IADSA Newsflash

April 2014

The IADSA Annual Week, Verona 2014

Words from Ric Hobby, New elected Chaiman

Dear Members

I am delighted to have been entrusted with the Chairman's role at this exciting time in IADSA's development.

Having been involved in IADSA since the founding meeting in 1998, I have constantly been impressed with the way the Alliance works so effectively together on so many diverse and complex issues, and achieves such impressive results.

To maintain this path requires us to continue to work closely together, whether from associations, small, medium or large companies or the scientific community.

Our unique style of working with government is clearly appreciated by decision makers. We need to continue to provide value to them and share our ideas on the direction for policy and regulation in our sector.

I welcome and invite your participation as we all work together over the next two years.

Ric Hobby
IADSA Chair

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International Alliance of Dietary/ Food Supplement Associations

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Recap of the week's event

The 2014 IADSA Annual Meeting held in the beautiful Italian city of Verona once again provided an opportunity for the members to address the major strategic issues facing the sector worldwide and meet with other members and with leading regulators from across the world. Regulators or leading scientific advisers to government attended from ASEAN, China, the EU, India, Korea, Mexico and Russia. In addition to the Annual Meeting, IADSA organised the first ever global Regulator Roundtable on botanical supplements and hosted meetings of its Scientific Council, Technical Group and the Board.

After two terms as IADSA Chair Pete Zambetti stepped down as Chair and RIc Hobby nominated by CRN UK, Bernd Haber, nominated by BLL Germany, and Michelle Stout nominated by CRN US, took on their two-year terms as Chair, VIce Chair and Treasurer respectively.

Two Global Leadership Awards were presented to two long-standing and extremely dynamic experts in the sector, HongMin Xu and Peter Berry Ottaway. Both had shown exceptional leadership over many areas.

It was agreed that the next Annual Meeting would be held in Singapore in 2015 in view of the approaching deadline for the completion of the ASEAN Economic Community which will create, in population terms, the world's largest single trading market. This meeting will be hosted by HSIAS, the Singapore association.

IADSA Global Leadership Awards

2014

HongMin Xu, Heads of the China Healthcare Association's Information Exchange Committee and is Director of Regulatory Policies for Amway China, for his exceptional work over many years in leading work to build a regulatory system to support the development of the Chinese market in food supplements.

Peter Berry Ottaway, key technical advisor to IADSA since its creation, who has represented IADSA in many Codex Alimentarius committees for his world-leading experience and analysis of the technical regulatory issues impacting the sector

2013

Zubaidah Mahmud, Chair of the ASEAN Traditional Medicines and Health Supplements Scientific Committee (ATSC), for her work to help create what is the most comprehensive regional regulatory model for supplements in the world.

Dr. John Hathcock, U.S. Council for Responsible Nutrition (CRN), for his exceptional contribution to the science that underpins dietary supplement regulation. John has worked for more than 20 years as a leading voice in the world on the science to underpin the regulation and use of supplements. He is the author of numerous publications that have helped shape the way regulatory bodies view food supplements.

Regulatory news

ASEAN

TMHS PWG Working towards finalisation of harmonized ASEAN Regulation

The Scientific Committee, Framework Task Force and GMP Task force of the ASEAN Consultative Committee for Standards & Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) met in Kuala Lumpur Malaysia from 3 - 7 March 2014. Though the scientific committee did not manage to complete pending technical requirements such as safety data requirements and limits of microbial contaminants, significant progress had been made. The finalisation of these technical requirements can be expected in the next 2 meetings. The next meeting for the scientific committee, Framework Task Force and GMP Task force, will be held from 23- 27 June 2014, back to back with the 22nd ACCSQ TMHS PWG meeting, at Siem Reap Cambodia.

India

Calls for data for more than 1x RDA

The Chair of the Sub-group on the draft Nutraceuticals Regulations has recently called for published data on the Indian population to support more than one RDA in view of revising the Draft Food/Heath supplement/ nutraceutical Regulation. The issue will be referred to the Indian Council of Medical Research (ICMR), the body responsible of the RDA for the Indian population.

