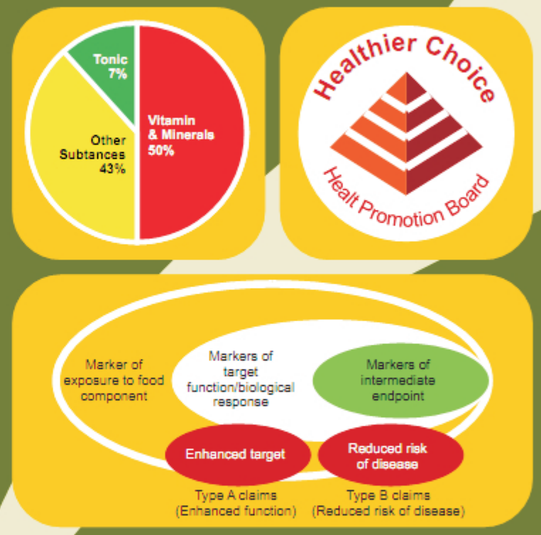
Handbook

NUTRITION IN FOOD INDUSTRY

revised edition



Editors :
Rina Agustina
Dwi Nastiti Iswarawanti
Evi Ermayani
Ingrid S. Surono

NUTRITION IN FOOD INDUSTRY revised edition

SEAMEO RECFON
Jl. Salemba Raya 6 Jakarta 10530 INDONESIA
Phone: 021 31930205, Fax 021 3913933
information@seameo-recfon.org
www.seamoe-recfon.org

SEAMEO RECFON
Southeast Asian Ministers of Education Organization
Regional Centre for Food and Nutrition
Jakarta, 2014

Handbook

NUTRITION IN FOOD INDUSTRY

revised edition

Editors :
Rina Agustina
Dwi Nastiti Iswarawanti
Evi Ermayani
Ingrid S. Surono

South East Asian Ministers of Education Organization
Regional Center for Community Nutrition
(SEAMEO RECFON)
Universitas Indonesia
Jakarta
2014

Perpustakaan Nasional: Katalog Dalam Terbitan (KDT)
Rina Agustina
Handbook ***Nutrition in Food Industry***
By Rina Agustina, DN Iswarawanti, Evi Ermayani and Ingrid S. Surono
Jakarta: SEAMEO- RECFON UI, 2014.
Bibilografi
ISBN 978-602-19494-8-1
I. Food Industry II. Judul III. Health Claim III. Labelling IV.Functional Food

Editors:
Rina Agustina
Ingrid S. Surono
Dwi Nastiti Iswarawanti
Evi Ermayani

Contributors:
Agustina, Rina
Dwihatmanto, Susilo
Fahmida, Umi
Purwantyastuti
Sadariskar, Ahmad
Surono, Ingrid S.
Sjarief, Damayanti

Design and lay-out:
Rina Agustina, CV Mulya Printing

Published by:
South East Asian Ministers of Education Organization
Regional Center for Food and Nutrition
Universitas Indonesia
(SEAMEO-RECFONUI)

Printed by
CV Mulya Printing

Revised Edition 2014

FOREWORD

SEAMEO RECFON conducts degree program in community nutrition as one of it's mission in capacity building. Nutrition in Food Industry as a module of MSc Program in Community Nutrition's curriculum emphasizes the role of nutrition in food industry in relation to all aspects of improving nutritional status of the South East Asia community.

A handbook as supporting materials to the module is necessary to include the scientific aspects of nutrition labeling and claims, food safety issue as well as food and nutrition policy in related country. The completion of this handbook by SEAMEO RECFON team is commendable.

On behalf of SEAMEO Regional Center for Food and Nutrition, I am pleased to present this revised edition of Handbook of Nutrition in Food Industry to be one of the references to the module. We welcome suggestions or new ideas to continue improving this handbook.

We appreciate and are grateful to the Ministry of Education and Culture for providing us with financial support.

Jakarta, December 2014

Director,

dr. Drupadi Dillon, PhD

PREFACE

Nutrition in Food Industry is one of the compulsory courses in the curriculum of Master of Science Degree Program in Community Nutrition at SEAMEO Regional Center for Food and Nutrition (RECFON), Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia. Nutrition in Food Industry was integrated in the curriculum of different courses in recent year of 2002. The general objective of this course is to enhance understanding on the role and application of nutrition science in food industries and the contributions of food industry to food and nutrition policy in promoting healthy lifestyle as well as to encourage active roles of nutritionists and health related professionals in disseminating nutrition information to consumer and community.

The main participants of this course are master students from South East Asia region, practitioners in food industry and nutrition such as regulatory affairs specialist, research scientist, consumer services, nutritionist dealing with food industry and other related institution, health and nutrition promotion consultant, etc. Right from the start of this course, SEAMEO RECFON is assisted by the local professionals in food and allied industry, and expert from South East Asia region. Ever since this course was established, this course has gain many interests from many different universities, food industry and nutrition and health professionals. The topics are regularly updated and modified according to the needs of graduates and participants into more interesting and practical knowledge to be implemented by related professionals.

References for nutrition in food industry nowadays have growth but still need effort to find and compile into the theme. This handbook gathers topics on: Overview of food industry and their role in nutrition; Nutrition promotion; Communication to consumer and marketing; Application of nutrition research in food industry; Dietary supplement and functional food; Nutrition for specific vulnerable groups and health condition; Nutrition labeling; Nutrition and health claim and its scientific substantiation of. Topics on food safety are not included in this handout because “Food Safety” course is also one of the course in the curriculum of Master of Science Program.

These topics cover the specific objectives upon completion of the course as follows: the participants should: (1) Understand the role of nutrition in food industry and the role of food industry in improving the nutritional status of the people in the region; (2) Be familiar with potential dietary supplement and functional food;(3) Be familiar with food and nutrition for specific dietary and medical purposes; (4) Be familiar with implementation of the results of nutrition research in food industry; (5) Understand food regulation especially on functional food, dietary supplement, and food fortification; (6) Understand the role of food industry in nutrition promotion and marketing in enhancing healthy lifestyle; (7) Understand nutrition and health claims in Asia regions; (8) Understand food labeling and how to design a food label based on food laws and regulation in the country.

The topics are presented in sequence as the followings: learning objective, subject content, key issues and references. Many of the subject contents are derived from the NFI lecture's material of previous years.

We are well aware that this handbook is just a beginning and improvements are continuously needed. Therefore, we would appreciate any comments and inputs for the improvement of the handout.

Jakarta, December 2014

Editors,

Rina Agustina, PhD
D. N. Iswarawanti, Dr
Evi Ermayani, MSc
Ingrid S. Surono, PhD

ACKNOWLEDGMENT

The authors express their gratitude to the Ministry of National Education, Republic of Indonesia for financial support, enabling this handbook to be realized.

We highly acknowledge the contribution of Ms. Pauline Chan, from Food and Nutrition Specialist Ltd, Singapore, for her involvement as consultant during the implementation of the course since the year of 2002 and for her dedication and contribution from time to time to shape up the course syllabus, which inspired us to develop this handbook.

We thank our reviewers and experts: Prof. Dr. Purwantyastuti (Farmacologist and Community Nutrition Specialist from Department of Farmacology, Faculty of Medicine University of Indonesia), Dr. M. Hayatie Amal, MPH (Director or the Evaluation of Food Safety/Deputy for Food Safety and Hazardous Control, National Agency for Food and Drug Control, Republic Indonesia) and Dr. Kartika Adiwilaga (Practitionnaire at the Food Industry/Head of ILSI Indonesia, Jakarta) for providing valuable inputs and comments in the finalization of the handbook.

We are very grateful to contributing authors of this handbook: Drs. Ahmad Sadariskar, MSi and Drs. Susilo Dwihatmanto (Chapter 3. Nutrition communication for consumers, nutrition marketing and advertisement). Dr. Umi Fahmida, MSc (Chapter 4. Nutrition research and food industry and Chapter 8. Food fortification in Asia and the role of public private partnership); Prof. Dr. Purwantyastuti, SpF (Chapter 6. Dietary/Food supplement); Dr. Damayanti R. Sjarif, SpA(K), PhD (Chapter 7. Food and nutrition for specific vulnerable groups and health condition).

We are sincerely thankful to Ratna Wulanti, for her contribution in collecting references; Ahmad Munawir, Apsah Radianita for their help; and DIPA Finance Unit of RECFON for their persistent supports during the development of this handbook.

Our gratitude to our beloved families who always give us their sincere loving and motivation for keeping us stronger to finalize this duty.

Editors,
Rina Agustina, PhD
D. N. Iswarawanti, Dr
Evi Ermayani, MSc
Ingrid S. Surono, PhD

LIST OF CONTENT

LIST OF TABLES

Chapter 8

Chapter 10

LIST OF FIGURES

LIST OF ABBREVIATIONS

ADA	American Dietetic Association
ADI	Acceptable Daily Intake
AGNS	Food Quality and Standards Services
ASEAN	Association of Southeast Asian Nations
BFAD	Bureau of Food and Drugs of the Philippines
BMI	Body Mass Index
CAC	Codex Allimentarius Committee
CCNFSDU	The Codex Committee on Nutrition and Foods for Special Dietary Uses
CEO	Chief Executive Officers
CHD	Coronary Heart Disease
CLA	Conjugated Linoleic acid
CODEX STAN	Codex Standard
CRN	Council for Responsible Nutrition
CVD	Cardio Vascular Disease
DFAT	Department of Foreign Affairs and Trade
DHA	Decosahexaenoic Acid
E.G.	*Exempli Gratia* / Example
EPA	Eicosapentaenoic Acid
Etc	*Et Cetera*
EU	European Union
FAO	Food Agriculture Organization
FFDCA	Federal Food, Drug, and Cosmetic
FFI	Flour Fortification Initiative
FNB	Food and Nutrition Board
FNFC	Foods with Nutrient Function Claims
FOS	Fructo-oligosaccharides
FOSHU	Foods for Special Health Uses
FUFOSE	Functional Food Science in Europe
FSANZ	Food Safety Austria and New Zealand
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product

GMP	Goods Manufacturing Practices
HOI	Highest Observed Intake
IADSA	International Alliance of Dietary/Food Supplement Association
IDA	Iron Deficiency Anemia
IFIC	International Food Information Council
IFT	Institute of Food Technologies
KFI	Koalisi Fortifikasi Indonesia (Coalition for Fortification in Indonesia)
KPI	Komisi Penyiaran Indonesia (Indonesian Broadcasting Commission)
LDL	Low-Density Lipoprotein
MHLW	Ministry of Health, Labor and Welfare (Japan)
NADFC	National Agency for Drug and Food Control Republic of Indonesia
NIP	nutrition information panel
NRV	Nutrient Reference Value
NZ	New Zealand
OECD	Organization for Economic Co-operation and Development
OSL	The Observed Safe Level
P31	Perhimpunan Pengusaha Periklanan Indonesia (Indonesia Advertising Agency Association)
PASSCLAIM	Process for the Assessment of Scientific Support for Claims on Foods
PEM	Protein Energy Malnutrition
PR	Public Relation
PUFA	Poly Unsaturated Fatty Acid
RBC	Red Blood Cell
RCT	Randomize Clinical Trial
RDA	Recommended Dietary Allowance
RDI	Recommended Dietary Intake
RfD	Reference Dose
SEA Region	South East Asia Region
SFDA	State Food and Drugs Administration China
SNI	Standard Nasional Indonesia (National Standardization Indonesia)
SPS	Sanitary and Phytosanitary Measures
TABD	The Transatlantic Business Dialogue
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom

UL	Upper Level
UN	United Nations
US EPA	United State Environmental Protection Agency
USA	United Stated Of America
USAID	United Stated Agency for International Development
USDA	U.S. Department of Agriculture
USFDA	U.S. Food and Drugs Administration
VAD	Vitamin A Deficiency
WHO	World Health Organization
WTO	The World Trade Organization
YLKI	Yayasan Lembaga Konsumen Indonesia (Indonesian Consumer Organizations)

CHAPTER 1

FOOD INDUSTRY: AN OVERVIEW

By: Rina Agustina and Ingrid S. Surono

LEARNING OBJECTIVES:

This chapter introduces a general overview of the food industry. Upon completion, you should be able to explain:

- Definition of food industry
- Scope of food industry: from farm to fork
- Current status in various countries, especially in Asia
- Partnership between government, academia and food industry
- Challenges and opportunities of food industry
- International regulatory situation affecting food industry

SUBJECT CONTENTS:

Food travels from harvesting of the agriculture products to the consumption through the mix and complex chains and systems called as food industry. Food processors and manufacturers are the key components in the food industry. Promoting better eating habits and positive health behavior is one of the most challenging tasks in the overall effort to improve nutrition. Food industry try the best effort to deliver food reaches consumers efficiently and contributes to safe and healthy live through research, educational programs, and some other collaborated activities. As an implication, food industries are a major force in shaping food culture world-wide. So far, too few companies give evidence of serious commitment to play a responsible role in promoting food culture. Food industry impacts on food trades and associated systems considered as important element of globalization.

1. DEFINITION OF FOOD INDUSTRY

Food industry is not a formally defined term; however, it is widely used to cover all aspects of food production: process, manufacture, distribution, market and sale of foodstuffs for human consumption. In this course, the term food industry is used to describe organizations involved in processed and prepackaged foods as defined by the Food Standards

Agency, the UK, below:

"...the whole food industry – from farming and food production, packaging and distribution, to retail and catering. It addresses food safety issues at every stage of the chain, providing information and guidance on best practice and legal requirements" (The Food Standards Agency, the UK, 2008).

The definition elaborates the complexity of food industry that plays a role in wide range of food chain.

Large food manufacturers start creating products with already-processed ingredients -- both processors and manufacturers strive for the right blend of diversification, product innovation, and market expansion to ensure future growth. Kraft Foods, Unilever, and Nestlé are among the oldest and largest food manufacturers and have been settled on a recipe of diversification. From one basic food niche (cheese, margarine, baby formula, respectively), and started to capitalize new products. Diversification is not a new trend in the US and Western European food markets. Brand-swapping deals are about the only shake-ups keeping many of the industry's major players somewhat active (Hoover's inc, 2008).

The biggest growth of Food industry is achieved by mega-mergers between industry giants. But geographic expansion, mega-mergers, and value-adding won't be enough expand the food industry if the companies do not realize that consumers are cooking less. More people are eating away from home. In response, food producers such as Campbell Soup Company are devoting more attention to products designed for restaurants, vending machines, and other foodservice providers (Hoover's inc, 2008).

Food industry should have full commitment on health issue and implement it through Corporate Social Responsibility Program, especially toward children and vulnerable population, focusing on diet, nutrition, education, and physical activity reflected by key performance indicators, not only by general statement.

The above mentioned comprehensive roles of food industry reveals that food industry is an integrated food system as defined by The Economic Research Service of the USDA which uses the term food system to define food industry.

"The U.S. food system is a complex network of farmers and the industries that link to them. The system also includes the food marketing system that link farms to consumers, via food manufacturing, wholesaling, and retailing (food stores and foodservice facilities).The U.S. food marketing system comprises five broad stages of economic activity: production, processing and manufacturing, wholesaling, retailing, and consumption. The food manufacturing and distribution stages serve as the bridge between production and consumption, coordinating the delivery of farm products in the form, place, and time preferred by consumer (USDA, 2007).

However, in this course, the term food industry is used to describe organizations involved in processed and prepackaged foods.

2. SCOPE OF FOOD INDUSTRY: FROM FARM TO FORK

The above definition characterizes the complex value chain that relates the available agricultural raw material, through the processing phase up to the final product for human consumption using distribution channel. This is thereby; the food industry involves the commercial movement of food from farm to fork. The food industry includes:

- Agriculture and Food manufacturing
- Food processing
- Wholesale and distribution
- Retail and Foodservice
- Food industry technologies
- Marketing
- Regulation
- Labor and education
- Research and Development

Promoting better eating habits and positive health behavior is one of the most challenging tasks in the overall effort to improve nutrition.

3. CURRENT STATUS OF FOOD INDUSTRY IN VARIOUS COUNTRIES

Processed food sales worldwide are approximately US$3.2 trillion in 2004. The information below illustrates food sales in various regions:

USA. The USDA reported that in 2001, the food and fiber marketing system contributed 12.3 percent to the U.S. Gross Domestic Product (GDP) and employed 23.7 million people, or 16.7 percent of total U.S. employment. Corresponding to U.S. Census Bureau data, the food marketing system also accounted for 9 percent of the value of all merchandise exported by the United States in 2005. The activities and services provided by food manufacturers and distributors accounted for about 81 percent of consumer food expenditures in 2002, while the farm value component accounted for the remainder (USDA, 2007).

Europe: The food and drink industry is one of Europe's most important and dynamic industrial sectors for a total of about 310,000 companies, and employed for 4 million people. The European food industry has a share of 1.9% in the value added of the total economy and 2.2% of the employment, often in rural areas. The food industry is, with 11% of the value added in 2003 of the manufacturing industries, important. The value added of the food industry grew faster than that of total manufacturing. The EU is also the largest exporter and importer of food products. However, the competitiveness of the European food industry is weak compared to the US and Canada and at approximately the same level as the Australian and Brazilian industry. Unless the productivity growth in the EU is higher than in the rest of the world, EU competitiveness remains weak. Regardless of the weak competitive performance, an adequate number of world leading food enterprises are located in the EU. Furthermore the

importance of the food industry in total manufacturing is growing, and the sub-sectors value added is higher than that of most other sub-sectors in manufacturing (Wijnands, 2007).

Australia: The food industry is a vital component of the Australian economy. Food accounts for 46 per cent of all retailing turnover in Australia, with total food and liquor retail spending in 2006–07 rising to $106.6 billion, an 8 per cent increase from the previous year. The industry makes a significant contribution to the economies of regional areas through employment, business and service opportunities. There were around 191 400 people employed in food and beverage manufacturing in Australia in 2006–2007(DFAT, 2008).

Asia-Pacific: The food industry in the Asia Pacific region is gigantic in size, and is therefore a key element in the economic development prospects for the region. It is estimated that in 2000, for example, total expenditure on food and beverages in Japan was at $322 billion, the second in China was worth $US 188.5 billion, the third in Korea was at $67 billion and the forth in Taiwan was at $46 billion. Yet it is clear that given the expansion of both populations and incomes in the region this market will expand rapidly over the next few years. Not only increasing in size, other demographic and social factors are also becoming important change in the nature and composition of this trade opportunity, such as rapid growth of industrial cities in the Asian region, increasing of aging population, changing demands for processed food, growth of supermarkets and similar retail outlets (McKay, 2007).

4. PARTNERSHIP BETWEEN ACADEMIA, GOVERNMENT AND INDUSTRY

Partnership can involve many different stakeholders namely government, inter-governmental organizations, community, family and individual, which forms a consumer-government-food industry triangle.

National governments should consider how to improve the monitoring of food companies based in their jurisdictions, and collaborate with others and with WHO to pool best and worst practice in the auditing of company impact on diet, physical activity and health.

Nowadays, university and the industry are eager in building strong and purposeful partnerships. The presence of industry in various segment of the academic are considered to be essential by providing program for internships, industry-based student projects, and representation on academic boards. On the other hand, the industry also looks for partnerships with universities because of the complexity of scientific knowledge, the increase of keen and greater size of competition and the drive for innovation (Narayanan, 2009).

A “triple helix” of academic-industry-government relations is likely to be a key component of any national or multi-national innovation strategy in the late twentieth century (Etzkowitz & Leydesdorff, 2009). The Triple Helix aims to achieve more innovation capability and better financial returns by coordinating resources and visions within a region. The Triple Helix model is based on three institutional spheres (public, private, and academic) working together, with a spiral pattern of linkages emerging at various stages of the innovation

process, to form a triple helix (Department of Economic Development & Innovation Region Skåne, 2009).

There are different models of the relationship among the institutional spheres such as one in which the spheres are separate from each other and do not collaborate or one in which one sphere dominates the others. Model 1; portray a model in which the state incorporates industry and the university, which represent the Former Soviet Union and some Latin American countries in a previous era, when state owned industries were predominant. The model of overlapping spheres is the model of institutional spheres as separate from each other, which, at least in theory is how the US supposed to work (model 2). From each of these above mentioned models, whether the state dominates the other institutional spheres or the spheres separate from each other, model 3 shows that we are moving to a model where the institutional spheres overlap, collaborate and cooperate with each other (Etzkowitz, 2002).

A survey in 1995 about private - public partnerships to eliminate micronutrient malnutrition revealed that among 95 representatives of multinational and national food companies and 68 representatives of government and international agencies, found to be a lack of communication from the public sector to the private sector, although both sides suggest that such communication would be effective and desirable. An international dialogue entitled "Sharing Risk and Reward: Public-Private Collaboration to Eliminate Micronutrient Malnutrition" was held in Ottawa in December 1995, where a framework for communication was established. From this foundation, many countries have initiated or reopened dialogues among governments, industry, agencies, academia, and civil Organizations to support the elimination of micronutrient and malnutrition (Maberly, 1998).

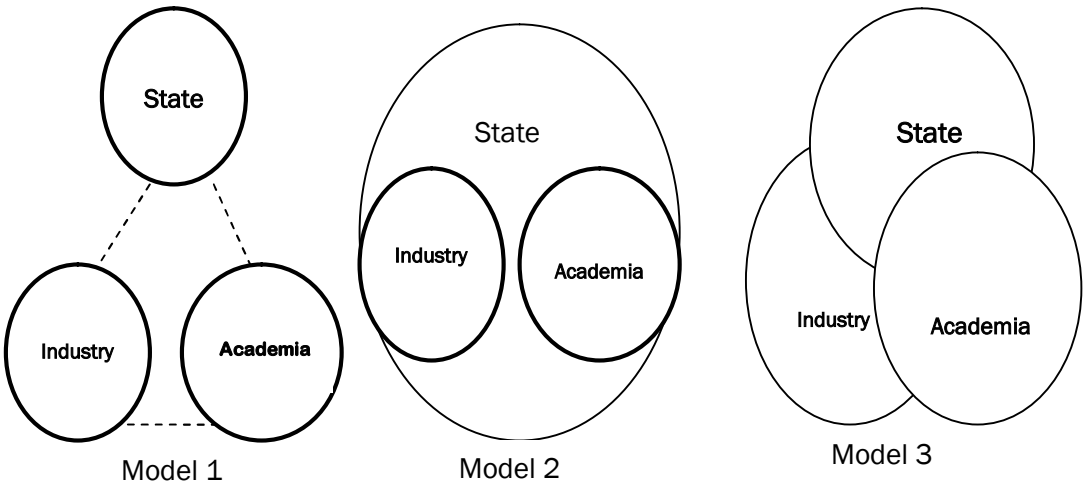


Figure 1. Model of the Triple Helix of University-Industry-Government (Maberly, 1998)

5. CHALLENGES AND OPPORTUNITIES IN FOOD INDUSTRY

Food industry will face several challenges, issues and trends over the next five years by climate change, global economic downturn, change of lifestyles, malnutrition, obesity and diet-related illnesses, food safety and consumer trust, and evolving consumer demands influencing challenges in facing the food industry (companies and markets, 2009). The food industry is in a unique position where both challenges and opportunities exist at the same time (Bhalkar, 2006). Food industries faced various challenges which in turn create opportunities for food industries as described in Table 1.

Table 1. Challenges and Opportunities of the Food Industry

Challenges:	Opportunities:
Lack of awareness on public health problems by the food industry	• Commitment to produce tasty, affordable and nutritious foods that foster the nutritional wellbeing of consumers • Form partnership with scientific bodies and health authorities to have quick and easy access for up to date information on new developments of nutrition and food
Regulatory environment that is not conducive to food production and promotion	• Collaboration with regulatory agencies to draft acts and regulations conducive to the promotion of healthy foods including health claims for consumers benefit
Inadequate return on investment	• Establish system whereby appropriate profit is possible and incentives for further investment
Effort often not recognized by health authorities and NGO's	• Establish equal partnership in eliminating malnutrition and micronutrient deficiencies • Be transparent • Recognition of the food industry's effort • Endorsement of the product by health authorities
Lack of trust towards industry	• Establish mutual trust and eliminate adversarial attitudes • Share information regarding needs in food, nutrition, organoleptic properties of the target populations • Collaborate in the support of research and education to further the nutritional wellbeing • New science promises "encouraging" health and functional claims • Recommended Daily Allowances being revised from "meeting needs" to prevent deficiency to values that" optimize health and well being" • Nutrition label becoming "required" information • Nutrition and health claim being regulated and approved

Source: Lecture's note of Nutrition in Food Industry (NFI) course, Pauline Chan (2008)

6. INTERNATIONAL REGULATORY SITUATION AFFECTING FOOD INDUSTRY

6.1. The Codex Alimentarius

The Codex Alimentarius (Latin: Food Law or Code) is the compilation of internationally adopted food standards, guidelines, codes of practice and other recommendations. It was established in 1962 to implement the Food Standards Programme of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) that is open to all member nations and associate members of FAO and WHO. It is a forum where member countries and international organizations can meet and exchange information and ideas relative to food safety and trade, with the main objective is to promote consumer protection and to facilitate world trade in foods through the development of food standard, codes of practice and other guidelines under the joint FAO/WHO Food Standard Program.

Over the past decade Codex has been dealing with new challenges related to scientific developments (e.g. biotechnology as well as the increase of consumer awareness of food issues and governments and the food industry started to develop a new approach to food control, food safety and food quality. To tackle with these new challenges, Codex will continue to expand as a global decision-making body. Member countries can review and provide comments at several stages of the development process of a Codex standard (IADSA, 2000).

The work of Codex is performed through four types of committees, which composed of member countries.

- **General subject matter committees,** such as Food Hygiene, Pesticide Residues, and Methods of Analysis and Sampling;
- **Commodity committees,** such as Fish and Fishery Products, Fresh Fruits and Vegetables, and Milk and Milk Products;
- ***Ad Hoc* Intergovernmental task forces,** such as the *Ad Hoc* Intergovernmental Task Force on Biotechnology, *Ad Hoc* Intergovernmental Task Force on Fruit and Vegetable Juices and the *Ad Hoc* Intergovernmental Task Force on Animal Feeding.
- **Regional coordinating committees** for areas such as Europe, Asia, and North America and the Southwest Pacific.

- **General subject committees**
- Codex Committee on Food Hygiene - *United States*
- Codex Committee on Food Import and Export Certification and Inspection - *Australia*
- Codex Committee on Food Additives and Contaminants -*The Netherlands*
- Codex Committee on Food Labeling - *Canada*
- Codex Committee on Pesticide Residues - *The Netherlands*
- Codex Committee on Residues of Veterinary Drugs in Foods -*United States*
- Codex Committee on General Principles - *France*
- Codex Committee on Methods of Analysis and Sampling-*Hungary*
- Codex Committee on Nutrition and Foods for Special Dietary Uses--*Germany*

- **Active commodity committees**

- Codex Committee on Processed Fruits and Vegetables-U*nited States*
- Codex Committee on Milk and Milk Products-*New Zealand*
- Codex Committee on Fish and Fishery Products-*Norway*
- Codex Committee on Fresh Fruits and Vegetables-*Mexico*
- Codex Committee on Fats and Oils-*United Kingdom*
- Codex Committee on Cocoa Products and Chocolate–*Switzerland*
- Codex Committee on Sugars - *United Kingdom*
- Codex Committee on Meat and Poultry Hygiene -*New Zealand*

- **Ad Hoc Intergovernmental task forces**
- Ad Hoc Intergovernmental Task Force on Biotechnology-*Japan*
- Ad Hoc Intergovernmental Task Force on Fruits and Vegetable Juices-*Brazil*
- Ad Hoc Intergovernmental Task Force on Animal –*Denmark*

6.2. World Health Organization

The World Health Organization (WHO) is established in 1948 as a specialized agency of the United Nations (UN) that function as the directing and coordinating authority on international health work. All UN members may become members of WHO. Other countries may be admitted after the approval of the World Health Assembly.

The aims of WHO is to attain the highest possible level of health for all people by giving world-wide guidance in the field of health, setting global standards for health, co-operating with governments in strengthening national health programs, developing and transferring appropriate health technology, information and standards.

WHO proposes conventions, agreements, regulations and recommendations related to health. It also develops, establishes and promotes international standards concerning foods and biological, pharmaceutical and similar substances.

6.3. Food and Agriculture Organization

The Food and Agriculture Organization (FAO), an autonomous agency within the United Nations, can be seen as the international forum for debate on food and agriculture issues. FAO has primarily focused on the alleviation of poverty and hunger in the world.

FAO aims to Raise levels of nutrition and standards of living, Improve agricultural productivity, better the condition of rural populations and promote food security - the access of all people at all times to the food they need for an active and healthy life. FAO tries to reach these aims by directing development assistance; collecting, analyzing and disseminating information; providing policy and plan advice to governments and acting as an international forum for debate on food and agriculture issues.

6.4. World Trade Organization

The World Trade Organization (WTO) was established in 1995 as the only international organization dealing with the global rules of trade between nations. Its importance is reflected by the fact that WTO agreements are the legal ground rules for international commerce. The main function of WTO is to ensure that trade flows as smoothly, predictably and freely as possible. The WTO is a forum for trade negotiations and handles trade disputes in the WTO's dispute settlement process. It also monitors national trade policies, it gives technical assistance and training for developing countries, and it cooperates with other international organizations.

6.5. Codex Decision-Making

The Codex Alimentarius Commission (CAC) must follow an eight-step procedure in deciding a Standard or any other measure. This procedure will involve the draft text normally being reviewed twice by CAC and by member states and interested non-governmental organizations before it is finally adopted by CAC.

Codex Decision Making Procedure

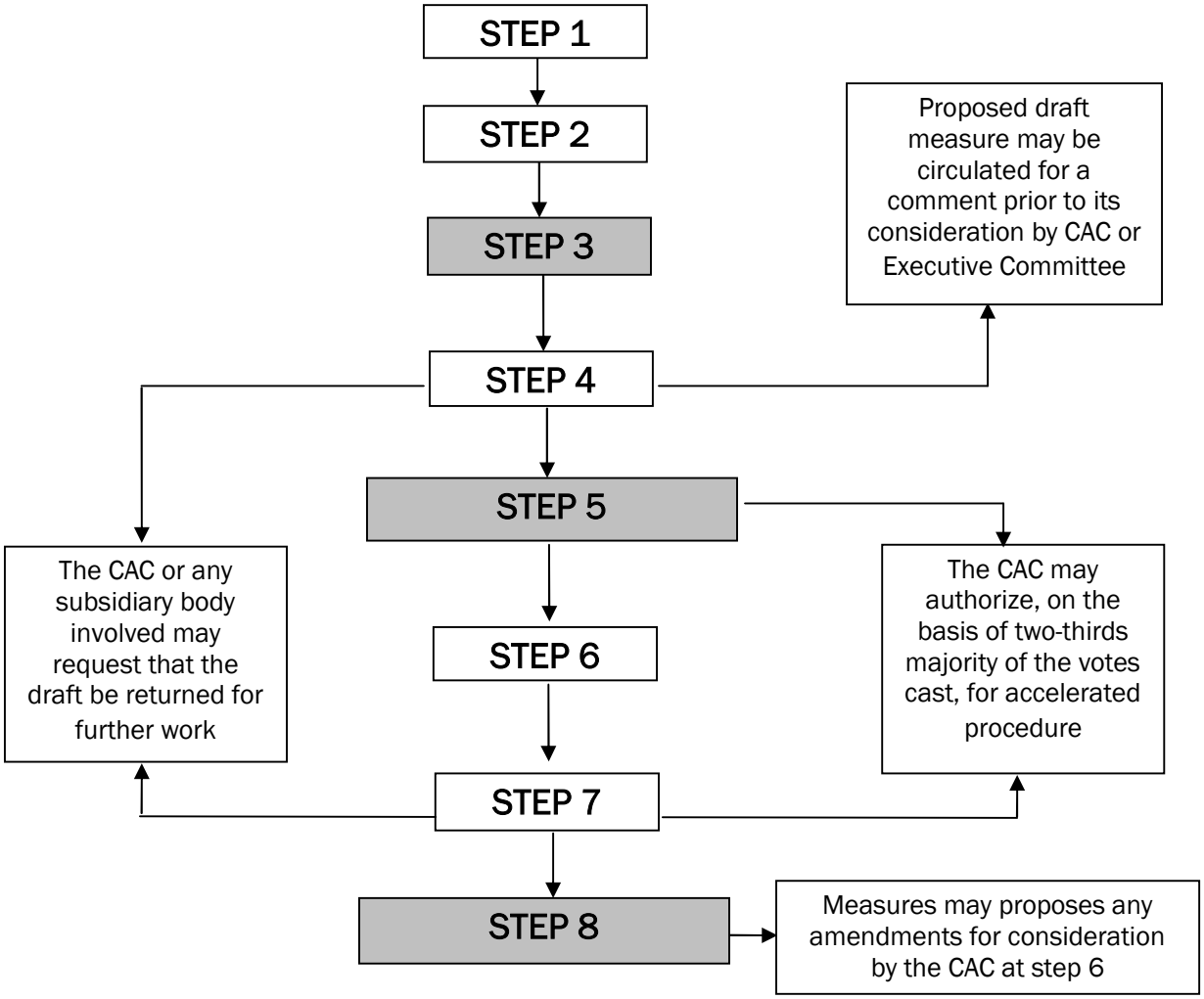


Figure 2. Codex Decision Making Procedures (IADSA, 2000)

Explanation of the procedure

Step 1
CAC agrees, on the recommendation of the members, to elaborate a Codex Standard or another measure and assigns work to the subsidiary committees.

Step 2
The Codex Secretariat arranges for the preparation of a proposed draft Standard, Guideline, Code of Practice or other Recommended Measure by one of the Codex committees. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is currently developing a draft Guideline on vitamin and mineral supplements.

Step 3
The 'proposed draft guideline' is sent to CAC members and interested non-governmental organizations for comment.

Step 4
The Secretariat gives these comments to the CCNFSDU. The committee has the power to amend the 'proposed draft guideline' and may decide to circulate it for government comment in order to advance the work.

Step 5
The 'proposed draft guideline' is sent to CAC via the Secretariat. The CAC can adopt the proposal as a 'draft guideline' with a majority of votes cast. The 'draft guideline' goes to step 6. At this stage, the CAC may authorize, on the basis of a two-thirds majority of the votes cast, the simplified procedure - direct to step 8. This procedure can be decided upon in the case of matters concerning new scientific information, new technology, urgent problems related to trade or public health or the revision or updating of existing Codex Standards.

Step 6
The 'draft guideline' is sent by the Secretariat to all CAC members and interested non-governmental organizations for comment.

Step 7
The Secretariat forwards comments received to the committee, which has the power to consider comments and to amend the 'draft guideline'.

Step 8

Prior to adoption, members may propose amendments for consideration. CAC then adopts the 'draft guideline' as a Codex Guideline. It is then sent to governments. CAC, or any subsidiary body involved, may request that the draft be returned to step 4 for further work.

The Global Decision-Making Bodies for the Food Industry are World Health Organization (WHO), World Trade Organization (WTO), CODEX Codex Alimentarius, Food and Agriculture Organization (FAO) and ASEAN ACCSQ (IADSA, 2000).

Regulatory Bodies Governing Nutrition Health Claim in Various Countries

Nutrition labels and health claims on foods have the potential to contribute to the achievement of public health objectives. Labeling provides consumers with information about the nutrition fact of a food and health claims (statements connecting a food, food component or a nutrient to a state of desired health) provide information to consumers about the nutritional and health advantages of particular foods. Health claims are also a marketing tools used by food companies.

At an international level, nutrition labeling and health claims are regulated in the Codex Alimentarius, a set of international standards, guidelines and related texts for food products developed by the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programmed, to protect consumer health and encourage fair practice in international food trade. The implementation of the Codex Alimentations is voluntary, but the World Trade Organization has recognized it as a reference in international trade and trade disputes.

The Codex Committee on Food Labeling develops guidelines on nutrition labelling and health claims. The Committee has developed three standards and guidelines relevant to nutrition labelling: the *General Standard for the Labelling of Prepackaged Foods* sets down the underlying principle that labelling should not be false, deceptive nor misleading; the *Guidelines on Nutrition Labeling* recommend that nutrition labeling be voluntary unless a nutrition claim is made; the *General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Use* recommends that all foods for special dietary uses display a nutrition label.

Many of the countries and areas already have regulations requiring some form of nutrition labeling, with development on going in several more. Typical objectives of national labeling regulations are: to provide consumers with information; to assist consumers in making healthful choices; and/or to encourage food manufacturers to develop healthful food products. There are many differences among countries on the specifics of nutrition labeling. Some countries lack any form of regulation while an increasing number of countries require mandatory nutrition labeling. Cost-benefit analyses suggest that savings in health care costs are relatively greater than the costs incurred by mandatory labeling. Table 2 shows regulatory bodies in various countries around the world.

Table 2. Regulatory Bodies Governing Nutrition Health Claims in Various Countries around the World (EU Commission and Scientifically Evaluated by the European Food Safety Authority, 2007)

Country	Regulatory Body for Nutrition Health claims	Corresponding Website
Australia/New Zealand	Food Standards Australia New Zealand	http://www.foodstandards.gov.au/.
Brazil	National Health Surveillance Agency	http://www.anvisa.gov.br/.
Canada	Health Canada	http://www.hc-sc.gc.ca/.
China	State Food and Drug Administration China	http://www.sfda.gov.cn/.
European Union[1]	European Food Safety Authority	http://www.efsa.europa.eu.
France	French Food Safety Agency	http://www.afssa.fr.
Japan	Ministry of Health, Labor and Welfare	http://www.mhlw.go.jp.
The Netherlands	Netherlands Nutrition Centre	http://www.voedingscentrum.nl.
Sweden	Swedish Nutrition Foundation	http://www.snf.ideon.se/snf/presentation/index.htm.
United Kingdom	Joint Health Claims Initiative	http://www.jhci.co.uk.
United States of America	Food and Drug Administration	http://www.cfsan.fda.gov/list.html.
Indonesia	National Agency of Drug and Food Control (NADFC)	http://www.pom.go.id/
Thailand	Food and Drug Administrative Thailand	http://www.fda.moph.go.th
Philippines	The Philippines Food and Drug Administration	http://www.bfad.gov.ph
Singapore	Agri-Food & Veterinary Authority of Singapore	http://www.ava.gov.sg/
Malaysia	National Food Safety and Nutrition Council (NFSNC)	http://fsq.moh.gov.my

As of July 1, 2007, European Union health claims will be governed by the EU Commission and scientifically evaluated by the European Food Safety Authority.

REFERENCES

The Food Standards Agency, the UK, 2008 http://www.food.gov.uk/foodindustry/ (accessed December 2008)

Hoovers inc. Top Food Industry Description. 2008. http://industries.hoovers.com/food (accessed September 9, 2009)

Martinez, SW. The U.S. Food Marketing System: Recent Developments, 1997-2006. Economic Research Report. Economic Research Service. United States Department of Agriculture (USDA) 2007; 42. http://www.ers.usda.gov/publications/err42/err42.pdf (accessed September 9, 2009)

Wijnands JHM, Bremmers HJ, van der Maulen BMJ, Poppe KJ. An economic and legal assessment of the EU food industry's competitiveness. Agribusiness 2008; 24 (4): 417 – 439 http://www.tekes.fi/eu/fin/7po/yhteistyo/bio/competitiveness_study.pdf (accessed September 9, 2009)

Department of foreign affairs and Trade (DFAT), Australian Government. about Australia, food industry. Fact sheet. 2008 http://www.dfat.gov.au/facts/food_industry.pdf (accessed September 9, 2009)

McKay, J. 2007. Food industry and economic development in the Asia Pacific. **:** Asia Pac J Clin Nutr. 2007; 16 (Suppl 1): S80-4.

