

IADSA NEWSFLASH

JULY/AUGUST 2007

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IADSA

The International Alliance of Dietary /Food Supplements Associations was founded in 1998 to address the globalization of dietary supplement markets and increasing regulatory challenges. IADSA brings together 59 dietary supplement associations with the aim of building a sound legislative and political environment for the development of the dietary supplement market worldwide.

IADSA serves its worldwide network of associations and companies by:

- Providing a fast flow of regulatory and policy information on dietary supplements, ensuring that there is an awareness and understanding of new developments.
- Coordinating strategy and action on global regulatory issues, particularly in relation to Codex Alimentarius initiatives.
- Widening and deepening the network of associations around the world by helping the establishment of new dietary supplement associations and supporting existing national associations.
- Organizing global and regional events to promote dialogue on the scientific and regulatory issues underpinning the dietary supplement market.

INTERNATIONAL DEVELOPMENTS

◆ IADSA

PHILIPPINES ASSOCIATION JOINS THE ALLIANCE

The Health and Dietary Supplement Association of the Philippines Inc. (HADSAP), has recently been welcomed into IADSA membership. Created in March this year, HADSAP brings together over 12 member companies, 60% of which are engaged in the manufacture/marketing of dietary supplements. IADSA now has 59 member associations throughout the world.

For further information on HADSAP please contact its President, Mr Dominador B. Bonquin, email: ador_bonquin@amway.com .

◆ CODEX

FOOD ADDITIVE LEVELS AND RISK ANALYSIS PRINCIPLES ADOPTED

As had been hoped, following intensive lobbying by IADSA and considerable input from IADSA member associations and companies, the Codex Alimentarius Commission, the decision-making body in Codex, have finally adopted the food additive provisions for Castor oil, Polysorbates, Polyvinyl alcohol, Acesulfame potassium, Aspartame, Cyclamates, Neotame, Saccharin and Sucralose of the General Standard for Food Additives (GSFA) at the higher levels proposed by IADSA.

This means that they become the official provisions within the GSFA, thereby avoiding any potential barriers to trade.

At the same meeting, the Codex Commission adopted the Working Principles for Risk Analysis for Application by Governments - another extremely important achievement because it has resulted in a set of Codex working principles for risk analysis which do not contain any mention of the precautionary principle. CRN USA has been particularly active in achieving this positive result.

For further information, contact the IADSA Secretariat at secretariat@iadsa.be.

A REGIONAL STANDARD FOR GINSENG?

The Codex Alimentarius Commission has held further intense discussions on the development of a Standard for Ginseng Products. The issue was whether to endorse the current draft standard as developed so far by the Codex Coordinating Committee for Asia (CCASIA) at Step 5 of the 8-step Codex decision-making procedure, and whether this draft standard should be finalised as a regional or international standard.

Eventually, the Codex Commission agreed the adoption of the draft standard at Step 5 and the proposal that it should be finalised by CCASIA as a regional standard, with the proviso that once the regional standard was finally adopted at Step 8, the Commission would have to decide whether to convert it or not into an international standard.

IADSA's particular interest is that the regional standard should only cover *Panax ginseng*, the main species in Asia. To quote David Pineda, IADSA manager of regulatory affairs, '*...as the regional standard will apply to the Asian members of Codex only, it is logical that it should cover only this species.*'

For further information, contact the IADSA Secretariat at secretariat@iadsa.be.

◆ EFSA/FDA

COOPERATION AGREEMENT SIGNED

On July 2nd, 2007, The European Food Safety Authority (EFSA) and the US Food and Drug Administration signed the first US/European agreement in the area of assessing food safety risk.

This is the first formal international cooperation agreement that EFSA has signed and the first formal step in cooperation between the two bodies, and is designed to facilitate the sharing of confidential scientific and other information, such as methodologies to ensure food is safe. The formal agreement ensures appropriate protection of such confidential information under the applicable legal frameworks in the United States and the European Union.

For further information, contact the IADSA Secretariat at secretariat@iadsa.be.

ASIA

◆ JAPAN

NEW COMMITTEE LOOKS AT HEALTH FOOD SAFETY

A new advisory committee of the Japanese Ministry of Health, Labour and Welfare (MHLW) has recently been formed, with the task of examining the safety of Health Foods.

The Committee will discuss measures to ensure the safety of health foods and any revisions to current practice that may be necessary, including the current Good Manufacturing Practice framework and safety inspection

guidelines. It will also consider the setting up of an adverse effect reporting system, a registration system for health food products, and the best ways to provide information to consumers.

The committee has 16 members, including representatives from three industry groups, the Japan Medical Association, the Pharmaceutical Association, the National Institute of Health and Nutrition, the National Institute of Health Sciences and Tokyo Metropolitan Government and three consumer groups. Four university professors of medicine, nutrition and law, and a scientific writer are also included in the committee, which must submit its proposals to MHLW by March 2008.