A 2006 law currently restricts the use of minerals or vitamins in amounts exceeding the RDA for Indians.

Japan

Consumer survey reveals that 40% of Japanese take supplements everyday

The Consumer Affairs Agency releasds early April the results of its consumer survey on 3,000 people, both males and females, from 15-69 years old. This survey was launched in the context of the reflection on the development of the new functional claims system based around he US model for dietary/food supplements (D/F supplements).

Results of this survey show:

- Ratio of intake D/F supplement past 1 year ca.44 %
- Frequency of intake: About 40% take supplements everyday
- Feeling of safety for D/F supplement: 20 - 40% believe that supplements are safer than drugs
- Impression for active ingredients of natural sources: more than 50% feel that these ingredients are safe
- Reasons for taking D/F supplement No.1 Health Promotion ca.40% - No.2 Balance of Nutrients: Ca.38%- No.3 Recovery of fatigue Ca.23%
- Impression for structure/ function claims in US: More than 70% think the can make their right choice themselves
- Scientific Evidence for functional claims of D/F supplement: More than 60% believe that human studies for all foods would be required. This percentage increases to 80% for both tablet/capsule forms.

Tawain

Taiwan FDA to revise health food efficacy evaluation methods for claims on liver protection

Taiwan FDA on 4 March issued revised draft "Efficacy Evaluation Methods for Claims on Liver Protection" for public consultation until 18 March 2014. The draft also includes requirements on claims, advertisements, and product labelling. Approved claims are related to the prevention and risk reduction of chemical induced liver damages, hepatitis related liver damages, liver fibrosis, and fatty liver. For more information: http://goo.gl/NBbpCz

New Zealand

Natural Health & Supplementary Products Bill expected later this year

The Bill is foreseen later this year, potentially prior to an October/November election and may likely enter into force 1 – 2 months after its enactment.

The Natural Health & Supplementary Products Bill seeks to regulate low-risk natural health products in New Zealand. Part 1 of the bill defines a natural health product according to how the product is consumed, its ingredients, and the type of claim of health benefit made. It also proposes the establishment of a regulatory authority within the Ministry of Health, which would recognise decisions made by other authorities, create an advisory committee to advise the authority, and maintain an online database of natural health products.

Part 2 sets out the regulatory scheme. It proposes that before products can be marketed, they would have to be notified on an online database. Part 2 would establish penalties, a code of manufacturing practice, and mechanisms for appeal and the recall of products. It would also require product notifiers to inform the authority about any serious adverse reactions to products, and any ingredients which were not previously notified.

Europe

Favourable EFSA opinion on vitamin D and contribution to normal bones and teeth development

EFSA has published a favourable scientific opinion on the substantiation of a health claim related to vitamin D and contribution to normal bone and tooth development pursuant to Article 14 of the Claims regualtion. The same Article 13(1) health claim has already been authorised for the general population, whereas this opinion is targeted at the population of infants and young children.

MEPs reject the new definition of nanomaterials

The European Parliament has rejected the European Commission's proposal to exempt from labelling engineered additives already in use at the nano size. MEPs have now called on the Commission to submit a new act.

EFSA publishes scientific opinions on DRVs for biotin and pantothenic acid

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) has now published their scientific opinions on Dietary Reference Values for biotin and Pantothenic acid. For more information: http://www.efsa.europa.eu/en/efsajournal/pub/3580.htmhttp://www.efsa.europa.eu/en/efsajournal/pub/3581.htm

Commission publishes Regulation with non-authorised Art. 13(5) health claims

The European Commission has recently published Regulation (EU) No 155/2014, refusing to authorise twelve Article 13(5) health claim. Full details are available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:050:0011:0016:EN:PDF

Illegal presence of meso-zeaxanthin in eye- health supplements

Strong suspicion were put on eye-health supplements containing lutein and zeaxanthin, following the occurrence of adverse events reported under the French Adverse Report System 'Nutrivigilance'. The investigation of the French Authorities DGCCRF concluded that '50*% of products were contaminated by meso-zeaxanthin, an unrated isomer of zeaxanthin. The ingredient present in this molecule was the result of a manufacturing process not authorized at European level that could cause adverse effects*".