Narayanan, TR. Academia–industry partnership: an impetus for strengthening teaching and research in higher education institutions; Current Science 2009; 96 (3): 343-6

Etzkowitz, H and Leydesdorff, L. The Triple Helix: University - Industry - Government Relation. http://www.easst.net/review/march1995/leydesdorff. (Accessed September 9, 09)

Department of Economic Development & Innovation Region Skåne. Skåne, a functional food success story. 2009 http://www.skane.com/invest (accessed September 9, 2009)

Etzkowitz, H. The Triple Helix of University - Industry – Government Implications for Policy and Evaluation. Working paper. Science Policy Institute, Stockholm. 2002 http://www.sister.nu (accessed September 9, 2009)

Maberly, GF, Bagrinsky, J and Parvanta, C.C. Forging partnerships among industry, government, and academic institutions for food fortification. Food and Nutrition Bulletin 1998; 2

Companies and markets. Summary of market report: Issues, trends and challenges facing the food and drink industry - forecasts to 2014. http://www.companiesandmarkets.com (accessed September 13, 2009)

Bhalkar, S. Capacity Building in the Indian Food Industry: Opportunities and Challenges Proc. Intl. Symp. Building Leadership Skills in Food and Nutrition Essential for National Development CFTRI, Mysore (India), June 23-25, 2006: page 46-48

International Alliance of Dietary/Food Supplement Association (ADSA). Dietary Supplement Policy the Guide to Global Decision – Making Bodies, March 2000, IADSA (International Alliance of Dietary/Food Supplement Association-IADSA)
Chan, P. Lecture's note Nutrition in Food Industry course. SEAMEO-TROPMED RCCN UI. 2008

CHAPTER 2

ROLE OF FOOD INDUSTRY IN PROMOTING NUTRITION AND HEALTH THROUGH CONSUMER EDUCATION AND POLICY DEVELOPMENT

By: Rina Agustina, Ingrid S. Surono and Evi Ermayani

LEARNING OBJECTIVES:

This chapter introduces definition of consumer, the role of food industry in promoting nutrition and health and consumer education. Upon completion, you should be able to explain:

Consumer, food industry and its relationship, role of food industry in promoting health and nutrition, in creating awareness and addressing issues related to malnutrition problem; role of food industry in consumer education; and partnership among academia, government and industry toward consumer education and policy development.

SUBJECT CONTENTS:

Based on nutrition intake and the needs, nutrition problems fall into two categories : insufficient food intake which usually associated with infections and nutrient deficiency, and excessive or unbalance food intake, usually related to degenerative disease or nutrient deficiencyIn developing countries, the main problem on nutrition is related to insufficient food intake which in turn causes nutrition deficiencies such as protein energy malnutrition, anemia, iodine deficiency disorders, vitamin A deficiency and other micronutrients. Moreover, excessive or unbalanced intakes of food associated with changes in lifestyle are now becoming nutritional challenges issues resulting to increasing number of degenerative diseases such as overweight and obesity. Promoting better eating habits and healthy behavior is one of the most challenging efforts to improve nutrition intake. Inappropriate dietary pattern reflecting excessive or unbalanced intakes and diet-related non-communicable diseases is a global public health important issue in both developing and developed countries. Food industry, as partner who provide process food, play important roles in promoting nutrition and health to the consumer through partnership among stakeholders i.e. government, academia and NGOs

1. CONSUMER AND FOOD INDUSTRY

Term of consumer commonly associated with human being and it has various definitions, The worldwide Oxford Dictionary define consumer as a person who purchases goods and services for personal use . CODEX STAN 1-1985 define consumer as a person or a family who purchase something in order to meet their personal needs. Nowadays, the people considered conventional term which is expanded to not only related to human such as person or families but further to institution i.e. incorporated bodies with annual turnover of € 3 million or less in the previous financial year or a member of a credit union (Howells and Twigg-Flesner, 2006). This handout use term of consumer which refer to the conventional definition.

Recently the researchers divide food consumer into various number of group. Segmentation or differentiation of food consumer are varies depend on objective of its differentiation. Verain et al (2012) reviewed the studies on consumer and classified them into 4 segmentation groups of demographic, personality characteristics, food-related lifestyle and behavior.

Table3. Segmentation and profiling variables classified by level (Verain et al, 2012)

Variables Categories	Segmentation Variables	Profiling Variables
Personal		
Need for cognition	4[b]	
Values	2,5	7,11
Lifestyle		
Balanced life	5 (stree-free lifestyle) 6 (life equilibrium)	
Mediterranean diet	6	
Food orientation	14 (necessity vs luxury/freedom) 14 (orientation to ethics of sobriety and restrain in food)	
Product-specific preferences	1 (wine preferences) 16 (attitude toward potato attributes)	1 (attitudes of wine purchasing) 11 (liking of bread types)
Organic beliefs	12 (environmental altruism scale) 13 (Organic beliefs)	2 (Organic beliefs) 13 (risk and benefits with regards to pesticides)
Environmental concern	5 (involvement in environmental issues) 8 (concern for fish welfare) 12 (ethical concern)	1 (concern about nature) 2 (attitudes and involvement towards organics) 4,6 (environmental concern) 13 (trust in organics fruits and vegetable consumption)
Health concern		1 (concern about food/health) 8 (health involvement)
Healthy lifestyle	5 (healthy consumption habits) 6 (health care)	
Technology attitudes	14 (attititudes toward novelty in food) 16 (attitudes toward the agrifood industry)	4 (concern about technology, attitudes toward genetic engineering) 8 (attitudes toward farmed fish) 10 (attitudes toward food quality and safety)
Environmental attitudes	3 (attitudes toward green products) 7 (environmental attitudes) 8 (ambivalance toward farmed fish) 12 (green purchased attitude scale) 13 (organics attitudes)	2 (attitudes and involvement with organics purchasing) 6 (attitudes towards organics food products) 11 (attitudes towards organics products)
Attitudes (eating out)		14
Societal attitudes		14 (political abd ethical sensibility, local/tradition vs cosmopolitan sensibility and traditional moral fundamentalism)
Food naturalness	6 (natural food consumption)	8 (food naturalness)
Knowledge	12 (perceived environmental knowledge)	8 (knowledge of fish farming)
Information		3 (looking at product information and reading labels) 8 (looking at environmental information)
Cooking enjoyment		14
Technological competence		14
Cultural taste		14
Active/Supportive/sociable		1

Variables Categories	Segmentation Variables	Profiling Variables
Environmental awareness		2 (awareness of environmental problem) 9 (environmental conciousness)
Willingness to pay organics		6
Behaviour		
Ecological behaviour	12 (green behaviour)	5 (Ecological behaviour)
Purchase intention	4 (purchased likelihood of oils) 12 (green purchase intention)	1 (wine purchase intention) 2 (exploratory buying behaviour tendency 3 (purchase intention) 13 (buying intention)
Fish consumption		8
Dieting behaviour		2
Organic consumption	7 (organoc buying frequency) 10 (organic product choices)	1 (organic wine consumption) 2 (frequency of organic purchase) 6 (organic food consumption) 10 (usual organic buying behaviour) 13 (consumption frequency of organic fruits and vegetables) 16 (organic potato consumption)
Cooking frequency		14
Frequency of eating out		14
Use of home meal replacements		14

Nowadays, consumer awareness on nutrition and health problems related with food industry is highly increased (Sibbel A, 2012). This is occurred due to the increasing of non communicable disease such as degenerative disease which many people associated to unhealthy diet of processing food.

2. ROLE OF FOOD INDUSTRY IN EDUCATING THE CONSUMER ON NUTRITION

Many countries are facing the multiple burden of malnutrition: (a) under nutrition brings hunger, chronic under nutrition and micronutrient deficiencies; and (b) over nutrition brings overweight/ obesity and diet-related chronic diseases. To be adequately nourished, people need: access to sufficient, safe and nutritious food; understanding of what constitutes a good diet for health; the skills and motivation to make adequate food and dietary choices.

2.1. Role of Food Industry to Increase Awareness on under Nutrition

Malnutrition remains prevalent in developing countries, particularly micronutrient deficiencies, even though energy and macronutrients deficiencies are uncommon. Both public and private sectors have a role to play in the global elimination of micronutrient deficiencies. Concerted and long-term government-sponsored education campaigns to highlight the importance of good nutrition, is needed. One of the good examples of food industry's role in combating micronutrient deficiency is the "Beijing Declaration" in China. "The Beijing Declaration" demonstrates that food companies are serious in helping to address vitamin and mineral deficiencies around the world. Leading representatives of the global food industry, civil society, government and academic experts, gathered in Beijing, China, on 22–23 October 2005, launched the Business Alliance for Food Fortification and discussed actions to reduce the devastating effects of vitamin and mineral deficiencies and improve the health of the world's poorest peoples (BAFF, 2005).

2.2. Role of Food Industry in Increasing Awareness to Reduce Obesity

Obesity rates have been increasing tremendously among both children and adults in developed and developing countries. Obesity in children is more than doubled since the late 1970s. In 2010 the number of overweight children under the age of five, is estimated to be over 42 million worldwide and around 35 million of them are living in developing countries (WHO). Many factors are affecting this epidemic problem such as poor eating behavior, poor portion control, increase consumption of ready to eat foods, and overwhelming of food advertisement. On the contrary, obesity problem in the past has not been regarded as public health threat, rather, perceived as a less priority issue of individual choice. Therefore, its serious health risks related to obesity and prevention efforts to reduce the obesity problem were not clearly appreciated.

The role of the food industry in response to the epidemic of obesity is depending on many factors. It includes the state of knowledge and awareness on the obesity burden, corporate policy and the interactive guidance from government and nutrition health's institute on best strategy to take and the best research to support (Grotz, 2006). The followings are areas of food industry can play roles in reducing the obesity problems:

1. Develop cooperates **commitment and policy**
2. The initial response of food industry to the growing of obesity is to **conduct research** on its own or to support other research conducted by other stakeholders. The marketing and academic research results will increase understanding on the cause, prevention and treatment of obesity. Continued research, food companies continue to support scientific research efforts aimed to improve ability to respond to the obesity.
3. **Support intervention program**, for example a school-based program for children in kindergarten through grade 5 that was created by teachers and students and initiated by the ILSI Foundation (Debra et al, 2011).
4. Develop new product and marketing strategies, for example the development of low fat and low calorie food product; and portion sizes of its single-serve packages; lower portion size; lower calorie beverages product; no vending machine of high-sugar soft drink to young children at school; ban television advertising of food and beverages from young children; posting of nutrition information in companies website; etc.
5. Enhance collaborations between industry and professional organization and government in developing program for management and prevention of overweight in young generation such as increasing physical activities and better food choices, etc Provide grants to relevant health care professional organizations in the efforts to help determining the best ways to combat obesity.

The WHO and FAO developed a Global Strategy on Diet, Physical Activity, and Health to address obesity and its health consequences. As ratified in 2004, the Global Strategy called on food companies to improve the nutritional quality of their products. Food companies, should ''practice responsible marketing that supports the Strategy, particularly with regard to the promotion and marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt, especially to children'' (WHO, 2004). The global strategy proposed by the World Health Organization (WHO) identifies the food industry and retailers as potential partners in promoting healthy diets. The WHO not only highlights the type of overall dietary change it sees as necessary but also refers to "functional foods" as foods aiming for specific health purposes,

including mental and physical performance. Hence, functional foods could play an important role in the risk-reduction of non-communicable diseases and by providing benefits beyond usual nutrition and in optimizing health and general well-being.

Obesity is caused by multifactor, not only associated with the intake of food and beverages, hence to reduce obesity prevalence, not only industries, partnership of others stakeholders such as consumers, academia, professional organizations and government will be essential. One example of government's role in combating obesity problem is the government of USA, in establishing rigorous standards of nutrition at school (US Department of Agriculture), bannig food marketing targeted to children (US Federal Trade Commission), and forbidding unsubstantiated health claims on food labels (US Food and Drug Administration). WHO estimated that in 2010 more than 42 million children under the age of five years are overweight or obese (WHO, 2010). WHO recommends that on the marketing of foods and non-alcoholic beverages to children considering overweight during childhood and adolescence is associated not only with an increased risk of adult obesity and NCDs, but also with a number of immediate health-related problems, such as hypertension and insulin resistance.

2.3. Role of Food Industry in Consumer Education

Understanding about nutrition education

Nutrition education may be defined as: "any set of learning experiences designed to facilitate the voluntary adoption of eating and other nutrition-related behaviours conducive to health and well being" (Contento et al, 1995).

Nutrition education promotes lifelong healthy eating habits by developing "nutrition-literate" citizens who make the right choices and can adapt in a changing world. Nutrition education helps people to select, prepare and preserve foods of high nutritional value, feed babies and young children appropriately, shop wisely, experiment with the new, and discuss their experiences with their families and others in the community (FAO, 2008).

Nutrition education is vital to ensure that a better and more diversified food supply translates into adequate diets for all groups; to integrate producers' and consumers' concerns along the food chain; to inform decision-making at every level, from individual food choices to the development of food security policies and programs (FAO, 2008).

"Knowledge of food and appropriate dietary practices is a prerequisite for improving access to and consumption of nutritionally adequate diets, which is fundamental for achieving nutritional well-being." (FAO, 2008)

What makes nutrition education effective?

As well as providing information, effective nutrition education activities and programs can:

- incorporate methods for behavior change;
- communicate in ways that motivate;

- emphasize improvement not perfection;
- speak to people in a language they understand;
- create supportive nutrition-friendly environments;
- include participation of individuals and the community;
- use different settings to reach people at different stages of life;
- advocate for nutrition-friendly public policies;
- Strengthen local knowledge and emphasize the value of local food and eating patterns. (FAO, 2008)

Challenges facing nutrition education

There are several challenges faced by industry related to education programs.

- **Lack of interest, causing limited funding from governments and donors**

  - Development of nutrition education is not considered scientific research, and is undervalued by health and nutrition professionals and policy-makers.
  - Professionals in the agriculture sector assume that "people know what to eat; they just don't have the food".
  - Health sector professionals focus on supplementation and fortification strategies, and overlook the promotion and adequate utilization of locally produced and available foods.
  - Nutrition education does not serve particular interest groups, generate money or promise quick solutions.

- **Insufficient and inappropriate communications**

  - The language used in nutrition education is often very technical, and the advice provided is sometimes perceived as impractical or too difficult to implement.
  - Insufficient use is made of the mass media for nutrition messages.
  - Developing countries lack funds to disseminate nutrition information.
  - Most nutritionists lack of experience in developing, implementing and testing communication materials.

- **Other challenges**

  - More research and hard evidence are needed to demonstrate how effective nutrition education can be.
  - The links between poor health and food intake are often overlooked (FAO, 2008)

The type of nutrition education programs can be as individual/group of education such as: health screening, individual counseling, cooking demonstration or mass health communication such as using: newsletter, poster campaigns, bulletin boards, etc

Detail information about the channel and method of nutrition education will be more elaborated in Chapter 3. Food industry may contribute to nutrition education by offering products that correspond to the current needs of consumers and by informing them of product ingredients and nutrition fact. They can give the important role in supplying the needs of good product to the population. Education is viewed as one of its social responsibilities. In the industrialized countries, food companies are already widely participating in this effort. All available communication channels are used, i.e. packaging, advertising, ad hoc information leaflets, educational materials in schools, professional associations, consumer agencies, etc. In the developing countries, nutrition education can have a beneficial influence where supplies are available but inadequately utilized. Despite communication problems that are more difficult to solve, food producers may also contribute to education in such situations, particularly through packages, information brochures and their distribution networks. The improvement of consumer education remains the responsibility of those authorities in charge of education and health problems. While private companies are inclined more and more to participate, they can only contribute to relieving the problem (Bomand G, 1986).

There are various roles of food industry in nutrition society in five (5) major aspects:

1. Legislation and regulation

Laws and regulations affect the development, positioning and promotion of products, therefore food Industry must take part for the development of policy and regulations of foods and nutrition. They can provide advice to policymakers and contribute to the development of regulatory process by providing scientific and technical expertise. In addition, food industry also has information that regulators may not have, such as product trends, the purchasing behavior of consumers, etc.

2 Education and training in nutrition

Food Industry should help consumers to choose healthy foods/ diet by broadening the selection of new products and educational efforts for consumers. They should also provide assistance to consumers in translating dietary recommendations into practices, shaping healthy and nutritious food . Food industry also should offer nutrition information materials to consumers and health professionals and explain how products can fit into dietary recommendations, and help consumers adhere to those recommendations by presenting products and combinations of them-within the context of the total healthy diet. Other role for this point are train educators and health professionals and assist in the training and development of curriculum for schools and organize symposium, seminar, discussion ,workshop and dissemination of information

3. Research on food and nutrition

Collaborate with scientific community in developing research on food and nutrition is one of contribution of food industry for scientific matters. Become a promoter to fund other scientific activities also could be done when scientific communities publish the study in peer reviewed journals anc consensus about nutrition and health—food Industry incorporate the new findings

into the products.

4 Formulation of nutritious foods

Formulation of nutritious food is part of innovation of food industry. Thus, role of industry in formulating nutritious food is important not only related with people healthiness but more to the food industry itself related with their existence and continuation of production. However, in this handout, we identify these activities as part of their role as well to the community. Below are some activities related with their role in formulating nutritious food:

- Producing nutritious, wholesome and safe foods, nutrition fact and ingredients composition of the foods
- Proper use of ingredients (e.g.: blend ingredients that provide desired sensory properties and nutrient contents)
- Preserve nutrients and maintain shelf-life of finished goods (e.g.: prevent rancidity, ensure levels of nutrients within declared shelf-life)
- Ensure bioavailability of naturally occurring and added nutrients (e.g.: minimize nutrient antagonists and inhibitors, maintain proper ratio of competing nutrients, gut health)
- Modify and improve nutritional quality of foods (e.g.: increase fiber, reduce saturated fats, reduce sodium, bioengineering)
- Increase functional components that are compatible with sensory properties of the food

5 Marketing

- Appropriate communication of nutrition messages through print, audio or visual media
- Service to consumers and customers (provide credible responses to consumers enquiries, reliable product information on labels and promotional and educational materials)
- Provision of useful information that will allow consumers to make informed decisions about dietary choices
- Prevent food and nutrition misinformation
- Good Label: include product attributes – ingredients, nutrients, health and nutrient claims (adhere to food regulations), dietary recommendations and guidelines
- Product values and benefits, Nutrition policy, Research findings, Nutrition reviews

In addition to the contribution of food industry in promoting health and education, Food Industry also could contribute to the health and well being, as well as economic growth. Food industry at the same time could influence health through alleviation and prevention of nutritional and health problems. Food industry could influence economic growth by increasing food production and productivity of agricultural crops, increasing food availability and reduce seasonality in order to control food availability and provide employment and trade.

REFERENCES

Bomand G. Role of the food industry in nutrition education.Hygie 1986; 5(4):41-6

Lugwid, David S & Nestle Marion. Can the food industry play a constructive role in the obesity epidemic? Jama. 2008; 300 (15): 1808-1811.

Contento I, Balch GI, Bronner YL, Lytle LA, Maloney SK, Olson CM, and Swadener SS. The effectiveness of nutrition education and implications for nutrition education policy, programs and research: a review of research. J Nutr Educ. 1995; 27(6): 277 - 422.

Debra L Kibbe, Jacqueline Hackett, Melissa Hurley, Allen McFarland, Kathryn Godburn Schubert, Amy Schultz, Suzanne Harris. Ten Years of TAKE 10!(®): Integrating physical activity with academic concepts in elementary school classrooms. Prev Med 2011 Jun 31;52 Suppl 1:S43-50. Epub 2011 Jan 31.

Grotz, VL. A look at food industry responses to the rising prevalence of overweight.Nutr Rev. 2006; 64(2 Pt 2):S48-52

Howells G, Twigg-Flesner C, The Yearbook of Consumer Law 2009. Ashgate Publishing, Ltd. 2011

Lang, T., Rayner, G. and Kaelin E.The Food Industry, Diet, Physical Activity and Health: A Review of Reported Commitments and Practice of 25 of the World's Largest Food Companies. 2006

Verain, MCD, Bartels J, Dagevos H, Sijtsema SJ, Onwezen MC, and Antonides G. Segments of sustainable food consumers: a literature review. International Journal of Consumer Studies 36, 123–132. 2012

Sibbel A. Public nutrition and the role of the food industry. British Food Journal. Vol. 114 No. 6,pp. 784-797. 2012

CHAPTER 3

NUTRITION COMMUNICATION FOR CONSUMERS, MARKETING AND ADVERTISEMENT

By: Ahmad Sadariskar, Rina Agustina and Susilo Dwihatmanto

LEARNING OBJECTIVES:

To complete the previous elaboration on nutrition education, this chapter elaborates in more details about basic knowledge on consumer communication to consumer, marketing and advertisement of nutrition message. Upon completion of this chapter, you should know:

- Definition of communication and consumer
- Effective nutrition communication
- Source of nutrition information
- Misinformation in nutrition communication to consumer
- Communicating nutrition evidence base to consumer
- Definition of nutrition marketing, and its opportunities and constrain
- Advertisement of nutrition message in food product and its impact in public health

SUBJECT CONTENTS:

1. WHAT IS COMMUNICATION?

Communication is the transmission of information, ideas, attitudes, or emotion from one person or group to another (or others) primarily through symbols. In most general sense, we have communication wherever one system, a source, influences another, the destination, by manipulation of alternative symbols, which can be transmitted over the channel connecting them. Communication may be defined as 'social interaction through messages. Thus, in the most general terms, communication implies a sender, a channel, a message, a receiver, a relationship between sender and receiver, an effect, a context in which communication occurs and a range of things to which 'messages' refer (Mac Quail & Windahl, 1993).

Communication implies the process of transferring information from a sender to a receiver with the use of a medium in which the communicated information is understood by both sender and receiver. Transferring NUTRITION information from a sender to a receiver can

use various means of communication channels such as nutrition labels, newspapers, magazines, advertising, word of mouth, internet (valid information), radio, TV, nutritionist/dietitians, doctors, nurses and other health professionals, food industry campaigns and government campaigns.

The Human Communication Process:

From our first cry at the birth, our survival depends on our ability to inform others or persuade them to take some action

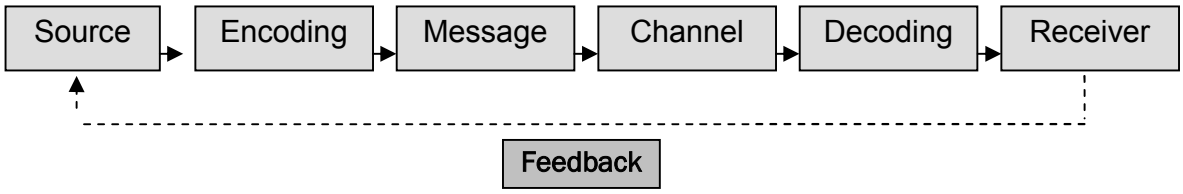


Figure 3. Communication Process (Arens, 2002)

2. WHAT IS CONSUMER?

Consumer refers to people who buy the product for their own or some one else's personal use (Arens, 2002). CODEX STAN 1-1985 define consumer as "person or families purchasing and receiving food in order to meet their personal needs"

3. SOURCES OF NUTRITION INFORMATION

The followings are nutrition information sources mentioned by Dutch consumers in decreasing order (van Dillen et al, 2003):

- **Family doctor**
  The information source that was most talked about in the viewpoint of the consumers. Family doctor is the one who diagnosed, advised, and eventually referred to another specialist, such as the dietitian. They are suitable as a nutrition information source in the following circumstances: disease in general, lowering cholesterol, eating less fat, eating less salt, diet, food allergies, and drugs.
- **Social environment**
  Another important nutrition information source was the social environment. Many consumers got nutrition information from their partner. In addition, their parents, friends, children, and other relatives acted as information sources. Social environment was especially important for the youngsters.
- **Magazines**
  Magazines were often used as an information source. Magazines mentioned were supermarket magazines for women, for parents, for consumers and culinary magazines

- Internet
  The Internet was seen as an important information source. The Internet was most popular among the youngsters.
- Dietitian
  The dietitian was considered a suitable source for topics such as diet, losing weight, and over- and underweight problems.
- Other sources of information are television, nutrition center (an independent institute that takes part in the public debate on food and nutrition; their products and services are aimed at consumers, physicians, dietitians, and teachers), food labels, media and food manufacturers

4. MISINFORMATION IN NUTRITION COMMUNICATION TO CONSUMER

Food and nutrition misinformation can be a serious problem to public health. Misinformed Consumers may have a false sense of security about their health and wellbeing and may delay appropriate, effective health care or replace it with products or behaviors that may be harmful to their health. Food and nutrition misinformation can lead to unneeded financial expenditure by consumers.

American Dietetic Association published their position statement about misinformation in nutrition communication to consumer as follows: "*It is the position of the American Dietetic Association (ADA) that food and nutrition misinformation can have harmful effects on the health, wellbeing, and economic status of consumers. Nationally credentialed dietetics professionals working in health care, academia, public health, the media, government, and the food industry are uniquely qualified to advocate for and promote science-based nutrition information to the public, function as primary nutrition educators to health professionals, and actively correct food and nutrition misinformation*." (ADA, 2006)

4.1. Type of Misinformation

- **Food fads ;** involve unreasonable or exaggerated beliefs that eating specified foods may cure disease or convey special health benefits
- **Health praud ;** promotion for financial gain
- **Misdirected claims ;** incorrect references about the health benefits of food

4.2. Sources of Misinformation and misleading

- **Media source;** the lack of sufficient context for consumers to understand the findings
- **Internet;** consumers must be informed that the accuracy of information appearing is not governed by any regulatory agency
- **Industry;** claims from the company that their product can cure a certain disease
- **Friend, family, culture***; (ADA, 2006)*

5. COMMUNICATING EVIDENCE-BASED NUTRITION TO CONSUMER

The impact of nutrition information on promoting healthful lifestyles is influenced by how effectively nutrition messages are communicated to consumers and how well consumers understand science-based advice. Nutrition information must be presented with sufficient context to provide consumers with a broader understanding of the issues and to determine whether it applies to their unique needs (ADA, 2006).

(a) The Roles of Dietetics Professionals

- Deliver current and science based nutrition information
- Clarify and demystify consumer-targeted nutrition messages
- Interpret emerging research for the media and consumers
- Encourage consumers to look to dietetics professionals as nutrition experts
- Able to accurately identify and counter food and nutrition misinformation

(b) The Roles of Allied Health Professionals

- Provide consumer-focused health education
- Train medical and health personnel
- Implement community nutrition education outreach efforts
- Seek the knowledge, skills and service of dietetic professionals
- Ensure of the consistent food and nutrition and health messages to consumers

(c) The Role of Government/Regulatory Bodies

- Regulate and disseminate food and nutrition information
- Employ dietetics professionals
- Collaborate with dietetics professionals to educate the media and the public
- Develop the public policy that related to nutrition education and misinformation

(d) The Roles of Media and Journalists

- Source of food and nutrition information that reflect sound scientific principles
- Collaborate with dietetic professionals to make sure that consumers receiving science based information about nutrition issue
- Minimize the dissemination of food and nutrition misinformation
- Provide consumer advice

(e) The Roles of Researchers

- Describe their study findings in a broader context to help readers understand the connection with studies that have the same or different outcomes
- Lay the groundwork for ensuring that their findings are presented accurately by underscoring the difference between correlation and causation and by noting the context of the results and what size dose (or serving) would be optimal for what type of effect
- Emphasize the limitations of the findings, how they relate to contrary findings, and the populations with whom they would be effective
- Communicate findings and the implications for consumers

(f) The Roles of the Food and Supplement Industry

- Provide complete and reliable food and nutrition information to the public.
- Help consumers understand emerging nutrition issues by providing accurate information
- Help shape the public's food choices, knowledge of nutrition and health, and ability to think more critically about food and nutrition issues
- Employ dietetics professionals
- Collaborate with health focus association to communicate positive, simple and consistent health messages for consumers

(g) The Roles of Consumers

- Recognize qualified dietetics professionals as credible resources to match their personal needs.
- Consider when reading nutrition information and be aware that food and nutrition information misinformation exists
- Obtain qualified source of food and nutrition information

6. RECOMMENDATIONS FOR NUTRITION COMMUNICATION

This section describes the recommendation for nutrition communication based on scientific findings from Dutch consumer. This recommendation may be also useful for Asian consumer:

- Give transparent information about food safety: make clear which food chains are involved in food production.
- The Nutrition Center could provide information to consumers, helping them cope with potential future food scares.
- Discuss weight: overweight is a social problem and should be a discussion topic among scientists and members of the general public.
- The emphasis should not be on losing weight, but on eating a balanced diet and getting enough physical activity. Family doctors and dietitians are considered to be suitable information sources.
- Disseminate a new message: healthy eating can also mean tasty eating. This is something the family doctor should take into account.
- Try the peripheral route for communication about fruit and vegetables: the central route probably does not work any longer because of information overload. The focus should be on peripheral cues: a clear statement by a reliable and expert information source, an attractive message form that is new and different, and attractive role models who show the best behavior to adopt.
- Educate youngsters about preparing and saving meals: raise awareness and increase their knowledge, attitudes, self-efficacy, and skills. School probably provides a good setting (eg, biology lessons, care lessons, techniques lessons).

- Fulfill the information needs of the elderly: provide information about new food topics. The family doctor should consider the needs of the elderly, because they frequently go to the doctor.
- Strengthen cooperation between family doctors and dietitians: both groups of health professionals should work together, because they could benefit from each other and play complementary roles.

7. NUTRITION MARKETING: OPPORTUNITIES AND CONSTRAINTS

7.1. What is Marketing?

Marketing is the process of planning and execution of the conception, pricing, distribution, and promotion ideas, goods, and services to create exchanges that satisfy the perceived needs, wants, and the objectives of individual and organizations (Bennett, 1995). Marketing is a societal process by which individuals and groups obtain what they need and want through creating, offering, and freely exchanging products and services of value with others (Kotler, 2000).

The ultimate goal of marketing process is to earn a profit for the firm by consummating the exchange of products or services with those customers who need or want them. And the role of advertisement is to inform, persuade, and remind groups or customers, or markets, about the need-satisfying value of the company's goods and services (Arens, 2002).

7.2. Nutrition Marketing

Nutrition marketing is essentially consumers oriented that need understand what consumers know, believe, value and do relating to food, diet and nutrition through formal means such as focus group, in-home observation(expensive) and surveys or informal means such as conversation and discussion among friends, co-workers, family members. Consumer is more demanding today than ever before (more educated, more looking with fortify example want bread with fiber). Food Industry needs to be closed to the consumer: wider range of product and increasing supply of media.

7.3. Nutrition Professional in Nutritional Marketing

Food industry needs nutrition professionals for product development directions. Nutrition professional can help to see what the need consumer by study habitual diets, identify nutrient gaps, use new research data, identify new nutritional and health trend, for example next year will be the trend of immunity; to address nutritional need of a population (for example fortification is different in each country; in Indonesia need fortify iodine but not in Singapore) and opportunities are development of new products to meet nutritional needs of a population.

Food industry also needs nutrition professional in positioning of products. The product should address a need, the brand as an answer to a problem (that is the brand promise). Nutrition professional involves for development of recipes to become more attractive; for advertising and promotion; for consumers queries; to develop background paper of application

of nutrition and health claims; to prepare dialogue with regulatory authorities & associations; to foresee on-coming opportunities on functional foods and ingredients and to provide early strategies to capitalize trends. Nutrition consultants are food industry partner in nutrition marketing because using nutrition science for that marketing edge. Nutrition consultants translating latest nutrition research into simple and effective messages for marketing of food products (because nutrition science is changing, dynamic science, they might not good communicator then they need marketing).

7.4. Constraint and Challenges

The communication gap between producers of functional food and the market place

Functional foods are unconventional and challenging products, the successful marketing of which requires versatile and intensive communication with different stakeholders. Diffuse and inconsistent regulation practices of authorities (e.g. the blurred distinctions of drugs, dietary supplements and foods in the USA), the confusing role of the media, and faltering public confidence in the benefits of functional foods are symptoms that there exists a communication gap between producers of functional food and key external stakeholders. Ignoring this gap may threaten the future conditions of success for the whole industry. Bridging the gap as indicated in the above figure requires a change in the overall communication strategy of the functional food industry and related science. Instead of considering health claims as the appropriate way of communicating with stakeholders, the industry should focus on the identification and maintenance of key relationships in the market place. In focusing on relationships, the interdependencies of the relationships also need to be mapped: good relationships with consumers are difficult to achieve without the help of the media, good relationships with regulators may give positive signals to the media, etc. (de Heer, 2002).

Other constraints:

- lack of funding support
- different regulatory environment in the region example different regulation in Indonesia, Malaysia and Singapore
- consumers understanding level varies
- competitiveness with many products that can be found at the supermarket. To get the product stand out should have nutritional value as a message. There are 5 factors to be considered to get product stand out :
- need to use sound science (scientific evidence)
- meet food regulations requirement to launch the product
- meet consumer needs even though there is no scientific evidence example MSG, there is no scientific evidence but consumer want to have free MSG product so food industry made it
- approved nutrition and health claims
- consumer education and understanding critical part which is how your consumer get your message

8. ADVERTISEMENT OF NUTRITION MESSAGE IN FOOD PRODUCT

8.1. Advertising Perspective

What is advertising?

Advertising is defined as any paid form of nonpersonal communication about an organization, product, service, or idea by identified sponsor (Belch & Belch, 1995). ".....advertising is the structured and composed non personal communication of information, usually paid for and usually persuasive in nature, about products (goods and services) or ideas by identified sponsors through various media" (Arens, 2002).

Advertising (the process)

"paid, mass-mediated attempt, to persuade" (O'Guinn, Allen & Semenik 2003)

What Makes Advertising Unique?

McCann-Erickson: Advertising is "truth well told". This means that ethical advertisers, and the agencies they employ, work as a team to discover and use the best methods possible to tell the story truthfully and creatively to the market-place. There are three functional divisions: Operation, Finance/Administration, and Marketing. Marketing is the only one whose primary role is to bring in revenue.

Advertising and the Marketing Process

Advertising acts to inform, persuade, and remind groups or customers, or markets, about the need-satisfying value of the company's goods and services. Advertising helps the organization achieve its marketing goals. An effective advertising specialist must have a broad understanding of the whole marketing process in order to know what type of advertising to use in a given situation.

Major institution involved in the field of advertising

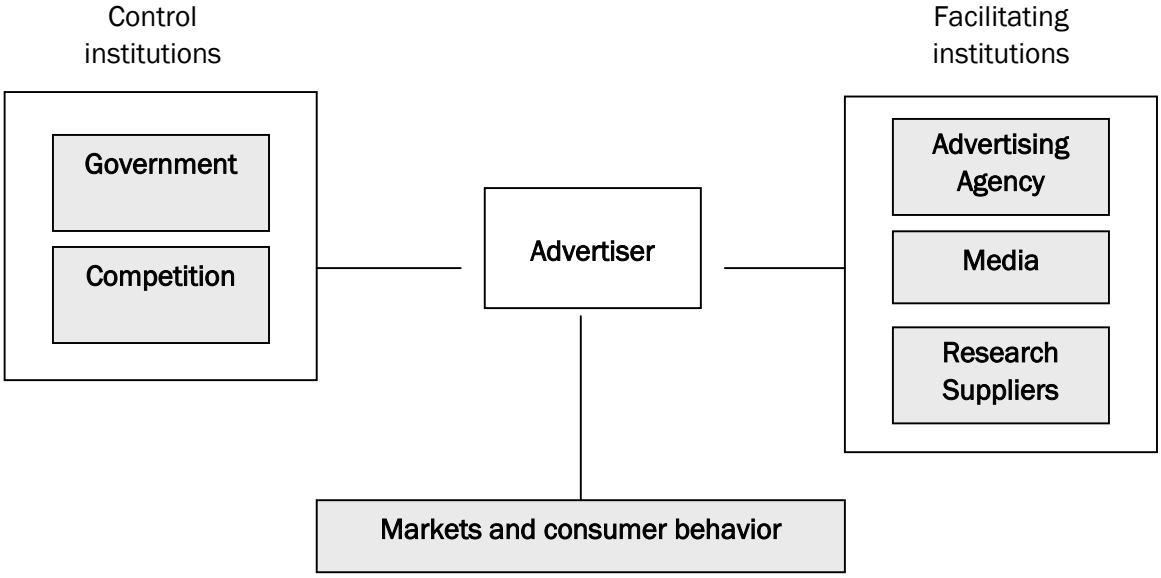


Figure 4. Major Institution Involved in the Field of Advertising Management (Myers, 1996)

In developing and managing an advertising campaign, the advertiser basically deals with numerous institutions, as figure illustrates. The advertising agency, the media, and the research suppliers are three supporting or facilitating institutions external to the advertiser's own organization. The agency and the research suppliers assist the advertiser in analyzing opportunities, creating and testing advertising ideas, and buying media time and space; the media of course, supply the means by which to advertise. Others are, in effect, control institutions that interact with and affect the advertiser's decision-making activities in numerous ways. Government and competition are two most important external control institutions. Most advertisers are affected by a wide range of government regulations concerning their products, services, and advertising. Direct or indirect competitors are usually present and serve as a major external control. What competitors do and how they react is thus important part of advertising management.

The markets or consumers the advertiser is attempting to reach through advertising can be thought of as yet another kind of external institution that both facilitates and controls advertising. The concepts of market and consumers will be used interchangeably to refer to any classification of individuals, organizations, or groups the advertiser is attempting to reach or "get a message to" (Myers, 1996).

Creative Strategy

"A good ad needs a good creative brief." A creative brief is a written statement that serves as the creative team's guide for writing and producing an ad. It describes most important issues that should be considered in development of ad (the who, why, what, where, and when), including a definition and description of the target audience, the rational and the emotional appeals to be used; the product features that will satisfy the consumer's needs; the style, approach, or tone that will be used in the copy; and generally, what the copy will say.

"A creative and effective ad should be relevant, original and has impact". If marketing communication is not relevant, it has no purpose. If it is not original, it will attract no attention. *If it does not strike with impact, it will make no lasting impression. The Initial ROI (for relevant, original, impact) are equated with the investment made by clients in marketing communication (Reinhard, 2002).*

Implementing Marketing Strategy

- Marketing Strategy is particular blend, or mix, of strategic elements: product concept, pricing, distribution, and communication.
- Advertising is just one of the marketing communication tools kit (others: personal selling, sales promotion, PR activities and etc.).
- Integrating Marketing Communication -- to achieve the consistency

Many Controversies about Advertising

As a social force, advertising has helped improve the standard of living around the world. Advertising makes us aware of availability of products, imbues products with

personality, and enables us to communicate information about our selves through the product we buy. However, advertising has also been severely criticized over the years for its lack of honesty and ethics. This has given rise to numerous consumer movements and a plethora of laws that now regulate the practice of advertising.

As one of most visible activities of business is both lauded and criticized for the role it plays in selling products and influencing the society. Advertising is deceptive; it manipulates people into buying unneeded products, it makes our society too materialistic. However, advertising offers many social benefits: (a) It encourages the development of new product and speeds their acceptance; (b) It fosters employment, gives consumers and business a wider variety of product choice, and helps keep prices down by encouraging mass production; (c) It stimulates healthy competition among companies and raises the overall standard of living.

Moreover sophisticated marketers know the best way to sell their products is to appeal to genuine consumer needs and be honest in their advertising claims. In USA Advertising is regulated by federal, state, local government, business-monitoring organizations, the media, consumer groups, and the advertising industry.

Branding

A brand is an identifying symbol, words or mark that distinguishes a product from its competitors (Websters dictionary).

"Good product + great brand will be more successful than great product + good brand."

PRODUCT	BRAND
"factory focus"	"consumer focus"
can be copied	is unique
easily outdated	long life span
commodity price	premium price
functional value	Emotional

For examples:

The world's strongest brands by brand rating in 2009 (Haigh, 2009) which are valued very high such as: Walmart is the highest brand value; Coca-Cola's enterprise value is US$104.5 billion, compared to Pepsi's US$85.4 billion, just 18% greater and Microsoft $ 152,1 billion. Google's brand value jumped from 20 to 5 ranks. Blind taste test (brand name concealed) 51% prefer Pepsi sample, 47% prefer Coke sample. Identified taste test (brand names revealed) 65% prefer Coke sample, 23% prefer Pepsi sample. Great brands deliver against the promise example Volvo=safety; conveys values example Walt Disney; know their boundaries example Toyota for medium class, Lexus for high class; create many icons example Mc Donalds with animations; forge emotional connections example Harley Davidson.

To promote the product the advertising often need endorsers. The common criteria of

endorsers are: (a) celebrity endorsers versus typical people; and (b) endorsers attributes: credibility and attractiveness. For example Jordan and Nike, in 1985 Nike sales dropped 80% of lack of advertising and then Nike developed "Just Do It" slogan and signed Jordan to endorse their shoes, with their new advertising schemes their sales double between 1987 and 1989 $1.7 billion.

