

IADSA NEWSFLASH

OCTOBER 2007

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KEY EVENTS

IADSA

The International Alliance of Dietary /Food Supplements Association 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

◆ CODEX

COMMENTS ON HEALTH CLAIMS

IADSA has now submitted comment to the Codex Nutrition Committee on its draft recommendations on the scientific basis of health claims.

IADSA's comments particularly emphasise:

- support for the concept of grading of scientific evidence as a practical and feasible way of reflecting emerging and consensus science
- concern that the current emphasis on all health claims being based on human intervention studies may not be feasible
- that the substantiation of health claims should be carried out on a case by case basis and the degree of substantiation and the sources and nature of the supporting evidence should be proportionate to the type of health claim and take into account the totality of the available evidence and the weighing of the evidence.

The draft recommendations will be discussed at the Committee's next meeting, to be held in Germany in November.

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

REVISION TO NUTRIENT REFERENCE VALUES

A discussion paper on *Proposals for additional or revised nutrient reference values for labelling purposes* is also on the agenda for the Codex Nutrition Committee meeting.

Again, IADSA has submitted comment, both supporting the establishment of Codex Nutrition Reference Values so as to facilitate the goals of protecting the consumer's health and ensuring fair practices in food trade, and, in particular, supporting the view held by the USA and the European Community that the revision should concentrate on vitamins and minerals, based on scientific reviews by independent authoritative bodies.

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

LABELLING OF GM FOODS

The Codex Alimentarius Commission is currently seeking comment on *The labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering*, to be considered by a Working Group at a meeting in Ghana in January 2008.

The terms of reference of the Working Group include:

- The rationale for adopting or not adopting a particular approach
- The communication strategies used in communicating information to the public on foods and food ingredients obtain through genetic modification/engineering
- An analysis of current Codex texts, particularly labelling texts, to evaluate whether they supply sufficient guidance on the labelling of GM foods
- Taking into account the issues above, consideration of appropriate ways forward, and the development of an outcome

IADSA's Scientific Group will be providing comment in due course.

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

ASIA

◆ JAPAN

NEW STATUTORY HEALTH CHECK FOR JAPANESE AGED 40+

In June of last year the Japanese parliament passed a new law, 'The Special Healthcare System' which requires all Japanese people aged over 40 to have a special physical examination, including measurement of body mass index and waist size, etc., and diagnosis of any health issues.

The main objectives of the new law, which will come into force in April 2008, are to improve the overall health of the Japanese nation, to prevent lifestyle related diseases and to cut the national medical bill. However, some observers also consider that its implementation will result in new market opportunities, with increased competition between the dietary supplement and the OTC industries.

Source: JIHFS

L-CITRULINE BECOMES A GENERAL FOOD MATERIAL

Earlier this year, L-Citruline was classified as a "Non-drug", and in August the Japanese Ministry of Health, Labour and Welfare (MHLW) announced their approval for its use as a general food material, but not as a food additive. A daily maximum limit was not decided.

As a result of this decision, Japanese manufacturers are now using L-Citruline manufactured in Japan or China, and finished products to maintain healthy blood pressure levels, fight fatigue, etc., will soon be launched.

Source: JIHFS

EUROPE

◆ EUROPEAN UNION

DISCUSSIONS ON MAXIMUM LEVELS

The European Commission and the Member States have had an initial discussion on the Commission's 'Orientation Paper' on establishing maximum levels for vitamins and minerals for food supplements and fortified foods.

Few Member States expressed their positions at this early stage. However, there did appear to be majority support for the establishment of levels for all vitamins and minerals, rather than the option given in the orientation paper of not requiring levels for some vitamins.

This issue will be further discussed at future meetings, and the next Working Group meeting is scheduled for November.

Source: EHPM

REVISION OF THE NOVEL FOODS REGULATION

The European Commission has announced that it is shortly to adopt a Regulation revising rules for the assessment, authorisation, labelling and use of novel foods in the European Union (EU).

The aim of the revised Regulation is to encourage innovation in the food sector and facilitate trade, while at the same time maintaining a very high level of food safety. The definition of novel foods will be clarified, taking into account new and emerging technologies which could have an impact on food production. The authorisation system will also become more transparent and efficient, with the European Food Safety Authority being central to the safety assessment of such products.

Additionally, the revised Regulation should mean that traditional foods from third countries wishing to enter the EU market for the first time will encounter a more proportionate assessment and authorisation procedure, which takes into account the safe history of use this food may have in other parts of the world.