Source: JIHFS / JHNFA

IRRADIATED SUPPLEMENT RECALLED

A fermented soybean extract imported from the United States for use in food supplements was recently found to have been gamma irradiated. Under the terms of the Japanese Food Sanitation Law, this has led to the recall of all food supplements on the market which contained the ingredient.

Source: NNFA-J

DISEASE RISK REDUCTION CLAIM APPROVED

The first FOSHU product with a disease risk reduction health claim has recently been approved. It is a skimmed milk product with the claim '*Calcium reduces the risk of osteoporosis*'.

Source: NNFA-J

EUROPE

◆ EUROPEAN UNION

HEALTH CLAIMS REGULATION UPDATE

European Commission Regulation 1924/2006 on nutrition and health claims for foods came into force from July 1st. While in terms of timescale for compliance there are a number of different transitional periods, the coming into force of the Regulation essentially means that any food product claiming to have a nutritional, health or disease-risk related benefit must now have prior approval based on evidence that substantiates the claim wording. Nutrition claims must accord with the Regulation's Annex of nutrition claims, health claims must be represented on the yet to be developed European Food Safety Authority (EFSA) central list of approved 'generic' claims, and for disease risk reduction claims must achieve EFSA approval of the individual claim dossier.

Following public consultation, EFSA has now published its final guidance to applicants on disease risk reduction claims and claims for children, and is now ready to receive such applications which its Scientific Panel on Dietetic products, Nutrition and Allergies (NDA) will assess within 5 months.

Further information on EFSA's preliminary discussion document on new nutrition claims, particularly relating to claims for Omega 3 and unsaturated fat content, are still awaited.

Separately, the food and the food supplement industry have been preparing a centralized European industry list of 'generic' claims. The list, which contains over 700 claims, has been put together from submissions from the national member associations of EHPM, ERNA and the Confederation of Food and Drink Industries of the EEC (CIAA). A grading of evidence system was used to judge the validity of the scientific evidence submitted in support of the claims. The completed list has now been returned to the national associations for submission to their national food authorities, who will then pass the submissions on to EFSA for assessment for the central list.

EFSA have two years to assess claims for the central list. However, considerable uncertainty remains as to the fate of the claims on the industry list because EFSA has not yet issued any guidelines as to the volume of type of scientific evidence they will require, or how the 'average consumer' (who must be able to understand the claim) is defined. In addition, for botanicals, the European Botanical Forum is concerned by EFSA's apparent reluctance to accept evidence of traditional use as a foodstuff.

Source: EHPM / ERNA

DEMANDS FOR SUPPLEMENT HEAVY METAL DETAILS

Following a recent meeting with the European Commission on their proposals for heavy metal maximum limits in supplements, the EHPM has advised its members that the following information is urgently required, and that unless it is forthcoming, the levels proposed by the Commission, which could have significant commercial consequences for many companies, are likely to be adopted:

- Batch by batch results of lead, cadmium and mercury assays on botanical extracts for as many batches of the raw materials as possible, together with details of the type of extract or extract ratios.
- Assay results for lead, cadmium or mercury results on as many batches of kelp as possible together with details of the origin of the kelp (North Atlantic, South Pacific) and the species of the kelp (laminaria, fucus).
- Information on heavy metals (Pb, Cd, Hg) in products containing botanicals or their extracts, algal sources or high inputs of mineral salt, giving the actual input of the active components in mg/tablet or capsule

as well as the total weight of the tablet or capsule.

Source: EHPM

NOVEL FOODS CATALOGUE

While the proposals to revise the Novel Food Regulations (applicable to food ingredients not used to a significant degree in foods legally sold in the European Union before May 1997) are under discussion, the European Commission is intending to publish an informal 'Novel foods catalogue' that was discussed at a recent meeting of the Standing Committee composed by the European Commission and the Member States of the European Union. The catalogue was described as '...a non-exhaustive list of products of plant or animal origin as well as of other substances which have been considered only in relation to their status within the meaning of the Novel Food Regulations'. The Commission intends to publish the catalogue by the end of this year.

The European associations, EHPM and ERNA have had sight of a current version of the draft catalogue and a meeting with the Commission is being sought to discuss issues of concern. In the meantime, a clear message has been delivered to the Commission that:

- There has been no consultation with industry on the content of the catalogue (it contains many plants currently included in the positive lists of a number of Member States, including Belgium, the Czech Republic and Italy)
- If it is published, it will have significant commercial implications
- There is no indication of the criteria used to establish the document

Source: EHPM / ERNA

NOVEL FOOD INGREDIENT APPLICATION FOR CLA

The European Commission has advised Member States of a submission to the Spanish Food Safety and Nutrition Agency (AESAN), for the authorization of Conjugated Linoleic Acid (CLA) as a novel food ingredient when added to foods other than food supplements.