Maximum level for citrinin set for supplements

Following concerns raised on the safety of citrinin, the European Commission published Regulation (EC) No 212/2014 setting a maximum level for this contaminant at 2000 µg/kg for food supplements based on rice fermented with red yeast *Monascus purpureus*. This level is to be reviewed before 1 January 2016 in the light of information on exposure to citrinin from other foodstuffs and updated information on the toxicity of citrinin, in particular as regards carcinogenicity and genotoxicity. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:067:0003:0004:EN:PDF

2 novel ingredients authorized for use for supplements

- 6S)-5-methyltetrahydro-folic acid, glucosamine salt as a source of folate in food supplements.
- Coriander seed oil in food supplements with a maximum dose of 600 mg per day.

Polyvinylpyrrolidone-vinyl acetate copolymer now authorise

Following a request from the European Commission, the European Food Safety Authority (EFSA) evaluated the safety of the food additive in food supplements and concluded in 2010 that this compound was unlikely to be of safety concern at the proposed uses.

Polyvinylpyrrolidone-vinyl acetate copolymer (E1208) has now been added to the list of food additives approved for use in solid form supplements at a level of 100,000 mg/kg.

Polyvinylpyrrolidone-vinyl acetate copolymer is a binding / coating agent known to improve film toughness, increase coating application rates and promotes better film adhesion.

EFSA evaluates the Qualified Presumption of Safety approach for botanicals

The EFSA opinion relating to the use of the Qualified Presumption of Safety (QPS) approach to botanicals is now available. http://www.efsa.europa.eu/en/efsajournal/pub/3593.htm

The QPS approach was originally developed for the safety assessment of micro-organisms. However, the context of botanicals is much more complex. According to EFSA, the QPS approach offers only limited advantages over the existing methodologies and may not be cost-effective in the short term. EFSA recommends its use as an extension of the 2009 EFSA guidance for the safety assessment of botanicals and botanical preparations intended to be used in food supplements

Brazil

ANVISA bans food for athletes with irregular substances

ANVISA has banned four products present as food for athletes in the Brazilian market for non-compliance with regulations. The causes of prohibition were the presence of vitamins in excess of the maximum limits permitted levels, the use of substances whose safety has not been evaluated by the authority, such as glutamine and ornithine, and the inclusion of substances in formulas considered unsafe for use in foods, such as conjugated linoleic acid (CLA).

Another cause of prohibition was that some products containing branched-chain amino acids which if presented to consumers as food for athletes also violates

Brazilian regulations (RDC 18/2010). The products were recalled and can no longer be sold in Brazil.

Ecuador

New notification process for food advertising

Following the regulation of the Communications Law in Ecuador users who wish to advertise their products for food and health no longer will need to request permits but must notify the advertising or promotion to the National Agency for Regulation, Control and Health Surveillance (ARCSA).

Under Article 62 of the General Regulation of the Communications Law "advertisers or agencies representing them in the media, should notify the Ministry of Public Health on advertising for food or health at national level, notification will serve as authorization. "

In this context, users who want to advertise their products shall first submit a notification to ARCSA in order to be able to start broadcasting their advertising.

Mexico

New bill on GMO labelling

Last March 13 a decree proposal about GMOs was published in the Parliamentary Gazette of Mexico. The bill seeks to add to the Federal Consumer Protection Act an article where it is established that genetically modified food must indicate its content of GMOs on its labels or containers.

Given the scope of the Federal Consumer Protection Act, the initiative would impact food supplements containing GMOs and a change in the labelling of the products that are currently marketed in the country will be needed.

