the morning by Dr Sesikeran had primarily dealt with the magnitude of micronutrient deficiencies globally and in India. The NNMB data on the nutritional status of the population presently available in India is mostly rural based. Urban data is lacking. The data show that intakes of most micronutrients are well below the RDAs. Among various short, medium and long term strategies discussed, policies regarding food fortification and nutrient supplementation would require fixing ULs for micronutrients in the interest of consumer safety. India lacks data which is required for risk assessment of nutrients and deriving ULs. It was finally felt that the data available from all sources, including and mostly from NNMB is inadequate and there is an urgent need to strengthen and expand NNMB to collect data periodically and establish data bank on food consumption patterns, nutrient intakes as well as diet related diseases. This will help not only in defining RDAs but also help in establishing ULs as well as risk assessment and management for not only nutrients but also for contaminants / toxicants.

In the first session, Dr. K. Madhavan Nair and Dr V. Prakash had presented their view points on food fortification as a necessary strategy. Nutrient supplementation programs had essentially failed to deliver because of poor coverage of beneficiaries. Mandatory fortification program like fortification of salt with iodine had been very successful in decreasing the prevalence of iodine deficiency disorders. Multi-nutrient fortification was probably the need of the hour rather than single nutrients, as more and more research evidence was indicating the interaction of nutrients with each other as well as with the food matrix. Iron bioavailability for instance would be much better when eaten along with

enhancers of its absorption like vitamin C. The importance of a holistic approach towards tackling the issue of micronutrient malnutrition was also emphasized. Dietary diversification was important to achieve nutrient adequacy. There is also a need for technological innovation to conserve nutrients by minimizing food and nutrient losses from the farm to the plate. Bioavailability issues of nutrients and other bioactive ingredients in functional foods also need to be addressed. Effect of processing on bioavailability of nutrients also needs to be assessed perhaps using nutrient retention factor.

Brief Review Of Session Two

Dr. V Prakash

International experts from USA, Europe and Korea shared their experiences and presented the risk assessment and risk management process of their countries/ regions. Risk assessment of all nutrients needs to be carried out and ULs derived using science- based evidence. For deriving the maximum and minimum levels, a model needs to be prepared for each population group. For exposure assessment food consumption data should be available for all population groups. Continuous monitoring is very important as dietary patterns change with time and hence periodic data generation is of utmost importance which can be done by a regular organization like NNMB with data collection centers across India.

Regulatory bodies would have to work out maximum levels of nutrients to be added to different types of foods, for instance, foods for special medical purposes and foods for special dietary uses would have to be looked at separately and would have different limits as compared to other foods for the general public. Technological limitations in assessing multiple nutrients need to be kept in mind from the regulatory point of view. It is important for India to undertake this exercise periodically for setting limits for the addition of micronutrients in foods on a priority basis.

Interaction With Dr. Soumya Swaminathan, Secretary, Department of Health Research & Director General, Indian Council of Medical Research

Process Of Safety Assessment In Different Countries

Dr. Soumya Swaminathan who joined the deliberations, enquired about process of safety assessment in different countries. Following responses were given by experts:

- Dr. Allison Yates, USA mentioned that risk assessment was done mostly by the scientific committees and panels while risk management was the responsibility of the government.
- Mr. Basil Mathioudakis explained that in Europe EFSA conducts the risk assessment process while risk management was the responsibility of the EU legislative Institutions.
- Dr Oran Kwon stated that in Korea global data is used for the purpose of risk assessment and a new Act has been formulated recently - the Health Promotion Act. As per the Act the Ministry of Health and Welfare funds are

utilized for research on risk assessment, but the scientific community actually carries out the risk assessment process.

- Dr Yates further supplemented that in the US the National Academy of Sciences, the Institute of Medicine and non-governmental bodies assess the Dietary Reference Intakes. They also play an advisory role to the Government, which is responsible for risk management.

Regularity Of The Process Of Risk Assessment

Following responses were given by experts to a question by Dr Swaminathan about the regularity of the process of risk assessment:

- Dr Yates responded that in the US regular collection of data on food consumption was carried out by the NHANES which includes the biannual WWEIA food and supplement surveys. Revision of DRIs is not a regular process but is done from time to time as the need due to new research evidence arises.

Status Of RDAs In India

Dr Swaminathan also wanted to know the status of RDA in India.

