

# IADSA NEWSFLASH

## APRIL 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 57 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

### ◆ CODEX

#### PRECAUTIONARY PRINCIPLE OUT OF RISK ANALYSIS DRAFT

Efforts to introduce the precautionary principle into Codex's draft risk analysis standards for food safety were again resisted at the recent Codex Committee meeting on General Principles, marking the third unsuccessful attempt by the European Union and other countries to include the principle in key Codex documents.

The precautionary principle allows governments to take certain preventative measures for foods in cases where scientific evidence on safety is uncertain, and the concern is that it could be used to create unjustified trade barriers.

For further information, contact the IADSA Secretariat at [secretariat@iadsa.be](mailto:secretariat@iadsa.be).

Source: IADSA

### SUPPLEMENT ADDITIVES TO STAY IN CODEX LIST?

At its next meeting in April in Beijing the Codex Committee on Food Additives will consider whether to maintain a number of additives in the list of the Codex General Standard for Food Additives (GSFA) for which further information on their use in food supplements was requested.

IADSA provided the electronic Working Group (eWG) addressing this issue with information on usage in supplements of erythrosine, iron oxides, castor oil and chlorophylls/copper complexes, in addition to 18 other additives widely used by the food supplement industry. As a result, contrary to last year, the eWG recommends to the Committee that these additives are kept in the GSFA list.

At the Beijing meeting, IADSA will be seeking to ensure that the eWG's recommendation of the adoption of the GSFA list is confirmed.

For further information, contact the IADSA Secretariat at [secretariat@iadsa.be](mailto:secretariat@iadsa.be).

Source: IADSA

## **ASIA**

### **◆ JAPAN**

#### HMPC APPROVED AS A FOOD ADDITIVE

Hydroxypropyl methylcellulose (HPMC) has been approved by Japan's Ministry of Health, Labour and Welfare as a food additive for use in general foods without a daily maximum limit.

Previously, its use had been permitted only for Foods with Health Claims, with the subcategories FOSHU (Food with Special Health Uses) and FNFC (Food with Nutrient Function Claims), in capsule or tablet form. The new approval now means that it is now also available for use in so-called health foods.

Source: JIHFS

# EUROPE

## ◆ EUROPEAN UNION

### DEBATE ON EFSA FEES CONTINUES

The European Food Safety Authority (EFSA) has written to the European Commission in response to the Consultation on the feasibility and advisability of EFSA charging fees for its activities.

The letter stresses that whatever system of fees might eventually be adopted, EFSA's independence and accountability must be paramount. EFSA further suggests that to distance EFSA from direct contact with financial matters, the Commission could itself collect the fees. However, it also questions whether '...the time is right to introduce a fee system while EFSA is still establishing its reputation and working practices'.

Source: ERNA

### EFSA INITIAL GUIDANCE ON HEALTH CLAIMS

The European Commission has formally requested to the European Food Safety Authority (EFSA) to issue an opinion on 'technical and scientific guidance for the application for authorization of health claims' by 1 July.

As a preliminary to this process, EFSA has now published pre-submission guidance for applicants on their web site. It covers health claims that fall under the scope of Article 14 (disease risk reduction and children's health and development claims) and Article 18 (health claims based on newly developed scientific evidence or proprietary data).

The information provided is very general, with the most interesting points as follows:

- EFSA and its Scientific Panel on Nutrition, Dietetic products and Allergies are working on a full guidance document to assist applicants in preparing their applications which is expected to be ready by summer 2007. EFSA advises applicants to wait until the guidance is available before they submit their claim submissions.
- A separate application must be prepared for each individual health claim. No combined files will be accepted. The dossiers should be submitted in English and the paper copy remains the formal submission. However, for the benefit of Small and Medium Enterprises where the costs may be a barrier, EFSA will make the translation, to be validated by the applicant.
- The summary of the dossier should not contain any confidential information as it will be published on EFSA's website.

Further information can be found at:

[http://www.efsa.europa.eu/en/science/nda/pre-submission\\_guidance.html](http://www.efsa.europa.eu/en/science/nda/pre-submission_guidance.html)

Source: EHPM

### EHPM SEEKS EXEMPTION FROM NUTRIENT PROFILE REQUIREMENTS FOR SUPPLEMENTS

The European Federation of Associations of Health Product Manufacturers (EHPM) has written to the European Commission seeking assurance that consideration will be given to the exemption of food supplements from the scope of the application of nutrient profiles under the Nutrition and Health Claims Regulation.

