IADSA NEWSFLASH
APRIL 2013

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KEY EVENTS

IADSA

The International Alliance of Dietary /Food Supplements Associations was founded in 1998 to address the globalization of food supplement markets and increasing regulatory challenges. IADSA brings together more than 50 food supplement associations with the aim of building a sound legislative and political environment for the development of the food supplement market worldwide.

IADSA serves its worldwide network of associations and companies by:

- Providing a fast flow of regulatory and policy information on food 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 food supplement associations and supporting existing national associations.
- Organizing global and regional events to promote dialogue on the scientific and regulatory issues underpinning the food supplement market.

INTERNATIONAL DEVELOPMENTS

◆ CODEX

THE CODEX COMMITTEE ON FOOD ADDITIVES

The 45th Session of the Codex Committee on Food Additives (CCFA) recently took place in Beijing, China, with 66 member countries of Codex Alimentarius present and 33 Non-Governmental Organisations (NGOs), including a delegation from IADSA.

Key points of relevance include:

- **Rosemary Extract (INS 392):** Following a referral from the Codex Committee on Fats and Oils for the consideration of the inclusion of Rosemary Extracts into the list of permitted additives in the proposed standard for fish oils, it was concluded that whilst Rosemary Extracts had been assigned an INS number, they had not yet been evaluated by JECFA (the Joint Expert Committee on Food Additives). This would

require the presentation and evaluation of a comprehensive dossier with full toxicological and exposure data.

A Circular letter will be sent to interested countries asking them to provide this information and confirm the availability of appropriate data for JECFA evaluation. IADSA Member Companies with an interest in Rosemary Extracts for use in fish oils should ensure that the required data is collated as soon as possible.

- **Food Additives without Corresponding Specifications:** 16 food additives had been identified which had no corresponding specifications. The CCFA will verify that they are all currently in commercial use as technological food additives. If not, they will be removed from the General Standard and will no longer be recognised as technological food additives. IADSA members are therefore requested to urgently review the list additives circulated in March and to contact the IADSA Secretariat without delay with any relevant information.

- .**Dietary Exposure to Magnesium Salts**: Following discussion on the context of JECFA recommendations on the evaluation of the additive Magnesium dihydrogen diphosphate, it was recommended that the total dietary exposure to magnesium from additives and other sources in the diet (for example, magnesium salts used as nutrient sources) should be assessed. JECFA would therefore welcome actual use levels of magnesium, in particular for food additives still authorised under GMP, and this discussion will be taken into consideration when usage levels are discussed in the dossier being developed for magnesium stearate.

- **Aluminium Containing Additives:** Following JECFA's recommendations and the revised Provisional Tolerable Weekly Intake (PTWI) for aluminium of 2mg / kg bw, the Committee considered reducing five aluminium containing food additives to the lowest practical levels of use and reducing the number of food category provisions in which the use of aluminium containing additives were allowed.

  The working group set up by CCFA recommended discontinuation of over 40 provisions, and reducing the levels of use in a number of others. A total diet study to evaluate the aluminium intake by individual age groups commenced in April 2011 and is due to conclude at the end of March 2013. The European Union (EU) delegation informed the Committee of measures already taken in the EU to reduce exposure to aluminium food additives, including aluminium lake colours.

- **Potassium Aluminium Silicate:** Following inconclusive discussions on the technical functions of Potassium Aluminium Silicate in 2012, the issue was referred to the International Numbering System (INS) electronic working party. Further confusion then emerged when an INS number was allocated to 'Potassium aluminium silicate – based pearlescent pigments' in addition to 'Potassium aluminium silicate'. It was agreed that the inclusion of 'Potassium aluminium silicate – based pearlescent pigments' should be postponed until it had been evaluated by JECFA.
  Potassium aluminium silicate with the INS Number 555 was adopted with the additional technological function of 'carrier'.

- **Magnesium Stearate:** Following a considerable amount of groundwork on the Magnesium stearate issue over the past year, IADSA called a pre-meeting in Beijing with the other interested industry groups, including the International Food Additives

Council (IFAC), the European Chemical Industry Council (CEFIC) and some confectionery industry representatives.

The objective was to plan the lobby campaign to get the JECFA evaluation of Magnesium stearate put onto the priority list for 2013 – 2014 which requires the support of at least one member country. IADSA and CEFIC put their case to the meeting and the application was supported by the European Union (EU) delegation and the arguments were accepted by the Priority Working Group and endorsed by CCFA. IADSA and CEFIC are now liaising with a specialist with considerable experience in the preparation of JECFA dossiers so that one can be submitted by end 2013, and the CCFA has put out a call for data.

For further information on any of the above, contact secretariat@iadsa.orgf

Source: IADSA

AFRICA

SOUTH AFRICA

ASSOCIATION CHOSEN AS THE CAMS CONTACT POINT

After indicating that it would prefer to communicate with one central body rather than individual companies, the South African Department of Health (DoH) has elected IADSA member The Health Products Association of Southern Africa (HPA), as the chosen organization with which to communicate on all matters relating to Complementary and Alternative Medicine (CAMS).