Endorser should be: well-known, credible, reputable, expertise, achievement. For example: how product x can sell higher than product y which is product x use typical people rather than celebrity for product y probably because weird endorsers.

Regulation for advertisement

- USA: federal, state, local government, business-monitoring organizations, the media, consumer groups, and the advertising industry itself (e.g. FDA)
- Indonesia: Association of advertising agency (P3I), National Agency for Food and Drug Control (NADFC-BPOM), commission for Indonesian broadcasting(KPI)
- Others: Consumer organization (YLKI), but YLKI do not have authority to regulate.

8.2. Advertising Nutrition Message

An advertising nutrition messages can be delivered in many different ways:

- Straight Sell or factual message
- Demonstration
- Testimonial
- Animation
- Fantasy
- Humor
- Scientific/technical evidence
- Comparison
- Slice of life
- Personality symbol
- Dramatization
- Combination

Obesity: Impact of advertising to community?

In USA, the effects of food marketing on children's food preferences, requests, consumption, and health, found significant correlations to the increment of obesity rate. Advertising pervades children's lives, mainly through television. Today's food marketers spend an estimated $10 billion annually to reach children through ''measured'' media – television, radio, print, and Internet – with additional expenditures for promotions, video games, and text messaging. Food industry marketing adversely influences the diets of adults as well as children. On this basis, WHO and the Food and Agriculture Organization (FAO) developed a Global Strategy on Diet, Physical Activity, and Health to address obesity and its health consequences. As ratified in 2004, the Global Strategy called on food companies to improve the nutritional quality of their products. Food companies, said WHO, should ''practice responsible marketing that supports the Strategy, particularly with regard to the promotion and marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt, especially to children'' (Lewin & Nestle, 2006).

In Europe, as part of the efforts to address increasing obesity rates in the EU, member state governments as well as the Commission have begun to consider the possibility of regulating the advertising of high fat, salt, and sugar food products to children, and the marketing of these products in schools. Most recently, the Commission's Green Paper on Healthy Diets and Physical Activity questioned how these advertisements can be regulated, e.g., whether voluntary codes or self-regulation by the industry would be sufficient for limiting the advertising and marketing of "energy-dense and micronutrient-poor foods." The Green Paper raises the possibility that industry self-regulation could be the preferred method by which to address the issue of advertising foods to children, but cautions that other options must be considered in the event that industry self-regulation fails to yield satisfactory results (Mansour & Key, 2006).

CASE STUDY 1

Background

XYZ's premier product is A, a soy based beverage. The brand is well known and easily identified. The product is preferred by individuals across all age groups.

Problem

Cardiovascular disease is on the rise in the region. Scientific studies showed that soy protein may help reduce blood cholesterol, thus reducing the risk of cardiovascular disease. Health claims on soy protein and heart health have been approved in USA and UK recently. However, the awareness level of the health benefits of soy products and health is still low in this region.

In addition, other food components such as omega-3 fatty acids, plant sterols/stanols and dietary fibers have shown positive results in improving heart health. The R & Dteam of XYZ company is keen to explore the opportunity in using these ingredients.

You are the Nutritionist of the company. You need to work with your marketing team to develop a nutrition marketing program to educate consumers the health benefits of your product among working adults. One of the nutrition education programs is a PowerPoint presentation on soy and health targeting at working women aged 35 and above. Please work with the marketing team to develop a 15-minute pot presentation for your company's soy beverage.

CASE STUDY 2

Background

PCC is one of the world's largest producers and marketers of orange juice. To target at the increasingly health-conscious consumers, PCC has launched a range of "functional orange juices" which include orange juice fortified with calcium (1), dietary fiber (2) and antioxidants Vitamin C, Vitamin E and zinc (3).

Problem 1

People do not usually view orange juice as a traditional source of calcium. Local Calcium RDA is set at 700-800 mg per day. Most individuals in your country do not achieve the local RDA. Current science indicates that calcium intake may need to be around 1200 mg per day for optimal bone strength.

Problem 2

The average fiber intake is only half of the recommendation level in your country. The health authority in your country is trying hard to encourage individuals to consume more fiber rich foods such as fruit, vegetables and wholegrain. However, the consumption of antioxidant-rich fruit and vegetables has remained stagnant over the last few years.

Opportunity

Approved nutrition claims for calcium, dietary fiber and Vitamin C and E in your country.
Calcium fortified orange juice as an alternative for those who have lactose intolerance and are unable to tolerate dairy products.

A cup of dietary fiber-fortified juice will help provide an additional 1/8 of recommended dietary allowance for fiber. Orange juice fortified with extra antioxidants nutrients would help boost up the immune function of individuals.

You are the Nutritionist of the company. You are called to work with the marketing team to work on a marketing program to increase awareness and sales of the 'functional orange juices" in your country. One of the strategies identified is a PowerPoint presentation on the juices targeting at young working adults. Please work with the marketing team to develop a 15-minute pot presentation for your company's orange juices.

CASE STUDY 3

Background

LMN is a premier dairy company. LMN's premier brands include milk, cheese and yogurt. The brands are well known and easily identified in Asian countries. Milk and milk products are not very popular commodities in the local diet.

Current scientific research indicates that calcium is good for bone health. Osteoporosis is on the increase.

Problem

Local RDA is set at 700-800 mg per day. Most individuals do not achieve the local RDA. Current science indicates that calcium intake may need to be around 1200 mg per day for optimal bone strength.

Opportunity

Approved health claim for calcium and bone health
Introduce milk and milk products into the local diet

You are the Nutritionist of the company. You are called to work with the production and marketing team and roll out a program to increase milk consumption in your country.

One of the strategies identified is a 15-minute PowerPoint presentation on milk, calcium and bone health targeting at primary school children. Please work with the marketing team to develop a 15-minute pot presentation for your company's milk.

LMN is a premier dairy company. LMN's premier brands include milk, cheese and yogurt. The brands are well known and easily identified in Asian countries. Milk and milk products are not very popular commodities in the local diet.

Current scientific research indicates that calcium is good for bone health. Osteoporosis is on the increase.

Source: Lecture's note of NFI course, Pauline Chan (2008)

GROUP WORK
• Define advertising from a marketing perspective and differentiate it from other forms of marketing communication. • Explain how advertising communication process differs from basic human communication. Understand and describe the role advertising plays in marketing communication process. • Explore the impact of advertising on society.

REFERENCES

McQuail D and Windahl S. "Communication Models" for study of mass communications, second edition, Longman, London and New York, 1993

Arens WF. Contemporary Advertising (International Edition), Eight Edition, McGraw-Hill, 2002.

Codex Alimentarius. Code General Standard for the Labeling of Prepackage Food. CODEX STAN 1-1985

Sonja ME van Dillen SME, Hiddink GJ, Koelen MA, de Graaf C, and van Woerkum CMJ. Understanding nutrition communication between health professionals and consumers: development of a model for nutrition awareness based on qualitative consumer research. Am J Clin Nutr 2003; 77(Suppl): S1065–72.

American Diet Association (ADA). Position of the American Diet Association: Food and Nutrition Misinformation. Journal of the American Diet Association 2006; 106(4): 601-607

De Heer AJ. Communication Barriers in the Market for Functional Foods the Dilemma of Using Health Claims In Business To Consumer Communication. M. Ginman, E. Väliverronen (eds.): Communicating Health and New Genetics: Workshop Proceedings, 17-18th September 2001). Finnish Information Studies 20, Åbo; Tampere; Oulu, 2002, pp. 57-84.

O'Guinn, Allen & Semenik. Advertising and Integrated Brand Promotion. 2003

Lewin A, Lindstrom L, Nestle M. Food Industry Promises to Address Childhood Obesity: Preliminary Evaluation. Journal of Public Health Policy 2006; 27: 327–348.

Mansour M and Key S. Food Industry Regulatory Outlook for 2006. A Foley & Lardner LLP Information Bulletin. 2006.

www.websters-online-dictionary.org

Bennett PD. American Marketing Association definition of marketing: Dictionary of Marketing Terms, 2nd Ed, and ed. (New York: American Marketing Association, 1995 in Arens WF. Contemporary Advertising (International Edition), Eight Edition, McGraw-Hill, 2002.

Kotler, P. "Marketing Management" TheMillenium Edition, The Prentice Hall, 2000.

Belch G E. & Belch MA. Advertising and Promotion" an Integrated Marketing Communications Perspective". Sixth Edition, Irwin, 1995.

Batra, R, Myers,JG, Aaker,DA. Advertising Management, Fifth Edition, Prentice Hall International, Inc. 1996,

Reinhard, K. IMC Using Advertising & Promotion to Build Brands, Tom Duncan, International Edition, McGraw Hill Irwin, 2002

Haigh, D. Global brand values weather financial storm. Intellectual Asset Management 2009; May/June:35-45 (accessed October 31, 2009)

Chan, P. Lecture's note of Nutrition in Food Industry course.SEAMEO-TROPMED RCCN UI. 2008

CHAPTER 4

NUTRITION RESEARCH AND FOOD INDUSTRY

By: Umi Fahmida, Ingrid S. Surono and Rina Agustina

LEARNING OBJECTIVES:

This chapter describes challenges and opportunities in implementing nutrition research on food industry and roles of different stake holders, as well as sponsor position. Upon completion, you should be able to explain about:

- Significant impact of interest in nutrition research towards strategic goals
- Future trend on technology and innovation for food product development in applied research
- Challenges and opportunities for food industry in nutrition research
- Role and position of sponsors in nutrition research

SUBJECT CONTENTS:

Nowadays, a growing awareness and conciousness on the importance of nutrition and diet for long-term good health should be taken into account by the food industries. Consumers concern on food quality especially the nutritional quality become more and more. Despite the high level of product innovation within the food sector, companies suppose to provide investment made in Research and Development (R&D), marketing, advertising and sponsorship.

1. SIGNIFICANT IMPACT OF INTEREST IN NUTRITION RESEARCH TOWARDS STRATEGIC GOALS

Nutrition research is not merely universities and government institutions' concerned; established food and nutrition industries have also taken significant part in nutrition research. The research may give benefit to company not only in terms of product innovation or development but also in terms of company image, consumer satisfaction and trust and other incentives. The prime targets for funding research activities nowadays are on "nutrition-related diseases" such as cardiovascular disease (CVD), cancer, obesity, anemia, osteoporosis, and dental caries. For food industry, funding research in those areas is justified and regarded as an investment, since it fulfills strategic needs of government, which is timely, and is commercially exploitable and offers challenges and opportunities.

The food industry should put interest in nutrition research prioritization both for short- and long-term commercial reasons and to fulfill its social responsibilities towards the consumers. Research priorities should take account of strategic goals as well as the technical capability of the nutrition research community at any particular point in time.(Richard, 2000).

Opportunities for co-operation in research funding should be based on the objective of the research, the research methodology, and the appointed the prominent principal investigator. A number of areas of research into the common `nutrition-related' diseases fulfill strategic needs, are practical and timely, commercially exploitable and also offer opportunities for co-operative funding. These areas should be prime targets for research funding from both public and private sources.

Building up a network with some research institutions, such as scientists and technologists in universities, research establishments and private industry by means of mutually beneficial partnership in line with continue to listen to consumers to anticipate their future needs. Research activities may vary from development or conceptualization to clinical or human trials. Research and development division forms the scientific base and creates the proprietary technology platforms in Nutrition.

Research and Development plays a key role in ensuring the best in products and processes. Working closely with leading universities and outside partners on cutting-edge science and technology innovative science and technology needed to build nutritional and health benefits into products, strong commitment in line with strict guidelines like the CODEX specifications for infant nutrition worked out with the World Health Organization.

Researchers, analysts and academics should consider how to develop capacity in monitoring food governance, and how best to refine and build on existing methodologies for health auditing food companies; to test company statements and commitments against actual performance and practice.

2. APPLIED RESEARCH: FUTURE TREND ON TECHNOLOGY AND INNOVATION FOR PRODUCT DEVELOPMENT IN FOOD INDUSTRY

Fortification

Fortification is *the addition of nutrients –vitamins, minerals, fibers, proteins and/or amino acids-- to foods irrespective of whether or not the nutrients were originally present in the food.* When doing fortification, one should consider what kind of foods to be fortified as proper vehicle for fortification, to what level, target populations and safety as well as technical considerations.

Some examples of fortification programs are: Na Fe EDTA in fish sauce (in Vietnam) in order to reduce anemia in pregnant women, micronutrient-coated rice (in Asia), vitamin A fortified peanut butter and wheat flour fortification program in Indonesia.

Nowadays advance technology such as microencapsulation enables fortification in developing innovative products. The benefits of microencapsulation are micronutrient becomes stable and may preserve the taste; although caution must be made in the cooking process.

Nanotechnology

It is important to have the right product concept that meets consumer expectations in order to achieve a successful business and in this, the food industry is no exception. Innovative products, leading edge technology, fast changing consumer needs and preferences, are all aspects that need to be focused on to help particular industries to lead.

Another aspect of some future functional foods that consumers should be willing to consider new technology such as the application of nanotechnology. An insight into consumer understanding of benefit-risk – something they need to understand to benefit from functional foods – will also help communication about safe new technologies.

The first challenge for the food technologist, after making a food edible and enjoyable, is to protect the nutritional qualities of the food. Both classical and new processes can and will help to protect compounds lost during traditional processing: a common example is the destruction of heat sensitive compounds during thermal processing. New technologies such as nanotechnology may for example find application in order to incorporate certain unstable bioactive compounds into foods, and to optimize the efficacy of the food.

Bio-Fortification

Micronutrient and protein deficiency as well as food security remain the most important challenges for developing countries. Biofortification is selectively breeding cultivars of increased nutrient density with agro economically acceptable characteristics, for example micronutrient enhancement in major staple crops with the following criteria:

- Crop productivity must be maintained or increased
- Micronutrient enhancement levels must have a significant impact on human health
- Micronutrient traits must be relatively stable in the environment
- Micronutrient must have good bioavailability for human
- Consumer acceptance must be good

The current most popular 'mega' rice variety such as Chinese hybrid rice has an incomplete amino acid profile and contains limited amounts of essential micronutrients. Rice lines with improved Fe contents have been developed using genes that have functions in Fe absorption, translocation and accumulation in the plant, as well as improved Fe bioavailability in the human intestine (Sautter *et. al*., 2006).

The nutritional quality of staple crops (rice, cassava, wheat, maize and beans) can be improved by breeding. Studies have shown the potential to exploit the genetic variation in seed concentration of iron and other minerals without the general negative effect on yield of adding new traits. The relationship between yield and mineral concentration may be positive, particularly in mineral-deficient soil (Gregorio, 2002).

Another examples are orange-fleshed (vitamin A rich) sweet potato (in Africa), high-mineral (zinc) wheat (in Asia) and beans (in Africa).

Bio-Molecular Technique

Bio-molecular technique as transgenic approach is also ongoing for rice, maize and other crops, to tackle vitamin A deficiency (high beta carotene transgenic rice or golden rice), to tackle iron deficiency (high iron rice) and protein-energy malnutrition (high quality protein rice).

Plant biotechnology can make important contributions to nutritional improvement. For example, the genetic engineered by Professor Ingo Potrykus 'Golden Rice' contains up to 35 microgram beta-carotene per gram of rice was a milestone in the application of gene technology to deliver both increase nutritional qualities and health improvement to wide sections of the human population. Provitamin A accumulates in the grain of Golden Rice as a result of genetic transformation. Beta-carotene derived from Golden Rice was effectively converted to vitamin A in humans. Determination of vitamin A equivalency of Golden Rice beta-carotene to project the potential effect of this biofortified grain in rice-consuming populations was conducted to commonly exhibit low vitamin A status volunteers (Tang *et al.,* 2009).

Nutrigenomic

Nutrients and bioactive may produce different physiological phenotypes among individuals because of genetic variability and not only alter health, but also disease initiation, progression and severity. The study and application of gene-nutrient interactions is called nutritional genomics or nutrigenomics.

To prevent the development of disease, nutrition research is investigating how nutrition can optimize and maintain cellular, tissue, organ and whole body homeostasis. This requires understanding how nutrients act at the molecular level. This involves a multitude of nutrient-related interactions at the gene, protein and metabolic levels. As a result, nutrition research has shifted from epidemiology and physiology to molecular biology and genetics (Müller and Kersten, 2003) and nutrigenomics was born.

Nutrigenomics is applying the sciences of genomics, transcriptomics, proteomics and metabolomics to human nutrition in order to understand the relationship between nutrition

and health. Nutrigenomics is a new science and has been defined as the application of high-throughput genomic tools in nutrition research, allows the examination of how nutrients affect thousands of genes present in the human genome. Nutrigenomics involves the characterization of gene products and the physiological function and interactions of these products, and study the effect of foods and food constituent's on gene expression. It is about how our DNA is transcribed into mRNA and then to proteins and provides a basis for understanding the biological activity of food components (Rawson, 2008), and has been associated with the idea of personalized nutrition based on genotype.

However, nutrigenomics is a rapidly emerging science which still in its beginning stages for personalized dietary advice; still in its infancy and its contribution to public health over the next decade is thought to be minor (Müller and Kersten, 2003)

In nutrigenomics, nutrients are seen as signals that tell a specific cell in the body about the diet. Once the nutrient interacts with such a sensory system, it changes gene, protein expression and metabolite production in accordance with the level of nutrient it senses. As a result, different diets should elicit different patterns of gene and protein expression and metabolite production (Kaput et al., 2007).

It is hoped that by building up knowledge in this area, nutrigenomics will promote an increased understanding of how nutrition influences metabolic pathways and homeostatic control, which will then be used to prevent the development of chronic diet related diseases such as obesity and type two diabetes. Part of the approach of nutrigenomics involves finding markers of the early phase of diet related diseases; this is the phase at which intervention with nutrition can return the patient to health. The aims of nutrigenomics also includes being able to demonstrate the effect of bioactive food compounds on health and the effect of health foods on health, which should lead to the development of functional foods that will keep people healthy according to their individual needs, tailoring diet on the basis of genotype.

The scientific new understanding of nutrigenomics has led to the increase of commercial development of nutraceuticals and functional foods that can be an opportunity to modify negative health effects, of individual genetic profiles, bringing the field to the "*food/genome*" junction. The more we know about how human genetics and nutrition interacted, the more we are able to help people in making decisions about what they should eat, how much they should eat, when they should eat.

3. CONTINUUM, CHALLENGES AND OPPORTUNITIES IN NUTRITION RESEARCH

The stakeholders involved in nutrition research are government, universities (academia), and food industry; and their involvement follows the continuum of research. Early stage research is funded largely through government grants at universities or within the government laboratory system. This will be followed by the translation of scientific advances into commercial products, involving academia and food industry. Finally, government may encourage institutions pursuing research on nutrition, including food industry by facilitating

research grant. When follow up research initiative is to be done, again academia and government (through research collaboration) will be involved (IFT expert report)

There are several types of nutrition research which may involve food industries. These include:

- Laboratory work, for instance to identify diverse roles for bioactive compounds in blocking, reverse or interfere on molecular level
- Epidemiological studies as observatory or retrospective cohort studies, such as study on correlation between diet and health
- Randomized Clinical Trial (RCT). This type of study is the most ideal to prove causality which is supporting intended health claim.

Research may benefit food Industry, and vice versa. Example of case where independent research finding benefits to food industry is scientific finding that high fiber diets such as breakfast cereals, protect against chronic non communicable disease was applied in the marketing of numerous high fiber foods and benefited millions, originated through research and observations by researchers in Africa not sponsored by the industry (Van der Meer et al., 2007)

On the other hand, industry-funded research may also benefit body of knowledge and policy maker, for instance, the application of vitamin D fortification in beverages (in USA) not containing fat was initiated by a beverage industry. Also food industries do research on how consumers use food labels has assisted by FDA in communicating better the calorie and serving size information to the community.

Several incentives for food industry involved in nutrition research are also identified by Institute of Food Technologies (IFT). These include:

- Confidential lead time prior to public notification which will provide initial market advantage
- Period of market exclusivity after public notification, resulting in temporary market monopoly for the company
- Royalties paid by others to use the newly authorized claim, creating additional revenue
- Reduced research cost via incentives, via providing exclusivity, tax holiday, and government research grants to organizations pursuing nutrition and health research supporting health claim registration

4. ROLE AND POSITION OF SPONSORS IN NUTRITION RESEARCH

There are five major positions from which the issue of industry sponsorship of scientific and professional nutrition activities can be regarded: the industry, the academic, the professional and scientific society, the nutrition and related journals, and the consumer.

The consumer has the right to make an informed choice, based on scientific evidence or on responsible advertising. Nestle (2002) urges the nutrition journals to introduce measures similar to those adopted by some medical journals. Many professional and scientific societies are concerned about funding issues.

The funding agency of the study should have no role in study design, data collection, data analysis, data interpretation, or writing report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication (Lesser, 2007).

5. INTEGRITY OF NUTRITION RESEARCH: CODE OF CONDUCT AND CONFLICT OF INTEREST

The commercial success of foods depends more and more on what science says about the effects of these foods on health. Most universities now have a code of conduct on relations with industry and conflicts of interest, but when the negotiations come down to the wire, and money and jobs are at stake, then a code of conduct may not be enough to keep a researcher on the straight and narrow (Katan, 2007).

Lesser et al. (2007) revealed several reasons on the bias. Food industry companies may wish to demonstrate the superiority of products to competitors; investigators are influenced by the funding in formulating research design and/or hypotheses; industry sponsors or research may suppress unfavorable results; authors of scientific reviews may deliberately bias their searches and interpretations to the benefit of their industry funders; scientific reviews may disproportionately represent studies “arising from industry-supported scientific symposia”

Academia’s role is to do rigorous scientific investigation on nutrition and health. To minimize the corrosive effects of financial conflicts of interest, universities should perform code of conduct according to institute systems to ensure independent review of industry sponsored research, including critical oversight of hypotheses, design, data collection, data analysis, interpretation, and decisions to publish.

The challenge is to recognize and minimize the risk of being influenced by sponsors which may create potential conflicts and to keep public health interest at the forefront of professional actions and opinions. Scientists should practice science and not advertise the product.

The research area, focus, questions, aims, objectives or expected outcomes are often formulated by the funding organization, resulting in academic research being driven or guided by pragmatic for its own financial or political benefit. Therefore, totally objective, creative and innovative research is rarely funded under such a system.

To anticipate susceptibility of research to bias due to industry-funded science, the International of Life Sciences Institute (ILSI) North America Working Group on Guiding Principles has proposed conflict of interest guidelines regarding industry funding, to protect the

integrity and credibility of the scientific record, particularly with respect to health, nutrition and food safety science (ILSI North America Working Group, 2009).

6. GUIDELINES OF CONFLICT OF INTEREST (ILSI North America working group, 2009)

In establishing research relationship between private/public all parties shall:

1. conduct or sponsor research that is factual, transparent, and designed objectively, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome
2. require control of both study designs and research itself to remain with scientific investigators
3. not offer or accept remuneration geared to the outcome of a research project
4. prior to the commencement of studies, ensure that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame.
5. require, in publications and conference presentations, fully signed disclosure of all financial interests
6. not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations
7. guarantee accessibility to all data and control of statistical analysis by investigator and appropriate auditors/reviewers
8. required that academic researchers when they work in contract research organization or act as contract researcher make clear statement of their affiliation, require that such researchers publish only under the auspices of the contract research organization.

The above eight principles are intended to provide a clear statement of responsibility on all sides, as a checklist to help ensure insulation of any research project from the provision of the resources enabling the project. A strong peer review system coupled with open declarations of research sponsorship in all scientific communications is a mandatory prerequisite for this guideline to be effective.

In most developing countries, funding for basic research is limited; therefore, reliance on sponsorship by food industries may be even greater than in the developed world. Many deserving projects and programs in the developing world have been funded by United Nations Agencies, and although these have produced results that benefited developing populations, this funding has probably guided research to the extent that individual researchers could not follow their own, creative initiatives.

A possible solution is to create an independent nutrition-funding agency, foundation or trust, acting at global, regional or national scales donated by industry from their research and

not their advertising budgets without dictating or knowing which research projects are being sponsored with their money.

Such a foundation or trust should be administered by a scientific panel, and researchers should not know which industry is funding them. This set-up should remove possible bias and subjective interpretation of results. It will also stimulate creative and innovative research agendas. Creating an independent structure will require enormous trust by industry in the nutrition research community.

Bias in nutrition research could have an adverse effect on the health of everyone. Findings of nutrition research influence the formulation of governmental and professional dietary guidelines, the design of public health interventions, and regulation of food product health claims. In addition, these findings may receive widespread publicity in the popular media, directly affecting consumer behavior increased government and other independent support for nutrition research will diminish the attractiveness of industry funding to investigators and dilute any bias resulting from publication of industry-funded science.

An unbiased research agenda is mandatory for producing credible results that can be applied for the benefit of mankind.

6. BEST COMMON PRACTICE TO DESIGN HUMAN INTERVENTION STUDIES IN SOUTH EAST ASIA REGION

Best practice guidance on how to conduct intervention studies to scientifically substantiate health benefits of foods and hereby support claims made on functional foods aims to analyze and explore:

a. Published studies as included in scientific dossiers supporting claims and registered in databases;
b. Control products – lack of perfect controls, and the type required depends on the nature of tested ingredients or foods;
c. Responder selection and status, including how to deal with ‘low’, ‘normal’ and ‘high’ responders;
d. Criteria for validation of biomarkers – rationale for supporting substantiated and valid markers;
e. Design of studies and ultimately propose a guideline for best practice of conducting intervention studies.

With the adoption of the EC health claims legislation in 2007, it is envisaged that this work will provide a solid scientific basis for the approval of future claims on foods as required by the new legislation.

7. WORLD CLASS RESEARCH AND DEVELOPMENT FACILITIES AS WELL AS MAN POWER

In a global business environment to keep pace with fast development of technology and innovations, it is essential for food industry to have world class research and development (R&D) and manufacturing facilities. Qualified human resources of intellectual human resources is another aspect of capacity building and is a very important asset for a successful business, to set up R&D facilities with international standards.

The industry players also need to focus on issues of capacity building right from striving for quality products meeting global standards, setting up world-class R&D facilities, training human resources to create awareness of concepts and developing affordable products for the masses. Above all, the industry should also become socially responsible and look at the opportunities to do something useful to the customer in return. The industry has a big role to play in its own interest as development of society will help in growing its market.

Nestle, Unilever, Danone, and Kraft and some others are the leading food industry supported by word class R & D facilities. Being faster and closer to the consumer through R&D considerably may strengthen food industry leadership in food, human nutrition and Health, where the body of world knowledge grows continuously.

Qualified man power could be achieved by working closely with leading universities and outside partners on cutting-edge science and technology, besides recruitment of open-minded and passionate innovators who can bridge science, technology and business needs.

REFERENCES

Richard, C.C. Nutrition research priorities for the food industry Nutrition Bulletin 2000; 25 (2): 163-173

Sautter C, Poletti S, Zhang P, Gruissem W. Biofortification of essential nutritional compounds and trace elements in rice and cassava. Proc Nutr Soc. 2006; 65(2): 153-9

Glenn B. Gregorio. Progress in Breeding for Trace Minerals in Staple Crops. J. Nutr. 2002; 132 (Suppl): S500–2

Tang G, Qin J, Dolnikowski GG, Russell RM, Grusak MA,. Golden Rice is an effective source of vitamin A. Am J Clin Nutr. 2009; 89: 1776-83

Müller M, Kersten S. Nutrigenomics: Goals and Perspectives.. Nature Reviews Genetics 2003; 4: 315 -322

http://en.wikipedia.org/wiki/Nutrigenomics

Trayhurn P. Nutritional genomics-"Nutrigenomics". BJN 2003; 89: 1-2.

Cottrell RC. Nutrition research priorities for the food industry. Nutr Bull 2000; 25(2): 163-73

Kaput J, Perlina A, Hatipoglu B, Bartholomew A, Nikolsky Y. "Nutrigenomics: concepts and applications to pharmacogenomics and clinical medicine" Pharmacogenomics 2007; 8(4)

Van der Meer JWM, de Gier AM, van Swaaij WPM, Katan MB. Independent medical research? Neth J Med. 2007

Nestle M. Food politics: How the food industry influences nutrition and health. Berkeley: University of California Press; 2002. p. 469

Nestle M. Food company sponsorship of nutrition research and professional activities: a conflict of interest? Public Health Nutr. 2001; 4: 1015 - 1022Lesser LI, and Ebbeling, CB, Goozner, M Wypij D., Ludwig DS. Relationship between funding source and conclusion among nutrition-related scientific articles. PLoS Med 2007; 4: e5

Katan MB. Does Industry Sponsorship Undermine the Integrity of Nutrition Research? PLoS Med 2007; 4(1): e6.

ILSI North America Working Group on Guiding. Funding Food Science and Nutrition Research : Financial Conflicts and Scientific Integrity.. J. Nutr. 2009; 139 : 1051-53

Finn S. Now and again: the food and beverage industry demonstrates its commitment to a healthy America. Am J Clin Nutr 2005: 82(Suppl): S253-5

IFT Expert Report. Functional foods: opportunities and challenges. The role of research in functional food development. 2006

Short D. When science met the consumer: the role of industry. Am J Clin Nutr 2005: 82 (Suppl): S256-8

http://www.harvestplus.org/endusers.html (accessed June 20, 2008)

CHAPTER 5

FUNCTIONAL FOODS

By: Rina Agustina

LEARNING OBJECTIVES:

This chapter describes the emerging issues on functional foods. Upon completion, you should be able to explain the following issues:

- Definition of functional food
- Functional food: Market Trends
- Functional food component
- Functional food development/production
- Functional Food: Research trend
- Scientific basis of functional food
- Scientific evidence of functional food
- Assessment of functionality of food and regulation

SUBJECT CONTENTS:

Foods are traditionally recognized as providing essential nutrients for nourishing the human body (Tee, 2004) and necessary for survival (Tapsell, 2009). In addition to its primary role in providing sufficient nutrient, food can also have beneficial physiological and psychological effects beyond its widely accepted nutritional effects. Moreover, food can not only be essential to achieve optimal health, but may also play a significant role in reducing the risk of disease and promoting health benefit (Diplock et al, 1999).

There has been an increase in the prevalence of chronic, non-communicable diseases (Ashwell, 2002) both in developed and developing countries, which simultaneously increases the interest in the relationship between diet and diseases (Tee, 2004). With growing scientific knowledge of the human biological system, and of food itself, there has been greater appreciation of how food influences not just survival, but also the quality and extention of life. It is therefore, the term “functional foods” or food provide benefits “beyond basic nutrition” represent this sense, but also raises questions on terms such as “basic nutrition” and definition of food itself (Tapsell, 2009).

The idea of food providing more that just nutrition is not new, as it is inspired by Hypocrates philosophy “Let food be thy medicine and medicine be thy food”, as an underlying the development of functional foods concept of "food as medicine” (Thompson and Mourgan, 2008).

The term 'functional foods' is a relatively new food category or concept that originated in Japan in the 1980s and has become more widely used over the past decade (Patch et al, 2004). Functional foods cannot be a single, well-defined or well characterized entity. Indeed, a wide variety of food products are (or in the future will be) characterized as functional foods. These include a variety of components, nutrients and non-nutrients.

1. DEFINITION OF FUNCTIONAL FOOD

There is no universally accepted or harmonized definition of functional foods. A variety of terms have appeared world-wide such as nutraceuticals, medifoods, vitafoods, dietary supplements and fortified foods. Yet, the term Functional Foods has been widely used (Subirade, 2007) in many different regions and institutions with various working definitions as follows:

1.1. The Institute of Medicine of the National Academy of Sciences, USA (1984) defines functional food as

"any modified food or food ingredient that may provide a health benefit beyond that conferred by the traditional nutrients the food contains".

1.2. The Institute of Food Technologist (IFT) (2004) defines functional food as

"foods and food components that provide a health benefit beyond basic nutrition (for the intended population). Examples may include conventional foods; fortified, enriched or enhanced foods; and dietary supplements. Functional foods provide essential nutrients beyond quantities necessary for normal maintenance, growth, and development, and/or provide other biologically active components that impart health benefits or desirable physiological effects"

1.3. The Food Quality and Standards Services (AGNS) & Food and Agriculture Organization of the United Nations (FAO) (2007) suggested that functional foods are:

"generally considered as those foods which are intended to be consumed as part of the normal diet and that contain biologically active components which offer the potential of enhanced health or reduced risk of disease".

Examples of functional foods include foods that contain specific minerals, vitamins, fatty acids or dietary fiber, foods with added biologically active substances such as photochemical or other antioxidants and probiotics. According to this definition, natural whole foods such as fruits and vegetables represent the simplest form of a functional food. For example, broccoli, carrots, or tomatoes would be considered functional foods because they are rich in such physiologically active components as sulforaphane, beta carotene, and lycopene, respectively.

1.4. Asia-Pacific Region

In Asia, functional foods have been regarded as an integral part of the culture for many years. Scientists and regulators have only recently begun to agree that the functionality of functional foods should be found in whole foods rather than in their individual components. Because the state of a person's health may range from optimal to a state of disease, it is believed that functional foods have a major role to play in all states of health, including maintaining health, promoting health and preventing disease.

- Japan

Japan is the first national authority to establish a specific regulatory framework for functional foods, classified as 'Foods for Specific Health Use' (FOSHU). In this framework, Functional foods are defined as: ***"(a) exert a health or physiological effect; (b) have the form of ordinary foods (not pills or capsules); (c) consumed as a part of an ordinary diet"*** (ILSI, 2008). So many more current updated information related to FOSHU

- China

''The guideline of registration for functional foods'' was promulgated by the State Food and Drugs Administration (SFDA) in 2005, and the definition of a functional food was extended as the following: ***''Health (functional) food means that a food has special health functions or is able to supply vitamins or minerals. It is suitable for consumption by special groups of people and has the function of regulating human body functions but is not used for therapeutic purposes. And it will not cause any harm whether acute or sub acute or chronic***'' (Yang, 2008).

- Korea

In Korea, the term "health/functional food" (HFF) refers to "***food supplement containing nutrients or other substances (in a concentrated form) that have a nutritional or physiological effect whose purpose is to supplement the normal diet***" (FAO, 2007).

- Indonesia

In Indonesia, the definition of functional food as "Process food contains one or more functional components based on scientific assessments has certain physiological functions, beyond its function, proven to have beneficial health effect and has no negative effect" (NADFC, 2004).

According to the Report on Functional Food (FAO, 2007), the Asia-Pacific Network for Food and Nutrition (ANFN) of the FAO Regional Office for Asia and the Pacific held its regional expert consultation on functional foods and their implications in the daily diet. A report was published on the development and status of Functional foods in different Asian countries including China, India, Bangladesh, Indonesia, Nepal, Malaysia, Philippines, Thailand, Sri Lanka, and Vietnam.

1.5. The Food Standard Australia New Zealand (FSANZ)

The term 'functional foods', has not recently been defined in food legislation and is not included either the general or special-purpose categories under the FSANZ jurisdiction (Ghosh, 2009). FSANZ defines functional food as "similar in appearance to conventional foods and are intended to be consumed as part of a usual diet, but have been modified to have physiological roles beyond the provision of simple nutrients requirements".

The National Centre of Excellence in Functional Foods (NCEFF), Australia, proposes a working definition for functional foods in broader perspective to include a multiplicity of meanings and in so doing, optimizes the commercial potential for Functional Foods. Functional Foods are "foods that meet consumer needs for general health and wellbeing, and the prevention and management of compromised health conditions. Functional Foods are those promoted on a health platform and based on scientific evidence (NCEFF 2005).

1.6. European Region

In contrast to Asia, the concept of functional foods in Europe is relatively new, and at present there are no Europe-wide regulations in place. In developing health claims legislation, the European Union has adopted a working definition resulting from a European consensus published in 1999 (EC Concerted Action on Functional Food Science in Europe (FUFOSE) – a working definition of functional food is "*a food that beneficially affects one or more target functions in the body beyond adequate nutritional effects in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease."*

Functional foods when consumed must remain as foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet: they are not pills or capsules, but part of a normal diet.

A functional food can be as natural food, a food to which a component has been added, or a food from which a component has been removed by technological or biotechnological means. It can also be a food where the nature of one or more components has been modified, or a food in which the bioavailability of one or more components has been modified, or any combination of these possibilities. A functional food might be functional for all members of a population or for particular groups of the population, which might be defined, for example, by age or by genetic constitution (Diplock et al, 1999).

1.7. FDA (USA) Perspective

The Federal Food, Drug, and Cosmetic Act (FFDCA; 1) does not provide a statutory definition of functional foods; has no authority to establish a formal regulatory category for such foods. In marketing such products, manufacturers may come under one of several existing regulatory options and it will help determine their product's regulatory status is whether the product is a food or a drug). With the absence of specific regulatory categories

for functional foods, their regulation is accomplished through existing food and drug regulations (Ross, 2000).

Drug is defined "…an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease…". A product may be subject to regulation as a drug if it makes a claim that it is an article (other than food) intended to affect the structure or any function of the body. Whereas foods are defined in the FFDCA as "articles used for food or drink or components of any such article". Through case law, foods have also been defined as substances that provide taste, aroma, or nutritive value. As discussed in the preamble of a recent final rule, foods can bear structure or function claims if the claim derives from their nutritive value. However, if a claim describes a structure or function effect that is not related to nutritive value, the claim can be made only if the product meets requirements for marketing as a dietary supplement.

2. FUNCTIONAL FOOD: MARKET TRENDS

Table 4. Frequency of Purchase for Particular Functional Food Categories in Different Regions

Functional Product Purchased Regularly	Asia/ Pacific	Europe	North America	Global average
	%	%	%	%
Whole grain, high-fiber products	37	38	55	40
Iodine-enhanced cooking salt	32	30	24	32
Cholesterol-reducing oils and margarines	28	27	41	31
Fruit juices with added supplements/vitamins	32	26	32	30
Yoghurts with acidophilus cultures/probiotic	30	20	22	25
Milk with added supplement/vitamins	25	12	23	19
Bread with added supplements/vitamins	24	10	25	18
Fermented drinks containing-good bacteria	21	14	4	17
Soy milk	27	6	10	14

Source: AC Nielsen (2005)

According to the FAO (2007) the world market for functional food and beverages is highly dynamic. In developing countries, demand for functional food is growing. For instance, India ranks among the top ten nationals in buying functional foods and the market size is expecting double in the next five years. Brazil and China also have the same trend. It is likely to continue as changing population demographics and the effects of lifestyle disease create greater demand for food products.

The recent market research carried out by New Zealand Trade and Enterprise (2009) described the functional food growing in Japan. According to consumer research of data

monitor, Japan is the second largest functional food and drinks market in the world. In 2007 it was valued at US$16.4 billion dollars. They predict that the functional food and beverages in Japan will grow 5.9 percent from US$16.4 billion to US$21.8 billion over the 5 year period from 2007-2012. In 2007 there were 755 FOSHU products approved for sale, with retail sales totaling US$6.5 billion. The digestive health category is the largest category accounting for 51 percent of sales. The next largest category, accounting for 24 percent of sales was weight management, followed by teeth health (14 percent) and metabolic syndrome risk factors (10 percent). The main factors that influence the growth of the functional foods market are: a high overall income, a rapidly aging society, an increase in lifestyle-related diseases, health conscious and awareness of consumer. Food's important role in curing illness has long been recognized in Japan. Recently the increase in lifestyle-related health issues has seen a growing emphasis on wellness products with indirect health claims such as digestive health, weight control and stress management.

The AC Nielsen Functional Foods and Organics Consumer Behaviors and Attitudes Survey in 2005 shows that consumers in South Africa, Brazil, Chile and Mexico are the most convinced of the value of foods promoting health benefits. In South Africa in particular, the share of regular buyers of healthy foods ranks the highest across six out of ten of the surveyed food types. High-fiber products were the most common functional food purchased worldwide, followed by iodine-fortified salt, cholesterol-reducing margarines and fortified fruit juices (Table 1). However, there were significant geographical variations in functional food consumption patterns. The differences appeared to reflect different emphases (both from media and cultural sources) on the health benefits of particular product categories. For example, 55% of North American consumers regularly purchase high-fiber products compared with 37% in the Asia/Pacific region, but fermented probiotic beverages were five times more likely to be purchased by Asia/Pacific consumers than their North American counterparts. These variations suggest that the sales of particular functional foods may rise in the different markets as consumer education and acceptance levels increase (Thompson & Moughan, 2008).