Under the terms of the Regulation, in order to carry claims, food products must comply with nutrient profiles (yet to be established), taking into account quantities of nutrients or other substances such as fat, salt, etc., the contribution of the food to the diet, the overall nutritional composition and presence of beneficial nutrients.

EHPM points out that the Regulation allows for exemptions for certain categories of foods, and that because of their particular nature and composition, this provision should be extended to food supplements.

Source: EHPM

### EXPERT GROUP ON NUTRITION LABELLING MEETS

The second meeting of the Expert Working Group on Nutritional Labelling covered the following issues relating to the review of the Nutritional Labelling of Foodstuffs Directive:

- Front of pack signpost nutritional labeling: the Commission is considering a framework for this type of labeling and sought views on which nutrients should be covered.
- Whether nutritional labeling should be mandatory: this was considered acceptable with appropriate exemptions for certain foods, non pre-packaged goods, etc.
- The nutrients which should be labeled on back of pack: the majority of Member States considered that trans fatty acids should be included, and the number of nutrients possibly limited to four or five.
- The presentation of nutritional labeling information: discussion covered presentation per 100g/per portion/serving information; tabular/linear format; order of nutrient declaration; minimum font size.

Source: EHPM

### PARNUTS DEROGATIONS EXTENDED

The derogation on ingredients for use in Products for Particular Nutritional Uses expired at the end of December 2006. It was granted because the

ingredients were being assessed by the European Food Safety Authority (EFSA) when the PARNUTS positive list was applied in April 2004.

Now, in 2007, these ingredients are still being assessed by EFSA, and have been further held back for combined assessment because they must also be assessed for the Food Supplements Directive. As a result, the Commission has prepared a Directive extending the PARNUTS derogation until December 2009 for the following ingredients:

- D-alpha tocopheryl PEG 1000 succinate
- Boric acid and Sodium borate
- Calcium, chromium, copper, iron, magnesium, manganese and zinc chelates
- Selenium enriched yeast
- Ferrous hydroxide
- Calcium, iron and magnesium pidolate

Source: EHPM

#### HEAVY METAL MAXIMUM LIMITS FOR SUPPLEMENTS?

As a result of the provision of data from several Member States which showed high levels of heavy metals in certain food supplements, the European Commission is considering setting maximum limits for arsenic, cadmium, lead and mercury in food/food supplements. Most Member States, many of whom already have national limits, are supportive of this proposal.

The Commission is now considering issues arising from the European Union definition of food supplements, as some products labelled as medicinal are considered food supplements in some Member States.

Source: EHPM

#### REPORT ON THE IMPLEMENTATION OF GMO REGULATION

A Report to the Council and the European Parliament on the implementation of Regulation 18829/2003 on Genetically Modified food and Feed has been published on

<http://register.consilium.europa.eu/pdf/en/06/st14/st14668.en06.pdf>

The Report concludes that more time is needed to gain practical experience of the Regulation, which has only been operational for a limited time, before any proposals to amend it should be brought forward.

Source: EHPM

#### EFSA COLLOQUIUM ON GMO RISK ASSESSMENT

The subject of the 8<sup>th</sup> Scientific Colloquium of the European Food Safety Authority (EFSA), to be held in June this year, is 'Environmental Risk Assessment of Genetically Modified Plants – Challenges and Approaches'.

The objectives of the colloquium are to consider approaches to environmental risk assessment in the light of current scientific thinking, encompassing issues such as environmental fitness, impacts on non-target organisms, long-term effects, and the impacts of large scale production. Broader environmental considerations and risks versus benefits will also be addressed.

The outcomes of the Colloquium will be considered by the Genetically Modified Organisms Panel in the continuous process of reviewing current Environmental Risk Assessment methodology.

Source: EHPM

#### EFSA REVIEWS EXEMPTIONS FROM ALLERGEN LABELLING

The European Food Safety Authority (EFSA) has been asked by the European Commission to evaluate 21 applications from industry concerning derivatives of food allergens so that a list of those derivatives that will be permanently exempted from mandatory labeling can be prepared.