- Dr Sesikeran remarked that the RDA had been recently revised in 2010. The need for setting the ULs for various micronutrients was now being felt especially from the point of view of regulation of foods which need to be fortified or have special dietary uses. In Korea the recommended dietary intake values are revised every five years.
- Dr Yates remarked that implementation and regulation would get very difficult if DRIs are revised very frequently.
- Mr. Mathioudakis commented that the recommended dietary allowances may change when endpoints for defining values change. If earlier prevention of adverse effects of deficiency were used as basis for defining these values, a revision in recommendations may be called for if the criteria changes to maintenance of optimal health.

During the course of discussion the participants and speakers stressed the need for reliable data on dietary patterns from each geographic region of the country. The data needed to be representative of the entire country, capturing the diversity in the eating habits. This would be more apt for identifying region specific solutions for addressing micronutrient malnutrition. The data would help decide for instance, the kind of foods which are the best to fortify in the region. Estimating bioavailability of nutrients from typical Indian diets from different regions is also important. Cultural practices need to be taken into account when deciding about foods to be fortified and technology to be adopted.

Dr Swaminathan agreed that Expert Consultation had identified important issues and asked Dr Sesikeran for his opinion on what the next steps should be for India and how the country should proceed for deriving ULs. She informed that ICMR was already in the process of formulating a committee for the same.

Dr Sesikeran said that separate sub-committees and panels would need to be formulated. Each of these would work on the risk assessment of a particular nutrient and review literature available on the minimum and maximum levels of the nutrient that should be consumed for maintaining health and preventing adverse effects. Dr. Bhaskarachary and colleagues from NIN have submitted a project proposal to FSSAI on conducting a Total Diet Study for the country to estimate nutrient intakes and exposure to contaminants and food additives. Data

generated would also help in the process of risk assessment. Mr. Panandiker and Ms. Rekha Sinha remarked that ILSI-India was also going to undertake a Total Diet Survey (Food consumption, nutrient intakes, Physical activity and diet related diseases) and a meeting was being organized on 24th December to look at gaps in available databases and identify the priority areas.

Vote Of Thanks

Ms. Rekha Sinha, Executive Director, ILSI-India, thanked Dr Swaminathan for sparing her valuable time and attending the meeting which was perhaps first of its kind dealing with the issue of ULs. She acknowledged with gratitude the guidance given by Dr Sesikeran for planning this meeting. She thanked the Expert group members for their active participation in the discussion. She expressed her gratitude to the Chairpersons of the various sessions as well as the speakers for sharing their viewpoints. Dr Bhaskarachary and Dr Pulkit Mathur were thanked for being rapporteurs for the sessions.

Appendix-1

Expert Consultation On Nutrient Risk Assessment For Determination Of Safe Upper Levels For Nutrients

December 4, Inspire Hall, Hotel Le Meridien, New Delhi

AGENDA

10.00-11.00 Hrs. — **Opening Session**

- **Welcome By Mr. D H Pai Panandiker,** Chairman, ILSI-India
- **Vote of Thanks By Ms. Rekha Sinha**, Executive Director, ILSI-India

11.00-11.15 Hrs.
- Tea Break

11.15-12.00 Hrs. — **Overview Session**

Chair: Mr. D H Pai Panandiker, Chairman, ILSI-India

- **Observations By Chair**

11.15-11.45 Hrs.
- **Overview of The Nutrition Status of Population In India and Disease Burden**
  Dr. B Sesikeran, Former Director, National Institute of Nutrition (NIN)

11.45-12.00 Hrs.
- **Discussions**
- **Sum Up By Chair**

12.00-13.30 Hrs. — **Session One**

Strategies To Address Nutrition Deficiencies In India

Chair: Dr. B Sesikeran, Former Director, National Institute of Nutrition

- **Observations By Chair**

12.00-12.30 Hrs.
- **Food Fortification: Benefits & Challenges**
  Dr. K. Madhavan Nair, Scientist F, Head, Micronutrient Research Group, National Institute of Nutrition

12.30-13.00 Hrs.
- **Management Of Micronutrients Through Food Fortification And Food Based Approach On The Platform Of Bioactives And Food Safety**
  Dr. V. Prakash, Vice President, International Union of Nutritional Sciences

13.00-13.15 Hrs.
- **Discussions**
- **Sum Up By Chair**

13.15-14.00 Hrs.
- Lunch Break

14..00-15.45 Hrs.