3. FUNCTIONAL FOOD COMPONENT

A functional food component can be divided into: ***Nutrient:*** a macronutrient if it has specific physiological effects (eg, resistant starch or Omega 3 fatty acids) or an essential micronutrient if its intake is more than the daily recommendations. It can also be a food component that, even though of some non essential nutrient (eg, some oligosaccharides); ***Non nutrient*** or is even of no nutritive value (eg, live microorganisms or plant chemicals) (Roberfroid, 2000). The following are list of known bioactive component of functional food:

- Nutrient: certain protein, amino acids, PUFA (omega-3, EPA,DHA) and vitamins and minerals

- Non Nutrient: dietary fiber, prebiotics (oligosaccharide), Probiotics, Phytoestrogen, phytosterols and phytostanols and their ester polyphenol and isoflavone, sugar alcohol

and antioxidant

The '*2006 Prepared Foods R&D Trends Survey: Functional Foods*' found that antioxidants, omega-3 fatty acids, dietary fiber, organic ingredients and calcium were most commonly identified by food manufacturers as key ingredients in their functional food formulation efforts (Wade 2006). According to 'ACNielsen Label Trends', sales of products touting antioxidants grew 22% over the year to March 2005, faster than those of products making any other health-related claims. French (2007) observed that consumer acceptance of probiotics, omega-3s and plant sterol is increasing rapidly throughout Europe (Thompson and Mourgan, 2008). International Food Technology listed the example of functional food components as seen in Table 5.

3.1. Candidate of Functional Food Component

Table 5. Examples of Functional Components*

Class/Components	Source*	Potential Benefit
Carotenoids		
Beta-carotene	carrots, pumpkin, sweet potato, cantaloupe	neutralizes free radicals, which may damage cells; bolsters cellular antioxidant defenses; can be made into vitamin A in the body
Lutein, Zeaxanthin	kale, collards, spinach, corn, eggs, citrus	may contribute in maintenance of healthy vision
Lycopene	tomatoes and processed tomato products, watermelon, red/pink grapefruit	may contribute in maintenance of prostate health
Dietary (functional and total) Fiber		
Insoluble fiber	wheat bran, corn bran, fruit skins	may contribute to maintenance of a healthy digestive tract; may reduce the risk of some types of cancer
Beta glucan**	oat bran, oatmeal, oat flour, barley, rye, mushroom	may reduce risk of coronary heart disease (CHD)
Soluble fiber**	Psyllium seed husk, peas, beans, apples, citrus fruit	may reduce risk of CHD and some types of cancer
Whole grains**	cereal grains, whole wheat bread, oatmeal, brown rice	may reduce risk of CHD and some types of cancer; may contribute in maintenance of healthy blood glucose levels
Fatty Acids		
Monounsaturated fatty acids (MUFAs)**	tree nuts, olive oil, canola oil, avocado	may reduce risk of CHD
Polyunsaturated fatty acids (PUFAs)—Omega-3 fatty acids—ALA	Walnuts, flax seed	may contribute to maintenance of heart health; may contribute to maintenance of mental and visual function
PUFAs—Omega-3 fatty acids—DHA/EPA**	salmon, tuna, marine, and other fish oils	may reduce risk of CHD; may contribute in maintenance of mental and visual function
Conjugated linoleic acid (CLA)	beef and lamb; some cheese	may contribute in maintenance of desirable body composition and healthy immune function
Flavonoids		
Anthocyanins—Cyanidin, Delphinidin, Malvidin	berries, cherries, red grapes	bolsters cellular antioxidant defenses; may contribute to maintenance of brain function

Class/Components	Source*	Potential Benefit
Flavanols—Catechins, Epicatechins, Epigallocatechin, Procyanidins	tea, cocoa, chocolate, apples, grapes	may contribute in maintenance of heart health
Flavanones—Hesperetin, Naringenin	citrus foods	neutralize free radicals, which may damage cells; bolster cellular antioxidant defenses
Flavonols—Quercetin, Kaempferol, Isorhamnetin, Myricetin	onions, apples, tea, broccoli	neutralize free radicals, which may damage cells; bolster cellular antioxidant defenses
Proanthocyanidins	cranberries, cocoa, apples, strawberries, grapes, wine, peanuts, cinnamon	may contribute to maintenance of urinary tract health and heart health
Isothiocyanates		
Sulforaphane	cauliflower, broccoli, broccoli sprouts, cabbage, kale, horseradish	may enhance detoxification of undesirable compounds; bolsters cellular antioxidant defenses
Minerals		
Calcium**	Sardines, spinach, yogurt, low-fat dairy products, fortified foods and beverages	may reduce the risk of osteoporosis
Magnesium	Spinach, pumpkin seeds, whole grain breads and cereals, halibut, brazil nuts	may contribute to maintenance of normal muscle and nerve function, healthy immune function, and bone health
Potassium**	Potatoes, low-fat dairy products, whole grain breads and cereals, citrus juices, beans, bananas	may reduce the risk of high blood pressure and stroke, in combination with a low-sodium diet
Selenium	fish, red meat, grains, garlic, liver, eggs	neutralizes free radicals, which may damage cells; may contribute to healthy immune function
Phenolic Acids		
Caffeic acid, Ferulic acid	apples, pears, citrus fruits, some vegetables, coffee	may bolster cellular antioxidant defenses; may contribute to maintenance of healthy vision and heart health
Plant Stanols/Sterols		
Free Stanols/Sterols**	corn, soy, wheat, wood oils, fortified foods and beverages	may reduce risk of CHD
Stanol/Sterol esters**	fortified table spreads, stanol ester dietary supplements	may reduce risk of CHD
Polyols		
Sugar alcohols**—Xylitol, Sorbitol, Mannitol, Lactitol	some chewing gums and other food	applications may reduce risk of dental caries
Prebiotics		
Inulin, Fructo-oligosaccharides (FOS), Polydextrose	whole grains, onions, some fruits, garlic, honey, leeks, fortified foods and beverages	may improve gastrointestinal health; may improve calcium absorption
Probiotics		
Yeast, Lactobacilli, Bifidobacteria, and other specific strains of beneficial bacteria	certain yogurts and other cultured dairy and non-dairy applications	may improve gastrointestinal health and systemic immunity; benefits are strain-specific
Phytoestrogens		
Isoflavones—Daidzein, Genistein	soybeans and soy-based foods	may contribute to maintenance of bone health, healthy brain and immune function; for women, may contribute to maintenance of menopausal health
Lignans	flax, rye, some vegetables	may contribute to maintenance of heart health and healthy immune function

Class/Components	Source*	Potential Benefit
Soy Protein		
Soy Protein**	soybeans and soy-based	foods may reduce risk of CHD
Sulfides/Thiols		
Diallyl sulfide, Allyl methyl trisulfide	garlic, onions, leeks, scallions	may enhance detoxification of undesirable compounds; may contribute to maintenance of heart health and healthy immune function
Dithiolthiones	cruciferous vegetables	may enhance detoxification of undesirable compounds; may contribute to maintenance of healthy immune function
Vitamins		
A***	organ meats, milk, eggs, carrots, sweet potato, spinach	may contribute to maintenance of healthy vision, immune function, and bone health; may contribute to cell integrity
B1 (Thiamin)	lentils, peas, long-grain brown rice, brazil nuts	may contribute to maintenance of mental function; helps regulate metabolism
B2 (Riboflavin)	lean meats, eggs, green leafy vegetables	helps support cell growth; helps regulate metabolism
B3 (Niacin)	dairy products, poultry, fish, nuts, eggs	helps support cell growth; helps regulate metabolism
B5 (Pantothenic acid)	organ meats, lobster, soybeans, lentils	helps regulate metabolism and hormone synthesis
B6 (Pyridoxine)	beans, nuts, legumes, fish, meat, whole grains	may contribute to maintenance of healthy immune function; helps regulate metabolism
B9 (Folate)**	beans, legumes, citrus foods, green leafy vegetables, fortified breads and cereals	may reduce a woman's risk of having a child with a brain or spinal cord defect
B12 (Cobalamin)	eggs, meat, poultry, milk	may contribute to maintenance of mental function; helps regulate metabolism and supports blood cell formation
Biotin	liver, salmon, dairy, eggs, oysters	helps regulate metabolism and hormone synthesis
Vit C	guava, sweet red/green pepper, kiwi, citrus fruit, strawberries, orange	neutralizes free radicals, which may damage cells; may contribute to maintenance of bone health and immune function
Vit D	Sunlight, fish, fortified milk and cereals	helps regulate calcium and phosphorus; helps contribute to bone health; may contribute to healthy immune function; helps support cell growth
Vit E	sunflower seeds, almonds, hazelnuts, turnip greens	neutralizes free radicals, which may damage cells; may contribute to healthy immune function and maintenance of heart health

* Examples are not an all-inclusive list.
** FDA approved health claim established for component.
*** Preformed vitamin A is found in foods that come from animals. Provitamin A carotenoids are found in many darkly colored fruits and vegetables and are a major source of vitamin A for vegetarians.
July 2006

Source: IFT (2006)

3.2. Functional Bioactive Compounds in Traditional Foods

Unlike western society, eastern oriental society recognized functional food for ages. It is embedded with culture and eating habit. Thereby, the innovation on functional food supposes to inspire greatly the eastern society. Table 6 describes the potential benefit of Philippine's food as a candidate of functional foods.

Table 6. Summary of Philippine Traditional Foods and their Potential Functional Attributes

Foods	Functional Component	Potential Benefit
Rice (*Oryza sativa* L.)	Dietary fiber	Control of blood sugar
	Lipids	Lowering of cholesterol
	Oryzanol, tocopherols, etc., phytic acid	Antioxidants; anti cancer
	B – vitamins in the bran	Anti-beri beri
Mungbean (*Vigna radiate* L. Wilczeki)	Dietary fiber	Antidiabetic
	Polyphenols	Antioxidant
Indigenous legumens – hyacinth bean (*Dolchos lablab*)	Unknown	Adjuvant activity, sedative, lowers fever
Pigeon pea (*Cajanus cajan*)	Unknown	Anti-sickling, hepatoprotective, antidiabetic
	Protein	
Rice bean (*Vigna umbellata*)	Unknown	Antifungal, hepatoprotective
Sabawel (*Mucuna pruriens* or *M. choncinensis*)	L- DOPA	Depressant Treats Parkinson's disease
Coconut (*Cocos nucifera* L.)		
Water (liquid endosperm)	Unknown components	Prevent stone formation
Meat (solid endosperm)		
	Oil	Antimicrobial, lowering of cholesterol, triglycerides, etc.
	Protein	Reduction of hyperlipedemia
	Dietary fiber	Lowering blood glucose and cholesterol
	Polyphenols	Antioxidant
Moringa oleifera (leaves)	Niazimin and other phytochemicals	Hypotensive
	Vitamin A, B and C	Antioxidants; antitumor
Momordica charantia (fruits)	Phytochemicals	Hypoglycemic; reduces triglycerides and LDL
	Protein	Insulin – like effects
Root crops: Sweet potato (*Ipomea batatas*) Taro (*Colocasia esculenta*) Greater Yam (*Dioscorea alata*) Cassava (*Manihot esculenta*)	Dietary fiber Polyphenols	Low Glycemic index Antioxidants

Source: Tecson-Mendoza (2007)

4. FUNCTIONAL FOOD DEVELOPMENT/PRODUCTION

1. There are natural, whole foods which meet Diplock's (1999) definition of a functional food in their native state. Examples of these include fruits, which may be rich in fibre and antioxidants, and oily fish which contain high levels of omega-3 fatty acids.
2. Functional ingredients may be added to minimally-processed foods, such as the fortification of orange juice with soluble fibre, to more highly formulated food products, including margarines containing plant stanols.
3. to alter the composition of whole foods to enhance the level of beneficial components. This can be achieved through breeding techniques (selection of tomato plants which produce fruit containing higher levels of lycopene or cows that produce milk higher in a certain protein), through customizing an animal's diet (cows fed a diet high in selenium produce organo-selenium enriched milk) or through genetic engineering (Thompson and Moughan, 2008).

A food product can be made functional by using any of these 5 approaches:

1) Eliminating a component known to cause or identified as causing a deleterious effect when consumed (e.g., an allergenic gluten, lactose, peanut).
2) Increasing the concentration of a component naturally present in food to a point at which it will induce predicted effects [e.g., fortification with a micronutrient to reach a daily intake higher than the recommended daily intake but compatible with the dietary guidelines for reducing risk of disease (4)], or increasing the concentration of a non nutritive component to a level known to produce a beneficial effect.
3) Adding a component that is not normally present in most foods and is not necessarily a macronutrient or a micronutrient but for which beneficial effects have been shown (e.g., non vitamin antioxidant or prebiotic such as fructan).
4) Replacing a component, usually a macronutrient (e.g., fats), whose intake is usually excessive and thus a cause of deleterious effects, by a component for which beneficial effects have been shown [e.g., chicory inulin such as Rafticream (ORAFTI, Tienen, Belgium)].
5) Increasing bioavailability or stability of a component known to produce a functional effect or to reduce the disease-risk potential of the food (Roberfroid, 2000).

ILSI EUROPE (Howlett , 2008)

From a practical point of view, a functional food can be:

- A natural, unmodified food
- A food in which one of the components has been enhanced through special growing conditions, breeding or biotechnological means
- A food to which a component has been added to provide benefits
- A food from which a component has been removed by technological or biotechnological means so that the food provides benefits not otherwise available

- A food in which a component has been replaced by an alternative component with favorable properties
- A food in which a component has been modified by enzymatic, chemical or technological means to provide a benefit
- A food in which the bioavailability of a component has been modified, either improved or reduced
- A combination of any of the above

5. FUNCTIONAL FOOD: RESEARCH TREND

There are the evolution developments in nutrition science that leads to different phase of research trends. In 1900 to 1970, the research was called attention to the classical nutrition which emphasized to the prevention of deficiencies. In 1970 up to 1990, this trend moved to attention in optimizing nutrition which highlighted the prevention of deficiencies and chronic disease by fortification. Later in 1990 up to now, the research is shifting to functional foods and dietary supplements which directed to health promotion. Corresponding to the evolution of research trend, the food industry is growing toward the third generation of the functional food. The main focus is on: (a) enhancement of food with novel ingredient/novel product which is newly developed functional ingredient /food based on mechanically proven efficiency; and (b) research based on clinical study and pharma type of screening, effect targeted development, lead to optimalization and bioavailability (Tapsell, 2008).

6. SCIENTIFIC BASIS OF FUNCTIONAL FOOD

Major part of this section will be based on the Consensus document of scientific concept of functional food in Europe (Diplock et al, 1999).

6.1. The Aim of Functional Food Sciences

There are four aims of functional food science as follows:

- To identify beneficial ***interaction(s)*** between a functional component within a food and one or more target functions in the body and to obtain evidence for the mechanism(s) of these interactions. (Results from studies carried out *in vitro*, in cells, in culture, the use of *in vitro/ex vivo* models and animal modelsfollowed by human studies, should be included.)
- To identify and validate ***markers*** relevant to these functions and their modulation by food components (see below).
- To assess the ***safety*** of the amount of food or its component(s) needed for functionality. This will require evidence that is equally applicable to all major groups in the population, including those who are indulging in behavior that might be expected to compromise the anticipated benefits of the functional food. It might involve post-marketing monitoring, including the effects on the whole diet.

- To prove ***hypotheses*** to be tested in human intervention trials that aim to show that the relevant intake of specified food components is associated with improvement or reduction in one or more target functions, either directly, or in terms of a valid marker of an improved state of health and well-being and/or a reduced risk of a disease and to find out the mechanism of action

6.2. Target Function of Health Outcomes

The identification of key target functions:

- that play a major role in maintaining an improved state of health and well-being and/or reduction of risk of disease;
- for which appropriate markers are available and/or feasible;
- for which potential opportunities exist for modulation by candidate food components.

According to FAO report (2007), the major target functions and on the science based required for providing evidence that specific nutrients positively affect function are as follows:

- **Gastrointestinal functions** - The GI target functions which are associated with a balanced microbiota together with an optimal gut associated lymphoid tissue are relevant to the state of well-being and health and to the reduction of the risk of diseases. Probiotics (e.g. lactobacilli or bifidobacteria) and prebiotic (such as inulin and its hydrolysate oligofructose) are recent concepts in nutrition that have already and will in the future be used to support the development of functional foods targeted towards gut function.

- **Defense against reactive oxidative species** - Oxidation of DNA, proteins and lipids by reactive oxygen species (ROS) plays an important role in aging and in a wide range of non communicable diseases, including cancer and cardiovascular, inflammatory and neurodegenerative diseases, such as Alzheimer's disease and other age-related degenerative conditions. But it is becoming more and more evident that ROS also play an essential role in regulating gene expression and in participating in cell signaling. Maintaining a balance between production and destruction of ROS is thus a key element in well-being and health and it is likely to play a role in reducing the risk of disease. Different target functions in relation to the maintenance of such a balance have been identified: i) Preservation of structural and functional activity of DNA that can be evaluated by measuring DNA integrity, DNA damaged based on specific gene expressions ; ii) Preservation of structural and functional integrity of circulating lipoproteins by measuring either lipid hydro peroxides or their derivatives or oxidized low-density-lipoproteins (LDL) cholesterol in plasma; iii) Preservation of structural and functional integrity of protein. Different studies evidenced that plant-based diets, in particular those rich in vegetables and fruits, provide a great amount of antioxidant such as vitamins C and E, phytochemicals, enzymes, such as glutathione, phenolic compounds (flavonoids) and vegetable pigments, which offer protection against cellular damage (Dimitrios 2006; Kuriyama et al.2006; Seifried et al. 2007, Zhang 2007 in Subirade 2007).

- **Cardiovascular Disease (CVD)** – Cardiovascular disease remains the principle cause of death in both developed and developing countries, accounting for roughly 20% of all worldwide deaths per year. Lifestyle factors including a diet high in saturated fat, in energy and in cholesterol- have an important role in the CVD risk. Epidemiological studies examining CVD risks in different populations have observed a positive correlation between elevated levels of low density lipoprotein (LDL) cholesterol and development of CVD as well as low levels of high density lipoprotein (HDL) cholesterol and CVD. Consuming a diet rich in natural antioxidants has been associated with prevention from and/or treatment of CVD. Bioactive components of food, which are of special interest, include the Vitamins E and C, polyphenols, carotenoids mainly lycopene and β-carotene, and coenzyme Q10, featured by antioxidant properties. (Kaliora et al. 2006 & 2007; Lovegrove & Jackson, 2000 in Subirade, 2007).

- **Cancer** – Dietary factors are thought to account for about 30% of cancers in western countries and thus, diet is second only to tobacco as a potentially preventable cause of cancer. The contribution of diet to risk of cancer in developing countries is lower, around 20 %. The interactions between diet and the biological processes leading to the development of cancer are extremely complex. However, over the past decades a large body of epidemiological evidence in favor to a protective effect of biologically active food components has appeared and become generally accepted by nutritionists and regulatory bodies. Dietary antimutagen which may provide a means of slowing progression toward cancer have been identified such as certain types of dietary fibers, certain probiotics or small molecule dietary antioxidants including ascorbic acid, vitamin E, glutathione, various polyphenols, carotenoids and selenium have been suggested to be important antimutagenic agents. These last ones possibly through their ability to scavenge free radicals, and prevent their interactions with cellular DNA. Many fruits and vegetables contain compounds that will protect against mutation and cancer by several mechanisms. For example, kiwifruit has antioxidant effects and may also affect DNA repair enzymes. Dietary folate may be a key factor in maintening methylation status, while enhanced overall levels of vitamins and minerals may retard the development of genomic instability. The combination of each of these factors could provide a sustainable intervention that might usefully delay the development of cancer. Although there are a range of potentially anti mutagenic substances in fruits, vegetables and cereals available, current intake is generally below the level of effective dose to protect from dietary or endogenous potential mutagens. Functional foods development could be provided as an alternative approach.

- **Osteoporosis** – Osteoporosis is a growing concern of the aging population. Quality of life is the credo. Governments develop health campaigns related to the prevention of osteoporosis in order to reduce its impact on public health costs. One of the problems consumers and governments are faced with is that the most important period to build bone mass is the age between adolescence and 30 years, long before signs of osteoporosis become apparent. In this respect it has been hypothesized that dietary measures to maximize bone mass in early life and reduce the loss of bone mass later in life are accepted best and are therefore most promising. Once food components are discovered which may help to prevent the risks of osteoporosis it is required that solid evidence is obtained on the

efficacy of these components when taken daily. Vitamin K, phyto-estrogens and non-digestible carbohydrates, in addition to the well-established key-nutrients calcium and vitamin D suppose to be taken into account (Pérez-López, in Subirade, 2007).

The most promising targets for functional food science are the followings: Subirade (2007) explain the major target functions and on the science base required for providing evidence that specific nutrients positively affect function as follows:

1) **Gastrointestinal functions** - These functions include those that are associated with a balanced colonic microbiota, mediated by the endocrine activity of the gastrointestinal tract, dependent on the tract's immune activity, in control of nutrient (minerals in particular) bioavailability, in control of transit time and mucosal motility, and modulators of epithelial cell proliferation (7; Roberfroid, unpublished observations, 1997).

2) **Defense against reactive oxidative species** - Redox and antioxidant systems. These systems require a balanced and satisfactory intake of antioxidant (pro-) vitamins as well as non vitamin food components such as polyphenols and other natural antioxidants of plant origin. Redox activities and antioxidant protection are important for almost every cell and tissue, and their imbalance is associated with miscellaneous pathologies. Although well-founded hypotheses often exist regarding the mechanisms of action of dietary antioxidants, demonstration of their beneficial effects, except when they are consumed as components of fresh fruit and vegetables (8), remains problematic. **Metabolism of the macronutrients - This targe**t concerns metabolism of carbohydrates, amino acids, and fatty acids and, in particular, hormonal modulation of their metabolism via insulin and glucagon balance or the production of gastrointestinal peptides. The objective of this process is to reduce the risk of pathologic effects associated with insulin resistance and cardiovascular disease; doing so will require the study of interactions between nutrient intake and regulation of gene expression [eg, the direct role of glucose or some polyunsaturated fatty acids (9) or more indirect interactions such as the reduction of hepatic lipogenesis by chicory fructans (10, 11)].

3) **Development in fetal and early life** - Both the mother's and the infant's diet can influence this development; examples are the importance of folic acid in the diet of pregnant women and the role of long-chain polyunsaturated fatty acids in the early stage of brain development.

4) **Xenobiotic metabolism and its modulation by nonnutritive dietary components, such as some phytochemicals** - Such modulations may have important implications for the control of toxicity or carcinogenicity caused by chemical contaminants present in food or the environment.

5) **Mood and behavior or cognition and physical performance** - Many questions have been raised about the effect of food components on these functions, but the border between nutritional and pharmacologic effects is not always easy to draw. Moreover, methodologies for studying such effects are generally perceived as inadequate to generate the firm quantitative data required for a reliable statistical analysis. New developments are expected in this field soon, which will make it possible to address these issues.

6.3. Markers

Markers relevant to functional foods (see Fig. 5) can also be classified according to whether they:

- ***related to the exposure to the food*** **component under study**, such as a serum, faecal, urinary or tissue marker. For instance, the increased level of red-blood-cell folate is a marker of exposure to folate in food and the increased level of blood tryptophan is a marker of exposure to tryptophan in food. Markers relating to exposure to the functional food component can give some indication, but not absolute proof, depend on the bioavailability of the food component.
- ***related to the target function or biological response***, such as changes in body fluid levels of a metabolite, protein or enzyme (e.g. the reduction in levels of plasma homocysteine as a possible response to dietary folate, and the increased levels of brain serotonin as a possible response to dietary tryptophan).
- ***related to an appropriate intermediate endpoint*** of an improved state of health and well-being and/or reduction of risk of disease, such as the measurement of a biological process that relates directly to the endpoint (e.g. the extent of narrowing of the carotid artery as evidence of cardiovascular disease, or functional of the brain by magnetic resonance imaging as an intermediate endpoint marker for the amelioration of depression).

6.4. Criteria for Marker

- Markers should ***represent relatively immediate outcomes***, which can be used to assess interventions in a reasonable timescale; they could, therefore, wherever possible, replace later and more remote outcomes as have been used in some epidemiological studies.
- Markers must be rigorously ***validated and amenable to standard quality-control procedures***.
- Markers must be clearly ***linked to the phenomena involved in the biological process being studied***. It is important to prevent the pursuit of increasingly accurate and precise measurements, which have limited biological significance.
- Markers should ***undergo single-centre studies to establish their sensitivity*** (i.e. the frequency of a negative test when the process is present) and their specificity (i.e. the frequency of a positive test when the process is absent). They must also be shown to be reproducible in different centers.
- Markers must be ***measurable*** in easily accessible material, or *obtainable* using methodology that must be both ethical and minimally invasive.
- Dynamic responses might be as useful as, or more useful than, static measurements. For example, changes in markers during clearance studies and in postprandial situations and studies of enzyme function, induction and suppression should be considered.
- Appropriate static and dynamic markers might also be based on objective assessments of psychological and physical performance and subjective assessments of quality of life or other similar outcomes.

7. SCIENTIFIC EVIDENCE OF FUNCTIONAL FOOD

Table 7 shows the list of scientific based evidences of bioactive component (IFIC, 2006) with its health benefit, strength of evidence, recommended amount and its regulatory

status. Opportunity of potential functional foods is wide depending on specific outcomes. In of example is the opportunity in relation to behavior and mental development (table 8).

Table 7. Scientific Based Evidence of the Food Component

Bio Active Component	Health Benefit	Strength of Science	Recommended Amount	Regulatory Status
Plant sterol and stanol esters	Reduce total and LDL cholesterol	Very strong	1.3 g/d for sterols 1.7 g/d for stanols	Health claim
Soluble fiber	Reduce total and LDL cholesterol	Very strong	1 g/d	Health claim
Protein (specific)	Reduce total and LDL cholesterol	Very strong	25 g/d	Health claim
β-glucan	Reduce total and LDL cholesterol	Very strong	3 g/d	Health claim
Proanthocyanidins	Reduce urinary tract infections	Moderate	300 mL/d	Conventional food
n-3 fatty acids	Reduce TG,reduce heart disease cardiac deaths and fatal and nonfatal myocardial infarction	Strong to very strong	Two fatty fish meals per week; 0.5–1.8 g EPAe + DHAf	Qualified health claim for dietary supplement
n-3 fatty acids	Reduce cholesterol	Weak to moderate	Unknown	Conventional food
Organosulfur compounds	Reduce total and LDL cholesterol	Weak to moderate	600–900 mg/d (dietary supplement) or approximately 1 fresh clove/d	Conventional food and dietary supplement
Prebiotics/ fructooligo-saccharides	Blood pressure control; serum cholesterol reduction	Weak	3–10 g/d	Conventional food
Catechins	Reduce risk of certain types of cancer	Moderate	4–6 cups Green Tea/d	Conventional food
Polyphenols	Reduced risk of coronary heart disease (58)	Weak/ Moderate		
Lutein/ Zeaxanthin	Reduce risk of age-related macular degeneration (67)	Weak to moderate	6 mg/d as lutein	Conventional food, dietary supplement
Lycopene	Reduce prostate cancer risk)	Moderate	½ cup/d (30 mg or 10 servings/week)	Conventional food
CLA	Reduce breast cancer	Weak	Unknown	Conventional food
Glucosinolates, indoles	Reduce risk of certain types of cancer	Weak to moderate	>½ cup/d	Conventional food

Source: International Food Information Council Foundation (IFIC) (2006)

Table 8. Examples of Opportunities for Modulation of Target Functions Related to Behavior and Mental Performance by Candidate Food Components

Target Functions	Possible Markers	Candidate Food Components
Appetite, satiety and satiation	Direct measurement of food intake Indirect measurement of food intake Subjective ratings of appetite and hunger Satiety-related hormones, peptides and molecular Markers	Protein Fat replacers Fat substitutes Sugar substitutes Structured fats Specific fatty acids Dietary fiber and non-digestible oligosaccharides
Cognitive performance	Objective performance tests Standardized mental function tests Interactive games Multifunction tests	Glucose Low and high glycemic carbohydrates Caffeine B vitamins Choline
Mood and vitality	Quality and length of sleep Attitudes (questionnaires) Standardized mental function tests Ratings of subjective states	Alcohol Low and high glycaemic carbohydrates Carbohydrate:protein ratio Tyrosine and tryptophan
Stress (distress) management **Blood pressure**	Blood catechol amines Blood opioids Skin electrical impedance Heart rate continuous monitoring	Alcohol Sucrose

Source: Diplock, et al (1999)

The existing functional foods in traditional Asian culture are mushrooms, Tea, Harthorn fruit and its extracts and Chinese wolfberry (fructus lycii) (Tee, 2004).

In general, the example of potential functional bioactive component in Asia regions are as follows:

- Asian herbal products
- Health related fat replacers prepared from grain
- Anti aging functional food
- Asian Fish sauces
- Traditional Korean functional food
- Dates fruits
- Japanese green tea
- Japanese miso soup
- Fermented soybean product
- Tempe

8. ASSESMENT OF FUNCTIONALITY OF FOOD AND REGULATION

8.1. JAPAN – FOSHU

The Japanese scientific academy in 1980 defined a functional food as a food having a tertiary or physiologically active function. In 1991, Food for Specified Health Use was introduced. The FOSHU system is unique because it focuses on health claims for specific products. Approved products are permitted to express health claims on product labels, after companies go through an application process that typically takes about one year to complete. Applications are reviewed by local prefecture authorities and the Ministry of Health and Welfare (MHW) with scientific documentation demonstrating the medical or nutritional basis for a health claim, the basis for recommended dose of the functional ingredient, information demonstrating the safety of the ingredient, information on physical and chemical characteristics, relevant test methods, and a compositional analysis. This information is expected to be accompanied by scientific papers in the fields of medicine and/or nutrition that substantiate the health claim.

The labels of FOSHU products must include: the approved health claim; recommended daily intake of the food; nutrition information; guidance on healthy eating; a warning against excessive intake, if necessary; any other special precautions relating to intake, preparation or storage; and other information. For example, on foods containing oligosaccharides a warning is required: "excess intake causes a loosening of the bowels." On some foods, a precautionary statement must appear on labels: "This food cannot cure disease." (Office of Health Policy on Newly Developed Food in Environmental Health Bureau, Ministry of Health and Welfare, Information Regarding Permission to Use FOSHU Label, May 20, 1998, in Japanese).

As per 2011, there are 955 foods are approved as FOSHU (Figure 5), and approved health claims on FOSHU are shown in Table 9.

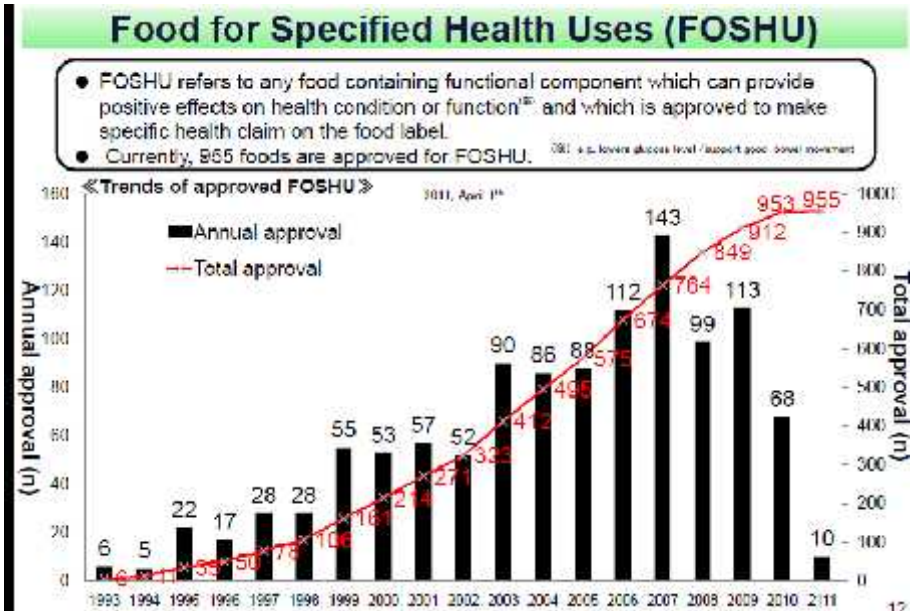


Figure 5. Food for Specified Health Uses (FOSHU)

Table 9. Approved Health Claims on FOSHU

Health uses	Food category	Ingredients (Example)	Model Claim, statements	Number approval (As of 2011/04/01)
GI Function	Table sugar	Oligisaccharides	▪ Help maintain good GI condition ▪ Help improve bowel movement	350
Cholesterol level	Powdered soft drink	Chitosan	▪ Helps lower cholesterol level	142
Triacylglycerol Body fat	Refined oil	Medium-chain fatty acids	▪ Help resist body fat gain	70
	Oolong tea	Polyphenol	▪ For those concerned about body fat	
Blood Pressure	Instant powder soup, candy	Peptides	▪ For those with high blood pressure	120
Bone	Soft drink	Soy isoflavone	▪ Promote calcium absorption ▪ Support bone health	53
Teeth	Chewing gum	Mature of Xylitol, Calcium Monohydrogen Phosphate and Fukuronori extract	▪ Helps maintain strong and healthy teeth	79
Blood glucose level	Soft drink, Instant miso soup	Indigestible dextrin	▪ For those concerned about blood glucose level	141

Source : Consumer affair agency, Food Labelling division, 2011.

Besides FOSHU, Health Food is also introduced in Japan. Dietary supplement, and other health related products are in the health food category with no health claims or function claims, while food with nutrient function claims, such as vitamin and mineral are allowed to indicate claims for nutrient function. Figure 6 shows Food category in Japan

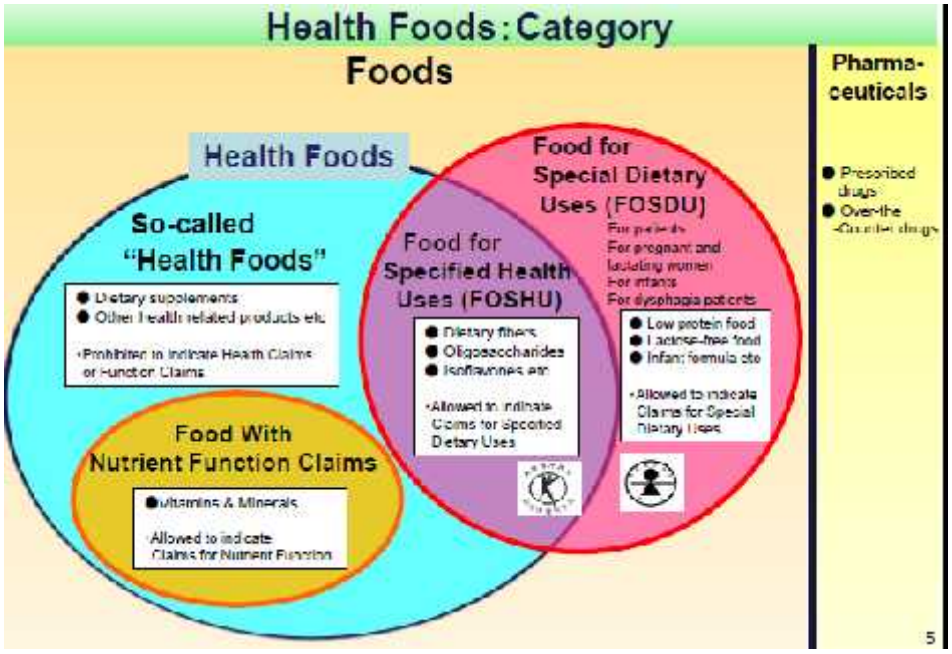


Figure 6. Health food category in Japan.
Source : Consumer affair agency, Food Labelling division, 2011.*

*Regulatory Systems of Health Claims in Japan. Consumer affair agency, Food Labelling division, 2011

Recently, Japan improve ''Food with Health Claims'' into 2 categories:

1. First category: ''Food with Nutrient Function Claims,'': the label may be freely used if a product satisfies the standard for the minimum and maximum levels per daily portion usually consumed.
2. Second category: ''Food for Specified Health Uses'' (FOSHU): FOSHU foods are those that contain dietary ingredients having beneficial effects on the physiological functions of the human body, maintain and promote health, and improve health-related conditions. Health claims on these foods correspond to the category of ''other'' function claims of the Codex Alimentarius. However, claims of disease-risk reduction are not currently allowed under FOSHU with an exception for calcium and folic acid (Yamada et al, 2008).

FOSHU (Foods for Specified Health Use)	**FNFC** (Food with Nutrient Functional Claims)	**All other Foods**	**Medical Drugs**
Require prior approval. Foods that can expect some specified health purpose and may label the claim	Approval not required but restricted to approve vitamins & minerals	Including nutritional supplements (General foods category)	Require prior approval

8.2. **EU – FUFOSE (**Functional Food Science in Europe), (ILSI, 2008).

There are two types of claims of FUFOSE:

- Type A- Enhanced Function Claims
  - Refer to specific physiological, psychological functions and biological activities beyond their established role in growth, development and other normal functions of the body
  - Similar to Structure/Function claims in US
  - Caffeine can improve cognitive performance
  - Folate can help reduce plasma homocycteine levels
- Type B Reduction of Disease Risk Claims
  - Related to consumption of a food or food component that might help reduce the risk of a specific disease or condition because of specific nutrients or non-nutrients contained within
  - Similar to Health claims in US
  - Folate can reduce a woman's risk of having a child with neural tube defects
  - Sufficient calcium intake may help to reduce the risk of osteoporosis in later life.

This section describes some example of functional assessment implemented in different countries. Instead, functional food science works from knowledge of the key processes in the attainment of optimal health or in the development of a disease to identify markers that can be used to monitor the mechanisms how those key processes are influenced by foods or food components. Provided that the role of those key processes in the attainment of optimal health or disease development is well established and the markers are chosen accurately to reflect the process, it is possible to study the effect of consuming the food on the final endpoint (the improved state of health or reduction of disease risk) by measurement of the markers. The markers could be chosen to reflect either some key biological function (markers of a target function) or a key stage in development that is unequivocally linked to the endpoint under study, in which case they serve as markers of an intermediate endpoint as shown in Figure 5 (Howlett, 2008).

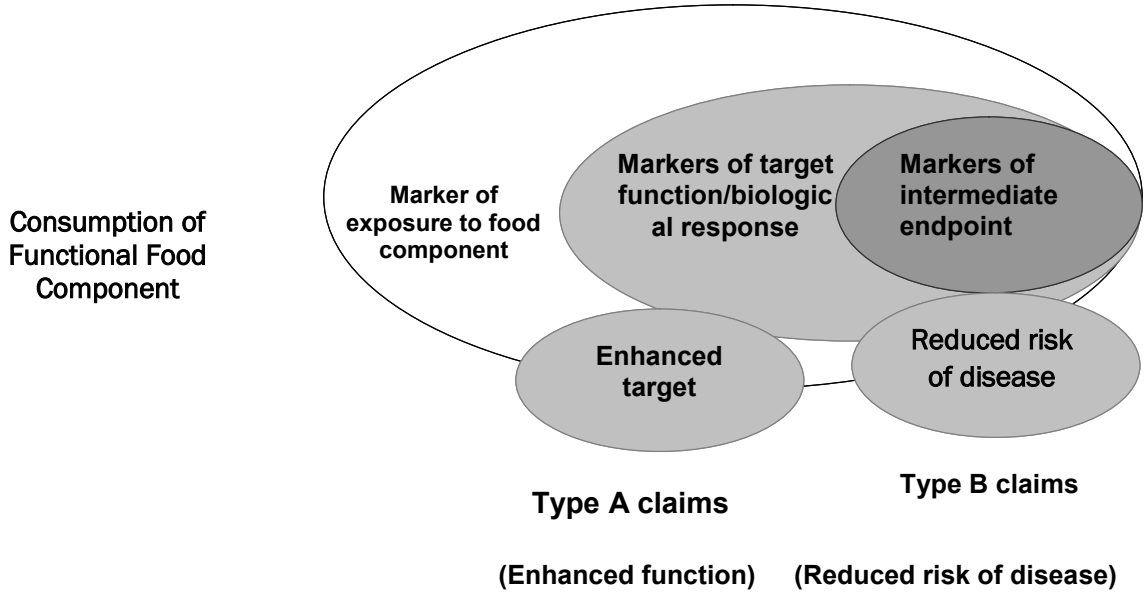


Figure 7. Functional Food Science in Europe, The Use of Markers to Link Food Consumption to Health Outcome (ILSI, 2008)

The difference between "enhanced function" and "reduction of disease risk" claims

Enhanced function claims concern specific beneficial effects of foods, nutrients, components or ingredients on physiological or psychological functions or biological activities beyond their established role in growth, development and other normal functions of the body. These claims relate to an improvement in healthy conditions and contain no explicit references to the risk of a specific disease. Examples of such claims include: "Certain non digestible oligosaccharides may improve the growth of a specific bacterial flora in the gut", "Caffeine can improve cognitive performance". "Folate can help maintain healthy plasma homocysteine levels".