HPA Chairman Bruce Dennison is quoted as saying: "*In order to achieve appropriate regulations for CAMS, the HPA has been in constant dialogue with the DoH for many years. Given the current situation where regulations are still pending, scheduling status of certain CAMS substances have been introduced, CAMS dossiers are being rejected, CAMS vitamin levels are being debated, GMP manufacturing standards and stability requirements are being discussed and advertising on CAMS is being restricted, it is imperative that industry stands together as a collective entity in its communication with the DoH."*

Mr Dennison went on to say, *'…. In the interests of achieving legitimate regulations and creating an appropriate environment for CAMS, the HPA consistently addresses pertinent issues and negotiates with relevant bodies,……and continues in its best endeavours to negotiate with the DoH so that when regulations are eventually introduced, they are appropriate to CAMS…",*

Source: HPA

ASIA

◆ CHINA

SFDA WARNING ABOUT 'FAKE' HEALTH FOOD PRODUCTS

China's State Food and Drug Administration (SFDA) recently announced a list of 11 'fake' food products and warned consumers against buying them. The products were found to contain chemical ingredients but were being marketed as health beneficial functional foods.

The SFDA urged local food and drug administrations to strengthen inspection of the functional food market and to 'severely punish' the producers of the offending products according to law.

Consumers were also invited to refer to www.sda.gov.cn, the SFDA's website, for licensing information for all functional foods, and to report to local administrations if they find illegal or fake products.

Source: IADSA

◆ JAPAN

DISCUSSIONS BEGIN ON CLAIMS REFORM IN JAPAN

The Regulatory Reform Council, which responds to the consultations of the Prime Minister of Japan, has begun discussing regulatory system for claims for foods with nutrient function claims in Japan. The Council will conduct a comprehensive analysis of international regulatory systems, and if the Japanese system proves to lack rationality, its deregulation will be requested to the Consumer Affairs Agency.

The Consumer Affairs Agency regulates the claims and warnings of Foods with Nutrient Function Claims, one of the two pillars of Foods with Health Claims, the other being FOSHU, or Foods for Specified Health Uses. The nutrients (12 vitamins and 5 minerals) have a set of basic claims and warnings to be used at the discretion of the marketer of the food product. The Council will go over those set claims (regulated in 2001) and eventually decide if such a claim as "*Research results show that [the nutrient] may lower the risk of ……."* could actually be placed on the label.

The Regulatory Reform Council believes that if the claims prove to be more useful and easier for the consumer to understand, they may help promote the prevention of diseases and maintenance of health, as well as stimulate the spirit of new product development for manufacturers, and eventually revitalize the industry.

Source: JHNFA, AIFN

PROGRESS TOWARDS THE UNIFICATION OF FOOD LABELLING

A recent Cabinet Meeting of the Japanese government has made a decision regarding the unification of the rules for Food labelling in Japan. At present, there are three kinds of legislation for Food labelling: the Food Sanitation Law (the responsibility of the Ministry of Health, Labour and Welfare (MHLW), the JAS Law (the standardisation and labelling of agricultural and forestry products - the responsibility of the Ministry of Agriculture, Forestry

and Fisheries, MAFF), and The Health Promotion Law (the responsibility of MHLW). This has sometimes made it difficult for consumers to understand the meaning of the terminology used because each set of legislation has its own rules. Unification aims to clarify this in the interests of the rights of consumers for the security of food safety and to receive appropriate information.

Under the new "the Food Labelling Law", the following issues will be addressed: penal regulation will be increased, as will fines for transgressions, and appropriate consumer bodies will have the right to demand an injunction for misrepresented labelling.

The policy of the Japanese Consumer Affairs Agency (CAA) is that correct nutrient labelling for energy, macro nutrients etc. is mandatory, and must be completed within 5 years.

Labelling for the region of origin of ingredients on processed foods, labelling rules for both home-meal replacement and foods at restaurant etc., and the application of labelling rules to products sold by internet will be discussed separately in the near future, as will the labelling of GM plants and food additives.

Source: AIFN

EUROPE

◆ EUROPEAN UNION

'ON HOLD' BOTANICAL CLAIMS

In the continued absence of a decision from the European Commission as to how the review of botanical claims should be conducted, over 1700 claims remain 'on-hold'.

Most recently, at a meeting in Italy on the 'BELFRIT' project, Basil Mathioudakis of the European Commission said that the outcome of the Commission's consultation with the Member States (MS) on options for the review of botanicals was:

- 7 MS were clearly in favour of option 1 (the *status quo* whereby the same process used for the review of other claims would be applied, probably resulting in the failure of most claims)
- 5 MS expressed their support for option 2 (a new, more comprehensive approach which recognises the 'peculiarities' of botanicals and would be likely include discussion on quality and safety issues).
- 3 MS had reservations with both options.
- 11 MS with a preference for option 1 but who also indicated that they would not oppose option 2. (The difficulties they foresaw in relation to option 2 included the time that such harmonisation would take and their concern with the fate of the on hold claims during that time.)