Source: ERNA

HEAVY METALS UPDATE

Further to the report in last month's Newsflash, EHPM has now submitted to the European Commission a compilation of data on heavy metal levels in over 100 food supplements from companies in Belgium, Czech Republic, France, the Netherlands and the United Kingdom.

Feedback from the Commission is now awaited before the next Working Group meeting, which is expected to be held at the end of October.

Source: EHPM

EFSA FOOD SAFETY SUMMIT

The European Food Safety Authority (EFSA) is to host a Food Safety Summit in Brussels on November 22nd to mark its 5 year anniversary, when key decision makers from the EU Institutions, international organizations and stakeholders will debate the future of food safety in Europe.

The event is organized jointly by EFSA and the Portuguese Government in collaboration with the European Commission, and is open to the general public.

Source: EHPM

EFSA OPINION ON GUAR GUM

The European Food Safety Authority (EFSA) Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food has now responded to a request from the European Commission to provide a scientific opinion the safety in use of a partially depolymerised guar gum as thickener, emulsifier and stabilizer in food.

Guar gum (E412) is already authorised for use as a food additive. The Panel's view was that the partially depolymerised gum did not present safety concerns, but that the specifications may need to be modified to take account of increased levels of salts and possible undesirable by products that may result from the processes for the production of partially depolymerised guar gum.

Source: EHPM

FIRST 'FOCAL POINT' FOR RISK ASSESSMENT NETWORK

On 1 October the European Food Safety Authority (EFSA) has signed an agreement with Italian national secretariat for risk assessment to establish the first national 'Focal point' in Italy: the 'Istituto Superiore di Sanità'.

The Institutes role is now to act as a collaborative centre in Italy with primary responsibility for supporting the Italian representative of EFSA's Advisory Forum in gathering data and transferring information between EFSA and relevant bodies in Italy.

The Advisory Forum will now continue to build its network of national 'Focal points' for EFSA across the Member States. The overall role of the final national 'Focal point' network, once established, is to co-ordinate national risk

assessment institutes and to cooperate with EFSA and the Advisory Forum in the preparation and implementation of work programmes.

For further information see:

http://www.efsa.europa.eu/EFSA/1178620777517/efsa_locale-1178620753812_National_Focal_Points.htm

Source: EHPM / ERNA

◆ BELGIUM

AGENCY APPROVES GOOD PRACTICE GUIDE

In 2006 the Belgian trade association NAREDI submitted a *Self-Regulatory Guide to Good Practice for Food Supplements* for the approval of its Food Safety Authority, AFSCA.

In August of this year, AFSCA gave the document its final approval. Its contents includes the requirements of:

- The European Union and the Belgian legal frameworks
- Good hygiene practice
- Good manufacturing practice
- HACCP
- Traceability and obligatory notification

AFSCA has also made a check-list, based on the Guide, which it will use to control both producers using the guide and those not using the guide. Their aim is to determine whether manufacturers are complying with Belgian safety/hygiene legislation (which is based on European Union legislation).

The Guide will be revised when necessary, on a regular basis, with the first revision, as agreed with AFSCA, planned for 2008.

Source: NAREDI

◆ FRANCE

HEALTH CLAIMS UPDATE

The French dietary supplement association (SDCA) and the French Food and Drink Federation (ANIA) will shortly present the European industry list of health claims (prepared by EHPM, CIAA, EBF), to the French authorities to be forwarded to the European Food Safety Authority (EFSA) for inclusion in the central register of Article 13 'generic' claims.

In addition, following a recent meeting between the French authorities, SDCA's members have until 31 October to forward traditionally used claims

for the psychological benefits of botanicals. It is anticipated that about 50 such claims will be submitted.

Source: SDCA

OTHER SUBSTANCES AND NUTRIENTS

The French decree on food supplements of March 2006 enforces the principle of a positive list of other substances and nutrients, with the application of the principle of mutual recognition.

The positive list will come into force in two steps:

- individual authorizations for companies following notifications of food supplements marketed in France
- one year later, an official text (arrêté) which consolidates all individual authorisations in a general authorisation.

The French authorities have put out for consultation a first proposal for an arrêté, taking in account authorisations received from March to August 2006. However, this first consultation represents only 3,000 notifications from a total of 11,000 notifications received by September 2007.

The proposal has been notified under Regulation 2002/1925/EC on the addition of nutrients and of other substances to foods. It will be presented to EU Member States during the October meeting of the Standing Committee. SDCA has prepared its initial observations and a Working Party is planned for November to progress the issue.