Reduction of disease risk claims relate to the consumption of a food, nutrient, component or ingredient that may help reduce the risk of a specific disease or condition. Such a claim is genuinely different from the medicinal claim to prevent a disease. The most important difference is that the concept of reduction of disease risk takes into account the complexity and multi factorial basis of most diseases as well as the complexity of the diet itself.

The concept of reduction of risk of a disease may lead to the development of functional foods that, if consumed on a regular basis as part of the diet, will help reduce significantly the risk of a disease for which a relationship with dietary intakes has been documented. For instance, such foods might do this by improving/rebalancing metabolic processes or strengthening natural defense mechanisms. A nutrition-based approach is aimed at a broad group of people to produce future, long-term benefits.

8.3. China

The use of markers to link food consumption to health outcome

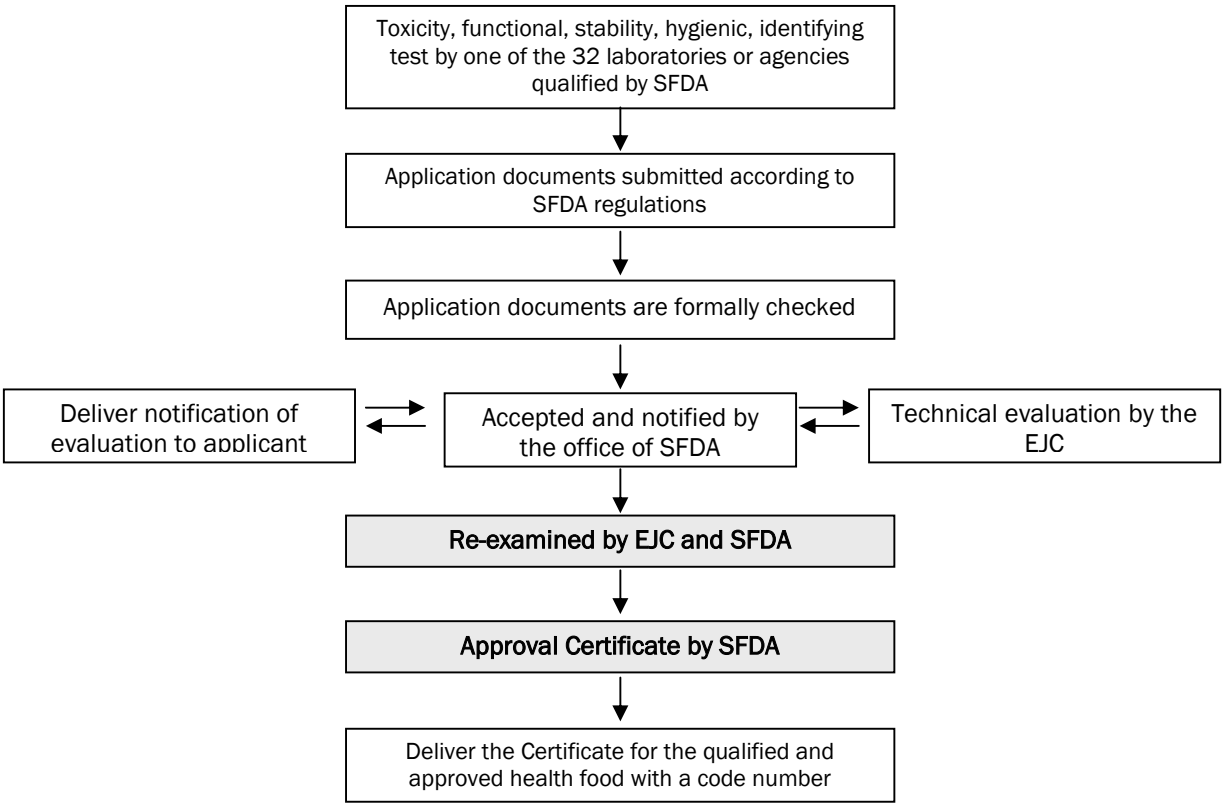


Figure 8. Examination and Approval Flow Chart for Functional Foods in China (Yang, 2008)

The SFDA has been authorized to direct and conduct all affairs relating to functional foods since 2003. For each functional food, many tests should be done before application, including security toxicity tests, functional tests (except for nutritional dietary supplements), stability tests, Hygiene tests, identifying tests for functional ingredients, etc. All the tests should be done following the standard procedures by specialized agencies or laboratories qualified by the MOH and SFDA. The approval flow chart for functional foods in China is illustrated in Figure 6.

Table 9. Main Rules for Functional Food Assessment in China

Regulation	Description of Regulation
"The standard functional assessment procedures and methods of health foods"	Describes the basic requirement for the test samples, details individual function standard procedures of assessment among 27 functions including animal and human tests; the biomarkers, determinants and judgment indicators in each method are included.
"Regulation on nutrient supplements"	Describes the definition of nutrient supplements, the amount and compounds of vitamins and minerals that can be used in nutrient supplements.
"The standard analytic methods for functional	Describes the basic requirements and components of herb, food, or extracts that must be tested if the substance is used in the product, and

Regulation	Description of Regulation
components"	the analytical methods involving 100 plant substances.

Source: Yang (2008)

8.4. Philippines

Currently, there are no specific regulations for functional foods in the Philippines. Food products that qualify as functional foods are evaluated based on scientific basis under existing regulations of the Bureau of Food and Drugs (BFAD) under the Department of Health. BFAD has also issued several guidelines on probiotics, on the formulation, labeling, technical specifications that will have to be provided for evaluation. The product information and other requirements for applications include:

- list of ingredients,
- physical, chemical and microbiology characteristics of the product
- presentation of actual sample for sensory evaluation
- presentation of sample label in which health or nutritional claims should refer to the functional ingredient or component and not to the finished product
- shelf life and methods used to determine such
- brief description of manufacturing process
- All health or nutritional claims should be supported by technical scientific reports

It was recognized that there is no consensus on the definition or usage of the term functional foods. Some countries include both dietary supplements and conventional foods in their definition of functional foods. Based on statements from BFAD the definition of functional foods that the Philippine government has recommended to be adopted is that of functional foods being conventional foods with nutrients that have potential health benefits or desirable physiological effects and that functional foods should not be confused with food supplements (Mendoza, 2007)

8.5. Indonesia

1. Criteria:
   - Bioactive compound must fulfill the requirement
   - Consume as food, have a sensory characteristic : color, texture or consistency accepted by consumer in a normal daily diet.
   - to be consumed as conventional food
2. Assessment is evaluated by Peer reviewer, a group of experts consists of nutritionist, food technologist, internist, pediatrics, pharmacologist as a functional food components reviewer responsible to review and recommend any bioactive components, physiological function, beneficial effects , serving size suggestion and possible negative effects
3. Nutrient claim, nutrition function claim and health claim , other function claims or reduction of disease risk claims

9. GENERAL PRINCIPLE OF FUNCTIONAL FOODS

(1) Safety issues:

If functional food contains novel ingredients (safety in novelty of raw materials) or is produced by a novel process, or of the potential use in the diet it becomes particularly important that safety as well as acceptability be considered. With traditional foods, safety comes from a long history of safe use by large populations over a number of generations, for example tempe (fermented soybean in Indonesia) suppose to be no doubt in safety concern due to its long history of consumption.

(2) No negative side effects at normal use:

If disease related claims (health claims) should be proven with Randomized Controlled Trial, any of side effect of the product should be proven.

(3) No disturbance of normal eating pattern

It should be consumed as part of normal diet (Roberfroid, 2002).

(4) Scientific substantiation of the claim (science based evidence).

The fundamental principle that any claim must be true and not misleading must apply to claims about health benefits. All such claims, therefore, should be scientifically valid and clear to the consumer. The key issue, however, is how this basic principle should be safeguarded without becoming a disincentive for the development and production of functional foods (an important determinant in trying to achieve the goal of improved public health) or for the acceptance of these foods by consumers (Ashwell, 2002).

The research and development on functional food can be initiated by screening for new functional food (bioactive *in vitro*), assessing the safety and efficacy in *in vivo* animal model, developing the biomarker and genotyping in human. When food is proven for its safety and efficacy, it can proceed to the production of food ingredients, food processing and

quality assessment. For example on approved ingredient by FDA, USA:

- soluble dietary fiber reduced total and LDL cholesterol: The study is very strong (meta analysis had been conducted and had consistent findings) with 1g/d (recommended amount): Health claim can be permitted
- omega-3 FA reduce trygliceride, reduce heart disease cardiac deaths and fatal and non fatal myocardiac infarction: the scientific basis show strong to very strong (many studied had been conducted and consistent finding) with 2 fatty fish meals/week (0.5-1.8 g EPA + DHA) : qualified health claim for dietary supplement.

REFERENCES

Siong Tee, E. Functional foods in Asia. Current status and issues. ILSI-SEA. 2004

Tapsell LC. Nutrients, foods and diets: challenging functional food development. Aust. J. Dairy Technol. 2009; 64: 5-7.

Diplock AT, Aggett PJ, Ashwell M, Bornet F, Fern EB and Roberfroid MB. Scientific concepts of functional foods in Europe. Consensus document. Br J Nutr. 1999; 81 (Suppl 1): S1-27

Ashwell M.Concepts of functional foods. ILSI EUROPE. 2002

Ghosh D. Functional food and health claims: regulations in Australia and New Zealand. Aust. J.Dairy Technol. 2009; 64: 152-154

National Centre of Excellence in Functional Foods. Functional Foods for the Australian Industry: Definitions and Opportunities. Wollongong, NCEFF. 2005

Subirade M. Report on functional foods. Rome: Food and Agriculture Organization; 2007

Howlett J. Functional Foods from Science to Health and Claims. ILSI EUROPE. 2008

Roberfroid MB. Global view on functional foods: European perspectives. Br J Nutr. 2002; 88 (Suppl 2): S133-8.

Sharon R. Functional foods: the food and drug administration perspective. Am J Clin Nutr. 2000; 71(Suppl): S1735-8

New Zealand Trade and Enterprise. Market Profile for Functional Foods in Japan. 2009 http://www.nzte.govt.nz/explore-export-markets/market-research-by-industry/Food-and-beverage/Pages/Functional-foods-market-in-Japan.aspx (accessed September 4, 2009)

Yang Yuexin. Scientific substantiation of functional food health claim in China. J Nutr. 2008; 138(Suppl): S1199-1205

Tecson-Mendoza, EM. Development of the Functional Foods in the Philippines. Food Sci.

Technol. Res. 2007; 13 (3): 179-186

ACNielsen. Foods with 'Healthy Supplements' and Organics Have Room for Growth. 2005, http://id.nielsen.com/news/20051128.shtml (accessed September 3 2009)

International Food Information Council Foundation (IFIC). Functional Food. http://ific.org © 2006 (accessed September 9, 2009)

Yamada K, Sano-Mino-N, Nagata J and Umegaki K. Health claim evidence requirements in Japan. J. Nutr. 2008; 138 (Suppl): S1192-98

ACNielsen Functional Foods and Organics Consumer Behavior and Attitudes survey. 2005 in Thompson AK and Moughan PJ, 2008
http://www2.acnielsen.com/reports/documents/2005_ cc_functional_organics.pdf
(accessed September 9, 2009)

CHAPTER 6

DIETARY/FOOD SUPPLEMENT

By: Rina Agustina and Purwantyastuti

LEARNING OBJECTIVES:

This chapter introduces dietary/food supplement. Upon completion of this course, you should be able to explain:

- Definition of food supplement by CODEX and other countries
- Type of ingredients of food supplement
- Maximum levels of RDA and risk assessment
- Regulation of food supplement in some countries
- Health benefit of vitamin and mineral
- Guidelines for consumers to choose appropriate dietary supplement

SUBJECT CONTENTS:

Dietary supplement is highly consumed in many parts of the world. Countries with the highest usage of dietary supplements are Thailand and Philippine (66%) followed by Lithuania (59%), Taiwan and USA (56%). People in North America and Asian countries consumed dietary supplements than in Europe and Latin America (The Nielsen 2009). The market for dietary supplement is enormous increasing to reach over $20 billion in the U.S (Kava, 2009) and £335 millions on food supplements and herbal remedies in the UK (Eberhardie, 2007). In USA, the high consumption is followed by increasing sales of this product of over $20 billion in 2005 (Dwyer et al, 2008). Many of these people around the world take supplements regularly for different reasons. They may think that they need more than just food and water to perform their best and to be in a good health. They may want to maintain good health and to ensure that they get an adequate intake of nutrients. Even though dietary supplement are not usually necessary for health, they provide convenience and practical way to obtain increased requirement of nutrient (USACHPPM, 2000). Recent survey by The Nielsen (2009) reported that the primary benefit that consumers globally expect from dietary supplement usage is a boost to immune system, to cover for a known diet deficiency and to ensure my diet is balanced. Although there is a growing scientific evidence to support the potential benefits of supplements, however some dietary supplements have no health benefit as expected, some vitamin and mineral supplements are not necessary because food can supply them and excessive and imbalance nutrition

might give harmful effect to human health (USACHPPM, 2000); yet the quality, efficacy, and safety of some dietary supplements remain questionable (Dwyer, 2008).

CODEX Guidelines for Vitamin and Mineral Food Supplements CAC/GL 55 – 2005 states that most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral food supplements serve to supplement the daily diet.

1. DEFINITION OF FOOD SUPPLEMENT BY CODEX AND OTHER COUNTRIES

Supplement containing vitamins or dietary minerals, which are recognized by the Codex Alimentarius Commission (the United Nations highest authority on food standards) as a category of ***Food Supplement.*** Food supplement category is adopted by 27 member countries of European Union Region and some countries which sign up to the European Economic Area Treaty (eg. Norway), some countries in Latin America (eg. Chile, Colombia, Mexico) and Asian Region (eg. Indonesia). The United State of America (USA) categorized the product intended to supplement the diet as ***Dietary Supplement***. This categorization is also adopted by many countries such as Argentina and Thailand. The 10 member countries of the Association of Southeast Asian Nations (ASEAN) have been using different categories either health supplements, food supplements or dietary supplement. The ASEAN agreed to use ***Health Supplements*** as the ASEAN category. Whereas in Japan, there is no specific category and definition for food supplement, because it has been partially integrated within the category of Foods for Special Health Uses (FOSHU).

1.1. CODEX Definition for Food Supplement

There is no specific definition of dietary supplement or food supplement that has been agreed at global and intergovernmental level. The Codex Guidelines CLC/GL55 (2005) defines food supplement which is specific to vitamin and mineral as follows: Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-unit quantities[1] but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet. This definition is addressing vitamin and mineral, but not yet to wide range of other ingredients (IADSA, 2006)

[1] This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements

1.2. Various other Definitions in Some Countries and Regions

Many countries and regions describe their own definition that covers similar elements as follows:

- The range of ingredient (focusing on vitamins and minerals, other nutrients and nutrient sub-components, plants and plant concentrates, or other foods and food concentrates);
- The purpose of maintaining and promoting health and supplementing normal intake from the diet;
- The form in which the supplement is delivered to the consumer (eg. capsules, tablets etc) (IADSA, 2006)

a. United States of America (USA)

In the United State of America (USA) categorized the product intended to supplement the diet as ***Dietary Supplement***. This categorization is also adopted by many countries such as Argentina and Thailand. In this country, dietary supplements may contain multiple ingredients (other than tobacco), including vitamins, minerals, herbs or other botanicals, and amino acids; dietary substances for use by humans to supplements the diet by increasing the total dietary intake; concentrates, metabolites, constituents, and extracts; or combinations of one or more of these ingredients (Yetley, 2007). This definition is regulated on the *DSHEA of 1994 United States Public Law 103-417*.

b. European Union (EU) Region

Since July 12, 2002 food supplements have been harmonized at the EU level under food law. At this stage, only the use of vitamins and minerals has been harmonized. Nevertheless, the definition of food supplements incorporates all substances with a nutritional or physiological effect, establishing their status as a specific category of foodstuffs (EAS, 2007). The European Commission defines **'Food supplements'** as foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. This definition is regulated on *Directive 2002/46/EC.*

c. Australia and New Zealand

The New Zealand Dietary Supplements Regulations was established in 1985. In this regulation, Dietary supplement means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food (SR 1985/208).

In Australia, all food supplements fall within the category of '***complementary medicines'*** by the Therapeutic Goods Administration (TGA) which are evaluated according to their level of risk, and include vitamin, mineral, herbal, aromatherapy and homeopathic products. A positive list of substances that may be used in supplements has been established (EAS, 2007).

d. ASEAN Region

The 10 member countries of the Association of Southeast Asian Nation (ASEAN) have been using different terminologies either health supplements, food supplements or dietary supplement and this terminology has been cited in the law/act in member counties. While ASEAN countries do not find it necessary to harmonize the terminology on health supplement, they agreed to use Health Supplements as the ASEAN working terminology.

The current draft definition of health supplements under development in ASEAN describes that " A Health Supplement means any product that is used to supplement a diet and maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the followings:

a. Vitamin, minerals, amino acids*, fatty acids, enzymes, probiotic and other bioactive substances*
b. Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolites
c. Synthetic sources of ingredient mentioned in (a) and (b) may only be used where the safety of these has been proven.

It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectable, eye drops).

**amino acids and other bioactive substances will be identified in the positive list"*

e. Indonesia

Regulation of Food Supplement was established in 2004 (HK.00.05.23.3644). New regulation is currently under formulation by National Agency for Drug and Food Control Indonesia. The regulation will be focused on Vitamin and Mineral Food supplement in the form of concentrate product that contain one or more vitamin and mineral, designed to be taken in small unit quantities but are not served in conventional form of food, marketed in forms of capsules, tablets, powders, solutions, etc and the purpose is to supplement the intake of vitamins and/or minerals from the normal diet (NADFC, 2008).

2. GUIDELINES AND REGULATION

CODEX guidelines for vitamin and mineral food supplements (CAC/GL 55 – 2005) emphasize many different aspects on composition, packaging and labeling to be recommended by the member countries as follows:

2.1. Composition

(a) Selection of vitamins and minerals

- Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognized by FAO and WHO.
- The sources of vitamins and minerals may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.
- Vitamin and mineral food supplements may contain all vitamins and minerals that comply with the criteria above, a single vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.

(b) Contents of Vitamins and Minerals

- The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.
- Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:
  1. upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;
  2. the daily intake of vitamins and minerals from other dietary sources.
- When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population. This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes (e.g. Population Reference Intake or Recommended Daily Allowance values).

2.2. Packaging

- The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

- The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

2.3. Labeling

- Vitamin and mineral food supplements should be labeled according to the Codex Standard for the Labeling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).
- The name of the product shall be "food supplement" with an indication of the category (ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.
- The amount of the vitamins and minerals present in the product should be declared in the labeling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labeling (CAC/GL 2-1985 Rev.1-1993).
- The amounts of the vitamins and minerals declared should be those per portion of the product as recommended for daily consumption and if different, the amount per unit for single use may also be given.
- Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labeling.
- The label should indicate how the product should be used (quantity, frequency, special conditions).
- The label shall contain advice to the consumer not to exceed the maximum one-day amount.
- The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.
- The label shall contain a statement that the product should be stored out of reach of young children.

The European Parliament established guideline in addition of vitamins and minerals and of certain other substances to foods in **Regulation (EC) no 1925/2006** and then amended by **Regulation (EC) no 108/2008.**

3. TYPES OF INGREDIENTS

There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to vitamins and minerals, amino acids and derivates, essential fatty acids, fiber and various plants and herbal extracts, enzymes, Pre- and

Probiotics, botanicals and botanical extracts (consumable), and other bioactive substances existed in food.

The European Advisory Services carried out research for European Commission identified six categories and chose 31 from 400 substances other than vitamins and minerals in order to review other substances with a nutritional or physiological effect in food supplements on the EU market (Table 11). The different categories are: *amino acids, enzymes, pre- and probiotics, essential fatty acids, botanicals and botanical extracts and miscellaneous bioactive substances.*

Table 11. Six Categories and 31 Substances of other Substances in the EU Market

Categories	Other Substances
Amino acids	- L-arginine - Other essential amino acids - Non-essential amino acids
Enzymes	- Lactase - Papaine
Pre- and Probiotics	- Inulin - *Lactobacillus acidophilus* - *Bifidobacterium* species - Yeast species
Essential fatty acids	- Gamma-linoleic acid - EPA/DHA - Evening Primrose oil (Oenothera biennis (L.)) - Borage oil (Borago officinalis) - Flax seed oil (Linum usitatissimum (L.))
Botanicals & botanical extracts	- Aloe (*Aloe vera* (L.)) - Ginkgo (*Ginkgo biloba*) - Ginseng (*Panax ginseng*) - Garlic (*Allium sativum* (L.)) - Green tea extract (*Camellia sinensis*) - Garcinia extract (*Garcinia cambogia*) - Guarana extract (*Paullinia cupana*)
Miscellaneous bioactive substances	- Lycopene - Lutein - Coenzyme Q10 - Taurine - Carnitine - Inositol - Glucosamine - Chitosan - Spirulina - Soy isoflavone

Source: Euromonitor, 2005 (EAS, 2007)

The total size of the EU food supplements' market and its segments: 50% for vitamin and mineral products, 43% for supplements containing other substances, and 7% for tonics and bottled nutritive drinks (*Euromonitor, 2005 in EAS, 2007)*

When the combined markets of seventeen the EU Member States were surveyed, the most commercially important other substances were identified by Euromonitor as being fish oils, probiotics and certain herbal ingredient as seen in Table 12 *(*EAS, 2007).

Table 13 presents the various example of food supplement preferred by consumer in four countries in 2006. It clearly shows that the market of fish oils, probiotic and botanicals (particularly echinacea and gingko biloba) are the most preferred by the consumer as this trend is also apparent in combined EU market. Combinations of substances in significant amount are found in the market in Germany and Japan.

Table 12. Market Size of other Substances across 17 EU Countries

Type of other Substances	Market Size (Euro mn)
Others	648.4
Fish Oils	314.6
Probiotics	252.4
Gingko biloba	171.5
Echinacea	140.6
Garlic	140.2
Gingseng	103
Evening Prime Oil (EPO)	64.8
Glucosamine	64.3
ST. John's Wort	59.2
Eye Health	49.4
Royal Jelly	38.5
Coenzyme Q10	23.7
Protein Powder	3.5

Source: Euromonitor, 2005 (EAS, 2007)

Table 13. Example of Food Supplement Preferred by Consumers in Four Different Countries in 2006

Country	National Preferences of Food Supplement
Germany	Mineral, Tonics, Echinacea, Other Artichoke, Calcium, Gingko Biloba, Fish oils, Combination, Hawthorn, St John's wort, Evening primrose
UK	Fish oil, Other DS, Glucosamine, Chlid specific Minerals, Garlic, Evening primrose, Gingseng, Tonics, Calcium, St John's wort, Eye health
Japan	Combination, Probiotics, Prune, Royal jelly, Calcium, Amino acid, Co-enzyme Q10, Agaricus

United States	Calcium, Glucosamine, Minerals, Fish oil, Co-Q-10, Probiotic, Noni, Garlic, Echinacea, Eye health, Gingko billoba, Sam-E

Source: summarize from the presentation of Pettman (2008)

Currently, several hundred substances such as botanicals and amino acids are included on the Australian positive list. The State Food and Drug Administration (SFDA) of China maintains positive and negative lists of substances that may be used in health foods/food supplements, including lists of botanicals, fungi and probiotics.

The uses of Botanical products in pre-dosed forms have been applied for decades for their health-promoting and therapeutic properties in many countries. Regulations of these products on their own territory have been implemented, both as medicinal products and as food supplements. Botanicals in foodstuffs includes use as vegetables and fruits, herbs and spices (e.g. garlic, rosemary, etc.), herbal teas and infusions (camomile, etc.), herbs added to foods and beverages for taste or functional purposes (e.g. guarana, gentian, etc.), botanical food supplements (functional ingredients derived from botanicals, used for their health-promoting properties, e.g. carotenoids, flavonoids, isoflavones, procyanidins, phytosterols, etc.) (Coppens, 2006).

The European Union has considered these products in several legislative texts (Coppens, 2006), however for example Germany and USA there are no special category and regulation for traditional medicine. While in ASEAN country such as Thailand and Indonesia, where there are abundant traditional medicines, traditional medicine regulations are existed. The used of botanical products in these countries are often in the combination of other ingredients. This practice can be also found in Indonesian market which is not in line with basic principle of food supplement. Example of combination product in Indonesia: vitamin with botanical. The practice of combining food supplement and traditional medicine might lead to the misuse of this combination in the field of functional food. It is very important to keep basic concept of food in developing new food product either in the form of food supplement and functional food (personal communication, Purwantyastuti, 2009).

4. MAXIMUM LEVEL: RDA VERSUS RISK ASSESSMENT

Some nutrients (e.g. vitamins A, D, E and B6 and Se) are well known to cause toxicity if consumed in excessive amounts. However, the evidence whether high intakes of these nutrient do have a deleterious influence on health remain unclear. Concern about overdosing on dietary supplements is nothing new. However, the publicized benefits of taking supplements and the huge variety of products on the market, together with the knowledge that £ 50% of the populations of Western countries take them has increased the safety concerns in more recent years. These concerns have encouraged several authorities worldwide to establish safe upper levels (UL) for vitamins and minerals. A recommended dietary allowance does not mean to be used for safety but used for meeting the need. Therefore, it is not suitable to be used as a reference for establishment of maximum level.

Currently, scientific risk assessment was introduced and adopted by CODEX Committee and commission in 2005: Codex Guidelines for Vitamin and Mineral Food Supplement.

The Codex Guidelines Wording is:

"When the maximum levels are set, due account may be taken of to the reference intake values of vitamins and minerals for the population." This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes (e.g. Population reference intake of recommended allowances values).

This guideline provides the structure for establishing the maximum levels of permissible vitamins and minerals and other ingredients in a supplement. In 2006, FAO/WHO Model for Establishing Upper Levels of intake for Nutrients and Related Substances was developed to provide guidance to governments across the world how to do this.

Summary of Risk Assessment (source: IADSA, 2006)

With the purpose of filling the needs of regulators and scientific bodies for quantitative safety assessment of such bioactive substances, IADSA's Scientific Group present report on risk assessments performed on a selection of bioactive substances in food. It describes the method used in detail and sets out the results of its application to a selection of bioactive ingredients. On risk assessment of vitamins and minerals in the United States of America (USA) or the European Union (EU), established the Upper Level (UL) values for the vitamins and minerals doest not mean that it is free from adverse effects. As a result, for vitamin B12 in particular, the absence of a UL has been misinterpreted to indicate that risk assessment is not a useful approach to identifying maximum values. The Observed Safe Level (OSL) method developed by the Council for Responsible Nutrition (CRN USA) and IADSA in 2004 was anticipated to fill this methodological gap. This method was recommended only for those substances that had substantial evidence relating to safety but with no evidence establishing any potential toxicity.

What is upper level.....

The Food and Agriculture and World Health Organizations report: A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances recommended a Highest Observed Intake (HOI) approach for substances without recognized adverse effect. The HOI approach to safety evaluation is extremely similar in concept to the OSL method, It is intended to complement IADSA's earlier publication on the safety of vitamins and minerals

and is the first in a series of risk assessments that it is hoped will provide important guidance to governments and scientific bodies worldwide.

Example of Risk Assessment in Indonesia

Risk assessment is based on intake/Total Dietary Study (TDS), but TDS Indonesia is not available. For this case, data from USA and European countries can be used to estimate risk assessment of vitamin mineral (personal communication, Purwantyastuti, 2009).

The IADSA Approach to Supplement Safety

Safety evaluation for dietary/food supplement ingredients is properly determined on a case-by case basis through nutrient-appropriate risk assessment, not as arbitrary multiples of the RDA for essential nutrients, and also not as arbitrarily restrictive limits for the non-essential nutrients. The IADSA approach to nutrient-appropriate risk assessment requires the safety evaluation to depend on or be identified as:

1. Identification of a hazard related to excessive intake, assessment of the dose-response relationship for the identified hazard, consideration of uncertainty, and finally derivation of a supplementation level that is not only safe but includes a reasonable margin of safety; or
2. If no data exist that establish adverse effects in humans, the highest intake level with sufficient scientific evidence of safety at that intake; or
3. If no scientific evidence is available related to safety of high intakes by humans, then animal data may be used with appropriate risk assessment extrapolation, or
4. If no scientific clinical or animal data exist, a compelling pattern of history of safe intake as components of foods commonly consumed by humans.

Safety Evaluation Based on Scientific Data Related to Human Intake (detailed can be seen in the related reference)

Option 1: Direct Safety Evaluation of Supplemental Intakes:
Option 2: Indirect or Difference Method for Supplement Safety:
Option 3: Observed Safe Level:

Safety Evaluation Based on Animal Data

If adequate quality and appropriate scientific data from human subjects are not available but animal toxicology data are available, a safe intake level for human consumption may be estimated through extrapolation from the animal data. Because of the uncertainties about the magnitude of uncertainty factors and body size extrapolations to use, IADSA prefers to depend on human data, if available.

History of Safe Food Use

If appropriate and sufficient clinical or preclinical toxicology data are not available, a history of safe use may be helpful if the following conditions are met:

- The chemical identity of the supplemental form is the same as that found in foods.
- The intake level, frequency of intake and duration of use are similar to those that occurred through food consumption.
- The population on which the history of use is based had sufficient health care to provide a good chance of observing any adverse effects.
- No established pattern of adverse effects has credibly related to intake of the substance.

(Hathcock et al, 2006)

Nutrient-Appropriate Scientific Risk Assessment for Vitamins and Minerals

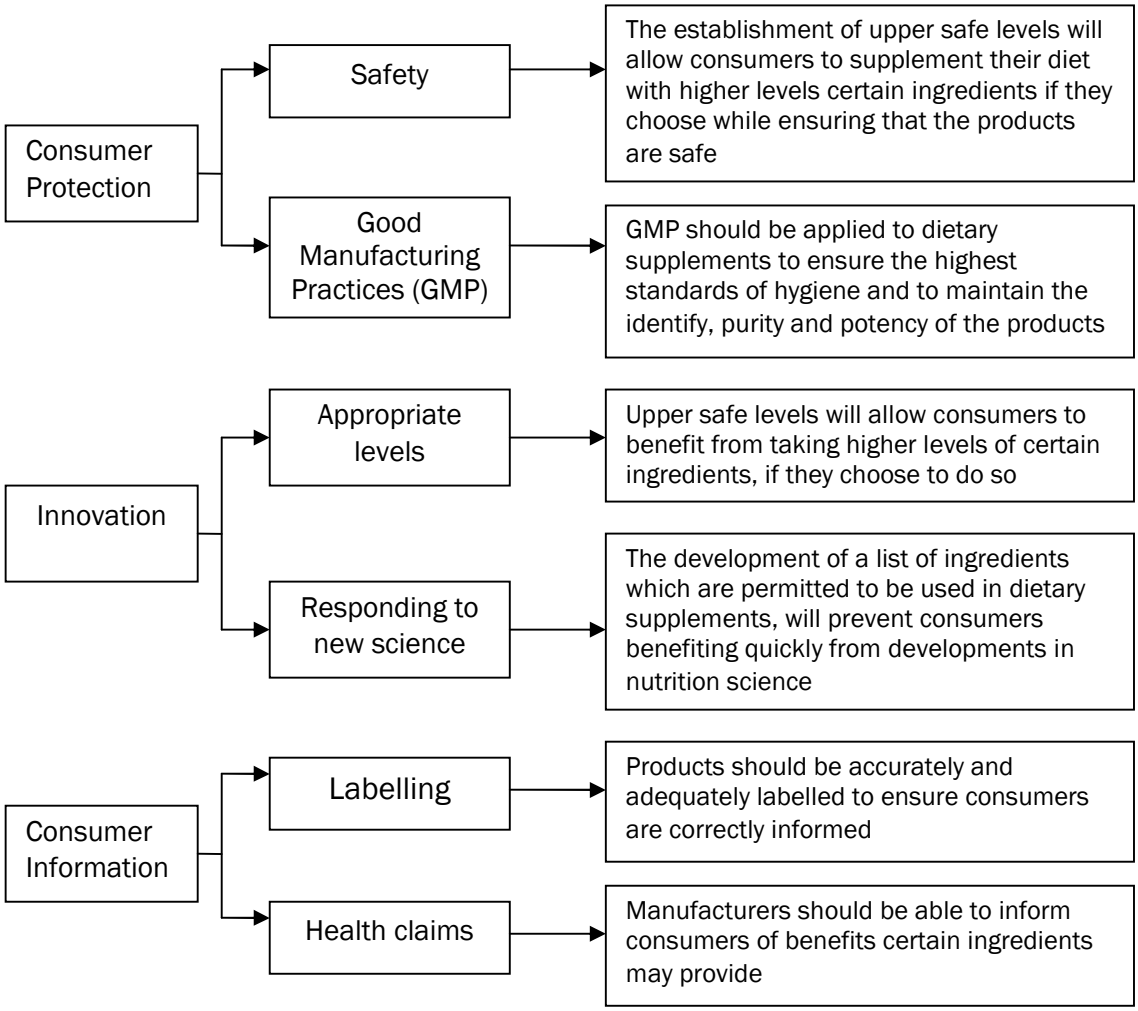


Figure 9. Ensuring the Correct Regulatory Framework for Dietary Supplement (IADSA,2005)

The term "nutrient-appropriate" used to describe risk assessment for vitamins and minerals and non-essential but beneficial dietary substances indicates that some risk assessment methods are not appropriate. Certain risk assessment methods use default uncertainty factors (sometimes called safety factors) that, although they are generally considered acceptable for identifying safe intakes of food additives and environmental contaminants, are unacceptably large for application in risk assessment of vitamins and minerals. That is, application of these factors leads to identification of "safety limits" that are below the recommended or beneficial daily intakes for some nutrients for certain age-gender groups. For example, the Acceptable Daily Intake (ADI)9 and the Reference Dose (RFD) used by the U.S. Environmental Protection Agency (US EPA) involve arbitrary uncertainty factors that calculate "safety limits" for zinc that are below the Recommended Dietary Allowance (RDA) for some groups. Arbitrary factors that reflect an excessive concern for scientific uncertainty, which is always present to one degree or another, can imply that the only "safe" intake is so low as to have no value. Because the value that is obtained from the risk

assessment because uncertain is used arbitrary It is important to take into account the RDA to reconsider the safety limit with reference to RDA. For example zinc, fall below the RDA, than take RDA.

5. STATUS OF CURRENT RESEARCH OF HEALTH BENEFIT OF VITAMIN AND MINERAL

Table 14 is an example of status of some subtended before 1999. Refer to USA 12 health claims.

Table 14. Overview of Health Benefits Related to Vitamins, Carotenoids and Minerals

Health Area	Type of Research	Current status
Cardiovascular Disease	• Relationship between vitamin E, supply and cardiovascular risk	• Strong evidence
	• Folic acid and vitamins B6 and B12 have been shown to be effective in reducing hymocysteine levels	
	• The role for β-carotene and vitamin C	• Under consideration
	• Magnesium in protecting against cardiovascular-related mortality	• promising
	• The importance of copper in cardiovascularis,	• the scope is not certain
	• A potential relationship between selenium and cardiovascular diseases has been suggested	• findings are un clear
Cancer	• Significant inverse correlation between vitamin C, E, β-carotene and Lycopene status and the risk of various forms of cancer, but need to be confirmed by intervention trials with supplements	
	• Long strict term intake of high doses of β-carotene appears to increase risk of lungs cancer in heavy smokers	
	• Encouraging result of calcium and selenium supplementation on reducing cancer risk	
	• Interesting findings on the association between folate and cancer prevention, but evidence is not conclusive	
Osteoporosis	• Calcium is needed for the adequate bone mass in children	
	• Vitamin D supplementation has been shown to significantly reduce a lost of bone density in post-menopausal and the elderly	
	• The protective role of vitamin K against osteoporosis appears to be a promoting area for ongoing research	
	• Magnesium has shown promoting results in delaying bones lose in the elderly, but additional studies are needed. Copper, manganese and zinc may also play a role	

Health Area	Type of Research	Current status
Eye	• Antioxidants C and E reduce the risk of age-related Macular Degeneration (AMD) • Evidence of the effect of lutein and Zeaxanthin of AMD requires further research • Some studies have pointed to the protective effect of vitamin C and E against cataracts, but findings are still conflicting	
Pregnancy	• Folic acid supplementation in early pregnancy reduces the risk of neural tube defects • In sufficient iron status may lead to birth complication	
Neuroprotection	• Destructive effects of free radicals of Alzheimer's diseases may be reduced by vitamin C and E supplements • Impaired cognitive developments is associated with iron deficiency anaemia, but cause and effects relationship and potential of supplementation not conclusive	
Immune System	• Supplementation with antioxidant vitamins, multivitamin, preparations and trace elements have demonstrated improvement in immune response in the elderly • Promising result suggesting a stimulative effects of copper on immune defense deserves further investigation • Interesting work on benefits of zinc and selenium on the immune systems require further research	
Growth	• Very good evidence of a beneficial of zinc supplementation growth of infants in populations with high rate of stunting • Mental retardation during growth related to iodine deficiency is preventable by iodine supplementation	

Source: Bassler, Hansen & Sandstrom (1999)

REFERENCES

The Nielsen. Thai consumers top the world in consuming vitamin/dietary supplements http://th.nielsen.com/news/20090317.shtml. (accessed 3 September 2009)

Kava R. Dietary Supplements: A Source of Regulatory Confusion (from Pharmacology Matters). http://www.acsh.org/healthissues/newsID.1796/healthissue_detail.asp. (Accessed 3 September 2009)

Dwyer J.T., Frances Picciano M., Betz J.M., Fisher K.D., Saldanha L.G., Yetley E.A., Coates P.M., Perry C.R. Progress in developing analytical and label-based dietary supplement databases at the NIH Office of Dietary Supplements. *Journal of Food Composition and Analysis* 2008;21 (Suppl.): S83-92

USACHPPM. Module 5: Dietary Supplement: A Basic Guide. The U.S. Army Center for Health Promotion and Preventive Medicine Directorate of Health Promotion and Wellness. Aberdeen Proving Ground, Maryland. 2000

Hathcock J, Richardson, Shao A. The Risk Assessment and Safety of Bioactive Substances in Food Supplements. The International Alliance of Dietary/Food Supplement Associations (IADSA). 2006

Yetley EA. Multivitamin and multimineral dietary supplements: definitions, characterization, bioavailability, and drug interactions. Am J Clin Nutr. 2007; 85(Suppl1): S269-76

European advisory services. The use of substances with nutritional or Physiological effect other than vitamins and Minerals in food supplements. Study undertaken For DG Sanco, European
Commission.2007.http://ec.europa.eu/food/food/labellingnutrition/supplements/documents/2007_A540169_study_other_substances.pdf (accessed 4 September 2009).

Coppens P, Delmulle L, Gulati O, Richardson D, Ruthsatz M, Sievers H, Sidani S, Use of Botanicals in Food Supplements Ann Nutr Metab 2006 ;50: 538–54

Official Journal of the European Communities. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the Multivitamin-multimineral dietary supplements 275S Downloaded from www.ajcn.org by on September 3, 2009 approximation of the laws of the Member States relating to food supplements.