Source: EBF

THE BELFRIT PROJECT

The Italian Ministry of Health recently organised a symposium in Rome to discuss the 'BELFRIT' project, a collaboration between the competent authorities of Belgium, France and Italy, aimed at developing a common list of plants, accepted for use in food supplements.

In his introductory address, Basil Mathioudakis of the European Commission, (EC) indicated that the project had highlighted to the Commission the importance of quality and safety. This was also reflected in a letter sent to EFSA by the heads of six of food safety agencies (Belgium, France, Spain, Denmark, Germany, Luxembourg) which expressed concerns about botanicals used in food and food supplements and asked EFSA to carry out a systematic safety assessment. In this context, Mr Mathioudakis pointed out that because botanicals are used both in traditional herbal medicinal products (THMP) and Food Supplements, consistency with both was needed and the work of the European Medicines Agency herbal medicinal committee would need to be considered.

In conclusion, Mr Mathioudakis said that that the BELFRIT project was a very important Member State initiative, but that ultimately success would depend on the critical mass of other MS that joined the project, the degree of support from the stakeholders and the Commission's decision on the two options for the review of botanical health claims.

Expressing support for the BELFRIT approach, a representative of the German Federal Consumer Protection Service said that there is also a German list of plants under development which contains about 630 botanicals. The list would have no legal status, but would be used to support enforcement.

Botanical experts then explained the Project in more detail. The original assignment was to combine the three existing lists (2045 botanicals in total; 645 botanicals on the Belgian, 558 on the French and 1182 on the Italian list (this higher number resulting from more detailed specification of subspecies and the inclusion of many Mediterranean herbs).

For each plant the scientific name, synonyms and family name were added. A literature search was carried out and the traditionally used plant part(s) specified, chemicals of concern identified and chemicals to be monitored highlighted. Data on side effects was also added, and information on markers. Judgement on acceptability and on conditions of use where relevant was then made. The outcome is a list of 1025 plants (396 featuring on all lists, 180 on lists of two of the countries and 449 on one of the lists). For 77 plants further information is required and for 79 use in food supplements is questionable and they have been put 'on hold. Some plants have been excluded, mostly because they are subspecies

The intention is for the BELFRIT list to be finalised by July and then integrated in the legislation of the three countries. It was noted that ongoing work would then be needed to manage the list, identify risk management measures where necessary (warnings, maximum levels, etc.).

Source: EBF

THE EUROPEAN FOCAL POINT NETWORK

All Member States, as well as Norway and Iceland, have renewed their Focal Point Agreements in 2012. The Focal Point network collects and shares information amongst themselves and with EFSA on a variety of issues on risk assessment or data collection. At the end of December 2012, the Information Exchange Platform contained over 1296 documents uploaded by Member States, EEA/EFTA countries and Pre-Accession countries. This included risk assessment outputs (83%) and mandates (5.3%), country specific profiles (5%), and annual and strategic work plans (6.7%).

To further consolidate the scientific cooperation between Member States and EFSA, the following Focal Point priorities will be continued in 2013:

- Exchange of relevant scientific information and planning of risk assessment activities via the Information Exchange Platform, email and national websites;
- Promotion of EFSA's database of external scientific experts, including its use at national level as a cooperation tool;
- Extension of national target audiences in cooperation with the Members of the Advisory Forum Communications Working group, allowing for EFSA's entire remit to be covered;
- Development of Focal Point and national websites as an important communication tool for national and EFSA's risk assessment activities;
- Promotion of training on food safety risk assessment at national level by liaising directly with the national BTSF contact points.

Source: ERNA

FOOD ADDITIVE RE-EVALUATIONS: NEW CALL FOR DATA

EFSA has prioritised the food additives for which scientific data are required to finalise their re-evaluation within deadlines established by European legislation. The Authority has launched a new call for data proactively, asking Member States and other stakeholders for two types of data for 51 food additives: figures from industry on the amounts of these additives they report using in their products; and data derived from analyses indicating actual levels of these additives found in foods and drinks from national food authorities, research institutions, academia, food industry and other stakeholders.

Submission of the data will ensure that EFSA can carry out its risk assessments of these food additives and support EU risk managers (European Commission, European Parliament, Member States) charged with regulating their use in food**.** Under EU legislation, EFSA is required to re-evaluate hundreds of food additives and their permitted uses by 2020. In addition, the Authority is reviewing some of its previous re-evaluations of certain food colours because consumer exposure to them for some population groups was originally estimated, based on limited data, to be higher than the Acceptable Daily Intake (ADI). For further information, see Call for food additives usage level and/or concentration data in food and beverages intended for human consumption

Source: ERNA

ALUMINIUM-CONTAINING FOOD ADDITIVES

In December 2012, the European Commission (EC) asked the European Food Safety Authority (EFSA) to support the EC in the preparation of an EU position for provisions for aluminium-containing food additives of the General Standard for Food Additives (GSFA) at the 45th Codex Committee on Food Additives (CCFA) held in Beijing on 18 to 22 March 2013, (as reported in 'International Developments – Codex', above).