This submission is a further illustration that proof of an ingredient's use in food supplements before May 1997 is not sufficient to support its non-novel food status if used in other food applications.

Source: ERNA

EUROPEAN PARLIAMENT SEEKS TOUGHER ADDITIVE REGULATION

Following a first reading, the European Parliament (EP) has voted through four regulations relating to food ingredients: on authorisation procedures, additives, enzymes and flavourings – all of them amendments aimed at strengthening and streamlining existing regulation in this area.

More transparency on decisions on authorisation procedures is sought, and the environmental aspects of chemicals is to be taken into account, together with enhanced protection for consumers with food intolerances, and the flagging of additives whose production has involved genetically modified organisms. Flavourings are only to be used if there is technological need, enzymes only if they do not mislead as to the quality of the product. One welcome amendment for industry is the proposed protection for 5 years of scientific data submitted to gain approval.

The second reading on these amendments is expected to take place in autumn 2007.

Source: EHPM

EFSA WORKING GROUP ON BOTANICALS

The European Food Safety Authority (EFSA) Working Group is now close to finalising its draft guidance document for the safety assessment of botanicals and botanical preparations, together with two compendia listing botanicals reported to contain toxic substances or reported to have food supplement and medicinal use.

It is understood that these documents will be submitted to EFSA's Scientific Committee in September. Additionally, following the identification of this activity by the Steering Committee on Cooperation as a possible 'front-runner' project, a new mandate will be prepared for enhancing cooperation on botanical issues between European Member States.

Source: ERNA

NEW EU HYGIENE RULES AND FISH OILS

Further to the report in last month's Newsflash, the future access of fish oil to the European market remains under threat though a European regulation which comes into force in November 2007. It brings fish oil manufacture within its scope, but places inappropriately high standards of manufacture on production plants.

EHPM and ERNA have had a number of meetings with the European Commission, with technical experts and member companies to try to resolve the issue. At present, while the Commission seems to be open to the idea of a permanent derogation for fish oils, some Member States are not, favouring one year extension of the time period for enforcement of the Regulation.

It is hoped that industry action will encourage the Commission to open up the debate in favour of a long-term solution which will not be detrimental to the future for fish oil production.

Source: EHPM / ERNA

SHOULD EFSA CHARGE FEES?

The Standing Committee composed by the European Commission and the Member States of the European Union met recently to discuss comments received from Member States on its consultation paper on the feasibility and advisability of establishing fees for European Food Safety Authority (EFSA).

It was noted that most Member States were not in principle opposed to a fee system, but had concerns about its feasibility. The main concerns were the need to safeguard EFSA's independence, the difficulties of identifying beneficiaries and the creation of an additional administrative and financial burden for small and medium enterprises. It was also considered unfair to establish fees for all applicants.

The need for further reflection on this complex issue was recognized, and an impact assessment to allow identification of additional costs and administrative burdens for industry may be carried out.

Source: EHPM

EMEA SEEKS COMMENT ON REVIEW OF THMPD

As required by the terms of the Directive, two years' after its coming into force the European Commission has issued a draft Report on the practical working of the Traditional Herbal Medicinal Products Directive, which is out for public consultation until mid-August.

The draft Report notes that as 31st March, only 79 applications had been introduced in only 12 Member States; that the distribution of applications was uneven with most Member States having few or no applications. Only 8 registration applications had been granted, and some Member States had yet to implement the Directive.

Other issues noted in the draft Report as important for the proper working of Directive were the need to develop monographs speedily – but lack of resources were cited as delaying that process. Similarly, in part because of the requirement for genotoxicity data, often not available for herbals, the central Community list of monographs which can be used by registration applicants, thereby reducing the amount of data that must be provided, is very slow to develop.

The draft Report also includes a lengthy discussion about the extension of Traditional Use Registration to categories of ingredient other than herbal, which could facilitate the registration of Ayurvedic and Traditional Chinese products, but no timescale or concrete plans for action are proposed.

Source: EHPM

◆ **CZECH REPUBLIC**

NEW PROCEDURES FOR SUPPLEMENTS AND CLAIMS

The Czech Ministry of Health has advised that from 1 July the licensing system for food supplements containing ingredients not listed in national Decree No.446/2004 (implemented from Directive 2002/46/EC plus a minor positive list) only applies to those vitamins and minerals not listed in national Decree No.446/2004 (vitamins and minerals from Directive 2002/46/EC). All other ingredients, including botanicals, will be subject to notification only, with the requirement to send the product label to the Ministry of Health, (copied to the Ministry of Agriculture), prior to placing the product in the market. This requirement also applies to fortified foods – and in future letters confirming the fulfillment of obligation to notify will no longer be issued.