Pettman, S. Global Regulation of Health Supplements Definition, classification and approaches. Presentation Summary at NADFC Jakarta, 2008

Official Journal of the European Union. Regulation (EC) No 1925/2006 of The European Parliament And of The Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. Downloaded from www.fsai.ie on September 3, 2009.

Official Journal of the European Union. Regulation (EC) No 108/2008 of The European Parliament And of The Council of 20 December 2006 on amending regulation (EC) no 1925/2006. Downloaded from www.fsai.ie on September 3, 2009.

CHAPTER 7

FOOD AND NUTRITION FOR SPECIFIC VULNERABLE GROUPS AND HEALTH CONDITION

By: Rina Agustina and Damayanti R. Sjarif

LEARNING OBJECTIVES:

This chapter provides information on international nutrition recommendation, guidelines and standard for foods for special dietary and medical purposes intended for: infants and young children; diabetic person; in low energy diet; and weight control. Upon completion, you should be able to explain:

- Definition of foods for special dietary uses and medical purposes
- CODEX Standard or Guidelines for:
  - Food intended for medical purposes
  - Food intended for infant and young children
  - Food intended for diabetic person
  - Food for use in very low energy for weight reduction
  - Formula foods intended for weight control

SUBJECT CONTENTS:

1. DEFINITION OF FOODS FOR SPECIAL DIETARY USES

1.1. Codex General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)

Food for special Dietary Uses is described by the Codex General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) as *"those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such ."* The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

Codex Committee on Nutrition and Foods for Special Dietary Uses **(CCNFSDU)** (Host Government - Germany)

CCNFSDU studies nutritional issues referred by the Codex Alimentarius Commission. It also develops guidelines, general principles and standards for food including food with special dietary uses

CODEX Alimentarius Commission developed standard relating to nutrition and foods for special dietary uses that have been endorsed and adopted into the international food code as follows:

- Canned Baby Foods
- Formula Foods for Use in Weight Control Diets
- Formula Foods for Use in Very Low Energy Diets for Weight Reduction
- Formulated Supplementary Foods for Older Infants and Young Children
- General Principles for the Addition of Essential Nutrients to Foods
- Guidelines on Vitamin and Mineral Food Supplements
- Infant Formula
- Labeling of and Claims for Prepackaged Foods for Special Dietary Use
- Labeling of and Claims for Foods for Special Medical Purposes
- Nutrition Labeling
- Processed Cereal-Based Foods for Infants and Children
- Use of Nutrition Claims.

1.2. USA: FDA - Section 411(c)(3) of the Federal Food, Drug, and Cosmetic Act

Special dietary use as " a particular use for which a food purports or is represented to be used, including but not limited to the followings:

1. Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

2. Supplying a vitamin, mineral, or other ingredient for use by humans to supplement the diet by increasing the total dietary intake.

3. Supplying a special dietary need by reason of being a food for use as the sole item of the diet. Regulations (21 CFR 105) under this section of the Federal Food, Drug, and Cosmetic Act prescribe appropriate information and statements which must be given on the labels of foods in this class.

Food for special dietary uses usually provides macronutrients (protein, carbohydrates, fat, calories, fiber), as well as vitamins and minerals. Vitamin and mineral supplements in pill form, one category of “dietary supplements,” do not usually contain macronutrients. The use of supplements cannot substitute for proper food choices.

1.3. Japan: Food for Special Dietary Uses (FOSDU)

FOSDU refer to foods that are approved/ permitted to display that the food is appropriate for specified dietary use. There are five categories of ''Food for Special Dietary Uses'' as

1) Milk powder for pregnant and lactating women;
2) Formulated milk powder for infants;
3) Food for elderly people with difficulty in masticating or swallowing;
4) Medical foods for patients; and
5) Food for special health uses (FOSHU)

2. FOODS FOR SPECIAL MEDICAL PURPOSES

2.1. CODEX Standard for the Libeling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991)

CODEX STAN 180-1991 defines foods for special medical purposes as: " a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision."

They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended. The labels, accompanying leaflets and/or other labeling and advertising of all types of foods for special medical purposes should provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use. The advertising of these products to the general public should be prohibited. The format of the information given should be appropriate for the person for whom it is intended.

2.2. European Union

EU Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (as amended by Directive 2006/141/EC) sets out rules for the

composition and labeling of foods that are specifically formulated, processed and intended for the dietary management of diseases, disorders or medical conditions of individuals who are being treated under medical supervision. These foods are intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods. The Directive gives guidance for the minimum and maximum levels of vitamins and minerals. Directive 2006/141/EC amended the levels of manganese in products intended for infants and young children. The Scientific Committee on Food has in its opinion (see below) on foods for special medical purposes of December 1996 provided the scientific advice on which these rules are based. Commission Directive 2001/15/EC sets out detailed rules on the sources of certain nutritional substances that may be used in foods for special medical purposes.

3. FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN

3.1. Growth and Development

Child is not a miniature of adult. Growth and development are essential features of life of a child and this distinguishes him or her from an adult. The process of GROWTH starts from the time of conception of the fertilized ovum (egg) and continuous until the child grows into a fully mature adult. DEVELOPMENT is defined as maturation of functions. The followings are Pediatric stages of development:

- Infancy (0 -1 yr)
- Toddler hood (1-2 yr)
- young children
- Preschool (3-5 yr)
- School age (6-9 yr)
- Adolescent (10-20 yr)
- Early adolescence (10-13 yr)
- Middle adolescence (14-16 yr)
- Late adolescence (17-20 yr)

(Feigelman, 2007)

The importance of ages 0-3 years is brain growth & development. The brain performs an incredible number of tasks:

(1) It controls body temperature, blood pressure, heart rate and breathing;
(2) It accepts a flood of information about the world around you from your various senses (eyes, ears, nose, etc.);
(3) It handles physical motion when walking, talking, standing or sitting.; and
(4) It lets you think, dream, reason and experience emotions.

The neuron growth & development is taking place in the cerebral cortex. About 100 billions neurons at born which chain of neurons, connected by synapses, create specialized

functions and are organized within specific areas of the brain. Synaptic density reaches its peak at around eight months of age. During the first year of life about 83 % of total dendrite growth occurs after birth with a child's cerebral cortex tripling in thickness, as a result of dendritic growth. It takes about two years before the neurons with their accompanying dendrites and synapses, to be fully matured

There are some factors affecting growth and development such as:

1 Genetic factors
   - The tall parents have tall children and so on.
   - In girls growth spurt occurs earlier at puberty

2 Environmental factors
   - *Nutrition*
   - *Chemicals* : food additives, etc
   - Injury
   - Infection
   - Social Factors
   - Emotional factors
   - Cultural factors

3.2. The Importance of Nutrition during Golden Ages Period (0-3 years)

Malnutrition has been responsible, directly or indirectly, for 60% of the 10.9 million deaths annually among children under five. Two-thirds of these deaths, which are often associated with inappropriate feeding practices, occur during the first year of life (WHO & UNICEF, 2003). Malnourished children who survive are more frequently sick and *suffer the life-long consequences of impaired development*. Early malnutrition over first 3 years of life may have permanent effects on the brain including: (1) Reduced dendritic development; (2) Reduced number of synapses; and (3) Reduced rate of myelination.

3.3. Global Strategy for Infant and Young Child Feeding (WHO & UNICEF 2003)

- Based on the evidence of nutrition's significance in the early months and years of life, and of the crucial role that appropriate feeding practices play in achieving optimal health outcomes.
- Children have the right to adequate nutrition and access to safe and nutritious food, and both are essential for fulfilling their right to the highest attainable standard of health.
- Exclusive breastfeeding is ideal nutrition and sufficient to support optimal growth and development for approximately the first 6 months after birth.
- ***Except*** for a few medical conditions, and unrestricted exclusive breastfeeding results in ample milk production.

- Infants weaned before twelve (12) months of age should not receive cow's milk feeding, but should receive iron-fortified infant formula (AAP, 1997)
- Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond (WHO, 2003)
- ***Low-cost complementary foods*, prepared with locally available ingredients using suitable small-scale production technologies in community settings, can help to meet the nutritional needs of older infants and young children.**
- ***Industrially processed complementary foods*** also provide an option for some mothers who have the means to buy them and the knowledge and facilities to prepare and feed them safely.
- Processed-food products for infants and young children should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

3.4. Infant Feeding Practice

Infant feeding depends on maturation of neuromotoric system, maturation of gastrointestinal system and Maturation of immunological system. CODEX Committee releases the guidelines for nutrition and foods for special dietary uses for infants and young children as follows:

Codex committee on nutrition and foods for special dietary uses (CCNFSDU): infant and young children

The followings are standards relating to nutrition and foods for special dietary uses intended for infants and young children that have been endorsed and adopted into the international food code:

- Codex Standard for Infant Formula and Formulas for Special Medical Purposes for Infant (CODEX STAN 72-1981)
- Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)
- Codex Standard for canned baby foods (CODEX STAN 73-1981)
- Codex Standard for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981).
- Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979)
- Guidelines on formulated supplementary foods for older infants and young children (CAC/GL 08-1991)
- Advisory Lists of Mineral salts and Vitamin compounds for use in foods for infants and children (CAC/GL 10-1979)

Codex standard for infant formula and formulas for special medical purposes for infant (CODEX STAN 72-1981)

Section A refers to Infant Formula

Section B deals with Formulas for Special Medical Purposes Intended for Infants

It means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labeling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

3.5. Formula for Special Medical Purposes Intended for Infant and Young Children

Almost all mothers can breastfeed successfully, which includes initiating breastfeeding within the first hour of life, breastfeeding exclusively for the first 6 months and continuing breastfeeding (along with giving appropriate complementary foods) up to 2 years of age or beyond. Exclusive breastfeeding in the first six months of life is particularly beneficial for mothers and infants. Nevertheless, a small number of health conditions of the infant or the mother may justify recommending that she does not breastfeed temporarily or permanently. These conditions, which concern very few mothers and their infants, are listed below together with some health conditions of the mother that, although serious, are not medical reasons for using breast-milk substitutes. Whenever stopping breastfeeding is considered, the benefits of breastfeeding should be weighed against the risks posed by the presence of the specific conditions as follows: Infant conditions (*Infants who should not receive breast milk or any other milk except specialized formula; Infants for whom breast milk remains the best feeding option but who may need other food in addition to breast milk for a limited period*) and maternal conditions (*maternal condition that may justify permanent avoidance of breastfeeding; conditions that may justify temporary avoidance of breastfeeding; during which breastfeeding can still continue, although health problems may be of concern*) (WHO & UNICEF, 2009).

Example of types of infant and young children formula:

A. Standard Formula for term infant

- Formula for starting up (0-6 months)
- Formula for follow up (6-36 months)

B. Standard Formula for Special Medical Purposes

- **Formula for premature infant**
  - Fortified human milks
  - Premature infant formula
  - Premature-discharged formula
- **Formula for cow-milk allergy**
  - Extensively hydrolyzed protein formulas

  - Amino-acid based formula
- Formula for inborn errors of metabolism
  - Phenylalanine free formula (PKU), branch-chain amino acids free formula (MSUD, MMA), etc
- Formula for gastrointestinal disorders
  - Acid Reflux: Thickened Formulas
  - Lactose-free formulas: lactose intolerance

Codex standard for canned baby foods (CODEX STAN 73-1981)

- Baby foods are foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food. They may be either in ready-to-eat form or in dry form requiring reconstitution with water only. They do not included products covered by the Codex Standard for Infant Formula (CODEX STAN 72-1981) or by the Codex Standard for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981)
- The term ***infant*** means a person not more than 12 months of age.
- The term ***young children*** mean persons from the age of more than twelve (12) months up to the age of three years.

Codex standard for processed cereal-based foods for infants and children (CODEX STAN 74-1981).

This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

Guidelines on formulated supplementary foods for older infants and young children (CAC/GL 08-1991)

To provide guidance on nutritional and technical aspects of the production of formulated supplementary foods for older infants and young children as defined in Section 3.1, including:

- Formulation of such foods, based on the nutritional requirements of older infants and young children;
- Processing techniques;
- Hygienic requirements;
- Provisions for packaging;
- Provisions for labeling and instructions for use.

Formulated supplementary foods for older infants and young children

- It means foods suitable for use during the infant's weaning period and for feeding young children as a supplement to breast milk or breast milk substitutes or other food available in the country where the product is sold.
- They are not suitable for use for infants before the beginning of the weaning period. These foods provide those nutrients which either are lacking or are present in insufficient quantities in the basic staple foods.
- The term ***older infants*** means persons from the 6th month and not more than 12 months of age
- The term ***young children*** mean persons from the age of 12 months up to the age of three years (36 months).

4. INTENDED FOR DIABETIC PERSON

4.1. International Nutrition Recommendations

International nutrition recommendations for persons with diabetes are established by many different organizations (Anderson, et al, 2004) such as American Diabetes Association, British Diabetes Association, Canadian Diabetes Association, European Association for the Study of Diabetes, India, Japan, South Africa, American Heart Association and National Cholesterol Education Panel (Adult Treatment Panel. All of these recommendations are summarized in Table 15.

The followings are the recommendations from the international community:

- Achieve and maintain a body mass index (BMI) of ≤25 kg/m^2
- Carbohydrate intake of 50–60% of energy with emphasis whole grains, vegetables, fruits and dry beans
- Specific restrictions on sugar intake
- Increase in dietary fiber intake
- Total fat intake is usually limited to <30% of energy with an emphasis on restriction of saturated and trans-fatty acids
- Moderation in polyunsaturated fat intake is recommended and monounsaturated are the fatty acids of choice

4.2 Recommended Ranges from International Organizations.

BMI Goal

- Mann and Lewis-Banned , summarizing recommendations for Europe and North America recommend a BMI goal of <25 kg/m^2. Because 58% of newly diagnosed Chinese

persons with type 2 diabetes are overweight;
- Pan recommends reducing weight to desirable (BMI <25 kg/m^2)

Range for total carbohydrate intake

- Three diabetes associations and Diabetes Australia recommend use of the glycemic index and only the American Diabetes Association does not recommend the glycemic index for general use
- The US National Academy of Sciences Institute of Medicine recently recommended that men under 50 years of age consume 38 grams of dietary fiber/day and that women under 50 consume 25 grams/day.

Protein Intake

- 11–18% of energy

Fat Intake

- Total fat, 25–30% of energy; saturated plus trans fatty acids, <10%; monounsaturated fatty acids, 9–14%; and polyunsaturated fatty acids, <9%. The recommended intake for dietary cholesterol is <200 mg/day for diabetic individuals

4.3 Evidence-Based Recommendations.

Recommendations regarding weight loss and maintenance

- A major nutrition goal is attaining and maintaining a desirable body weight (BMI ≤25 kg/m^2).

Dietary fiber intake

- Vegetables are universally endorsed as promoting health and four servings per day are recommended
- Fruit intake should not be restricted.
- Added monosaccharide and disaccharides, not from fruit or vegetables, should be used in moderation.
- Fiber intake of 25–50 grams/day or 15–25 grams/1000 kcal. These levels can be readily achieved by following general nutrition guidelines for intake of these foods: whole grains, especially oats and barley; whole grain breads, cereals, and pastas; brown rice, dry beans, peas and lentils; nuts; fruits; and vegetables.

Use of glycemic Index

- Short-term increases in the intake of low glycemic foods significantly lower fasting plasma glucose values and produces favorable trends in other glycemic and lipidemic parameters.
- Long-term intake of larger amounts of low glycemic index foods is related to higher HDL-cholesterol values and a lower risk for developing CHD
- Glycemic index be incorporated into diabetes exchange lists and nutrition teaching material to be an integral part of medical nutrition therapy.

Protein Recommendations

- Recommendation that protein provide 12 – 16% of energy relate to the likelihood that excessive animal protein intake acts to sustain abnormal renal hyperfiltration that may contribute to development of diabetic nephropathy
- Reducing animal protein and increasing soy protein may have renoprotective effects at all stages of renal function.

Soy protein intake has other health benefits, especially for diabetic individuals. Soy food intake improves serum lipid values, lowers CHD risk factors such as homocysteine and oxidation of LDL and decreases risk for CHD in a variety of other ways.

Dietary Fat

- De-emphasize animal protein intake in favor of vegetable proteins such as soy we recommend that dietary cholesterol be restricted to <200 mg/day.

These are fundamentals nutrition goal for diabetes management:

- Blood glucose management
- Achieving and maintaining a desirable body weight
- Managing serum lipoproteins
- Reducing other risks for atherosclerotic cardiovascular disease and reducing risks for micro vascular disease

Table 15 International Recommendations for Medical Nutrition Therapy for Persons with Diabetes

Parameter	ADA [3]	BDA [4]	CDA [5]	EASD [6]	Japan [8]	S Africa [9]	India [7]	AHA [10]	NCEP [11]
Weight Reduction	Modest weight loss (5–7%)	BMI to approach desirable weight	Maintain healthy weight (7–10%)	BMI 18.5–25 desirable weight	Attain & maintain desirable weight	Achieve & maintain reasonable weight	19–23 BMI desirable weight	Achieve & maintain desirable weight	Maintain desirable weight
Carbohydrate	50–60%	50–55%	50–60%	45–60% (55–60% with low GI foods)	60%	55–60%	>65%	45–55%	50–60%
Polysaccharides	Whole grains, fruits, vegetables	Most of CHO, rich in fiber or resistant starch	Whole grain cereals & legumes	Low GI foods	Vegetables-300 g	Whole grain cereals & legumes	Vegetables, fruits, legumes—40 g/d; cereal—40 g		Grains, whole grains, fruits, vegetables
Mono- & Disaccharides	No restriction	<25 g/d	≤10% added	<10% calories	1 serving fruit	<10% added sugar	From foods	No comment	No comment
Glycemic index	Does not recommend for general use	Discusses	Includes low GI foods	With meals, low GI foods recommended	Recommended	Quotes supportive references			No comment
Fiber, total	As for general population	>30 g/d	25–35 g/d	Increase with low GI foods	1 fruit, 400 g vegetables	40 g/d	From fruits, vegetables, legumes	≥25 g/d	20–30 g/d
Protein	15–20%	10–15%	11%, 0.86 g/kg/d	10–20%	15–20%	12–20%		~15%	~15%
Total fat **Saturated/Trans Fatty Acids**	25–35% <10%	30–35% <10%	≤30% <10%	≤35% <10%	20–25%	<30% <10%	<21% <7%	<30% <10%	25–35% <7%
Monounsaturated Fatty Acids	10–20%	10–15%	10–15% favored	10–20% favored		<13%	<7%	<11%	up to 20%
Polyunsaturated Fatty Acids	~10%	<10%	≤10%	≤10%		6–8%	<7%	<10%	up to 10%
Cholesterol	<300 mg/d	<300 mg/d		≤300 mg				<200 mg	<200 mg

Source: Anderson JW (2004)

Table 16. Evidence-Based Nutrition Recommendations for Persons with Diabetes

	Weighted Values from International Bodies	Evidence-Based Recommendations
Weight Reduction	Attain & maintain desirable weight (BMI≤25)	Attain & maintain desirable weight (BMI≤25)
Carbohydrate	50–60%	55–65%
Polysaccharides	Whole grains, legumes, vegetables	Whole grains, legumes, vegetables
Mono- & Disaccharides	<40 g/d, fruits and vegetables	Moderation
Glycemic Index	Low GI foods favored	Incorporate GI into exchanges and teaching material
Fiber, Total	25–35 g/d	25–50 g/d (15–25 g/1000 kcal)
Protein	11–18%	12–16%
Total fat	25–30%	<30%
SFA/Trans	<10%	<10%
MUS	9–14%	12–15%
PUFA	<9%	<10%
Cholesterol	<200 mg	<200 mg/d
Glycemic Index	Low GI foods favored	Incorporate GI into exchanges and teaching material

Source: Anderson JW (2004)

5. FOODS FOR USE IN VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION

Codex standard for formula foods for use in very low energy diets for weight reduction (CODEX STAN 203-1995)

Foods use in very low energy diets are defined as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity. The matter of sale on prescription should be a decision made at national level. It does not apply to prepackaged meals presented in the form of conventional foods (Codex standard for formula foods for use in very low energy diets for weight reduction *CODEX STAN 203-199).*

Definition

A formula food for use in very low energy diets is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450 – 800 kcal which represent the sole source of energy intake.

Essential Composition and Qualify Factors

The product as sold should comply with the following composition and quality factors:

1. Energy content, the source of energy shall provide 450 – 800 kcal daily energy intakes.
2. Nutrient content
    - *Protein*
        - Not less than 50 g protein with a nutritional quality[2] equivalent to a protein

digestibility-corrected amino acid score of 1 shall be present in the recommended daily intake of energy.

- Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

- ***Fats*** - Very low energy diets shall provide not less than 3 g of linoleic acid and less than 0.5 g a-linolenic acid in the recommended daily intake with the linoleic acid/a-linolenic acid ratio between 5 and 15.
- ***Carbohydrates*** - Very low energy diets shall provide not less than 50 g of available carbohydrates in the recommended daily intake of energy.
- ***Vitamins and Minerals*** - Very low energy diets shall provide 100% of the recommended daily intakes for vitamins and minerals.

3. Ingredients

Very low energy diets shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product.

6. FORMULA FOODS INTENDED FOR WEIGHT CONTROL

Codex standard of formula foods for use in weight control diets (CODEX STAN 181-1991)

Description

Formula foods for use in weight control diets are foods which, when presented as "ready-to-serve" or when prepared in conformity with the directions for use, are presented as a replacement for all or part of the total daily diet.

Essential Composition and Quality Factors

1. Energy content
   - A formula food presented as a replacement for all meals of the daily diet shall provide not less than 800 kcal (3350 kJ) and not more than 1200 kcal (5020 kJ). The individual portions or servings contained in these products shall provide approximately one third or one fourth of the total energy of the product depending on whether the recommended number of portions or servings per day is 3 or 4 respectively.
   - A formula food presented as a replacement for one or more meals of the daily diet shall provide not less than 200 kcal (835 kJ) and not more than 400 kcal (1670 kJ) per meal. When such products are presented as a replacement for the major part of the diet the total energy intake shall not exceed 1200 kcal (5020 kJ).

2. Nutrient content
   - Protein

A minimum of 25% and a maximum of 50% of the energy available from the food, when ready-to-serve, shall be derived from its protein content. The total amount of protein shall not exceed 125 g per day.

The protein shall be:

(i)A nutritional quality equivalent to egg or milk protein (the reference protein);

(ii) If the protein quality is less than the reference protein, the minimum levels should be increased to compensate for the lower protein quality. No protein with a quality of less than 80% of that of the reference protein shall be used in a formula food for use in a weight control diet.

Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

- Fats
  Not more than 30% of the energy available from the food shall be derived from fat including not less than 3% of the energy available derived from linoleic acid (in the form of a glyceride).
- Carbohydrates
  Very low energy diets shall provide not less than 50 g of available carbohydrates in the recommended daily intake of energy.
- Vitamins and Minerals
  For a formula food represented as a replacement for all meals per day, at least 100% of the amounts of vitamins and minerals specified below shall be present in the daily intake.

  For a formula food represented as a replacement for a single meal, the amounts of vitamins and minerals shall be reduced below the amounts specified in 3.2.3.1 to provide a minimum of 33% or 25% of these amounts, depending on whether the recommended number of servings per day is 3 or 4 respectively.

3. Ingredients
   Formula foods for weight control shall be prepared from protein constituents of animals and/or plants which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product.

POINT OF DISCUSSION

Discussion on issue related to food for specific dietary uses and medical purposes: Infant and childhood nutrition

1. What kind of problems addressed in the community related to infant and childhood nutrition in your country
2. What kind of recommendation by the government and academia to overcome such problems

3. What type of food and nutrition related product that need to be developed and promoted in response to the problems and recommendation above
4. National and International policy related to infant formula

REFERENCES

Codex Alimentarius. General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)

US FDA - Section 411(c)(3) of the Federal Food, Drug, and Cosmetic Act

Ministry of Health, Labour and Welfare Japan. Food with Health Claims, Food for Special Dietary Uses, and Nutrition Labeling. http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html (accessed October 31, 2009)

Codex Alimentarius. CODEX STAN 180-1991. Codex standard for the labelling of and claims for Foods for special medical purposes

European Commission on food safety. Foods for special medical purposes http://ec.europa.eu/food/food/labellingnutrition/medical/index_en.htm (accessed October 31, 2009)

Food safety Authority of Ireland. Dietary Foods for Special Medical Uses. http://www.fsai.ie/legislation/food_legislation/foods_for_particular_nutritional_uses/dietary_foods_for_special_medical_uses.html

Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC

Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (accessed October 31, 2009)

Feigelman S. Growth development and Behaviour. Eds Kliegman RM, Behrman RE, Jenson HB, Stanton BF. In Nelson Textbook of Pediatrics. Edn. 18th Vol.1, Saunders Elsevier. New Delhi. 2008; pp:43-65.

WHO & UNICEF. Global Strategy For Infant And Young Child Feeding. 2003

WHO & UNICEF. Acceptable medical reasons for use of breast-milk substitutes. 2009

Codex Standard for Infant Formula and Formulas for Special Medical Purposes for Infant (CODEX STAN 72-1981)

Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)

Codex Standard for canned baby foods (CODEX STAN 73-1981)

Codex Standard for Processed Cereal-Based Foods for Infants and Children (CODEX STAN 74-1981).

Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979)

Guidelines on formulated supplementary foods for older infants and young children (CAC/GL 08-1991)

Advisory Lists of Mineral salts and Vitamin compounds for use in foods for infants and children (CAC/GL 10-1979)

Anderson JW, Randles KM, Kendall CWC and Jenkins, DJA. Carbohydrate and Fiber Recommendations for Individuals with Diabetes: A Quantitative Assessment and Meta-Analysis of the Evidence. Journal of the American College of Nutrition 2004; 23(1): 5-17

Codex Standard For Formula Foods For Use In Very Low Energy Diets For Weight Reduction (CODEX STAN 203-1995).

Codex Standard of Formula Foods for Use in Weight Control Diets (CODEX STAN 181-1991).

CHAPTER 8

FOOD FORTIFICATION IN ASIA

AND THE ROLE OF PUBLIC PRIVATE PARTNERSHIP

By: Rina Agustina and Umi Fahmida

LEARNING OBJECTIVES:

This chapter describes the burden of malnutrition and micronutrient deficiencies and the global strategy to eradicate these problems. Upon completion, you should be able to explain:

- Malnutrition problems
- Micronutrient deficiency
- Fortification as global strategy
- Public-private partnership in fortification

SUBJECT CONTENTS:

Food fortification is defined as intentional practice in increasing the content of essential micronutrients (i.e. vitamins, minerals including trace elements) in a food to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health (WHO/FAO, 2006). Food fortification program usually related with micronutrient deficiencies problem which is different in every place or country. By that, type of fortification and law order also different based on huge of the problems.

1. MICRONUTRIENT DEFICIENCIES IS A GLOBAL PROBLEM

Micronutrient malnutrition (MNM) is widespread in the industrialized nations, but even more so in the developing regions of the world (Allen et al., 2006), including most Asian countries. Micronutrient deficiencies have devastating impacts at population level including reduced IQ, reduced resistance, stunted growth and the clinical manifestations of micronutrient deficiencies (goiter, anemia, blindness), even death. Worldwide 1.6 billion people suffer from iodine deficiency, 2.0 billion from iron deficiency and 0.8 billion from vitamin A deficiency. Each day, 300 women died during delivery due to iron deficiency, 4000

under-five children diet due to vitamin A deficiency, and 50,000 infants born with potential inadequate mental and IQ development, due to iodine and iron deficiencies.

The international commitments are to reduce iron deficiency anemia by 1/3 by year 2015, eliminate VAD and eliminate IDD. The global strategy to tackle problem of micronutrient deficiencies should include complementary actions, including improvement of food consumption (balance diet), supplementation, fortification (including bio-fortification), prevention and treatment of infections, and improvement of environmental health and sanitation.

Table 17. Prevalence of the Three Major Micronutrient Deficiencies by WHO Region

WHO region	Anaemia [a]		Insufficient iodine intake [b]		Vitamin A deficiency [c]	
	(total population)		(total population)		(preschool children)	
	No (millions)	% of total	No (millions)	% of total	No (millions)	% of total
Africa	244	46	260	43	56	49
Americas	141	19	75	10	16	20
South-East Asia	779	57	624	40	127	69
Europe	84	10	436	57	No data available	
Eastern	184	45	229	54	12	22
Mediterranean Western Pacific	598	38	365	24	42	27
Total	2030	37	1989	35	254	42

[a] Based on the proportion of the population with haemoglobin concentrations below established cut-off levels.
[b] Based on the proportion of the population with urinary iodine <100µg/l.
[c] Based on the proportion of the population with clinical eye signs and/or serum retinol ≤0.70µmol/l.
Source: WHO/FAO (2006)

2. FORTIFICATION AS A GLOBAL STRATEGY TO ERADICATE MICRONUTRIENT DEFICIENCIES

Some countries had implemented fortification program with various approaches. Below are some examples of the implementation of fortification program in many countries:

1) Soy sauce fortification with Fe in China improved Hb level, reduced anemia, and improved weight and height (Chunming, 2003; Wang et al, 2008)
2) Sugar Fortification with vitamin A in Central America. This has been proven to have positive effect on children having plasma retinol<20Ug/dl-U5.
3) Mandatory Fortification in Indonesia:

- Salt Iodization : mandatory by Joint Ministerial Decree (MOH,MOIT,M.Interior), 1982; Joint 4 Ministerial Decree (plus Agriculture), 1984; and Presidential Decree N0.69 / 1994
- Wheat Flour Fortification: mandatory by Ministry of Industry and Trade's Decree SNI (Standar Nasional Indonesia- National Standard in Indonesia) of Wheat Flour, which stated that "All wheat flour produced and marketed in Indonesia has to be fortified

with Iron, Folic Acid, Zinc, and Vitamin B1 and Vitamin B2"

4) Sprinkle –"Spice-like" (not spice) added with micronutrients (Fe, Zn, AF, Vit A, B, etc) sprinkled to home-made complementary foods for young children 6 – 24 months. Sprinkle containing iron and zinc. In Ghana this has been shown to be effective in reducing anemia. In Zambia, the sprinkle was effective to cure anemia but it did not improve zinc status (MOST, USAID, 2003) .In Indonesia: efficacy study done by Hellen Keller Indonesia (unpublished data, 2004) showed that anemia decreased in the experimental group receiving the sprinkle.

3. LEGISLATION IN FOOD FORTIFICATION

The primary purposes of food legislation are to protect the health of the consumer, to protect the consumer from fraud, and to ensure the essential quality and wholesomeness of foods. The following principles should be considered in the development of food-fortification legislation (Orriss, 1998):

- Fortification should always be in the best interests of the selected population;
- There should be input from interested parties in the development of the law and regulations;
- The provision of the law should allow flexibility;
- The law should state clearly what is required or prohibited;
- The law should create a device for enforcement;
- The law should provide for quality assurance;
- The law should provide the government with adequate inspection and sampling powers;
- The law should contain both incentives and penalties;
- The law should treat everyone equally and fairly.

From the law or legal point of view, there are two approaches from the government for food fortification implementation: mandatory and voluntary fortifications (WHO/FAO, 2006). The essential differences between two of them is the level of certainty over time that a specific food will contain a pre-determined quantity of micronutrient. Mandatory fortification take place when governments oblige food producers to fortify foods or categories of food with specified micronutrients legally while in voluntary fortification, food producers are freely to choose particular food to be fortified which are permitted or encouraged by the government.

Table 18. Status of Food Fortification Program Activities in Some Developing Countries.

Country	Food Fortifications Opportunities	Status/Plan
PRC	Soy sauce : Fe Wheat : Fe, folic acid,vit A Rice : Fe, plans for vitamin A	Efficacy/effectiveness trials
India	Wheat flour : Fe,folic acidd,vit B Sugar : vit A Oils and fats : vit A Tea, milk : vit A	Permitted Feasibility/effectiveness trials Permitted for fats Stability trials for oils Permitted
Indonesia	Wheat flour : Fe,Zn,folic acid,B1,B2	Mandatory

	Salt : Iodine Cooking Oil : vit A	Mandatory Permitted
Fiji Islands, Rep of	Wheat Flour: Fe,Zn,folic acid, vit A,B1, B2,niacin Sugar: vit A Oils: vit A	Voluntary fortification under consideration
Philippines	Wheat flour: Fe,folic acid, vit A Rice: Fe	Bill under review for mandatory fortification
Thailand	Noodles : Fe,I, vit A Rice : Fe,B1,B2,B6, niacin	Permitted
Vietnam	Fish sauce : Fe Sugar : vit A	Effectiveness trials No regulation in place yet

Source: Lecture's note of NFI course, Soekirman (2008)

4. BIO-FORTIFICATION

- Bio-fortification is a process for micronutrient enhancement in major staple crops, such as maize, rice, wheat, cassava, beans and sweet potato. This activity can be done conventionally by plant breeding or by modern technology. At least, 5 advantages occur with this program (Nestel P et al, 2006):It took benefit on the regular daily intake of a consistent and large amount of food staples by all family members. With staple foods predominate in the diets of the poor, this strategy implicitly targets low-income house-holds.
- Following the one-time investment to develop seeds that fortify themselves, recurrent costs are low, and germplasm can be shared internationally. This multiplier aspect of plant breeding across time and distance makes it cost-effective.
- Once established, the bio-fortified crop system is highly sustainable. Nutritionally improved varieties will continue to be grown and consumed year after year, even if government attention and international funding for micronutrient issues fade.
- Bio-fortification provides a feasible means of reaching undernourished populations in relatively remote rural areas, delivering naturally fortified foods to people with limited access to commercially marketed fortified foods that are more readily available in urban areas. Bio-fortification and commercial fortification, therefore, are highly complementary.
- Breeding for higher trace mineral density in seeds will not incur a yield penalty

Transgenic approaches to tackle the major nutritional deficiency diseases include:

1. for Vitamin A Deficiency : Golden Rice
2. for Iron Deficiency Anemia (Iron) : High Iron Rice
3. for Protein Energy Malnutrition : High Quality Protein Rice
4. for Iron Deficiency Disorder : No transgenic strategy yet

The current and future areas for bio-fortification are:

1 Maize Breeding. Conventional breeding can be done for high lysine, tryptophan, zinc, and carotene maize. At present varieties have been developed which contain 25-30% higher iron and zinc. Looking for molecular markers for iron and zinc;

2 Rice Breeding. The goal is to develop rice with 50-80% increased content of iron and

zinc. Currently rice varieties having twice as much as iron and zinc and Golden Rice with high carotene content are available.

3 Other Crops Breeding.
- Sweet Potato: orange flesh varieties with high carotene content have been identified
- Cassava: varieties with high carotenoid content have been identified
- Beans : varieties with high iron content have been identified
- Wheat: screen for sources high iron, zinc, and carotene are currently being developed. Some varieties with 50-100% increases in iron and zinc are already available.

5. PUBLIC-PRIVATE PARTNERSHIP IN FORTIFICATION: WHY WE NEED IT?

Barriers of Food to Fortification Program

(Courtesy Dr. G. Maberly, Flour Fortification Initiative- FFI, 2000)

These are the top barriers to food fortification:

1. Political issues
   There are no signals of support on the needs of fortified foods form: research community, medical and health community, local government and internationals agency
2. Marketing issues
   Lack of public awareness of micronutrient malnutrition, additional cost of fortified products and lack of consumers demand for fortified products, no consumers priority on nutrition claim are the marketing issues.
3. Regulatory issues
   Unclear health claims, lack of level playing field
4. Food Technology
   Large companies rank vitamin stability and organoleptic change as low priority issues

A strategic alliance supposed to be established among the major stakeholders: the scientific community, government, international agencies, non-government organizations and industry. public and private sectors partnership will not only benefit the parties involved but also, more importantly, will deliver a sustainable fortification program through leveraging each party's strength (Mehansho, 2002). Investment in Food fortification for Private Sector strengthening by public education, data bank, regulatory and inspect system, tariff and tax incentives and public markets, will expand social responsibilities including the good conduct in business.

6. SAFETY ISSUES

In 2006, WHO/FAO published guideline for Food Fortification. Below are some recommendations of micronutrient fortificants from the guideline.

Table 19. Factors that Can Limit quantity of Fortificans that Can Be Added to a Single Food Vehicle

Nutrient	Technological/Sensory	Safety	Cost
Vitamin A	X	XXX	XXX
Vitamin D	-	X	X
Vitamin E	-	X	XXX
Vitamin C	XX	X	XXX
Vitamin B-1	-	-	--
Vitamin B-2	XX	-	-
Niacin	-	XXX	X
Vitamin B-6	-	X	--
Folic Acid	-	XXX	-
Vitamin B-12	-	-	X
Iron	XXX	XX	X
Zinc	XXX	XXX	X
Calcium	X	XX	XXX
Magnesium	-	-	-
Selenium	-	X	X
Iodine	X	XXX	-
Fluroide	-	XXX	X

Source: WHO/FAO (2006)

Table 20. Tolerable Upper Levels Intake (UL) Recommended by WHO for Food Fortification

Nutrient	1-3 years old	4-8 years old	9-13 years old	19-70 years old
Vitamin A(µg RE)	600	900	1,700	3000
Vitamin D (µg)	50	50	50	50
Vitamin E (mg ά-tocoferol)	200	300	600	1,000
Niacin (mg)	400	650	1,200	1,000
Vitamin C (mg)	40	15	20	35
Vitamin B6 (mg)	30	40	60	100
Folic acid (µg)	300	400	600	1,000
Choline (mg)	1,000	1,000	2,000	3,500
Iron (mg)	40	40	40	45
Zinc (mg)	7	12	23	45
Copper (mg)	1	3	5	10
Calcium (mg)	2,500	2,500	2,500	30,000
Boron (mg)	30	6	11	20
Phosporus (mg)	3,000	3,000	4,000	4,000
Magnesium (mg)	65	110	350	350
Manganese (mg)	2	3	6	11
Molibdenum (µg)	300	600	1,100	2,000
Nickel (µg)	200	300	600	1,000
Selenium (µg)	90	150	280	400
Iodine (µg)	200	300	600	1,100
Fluoride (µg)	1,300	2,200	10,000	10,000

Source: WHO/FAO (2006)

7. ORGANIZATIONS INVOLVED IN FORTIFICATION

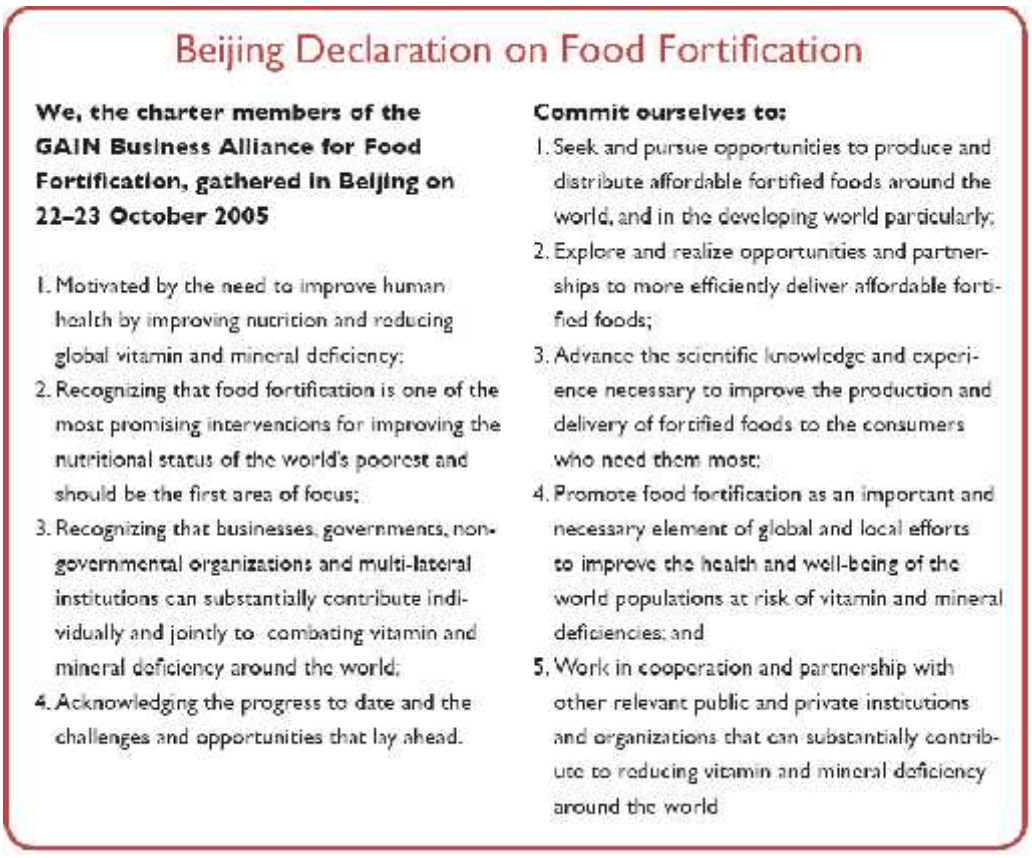
Koalisi Fortifikasi Indonesia (KFI)

Indonesian Commiitee of fortification (KFI), founded on May 7, 2002, is a public-private partnership organization for fortification in indonesia. It is an independent, non-profit non-government organization.

