

## Estimation of Daily Intakes of Food Additives in Children

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### <Summary>

Daily intakes of food additives such as colors, preservatives, sweeteners and food manufacturing agents for children (1-6 years) in Japan were estimated using market basket method in 2009 and 2014. A list of daily consumption of processed foods was prepared based on National Health and Nutrition Survey (2001-2003) and the special survey for daily intakes of foods (2011). The food additives with the highest daily intake was orthophosphoric acid (9.4 mg/kg bw/day in 2009 and 11 mg/kg bw/day in 2014, expressed as phosphorus), followed by condensed phosphoric acid (0.76 mg/kg bw/day in 2009 and 1.0 mg/kg bw/day in 2014, expressed as phosphorus), and propylene glycol (0.47 mg/kg bw/day in 2009 and 0.73 mg/kg bw/day in 2014).

Acceptable daily intake (ADI) and maximum tolerable daily intake (MTDI) set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or Food Safety Commission of Japan were compared with the estimated daily intake of food additives in children. The ratios of the estimated daily intake to ADI for the colors, preservatives, sweeteners and propylene glycol ranged from 0 to 1.9 % in 2009 and from 0 to 2.9 % in 2014, respectively. The results of the propylene glycol were the highest in each year. The ratio of the estimated daily intake to MTDI for phosphorus compounds was 15% in 2009 and 18% in 2014, respectively.

## Are Food Additives Unsafe?

### - How to Communicate about Food Safety -

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#### <Summary>

Food additives have an important role, and are almost indispensable in processed foods or modern dietary life. Although usage of food additives are strictly regulated by the Food Sanitation Act under the basis of well scientific safety evaluation of each food additives, consumers generally recognize them quite unsafe or bad for health and are tend to avoid them, while most of food safety specialists recognize them safe enough.

In this article a meat curing or coloring agent, nitrite, is exemplified first to describe issues and studies on safety of food additives in these decades. Next topic is the unsafe recognition of consumers on food additives. To elucidate the reasons of the recognition, we examined the description on food additives in textbooks for junior high school students. In some textbooks they describe that food additives are generally not safe enough and to be consumed as little as possible.

Finally I describe how I have been making various efforts for years to educate dietitian students to learn not only knowledge on food safety, but also scientific ways of thinking on food safety.

## Evaluation of the Efficacy and Safety of Functional Foods

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### <Summary>

The concept of “food functions” was created in Japan in the 1980s, and this brought about the development of a class of foods called “functional foods”. A unique regulation system called “Food for specified health uses (FoSHU)” was established in 1991, followed by another “Food for nutrition function claims (FNFC)” in 2001. “Food with function claims (FFC)” is the newest functional food claim regulation system and was established in 2015. Evaluation methods for food functions and safety are important in developing functional foods. Based on the development of evaluation methods, validation of claims under the regulation systems is carried out. New guidelines for human testing for FoSHU evaluation was established in 2014. Evaluation of functional foods by reviewing scientific literature from databases was also considered as a novel evaluation method. This method, known as a systematic review, looks useful and is now being employed for evaluating FFC products. The history, current status, and future prospects for evaluation methods used for Japanese functional food products are discussed in this article.

## To Sustainable Agriculture in Japan

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### <Summary>

Agricultural products were effectively supplied from farmers with high levels of motivation due to the freedom of agricultural fields in Japan after the World War II. During industrial and economic diversity, the sustainability of agriculture has decreased in Japan. Today, most agricultural products are supported by tax subsidies. Ministry of Agriculture, Forestry and Fisheries with the Japanese government and Japanese Agricultural Cooperative (JA) should have understood how to lead the system of agriculture as leaders in Japan. However, the stated reason of their organizations, polite fiction, and their immediate profits prevent the Japanese agriculture system from being reconstructed. Here I analyze the present situation of agriculture in Japan to be understood as real intention. In the last chapter, I show the success of agriculture in Holland as one of the examples.

## HACCP in Response to Food Globalization

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### <Summary>

The globalization of food trade has rapidly been spreading. Japanese economy in food trade is rapidly and internationally growing with the politics of the Japanese government. However, since the implementation of HACCP system in the companies in Japan is behind compared to USA or European countries, the Japanese companies should consider the implementation of HACCP and international harmonization of food safety management and standards and pay attention to the assurance of food safety for the expansion of food trade.