Source: SDCA

THE BORDERLINE BETWEEN FOOD SUPPLEMENTS AND CONVENTIONAL FOODS

The French food authority (DGCCRF) has opened a national consultation on the interpretation of the definition of food supplements (as defined by Directive 2002/46/EC), and in particular the borderline with conventional foods.

DGCCRF are concerned that conventional foods may try to use food supplement status to enhance the claims for their products, without applying the requirements of the Nutrition and Health Claims regulation and the restrictions of nutrient profiles. SDCA has responded that assessment can only be on a case by case basis, but has proposed some criteria to be taken into account in including or excluding a product from food supplement status.

The French authorities will consolidate national responses before putting the question to the European Commission. To raise the profile of this issue and to open a wider debate, SDCA are now hoping to organise a European Workshop on the Application of Food Supplement Directive 5 years after its entry into force.

Source: SDCA

◆ **NETHERLANDS**

NEW CARBON-BASED PACKAGING TAX PROPOSED

As part of its government's plan to double recycling rates by 2012, the Netherlands is to launch a carbon-based packaging tax, based on the estimated CO2 emissions produced in making particular packaging.

The new tax, due to be implemented in January 2008, has been agreed between the Netherlands environment ministry, local authorities and industry. According to the terms of the proposal, producers and importers will be obliged to pay tax on the packaging materials they use, including glass, aluminum, plastics, paper, etc. The proceeds will be used to establish a fund to help reducing waste throughout the country.

Source: NPN

◆ **UNITED KINGDOM**

FSA SEEKS VIEWS ON LYCOPENE APPLICATION

A Spanish company has applied to the Food Standards Agency (FSA) for approval for lycopene in a cold water dispersable form as a novel food ingredient, for use in a variety of food products.

The application is similar to the use of lycopene in an oil suspension form which was authorised as a novel food in 2006. The FSA is now seeking comment on this new application.

Source: HFMA

INITIAL OPINION ON GLUCOSAMINE APPLICATION

Last year the Food Standards Agency (FSA) consulted on an application to use glucosamine hydrochloride in a range of foods, including sports drinks.

The initial assessment was carried out by FSA's Advisory Committee on Novel Foods and Processes (ACNFP) who have concluded that further assessment is required, comment should be invited from other EU countries and that a decision on the authorisation of the novel food ingredient should be taken once European Food Safety Authority (EFSA) advice is available.

The glucosamine that is the subject of this application is sourced from a fungus, *Aspergillus niger*. All other known commercial glucosamine products are derived from shellfish.

Source: CRN

LEGAL OPINION ON MAXIMUM LEVELS

Recently, the UK trade association, The Health Food Manufacturers' Association, commissioned a leading European food lawyer to provide a series of legal opinions on setting maximum levels for food supplements in the European Union (EU). In particular his views were sought on the viability of the 'two-tier' system favoured by the UK Food Standards Agency whereby the lower levels are set by the European Commission but Member States are also able to add their own higher levels, subject to appropriate labelling.

The lawyer's advice was that a two tier system based on Member State discretion was not tenable – however his opinion was that a two-tier system harmonised throughout the EU, with the upper tier utilising 'conditions of use'-based advisory statements, would meet all relevant legal criteria, notably risk analysis, food safety, proportionality, subsidiarity and equal treatment.

A detailed summary of these opinions has been reviewed by FSA lawyers and the UK Cabinet Office and has now been passed to the European Commission for consideration.

Source: HFMA

INDUSTRY SLOW TO REMOVE COLOURS, SAYS FSA

Last month's Newsflash reported the publication of a report commissioned by the Food Standards Agency which revealed the potentially adverse effect of certain food colours on children's behaviour, and that the report had been forward to the European Food Safety Authority (EFSA) for consideration.

EFSA has now said that it will prioritise its own review of these colours, and expects to complete its assessment by January 2008, and has asked FSA for further information to enable its Panel to '*... assess the implications of the findings and their relevance for drawing definitive conclusions on cause and effect and the possible role of particular colours*'

In the meantime, following a recent open meeting, the FSA Board has expressed its '*...astonishment that industry has not moved more quickly to remove these artificial colours from their products, in the light of serious concerns raised by consumers.*'

Source: HFMA

ASA ACTS ON ANTIOXIDANT CLAIMS

Following complaints from members of the public, the UK Advertising Standards Authority (ASA) has criticised the UK Tea Council for making claims for the health benefits of the antioxidant properties of tea. The grounds for the ASA's action were that whilst scientific literature does show

that tea contains antioxidants, the evidence for its health benefits, whilst promising, is inconclusive.