KFI's is engaged in activities with the objectives to:

1. Increase organization/agency skills with respect to food fortification in an effective manner through public-private partnerships in the national, regional and international levels.
2. Advocate, promote and socialize food fortification.
3. Facilitate and encourage Research and Development on micronutrient problems and the solution thereof through food fortification.
4. Develop a food fortification information system.
5. Seek and provide support with respect to resources locally and from abroad to promote the food fortification program.
6. Develop political and financial support for a cost effective fortification program.

Beijing Declaration: GLOBAL ALLIANCE FOR IMPROVED NUTRITION (GAIN) in China



Beijing Declaration on Food Fortification

We, the charter members of the GAIN Business Alliance for Food Fortification, gathered in Beijing on 22–23 October 2005

1. Motivated by the need to improve human health by improving nutrition and reducing global vitamin and mineral deficiency;
2. Recognizing that food fortification is one of the most promising interventions for improving the nutritional status of the world's poorest and should be the first area of focus;
3. Recognizing that businesses, governments, non-governmental organizations and multi-lateral institutions can substantially contribute individually and jointly to combating vitamin and mineral deficiency around the world;
4. Acknowledging the progress to date and the challenges and opportunities that lay ahead.

Commit ourselves to:

1. Seek and pursue opportunities to produce and distribute affordable fortified foods around the world, and in the developing world particularly;
2. Explore and realize opportunities and partnerships to more efficiently deliver affordable fortified foods;
3. Advance the scientific knowledge and experience necessary to improve the production and delivery of fortified foods to the consumers who need them most;
4. Promote food fortification as an important and necessary element of global and local efforts to improve the health and well-being of the world populations at risk of vitamin and mineral deficiencies; and
5. Work in cooperation and partnership with other relevant public and private institutions and organizations that can substantially contribute to reducing vitamin and mineral deficiency around the world

REFERENCES

Chunming C. Iron fortification of soy sauce in China. Agriculture (FAO)2003; 32: 76-84 http://www.fao.org/docrep/005/y8346m/y8346m10.htm

Bo Wang, Siyan Zhan, Jing Sun and Liming Lee. Social mobilization and social marketing to promote NaFeEDTA-fortified soya sauce in an iron-deficient population through a public–private partnership. Public Health Nutrition 2008; 12(10): 1751–1759

Mehansho, Haile. 2002. Forging Effective Strategies to Combat Iron Deficiency. Eradication of Iron Deficiency Anemia through Food Fortification: The Role of the Private Sector. The Journal of Nutrition, 831S – 833S

http://www.ifpri.org/themes/grp06/papers/bouis.pdf (accessed October 31 2009)

http://www.harvestplus.org/pdfs/harnessing.pdf (accessed October 31 2009)

http://www.sph.emory.edu/PAMM/IH552/cnyhus2000/runpage.html (accessed October 31 2009)

Nestel P, Bouis HE, Meenakshi JV, Pfeiffer W. Biofortification of Staple Food Crops. The Journal of Nutrition. 2006; 136: 1064-1067

Orriss, GD. Food fortification: Safety and legislation. Food and Nutrition Bulletin 1998.: 19: 109-116

WHO/FAO. Guidelines for food fortification with micronutrients. World Health Organization and Food and Agriculture Organization of United Nations. 2006

CHAPTER 9

NUTRITION

LABELLING IN THE REGION

By: Rina Agustina

LEARNING OBJECTIVES:

This chapter presents the overview of CODEX guidelines and standard on nutrition labeling and the status of nutrition labelling in different regions and countries. Upon completion, you will be able to explain:

- Definition of nutrition labelling
- Guidelines related on nutrition labeling
- Standard for labeling of prepackaged food
- Nutrition labeling in various countries
- Use of RDA/NRV for the application of nutrition labeling

SUBJECT CONTENTS:

Food labeling is the primary means of communication between the producer and seller of food on one hand, and the purchaser and consumer on the other hand. Nutrition labelling is a component of the labeling of prepackaged foods. For this purpose the Codex Alimentarius Commission (CODEX) General Standard for the Labeling of Prepackage Foods (CODEX STAN 1-1985) was published and adopted by the Codex Commission at its 14th Session, 1981 and subsequently revised in 1985 and 1991 by the 16th and 19th Sessions. The scope of this standard applies to the labeling of all prepackaged foods to be offered as such to the consumer or for catering purposes and to certain aspects relating to the presentation thereof. The followings are some details on the guidelines which are cited from the CODEX as well as various countries and regions.

1. DEFINITION OF NUTRITION LABELLING AND BENEFITS FOR CONSUMER

The CODEX defines *Label as* any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of food (CAC/GL2-1985).

Labelling includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

Nutrition labelling is a description intended to inform the consumer of nutritional properties of a food. The aim of the nutrition labelling is to provide consumers with the information they need to make informed choices. With current global world and advanced information technology the consumer have access information about the importance of diet and nutrition in maintaining good health and preventing disease. Their increasing awareness is reflected in the changes to their purchasing behaviours. Nowdays, consumer actively choose products for their quality nutritional value. Accurate nutrition labels will convey the right nutritional information to consumers and allow them to compare the nutritional value of similar products.

2. GUIDELINES RELATED ON NUTRITION LABELLING

In the Codex framework, nutrition matters are the responsibility of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), while nutrition labeling falls under the Codex Committee on Food Labeling (CCFL).

Codex Committee on Food Labelling (CCFL) has developed three standards and guidelines relevant to nutrition labelling:

1. *General Standard for the Labelling of Prepackaged Foods* (Codex Stan 1_1985, revised 1991, 2001)
2. *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Use* (CODEX Stan 146_1985)
3. *Guidelines on Nutrition Labelling* (CAC/GL 2_1985, revised 1993).

Recognizing the importance of nutrition labeling as a public health tool, the Codex Alimentarius Commission (Codex) and many food authorities worldwide have established guidelines or regulations on nutrition labeling for consumer protection. The purposes of the Codex Guidelines are:

- To provide the consumer with information about a food so that a wise choice of food can be made;
- To provide a means for conveying information of the nutrient content of a food on the label
- To encourage the use of sound nutrition principles in the formulation of foods which would benefit public health;
- To provide the opportunity to include supplementary nutrition information on the label;
- To ensure that nutrition labeling does not describe a product or present information about it which is in any way false, misleading, deceptive or insignificant in any manner; and
- To ensure that no nutritional claims are made without correct nutrition labelling.

CAC elaborates that nutrition labeling consists of two components namely nutrient declaration and supplementary nutrition information

A. Nutrient declaration

Nutrition declaration means a standardized statement or listing of the nutrient content of a food. Information supplied should be used for the purpose of providing consumers with a suitable profit of nutrients contained in food and considered to be of nutritional importance. The information should not mislead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain good health, but rather to convey an understanding of the quantity of nutrients contented in the product. A more exact quantitative *delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labeling.*

Nutrient declaration should be mandatory for all prepackaged foods for which nutrition or health claims, as defined in the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)*,* are made. Nutrient declaration should be mandatory for all other prepackaged foods except where national circumstances would not support such declarations. Certain foods may be exempted for example, on the basis of nutritional or dietary insignificance or small packaging.

B. Supplementary nutrition information

The content of supplementary nutrition information will vary from one country to another and within any country from one target population group to another according to the educational policy of the country and the needs of the target groups.

Supplementary nutrition information is intended to increase the consumer's understanding of the nutritional value of their food and to assist in interpreting the nutrient declaration. There are a number of ways of presenting such information that may be suitable for use on food labels.

The use of supplementary nutrition information on food labels should be optional and should only be given in addition to, and not in place of, the nutrient declaration, except for target populations who have a high illiteracy rate and/or comparatively little knowledge of nutrition. For these, food group symbols or other pictorial or colour presentations may be used without the nutrient declaration. Supplementary nutrition information on labels should be accompanied by consumer education programmes to increase consumer understanding and use of the information.

There are some beneficial effects of nutrition labelling for consumer such as:

- To help assess the nutritive value of any given food;
- To compare products and make informed choices, and to find out how the food contributes to the diet;
- To assist in food selection to meet their individual needs and preferences

The merits of nutrition labelling for Food Industry can be used as a marketing strategy in today's health conscious society. Labelling is useful tool in improving market share. It helps to educate consumer in order to introduce healthier alternatives foods. Labelling could provide direction and scope for product development efforts which meet the needs of consumers.

3. STANDARD FOR LABELING OF PREPACKAGED FOODS

General principles CODEX STAN 1-1985 indicates that:

- *Prepackaged Foods* shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect".

- *Prepackaged Foods* shall not be described or presented on any label or in any labeling by words, pictorial or other devices which refers to are suggestive either directly or indirectly, or if any other product with which such food might be confused, or such in a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

3.1. There are some items which are mandatory for prepackaged foods labeling :

- The name of the food
- List of ingredients
- Processing ads and carry-over of food additives
- Net contents and drained weight
- Name and address
- Country of origin
- Lot identification
- Date marking and storage instruction
- Instruction for use

Several additional mandatory requirements are:

- Quantitative ingredient declaration
- Irradiated foods

3.2. Significant issues of labeling derived from the Codex Guidelines on Nutrition Labelling (WHO, 2004)

- Nutrition labeling should be voluntary unless a nutrition claim is made.
- When a nutrition claim is made, declaration of four nutrients should be mandatory — energy, protein, available carbohydrate, fat — plus any other nutrient for which a claim is made.
- Where a claim is made for dietary fiber, dietary fiber should be declared.
- If a claim is made for carbohydrates, the amount of sugars should be listed as well as the four basic nutrients.

- When a claim is made on fatty acids, the amount of saturated and polyunsaturated fatty acids should be listed.
- Any other nutrient deemed by national legislation to be important for maintaining good nutritional status may also be listed.
- Nutrients should be listed per 100g or 100ml or per portion (provided that the number of portions is stated).

4. NUTRITION LABELING IN VARIOUS COUNTRIES

This handbook provides summary of nutrition labeling requirement in various different region such as Asia Pacific (Malaysia, Indonesia Thailand, Japan, China), America (USA, Canada and Latin America), Australia and Europe.

4.1. Malaysia

Previously, the Food regulation of Malaysia did not require the mandatory nutrition labeling for food products, except for special purpose foods and foods that have been enriched or fortified. As a result of this situation, each manufacturer followed their own format of listing nutrient. Due this inconsistency of nutrition labels and the wide variety of claims, new Malaysian Food regulation mandatory nutrition labeling for a wide variety of food product.

- A nutrition label is a listing of the level of nutrient(s) as displayed on the food label. It is meant to provide factual information about the nutritional contents of the product. The categories of foods requiring nutrition labeling covering prepared cereal foods, bread, milk products, flour fortification, canned meat, canned fish, canned vegetables, canned fruit and fruit juices, soft drinks, salad dressings and mayonnaise. Several issues on labeling that should be considered are :
- Foods not listed in mandatory category may also carry nutrition labeling. However, they must comply with the format and requirements stipulated in this nutrition labeling and claims regulations.
- The nutrients that must declare on a nutrition label are energy, protein, carbohydrate and fat. In addition, total sugars must also be declared for ready-to-drink beverages. In these regulations, ready-to-drink beverages include ready-to-drink soft drink, fruit and vegetable juices, ready-to-drinking malted milk and flavored milk. The do not include alcohol beverages.
- Information on energy value is to be expressed as kcal (kilocalories) per 100 g or per 100 ml of food of the foods on per package if the package contains only a single portion. In addition, the energy value should also be given for each serving of the food as quantified on the label. Beside kcal, energy value may also be expressed as kJ.
- The amount of protein, carbohydrate and fat should be expressed as g per 100 g or per 100 ml of the food or per package if the package contains only a single portion. In addition, the amount of these nutrients in the food should also be given for each serving of the food as quantified on the label.
- Vitamin and mineral can only be declared if they meet the following requirements:

  - Only vitamins and minerals listed in the Nutrient Reference Value (NRV) can be declared on a food label. Other vitamins and minerals must have prior written approval of the Deputy General of Health (Public Health), Ministry of Health Malaysia, before they can be declared on the label.
  - Vitamins and minerals must be present in significant amounts before they can be declared on the food label. In the other words, the vitamin and mineral content must be at least 5% f the NRV per serving
- Dietary fiber can be declared on the label, expressed as per 100 g or per 100 ml, or per package if the package contains only a single portion. In addition, this information should be given per serving as quantified on the label.
- Cholesterol and sodium may be declared on the label, expressed in mg per 100 g or per 100 ml, or per package if the package, contains only a single portion. In addition, this information should also be given per serving as quantified on the label.
- Where a claim is made regarding he amount or type of fatty acids, the amount of all the four main types of fatty acids, namely saturated, monounsaturated, polyunsaturated and trans fatty acids shall be declared in gram.

4.2. Singapore

In line with the policy of the National Healthy Lifestyle Program, the Ministry of Health (MOH) of Singapore implemented the nutrition labeling program since 1998 to encourage the food industry to display the nutrition panel in order to educate consumer in reading food labels. The Health Promotion Board (HPB) is the statutory board of the MOH which administers this nutrition labeling program and one of the program is the Healthier Choice Symbol (HCS).

Products carrying the HCS are generally lower in total fat, saturated fat, sodium and sugar. Some are also higher in dietary fibre and calcium compared to similar products within the same food category. Each food category has a separate set of nutritional criteria to adhere to. For example, breads displaying the HCS should contain no trans fat, less sodium (450 mg/100g) and more dietary fiber (3g per 100g) compared to the regular bread. 3-in-1 coffee sachets, on the other hand contains no trans fat, less saturated fat (0.6 g/100ml) and less sugar (5 g/100ml) compared to regular 3-in-1 coffee powders. Further information of HCS related to health claim is elaborated in Chapter 10.

The Food Regulations of Singapore require nutrient declaration in an acceptable nutrition information panel, for pre packed foods. Declaration of other nutrients is mandatory when such nutrients are the subject of a nutrition claim. The information to be declared in the panel includes the energy, protein, fat and carbohydrate contents of the food.

- Mandatory nutrition labeling only required for foods enriched or fortified with permitted vitamins, mineral, essential amino acids and fatty acids. It also required for special purposes foods such as infant formula.
- NIP (nutrition information panel) includes 8 cores nutrients expressed in per serving and per 100g/ml : energy, protein, total fat and saturated fat, cholesterol, CHO, dietary fiber and sodium

Foods claimed to be a *source of energy* are required to state on their labels the quantity of that food to be consumed in one day, which should yield at least 300 kcal. The labels should also include an acceptable nutrition information panel.

Foods claimed to be a source or *an excellent source of protein* should include on the label the quantity of that food to be consumed in one day, and an acceptable nutrition information panel. To claim as a source of protein, at least 12% of the total calorie yield of the food should be derived from protein. To claim as an excellent source of protein, at least 20% of the total calorie yield of the food should be derived from protein. In addition, the amount of food stated on the label as the quantity to be consumed in one day should also contain at least 10g of protein.

Examples of the daily recommendation statement are
"Recommended daily intake: 3 servings";
"Add 20g powder in 200ml water. Drink 2 times daily."

Nutritional claims are permitted in Singapore:

- nutrient content claims
- nutrient comparative claims
- nutrient function claims (based on the available scientific evidence) : can be positive nutrient claims is a present in an amount that is at least 1/6 of the daily allowance and negative nutrient function claim should only be present in a "low" amount, or less, not imply that the nutrient is a cure/treatment for the disease or gives protection from disease.

4.3. Philippines

The Philippines has adopted the Codex guideline on the use of Health and Nutrition Claims for food since 2007. Mandatory labeling for limited number of foods including enriched or fortified foods.

Nutrients such as vitamin and minerals are expressed as % of the Philippines RDA core nutrients include energy, protein, CHO, fat and sodium expressed in per 100g/ml or per serving

Other nutrients should be declared if a claim is made. All nutrient quantities should be declared in usual serving size. Two types of claims health and nutritional:

- nutrient content claims
- structure function claims: 12 claims

4.4. Thailand

The food regulation of Thailand does not require mandatory nutrition labeling for food products. The regulations on nutrition labeling are based on the Ministerial Notification No. 182 of B.E. 2541 (1998) and No. 219 of B.E. 2544 (2001). However, nutritional labeling is mandatory for the following types of food :

- Food making a specific nutritional claim;
- Food which makes use of nutritional values in sale promotion;
- Food stating specific groups of consumers for sale promotion e.g. students, executives, elderly people, etc;
- Other foods as prescribed by the Food and Drug Administration with the approval of the Food Committee.

Exemptions from these nutrition-labeling regulations (as defined in Ministerial Notification No. 182) are infant food, supplementary food for infants and children and other types of food for which labeling requirements have been otherwise regulated; food not directly sold to consumers; and food packed in small containers, which aims to be repacked and sold in a larger container. Nutrition labeling must be presented in Thai and a foreign language is optional.

1. The full format of label include listing 15 nutrients expressed per serving of the food and as % of the Thai RDI namely calories and calories from fat, total fat and saturated fat, cholesterol, protein, total CHO and dietary fiber, sugar, sodium, vitamin A, B1 and B2, calcium and iron and nutrient as claimed. Nutrient expressed based on per serving size.

There are three types of nutrition and health claims: nutrient content claims “source of”, comparative claim “more than”, nutrient function claim “. And there are no messages of prevent and cure any disease (no health claim).

Nutrition Data

One serving : .....(.....)

Quantity of serving per .... : .....

Nutrition value per one serving

Total energy .....kilocalories (energy from fat .....kilocalories)

	Percentage of Daily Recommended Quantity*
Total fat .....g	.....%
Saturated fat ....g	.....%
Cholesterol .....mg	.....%
Protein .....g	.....%
Total carbohydrate .....g	.....%
Fiber .....g	.....%
Sugar .....g	.....%
Sodium .....g	.....%

Percentage of Daily Recommended Intakes*

Vitamin A	.....%	Vitamin B1	.....%
Vitamin B	.....%	Calcium	.....%
Iron	.....%		

*Percentage of Thai recommended daily intakes (Thai RDI) based on the demand of energy of 2,000 kilocalories.

The need of energy of each person is different. The person who needs energy of 2,000 kilocalories daily should receive nutrients as follows:

Total fat	less than	65 g
Saturated fat	less than	20 g
Cholesterol	less than	300 mg
Total carbohydrate		300 g
Fiber		25 g
Sodium	less than	2,400 mg

Energy (kilocalorie) per gm : Fat = 9; Protein = 4; Carbohydrate = 4

Figure 11. Example of nutrition data of Thailand

4.5. Indonesia

Indonesian version	English version
INFORMASI NILAI GIZI	**NUTRITION INFORMATION**
Takaran saji ..... (URT) ..... (g/ml) Jumlah sajian per Kemasan :	One serving ..... (URT) ..... (g/ml) Quantity of serving per package: ....
JUMLAH PER SAJIAN **Energi Total .....kkal** Energi dari Lemak ... kkal Energi dari Lemak jenuh ... kkal	**Nutrition value per one serving** **Total energy ..... kilocalories** Energy from fat ... kilocalories Energy from saturated fat ... kilocalories
% AKG*	**Percentage of Daily Recommended Quantity***
Lemak Total .....g .....%	Total fat .....g .....%
Lemak Jenuh .....g .....%	Saturated fat .....g .....%
Lemak tidak jenuh tunggal .....g	Monounsaturated fat .....g
Lemak tidak jenuh ganda .....g	Polyunsaturated .....g
Lemak Trans .....g	Trans fat .....g
Kolesterol .....mg .....%	Cholesterol .....mg .....%
Protein .....g .....%	**Protein .....g .....%**
Karbohidrat Total .. .. g .....%	**Total carbohydrate .. .. g .....%**
Serat Pangan .....g .....%	Fiber .....g .....%
Serat pangan larut .....g	Soluble fiber .....g
Serat pangan tidak larut .....g	Unsoluble fiber .....g
Gula .....g	Sugar .....g
Gula alkohol .....g	Alcohol sugar .....g
Karbohidrat lain .....g	Other carbohydrate .....g
Natrium .....mg .....%	**Natrium .....mg .....%**
Kalium .....mg .....%	**Kalium .....mg .....%**
Vitamin A .....%	Vitamin A .....%
Vitamin C .....%	Vitamin C .....%
VitaminLain .....%	OtherVitamin .....%
Kalsium .....%	Calcium .....%
ZatBesi .....%	Iron .....%
Mineral Lain .....%	Otherminerals .....%
* Persen AKG berdasarkan kebutuhan energi 2000 kkal. Kebutuhan energi anda mungkin lebih tinggi atau lebih rendah.	* Percent daily value are based on 2000 kilocalories. Your daily values may be higher or lower depending on your calories need

Figure 10. Example of nutrition information of Indonesia (Badan POM, 2004)

The National Agency of Food and Drug Control Republic Indonesia provides guideline on nutrition information for prepackaged food particularly foods which are enriched/fortified with vitamin and minerals according to the law. The guideline indicates nutrients items which mandatory be claimed such as total energy, total fat, protein, total carbohydrate and sodium (BPOM, 2005, 2011). . Other mandatory nutrient under specific circumstance are energy derived from fat, saturated fat, trans fat, cholesterol, fibre, sugar, Vit A, Vit C, Calcium, Iron. The guidelines also applicable to voluntary labeling of other types of foods with some required information as the following:

Serving size in household measurement- number of servings per pack

- energy content, expressed in cal per serving
- protein content, expressed in metric units per serving
- CHO content, expressed in metric units per serving

- fat content, expressed in metric units per serving
- sodium content, expressed in metric units per serving
- breakdown of the % NRV derived from fat, protein, CHO and sodium
- vitamins and minerals, expressed in % NRV per serving
- amounts of other nutrients for which a claim is made, expressed in metric units
- other nutrients which are considered relevant for preservation of good nutritional status
- other nutrients must be declared when their contents reached certain amounts determined by the regulation:
- energy from fat (>4.5 cal), saturated fat content (>0.5 g), trans fat contents (>0.5 g), cholesterol content (>2g), dietary fiber content (>0.5g), sugar contents (>1g). These nutrients must be expressed in g per serving.
- vitamin A (>2% NRV), vitamin C (>2% NRV), calcium and iron contents (>2%NRV), expressed in % NRV.
- other nutrients that must be declared under special circumstances

4.6. JAPAN

Labeling of functional foods is considered important for both consumers and producers. Through labeling, consumers can understand the features, contents, and usage of the foods and then choose the proper foods for them using the information provided on the label. With more public information on health benefits of food than ever before, consumers' interest in health issues has become a leading factor in their purchasing decisions. Manufacturers can emphasize the characteristics of their products and thus promote sales by the labeling or claims made. Therefore, the labeling should be clear and correct and avoid any chance of misinterpretation. The labeling of health claims on foods should always be based on scientific evidence.

Food labels with health claims should meet the following conditions:

1) be consistent with the national nutritional goal and public health policy
2) prove that the food is useful for supplying nutrition or specified health effect
3) be based on acceptable scientific data and be a simple as well as an understandable expression,
4) offer appropriate information to the consumer
5) declare attention and warning, including appropriate intake, to prevent adverse effects on health from overdose
6) fit under the Food Sanitation Law, Health Promotion Law, and other related laws, and
7) avoid confusion with drugs and not provide labels that imply prevention, treatment, and diagnosis of human disease.

Labeling of nutrient function should be based on internationally recognized findings, i.e., examples of nutrient function claims include a reference to the Codex Alimentarius (CAC/GL23) and should be easy to understand for consumers. Food labels with health claims also require attention and warning of intake ranges consistent with safe

consumption. Attention and warning should also be provided on labels for every nutrient including information concerning excess intake of the product. A message giving the recommended consumption should be provided. For instance, for vitamin A, it must be stated that women who are pregnant should be careful of excess intake. Similarly, for folic acid, it should be stated that folic acid is a nutrient that contributes to the normal growth of the fetus but does not improve the growth of fetus with excess intake.

Documentation required for application to MHLW for FOSHU status for a product sample of the entire package with labels and health claims are ;

- Documentation that demonstrates clinical and nutritional proof for the product and/or its functional component for the maintenance of health
- Documentation that demonstrates clinical and nutritional proof of the intake amount of the product and/or its functional component
- Documentation concerning the safety of the product and its functional component, including additional human studies about the eating experience
- Documentation concerning the stability of the product and its functional component
- Documentation of the physical and biological characteristics of the product and the functional component
- Methods of qualitative/quantitative analytical determination of its functional component, and analytical assay results of the component in the product
- Report on the analysis of the designated nutrient constituents and energy content of the product
- Statement of the production method, list of factory equipment, and an explanation of the quality control system

(source: -Yamada, et al., ,Health claim evidence requirements in Japan. J. Nutr. 2008;138 (Suppl): S1192)

4.7. Republic of China

China's Ministry of Health released the National Food Safety Standard for Nutrition Labeling of Prepackaged Foods (GB 28050-2011). This standard prescribes the basic principles and requirements for the nutrition labeling and claims on pre-packaged foods directly offered to consumers. The standard also applies to the description and explanation of nutrition information on nutrition labeling of pre-packaged foods.

Mandatory labeling items regulated by the standards:

1. Energy value and core nutrient content and their percentages in NRV (nutrient reference value) are mandatory labeling items on a nutrition label. When there are other nutritional components to be claimed, appropriate measures shall be taken to highlight the claims of energy and core nutrients.
2. As to the nutrition claim or nutrient function claim for other nutritional components other than energy and core nutrients, the contents of the nutritional components and their percentages of NRV shall be listed in the Nutrition Information.
3. The content of trans-fat (fatty acid) shall be listed in the Nutrition Information if ingredients contain hydrogenated fat and (or) partial hydrogenated fat, or it/they are used in the production process.
4. As to the nutritional components with no specified NRV, only content shall be claimed.

Optional Labeling Items regulated by the standards :

1. Other nutritional components such can also be listed in the Nutrition Information besides the mandatory labeling items.
2. A nutritional component in the food, if in compliance with the content requirements and restrictive conditions is subject to the content claim. Any nutritional component can use the comparative claim if its content is in compliance with the content requirements and restrictive conditions. When a nutritional component meets both the requirements of the content claim and that of the comparative claim, it may be claimed by using both claims or only use the content claim.

The prepackaged foods listed below are exempt from mandatory nutrition labeling requirements:

- Fresh food, such as packed raw meat, raw fish, raw vegetables and fruits, eggs, etc;
- Alcoholic beverages that contains 0.5% or more alcohol;
- Packaged food with total surface area ≤100 cm2, or the largest surface area of the package ≤20 cm2;
- Non-pre-packed food sold on the site where it is produced;
- Bottled drinking water;
- Prepackaged foods of daily intake amount ≤ 10g or 10ml;
- Other prepackaged foods exempted from nutrition labels according by other laws, regulations or rules;
- Pre-packaged foods that are exempt from mandatory nutrition labeling shall follow this Standard if it labels any nutrition information in its product packaging,

4.8. USA, CANADA AND LATIN AMERICA

United State of America (USA)

Nutrition labeling of all prepackage foods was previously voluntary. It becomes mandatory since the implementation of the Nutrition Labeling and Education Act (NLEA) of 1990 (implemented 1994). Subsequently, as a means of "promoting healthy dietary practices" the law required a "nutrition facts" panel to be printed on all prepackaged foods (Figure 11), including nutrients associated with diet-related disease. Under the label's "Nutrition Facts" panel, manufacturers are required to provide information on fifteen core components. More recently, the Food and Drug Administration (FDA) issued a regulation requiring manufacturers to list *trans*fatty acids on the nutrition facts panel (WHO, 2004).

NLEA permits a simplified label format for foods that contain insignificant amounts of seven or more major nutrients. "Insignificant" means that a declaration of zero could be made in nutrition labeling, or, for total carbohydrate, dietary fiber, and protein, the declaration states "less than 1 g". The simplified label, commonly used on vegetable oils and

soft drinks, must include the serving size, total calories, total fat, sodium, total carbohydrates and sugars, and protein (Figure 12).

Canada

Canada applies the mandatory labeling system in January 2003, replacing a voluntary system (which had required labeling when a nutrition claim was made). This application aim at "helping Canadians make informed choices for healthy living" the regulations require most prepackaged food labels to list calories and 13 nutrients (Figure 13) (WHO, 2004)

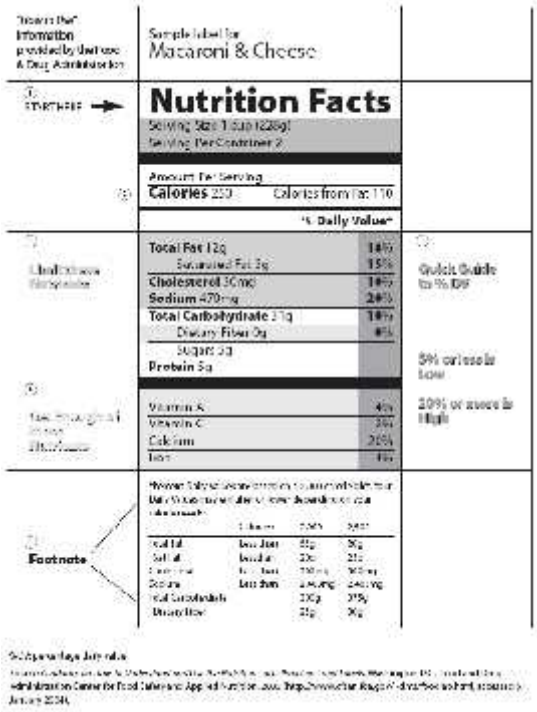


Figure 12.Example labeling USA

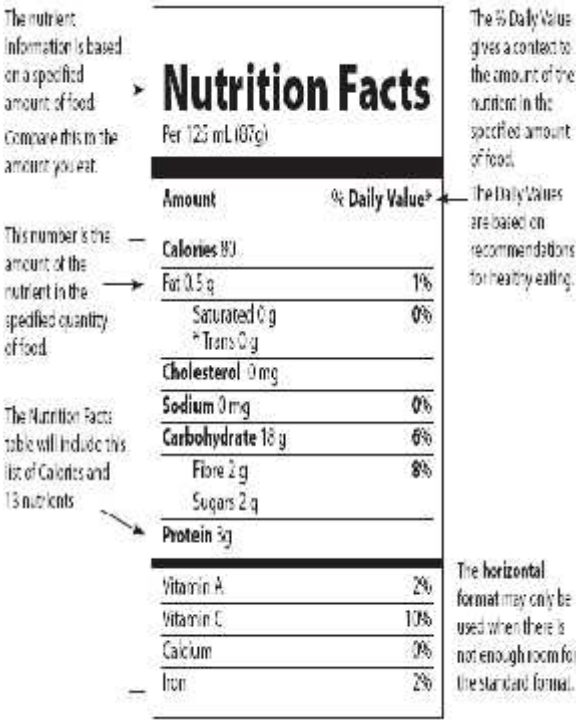


Figure 13. Example labeling Canada

Figure 14. Example of simplified format of USA

Latin America

Regulations in Latin American vary from no regulations on nutrition labeling (e.g. El Salvador, Guatemala) to mandatory labeling (Brazil). Argentina, Paraguay and Uruguay currently require labeling on prepackaged food under the requirements of the MERCOSUR, when a nutrition claim is implemented. The mandatory of nutrition labeling under the MERCOSUR in 2003, is started to be implemented across all four member countries in 2006. Unlike Venezuela, nutrition labels are required only on foods with special dietary uses. Nutrition labeling in Chile is voluntary unless a nutrition claim is made. This regulation is similar with Mexico that instituted new regulations in 1999 requiring labeling when a nutrition claim is made (WHO, 2004).

4.9. Austria - New Zealand

- A number of features of the new Code relate specifically to labeling and include: warning and advisory statements; ingredients lists; date marking; directions for use and storage; nutrition information; legibility requirements; and percentage labeling.
- One of the key features of the Joint Code is the requirement for most packaged foods to bear a nutrition information panel (NIP).
- Information must be presented on the amount of fat, saturated fat, protein, energy, carbohydrates, sugars and sodium.
- For the majority of foods the label is the first and only source of information regarding the nutritional content of food purchased.
- Mandatory nutrition labeling will ensure that consumers are provided with key nutritional information about foods.
- Single ingredient produce such as fruit and vegetables, and some other foods such as spices, tea and coffee will be exempt.
- The new requirements will give consumers more nutritional information to allow product comparison.
- All products will be required to provide information on these nutrients on both a per 100 g basis and in terms of an average serving. In addition to the mandatory nutrient declarations NIP are also required to carry additional data for any substance for which a nutrition claim is made. During the 2-year transition period to December 2002 ANZFA will be working with industry, enforcement agencies and consumers to help to ensure that there is a smooth transition to the Joint Food Standards Code.

4.10. Europe

The European Commission established Council Directive 90/496/EEC on nutrition labeling for foodstuffs in 1990. Te Directive required Member States to make nutrition labeling optional, except in cases where a nutrition claim was made. The objective: to facilitate the smooth functioning of the internal European Union market, and to provide consumers with the information needed to choose a more healthful diet. Food

manufacturers also apply nutrition labels on a voluntary basis Throughout Europe. The European Commission is currently considering a new regulation that would make nutrition labeling mandatory. According to the consultation document issued by the Commission: *"Given growing consumer interest in food, nutrition and its relation to health… it is timely to reconsider whether nutrition labeling should not be provided on all foodstuffs, and even in the absence of a nutrition claim" (WHO, 2004).*

5. USE OF RDA/NRV FOR THE APPLICATION OF NUTRITION LABELING

1. RDA or RDI is the amounts of selected nutrients considered adequate to meet the known nutrient needs of healthy people.
2. RDA/RDI should reflect current scientific judgment on nutrient allowances for growth and maintenance of good health for all.
3. Nutrient Reference Value (NRV) :
   - established by Codex as a set of nutrient values for nutrition labeling and intended to assist consumers to evaluate the contribution of a food to their daily nutrient intake and to compose a diet suitable for their individual needs
   - for labeling purposes in the interest of international standardization and harmonization
   - various countries have developed or adopted their own NRVs, maybe under different terminologies
4. RDA versus NRV
   - RDAs or RDIs differ from country to country
   - different for gender , age group
   - difficult to express % of nutrients against RDAs or RDIs
   - food manufactures need to change the values for comparison for different countries
5. National nutrition labeling reference
   - same set of values regardless of age and gender in the country
   - for nutrition labeling purpose only
   - may be different for different countries
6. NRVs (Codex reference) -> only Malaysia use it
   - established by CODEX
   - same set of figures to be used globally
7. Use of Reference value for Labeling
   - Some countries uses RDAs : different sets for RDA for different population
   - Some countries use Reference value which are different from RDAs : US, Singapore
   - Some countries use NRVs developed by CODEX
8. Using RDAs/RDIs/National NRVs
   - different values for different countries
   - in same country :different set of RDAs for different age group and gender
     - Which number to use NRVs/DVs?
     - the highest across all age groups and gender?

- use EAR instead as suggested by IOM, not higher level but if higher level everyone can meet the requirement
- setting up NRVs for products specifically targeted at consumption by specific consumers groups

9. Issues to Consider
   - Food industry can propose NRVs to regulatory agencies in some countries (eg, Malaysia) : Nutrient and its function; Proposed level Scientific justification
   - Difficult to fulfill for products sold in multiple countries (eg.cabdies, chocolates, etc)

Source: Lecture's note of NFI course, Pauline Chan (2008)

REFERENCES

Codex Guidelines on Nutrition Labeling by Codex Allimentarius Commissions as its 16thSession ,1985.

Codex Guidelines on Nutrition Labeling, Rev.1_1993. Rome, Food and Agriculture Organization of the United Nations / World Health Organization, 1993 (CAC/GL 2_1985).

Guide to nutrition labeling and claims (food Safety and Quality Division Ministry of Health Malaysia), 2007

Hawkes, D. Nutrition Labels and Health Claims: The Global Regulatory Environment. WHO. 2004

Yamada K, Sano-Mino-N, Nagata J and Umegaki K. Health claim evidence requirements in Japan. J. Nutr. 2008;138 (Suppl): S1192-8

Chan P. Lecture's note of Nutrition in Food Industry course, SEAMEO-TROPMED RCCN UI, 2008

Direktorat Standardisasi Produk Pangan. Pedoman Pencantuman Informasi Nilai Gizi Pada Label Bahan Pangan. Badan Pengawas Obat dan Makanan Republik Indonesia. 2004.

Ee Siong, Tee. Nutrition labelling: purpose, scientific issues and challenge. Asia Pacific Journal of Clinical Nutrition. Volume 11, Issue 2, pages S68–S71, June 2002

Peraturan kepala badan pengawas obat dan makanan Republik indonesia nomor hk.03.1.23.11.11.09605 tahun 2011 Tentang perubahan atas peraturan kepala badan pengawas obat dan makanan nomor HK.00.06.51.0475 tahun 2005 tentang Pedoman pencantuman informasi nilai gizi pada label pangan

National food safety standard General Rules for the labeling of prepackaged foods. Ministry of Health. People Republic of China GB7718-2011

Guide to nutrition labeling and claims (food Safety and Quality Division Ministry of Health Malaysia), 2007.

A Guide to Food Labelling and Advertisements. A publication of the Agri-Food & Veterinary Authority, Singapore. First published Feb 2010. Amendments Oct 2011 and Oct 2013

CHAPTER 10

NUTRITION AND HEALTH CLAIMS AND ITS SUBSTANTIATION

By Rina Agustina, D. N. Iswarawanti and Evi Ermayani

LEARNING OBJECTIVES:

This chapter describes about the nutrition and health claim regulated by CODEX and its application in various countries. Upon completion, you will understand:

- Definition of nutrition and health claim
- CODEX guidelines on nutrition and health claim
- Application of nutrition and health claim in various countries

This chapter also explores the global overview of scientific substantiation of claim which upon completion you should understand various guidelines and approach from one region and another.

SUBJECT CONTENTS:

1. DEFINITIONS

Generally, claim is define as follows:

- Any statement (or suggestion, or implication) that a food has a particular property
- A way to inform consumers about the properties of the product
- A marketing tool that could confuse consumers
- A way to encourage people to eat a healthy diet and live life to the full

There are many definitions on health and nutrition claims. At least Codex Alimentarius Guidelines and IADSA give term for nutrition and health claims as follows

Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:

(a) The mention of substances in the list of ingredients;

(b) The mention of nutrients as a mandatory part of nutrition labeling;

(c) Quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

Nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: “source of calcium”; “high in fiber and low in fat”.)

Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods. (Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

- ***Nutrient function claims*** – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

  Example:

  "Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

- **Other function claims** – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

  Examples:

  "Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

- **Reduction of disease risk claims** – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition. Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

  Examples:

  "A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A.""A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A."

Structure and/or function claims describe the role of a nutrient or dietary ingredient intended to affect a structure or function in humans. In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, or they may describe general well-being from consumption of a nutrient or dietary ingredient.

A medicinal claim is a claim that states, suggests or implies that a food or a food component (including a nutrient) has the property of treating, preventing or curing human disease, or makes references to such a property. These claims are prohibited in the labelling and advertising of food products.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors, and presentation of risk reduction claims must

ensure, by use of appropriate language and reference to other risk factors, for example, that consumers do not interpret them as prevention claims.

Generic health claims refer to those claims based on well-established, generally accepted knowledge from evidence in the scientific literature and/or to recommendations from nationally or internationally recognized public health bodies. A generic claim may be relevant for complying diets, foods or food components. A complying food or food component comprises or contains the functional component in sufficient quantity to produce the claimed effect(s), or falls within the category of foods to which the generic claim applies.