EFSA carried out a dietary exposure assessment for aluminium-containing food additives by using the maximum levels as defined in the recommendations for provisions for aluminium-containing food additives of the GSFA (CX/FA 13/45/8, December 2012) for the following five aluminium-containing food additives included in the GSFA:

- E 523: aluminium ammonium sulphate
- E 541 (i, ii): sodium aluminium phosphates (acidic and basic)
- E 554: sodium aluminosilicate
- E 556: calcium aluminium silicate
- E 559: aluminium silicate.

For the dietary exposure estimates, EFSA used the maximum levels proposed for the five aluminium-containing food additives according to the following 2 scenarios:

- Scenario 1: maximum levels recommended for adoption by the CCFA (recommendation 2)

- Scenario 2: maximum levels: (i) recommended for adoption by the CCFA (recommendation 2), (ii) recommended to be discussed further (recommendation 3) and (iii) recommended to be circulated for comment

Food consumption data of European countries from the EFSA Comprehensive Food Consumption database were used (EFSA, 2011a). Depending on the dietary surveys, the exposure to the five aluminium-containing food additives for scenario 1 in five population groups (toddlers, children, adolescents, adults and the elderly) ranged from 2.3 to 76.9 mg/kg body weight (bw)/week at the mean and from 7.4 to 145.9 mg/kg bw/week at the 95th percentile. For scenario 2, the results ranged from 18.6 to 156.2 mg/kg bw/week at the mean and from 35.3 to 286.8 mg/kg bw/week at the 95th percentile.

Source: ERNA

EFSA PRIORITIES 2014 – 2016

The Management Board of the European Food Safety Authority has held an initial discussion on EFSA's draft Multiannual Plan outlining key priorities and initiatives for the three years 2014-2016.

In the draft, EFSA identified three key priority areas for the period 2014-16 with a series of initiatives related to: ensuring EFSA is fit for purpose; optimising the use of resources; and building more transparency and trust.

- *fitness for purpose* – EFSA will strive to enhance the quality of its outputs and to meet the needs of its customers. In line with its Science Strategy, EFSA will intensify its cooperation and networking activities with national food safety authorities, international organisations and other stakeholders to build richer data sources for

risk assessment and to promote further harmonisation of risk assessment methodologies.

- *optimising the use of resources* – EFSA is proposing to redistribute some of its scientific work between external experts and internal staff from 2014 in the area of regulated products (GMOs, food ingredients and packaging, feed additives and health claims) by providing further support to Panels in relation to some routine preparatory work currently being carried out by Panel Working Groups. EFSA will also increase its efficiency in handling applications by streamlining its administrative processes.
- *building more transparency and trust* – EFSA will push forward with its transparency initiative developed with its institutional partners and stakeholders, focusing on transparency with respect to the data and processes used in risk assessment. The review of its Communications Strategy in 2013 will build on simplicity, transparency, cooperation with Member States and the international risk assessment community, and communicating the role of EFSA and the independence of its risk assessment work.

For further information, see: Draft Multiannual Plan (2014-2016) EFSA Science Strategy 2012-2016

Source: ERNA

NEW EUROPEAN SUPPLEMENT ASSOCIATION CREATED

Members of the European Responsible Nutrition Alliance and some European national associations have created a new supplement association, 'Food Supplements Europe

The aims of the new organisation are to:

- Assist regulators and scientists with technical and scientific support from the sector
- Support the establishment of a safety based and innovation driven legal environment
- Increase awareness of the important role of food supplements for public health in Europe.

For further information, contact secretariat@foodsupplementseurope.org

Source: ERNA

◆ FRANCE

SYNADIET PRESIDENT IS THE NEW CHAIRMAN OF EHPM

Alban Maggiar, president of the French association SYNADIET, has been elected as the new Chairman of the European Federation of Associations of Health Product Manufacturers (EHPM). Three new board members, from associations in Germany, Italy and Greece, were also elected to join existing board members from the UK, Belgium, Spain and The Netherlands . EHPM has now moved to a new office location in Brussels and has engaged the services of a full time Director General.

For further information, contact: p.ahern@healthproductmanufacturers.eu

Source: SYNADIET, EHPM

◆ GERMANY

BfR CONCERNS ABOUT BITTER ORANGE SUPPLEMENTS

The German Federal Institute for Risk Assessment (BfR) has assessed the risks of sports and weight loss products containing bitter orange (*citrus aurantium*) which is chemically related to ephedrine. Some products offered as sports and weight loss supplements contain synephrine in the form of added bitter orange extract. Often such products contain caffeine and other active ingredients and are sometimes referred to by manufacturers as food supplements or dietetic foods.