This symposium entitled “HACCP in response to Food Globalization” was held on May 18, 2016 at Tokyo Big Site in Koto-ku, Tokyo organized jointly by the Japanese Society for Food Hygiene and Safety, Japanese Society of Food Microbiology and Japanese Society of Food Chemistry, and jointly sponsored by IFT Japan, ILSI Japan, Japan Food Hygiene Association, Japan Food Industry Association and Food Chemical Newspaper Inc. Approximately 125 people participated and discussed in the symposium.

## ILSI Japan Biotechnology Research Committee Workshop “What Are Assessment Endpoints in ERA of GMO?”

Ryo Ohsawa, Ph.D.  
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### <Summary>

ILSI Japan Workshop on “What are assessment endpoints in ERA of GMO?” was held on May 19, 2016.

Although GM crops are not commercially cultivated in Japan, Japan is one of the world’s largest importers of agricultural products intended for food and feed that have been produced using GM crops. Due to its high dependence on grain supplied from foreign countries, GM crops have already become essential elements to securing Japan’s food supply.

Japan ratified the Cartagena Protocol on Biosafety in 2003. Under the “Cartagena Law”, the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Environment (MOE) grant joint approvals for cultivation or for the use of GM crops as food and feed. A joint MAFF and MOE expert panel carries out an Environmental Risk Assessment (ERA) to determine the potential for adverse effects on biodiversity, focusing on “the influence of competition on native wild species by GM crops (competitive superiority)”, “the influence of GM crops which produce harmful substances (potential production of harmful substance)”, and “the influence of GM crops hybridizing with wild relatives (crossability)”. As 13 years have passed since ERA for major GM crops such as Bt and/or HR corn, and HR soybean etc. started in Japan, Japan’s review system could benefit from leveraging their cumulative data and experiences.

New GM crops of various traits such as drought resistance, improvement of nutrition etc. are developed in recent years, and a regulation judgement according to that can have been asked now. We should reconsider a way to ERA in our country and make the meaning of the assessment endpoints clear in this workshop.

Assessment endpoints are defined during the problem formulation process, which comprises the initial step of an ERA. The first half in this workshop, we received a topic offered about a definition of an assessment endpoint. After that, we discussed a case of each country about regulation based on the definition. In the second half, for understanding what is risk or hazard in ERA, we discussed the introgressive hybridization from GM crops to wild relatives or ancestors, weed characters and allelopathy concerned with assessment endpoints.

The Agenda of the meeting was as follows,

#### Opening Remarks

Mr. Takuji Yasukawa (President, ILSI Japan)

#### Purpose of the Workshop, Definition of Protection Goals and Assessment Endpoints

Dr. Ryo Ohsawa (University of Tsukuba, Japan)

#### Application of Problem Formulation to Define Assessment Endpoints for GM Crops

Dr. Andrew Roberts (ILSI CERA, US)

#### Case Studies of Each Country

- Assessment Endpoints in Japanese Guidelines  
Dr. Akihiro Hino (Chair of MAFF/MOE Subcommittee, Japan)
- Assessment Endpoints in Australia  
Dr. Michael Dornbusch (Assistant Secretary, Evaluation Branch, Office of the Gene Technology Regulator, Australia)
- Assessment Endpoints in the US  
Dr. Andrew Roberts (ILSI CERA, US)

#### What Is Risk or Hazard in ERA

- Corn Breeding: Insight on Biology and Domestication for ERA  
Dr. Linda Pollak (Windy Acres Genetics, Retired Research Geneticist from USDA's Agricultural Research Service, US)
- What Are Weed Characteristics and What Need to Be Evaluated for Weediness?  
Dr. Ayako Shimono (Toho University, Japan)
- What Is Allelopathy and What Need to Be Evaluated for Allelopathy?  
Dr. Yasuhiro Yogo (National Agriculture and Food Research Organization, Japan)
- Comparison between Japanese and U.S. Confined Field Trials (CFT) for Genetically Modified(GM)Crops  
Dr. Shuichi Nakai (ILSI Japan Biotechnology Committee / Monsanto Japan)

#### Panel Discussion

Moderator: Dr. Ryo Ohsawa (University of Tsukuba, Japan)

All speakers

Comparison of Assessment Endpoints in Japan, Australia, Canada and the US Reported Today

#### Closing Remarks

Dr. Kenichi Hayashi (Emeritus Member of Advisory Council of ILSI CERA, Japan)

#### [Speech Abstracts]

### **(1) Application of Problem Formulation to Define Assessment Endpoints for GE Crops**

*Dr. Andrew F. Roberts (ILSI-CERA, USA)*

One of the fundamental principles of environmental risk assessment for GE plants is that assessments are conducted on a case by case basis. This means that each assessment is done with consideration of the particular plant, the introduce GE trait and the circumstances of its use. Every assessment can therefore be considered independently using the process of Problem Formulation – a scoping exercise which identifies relevant protected or valued aspects of the environment and plausible pathways by which they might be harmed by the GE plant. The likelihood of harm occurring is the subject of the risk assessment, and problem formulation helps you identify what information will be relevant to assessing the case. Why then, when we look at risk assessment reports from countries around the world do we see the same assessment endpoints considered over and over again?

The answer has largely to do with two things. First, we have a very good understanding of how plants behave in the environment, and more importantly, the environmental harms that are caused by plants. These harms are associated with aggressive growth, which may lead to the plant being considered a weed or an invasive species, or with the production of substances that cause harm to organisms in the environment. The second truth is that risk assessments for GE plants have also dealt almost exclusively with highly domesticated species used in agri-

culture. These plants have familiar and well characterized biology, which precludes consideration of more exotic pathways to harm. As it turns out, the conclusions of a risk assessment must indeed be formulated on a case by case basis. But the context and the protection goals that feed into the problem formulation rarely, if ever, change related to the type of organisms and intended use that are considered frequently for GE plants. These shared characteristics, and the knowledge of how similar assessment endpoints are derived time and time again in considerations of ERA for GE plants suggest that trait specific considerations typically don't impact the identification of relevant assessment endpoints. This may be especially true when considering low exposure scenarios.

## (2) Assessment Endpoints in Japanese ERA System

*Akihiro Hino (Chair of MAFF/MOE Subcommittee, Japan)*

The first regulation on Genetically Modified Organisms(GMO; LMO)for ERA in Japan is “the Guideline for Safety Assessment of GMOs for Open-Field Use” announced by the Ministry of Agriculture, Forestry and Fisheries(MAFF)in 1989. This guideline was implemented to address the discussion on risk assessment of GMOs developed in Japan for industrial applications. The content of the guideline was in line with the recommendations discussed by OECD and other regulatory bodies. With the first of GM crop import from overseas, the same risk assessment concept is applied to GMOs developed in overseas, and import of GM soybean, canola, corn and other crops were started. At the same time, however, application of innovative technologies to food products both in the country and overseas gave rise to a feeling of apprehension. After the ratification of the Cartagena Protocol on Biosafety in 2003, the “Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms” (the Cartagena Law) was implemented in Japan, and current regulatory system has been established. Here, a brief overview of the Japanese regulatory system is provided.

The purpose is to conduct biological diversity risk assessment of GMOs based on the Cartagena Law.

- The ERA application is accepted for each transformation event.
- Biological diversity risk assessment is conducted with science-based analysis and review. Applicants provide additional information related to the questions and comments from the expert panel raised during review, and the conclusion is judged through consultation among members of the expert panel.
- Information required for the assessment includes information on host species, transgenes, and differences between GM and host plants. This information should be those excerpted from peer-reviewed articles and/or the event-specific data generated by the applicants.
- Whether or not a GMO possesses properties which may cause adverse effects to biological diversity is judged in terms of “Competitiveness”, “Productivity of harmful substances”, “Crossability”. If there is a possibility of possessing such properties, wildlife likely to be affected is identified, and assessments of adverse effects are conducted. Based on these assessments, the existence of adverse effects on biological diversity is determined.
- Species introduced to Japan during Meiji Era or later (introduced species) are not the target of the assessment. Pest species of host plants are, in principle, also excluded from the assessment.

Efficient and effective assessment have been conducted by revising the required information etc. by taking, for example, the advancement of science and technology, accumulation of scientific knowledge, and international trend into account.



**(3) Assessment Endpoints in the U.S.**

*Dr. Andrew F. Roberts (ILSI-CERA, USA)*

The United States has reviewed and commercialized more GE plants for cultivation than any other country. This presentation will provide a brief review of the regulatory structure pertaining to the use of GE plants in the environment in the United States. The analysis will consider the protection goals identified in U.S. legislation, as well as the assessment endpoints used in practice for U.S. regulatory assessments.

**(4) Risk Identification and Assessment Endpoints in Australian Risk Analysis of GMOs**

*Dr. Michael Dornbush*

*(Office of the Gene Technology Regulator, Australian Government Department of Health)*

Although there appears to be different approaches and terminologies used for environmental risk analysis for regulatory purposes, there are similar underlying principles. The first step in any environmental risk analysis is to establish the goals of the assessment, its scope and boundaries, a risk hypothesis, assessment criteria and the methodology to be used. This first step is called problem formulation, often also called hazard identification or in the assessment approach used in Australia, this includes elements of the risk context and risk identification.

Assessment endpoints can be considered explicit expressions of environmental values to be protected from harm. Values to be protected may be derived from legislation or regulations. In Australia the object of the Gene Technology Act is to protect people and the environment and Regulations outline risk criteria that must be taken into account when preparing a risk assessment. However, there is often a need to further refine these high level statements to put them into practical operation for case-by-case risk assessments.

Harm is an undesirable change, usually an adverse or negative effect of human health or the environment. Defining the nature and level of harm is a central part of establishing the criteria for risk assessment. Without explicit descriptions of harm, the assessment may result in identifying changes or effects rather than identifying risks. For this reason, risk scenarios(or risk hypotheses)used in the risk identification stage of assessment must always include clear statements of the source of potential harm(hazard)and the potential harm(assessment endpoint)that could occur as a result of a plausible sequence of events that connect them.

Australia's approach to risk analysis of GMOs has incorporated already established and validated methods for the risk analysis of weeds. This methodology assesses the potential invasiveness and impacts of plants and provides practical and useful assessment endpoints (and measurement endpoints) that are easily applied to assessing the potential weediness of GM plants.

**(5) Corn Breeding: Insight on Biology and Domestication for ERA**

*Dr. Linda Pollak*

*(Windy Acres Genetics, Retired Research Geneticist from USDA's Agricultural Research Service, USA)*

Farmers in Mexico domesticated maize from a wild grass, teosinte. Maize and teosinte differ by only five genes or groups of genes but are dissimilar phenotypically. It is thought that very early in domestication the five genes had mutations with dramatic effects. Modern maize has very little variability in these five genes which suggests that the mutations happened early in domestication. As early maize spread through Mexico and Central America, where teosinte is wild, it is thought that more subtle variation in maize appeared from hybridization with other teosinte races and varieties of early maize. Genetic diversity continued to

increase because farmers created varieties adapted to their environments and needs, and crossing among varieties occurred through trading and human migration to new areas. A maize race is a group of populations that have more in common genetically than varieties belonging to another race. More than 25,000 populations belong to 200 races in the Americas, and many more are found all over the world where maize spread. A race adapted to a specific environment needs a period of selection to adapt to a new environment. Although the amount of genetic variability in maize is large the genetic base of commercial maize is much smaller. Very few races are used commercially worldwide, and in most countries commercial maize traces back to only three to four high-yielding populations. There is always need for ever more productive germplasm developed by breeding.

The critical first step in breeding is to determine the best genetic materials with desired characteristics for the market and make crosses. Commercial breeding crosses are usually made from two good commercial inbred lines, then the cross is self-pollinated to make a population with genetic variation.

The second step is to make the right selections. Inbred line development is a cycle of fixing genes by self-pollinating, meanwhile selecting on phenotype and also selecting for productivity using experimental hybrids. Experimental hybrids are tested over many environments so that environmental variation can be separated from genetic variation. The environment of adaptation can also be determined. Other important traits selected for or against can be done in additional nurseries or in the laboratory.

A third critical step in maize breeding is to generate experimental hybrid data of good quality so that statistical analysis can provide accurate genetic information about genotype versus environment and to aid in selecting good inbred lines. Statistical analysis is an essential tool when dealing with quantitative variation that cannot be measured precisely.

The final critical step is to deliver the new hybrids to farmers by the seed industry. Possibilities of unintended phenotypes appearing in conventional breeding are small because of the cycles of selection that would eliminate unwanted phenotypes. Maize becoming a weed is also unlikely because maize is a crop developed by humans and has a 9-10,000 year history of interdependence with humans. Because maize and humans had a unique dependent relationship during much of its domestication maize has spread throughout the world and become an important crop in many countries.

## **(6) What Are Weed Characteristics and What Need to Be Evaluated for Weediness?**

*Dr. Ayako Shimono (Faculty of Science, Department of Biology, Toho University)*

Weediness is sometimes used synonymously with “ability to establish (naturalize)” and/or “invasiveness”, because of two definitions in the terms of “weed” as below,

1. Ecological definition: Plants that grows spontaneously in an environment that has been modified by human.
2. Definitions based on human’s values: Plants that grow in sites where they are not wanted and which usually have detectable economic or environmental effects.

Because the biosafety regulation requires applicants to assess the possibility of the LMOs becoming invasive, it makes the endpoint clarify to distinguish “establishment” from “invasiveness”.

Under domestication process, most of crops lost their ability for self-propagation and became dependent on humans for survival. Corn, soybean, and cotton, that are major LMOs, are highly domesticated and have not become established plants in Japan. These crops must overcome reproductive (self-replacing) barrier to sustain populations without intervention by humans. The barriers are probably related to domesticated traits of the germination and re-

productive characteristics, that is needed to be evaluated for weediness.

### **(7) What Is Allelopathy and What Need to Be Evaluated for Allelopathy**

*Dr. Yasuhiro Yogo*

*(Director, Division of Biodiversity Institute for Agro-Environmental Sciences, NARO National Agriculture and Food Research Organization)*

Allelopathy is the effect on growth/development of one species, caused by a chemical released from another species. There are several senses on allelopathy, but only adverse effect is taken up in genetically modified organisms (GMO). There are several words concerning about allelopathy, such as harmful substances in OECD, accidental conversion to pathogen by toxic chemicals in National Academy of Science, toxin affecting non-target organisms in Biosafety Clearing-House (BCH), which is the mechanism set up by Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity. However, no organization use the word of “allelopathy”.

We also have been treating the GMO since late 1980's in Japan. Before introducing CPB, environmental safety assessment of GM crops was conducted in accordance with the guidelines of MAFF for recombinant DNA organisms. Assessment items in relation to allelopathy are unknown production of chemical substances in plant, adverse effect of the chemicals exuded from root, volatilized from leaf, and plant residue on other plants, although we also do not use word of “allelopathy”. And soil microflora such as bacteria, actinomycetes, filamentous fungi, and the surrounding vegetation were also assessed. Key judgement point is sequential equivalence to non-GM crop, resulting no adverse effect on environment. After introducing CPB, adverse effect of harmful substances on domestic wild species are assessed on Type I use of GMO, including FFP, by using similar assessment items in the previous guideline, although the concept of “Familiarity” were introduced in biodiversity view point.

There are several points to be considered, such as intended or unintended, assessment end points, familiarity, controllability, acceptability and so forth, in risk assessment of allelopathy in GMO.

### **(8) Comparison between Japanese and U.S. Confined Field Trials(CFT)for Genetically Modified(GM)Crops**

*Dr. Shuichi Nakai (ILSI Japan Biotechnology Committee Monsanto Japan)*

Conducting Confined Field Trials (CFT) for Genetically Modified (GM)crops prior to unrestricted release is well-established among countries with domestic regulations for the cultivation approval of GM crops. In recent years, transportability of CFT data for Environmental Risk Assessment (ERA) of GM crops is actively discussed. The definition of transportability of CFT data here is that leveraging the CFT data for GM crop collected in one cultivation country for ERA in other countries where the same GM crop is planned to be cultivated and/or imported.

Scientific reliability of CFT data collected in the cultivation country is one of the important factors to judge transportability of CFT data to other countries. In this presentation, scientific reliability of CFT data collected in the U.S. was reviewed by comparing purpose of CFT, geographical locations, experimental design and evaluation items with that of Japan. To compare evaluation items, GM corn MON 87411 which was conferred coleopteran resistance and glyphosate tolerance was used as case study. As the result of comprehensive review, it was concluded that CFT data collected in the U.S. are reliable to evaluate weediness of GM crops in Japan due to the following three reasons.

1. Key characteristics to assess weediness (e.g. dormancy, seed dispersal, lodging)are al-

- ways examined in U.S.
2. CFTs in U.S. are conducted in diverse geographical conditions without adding physical stress to GM corn to prevent out-crossing. 3. The U.S. undergoes rigorous process to interpret statistical significant differences detected in CFTs by obtaining the range of values of the reference varieties.

## Report of the 43rd Session of the Codex Committee on Food Labelling

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### <Summary>

The 43rd Session of the Codex Committee on Food Labelling (CCFL) was held in Ottawa, Canada from 9 to 13 May 2016. The Session was chaired by Ms Lyzette Lamondin, Acting Executive Director, Food Import, Export and Consumer Protection Directorate, Canadian Food Inspection Agency and attended by delegates from 52 member countries and one member organization (the European Union) and observers from 17 international organizations. The Japan Delegation consisting of 2 from the Consumer Affairs Agency, 3 from the Ministry of Agriculture, Forestry and Fisheries (including the author) and 2 technical advisors was headed by Dr Toshitaka Masuda of the Consumer Affairs Agency. The summary and conclusions of the Session are as follows.

The Committee:

- Advanced the proposed draft revision of the General Standard for the Labelling of Pre-packaged Foods: Date Marking to Step 5 for adoption by CAC39;
- Forwarded the project document for approval as a new work: Guidance for the labelling on non-retail containers;
- Proposed that CAC39 identify an appropriate forum to continue work on the proposed draft revision of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: Organic Aquaculture or to discontinue this work;
- Discontinued discussion on issues related to internet sales of food;
- Agreed not to proceed the revision of the General Guidelines for the Use of the Term “Halal” (CAC/GL 24-1997), but to consider a discussion paper on issues surrounding consumer preference claims;
- Agreed to prepare discussion papers on front-of-pack labelling and future work of CCFL;
- Agreed there was no need to develop a particular work management approach, but could consider such a need in the future;
- Endorsed the labelling provisions in the standards submitted by CCASIA, CCSCH, CCFFV and CCFA;
- Agreed not to consider the matter of food integrity/food authenticity, but to wait for discussion and decision from CCFICS; and
- Agreed to request advice from CCFH on the appropriateness of the food safety criterion 1 to exempt foods from date marking.

The official report of the Session and related documents can be found on the Codex website at <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCFL&session=43>

< Friends in ILSI >

International Symposium on Health/Function Claims of Foods with Focus on Nutrient Function Claims

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Nutrition labeling, as well as nutrition and health claims, are important tools to communicate the nutritional quality and health benefits of a food product to consumers. They provide point-of-sale information to help consumers make healthful food choices. Moreover, those nutritional labeling and health claims information, disseminated through food package, advertising, promotion and education, contributes to shaping the consumers' knowledge of nutrition and development of healthy lifestyles.

People in Eastern countries often believe that food and medicine come from the same source. Traditional herbal products and foods with healthcare concept are popular in Asia. To promote innovation in the food industry, and more importantly, to ensure food safety and not to mislead consumers and public health promotion with the claims, the establishment of a regulatory framework on nutrition labeling and health claims are crucial.

As we trace the evolution of functional foods and their regulation development in Asia, the regulation on "Food for Special Dietary Uses"(FOSHU) was firstly introduced in Japan in 1991. Taiwan followed and promulgated its □Health Food Control Act □ in 1999. Korea started in 2002 and has gone through a 10- year journey on Korean Health/Functional Food Act (HFFA). There is wide disparity among label formats and permitted claims among countries in Southeast Asia (SEA), causing confusion to

consumers and resulting in trade barriers for food manufacturers and distributors. The need on harmonization of nutrition labeling and claims has been proposed and the dialogue among ASEAN countries should be continuously supported.

The International Symposium on Health/Function Claims of Foods, held in Taipei, Taiwan on July 15, 2016, provided an update on developments and regulatory changes in Japan, Korea and ASEAN countries. The highlight of the symposium was on the Health/Function claims of Foods with focus on Nutrient Function Claims, and the experiences in some countries on the substantiation of claims.

This symposium was organized by the International Life Sciences Institute Taiwan(ILSI Taiwan), sponsored by the Food and Drug Administration of Taiwan, Ministry of Health and Welfare. It has attracted more than 250 attendees including regulators from governmental and non-governmental organizations, and industrial companies, to learn the regional regulatory update and international perspective about health/function claims.

### 1. Symposium Program

The symposium was chaired by Prof. Fuu Sheu, Deputy Executive Director of ILSI Taiwan. In the welcoming remarks, he addressed Taiwan government is re-evaluating its current enforcement rules on nutrient function claims via a project commissioned by ILSI Taiwan.

Mr. Hiroaki Hamano, former technical advisor of the Ministry of Health, Labour, and Welfare of Japan for the Codex Committee on Nutrition and FOSHU as well as Food Labelling and the current technical advisor to the Consumer Affairs Agency (CAA) on Food Labeling, kicked off the first presentation by providing an update about Regulatory Framework on Nutrition Labeling and Health Claims in Japan. He illustrated that the new Food Labeling Act of Japan has entered into effect in April 2015, with the existing voluntary nutrition labeling becoming mandatory. A new system called “Foods with Function Claims”, is also introduced in the new laws to operate alongside Japan’s FOSHU health claims system. This system was proposed by the Council of Regulatory Reform organized under Cabinet office, to promote innovation in a market that was badly-hit by the economic recession. The new system which enables food business operators (FBOs) to make Function Claims not only on processed or prepackaged foods including so-called dietary supplements, but also on fresh produce supported by the scientific evidence-based substantiation under FBOs’ own responsibility.

An overview of the Health/Functional Food Act (HFFA) and regulations on food with function claims in Korea was presented in the second session by Dr. Oran Kwon, Professor of the Ewha Womans University. HFFA was narrowly defined as the synonym



Photo 1 Mr. Hiroaki Hamano, advisor of ILSI Japan, presented “Regulatory Framework on Nutritional Labeling and Health Claims in Japan”.



Photo 2 Mr. Hiroaki Hamano, advisor of ILSI Japan, addressed to the audience.



Photo 3 Mr. Chao-Kai Hsu, Deputy Director of Division of Food Safety of Taiwan Food and Drug Administration, presented an award to Mr. Hiroaki Hamano in appreciation of his speech on “International Experiences on Management and Regulation of Health Claims.”

of dietary supplements when it was initially introduced in 2002. With an effort on regulation progress, the definition of Health/Functional Foods has been extended to cover not only dietary supplements but also functional foods in conventional food forms. Furthermore, a clear legal framework with detailed technical guidelines on scientific substantiation of function claims was provided. The amended Act requires both functional ingredients and consumer products to obtain the recognition of the Ministry of Food and Drug Safety (MFDS). In Korea, there are two pathways to obtain the claim permission of functional ingredients. One is granted by MFDS through their pre-authorized ingredient monograph list, which is available to any manufacturer or distributor who can ensure the conformity with the standard required. The other pathway is through individual registration dossier submission by the applicant to get the claim’s approval of functional ingredients for exclusive use. Dr. Kwon also addressed

that standardization, safety & effectiveness are the golden triangle of evaluation of scientific substantiation of function claims.



Photo 4 Dr. Oran Kwon, Professor of Ewha Womans University, presented "Regulations on Food with Function Claims in Korea".

In the final session, Ms. Pauline Chan from ILSI Southeast Asia Region presented a comprehensive review of the regulatory status of various types of health claims permitted in the 5 select SEA countries-Indonesia, Malaysia, Philippines, Singapore and Thailand. The available positive list of permitted claims, regulatory framework for application, review criteria of claim applications as well as the scientific substantiation requirement were all included. In addition, the key learnings of claim applications were also highlighted. In the end, Ms. Chan addressed the need and effort in ASEAN to continue harmonization of the nutritional labeling & claim regulations.



Photo 5 Ms. Pauline Chan, Scientific Program Director of ILSI Southeast Asia Region, presented "Status of Health/Function Claims and Scientific Substantiation in South East Asia Region".

## 2. Conclusion

The success and value of the symposium was acknowledged by the attendees in providing update, sharing good regulatory practice, modeling on health claim regulation management, and defining the guidelines for evaluation of the substantiation of claims. A high level conversations on capturing regional regulatory trend and fostering harmonization were also addressed in the panel discussion.



Photo 6 Dr. Fuu Sheu, deputy executive director of ILSI Taiwan (the first one from the left), chaired the panel discussion for attendees with all the speakers.



Photo 7 Dr. Oran Kwon answered questions during the panel discussion.

Outreaching to countries with successful experience on regulatory framework development in addition to utilizing global evaluation scheme on scientific substantiation of health claims may serve as a good guidance for a country like Taiwan in proceeding current regulatory progression.