Product-specific claims refer to any claim that a relationship exists between a specific food or food component and health. This type of claim concerns the health-promoting effect of the product itself. The food or food supplement must have been designed to provide a specific and documented effect.

A health claim for food is also considered to be ''any representation in labeling and advertising that states, suggests, or implies that a relation exists between the consumption of foods or food constituents and health'' (1) which advertising means any commercial communication to the public, by any means other than labeling, in order to promote directly or indirectly, the sale or intake of a food through the use of nutrition and health claims in relation to the food and its ingredients. Any nutrition and health claims must be accepted by or be acceptable to the regulatory authorities of the country where the product is sold. The health claims should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practices.

2. APPLICATION OF NUTRITION AND HEALTH CLAIM IN VARIOUS COUNTRIES

2.1. Health and Nutrition Claims in Indonesia

Monitoring and regulation about health and nutrition claims in Indonesia are administered under Badan POM (The national Agency for Food and Drug Control). Based on the regulation there are 3 types of claim:

- Nutrition claim: nutrition content claim and nutrition comparation claim
- Health claims: Nutrition function claim, other function claim,
- Glycemix Index claim: disease risk reduction claim

To get the goal of monitoring, the agency establish an expert team called tim Mitra Bestari who work through over the claims and give recommendation related to claims and usage of new component. Guidance or standard about those claims is regulate in Decree of head of Badan POM RI no HK. 03.1.23.11.11.09909 year 2011 about Monitoring of claim in labelling and advertisement of food processing.

2.2. Health and Nutrition Claims in USA

There are four (4) kind of health claims permitted in USA:

1 ***Health claims***: describes a relationship between a food, food component or dietary supplement ingredient and reducing risk of a disease or health related condition and

approved 12 claims

2 ***Qualified health claims***: describes a relationship between a food, food component or dietary supplement ingredient and reducing risk of a disease or health related condition, include disclaimer.
FDA may allow qualified health claims to be made when the evidence is not well enough established to meet the significant scientific agreement standard required for FDA, include disclaimer

3 ***Structured function claims***: describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans

4 Nutrient content claims

However, there are three categories of claims which currently be used on food and dietary supplement labels in the United States namely: 1) health claims, 2) nutrient content claims, and 3) structure/function claims.

Health claims are authorized under the NLEA of 1990. Health claims describe a relation between a food, food component, or dietary supplement ingredient and reducing risk of a disease or health-related condition. An example of an NLEA-approved health claim is ''Food containing 0.7 g or more of Plant Stanol Esters per serving eaten two to three times a day with meals may reduce the risk of heart disease as part of a diet low in saturated fat and cholesterol. A serving of BENECOL_ Spread contains 1.7 g of Plant Stanol Esters.''

A second claim category is **nutrient content claims**. Such claims are used to describe the percentage of a nutrient in a product relative to the daily value (DV). The DV indicates the amount of a nutrient that is provided by a single serving of a food item. An example of a nutrient content claim is ''good source of calcium.'' To state that a product is a ''good source'' of calcium, this nutrient must provide 10% of the DV. To say ''excellent'' source, calcium must be 20% of the DV.

The last categories, structure/function claims were authorized under the Dietary Supplement Health and Education Act of 1994. Such statements describe the effect of a dietary supplement on the structure or function of the body. An example of a structure/function claim is ''helps promote bone health.'' Such claims do not require pre-approval by the FDA before being used on labels and must be accompanied by the following disclaimer: ''this statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.''

The food and Drugs Administration (FDA) approved some health claims for food labeling (Hasler, 2008) namely:

1. Dietary saturated fat and cholesterol and risk of CHD
2. Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of CHD
3. Sodium and hypertension
4. Dietary lipids (fat) and cancer
5. Fiber-containing grain products, fruits, and vegetables and cancer
6. Fruits and vegetables and cancer
7. Calcium and osteoporosis

8. Folate and neural tube defects
9. Whole oat soluble fiber and CHD
10. Sugar alcohol and dental caries
11. Psyllium seed husk and CHD
12. Soy protein and CHD
13. Sterol and stanol esters and CHD
14. Oatrim and CHD
15. Barley soluble fiber and CHD

Table 21. Scientific Substantiation Supporting Currently Approved Health Claims

Diet–Disease Relation	Clinical Trial Support	Allowed Health Claim	Effective Level
Whole oat soluble fiber and CHD	37 submitted 33 reviewed1 17 priority2	Diets low in saturated fat and cholesterol that include soluble fiber from whole oats may reduce the risk of heart disease.	3 g/d; 0.75 g/serving 4 times/d
Psyllium seed husk soluble fiber and CHD	21 submitted 21 reviewed 7 priority	• Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. • A serving of [name of food] supplies [x] grams of the soluble fiber necessary per day to have this effect.	7 g/d; 1.7 g/serving 4 times/d
Oatrim and CHD	5 submitted 1 reviewed	Diets low in saturated fat and cholesterol that include soluble fiber from Oatrim may reduce the risk of heart disease.	0.75 g/serving
Barley soluble fiber and CHD	11 submitted 5 reviewed	• Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. • A serving of [name of food] supplies [x] grams of the soluble fiber necessary per day to have this effect.	3 g/d
Soy protein and CHD	43 submitted 41 reviewed 14 priority	Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides 6.25 grams of soy protein.	25 g/d; 6.25 g/serving
Plant sterol esters and CHD	15 submitted 9 reviewed 8 priority	Plant sterols: Foods containing at least 0.65 grams per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 1.3	1.3 g/d; 0.65 g/serving

Diet–Disease Relation	Clinical Trial Support	Allowed Health Claim	Effective Level
		grams as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [x] grams of vegetable oil sterol esters.	
Plant stanol esters and CHD	24 submitted 15 reviewed 14 priority	Plant stanol esters: Foods containing at least 1.7 grams per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [x] grams of plant stanol esters.	3.4 g/d; 1.7 g/serving

[1] The FDA conducts its own independent review of the literature.

[2] The FDA excludes studies that do not meet crucial study design criteria.

Source: Hasler (2008)

Table 22. Scientific Ranking and Proposed Qualifying Language for Qualified Health Claims

Level of Scientific Evidence	FDA Category	Proposed Qualifying Language
High	A	Category A health claims are unqualified claims that meet the significant scientific agreement standard
Moderate/good	B	"Scientific evidence suggests but does not prove."
Low	C	"Some scientific evidence suggests; however, FDA has determined that this evidence is limited and not conclusive"
Lowest	D	"Very limited and preliminary scientific research suggests; FDA concludes that there is little scientific evidence supporting this claim."

Source: Hasler (2008)

2.3. Health Claims in Canada

Specific health claims are claims about the effects of a food, or food constituent, on a specific organ, disease, biomarker, or health condition.

There are 2 types of specific health claims:

- Disease risk-reduction claims:
  Link the consumption of foods or food constituents to a reduced risk of disease in the context of the total diet (considered drug claims under the FDR).
- Function claims:
  claims about the maintenance of body functions that are necessary to the maintenance of good health and normal growth and development (e.g., nutrients with well-established functions); claims about maintaining or supporting body functions associated with the

maintenance of good health or performance (e.g., for a broader range of substances in foods and to a broader range of physiological functions); and claims about restoring, correcting, or modifying body functions (functions that are considered drug claims under the FDR).

General health claims are claims that do not refer to a specific health effect, disease or health condition (e.g., broad "healthy for you" or "healthy choice'" claims that promote choosing a food for overall health, promote healthy eating, or provide dietary guidance). (L'Abbe´ et. Al, 2008).

Table 27. Mechanism for Review and Approval of Health Claims in Canada and in Selected Other Countries1

Region	Type of Claim			
	Disease Risk Reduction Claims	Claims for Established Functions of Known Nutrients	Other Function Claims	General Health Claims about "Healthy Choice'"
CANADA	Approved claims for diseases require claim-specific authorization or amendments to regulations or standards; FDA can also accept claims based on authoritative statement from government bodies or the National Academy of Sciences. Food bearing the claim must meet specified requirements.	Claims are permitted by general regulatory provisions without the need for authorization or claim-specific amendments to regulations. Examples of acceptable claims are provided in guideline	For a health claim that would bring a food within the definition of a drug, a claim specific regulatory amendment of FDR is required. For a health claim that would not bring a food within the definition of a drug, regulatory amendment of FDR is not required.	Guidelines are provided for the use of claims about "healthy choice'" that would not be considered misleading.
USA	Approved claims for diseases require claim-specific authorization or amendments to regulations or standards; FDA can also accept claims based on authoritative statement from government bodies or the National Academy of Sciences. Food bearing the claim must meet specified requirements.	There is no specific regulation or other form of positive listing governing the use of function claims for food. However, they must be truthful and not misleading and be derived from the nutritional value of the product.	As above	Claims using descriptors such as "healthy'" or about a food being useful in maintaining healthy eating practices are prohibited unless provided for in regulation.
EU	Approved claims for diseases require claim-specific authorization or amendments to regulations or standards; FDA can also accept claims based on	Positive lists will be used without the need for community authorization through Regulatory amendments (except for claims related to	As above. Application for inclusion in the Community list by submitting a full dossier is required when a	Implied nutrition or health claim may be made only if accompanied by a permitted

Region	Type of Claim			
	Disease Risk Reduction Claims	Claims for Established Functions of Known Nutrients	Other Function Claims	General Health Claims about "Healthy Choice'"
	authoritative statement from government bodies or the National Academy of Sciences. Food bearing the claim must meet specified requirements.	children's development and health). Claims will be included in a Community list of permitted health claims based on generally accepted scientific evidence following consultation with the European Food Safety Authority.	claim is based on newly developed scientific knowledge and/or when the protection of verifiable proprietary data is requested.	specific claim.
FSANZ	Approved claims for diseases require claim-specific authorization or amendments to regulations or standards; FDA can also accept claims based on authoritative statement from government bodies or the National Academy of Sciences. Food bearing the claim must meet specified requirements.	Claims that meet the criteria for general level claims and are not on a list of preapproved nutrient function statements do not require premarket review, provided supporting data are available on request.	For claims that are considered general-level claims (including Enhanced function claims that refer to risk reduction of nonserious diseases), an approach similar to that for established function claims for known nutrients has been proposed.	Proposed that conditions for claims about dietary information be specified in the Food Standards Code.

Source: ILSI (2005)

2.4. Nutrition and Health Claims- Australia and New Zealand

This bi-national government agency develops food standard code including nutrition and health claims. In this region, nutrition content claims states about the content of specific nutrients in a food meanwhile health claims refer to an alliance between food and health rather than statement of content. There are 2 kind of nutritional and health claims:

- general level claims : nutrition claims and general level health claims
- high level claim : biomarker claim, risk reduction claims

- For general level claims -> no need pre-approval (once meet the criteria the product can be disseminated, but the authority will check someday), but for high level claims need pre-market assessment and approval
- Experts have reviewed 7 high level claims

In constructing a health claim, industries also have to meet other standard called Nutrient Profiling Scoring Criterion (NPSC). The NPSC set out standard for foods which could be claimed.

In January 2013, The board of FSANZ establish standard 1.2.7 on nutrition, health and related claims which consist of framework and general principles, claim requirements and the endorsement. (FSANZ, 2013). This standard will help the region to:

- reduce the risk of misleading and deceptive claims about food
- expand the range of permitted health claims
- encourage industry to innovate, giving consumers a wider range of healthy food choices
- provide clarity for the jurisdictions enforcing the Standard (www.foodstandards.gov.au).

2.5. Health Claim in Europe

Two types of claims:

- type A-enriched function claims , similar to structure/function claims in US
- type B-reduction of disease risk claims, similar to health claim in the US

Table 28. Categories of Health Claims in the European Regulation

Article 13 Health claims other than those referring to the reduction of disease risk and to children's development and health 13.1 Health claims describing or referring to: (a) the role of a nutrient or other substance in growth, development, and the functions of the body; or (b) psychological or behavioral functions; or (c) without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or the reduction of available energy from the diet 13.5 Claims based on newly developed scientific evidence and/or that include protection of proprietary data
Article 14 Reduction of disease risk claims and claims referring to children's development and health

Source: Asp, Nils-Georg and Bryngelsson S (2008)

2.6. Food with Health Claims in Japan

The Japan government enacted a new regulatory system called 'Foods with health claims' in April 2001, which consists of 'Foods for Specified Health Use' (FOSHU) and 'Foods with Nutrient Function Claims' (FNFC).

Health claims on FOSHU must not express medical claims such as ''prevent,'' ''cure,'' ''treat,'' and ''diagnose.'' Here are some examples of permitted and non permitted claims for human diseases:

1. Maintain or improve a marker determined by self diagnosis or health check-up. An example of a permitted claim is ''this product helps to maintain normal blood pressure, blood sugar, or cholesterol.'' An example of a non-permitted claim is ''this product improves hypertension.''

2. Maintain physiological function and organ function of the human body in good condition or improve them. An example of a permitted claim is ‘‘this product enhances the absorption of calcium’’ or ‘‘this product helps to improve the movement of the bowel.’’ An example of a non permitted claim is ‘‘this product is an effective food for intoxication’’ or ‘‘Enhances fat metabolism.’’
3. Improves the occasional change of body condition but not a chronic change. Permitted claims include ‘‘this product is good for or helps people who feel fatigue,’’ whereas a non permitted claim would include ‘‘this product helps to slow aging.’’

The existing health claims on FOSHU can be classified into 8 groups according to the health claims:

1. GI Conditions.

About half of all FOSHU products claim improvement of GI conditions. The effective component is usually a carbohydrate, which can be divided into oligosaccharides, dietary fiber, and lactic acid bacteria. Approved products containing these components can, for instance, claim that they help increase intestinal bifidobacteria and thus help maintain a healthful GI condition.

2. Blood Pressure.

Effective components including lactotripeptide from fermented milk, dodecapeptide from casein, a group of peptides from sardine, dried bonito, or a kind of seaweed, and g-aminobutyric acid are proposed to reduce blood pressure. Approved products containing these components can claim that they are suitable for people with moderately high blood pressure.

3. Serum Cholesterol.

Effective components include soy protein, chitosan, low-molecular-weight sodium alginate, and phytosterols. Approved products containing these components can claim that such products help to decrease serum cholesterol levels.

4. Blood Glucose.

Effective components include indigestible dextrin, wheat albumin, and L-arabinose. Approved products containing these components can claim that these materials are helpful for those who are concerned about their blood glucose level.

5. Absorption of Minerals.

Fructo-oligosaccharides and casein phosphopeptide are thought to improve calcium absorption within the small intestine. Approved products containing these components can claim improved absorption of calcium. Approved products containing heme iron from hemoglobin can, under FOSHU, claim that this is suitable to control mild iron deficient anemia.

6. Blood Neutral Fat.

Diacylglycerol, eicosapentaenoic acid, docosahexaenoic acid, and digested globin are believed to decrease blood neutral fat levels after meal consumption. Approved products containing these constituents claim that they help to reduce postprandial blood triglyceride levels. Additionally, a product containing diacylglycerol is permitted to claim that this product makes it difficult for fat to ''cling to the body.''

7. Dental Health.

Some sugar alcohols such as xylitol, maltitol, erythritol, and palatinose are considered to be hypocariogenic, whereas green tea polyphenol is regarded as noncariogenic. Approved products containing these sugar alcohols can claim that these products are low or noncariogenic. Additionally, some FOSHU-approved products can claim that these aid in making strong and healthy teeth.

8. Bone Health.

Vitamin K-2 and soy isoflavone are regarded as promoters of bone calcification. Approved products containing these components can claim such effects.

In February 2005, three amendments were made to the FOSHU claims system:

1) A system was set up to approve qualified health claims
2) Approval was given for risk reduction claims for calcium and folic acid
3) Standardized claims have been introduced for dietary fiber and oligo-saccharides.

Table 29. The Classifications of FOSHU

Classification	Content
FOSHU	These are allowed to use labels that inform consumers who ingest the food for specific health purposes that their purpose may be achieved by consuming the product.
"Qualified'" FOSHU	These are allowed to use qualified or conditional labels that inform consumers who ingest the food for specific health purposes that their purpose may be achieved by consuming the product. With the aim of promoting the provision of proper information to people, it was decided to allow health claims with some conditions (qualified) under the FOSHU system for food products that do not have sufficient scientific evidence required in the course of current licensing examination procedures but are considered to have certain efficacy.
"Standardized'" FOSHU	These are the FOSHU for which a license/approval is granted on the basis of compliance with the separately prescribed standards.
"Reduction of Disease-Risk" FOSHU	A FOSHU with a label containing any indication of a reduction of risks of developing certain diseases. At this moment, foods containing calcium or folic acid are permitted. However, in issuing an approval, the label will be required to contain a sufficient warning that the relevant disease has many risk factors and that sufficient exercise is also required for

	healthy life. The label also will be required to contain a sufficient warning for excessive intake.

Source: Yamada, et al (2008)

Table 30. Reduction of Risease-Risk FOSHU

Functional ingredient	Health claim approved	Precautions in ingestion
Calcium Daily intake of calcium from the FOSHU products should be between 300 and 700 mg.	This product contains adequate calcium. Intake of a proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones of young women and reduce the risk of osteoporosis when aged.	Diseases are generally caused by various factors. Excessive ingestion of calcium will not eliminate the risk of developing osteoporosis.

Source: Yamada, et al (2008)

2.7. Health Claim in The United Kingdom

Several other definitions of health claims are in general use. Two are of particular note, both developed by the United Kingdom's Joint Health Claims Initiative:

1. Generic health claims: a "health claim based on well-established, generally accepted knowledge from evidence in the scientific literature and/or to recommendations from national or international health bodies". These may be "nutrition function claims," Other function claims" or "disease risk-reduction" claims as defined by the Codex.
2. Innovative health claims: a "health claim other than a generic health claim based on scientific evidence applied to existing or new foods". These claims must be substantiated according to a process set out in the Joint Health Claims Initiative Code. These are more likely to be the "other function" and "disease risk-reduction" claims as defined by the Codex.

2.7. Nutrition Function Claims in China

The Ministry of Health of the Republic of China regulates that the nutrient content should meet conditions for nutritional claims. The claim expression should consistent with the given sentences and not allowed changing

There are 60 function claims which could not be changed even a word and
there are 27 health claims used in functional food in china

Table 31. Permitted Health Claims in China

Claims	
Function	
1) Enhance immunity	*13*) Increase bone density
2) Antioxidative	*14*) Improve nutritional anemia
3) Assist in memory improvement	*15*) Assist in protecting against chemical injury to the liver
4) Alleviate eye fatigue	*16*) Eliminate acne
5) Facilitate lead excretion	*17*) Eliminate skin chloasma
6) Moisten and clean throat	*18*) Improve skin water content
7) Improve sleep	*19*) Improve skin oil content
8) Facilitate milk secretion	*20*) Regulate gastrointestinal tract flora
9) Alleviate physical fatigue	*21*) Facilitate digestion
10) Enhance anoxia endurance	*22*) Facilitate feces excretion
11) Assist in irradiation hazard protection	*23*) Assist in protecting against gastric mucosa damage
12) Improve child growth and development	
Reduction of disease risk	
24) Weight loss	*26*) Assist in blood sugar reduction
25) Assist in blood lipids reduction	*27*) Assist in blood pressure reduction

Source: Yang (2008)

3. GLOBAL OVERVIEW OF SCIENTIFIC SUBSTANTIATION OF CLAIM

Codex - Joint Nutrition and Health Claim Guidelines

3.1. Codex Alimentarius Commission

- Codex Alimentarius Commission (CAC) is an Intergovernmental organization that coordinates food standards at the international level. Jointly hosted by FAO/WHO, the commission adopted new joint nutrition and health claim guidelines in June 2004 where nutrition claims include:
- Content claims
- Comparative claims

Some points related with substantiation:

- arise from consumption of reasonable quantity of food
- level of scientific justification shall be sufficient
- level of evidence differs depending on the type health claims
- scientific substantiation should be reviewed as new knowledge become available
- Nature of scientific evidence
- characteristics of the product: origin, nature
- constituent claimed must be presented and bio available in quantity and form needed (justify
- scientifically validated
- safety evaluation
- nutritional safety

- claims should be supported by scientific evidence along one or several approaches (in vitro studies, animal studies, epidemiological or observational studies, clinical intervention studies, others such as consensus reports)
- reduction of disease risk claims : primarily based on human intervention studies, animal studies in vitro studies (may be provided as supporting knowledge)
- others types of health claims : based on the evidence provided by studies of humans

3.2. US Food and Drug Administration Guidelines - USA

Standard of scientific validity for health claim includes 2 components:

- the totality of the publicity available (support or not support the substance/disease related to the subject/claim)
- significance scientific agreement among qualified experts that the relationship is valid

Types of studies required for scientific substantiation:

- intervention studies (Randomized Clinical Trial-RCT)
- observational studies
- cohort (longitudinal studies)
- case-control studies
- cross-sectional studies
- uncontrolled case series or cohort studies
- time series studies
- ecological or cross population studies
- descriptive epidemiology
- case reports

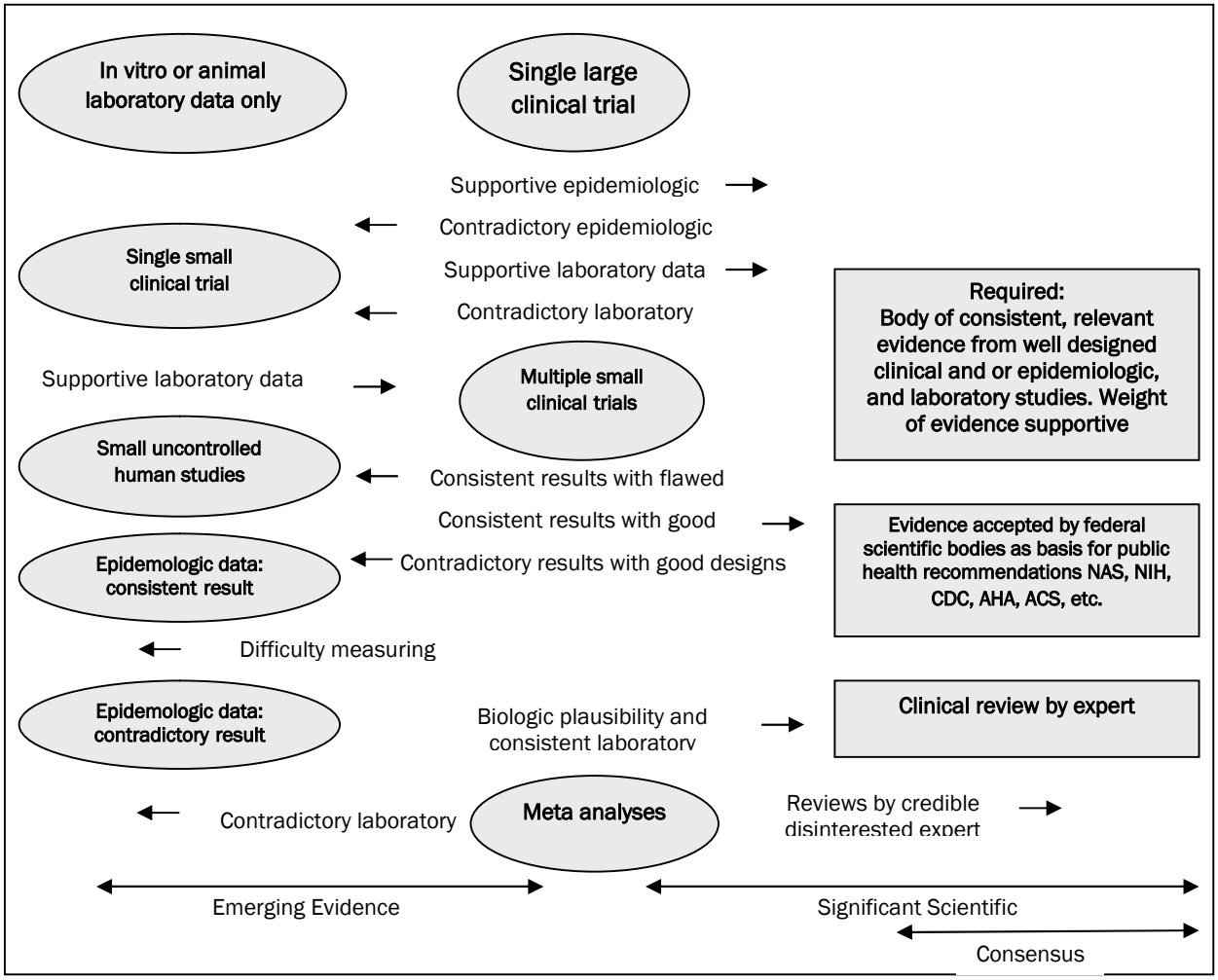


Figure 14 . Schema for Assessing Strength and Consistency of Scientific Evidence Leading to Significant Scientific Agreement (Hasler, 2008)

3.3. FSANZ Approach - AUSTRALIA AND NEW ZEALAND

For General Level Claims

Substantiation based on an authoritative, current and generally accepted information source (dietary guidelines for Australia and NZ, reports health claims approved overseas, authoritative and current university levels texts)

For High Level Claims

- subject to full pre-market assessment and approval through FSANZ application and proposal process
- FSANZ responsible for assessing totality of scientific evidence relevant to high level claims and determining whether substantiation requirement are met

FSANZ's draft framework for substantiation

- reduction of study categories to four
- experimental (interventional)

- observational
- systematic reviews
- supporting evidence
- animal studies , cellular or chemical in vitro or in vivo

3.4. Functional Food Science in Europe (FUFOSE)

Recommended that substantiation be based on systematic review of evidence relevant to the claim drawn from 3 types of studies, following the preferred hierarchy of their value :

- experimental human trials (clinical or intervention trials)
- observational human studies
- animal studies and in vitro studies

Criteria for scientific substantiation of claims:

If true end point of claimed benefit can not be measured directly, studies should use markers (valid biologically and methodologically)

Criteria for the scientific substantiation of claims (PASSCLAIM):

1) The food or food component to which the claimed effect is attributed should be characterized.
2) Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:
   - Study groups that are representative of the target group.
   - Appropriate controls.
   - An adequate duration of exposure and follow up to demonstrate the intended effect.
   - Characterization of the study groups' background diet and other relevant aspects of lifestyle.
   - An amount of the food or food component consistent with its intended pattern of consumption.
   - The influence of the food matrix and dietary context on the functional effect of the component.
   - Monitoring of subjects' compliance concerning intake of food or food component under test.
   - The statistical power to test the hypothesis.
   - When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.
3) Markers should be:
   – biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known;
   – methodologically valid with respect to their analytical characteristics.
4) Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consisten with the claim to be supported.
5) A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.

3.5. Foods for Specified Health Use (FOSHU) - JAPAN

The Japanese Ministry of Health, Labour and Welfare (MHLW) set up Foods for Specified Health Use (FOSHU) in 1991 as a regulatory system to approve statements on food labels concerning the physiological effect of a food or food component on the human body. The scope of the regulations was expanded in 2001 to include food supplements, and the MHLW enacted a new regulatory system, Foods with Health Claims, which encompasses the FOSHU system, and Foods with Nutrient Function Claims (FNFC). The nature of the claims is consistent with developments in the USA, Europe and Codex Alimentarius. FOSHU applications are accepted every three months, and the minimum time required for the approval process is 6 months. When MHLW grant approval, the successful applicant can use the approved health claim and the FOSHU logo, which graphically represents the regulators' seal of approval.

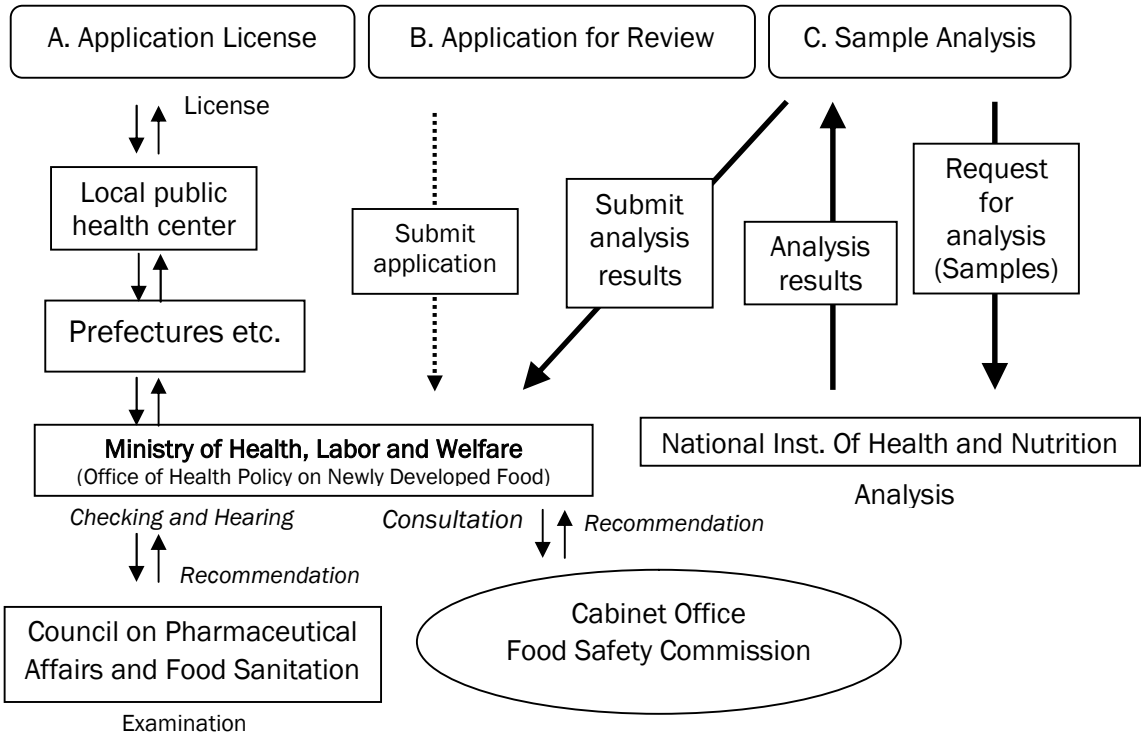


Figure 15. Flow of FOSHU Approval. Applicant must pass all 3 processes, A, B, and C - (Yamada, et all, 2008: 1194S)

The Japanese **Requirements for FOSHU Approval**

- Effectiveness on the human body is clearly proven
- Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- Use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.)
- Guarantee of compatibility with product specifications by the time of consumption
- Established quality control methods, such as specifications of products and ingredients, processes, and methods of analysis

There are three essential documentary requirements for FOSHU approval:

1. Effectiveness of the food or food component based on scientific evidence
2. The safety of the product with additional safety studies in human subjects
3. The analytical determination of the effective component(s)

- The documents in support of a claim must be based on scientific substantiation not only by human intervention studies, but also by supporting evidence from in vitro biochemical and metabolic studies, and animal studies where appropriate.

Source: Lecture's note of NFI course, Pauline Chan (2008)

3.6. SOUTH EAST ASIA (SEA)

Philippines:
- follow US Code of Federal Regulations
- 12 claims are allowed
- new claims based on scientific evidence

Indonesia: health claims allowed for functional foods for selected bioactive component

ILSI SEA regions coordinated a series of workshops in nutrition labeling and claims
Based on PASSCLAIM criteria, guidelines for scientific substantiation of claims:
- characteristics
- types of studies required for substantiation of claims
- biomarkers
- research design and methodology
- evaluation based on totality of data
- re-evaluation

REFERENCES

Appendix IV: Draft Guidelines for Use of Nutrition and Health Claims. In: *Report of the Thirty-First Session of the Codex Committee on Food Labelling.* Ottawa, Canada, April 28 – 2 May 2003. Rome, Codex Alimentarius Commission, 2003: 38-39.

Asp, Nils-Georg, Bryngelsson, S. Health Claims in Europe: New Legislation and PASSCLAIM for Substantiation. J. Nutr. 2008; 138 (Suppl): S1210-15

http://www.foodstandards.gov.au/consumer/labelling/nutrition/Pages/default.aspx.

Chan, P. Lecture's note of Nutrition in Food Industry course. SEAMEO-TROPMED RCCN UI. 2008

Guidelines For Use of Nutrition Claims,CAC/GL 23-1997.Rome, Food And Agriculture Organization of the United Nations / World Health Organization, 1997.

Food Standards Australian New Zealand. Standard 1.2.7 – Nutrition, Health and Related Claims, 2013.

Hasler, Clare M. Evidence for Health Claims on Food: How Much is Enough? Health Claim in the United Stated: An Aid to the Public or a Source of Confusion? J. Nutr. 2008; 138 (Suppl): S1216–20

International Life Sciences Institute (ILSI) – PASSCLAIM (PROCESS FOR THE ASSESSMENT OF SCIENTIFIC SUPPORT FOR CLAIMS ON FOODS) – Consensus on Criteria, Eur J Nutr (2005) [Suppl 1] 44: I/5–I/30. http://passclaim.ilsi.org/CX/NFSDU 07/29/6 page 5

Peraturan Kepala badan Pengawas Obat dan Makanan Republik Indonesia nomor HK.031.1.23.11.11.099099 tahun 2011 tentang Pengawasan Klaim dalam Label dan Iklan Pangan Olahan. Badan POM RI. 2011

Richardson, D. The Scientific Subtantiation of Health Claim. The International Alliance of Dietary/Food Supplement Association (IADSA). 2005

Yang Yuexin. Scientific substantiation of functional food health claim in China. J Nutr. 2008;138 (Suppl):S1199-1205.

Yamada K, Sano-Mino N, Nagata J and Umegaki K. Health claim evidence requirements in Japan. J. Nutr. 2008; 138 (Suppl): S1192-98

ABOUT THE AUTHORS

Rina Agustina, MD, MSc, PhD completed her PhD in Human Nutrition at Wageningen University, Wageningen, the Netherlands through a fellowship from the International Nutrition Foundation/Ellison Medical Foundation USA (2012). She obtained her MD from the Faculty of Medicine, GadjahMada University (1997). She finished her Master (MSc) degree program in Nutrition at SEAMEO-TROPMED and Faculty of Medicine, Universitas Indonesia with a fellowship from the German Technical Cooperation (GTZ) (2000). Dr. Agustina has served the Ministry of Health, Republic of Indonesia to work as a physician at a primary health center in Menteng, Central Jakarta (1999). Since year 2000, she has been lecturing for post-graduate study Program in Nutrition at the Department of Nutrition Faculty of Medicine and SEAMEO RECFON Universitas Indonesia. Currently, her position is a Research Coordinator and Secretary for Doctorate Study Program, Department of Nutrition, Faculty of Medicine, Universitas Indonesia. She formerly served as a Deputy Director Resource Management, of SEAMEO Regional Center for Food and Nutrition. In these positions she has experience in leading teams of researchers with diverse backgrounds to focus on a core research question. Her expertise is in the area of child health and nutrition, especially in the field of Gut Health and Dietary Modulation of Intestinal Infection with Probiotics, Prebiotics and Micronutrient (eg. calcium. Iron and zinc). She has extensive experiences in conducting several research projects and clinical trials in Indonesia. Recently, she carried out a large scale intervention trial with enrollment screening of 4000 children, with approximately 500 being enrolled and followed-up. This included coordination of more than 100 co-workers including research assistants, study physicians, supervisors, fieldworkers, database and logistic personnel, nutritionists and local women volunteers. The study produced high quality data with excellent compliance rates and has productively published papers in high impact international journals such as Pediatrics, Journal of Nutrition, Asia Pacific Journal of Clinical Nutrition, European Journal of Clinical Nutrition, and BMC Public Health. She received an “International Award” from the North America Society of Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) at the 2012 World Congress in Taipei, and the Rector of the University of Indonesia. She was a Featured Fellow of the International Nutrition Foundation, Boston, MA, USA and was selected as a finalist from 176 researchers in Indonesia for the Best Research of the RIstek-Kalbe Science Award in 2014. Dr Agustina also received a fellowship from the Higher Education Network Ring Initiative to attend the summer course program at the Harvard School of Public Health, Harvard University, Boston, MA, USA, and in this program she published an additional paper concerning maternal empowerment in Maternal and Child Health Journal. She has been appointed as a course coordinator of Nutrition in Food Industry since 2002. She involves as a member of Expert Committee on Functional Food (eg Probiotics) and Food for special Dietary uses. She recently represented Indonesia to attend the meeting of CODEX Committee on Nutrition and Foods for Special Dietary Used in Denpasar Bali. She is the first author for the first edition of Handbook of Nutrition in Food Industry (2009).

Ingrid S Surono, MSc, PhD graduated from Food Technology Bogor Agricultural University in 1980. She earned MSc in Dairy Microbiology and Food Processing from Asian Institute of Technology (AIT), Bangkok-Thailand, in 1984. PhD was obtained from The United Graduate School, Gifu University-Japan, in 1996. She dedicated herself to probiotic research since 1992, and her research interests are in child nutrition, functional foods and food safety. There are 28 international published papers in peer reviewed journal mainly on probiotics, and she is also a reviewer of British Journal of Nutrition, Beneficial Microbes, and some national journals. She has been involved as assistant course coordinator of Nutrition in Food Industry at the Master Course of Department of Nutrition, Faculty of Medicine, University of Indonesia since 2009 and Food Safety since 2008, and in 2010-2012 as Course Coordinator of Nutrition in Food Industry and and Course coordinator of Food Safety. She has published 5 books, and wrote 1 chapter in text book published by CRC, and wrote 3 chapters in Encyclopedia of Dairy Science. She is actively involved as a member of expert team at National Agency of Drug and Food Control Republic of Indonesia (NADFC) especially in Food Safety and member of task force on Probiotics and Prebiotics Guidelines. She is an author of Probiotic, Fermented Foods and Human Health, published in 2004 in Indonesian. She is a visiting Professor at Functional Foods Forum, University of Turku-Finland, during 2004-2006. In 2011, Science and Technology Award has been granted to her from Toray Foundation. In 2012, she was nominated as ten best researcher of RISTEK KALBE SCIENCE AWARD 2012. A patent on Probiotic has been granted in 2010. She also serves as Advisory Council of Swedish South Asian Network on Fermented Foods (2009 - present time). She is President of Indonesian Scientific Society for Probiotics and Prebiotics (ISSPP). She is one of Scientific Members at Danone Institute Indonesia since 2014. At present time she is appointed as Head of Food Technology Department, Faculty of Engineering, BINUS University, Alam Sutera Campus, Tangerang, Indonesia

Dwi Nastiti Iswarawanti is academic staff at SEAMEO Regional Centre for Food and Nutrition since 1995. She pursued her Doctorate degree in Nutrition at Medicine Faculty-Universitas Indonesia (2011), earned MSc in Community Nutrition at Faculty of Medicine, University of Indonesia and her bachelor's degree from Faculty of Agriculture, Bogor Agriculture University (1991).She charges as course coordinator and lecturer at the SEAMEO RECFON Master's program in Community Nutrition in the following courses: *Food Safety, Health Promotion on Nutrition Program, Nutrition in Food Industry*, *Food Economics and Food Security, Nutritional Epidemiology and Surveillance.* Her research interest is food safety (related on education and behavior); Infant and Young Child Feeding, Children nutritional status and food security. She has made publications in international peer-reviewed journals. In 1997 she received University of Indonesia Award on International Scientific Publication. She contributed her expertise on development of Food Safety including food hygiene and HACCP module and guidelines for various stakeholders. She is senior food safety and HACCP auditor of food and bottled water. She has played as a leading national and international role in facilitating the roll out of the ICD/SEAMEO courses in the region. She has been developing and maintaining the collaboration between SEAMEO and the Industry Council for Development (ICD) which has mission empowering the nutritionist and health professional on food safety. She was a main editor chief of some Indonesian versions of the WHO documents and guidelines on Food Safety and also editor chief of ICD/SEAMEO Food Safety Newsletter.

Evi Ermayani, MSc. She is currently the Head of Degree Program at SEAMEO RECFON. She also the Head of Master Degree Program of Community Nutrition, Nutrition Study Program, Faculty of Medicine, Universitas Indonesia (UI). She obtained her master degree in Nutrition from the Universitas Indonesia in 2011. Her recent research focuses on food safety issue. She also has interest in nutrition education for children and adolescent. Email address: evi.badruzaman@gmail.com.