Sessions Two

Nutrient Risk Assessment & Upper Levels: Country / Regional Experiences

Chair: Dr. V Prakash, Vice President, International Union of Nutritional Sciences

- **Observations By Chair**

14.00-14.30 Hrs. **USA**

- **Dr. Allison A. Yates,** Former Director, Food and Nutrition Board (FNB), Institute of Medicine, U.S. National Academy of Sciences

14.30-15.00 Hrs. **Europe**

- **Mr. Basil Mathioudakis,** Former Head of European Commission Unit on Nutrition & Food Composition

15.00-15.30 Hrs. **ASIA**

- **Dr. Oran Kwon,** Professor , Department of Nutritional Science & Food Management, Ewha Woman's University, Republic Of Korea

15.30-15.45 Hrs.

- **Discussions**
- **Sum Up By Chair**

15.45-16.00 Hrs.

- Tea Break

16.00-17.30 Hrs.

Sessions Three

Interactive Session With Director General, Indian Council Of Medical Research On Approach Towards Determination Of NRA And UL For Indian Population

Chair: Dr. B Sesikeran, Former Director, National Institute of Nutrition

- **Observations By Chair**
- **Brief Review Of Session One**
  Dr. B Sesikeran
- **Brief Review Of Session Two**
  Dr. V Prakash
- **Interaction With**
  Dr. Soumya Swaminathan, Secretary, Department of Health Research & Director General, Indian Council of Medical Research
- **Suggestions By Speakers and Participants**
- **Sum Up By Chair**

Appendix-2

BRIEF CVs OF SPEAKERS

Dr. B Sesikeran

Former Director, National Institute of Nutrition, Hyderabad

Till August 2012 Dr Sesikeran was the Director of National Institute of Nutrition (NIN), Indian Council of Medical Research, Hyderabad. He is a medical Pathologist by training and was with the National Institute of Nutrition since 1977. The major area of his research has been in Nutritional Pathology, particularly in understanding the role of nutrients in cancer prevention. During the six and a half years tenure as the NIN Director the Recommended Dietary Allowances for Indians (RDA) and Dietary Guidelines were revised and the food composition data base project was initiated to update the data on Nutritive Value of Indian Foods.

Dr Sesikeran is a fellow of the National Academy of Medical Sciences, International Medical Scientists Academy and the Andhra Pradesh Academy of Sciences. Currently he is the Vice President of Nutrition Society of India and Chairman of the National Committee of the International Union of Nutrition Sciences (IUNS) in the Indian National Science Academy (INSA). He is also on the Board of ILSI-India and ILSI, Washington DC. His other major responsibilities include: Chairman of Food Labeling Committee of the Food Safety and Standards Authority of India (FSSAI), and Chairman of the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology. Dr Sesikeran has published a little over 100 research papers, and written chapters in 5 books. He has developed guidelines for GM Safety Testing, Food Labeling (draft form), Guidelines for Probiotics in Foods and Guidelines for Similar Biologics.

Dr. K. Madhavan Nair

Scientist F, National Institute of Nutrition, Hyderabad

Dr. K. Madhavan Nair is working as Scientist – F at the National Institute of Nutrition, Indian Council of Medical Research, Hyderabad, India. He has received training from the International Center for Control of Nutritional Anemia. His expertise includes basic, applied and population based micronutrients intervention programs. He is an expert in the area of food fortification. He has received the Public Health Service International Research Fellow Award, NIH, USA and B.G.R.C. Silver Jubilee Oration Award of ICMR. He holds fellowships from three Indian Academies; the Academy of Medical Sciences, Academy of Agricultural Sciences and Telangana Academy of Sciences.

Dr. V Prakash

Distinguished Scientist of CSIR-India, Vice President, International Union of Nutritional Sciences (IUNS), Director of Research, Innovation And Development At JSSMVP, Mysore

Dr. V. Prakash is currently working as Distinguished Scientist of CSIR-India in the prime area of Food Science and Technology, Nutrition Security, Nutritionals, and Food Safety with a focus on Policy matters and Nutritional Intervention for the masses especially from a non-governmental organization where he is Honorary Director of Research, Innovation and Development at JSS Group of Institutions at Mysore, India. Dr. Prakash is currently the Vice President of the International Union of Nutritional Sciences.

Dr. Prakash has more than 200 original research papers to his credit. He is also the author of eleven books and has contributed 50 review chapters in various books and journals and has more than 49 patents to his credit. He is a Fellow and Council Member of most of the academies in India. He is the Fellow of the Royal Society of Chemistry, Fellow of the International Food Technology Institute and currently holds a large number of awards including prestigious award of India, Padmashri award in recognition of his outstanding service to the nation in the field of Biological Science. During 2014 he was decorated with Life Time Achievement Award of IUFoST at Montreal Congress of IUFoST.