Also, as from 1 July, the Ministry of Health will take over responsibility from the Ministry of Agriculture for the Nutrition and Health Claims regulation, and has advised a deadline of 15 October for the receipt of health claim applications for the national list.

Source: CASP

◆ **FRANCE**

HEALTH CLAIM LIST OPEN

Following a meeting with the French industry association SDCA, the French food authorities have now agreed to receive health claim applications for Article 13 of the Regulation on Nutrition and Health Claims. Providing they meet the conditions of the Regulation, the claims will be submitted to the European Commission without pre-assessment.

Additionally, providing they conform the general conditions of the regulation, the French authorities have agreed to accept applications based on tradition of use – a particularly point for botanicals.

Source: SDCA

ASSOCIATIONS' QUALITY GUIDE FOR SUPPLEMENTS

With the aim of assisting stakeholders to ensure that the products they place on the market fully conform to new regulatory requirements, two French supplement associations, Synadiet and SDCA, have been working together to prepare a Quality Charter for Food Supplements.

An interactive document on Cdrom, has now been prepared, covering all the relevant regulation, and it has now been sent out for comment to other associations, consumer groups, and the French food authorities.

For further details, contact charte.qualite@synadiet.org

Source: SYNADIET/ SDCA

UPDATE ON SUPPLEMENT PLANT LIST

As reported in the June Newsflash, the French food supplement association SYNADIET recently received a letter from the Food agency (DGCCRF) advising that the French Medicines Agency (AFSSAPS) is considering the re-classification of 3 plants currently listed for food supplement use. Their reason is that they consider them to be medicinal by function.

Since then, Synadiet has held meetings with the regulatory authorities and with government Ministers, and has particularly concentrated on the following issues:

- The criteria on which the proposed reclassifications are based, and the list of plants which have been examined.
- The creation of a joint food/medicine working group with the aim, within an agreed timescale, of agreeing those plants whose food supplement/medicine status is contentious.
- The early publication of the decree which will allow the public sale of 147 plants included in the pharmacopoeia.

It is understood that the Health Ministry (DGS) has accepted in principle that it will not, as a general rule, oppose the use in food supplements of plants listed in the pharmacopoeia and authorized by the DGCCRF under the Article 16 procedure – unless it considers that they pose a risk to public health.

Source: SYNADIET

◆ GERMANY

ASSOCIATION'S CONCERNS ABOUT PLANT SAFETY

Discussions at the fourth Consumer Protection Forum have resulted in the German Federal Institute for Risk Assessment (BfR) advising that plant ingredients used in foods and food supplements should be properly assessed.

Examples of extracts discussed included coumarin, found in some types of cinnamon, which may in high dose cause liver damage, the potential side-effects from isoflavones in isolated, enriched or high dose form, and the sunburn-like effects of the furocoumarin content of celery on sensitive individuals.

Additionally, in its information letter Nr. 012/2007, BfR is advising consumers to avoid consumption of jojoba seeds, *Simmondsia chinensis samen*, because of a potential risk suggested by animal tests.

According to BfR jojoba seeds are not used in foods or food supplements in Germany and are not sold in any retail outlets and would have first to undergo

an evaluation of novel/non-novel food status before being placed on the market. However, consumers can currently purchase such products via Internet from other countries.

Source: BLL

◆ IRELAND

DISCUSSION ON SUPPLEMENT LEVELS CONTINUES

Following last month's report on industry concerns at the proposal from the Food Safety Authority of Ireland (FSAI) for a 1 x RDA maximum level for vitamins and minerals, further discussions between EHPM Scientific Advisor Dr. Derek Shrimpton, the Irish Health Trade Association (IHTA) and the Irish authorities have been held. Several amendments to sections of the FSAI's response were suggested, and the importance of the role of risk assessment was emphasized.

While it is understood that FSAI, who had previously said that they would be 'guided by science', are unlikely to amend their submitted position paper at this stage, it is hoped that they may yet consider adjustments to their position as discussions on maximum levels reach their final stage.

Complementing industry action, the Irish Association of Health Stores has launched a campaign aimed at protecting the rights of Irish consumers to buy high strength food supplements.

Source: IHTA

◆ NETHERLANDS

DUTCH CLAIMS PROCEDURE GOES LIVE

The Dutch Ministry of Health has posted to its website a procedure for submissions to the national health claims list required by the EU Regulation on Nutrition and Health Claims on Foods.