The bill, proposed by Senator Fernando Herrera Avila from the National Action Party (PAN), was presented to the Senate plenary on March 13 and given to committees of Commerce, Industrial Development and Legislative Studies where the analysis will be conducted and an opinion will be delivered.

GCC (Gulf Cooperation Council)

GSO draft standard on food additives notified to the WTO

The GCC Standardisation Organisation (GSO) has notified the draft standard on additives permitted for use in foodstuffs (GSO 5/DS.....:2013) to the WTO. Many additives (e.g E160a carotenes beta vegetables, E900 polydimethylsiloxane, E952 cyclamates, E962 aspartame acesulfame salt used in food supplements are missing.
Two other standards, the GSO 23/1998 “Colouring matters permitted in foodstuffs” and GSO5/FDS..../2013 "Sweeteners Permitted for Use in Food Products" have also been notified. Warning statement will be required for Sunset Yellow E 110 and Allura Red E129.
https://members.wto.org/crnattachments/2014/sps/SAU/14_1282_00_e.pdf

Morocco

Morocco harmonises labeling rules with EU

The Moroccan Food Safety Office (ONSSA) introduced a draft decree number 2-12-389 on food labelling based on the EU labellling regulation. This decree laid down restrictions on minimum font size, and imposes mandatory country of origin labelling for primary ingredients). Its implementation is expected in May 2014.

Africa regional groups

East African Community (EAC) Discusses harmonized draft standard for supplements

Regulators are currently working on a harmonised draft standard and guidelines on fortified foods and food supplements. The draft East African Community Standard on vitamins and mineral food supplements requirements specifies the terms and definitions, the general requirements, composition requirements, the labelling and packaging requirements for food supplements. The EAC countries are still working on setting maximum levels and establishing recommended nutrient intakes.

United States

FDA about to revise its labeling regulations

The Food and Drug Administration (FDA) is proposing to amend its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. This would include an update of the list of nutrients that are required or permitted to be declared; revision of Daily Reference Values and Reference Daily Intake values ; amendment of requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establishment of nutrient reference values specifically for these population subgroups, and finally the revision of the format and appearance of the Nutrition Facts label.

FDA issues draft guidance for honey labeling (FDA)

This draft guidance summarizes FDA's legal authority over honey and honey products and provides a commonly used definition of honey. FDA also provides draft guidance on labeling issues like the floral source of honey, blends of honey and other sweeteners and blends of honey and other ingredients, such as flavors. It also describes some of the measures FDA takes to guard against honey adulterated with cane sugar, corn syrup, or residues of chloramphenicol or fluoroquinolones.

FDA extends comment period on proposed rule on intentional adulteration

FDA has announced the extension of the comment period to 30 June on “Focused

Mitigation Strategies to Protect Food Against Intentional Adulteration," and the associated Draft Qualitative Risk Assessment, which was published in December. The subject of this proposed rule is to protect food from intentional adulteration when the intent is to cause large-scale public harm. Each food facility would be required to identify and implement focused mitigation strategies to minimize or prevent significant vulnerabilities in its food production process. FDA is proposing these requirements as part of the implementation of the FDA Food Safety Modernization Act (FSMA).

Import Alert on Dietary Ingredient Kratom

FDA has published an import alert notifying its field personnel that they may detain certain products containing kratom, without the need for a physical inspection.
Kratom is a new dietary ingredient that does not appear to have a history of safe use. Its Consumption could 'lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms' said FDA.
FDA has seen an increase in the number of shipments of dietary supplements and bulk dietary ingredients containing this ingredient. These shipments of kratom have come in a variety of forms, including whole leaves, processed leaves, leaf resins, leaf extracts, powdered leaves, and bulk liquids made of leaf extracts.