Dr. Allison A. Yates

Former Director, Food and Nutrition Board (FNB), Institute of Medicine, U.S. National Academy of Sciences

Dr. Allison A. Yates served on the faculties of the University of Texas Health Science Center in Houston, Emory University School of Medicine in Atlanta, and was the founding Dean of the College of Health and Human Sciences at the University of Southern Mississippi in Hattiesburg. Her research focused on human protein and energy requirements. In 1994 she was named Director of the Food and Nutrition Board (FNB) of the Institute of Medicine, U.S. National Academy of Sciences, where, over a 10-year period through 2004, she led the expanded approach to establishing human requirements and recommendations for nutrients (RDAs), termed Dietary Reference Intakes, which includes upper reference values, for the United States and Canada.

During this period, in addition to overseeing the activities of the FNB, she served as study director for a Congressionally mandated study on how to improve the food safety system in the U.S., and at the request of the U.S. Food and Drug Administration, directed the 2002-2004 study to design a framework for evaluating the safety of dietary supplements. In 2004, Dr. Yates was appointed Director of Nutritional Sciences at ENVIRON Health Sciences Institute in Arlington, VA and two years later she joined the U.S. Department of Agriculture, Agricultural Research Service (ARS), as Director of the Beltsville Human Nutrition Research Center. In 2011, she was appointed Associate Director for the Beltsville Area region of ARS, retiring in October 2014. While at USDA, she served as the alternate delegate for the United States to the WHO/FAO Codex Committee on Nutrition and Foods for Special Dietary Uses.

Mr. Basil Mathioudakis

Former Head Of European Commission Unit On Nutrition & Food Composition

Mr. Basil Mathioudakis joined the European Commission in 1982. After 33 years of service he retired at the end of February 2015. During the whole of his career Mr. Mathioudakis has worked on food legislation and nutrition covering a variety of dossiers including foods for infants and young children, foods for special medical purposes, foods for weight control, food supplements, nutrition labelling, addition of vitamins and minerals to foods, food information for consumers and nutrition and health claims. In 2004 he became head of the Unit responsible for these subjects in the Directorate-General for Health and Consumers.

Mr. Mathioudakis chaired the Standing Committee on Plants, Animals, Food and Feed, Section General Food Law, which votes on all relevant implementing legal measures, including the authorization or not of the nutrition and health claims. At international level, as Head of the

delegation of the European Union, Mr. Mathioudakis was actively involved in the work at the Codex Alimentarius Committees on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and on Food Labelling (CCFL), and followed the relevant work of World Health Organisation and Food and Agriculture Organisation. He has also followed closely the work of the scientific advisory bodies, in particular that of the European Food Safety Authority (EFSA) in the area of Nutrition in general and in particular on the subjects for which his unit is responsible. For 15 years (1982-1997) he was the Secretary of the Working Group on Nutrition and Dietetic Foods of the Scientific Committee for Food of the European Commission, which was the predecessor of the NDA Panel of EFSA.

Dr. Oran Kwon

Professor, Department of Nutritional, Science & Food ManagementEwha Woman's University, Korea

Dr. Kwon is a Professor in the Department of Nutritional Science and Food Management and Director of the BioFood Network at the Ewha Woman's University. From 1995 to 1997, Dr. Kwon worked in the laboratory of Molecular &and Clinical Nutrition Section at US NIH (National Institutes of Health) as a postdoctoral fellow. While at US NIH, she described for the first time how vitamin C metabolite dehydroascorbic acid is transported by different glucose transporter isoforms. Again as a research fellow in this laboratory 2001 to 2003, she visited the same laboratory as a research fellow. At that time, she demonstrated that flavonoids have a novel mechanism of action to regulate nutrient absorption in the intestine by using molecular biology, biochemistry and animal biology.

Just before joining the Ewha Woman's University in 2008, she was a Director of the Division of Food Supplement Evaluation and Standards at Korean Food and Drug Administration (KFDA) and played an important role in implementing the new regulation on dietary supplements and functional foods in Korea. Her current research is focused on bioactives in culinary plants; especially on studying how multi-components in traditional herbs give impacts on the health from preclinical to clinical levels. She has been the primary investigator for numerous technical papers and articles. Currently, Dr. Kwon is a member of many scientific organizations. She has been on advisory board of Prime Minister's Office, Ministry of Agriculture, Food and Rural Affairs, Ministry of Food and Drug Safety, and Ministry of Health and Welfare.