Submissions, which can only come from companies with trade in the Netherlands, must be posted by 31 October 2007. The Ministry will not carry out any pre-assessment of the content of the submissions, only of their format. For further details, see www.row.minvms.nl

Source: NPN

◆ UNITED KINGDOM

STUDY SHOWS CONSUMERS CONFUSED BY CLAIMS

The UK Food Standards Agency has recently published a study on consumer understanding of health claims.

Amongst the key findings were:

- consumers are sceptical about claims on food labels, seeing them as attempts at marketing – but equally, consumers are influenced by such claims
- claims are more likely to be interpreted accurately if the consumer is familiar with the nutrient referred to. Simple, brief claims are likely to be better understood.
- There is considerable contradiction in the research as to which claims are most accurately understood. Words such as ‘may’ are sometimes regarded as clear, sometime not.
- Health claims cause consumers the most confusion in terms of interpretation and understanding.
- Disclaimers are not popular, often confusing consumers as they appear to contradict the claim rather than qualify it.
- Brands and brand attributes such as colours and logos are crucial to consumer understanding, trust and acceptance of health claims.
- Consumers do not categorise claims into nutrient, health or disease risk reduction claims, and do not always understand the difference.

Source: CRN

UK DATA CONFIRMS NON-NOVEL STATUS OF GOJI BERRIES

Further to the report in last month’s Newsflash, the UK Food Standards Agency (FSA) has now confirmed that Goji berries are not to be classified as a ‘novel food’.

Evidence collated by the Health Food Manufacturers Association (HFMA) including the sale of the berries in Chinese food stores, their use in soft and alcoholic drinks, published recipes including the berries, plus a Belgian decree and a German decision classifying the berries as foods was deemed sufficient by the FSA to confirm their non-novel food status.

Source: HFMA

OPINIONS SOUGHT ON GLUCOSAMINE, KIWI CONCENTRATE AND ALGAL EXTRACT

Glucosamine Hydrochloride: in a previous ruling the Food Standards Agency (FSA) had ruled that a vegetarian glucosamine hydrochloride (HCl), derived from *A. niger*, was substantially equivalent to glucosamine derived from shellfish. However, it has now delayed issuing its opinion on whether to allow

HCI as a novel food ingredient for use in beverages and yogurts for joint health because of a lack of information on its effect on diabetics.

Kiwiberry Concentrate: The FSA is seeking comment on an application to approve kiwiberry concentrate as a novel food ingredient in a range of food products, including drinks and cereal products.

Algal extract: The Advisory Committee on Novel Foods and Processes has been asked to approve an algal extract from *Haematococcus pluvialis* algal meal, previously approved for marketing by another company. The carotenoid Astaxanthin is found in *H.pluvialis*, and the raw material supply company for the previous approval now wants to market their extract themselves as an ingredient for food supplements manufacturers to use in capsules and tablets. The same starting material and extraction process is used, and the company is seeking approval on the grounds that it is 'substantially equivalent' to the previously authorised material.

Source: HFMA

ORGANIC CERTIFICATION FOR HERBAL MEDICINES?

The UK Herbal Forum and the Soil Association are currently discussing with the UK Medicines and Healthcare products Regulatory Agency the development of organic standards appropriate to the production of herbal medicinal products, and how products meeting those standards can be identified in terms of wording on labels and advertisements.

It is hoped that an appropriate scheme, analogous to that for food products, can be finalised by the end of the year.

Source: HFMA

NORTH AMERICA

◆ CANADA

GOVERNMENT INVESTS IN NATURAL HEALTH PRODUCTS

The Canadian Government has announced a \$721,000 investment in the Nutri-Net Canada project to help expand market opportunities for the Canadian functional food and natural health products industry.

Via a nationwide industry networking website, case studies and national and regional workshops and conferences, Nutri-net Canada aims to bring together public and private stakeholders to develop a national strategy and an action plan to lay a firm foundation for a sustainable national network and to accelerate the growth of the industry.

The project is administered by the Canadian Health Food Association (CHFA) on behalf of the coalition of functional food and natural health product organisations, and will receive further funding of over \$900,000 from these sources.

Source: CHFA

REVISED RECOMMENDATIONS ON VITAMIN D

Health Canada is currently considering the growing body of evidence on the role of vitamin D in relation to health, but has advised that a comprehensive review encompassing benefits and safety should be undertaken before making any recommendation to revise the current adult Tolerable Upper Intake Level of 2000IU/day from all sources, including supplements.

For this reason, Health Canada is to take part in a Conference to be held by the US National Institute of Health in September, which will evaluate the efficacy and safety of vitamin D across all age groups. For further details, see <http://VitaminDandHealth.od.nih.gov>

Source: CHFA

DEADLINE FOR REMOVING TRANS FATS

Following the recommendations of a task force report proposing a trans fat limit of 2% total fat in vegetable oils and margarines, and 5% in all other foods, the Canadian Health Minister, Tony Clement has given the food industry two years to voluntarily remove trans fats from their products.

This time period is considered adequate to allow the industry to reformulate appropriately. However, in announcing the voluntary initiative, the Minister added that, 'If significant progress has not been made over the next two years, we will regulate to ensure the levels are met.'

Source: CHFA

◆ UNITED STATES

GMP RULES PUBLISHED

The US Food and Drug Administration (FDA) has now published its long awaited final rule, *Current Good Manufacturing Practice in Manufacturing, labelling or Holding Operations for Dietary Supplements (CGMPs)* – see www.fda.gov/OHRMS/DOCKETS/98fr/cf0441.pdf. The document establishes the minimum CGMPs necessary for activities related to manufacturing, packaging, labelling, or holding dietary supplements to ensure the quality of the dietary supplement.

Key elements include:

- The rule is relevant only to dietary supplements, not raw material suppliers or retailer. It is relevant to all supplements sold or offered for sale in the United States, so its standards also apply to foreign companies,
- The rule requires the testing of every incoming dietary ingredient, although companies may petition the FDA for exemption if they have the data to support a system that offers the same assurance as that provided by 100% identity testing.
- The rule focuses more on process control than finished product testing, requiring the establishment and use of many written procedures and records.
- It is the responsibility of the manufacturer to confirm ingredient identity/quality, which can be via certificate of analysis if an adequate supplier assurance system is used.
- There is no requirement for an expiry date, but if such data is used, then supporting data must be available
- Companies with less than 20 employees have a 3 year compliance period, those with less than 500 employees have 2 years, and larger firms one year.
- FDA will exercise 'discretion' with regard to products made by practitioners 'adequately trained in their profession', using them in one to one consultation.

Source: AHPA / NPA / UNPA

THE SIDI PROTOCOL

The Standardised Information on Dietary Ingredient (SIDI) protocol will be the subject of a top-level panel discussion at a forthcoming annual Expo in Chicago.

Developed jointly by the Natural Products Association (NPA), the American Herbal Products Association (AHPA), the Consumer Health Products Association and the Council for Responsible Nutrition, the SIDI protocol aims to standardise ingredient information exchange so as to increase productivity and assist in understanding analysing, controlling and documenting the manufacturing process throughout the supply chain.

Source: NPA / CRN USA

DSEA REPORT SHOWS HUGE HEALTHCARE SAVINGS

The final report of a study commissioned by the Dietary Supplement Education Alliance (DSEA) shows that over the next 5 years, appropriate use of certain dietary supplements could both improve the health of key populations, and save more than \$24 billion in healthcare costs.

Amongst the key findings of the study, which updated research carried out by the Lewin Group in 2004/5, were that over 5 years:

- Calcium with vitamin D could save \$16.1 billion by avoiding hospital care for hip fractures.
- Folic acid could save \$1.4 billion by preventing neural tube defects.
- Omega 3 fatty acids could save over \$3.2 billion by reducing the occurrence of coronary heart disease in the over 65s.
- Lutein with zeaxanthin could save £3.6 billion by helping people with age-related macular degeneration avoid dependency on community or nursing care.

Source: NPA

FDA'S FOOD SAFETY AND LABELLING PRIORITIES

In its recently published FY 2007 Report to Stakeholders, the Food and Drug Administration (FDA)'s Centre for Food Safety and Applied Nutrition (CFSAN) has identified its priorities for food safety and labelling.

Priorities relevant to the supplement/health products industry include:

- Advisory labelling for food allergens
- A rule for gluten-free labelling
- The development of analytical methods for low levels of trans fatty acids
- The publication of *Guidance on an evidence-based scientific review system for health claims* (recently published in draft)
- Seeking comment on updating daily values on nutrition labelling
- A rule to revise existing regulation requiring irradiated food to be labelled.

Source: NPA

FDA LOOKS AT ALLERGY LABELLING

A recently published study by the US Food and Drug Administration (FDA) has revealed that many consumers have serious problems understanding food labels to help them avoid ingredients to which they may be allergic.

General problems highlighted were lengthy ingredient lists which made it difficult to locate a particular ingredient, and the use of hard to understand 'technical' language. Additionally, over 40% of participants in the study identified as problems:

- Ingredients lists which give a general name to the ingredient, without specifying the source – such as spices and flavours
- Different words used to describe an allergen on different food products
- Labels which do not actively alert consumers to a new ingredient in the food (despite it being included on the ingredient list)

Source: CRN USA

NEW PROGRAMME TO PROTECT AGAINST BIO-TERRORISM

The US Food and Drug Administration (FDA) has released details of a new software programme, the CARVER + Shock Software Tool, to help the food industry determine the vulnerability of individual food facilities to biological, chemical, or radiological attack.

As a science-based prevention strategy to safeguard the food supply, the tool is an example of the type of approach currently being developed as part of FDA's broader food protection strategy.

Source: CRN USA

NEW AER GUIDANCE FOR SUPPLEMENTS?

It is understood that the Food and Drug Administration (FDA) is considering taking legal advice on how the new adverse event reporting law may apply to supplements and over the counter (OTC) drugs, and whether there should be an amendment in law to clarify their slightly different reporting requirements.

FDA would prefer to issue two separate industry guidance documents, rather than the one currently mandated. Apparently anticipating a heavy influx of adverse events, FDA are also concerned about how they would notify manufacturers if they received prior knowledge of an adverse event, how they should collaborate with poison control centres in relation to the reporting of such events, and whether a full postal address would be the best way to help consumers to report an adverse event.

The dietary supplement industry is now concerned that the FDA's ongoing concerns may lead to delay in the publication of their guidance, which would adversely impact on industry's ability to meet the anticipated compliance date of December 2007.

Source: UNPA

RISK-BASED ASSESSMENT FOR IMPORTED FOODS

Following a recommendation in its 2002 Import Strategic Plan, the Food and Drug Administration is now actively considering the imminent implementation of risk-based inspections for imported foods.

The proposed new procedures are likely to require importers and manufacturers to provide more information to inspectors who currently have little advance information on imports. It is hoped that the new system would help to enable inspectors to concentrate on shipments that pose a risk to food safety, whilst reducing shipment time overall.

Source: NPA

LABEL WARNINGS FOR BLACK COHOSH AND GREEN TEA?

The US Pharmacopoeia (USP) is proposing warning statements on the labels of dietary supplements that claim to contain USP-grade black cohosh or green tea extract.

The proposed statements are:

Caution: In rare cases black cohosh has been reported to affect the liver. Discontinue use and consult a healthcare practitioner if you have a liver disorder or develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice.

Caution: Must take with a meal. In rare cases extracts from green tea have been reported to adversely affect the liver. Discontinue use and consult a healthcare practitioner if you have a liver disorder or develop symptoms of liver trouble, such as abdominal pain, dark urine, or jaundice.

Following a 60 day comment period, the black cohosh proposal is due to be published in September. No date has yet been set for the publication of the green tea proposal.

Source: AHPA

ORGANIC INGREDIENT RULE NEARS FINALISATION

The US Department of Agriculture (USDA) is seeking comment from organic food producers on the proposed addition to the list of ingredients permitted for use in organic products of 38 non-organic ingredients, including colours, starches and oils.

Colours from a number of plant sources, including blueberry, elderberry and pumpkin juices are included in the proposal. Other examples include omega 3 for baked goods and beverages, kelp as a thickener in supplements, oligofructose enriched inulin, and unbleached lecithin.

Source: AHPA

SUPPLEMENT PRODUCTS FAIL TO MEET LABEL CLAIM

Recent tests by Consumerlab.com of nine milk thistle supplements have revealed that only two contained the claimed amount of silymarin compound.

Similarly, of 11 Chondroitin products recently tested, Consumerlab.com found that 7 failed to meet label claim.

Source: UNPA

PR LIFESTYLE INITIATIVE

The US Council for Responsible Nutrition (CRN USA) has announced plans to launch a multi-year, multi-million dollar public relations campaign, 'Life....supplemented', focused on the more than 150 million Americans who take dietary supplements.

Year one will see the launch of a microsite to provide consumers with information on the pillars of a healthy lifestyle, offering a unique tool to help them with their personal wellness regime. The programme will also focus on lifestyle research projects that will be shared with the public via the website, and other publicity. The second and third years will build on and develop the experience of year one.

Source: CRN USA

CHINESE INGREDIENT TEST PROGRAMME LAUNCHED

The Natural Products Association (NPA) has recently launched a new programme to test Chinese raw materials for purity and composition.

Under the new programme, raw materials commonly used in dietary supplements will be tested in the laboratory of the United States Pharmacopoeia in Shanghai, China. NPA will provide test results to member companies and build a database on raw material suppliers which will be made available to manufacturers to inform supply-chain decisions.

Source: NPA

GINSENG LABELLING ACT INTRODUCED IN CONGRESS

Legislation was introduced last week in both the US Senate and House of Representatives that would require that ginseng (*Panax spp.*), when sold in its whole form, is labelled to identify its country of harvest.

Senate Bill 1953, the Ginseng Harvest Labeling Act of 2007, has long-standing support from ginseng farmers and the Ginseng Board of Wisconsin as well as the support of the American Herbal Products Association (AHPA) and the United Natural Products Alliance (UNPA).

"This bill will ensure that buyers of whole ginseng root are given truthful information as to its source, without creating unnecessary labelling requirements for other herbal ingredients or for finished herbal products," Michael McGuffin, AHPA's President said.

Text of the bill is online at:

http://www.ahpa.org/Portals/0/pdfs/07_08_S1953_ginseng.pdf.

Source: AHPA

SOUTH WEST PACIFIC

◆ AUSTRALIA & NEW ZEALAND

TRANS TASMAN HARMONISATION

Because it currently has insufficient parliamentary support, the Government of New Zealand has decided not to proceed with legislation aimed at establishing a joint agency with Australia to regulate therapeutic products.

However the NZ State Services Minister, Annette King, emphasised the Government's continued support for a joint trans-Tasman therapeutics authority, and said that the Therapeutic Products and Medicines Bill would remain on the Order Paper to be revisited when sufficient votes can be obtained.

Source: CHC

MOVES TO STREAMLINE FOOD REGULATION

Changes to food regulations in Australia aim to significantly improve the assessment and consultation procedures for new and amended food standards.

Until now, Food Standards Australia New Zealand (FSANZ) has had a single model for assessing applications to amend food standards, regardless of the scope of the proposed change. The new regulations allow three different streams for applications, based on the level of complexity. In addition, applications must be completed within a given time-scale: major changes can take up to 12 months but minor changes must be processed within three months.

Source: CHC

INDEX OF ASSOCIATION CONTRIBUTORS

- AHPA (American Herbal Products Association): ahpa@ahpa.org
- BLL (German Federation for Food Law and Food Science): srams@bll.de
- CASP (Ceská Asociace Pro Speciální Protaviny): info@casponline.cz
- CHC (Complementary Healthcare Council of Australia): chc@chc.org.au
- CHFA (Canadian Health Food Association): awilkie@chfa.ca
- CRN (UK) (Council for Responsible Nutrition): juliehcrn@aol.com

- CRN (USA) (Council for Responsible Nutrition): webmaster@crnusa.org
- EHPM (European Health Product Manufacturers Association): secretariat@ehpm.be
- ERNA (European Responsible Nutrition Alliance): secretariat@erna.be
- HFMA (UK) (Health Food Manufacturers' Association): hfma@hfma.co.uk
- IHTA (Irish Health Trade Association): info@ihta.org
- JIHFS (The Japanese Institute for Health Food Standards): info@jihfs.com
- JHNFA (Japan Health Food & Nutrition Food Association): jhnfa@jhnfa.org
- NNFA-J (JAPAN) (National Nutritional Foods Association): info@nnfajapan.com
- NPN (Natuur- & GezondheidsProducten Nederland): info@npninfo.nl
- NPA (US) (Natural Products Association): natural@NaturalProductsAssoc.org
- SDCA (France) (Syndicat de la Diététique et des Compléments Alimentaires): j.lallain@alliance7.com
- SYNADIET (France): jacques.karlsson@synadiet.org
- UNPA (United Natural Products Alliance): loren@unpa.us

KEY EVENTS: SEPTEMBER – DECEMBER 2007

Date	Conference	Place
September 06 - 09	CHFA Expo East www.chfa.ca	Toronto, Canada
September 13 - 16	SANA 2007: International Exhibition of Natural Products - Nutrition, Health, Environment www.eventseye.com/fairs/trade_fair_event_8250.html	Bologna, Italy
September 26 - 28	Food Ingredients Asia http://asia2007.fi-events.com/	Bangkok, Thailand

September 26 - 29	Natural Products Expo East www.expoeast.com	Baltimore, MD, United States
Date	Conference	Place
October 10 - 12	Natural Products Expo Japan 2007 www.naturalproductsjapan.com	Tokyo, Japan
October 30 - November 01	Food Ingredients Europe http://europe2007.fi-events.com/	London, United Kingdom
October 30 - November 01	Natural Ingredients - Exhibition & Conference www.ni-events.com	London, United Kingdom
November 06 - 08	Supply Side West - International Trade Show and Conference www.supplysideshow.com/west/	Las Vegas, NV, United States
November 12 - 16	Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) www.codexalimentarius.net	Bad Neuenahr, Germany
November 14 - 16	Cosmoprof Asia - Where beauty meets trends and Business www.cosmoprof-asia.com	Hong Kong, China
November 20 - 22	Health Ingredients Japan 2007 www.hijapan.info/en/	Tokyo, Japan
December 04 - 06	Executive Committee of the Codex Alimentarius www.codexalimentarius.net	Geneva, Switzerland

Prepared by the
INTERNATIONAL ALLIANCE
OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS
rue de l' Association 50
B-1000 Brussels
Tel: (00) (32) (2) 209 11 55; Fax: (00) (32) (2) 223 30 64,
E-mail: secretariat@iadsa.be - Website: www.iadsa.org

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