Russia

Russian ministries seek to pose more restrictions on GMO foods

In accordance with the Russian president's instruction, the Russian Education Ministry has prepared a draft federal law on improving government regulation with regard to genetic engineering, the oversight of the circulation of genetically engineered and genetically modified organisms and products manufactured with the use of such organisms or containing such organisms, and on introducing sanctions for breaching the Russian legislation related to genetic engineering.

The bill is aimed at strengthening government regulation of genetic engineering by means of:

- Introducing controls over cross-border movements of genetically engineered and genetically modified organisms;
- Setting up a monitoring system for GMOs intended for release into the environment, and for products manufactured with or containing such organisms;
- Introducing a mandatory requirement for labelling GMO products (the bill does not establish a threshold of 0.9% for knowingly processing ingredients);
- Granting the Russian government the right to restrict or ban the use of GMOs in the manufacture of individual products, including the use of GMO at individual processing stages.

The key impact of the bill is the possibility of the Russian government restricting the use of GMO in the manufacture of individual products, including at individual processing stages. The authors of the bill insist that this provision fully meets international practice. The bill also imposes sanctions for violations of the

Russian legislation related to genetic engineering; owing to this fact, the bill proposes introducing corresponding amendments to the Russian Code of Administrative Offences. At the same time, the Russian consumer rights watchdog Rospotrebnadzor has prepared a draft federal law on amending the Russian Code of Administrative Offences to toughen sanctions for failure to observe the food labeling requirements.

The bill applies to manufacturers and sellers of food products. It imposes more severe penalties for failure to omit from the label of a food product information about its having been manufactured with the use of genetically modified or genetically engineered organisms or containing such organisms. Proposed measures will fully apply to food supplements.

Ukraine

Ukraine allows a number of food additives in supplements

The State Sanitary and Epidemiological Service of Ukraine has recently approved the use of food additives sorbitol E420, cellulose E460, salts of fatty acids E470, magnesium oxide E530 in the composition of dietary supplements.
In accordance with the recommendations of the National Commission of the Codex Alimentarius, No maximum limits will be set for those ingredients. Amounts of use will be left to the discretion of companies in accordance with the production technology.

Codex Events 2014 & 2015

Codex Alimentarius Commission (CAC37)
Geneva, Switzerland
From: 14/07/14 To: 18/07/14

Codex Committee on Food Labelling (CCFL42)
Place: To be confirmed
From: 21/10/14 To:24/10/14

Codex Committee on Food Hygiene (CCFH46)
Place: To be confirmed
From: 17/11/14 To: 21/11/14

Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU36)
Bali, Indonesia
From: 24/11/14 To: 28/11/14

Codex Committee on Fats and Oils (CCFO24)
Malaysia
From: 09/02/15 To: 13/02/15

Codex Committee on Contaminants in Foods (CCCF9)
Netherlands
From: 16/03/15 To: 16/03/15

Codex Committee on Food Additives (CCFA47)
China
From: 23/03/15 To: 27/03/15

Codex Alimentarius Commission (CAC38)
Geneva, Switzerland
From: 06/07/15 To: 11/07/15

Codex Committee on Food Hygiene (CCFH47)
United States of America
From: 09/11/15 To: 13/11/15

Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU37)
Germany
From: 23/11/15 To: 27/11/15

Focus on harmonisation in the world

IADSA's initial work in 1998 focussed on global harmonisation in Codex Alimentarius, the international food standards setting body that was working on a global Guideline on Vitamin and Mineral Supplements. It was however recognised that in a number of regions governments were inevitably going to be working to build frameworks for supplementation (or at least discuss frameworks) which would draw on this Codex work but apply much more detail.

