

A large graphic consisting of two overlapping circles. The top-left circle is light grey, and the bottom-right circle is bright red. The text is positioned within the grey circle.

YOKOHAMA

International Perspectives on
Dietary Supplement Regulation

Yokohama, Japan, 17 April 2007

Report

IADSA

International Alliance of Dietary/
Food Supplement Associations

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Nearly 300 hundred delegates, including regulators and government officials from the Association of South East Asian Nations (ASEAN), China, the European Union (EU), Japan, Mexico, and the United States of America (USA), scientific bodies, trade associations and industry attended the workshop 'International Perspectives on Dietary Supplement Regulation', held in Yokohama, Japan on April 17 2007.

The event was organised by the International Alliance of Dietary/Food Supplement Associations (IADSA), in conjunction with its four Japanese member associations: Japan Health Food & Nutrition Food Association, National Nutritional Foods Association Japan, The Japanese Institute for Health Food Standards, and the Nutrition and Food Technology Society.

Welcoming delegates to the Workshop - the first time that representatives from Japan, the EU, the USA and ASEAN have met together to present, compare and discuss their regions' regulatory models - IADSA Chairman, Randy Dennin read a message from the Japanese Prime Minister, Shinzo Abe, in which he offered his support and good wishes for a successful and productive day.



IADSA Chairman Randy Dennin and Dr Kiyomichi Fujisaki from the Japanese Ministry of Health, Labour and Welfare.

The opening session, Global Developments: Dietary Supplements, was jointly chaired by Dr Toshihiko Osawa, Professor at Nagoya University, Japan, and Daniel Quek, Chairman of the ASEAN Alliance of Health Supplement Associations.

Clarity of goals

Simon Pettman, Executive Director of IADSA, began the day with a wide-ranging presentation entitled Global Regulatory Trends. He first reviewed how regulation had evolved in the ten years that IADSA has been working with governments, industry and the scientific community across the world. He outlined the key regulatory reference points in dietary supplement regulation, the many areas of the world where this regulation is under discussion, and its focus: on claims, maximum levels for vitamins and minerals and other bioactive substances, and Good Manufacturing Practice.

Discussing the challenges of harmonisation, the trends that are likely to emerge and the potential impact on companies and markets over the next ten years, Mr Pettman highlighted the need for clarity of goals to ensure that regulation offers consumer protection and choice, is globally competitive, promotes free trade and is proportionate.

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Other relevant factors included the power and influence of tradition, legal approaches (common law), the need to create categories for functional foods, food supplements, traditional medicines and pharmaceutical medicines, and to clarify the scope of these categories. Safety and Manufacturing quality were further important factors, as was implementation and enforcement. Finally, as an alternative or perhaps as an adjunct to regulation, Simon highlighted the role that can be played by industry Codes of Conduct.

Japanese regulatory system

Dr Keiichi Nakabayashi, Counsellor from the Minister's Secretariat at the Japanese Ministry of Health, Labour and Welfare spoke next. Dr Nakabayashi's presentation, Key Developments in Japan, offered a very clear and succinct explanation of the framework of the Japanese regulatory system for claims where Foods for Specified Health Uses (FOSHU) and foods with nutrient function claims play a major role.



Dr Keiichi Nakabayashi, from the Japanese Ministry of Health, Labour and Welfare gave an overview of regulatory developments in Japan.

Dr Nakabayashi first outlined the background to and system for Foods with Health Claims, Foods with Nutrient Function Claims, Foods for Specified Health Uses, Foods for Special Dietary Uses. He then explained how the system offers an opportunity for people to choose the foods they need to remain healthy. However, when discussing the regulations designed to ensure the safety of 'health foods' and the regulations to prohibit false and misleading advertising, Dr Nakabayashi pointed to the problems that can be caused in relation to both safety and advertising.

United States regulation explained

The next speaker, Dr Barbara Schneeman, Director, The Office of Nutritional Products, Labelling and Dietary Supplements at the Centre for Food Safety and Applied Nutrition of the United States Food and Drug Administration, was unable to attend the Workshop in person. Instead, her presentation, Key Developments in the United States, was broadcast on video, and in it Dr Schneeman set out the framework of the Dietary Supplement Health Education Act, which has now been in law in the United States for over 12 years.

She first addressed the legal authority of the Food and Drugs Administration to regulate in the area of dietary supplements, and then their definition. Next, the pre-market notification system for New Dietary Ingredients was explained, and the arrangements for both post-marketing surveillance and the recent initiative on Adverse Event Reporting. Finally, Dr Schneeman covered mandatory labelling information and the use of claims on dietary supplements, including those where pre-market review was required.

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Regulatory harmonisation in the EU

The first speaker after the coffee break was Basil Mathioudakis, Head of Unit for Food Law, Nutrition and Labelling, Directorate General for Health and Consumer Protection at the European Commission. Against a background where the European Union is in the process of implementing the most ambitious programme of legislation in the area of food supplements and fortified foods ever envisaged by a regional body - establishing a single definition and regulatory framework across 27 countries - Mr Mathioudakis' presentation, Key Developments in the European Union, outlined both achievements to date and challenges to come. Having first outlined the general objectives of food law - the protection of human life and health, the free movement of goods in the EU internal market and the need to take international standards into consideration - Mr Mathioudakis explained that food law is based on Risk Analysis, which itself is split into three parts: risk assessment, risk management and risk communication. Mutual recognition amongst the EU Member States so as to ensure the free circulation of goods was a further basic principle. Mr Mathioudakis then centered on the key points from the areas of EU regulation relevant to food supplements that are currently under discussion, including the setting of maximum levels for vitamins and minerals and other ingredients, and the regulations for Novel Foods, Fortified Foods and Health Claims.



Attendees at the event included (from left to right) Simon Pettman, IADSA Executive Director, Basil Mathioudakis, Head of the European Commission's Food Law Unit, regulators Zubaidah Mahmud from Brunei and Anise Talib from Malaysia, Mawarwati Djamaluddin, Chair of the ASEAN Product Working Group on Traditional Medicines and Health Supplements, and Daniel Quek, Chairman of the ASEAN Alliance of Health Supplement Associations.

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ASEAN - 11 priority sectors

Mawarwati Djamaluddin, Chair of the ASEAN Product Working Group on Traditional Medicines and Health Supplements spoke next. The 10 countries which make up the Association of South East Asian Nations (ASEAN) are in the process of harmonising their regulation in a region that brings together more than 500 million people and includes some of the world's most dynamic markets.

In her presentation Mrs Djamaluddin set out the objectives of the harmonisation process, its status and the future work-programme. 11 priority sectors had been identified, including Traditional Medicines and Health Supplements, to be fast-tracked for harmonised regulation by 2010, as part of the 'Road Map' for integration of the Healthcare sector.

The areas under discussion by a government Working Group were Definition and Terminologies; Market Authorisation Procedures, Safety and Quality Requirements, Labelling, Claims, Post Marketing Surveillance and a Post Marketing Alert System.

The morning session ended with a Panel Discussion with the speakers joining the Chairmen to take questions from the audience. Mr Mathioudakis said that following its Consultation Paper the European Commission was now drafting an Orientation Paper on maximum levels for vitamins and minerals with the aim of having it ready by July. A proposal for a Commission Directive could be expected by the end of 2007. However, with regard to possible extension of the Food Supplement Directive to other ingredient categories, Mr Mathioudakis said that the Commission were 'not ready' for a further big regulatory effort at the present time, but that some categories of ingredients might be 'more ready' from a scientific point of view, particularly herbals.

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Shuhei Yoshida, Chairman of the Japanese Nutrition and Food Technology Society, took over the Chair for the first part of the afternoon session, which dealt with The Regulation and Substantiation of Health Claims.

Noting that the establishment of effective regulatory frameworks for claims is currently one of the most complex and significant areas of activity throughout the world, Professor David Richardson, Scientific Advisor to the UK Council for Responsible Nutrition and the European Federation of Associations of Health Product Manufacturers (EHPM), presented A Global Comparison of Approaches.

Worldwide research

This offered a comprehensive overview of the developments underway at national, regional and international levels in relation to functional foods, including worldwide research on the effects of foods and food components on health outcomes. Contrasting their key elements with reference to how claims are substantiated, Professor Richardson highlighted the need for a common approach for claim substantiation for ASEAN, the European Union, North America and Codex. He also addressed the need for substantiation to reflect the evolution of science as well as consensus science. Professor Richardson further emphasised that central to any approach was the need to improve the free movement of goods and promote and protect innovation. He then joined the Chairman for a Question and Answer Session.



Professor David Richardson addressed the need for a common global approach towards claims substantiation.

For the next Session, entitled Towards a Global Approach to the Safety of Bioactive Substances in Supplements, Kazuo Sueki, Chief Executive Officer of The Japanese National Nutritional Foods Association took over the Chair, together with Dr Hirobumi Ohama, Chairman of The Japanese Institute for Health Food Standards.

Workable model to assess safety of bioactives ingredients

Dr John Hathcock, Vice President of Scientific and International Affairs at the Council for Responsible Nutrition in the United States spoke next. His subject was Establishing a Model for the Safety Assessment of Bioactive Substances in Supplements, and he explained that the safety of vitamin and mineral ingredients had been the subject of considerable national, regional and international discussion over many years - and that while vitamins and minerals represent the majority of the dietary supplement market in many countries, the use of other bioactive ingredients is on the increase.

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Pointing out that ensuring that there is a workable model for assessing the safety of these ingredients and then testing that model has been a key priority, Dr Hathcock presented the latest thinking in the area, focussing on the models for application for a range of bioactive ingredients, including CoQ10, glucosamine and amino acids.

Dr Shaw Watanabe, Director General of the National Institute of Health and Nutrition continued the theme of the safety of Bioactive substances in his presentation, Intake of phytochemicals by Japanese and their health effects. Noting that more than 600 food factors in vegetables and fruits are considered to influence the various metabolic stages in the body, Dr Watanabe made the point that non nutrient food chemicals are increasingly coming to public attention because of their various possible effects in health promotion and disease prevention. However, human intervention studies have so far failed to demonstrate these effects and, to facilitate the proper evaluation of functional food factors (FFF), a database of non-nutrient FFF is now under development. The particular advantage of this database is that from dietary records the total intake of phytochemicals can be estimated and from epidemiological studies the most effective combination of FFF for human health can be evaluated.

Dr Toshihiko Osawa then addressed the subject of Bioactives and the consumer: use, misuse and their role in maintaining health. With the possibilities for the development of Functional Foods adapted for particular health conditions in mind, Dr Osawa's presentation centered on the evidence for fruit and vegetables and the application of their biomarkers for disease prevention.

Next, David Seckman, Executive Director/CEO of the Natural Products Association in the United States, discussed the Effect of Dietary Supplements on US Health Care Cost Reduction. Pointing to the increasing healthcare costs of ageing populations, Mr Seckman's presentation covered the outcomes of a study commissioned by the Dietary Supplement Health Alliance, and carried out by the Lewin Group. One of the key findings of the study was that supplementation with Calcium with Vitamin D, Folic Acid, Omega-3 Fatty Acids and Lutein with Zeaxanthin could result in an estimated healthcare cost saving of over \$20.1 billion over a five year period.

Vision of the future

In the final session Dr Yozo Hayashi, Director General, The Japan Health Food & Nutrition Food Association, and Dr Tohru Inoue from the Biological Safety Research Centre, of The Japanese National Institute of Health Sciences shared with delegates the conclusions they had drawn on the development of global regulation for food products and their vision of the future application and benefits of food supplements and functional foods. This ended a highly successful day where, to quote IADSA Chairman Randy Dennin,

'The Workshop demonstrated that while there continue to be many different approaches to regulating dietary supplements, the principles that form the basis of these are increasingly consistent throughout the world. IADSA will build on this global workshop with increased dialogue to encourage further detailed discussions at national levels.'

The International Alliance of Dietary/Food Supplement Associations (IADSA) brings together over 50 associations of dietary/food manufacturers and distributors from across the world. IADSA's central goal is to ensure a greater exchange of information about dietary supplements and ingredients among scientists, regulators, industry and consumers.

IADSA

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