BFR has expressed concern about products contain caffeine and synephrine particularly when ingested in bolus doses (when the daily dose is taken all at once) Due to known synergetic effects, BfR have assumed that the substances caffeine and synephrine mutually reinforce each other in their cardiovascular effects. This applies to both, to substances' potential for increasing the heart frequency and their blood-pressure increasing properties. They also consider that additional enhancements of these effects through other phenylethylamines with sympathomimetic activity contained in *Citrus aurantium* extracts are possible.

BfR now recommends that quantities of health-relevant components of *Citrus aurantium* ingested through such products should be limited to the intake levels from conventional foods such as oranges and bitter oranges. For synephrine, this means that no more than 6.7 milligrams per day should be consumed in the form of a food supplement. This quantity of synephrine represents the intake via conventional foods with maximum contents of synephrine for average consumers. This would ensure even for frequent consumers that their total intake of synephrine from both conventional foods and food supplements does not exceed 25.7 milligrams.

However, BfR concludes for some products currently available on the market, there are, due to the dosage levels, sufficient reasons to suspect that the products do not meet such requirements and for this reason they should be classified as unsafe. BfR also make the point that their view takes into account that the target group of the food supplement are persons who, as a result of physical exertion, already put an increased strain on their cardiovascular system which may be further exacerbated if they are overweight.

Source: BLL

◆ ITALY

REVISIONS TO NATIONAL BOTANICALS GUIDANCE

The Italian Ministry of Health has recently undertaken a revision of its guidelines on references to physiological effects applicable in respect of the definition of "claims" for botanicals at Community level. Changes include:

- Deletion of authorised health claims at national basis for non-botanical substances in particular "bee products" " such as propolis, royal jelly and pollen. (These substances can continue to be used in Food Supplements but can no longer make national use of the health claims that were included in the 2012 guidelines.)

- amendment to the plant parts permitted from Carica papaya: (The mention of fructus fermentatus from Carica papaya was deleted since the indication should apply to all fruits and not only to fermented fruits.)
- Deletion of Amorphophallus Konjac Koch tuber, amylum (There are new specific 13.1 Health Claims approved for Glucommanan, therefore the national rules no longer apply.)

The new guidelines can be found at the following link:
www.salute.gov.it/imgs/C_17_pagineAree_1268_listaFile_itemName_2_file.pdf

Source: AIIPA

UPDATE TO NATIONAL VMS MAXIMUM LIMITS

The Italian Ministry of Health has recently updated its list of maximum limits of vitamins and minerals. The 2013 changes for the maximum limits are:

- vitamin D: from 10 µg to 25 µg
- vitamin B6: from 6 mg to 9.5 mg
- iron: from 21 to 30 mg

In addition, the revised guidelines now provide a new clear minimum level specification for boron, now indicated as 15% of the max level (0.23 mg)

Additional information can be found at:
www.salute.gov.it/imgs/C_17_pagineAree_1268_listaFile_itemName_5_file.pdf

Source: AIIPA

◆ UNITED KINGDOM

NOVEL FOOD APPLICATIONS

Probiotic strain: the UK Food Standards Agency (FSA) is calling for views on an application from a Japanese company for European Union Novel Foods status for a probiotic strain. This is the first time that a live microorganism, which is intended for use as a food supplement, has been assessed under the Novel Foods Regulation, which requires that substances and processes not on the EU market in reasonable quantity prior to May, 1997, undergo a safety assessment before being placed on the EU market.

Algal oils: FSA) is also calling for views on two applications to extend the European Union Novel Foods status for DHA and EPA-rich algal oils, both a source of omega-3 fatty acids and extracted from two different strains of Schizochytrium microalgae.

The oils were initially evaluated for use in the EU as a novel food ingredient in 2011, and were confirmed for a range of uses in July 2012. However the applicant now wishes to extend the uses of the oils to use them in food supplements for doses of up to 3g per day.

The UK Advisory Committee on Novel Foods and Processes (ACNFP) has already formulated a draft positive opinion on the applications, but now invites further comment.

Source: HFMA

FSA SUPPORT FOR INTERNATIONAL ALLERGY PROJECT

The UK Food Standards Agency (FSA) is supporting a recently launched international study into food allergy led by the University of Manchester and funded by the European Commission, which will involve leading experts from across the world, including the UK, Europe and the United States of America.

The Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM) is expected to produce a standardised approach to allergen management for companies involved in food manufacturing. It will also develop tools to inform new health advice to prevent the development of food allergies.

iFAAM, which is expected to take three years to complete, will also work with groups of children from several countries including the UK, who have been monitored from birth. The aim is to be able to look at development of food allergy and other allergic diseases, such as asthma or eczema, in early life.

Source: HFMA, CRN UK

GUIDANCE ON ALLERGEN LABELLING

The British Retail Consortium has made available guidance on allergen labelling, which has been produced in partnership with the Food and Drink Federation to assist companies with compliance with the requirements of Regulation 1169/2011.