It is estimated that this task will be completed by October this year. For further information see ([http://www/efsa/europa.eu/register/qr\\_panels\\_en.html](http://www.efsa.europa.eu/register/qr_panels_en.html))

Source: EHPM

### ◆ DENMARK

#### COMMISSION DROPS TRANS-FAT CASE

The European Commission has dropped its threat to take Denmark to the European Court of Justice over its national restrictions on trans fats in foods and labeling rules.

The reason for the change is that the Commission has now accepted the arguments put forward by the Danish Government in relation to the national measure and the health of the Danish population.

Source: DDFD

### ◆ FRANCE

#### ASSOCIATION SEEKS INFORMATION ON BOTANICALS

The Plant Commission of the French trade association Synadiet is seeking information from its membership on health claims for botanicals. To try to ensure the future use of such claims, the Commission intends to prepare a list of claims for consolidation into the European industry list being collated by the European Botanical Forum. This list of claims will then be submitted for

evaluation by the European Food Safety Authority (EFSA) for inclusion in the central list of Article 13 (generic) claims.

Initially, the Plant Commission will look at the possibilities offered by the 147 plants which will be able to be sold from retail outlets other than pharmacies. It also wants to work on the plants and plant parts already authorized for use in food supplements within the framework of the French article 16 declaration which, together with their conditions of use, will be listed in an Order defined by Article 7 of Decree 2006 -352. However, it is not expected that this Order will be published in the coming months (perhaps not until 2008) - hence the need to work actively to include botanical health claims on the EU Industry central list.

Source: SYNADIET

## ◆ GERMANY

### REGULATION ON BETA-CAROTENE/VITAMIN A?

The German food industry association, BLL, has petitioned the German Federal Government to refrain from issuing a national regulation which would lead to reductions in the addition of beta-carotene to fortified foods and to reductions in the use of beta-carotene and vitamin A in food supplements.

For food supplements, the draft regulation proposes a limit of no more than 400 micrograms per daily dose, and that supplements containing more than 200 micrograms should carry a warning to the effect that the supplement is not suitable for children under 10.

Instead of issuing a national regulation, the BLL are asking the Federal Government to urge, within the framework of its Presidency of the European Union, that priority be given to efforts to establish EU-wide maximum amounts for fortified foods and food supplements.

## ◆ SPAIN

### NO DEROGATIONS FOR UNAUTHORISED VMS

Article 6(4) of the Food Supplements Directive permits Member States to allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that certain conditions are met. However, the Spanish Food Safety and Nutrition Agency (AESAN in its Spanish acronym) has now stated that it will not allow the use of vitamins and minerals in Spain that are not included in the Directive.

Despite the fact that Article 6(4) does not require the existence of a previous law as a prerequisite to allow derogations, AESAN justifies its rejection on the

fact that there was no rule in Spain permitting the use of these nutrients before the Directive entered into force.

It is feared that this decision will further create obstacles to the free movement of food supplements within the European Union - already impaired because various Member States have established different maximum levels of vitamins and minerals, the differences in some cases varying widely.

Source: AFINUR

### CHALLENGE TO SPANISH BAN ON HERBAL IMPORTS

The European Commission is to challenge Spain at the European Court of Justice over its prohibition on the import of herbal products, on the grounds that it *'... considers the absence of adequate procedures for assessing the risk to public health allegedly posed by products containing plant extracts an unjustified and disproportionate barrier to intra-EU trade'*.

Products containing herbal ingredients are classified as medicines in Spain, unless they are included on its list of permitted plants. This list was last updated over 30 years ago, and does not contain many more 'modern' extracts available elsewhere in the European Union, such as ginseng or guarana. The only current route to the Spanish market for such products is to obtain medicines marketing authorizations – a lengthy, difficult and costly exercise.

Source: AFEPADI

## ◆ UNITED KINGDOM

### CONSULTATION ON AMENDMENTS TO THE FOOD SUPPLEMENTS DIRECTIVE ANNEXES

The UK Food Standards Agency (FSA) is seeking stakeholders' views on the European Food Safety Authority (EFSA) opinions and the anticipated proposal for amendments to the Annexes of the Food Supplements Directive to add calcium malate, magnesium malate, zinc malate and magnesium potassium citrate to the list of permitted vitamin and mineral substances.

EFSA have recently issued favourable scientific opinions on these substances for use in foods for particular nutritional uses, food supplements and foods intended for the general population.

Source: HFMA

### JOINT HEALTH CLAIMS INITIATIVE CLOSES

The adoption of the European Union Regulation on Nutrition and Health Claims on Foods has led to the closure of the Joint Health Claims Initiative

(JHCI), an independent coalition made up of representatives of consumer groups, enforcement agencies and industry.