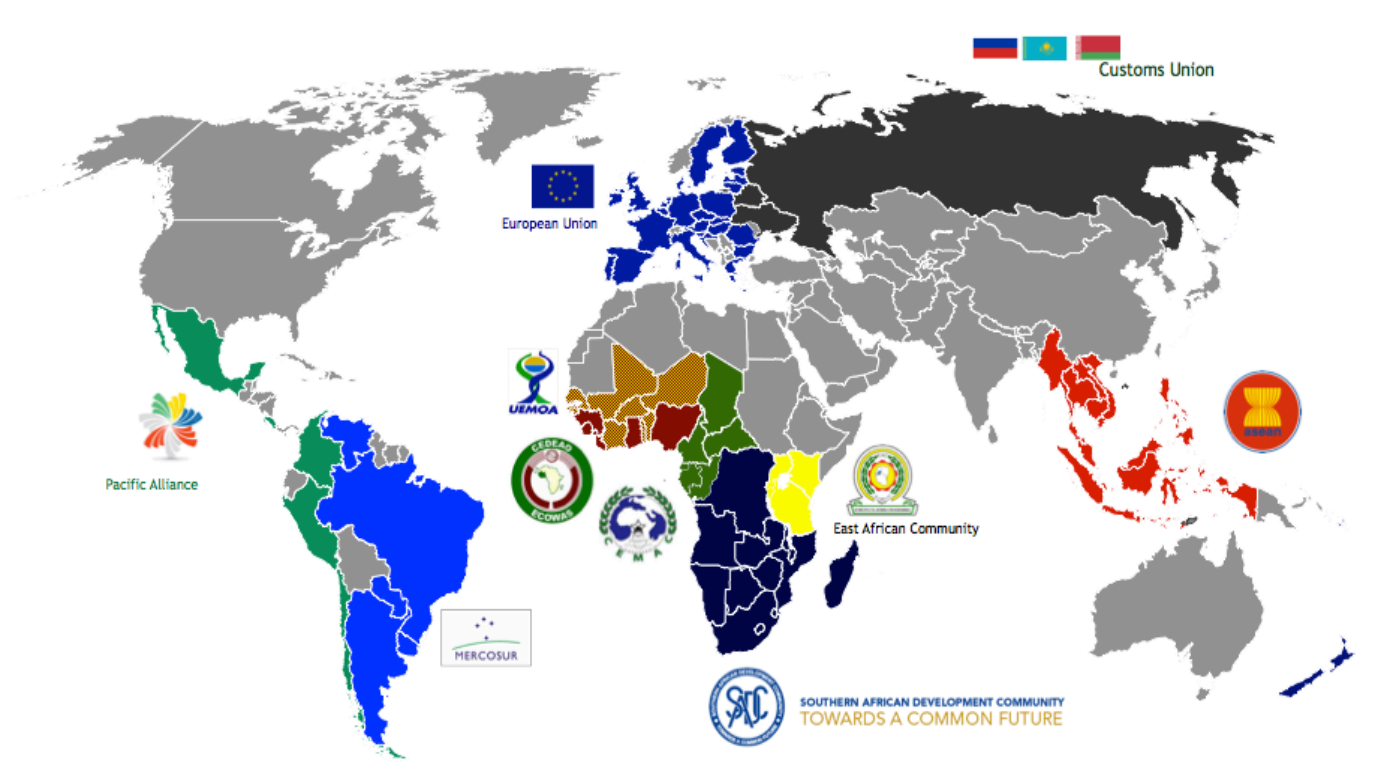
The EU led the way with its Food Supplement Directive of 2002 which now creates legislation for 28 Member States. This has been followed by extensive work in ASEAN which is now coming to the end of the first critical phase, to the Customs Union which is just beginning, to a number of initiatives in Africa and in Latin America, where the new Pacific Alliance has just started work to build a new framework.

European Union. The European Union is currently the most developed Single Market in the world, with a track record of work stretching back more than 40 years. Supplements are currently covered by a core piece of legislation, the Food Supplement Directive, plus a range of other legislative texts on manufacturing, additives, contaminants, etc that apply across more categories than supplements. All legislation is supported by the principle of mutual recognition of goods, which means that a product legally marketed in one country of the EU can be sold in all others.