This document appears to have the approval of the UK Food Standards Agency, as it contains the statement "The Food Standards Agency very much welcomes the BRC's efforts to achieve greater consistency in allergen labelling and interpretation of the new provisions. This consistent approach will make it much easier for the allergic consumer to find and understand the allergen information provided on prepacked foods and help them to make safer food choices".

However, it should be noted that this is industry-produced guidance for the UK market only; it is possible that not all EU member states would agree with the labelling proposals within this document.

A copy of the guidance can be obtained from the CRN office: secretariat@crnuk.org

Source: CRN UK

FSA CONSULTS ON CONSOLIDATION OF ADDITIVE LEGISLATION

As part of the UK Food Standard Agency's (FSA) intention to introduce a simplified system of food safety legislation, it is proposed that all legislation within the FSA's remit covering food additives, flavourings, enzymes and extraction solvents are revoked and re-enacted into a single consolidated statutory instrument called The Food Additives, Flavourings, Enzymes And Extraction Solvents (England) Regulations 2013 (the FSA in Scotland, Wales and Northern Ireland will be carrying out consultations on parallel but separate Regulations relating to those parts of the UK).

The proposed legislation will introduce the use of compliance notices for non-safety related offences for enforcement purposes; update the food additive legislation to reflect the

establishment of Annexes II and III to the Additive Regulation (EC) No. 1333/2008 and the removal of the transitional measure for the additive Directives.; amend the flavouring legislation to refer to the revised transitional measures; revoke The Food (Suspension of the Use of E128 Red 2G as Food Colour) (England) Regulations 2007 No. 2266.

While an Impact Assessment is not planned, the FSA would like to hear to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage them to comment on all aspects of this proposal.

Documents and related details can be found at http://www.food.gov.uk/news-updates/consultations/consultations-england/2013/foodadditives-consulteng2013#.UWb_t3D3M20

Source: CRN UK

LATIN AMERICA

LATIN AMERICAN REGULATORY UPDATE

ANVISA publishes guide for checking the safety of foods and ingredients: the Brazilian Regulatory Agency of Health Surveillance (ANVISA) has published guidance on the regulation and safety reporting to new foods and ingredients, foods with functional and health claims, and bioactive substances and probiotics. Members of the Technical-Scientific Advisory Committee for Functional Foods and Novel Foods, with more than a decade of experience in the evaluation of the safety of foods, have participated in the production of the Guide

With reference to the use of botanicals in novel foods, the Guide clarifies that those botanicals with therapeutic use which are traditionally used in folk medicine as pharmaceutically active, may not be used. Examples listed include Aloe Vera, Ginko Biloba, Panax Ginseng.

The Guide also includes a list of applications related to be checked for the food safety presented to ANVISA. However, it should be noted that the mention of certain foods and ingredients in the Guide does not mean that they have been approved.

ANVISA open a debate on new regulation for phytotherapeutics: ANVISA has recently approved the revision of the regulation of phytotherapeutics or medicinal plants in Brazil in order to include traditionally used medicinal plants. To do this, ANVISA will consider reports of efficacy and safety approval for these plants which are based on existing scientific literature on traditional use.

This review will include in its scope some important plants that have been losing ground in the market: for instance, substances that currently do not meet the requirements for registration of drugs, even though they have a history of known and positive use in the population.

However, the revision of the regulation on phytotherapeutics could have a negative impact on the commercialization of certain botanicals as ANVISA does not allow the use of botanicals with therapeutic effects on foods. Therefore there is a risk that new traditionally used medicinal plants traditionally as approved phytotherapeutics could not be commercialized as food supplements in tablets within the category of novel foods. Some

examples of phytotherapeutics already approved by ANVISA as new foods are garlic, broccoli and beets. The revision of the regulation on will soon be put out for public consultation.

*Truths and lies about dietary supplements***:** the National Administration of Drugs, Food and Medical Technology of Argentina (ANMAT), has recently published on its website a document on the truths and lies of dietary supplements. The paper focuses on the labeling and advertising of dietary supplements, and energy drinks. For further detail, see http://www.anmat.gov.ar/consumidores/suplementos_dietarios-verdades_mentiras.pdf

National bill on the responsible use of dietary supplements an Argentinean senator has recently submitted to the Argentinean National Senate a bill for the development of an informative campaign aimed to raise awareness about the responsible use of dietary supplements, which, once approved, would be implemented for one year. The bill has first been assigned to the Commission of Health and Sports and will then go to the Commission of Systems, Communication Media and Freedom of Expression.

Source: ALANUR

NORTH AMERICA

◆ CANADA

NEW APPROACH IS REDUCING THE NHP BACKLOG

Canada's Parliamentary Secretary of Health, Dr. Colin Carrie, has recently highlighted the ongoing success of Health Canada's more efficient approach to natural health products (NHPs), with more than 60,000 products authorized. "*By reducing the burden for authorizing those natural health products that we know a lot about, Health Canada can focus its efforts on evaluating the more complex ones,"*.