In a separate ruling, the ASA has ordered a company to stop making claims for a '*natural detox superfoods smoothie*', containing '*..even more antioxidants than the average five a day*', because the evidence provided by the company did not substantiate the claim.

Source: HFMA

NORTH AMERICA

◆ CANADA

CANADA-CHINA SCIENTIFIC AND TECHNOLOGICAL COOPERATION

Under the Canada-China Scientific and Technological Cooperation Agreement, the two governments have agreed to foster joint research and development projects under a bi-lateral program is implemented by the Ministry of Science & Technology in China (MOST), and ISTP Canada Inc., incorporated in Canada.

A joint call for proposals for collaborative projects has been made, open to all projects that include science and technology (S&T) development leading to commercial success and benefit to both countries. Initially, however, there is specific emphasis on following technology areas:

- Agriculture Foods and Bio-products
- Energy
- Environment
- Health & Life Sciences/Biotechnology

Source: CHFA

◆ UNITED STATES

COMMENT PERIOD ON AER DRAFT GUIDANCE

The Food and Drug Administration (FDA) has opened a comment period regarding the newly released draft guidance for the Adverse Event Reporting (AER) law.

The draft guidance addresses the major provisions of the AER act, specifically providing some greater detail on reporting responsibilities as put forth in the draft guidance. The draft guidance offers an appendix with some detailed instruction for the "manufacturer, packer, or distributor" on how to best complete the 3500A form with the necessary information for compliance. This

process was and remains an area of concern, as how to best use the 3500A form to submit AER's for dietary supplements. The 3500A was originally designed for surveillance in a clinical setting, but is now to be used and adapted to gather information on consumer health products in the marketplace.

The guidance also elaborates and offers some clarification on the use of agreements between retailers and manufacturers to transfer the responsibility for submitting adverse event reports for the product to the manufacturer. Additionally, the guidance states that when submitting a report to FDA, "...a copy of the label on or within the retail packaging of that dietary supplement must be included with the serious adverse event report to FDA" and that the agency encourages the responsible person to attach any relevant clinical, laboratory or other critical data with the 3500A form.

Comments to the agency are due 14 December 2007. The draft guidance and instructions for submitting comments are available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0388-gdl0001.pdf>.

Source: NPA

2006 SUPPLEMENT RESEARCH LIST PUBLISHED

The Office of Dietary Supplements (ODS) at the National Institutes of Health have recently published its *2006 Annual Bibliography of Significant Advances in Dietary Supplement Research*, highlighting 25 of the most significant dietary supplement research advances in the past year.

The Annual Bibliography is part of the ODS' commitment to improve the quality of dietary supplement research and subsequent health messages. The 2006 edition includes data on the potentially favourable effects of black cohosh in bone remodelling, ginkgo and omega-3 fatty acids in cognitive health and vitamin D in reducing risk of prostate cancer.

For further details, see:

http://ods.od.nih.gov/Research/Annual_Bibliographies.aspx

Source: AHPA

NIH SEEK DATA ON CHILDREN'S SUPPLEMENT INTAKE

A recently published study carried out by the National Institutes of Health which analysed nationally representative data from the *National Centre for Health Statistics 1999 – 200 National Health and Nutrition Examination Survey* has found that about a third of US children take dietary supplements regularly – a significant part of their diet which the survey did not address.

As a result, NIH researchers are quoted as saying, '*To truly assess the nutrient status and estimate the potential health risks of US children, we must include nutrient intakes from dietary supplements as well as from food*'

The supplements most commonly used were multivitamins and multiminerals, vitamin C, retinol, vitamin D, calcium and iron, with the highest regular consumption being found in families with a favourable socioeconomic environment.

Source: UNPA

NEW FOUNDATION TO ADVANCE FDA MISSION

The US Food and Drug Administration (FDA) has announced that patient and consumer advocacy groups, professional scientific and medical societies and industry trade organisations can nominate candidates to serve on the Board of a new not-for-profit foundation, the *Reagan-Udall Foundation for the Food and Drug Administration*.

The purpose of the Foundation is to 'advance the mission of the Food and Drug Administration to modernise medical, veterinary, food, food ingredient and cosmetic product development, accelerate innovation and enhance product safety'. The duties of the Foundation include the identification of unmet needs in the development, manufacture and evaluation (including postmarket evaluation) of the safety and effectiveness of FDA-regulated products, and the establishment of scientific and other projects and programmes to meet those needs.

Source: NPA

FDA APPROVES HEALTH CLAIM FOR ISOMALTULOSE

A health claim for the non-cariogenic effect of the carbohydrate sweetener isomaltulose has recently been approved by the Food and Drug Administration (FDA).

It is understood that the FDA approval for the sweetener, which recently also obtained novel foods approval from Food Standards Australia New Zealand, will permit claims such as '*may reduce the risk of dental caries*' to be made.

Source: CRN USA

FDA CONCERNS ON HERBAL GRIPE WATER & HERBAL SWEETENER

The Food and Drug Administration (FDA) has recently warned consumers that a particular batch of brand of apple flavoured herbal Gripe Water, contains a parasite that can cause intestinal infections.

A full product recall has been put in place, and parents of children who have taken the product have been advised to be alert for signs of infection and to seek medical advice where necessary.

FDA has also recently sent a warning letter to a company making teas and drink mixes about its use of the sweetener Stevia, in its products. The reason for the FDA action is that in the United States Stevia, derived from the South American plant *Stevia rebaudiana*, is permitted in dietary supplements but not in conventional foods or beverages.

FDA's concern is that Stevia may have an adverse effect on blood sugar levels, and on the reproductive, cardiovascular and renal systems. To be able to use Stevia in foods, manufacturers would either have to obtain Generally Recognised as Safe (GRAS) status, which requires appropriate scientific substantiation, or they could petition the FDA to approve the ingredient as a food additive.

Source: AHPA

NEW SUPPLEMENT CAMPAIGN LAUNCHED

A new campaign, '*Life...Supplemented*', managed by the US Council for Responsible Nutrition (CRN), has announced that it is sponsoring new research among health professionals to better understand their personal use of dietary supplements and how it may impact on the way they counsel their patients about dietary supplements.

Currently there is very little data on the correlation of personal use of supplements by healthcare professionals and their recommendations to their patients, and it is hoped that this study will fill that gap. The results of the survey are expected to be released in November.

The aim of the '*Life...Supplemented*' campaign is to help consumers create a healthy lifestyle and a personal culture of wellness that focuses on healthy diet, supplements and exercise. Its new website, www.lifesupplemented.org incorporates a *My Wellness Scorecard*, an interactive tool to help consumers determine their personal level of.

Source: CRN USA

GUIDANCE ON FOOD ADDITIVES PUBLISHED

The US Food and Drug Administration (FDA) have recently published guidance for submissions for approval of antimicrobial food additives.

The aim of the guidance is to set out all the data requirements, including the intended effect of the ingredient, its chemical identity, conditions of use, the quantity required and the safety assessment.

Source: CRN USA

SOUTH WEST PACIFIC

◆ AUSTRALIA & NEW ZEALAND

UPDATE ON HEALTH CLAIMS

Following extensive consultation and a subsequent draft report, Food Standards Australia New Zealand is now preparing its final report giving its recommendations for regulating health claims on foods.

The report is likely to go to government in the first half of 2008 and it is expected that the regulatory structure proposed will be similar to that of the European Union.

Source: CHC

THE NATIONAL INSTITUTE OF COMPLEMENTARY MEDICINE

The Complementary Healthcare Council of Australia (CHC) recently made a formal presentation at the industry forum of the National Institute of Complementary Medicine (NICM), one of a series of stakeholder forums NICM has held since its inception early this year.

The basis of CHC's submission was:

- NICM'S funding and timing constraints mean that industry is best served by building on existing domestic capabilities, targeting priorities which reflect existing strengths and expertise
- Research - NICM should be seen as a credible source and the central point of reference, and should assist researchers to achieve best outcomes.
- Linkage with the wider research community, including universities, government, industry, practitioners is important as there is currently insufficient depth of capacity in complementary medicines research.
- NICM should have key role in coordinating and disseminating research outcomes so as to raise the profile of complementary medicines with consumers.
- Preventative health and research should reflect the intent of the government National Medicines Policy as well as aim to deal with the 'burden of disease' as this has implications for national healthcare budget.

A report on the development of NICM will shortly be presented to Government, expressions of interest for funding will be called for this month and a new NICM website will be launched in the near future.

Source: CHC

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KEY EVENTS: NOVEMBER - DECEMBER

Date	Conference	Place
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 - 07	Executive Committee of the Codex Alimentarius www.codexalimentarius.net	Rome, Italy

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