The JHCI was set up in 2000 to provide voluntary assessment of health claims on foods, but its role is now overtaken by the EU Regulation which comes into force on 1 July and provides a mandatory legal framework for the approval of health claims.

Source: HFMA

#### GOJI BERRIES: NOVEL FOOD STATUS?

The Food Standards Agency (FSA) has advised interested parties that it has received more than 50 responses to its request for information about consumption of goji berries before May 1997, the date when legislation on novel foods came into force.

FSA will now check the information received and will consult as necessary with other EU Member States and/or the European Commission, before concluding their analysis.

Source: HFMA

#### 'JUNK FOOD' BAN NOW IN FORCE

In an effort to combat UK obesity rates, a new restriction on advertising of foods to children has now come into force. Television advertisements for foods high in fat, salt and sugar are no longer permitted in or around programmes targeted or likely to be of particular appeal to children up to 9 years old.

From 1 January 2008, this prohibition will be extended to programmes likely to be of particular appeal to children up to 15 years old, with full implementation for children's channels by December 2008.

The Food Standards Agency will carry out a first review of the impact of the restriction in early 2008.

Source: CRN UK

## **NORTH AMERICA**

### **◆ CANADA**

#### WARNING ON CHINESE SLIMMING PILLS

Health Canada has advised consumers against using a brand of Chinese manufactured slimming pills because they have been found to contain a prescription only ingredient that could both cause serious side effects and interact with other medicines.

The product has not been authorised for sale in Canada but is available to Canadian consumers via the internet.

Source: CHFA

## ◆ UNITED STATES

### ASSOCIATION SUPPORTS REVISION OF LEGISLATION

The American Herbal Products Association (AHPA) has expressed its support of two bills introduced in the 110<sup>th</sup> Congress that would revise current laws so as to be more inclusive of some classes of dietary supplements.

The Food Stamp Vitamin and Mineral Improvement Act would amend the Food Stamp Act to allow people who qualify for food stamps to use them to buy 'nutritional supplement(s) providing a vitamin or mineral, or both'.

The Dietary Supplement and Healthy Meal Replacement Tax Parity Act would amend the Internal Revenue Code to qualify dietary supplements and meal replacement products that are authorised to bear Food and Drug Administration-approved health claims as deductible medical expenses.

Source: AHPA

### POSITIVE SPORTS SUPPLEMENT TEST RESULTS

A recent independent laboratory test of eight popular sports supplements by the Natural Products Association found no steroid or stimulant contamination. The test was conducted as part of the association's TruLabel program, which subjects supplements to regular and random analysis to ensure label and ingredient authenticity and accuracy.

Under the programme, products are selected randomly from store shelves and sent to independent laboratories for purity tests. More than 23,000 product labels are currently registered as part of the TruLabel program.

For further information on tested sports supplements, see [www.NaturalProductsAssoc.org/sportstests](http://www.NaturalProductsAssoc.org/sportstests).

Source: NPA

## HIGH CONTAMINATION LEVELS IN KELP SUPPLEMENTS

As a result of work on a case of arsenic poisoning caused by ingestion of kelp supplements, scientists at the University of California have carried out further investigations and found that of nine commercially available kelp supplements tested, eight were contaminated with arsenic, with seven being above the highest tolerance level for foods in the USA.

The arsenic levels in the samples tested ranged from 1.59 - 65.5 ppm. The highest amount permitted in foods in the US is 2 ppm).

Source: UNPA

## CHARITY PROVIDES VITAMINS FOR HURRICANE VICTIMS

The effects of Hurricane Katrina are still being felt by many thousands of people living in cramped temporary accommodation without adequate cooking facilities – and increasing numbers of children are suffering from malnutrition.

In attempt to combat this growing humanitarian crisis, the charity Vitamin Relief USA has joined with medical networks including the New Orleans Department of public health to deliver vitamin supplements every day for three years - directly to the families greatest need.

Source: CRN USA

## HERBAL LEGACY CAMPAIGN LAUNCHED

The American Botanical Council (ABC), a non-profit research and education organisation, is to launch a new initiative, 'Creating a Herbal Legacy'.

The purpose of the initiative, which has the support of the United Natural Product Alliance (UNPA), is to ensure that herbal medicine continues to play an increasingly important role in both self-care and healthcare.

The ABC Legacy campaign will aim to provide long-term financial support for:

- An Endowment Fund to ensure the stability and international impact of the ABC
- A Scholarship Fund support students participating in ABC's pharmacy and dietitian internships and ethnobotanical eco-tours
- A Green Development and Beautification Fund to improve facilities and gardens at the ABC headquarters, including rainwater harvesting, solar electricity generation and herbal medicine gardens.

Source: UNPA

## **SOUTH WEST PACIFIC**

### **◆ AUSTRALIA & NEW ZEALAND**

## FSANZ FINALISING HEALTH CLAIMS STANDARD

Food Standards Australia New Zealand (FSANZ) are consulting on their proposed new voluntary Standard for health and nutrition claims which will permit manufacturers to promote their products.

The Standard provides rigorous assessment procedures for the approval of both high level claims, where fully convincing evidence is required, and general level claims which require a lesser degree of evidence.

Several health claims have been pre-approved in advance of the final standard, including those for calcium and osteoporosis, sodium and blood pressure, and folic acid and neural tube defect.

Source: CHC

### INDEX OF ASSOCIATION CONTRIBUTORS

- AFEPADI (Spanish Association of Manufacturers of Dietetic and Plant Products): [afedpadi@afepadi.org](mailto:afedpadi@afepadi.org)
- AFINUR (Spanish Association of Phytotherapy and Responsible Nutrition): [afinur@afinur.net](mailto:afinur@afinur.net)
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**KEY EVENTS:      APRIL - JULY**

Date	Conference	Place
April 16	IADSA Annual General Meeting (AGM)	Yokohama, Japan
April 17	IADSA Workshop - International Perspectives on Dietary Supplement Regulation <a href="http://www.iadsa.org">www.iadsa.org</a>	Yokohama, Japan
April 16 - 20	Codex Committee on Contaminants in Foods (CCCF) <a href="http://www.codexalimentarius.net">www.codexalimentarius.net</a>	Beijing, China
April 19 - 22	CHFA Expo West <a href="http://www.chfa.ca">www.chfa.ca</a>	Vancouver, Canada
April 23	BfR Conference: Nutrition profiles- Basis for health claims	Berlin, Germany
April 24 - 28	Codex Committee on Food Additives (CCFA) <a href="http://www.codexalimentarius.net">www.codexalimentarius.net</a>	Beijing, China
April 30 - May 02	Supply Side East - International Trade Show and Conference <a href="http://www.supplysideshow.com/east/">www.supplysideshow.com/east/</a>	Secaucus, NJ, United States
April 30 - May 04	Codex Committee on Food Labelling (CCFL) <a href="http://www.codexalimentarius.net">www.codexalimentarius.net</a>	Ottawa, Canada
May 08 - 10	Vitafoods International <a href="http://www.vitafoods.eu.com">www.vitafoods.eu.com</a>	Geneva, Switzerland
May 09 - 11	Functional Foods in Europe - International Developments in Science and Health Claims <a href="http://europe.ilsa.org/events/upcoming/functionalfoods">http://europe.ilsa.org/events/upcoming/functionalfoods.</a>	Portomaso, St. Julian's, Malta

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Date	Conference	Place
May 11 - 13	Cosmofarma Exhibition 2007 <a href="http://www.cosmofarma.com/index.asp">www.cosmofarma.com/index.asp</a>	Bologna, Italy
June 26 - 30	Executive Committee of the Codex Alimentarius <a href="http://www.codexalimentarius.net">www.codexalimentarius.net</a>	Rome, Italy
June 27 - 29	Natural Products Expo Asia <a href="http://www.naturalproductsasia.com/eng_main.php">www.naturalproductsasia.com/eng_main.php</a>	Hong Kong, China
July 02 - 07	Codex Alimentarius Commission (CAC) <a href="http://www.codexalimentarius.net">www.codexalimentarius.net</a>	Rome, Italy
July 15 - 17	Cosmoprof North America 2007 - The Business of Beauty <a href="http://www.cosmoprofnorthamerica.com">www.cosmoprofnorthamerica.com</a>	Las Vegas, NV, United States
July 20 - 22	NPA Annual Natural Products Convention and Trade Show <a href="http://www.naturalproductsassoc.org">www.naturalproductsassoc.org</a>	Las Vegas, NV, United States

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