The new approach has played a key role in clearing the backlog of more than 10,000 natural health product applications to create a more stable, predictable regulatory environment for the efficient review of these products. However, safety remains the Government of Canada's top priority: the measures in place to protect consumer safety stay the same, and products continue to be labelled with important information to help consumers make informed choices.

The new approach is in keeping with the *Natural Health Products Regulations*, which have been in place since 2004 and continue to set the standard and requirements for authorizing NHPs in Canada, and Health Canada will continue to work with the natural health products industry to ensure all NHPs sold in Canada have natural product numbers (NPNs). Products bearing NPNs have been authorized by Health Canada as being safe and effective when used according to the instructions on the label.

Source: IADSA

◆ UNITED STATES

DMAA

In a recent Consumer Advisory, the US Food and Drug Administration warns that having evaluated the evidence, its view is that DMAA is unsafe and presents unreasonable health risks to consumers. FDA also stated that, in its view, products containing DMAA are illegal and should not be sold as dietary supplements.

US dietary supplement Association the Council for Responsible Nutrition (CRNUSA) has now called on dietary supplement manufacturers to stop manufacturing these products and has advised consumers to stop using them.

In addition, addressing FDA, CRNUSA has said that '*The safety and well-being of consumer is always our highest priority. Given the agency's serious warnings about DMAA, we expect the agency will use the full range of its regulatory authority under the Dietary Supplement Health and Education Act (DSHEA) and take further action beyond the Consumer Advisory….to protect consumers.* The Association then points out that '*Exercising that authority will demonstrate that the current law provides a robust framework to protect consumers when the agency believes a product regulated under its jurisdiction is unsafe."*

Source: CRNUSA

DOCTORS URGE FDA TO RESTRICT CAFFEINE IN ENERGY DRINKS

A group of doctors, researchers and public health experts has joined the voices urging the Food and Drug Administration (FDA) to take action on energy drinks to protect adolescents and children from the possible risks of consuming high amounts of caffeine.

Their letter to FDA Commissioner Dr. Margaret A. Hamburg said that energy drink makers had failed to meet the regulatory burden placed on them to show that the ingredients used in their beverages were safe, specifically where children, adolescents and young adults are concerned. Specifically, the group urged the FDA. to restrict caffeine content in the products and to require manufacturers to include caffeine content on product labels.

Source: UNPA

PROPOSAL TO INCREASE SUPPLEMENT LABELLING REGULATION

A US Senator has announced his intention to re-introduce a bill aimed at more heavily regulating energy drinks and supplements. Entitled 'The Dietary Supplement Labeling Act', the bill requires regulators to compile a list of dietary supplement ingredients and proprietary blends of ingredients that are judged to be capable of causing potentially serious adverse events, drug interactions or risks to subgroups such as child or pregnant or breastfeeding women. It would also expand registration requirements by mandating manufacturers to submit a list of all the products and their ingredients that they make at a given facility. New products or reformulations would require new registrations.

It is understood that the Senator's initiative in re-introducing the bill, which covers all supplements, is particularly in response to current concerns about caffeine, energy drinks and stimulants. The supplement industry's response to date has been that while these

particular concerns are appreciated, the proposed Bill is not an appropriate method of dealing with them in that it would not affect the increasing number of such products which are marketed and labelled as foods as opposed to dietary supplements.

Source: UNPA, AHPA.

ASSOCIATIONS RESPOND TO CONCERNS ABOUT CAFFEINE

In response to the current controversy regarding caffeine in health products, the American Herbal Products Association (AHPA) has recently amended its policy on caffeine labelling, part of its Code of Ethics and Business Conduct, by extending its scope from supplements to now include foods that contain added caffeine. Separately, the US Council for Responsible Nutrition, CRNUSA has issued new guidelines for its members on the labelling of supplements containing caffeine**.**

For further information, contact http://www.ahpa.org/Default.aspx?tabid=224 or http://www.crnusa.org/caffeine/

Source: AHPA, CRNUSA

THE 8TH ANNUAL HERB DAY

The 8th annual Herb Day, an event sponsored by the HerbDay Coalition, which includes the American Herbal Products Association (AHPA), will be held in early May.

HerbDay is a coordinated series of independently produced, public, educational events that celebrate the importance of herbs and herbalism. HerbDay was conceived to raise awareness of the significance of herbs and the many ways they can be used safely and creatively for health, beauty, and culinary enjoyment. It also aims to increase familiarity with herbs so as to aid informed use of herbal products and build public support for maintaining personal choice in the use of botanicals.

The volunteer-based HerbDay Coalition is made up of the American Botanical Council, United Plant Savers, AHPA, the American Herbal Pharmacopoeia, and the American Herbalists Guild.

For further information ,see the HerbDay website.