Latin America. Progress is much slower in much of the Latin American region than either ASEAN or the EU but recently a trade accord which removes tariffs on 92% of trade has been signed by the regional trade block "Pacific Alliance" composed of Chile, Colombia, Mexico and Peru. This agreement will have a direct impact on supplements. In order to make free trade more efficient the Pacific Alliance established the need to develop Guidelines for the Approximation of Regulations on a number of priority sectors, cosmetics, medicines and processed foods. In this regard, Pacific Alliance member governments have requested their National Industries Chambers to develop and provide a proposal for Guidelines for the Approximation of Food Supplements Regulations.

Customs Union in Eastern Europe. Bzielorussia, Kazakhstan and Russia initiated a new Customs Union in 2010 which will be a region with shared borders, customs and harmonised technical standards. Once a product is approved for sale in any member country it will be accepted in all others. The Customs Union initiative is a part of a bigger entity created eleven years ago called EurAsEC (Eurasian Economic Community) which brings together Russia, Belorussia, Kazakhstan, Uzbekistan, Tajikistan and Kyrgyzstan as full members and Ukraine, Moldova and Armenia as observers.

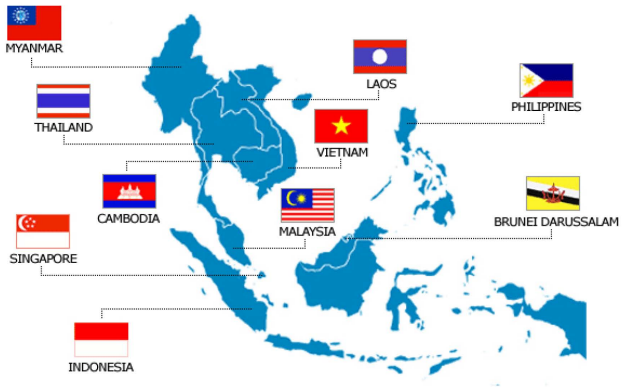
Overview of harmoninisation of food/health supplement regulation



Focus on ASEAN Harmonisation
A model for governments

ASEAN: 10 Countries who plan to harmonise by 2015 their regulations on Health Supplements and Traditional Medicines (TMHS).

By joining ASEAN each member country has agreed that it will change its existing legislation and introduce new legislation.



THE ASEAN COMMUNITY

The ASEAN Community comprises three pillars each of which has its own Blueprint. These, together with the Initiative for ASEAN Integration (IAI) Strategic Framework and IAI Work Plan Phase II (2009-2015), form the Roadmap for an ASEAN Community by 2015.

POLITICAL-SECURITY COMMUNITY (APSC)

ECONOMIC COMMUNITY (AEC)

SOCIO-CULTURAL COMMUNITY (ASCC)

The establishment of the ASEAN Economic Community by 2015 is crucial for the ASEAN health supplement sector because of the opportunities it will create to increase trade between ASEAN Member States and build opportunities to market products internationally.

Overview of the ASEAN harmonization of regulations for TMHS

Currently 10 areas for harmonisation have completed their respective guidelines. Some areas are in more advanced stages as compared to the others while work on one area (products at interface) has yet to commence.

Key discussions include harmonisation initiatives on terminologies, common technical requirements on product placements, Post-marketing alert (PMA) systems, Good Manufacturing Practices (GMP), labelling requirements, mapping and building the capacities of member countries. An ASEAN Scientific Committee (ATSC) was established in July 2007 to provide risk assessments and the appropriate scientific recommendations on key areas of the emerging regulatory framework.

IADSA and its regional partner AAHSA has long supported this ASEAN vision and work continues to provide the scientific, technical and regulatory expertise as required by the governments in this process. Achieving this goal of one legal framework across the priority integration sectors will create greater incentives for international companies to invest in the region and a stronger framework from which ASEAN companies can export to the world's major markets. AAHSA-IADSA have recently completed the first scorecard on this process for governments and the section providing an overview of the timing is as below: