Health claims are important tools used to communicate the health benefits of a food product to consumers, providing point-of-sale information to assist them in making informed choices. Globally, there is wide disparity between permitted claims across countries, and the process and requirements used to substantiate these claims. This presents a number of challenges for key stakeholders including regulatory bodies, industry and researchers.

The half-day seminar ‘Scientific Substantiation of Claims’, held in Bali, Indonesia prior to the 36th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), reviewed the current status and substantiation process for nutrition and health claims as well as the challenges faced in Australia, Europe, Japan and Southeast Asia. It also provided an update on new biomarkers and parameters for evaluating health benefits, such as weight control. Attended by 90 regional and international participants including government and food industry regulatory personnel, the seminar commenced with a welcome address from ILSI Southeast Asia Region Executive Director Mrs. Boon Yee Yeong.

Mr. Basil Mathioudakis, Head of the Nutrition, Food Composition and Information Unit of the European Commission outlined the current state of affairs with regards to authorised claims in the EU. He noted that nutrition and health claims are regulated in the EU by Regulation (EC) No 1924/2006, gazetted on 20 December 2006, which sets the definitions, general principles and conditions as well as the procedures for the adoption of the implementing measures that authorise or reject claims. Only authorised claims can be used in the labelling, advertising and presentation of foods in the EU. One of the most important criteria for their authorisation is that they should be substantiated by generally accepted scientific evidence. Over 2200 claims have been evaluated thus far by the European Food Safety Authority (EFSA), with 259 authorised and just over 2000 rejected. About 2000 claims, mainly concerning botanical substances, are still under consideration and they can remain on the market until a final decision is reached, provided the other provisions of the Regulation are fulfilled.

Key learnings and considerations in the scientific substantiation of claims in the EU was then presented by Dr. Ariane Titz from the Nutrition Unit, EFSA. She reviewed the scientific assessment of health claims performed by the Panel on Dietetic Products, Nutrition and Allergies (NDA) of EFSA, explaining the principles of assessment. All relevant studies with sufficient quality are weighed with respect to their strength, consistency and specificity, and additional consideration is given to dose-response and biological plausibility. She noted that selecting relevant human studies for scientific substantiation of the claim, studies should be carried out with the food/constituent for claim, and using the appropriate outcome measure(s) for the claimed effect. Conditions for the studies should be comparable to conditions of use for the claim (e.g. dose tested vs. dose proposed) and study groups should be representative of the target group or able to be extrapolated to the target population. She went on to cite examples of the most common pitfalls encountered by the Panel in the evaluation of health
claims, concluding by encouraging industry to use the EFSA website applications ‘help desk’ to assist in the preparation of claims applications.

Dr. E Siong Tee, ILSI Southeast Asia Region, Malaysia described the process and key learnings in scientific substantiation of health claims in Southeast Asia. Dr. Tee began by noting that health claims are currently permitted in some countries in Southeast Asia, mostly arising from applications from food industry for other function claims and disease risk-reduction claims. Dr. Tee presented a summary of the permitted claims in the region, noting that regulatory systems related to claims approval varied from country to country in the region. He reviewed the claims application process, with each claim submitted in a prescribed format, and accompanied by scientific substantiation to be reviewed by a panel of experts appointed by the relevant regulatory agency. Two critical components of the application are the minimum level that the nutrient must be present for the claim, and sound scientific evidence for the claim, based on randomized, placebo-controlled double blind clinical trials and other appropriate scientific data. Dr. Tee highlighted examples of some errors or inappropriate submissions for health claim applications in Malaysia. Some applications were rejected due to inadequately prepared dossiers, with sections of the application poorly explained, particularly the section on scientific substantiation. Other examples include wording of the proposed claim not matching the findings of the studies or extrapolated beyond the findings; the compound used in the study not matching the compound that is the subject of the claim; the food vehicle for the compound not matching the intended claim; studies were carried out using the ‘pure’ compound, rather than in food vehicles; or the study findings were not appropriate for the general population.

The nutrition labelling system in Japan was then discussed by Dr. Toshitaka Masuda, Food Labelling Division, Consumer Affairs Agency (CAA), Government of Japan. In order to ensure consumers’ safety and their ability to choose foods offered for sale independently and rationally, the Food Labelling Bill was passed in Japan on 21 June 2013, followed by the Food Labelling Act, gazetted on 28 June 2013, moving the existing voluntary Nutrition Labelling System to a mandatory framework. Dr. Masuda noted that considerable time was spent investigating the issue of mandatory nutrition labelling, with the CAA firmly believing that such labels are necessary for the improvement of consumers’ health, enabling them to manage their nutritional status and dietary habits. The CAA encourages food manufacturers to use nutrition labelling on a wide range of food products, and educates consumers on how to put healthy dietary habits into practice by helping them understand nutrition labelling and how to make practical use of its information. In Japan, function claims are only permitted for two food categories under the Food Sanitation Act and the Health Promotion Act: Food for Specified Health Uses and Food with Nutrient Function Claims. The government of Japan is developing a new system enabling manufacturers to make function claims on processed and fresh food using scientific evidence-based substantiation, using the U.S. dietary supplements regulatory system as a reference.

Dr. Pichet Itkor, Food Industry Club, Federation of Thai Industries, then outlined the industry challenges in the preparation of scientific dossiers for claims. He noted that food industries are now implementing nutrition labelling and displaying nutrition/health claims not only to provide information about the product to enable consumers to make an informed choice of purchase, but also to increase their competitiveness in the market place. ‘Recommendations on the Scientific Substantiation of Health Claims’, an Annex to ‘Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)’, have been established to assist regulatory authorities in their evaluation of health claims in order to determine their acceptability for use by industry. These recommendations state that health claims shall be supported by a sound and sufficient body of scientific evidence to substantiate the claim, and provide truthful and non-misleading information to assist consumers in choosing a healthful diet. In most of the ASEAN countries, there are positive lists of approved nutrient function claims, other function claims and disease risk-reduction claims. To substantiate any new health claim, industry is obliged to submit well-designed human intervention studies clearly demonstrating the consistent association between the food or food constituents and the health effect. The totality of evidence, including evidence that supports or contradicts the claim effect and evidence that is ambiguous or unclear are also required. Dr. Itkor
noted that the differences in regulatory requirements for health claims among ASEAN countries remains the most critical trade barrier to the commercial distribution of food products in Southeast Asia. He emphasized the need for a platform for harmonization of regional regulation on the use of nutrition and health claims, noting that ILSI SEA Region has been working in this area, including developing ‘Guidelines for Scientific Substantiation of Nutrition and Health Claims for Food/Functional Foods’, along with a regulatory framework for harmonization of nutrition labelling and claims.

**New biomarkers and parameters for evaluating health benefits** were then presented by Dr. Judy Cunningham, Food Standards Australia New Zealand (FSANZ). A standard for the use of health claims on food labels has been in operation in Australia and New Zealand since January 2013. Standard 1.2.7 of the Australia New Zealand Food Standards Code sets out the requirements for health claims and identifies two types of health claims – general and high level. High level claims refer to serious diseases or biomarkers of serious disease, such as serum cholesterol. There are over 200 pre-approved food health relationships in Standard 1.2.7 that companies can use to formulate the wording of health claims that accurately reflect the relationship and any established conditions for the claim. In Australia and New Zealand, new health claims require a systematic review of all available evidence to establish whether a relationship exists between the food and the health outcome. Dr. Cunningham noted that biomarker evidence used to substantiate a health claim must be assessed for quality in the same way that studies of other health outcomes would be assessed. Biomarkers used should be well established, relevant to the claimed health outcome, measurable and responsive to dietary intervention. Although there is a lot of current research into a range of biomarkers, there appear to be few ‘new’ biomarkers suitable for use in regulatory systems that require a high degree of certainty in the evidence supporting new health claims. Dr. Cunningham recommended that food companies who wish to use biomarker evidence to substantiate a new health claim should understand the requirements in each country where they wish to use the claim.

The presentations from this seminar are now available through the ILSI SEA Region website [www.ilsi.org/sea_region](http://www.ilsi.org/sea_region)