Appendix-3

Expert Consultation On Nutrient Risk Assessment For Determination Of Safe Upper Levels For Nutrients

List Of Participants

1. Dr. Anuja Aggarwal, Dietitian, Resident Adviser, All India Institute of Medical Sciences
2. Dr. A S Bawa, Vice President, Amity Food & Agriculture Foundation & Director, Amity Institute of Food Technology
3. Dr. K Bhaskarachary, Assistant Director/Scientist D (Food Science & Dietetics), National Institute of Nutrition
4. Dr. Kumar Bhatia, Ex. Chief Engineer, Ministry of Food Processing Industries, GOI
5. Dr. Deepti Gulati, Consultant, Global Alliance for Improved Nutrition (GAIN)
6. Ms. Rachita Gupta, World Health Organization Country Office
7. Dr. Parmeet Kaur, Senior Dietician, All India Institute of Medical Sciences
8. Dr. S C Khurana, Consultant, Food Safety and Standards Authority of India
9. Dr. Oran Kwon, Professor, Department of Nutritional Science, and Food Management, Ewha Women's University, Korea
10. Dr. A Laxmaiah, Sr. Deputy Director (Scientist F Epidemiology) Head, Division of Community Studies, National Institute of Nutrition
11. Dr. T. Longvah, Director-in-Charge, National Institute of Nutrition
12. Dr. Kumkum Marwaha, Nutrition Advisor, Directorate General of Health Services, Ministry of Health, GOI
13. Mr. Basil Mathioudakis, Former Head of European Commission, Unit of Nutrition and Food Composition
14. Dr. Pulkit Mathur, Asst. Professor, Lady Irwin College
15. Dr. K. Madhavan Nair, Scientist 'F' & Head, Micronutrient Research Group (Nutrition Biochemistry), National Institute of Nutrition
16. Dr. B K Nandi, Former Senior Food and Nutrition Officer, Food and Agriculture Organization
17. Mr. D H Pai Panandiker, Chairman, ILSI-India
18. Dr. V Prakash, Vice President, International Union of Nutritional Sciences (IUNS)
19. Dr. Pradeep Saxena, Additional Dy. Director General, Ministry of Health, GOI
20. Dr. B Sesikeran, Former Director, National Institute of Nutrition
21. Ms. Rekha Sinha, Executive Director , ILSI-India
22. Dr. Soumya Swaminathan, Secretary, Department of Health Research & Director General, Indian Council of Medical Research, GOI
23. Dr. Allison A. Yates, Former Director, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, USA

About ILSI India

ILSI-India is a branch of International Life Sciences Institute (ILSI) with headquarters in Washington DC. ILSI-India provides scientific inputs and secretariat assistance to the South Asian Region, which includes Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka.

ILSI-India activities primarily focus on local and regional issues and involve leading national and international experts in the deliberations. ILSI-India has taken the lead in the region in focusing attention and devoting resources on critical areas in food and water safety, nutrition, risk assessment, harmonization of food regulations, improvement in the health profile of malnourished children and women and agriculture sustainability including biotechnology. Special attention has been given to the importance of complementary foods and food fortification.

ILSI-India carries out its mission through sponsoring workshops, symposia, conferences, seminars training programs, research projects and publications. ILSI-India works closely with government, industry, research institutions, academia and international organizations.

ILSI is a nonprofit, worldwide foundation whose mission is to provide science to improve the human health and well-being and safeguards the environment. Prominent researchers from industry and academia jointly lead the organization, guiding its work to conduct research, harmonize the use of science and encourage scientific dialogue and then resolving outstanding scientific questions in four thematic areas that capture the core of ILSI's work:

- Food And Water Safety
- Toxicology And Risk Science
- Nutrition, Health And Well-Being
- Sustainable Agriculture And Nutrition Securityp

These focus areas provide structure for responding to and raising awareness of the pressing issues society faces. They also help elucidate new opportunities for driving scientific progress. ILSI's work is guided by its Code of Ethics and Organizational Standards of Conduct.

ILSI has a worldwide network. ILSI Branches currently operate within Argentina, Brazil, Europe, India, Japan, Korea, Mesoamerica, Mexico, Middle East, North America, North Andean, South Africa, South Andean, Southeast Asia Region, Taiwan as well as a Focal Point in China. ILSI's global branch, the ILSI Health and Environmental Sciences Institute is focuses on global issues of human health, toxicology, risk assessment, and the environment. ILSI also accomplishes its work through the ILSI Research Foundation.

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