Source: AHPA

FDA SHUTS DOWN COMPANY FOR GMP COMPLIANCE FAILURES

A supplement manufacturing company with a history of Good Manufacturing Practice (GMP) compliance failures has been shut down by the Food and Drug Administration (FDA) by permanent injunction, until such time as it can be shown to be meeting current requirements.

The company, which had received warnings from FDA as far back as 2010, had been

subject to a previous injunction in 2012, but following more recent FDA inspections, had still been found to have taken insufficient action. The many violations included the distribution of products which failed to meet the product specifications, failure to review and act on product complaints, lack of adequate segregation of raw materials, the inclusion in products of undeclared and/or allergenic ingredients.

Source; AHPA

MISLEADING ADVERTISING FOR VITAMIN SUPPLEMENT

A lawsuit accusing America's largest drugstore chain of falsely advertising the powers of vitamin E has been filed recently in Chicago. It challenges a label on the chain's Vitamin E 400 IU Dietary Supplement that says the product "*naturally contributes to cardiovascular health by helping to protect LDL cholesterol from oxidation which may cause cellular damage."* The plaintiff claims that the representation is false and misleading because clinical studies show that Vitamin E does not work as the retailer advertised and that, used as directed the product is not effective and does not work.

In 2010, the same chain agreed to pay nearly $6 million to settle Federal Trade Commission charges that the company deceptively advertised a line of dietary supplements that claimed that they could prevent colds, fight germs and boost the immune system.

Source: UNPA

FDA GUIDANCE ON FOOD FACILITY REGISTRATION

The US Food and Drug Administration (FDA) has issued draft guidance for FDA staff regarding food facility registration enforcement. For domestic facilities that are not registered, FDA investigators are to educate facility management and, if after education they are not registered, an "untitled letter" may be issued to the food facility by the district office. For foreign facilities, the Centre for Food Safety and Applied Nutrition or the Centre for Veterinary Medicine, as appropriate, are authorized to issue "untitled letters" if the facility has been advised of the need to register.

For further details, see Compliance Policy Guide Sec. 100.250 Food Facility Registration - Human and Animal Food

Source: AHPA

SOUTH WEST PACIFIC

◆ AUSTRALIA & NEW ZEALAND

ASSOCIATION INVITED TO COMMENT ON TG AMENDMENT BILL

The purpose of the Therapeutic Goods (TG) Amendments Bill is to make a number of changes that aim to streamline and improve the operation of the regulatory scheme across all therapeutic goods under the Act, often standardising or replicating existing regulatory requirements so that common regulatory rules and processes apply to all classes of therapeutic goods.

The Australian health product trade association, the Complementary Healthcare Council (CHC) has been invited by the Community Affairs Legislation Committee to make a submission outlining the impacts on industry of this Bill, now at second reading stage.

Measures in the Bill include powers for the Health Ministry to:

- exclude products from the definition of 'therapeutic goods' , thus removing them from regulation under the Act. and the Therapeutic Goods Register, e.g. foods where therapeutic claims are made and are not otherwise excluded, or a product that may have come within the definition when it was included but no longer does so, for instance where claims about its therapeutic use are no longer being made.
- suspend or cancel the registration or listing of therapeutic goods where the presentation of the goods is not acceptable or, in the case of listed goods, is unacceptable. For instance where its presentation (name, labelling, packaging of the goods and any advertising or other informational material associated with the goods) no longer reaches an acceptable standard.
- cancel the registration or listing of therapeutic goods where a sponsor does not respond to a request to provide specified information or documents.
- require in particular circumstances (for instance where therapeutic goods have been suspended or cancelled from the Register, or where the safety, quality, efficacy/performance, or presentation of therapeutic goods, is considered unacceptable), their sponsor to provide information about them to the public or health care professionals or patients, and to give to the Secretary information about persons to whom the goods have been supplied. .

Amendments in the Bill will ensure that information and documents relating to any certifications can be requested from the sponsors of all classes of lower-risk therapeutic goods - Complementary Medicines (CMs), biologicals and medical devices. This requirement acknowledges that lower-risk products are included in the Australian Register of Therapeutic Goods (ARTG) and available for supply in Australia without pre-evaluation by the Therapeutic Goods Authority (TGA).

Source: CHC

THE NEW ZEALAND NATURAL HEALTH PRODUCTS BILL

The New Zealand Natural Health Products Bill has now passed its second reading in Parliament, with an almost unanimously positive vote. For further detail of the debate, see www.parliament.govt.nz and search for Natural Health Products Bill.

The Bill creates the Natural Health and Supplementary Products Regulatory Authority, as well as an advisory committee. The authority is to oversee the pre-market notification of products. To bring a product to market, a notifier must tell the authority what is in it, and it must consist solely of constituents from an open-ended list of permitted ingredients. There is also to be a list of forbidden ingredients, which will include prescription medicines and controlled drugs. The notifier must hold evidence, either scientific evidence or evidence of traditional use, to back up any claims of health benefit being made for the product. The notifier must provide the authority with that evidence if it is decided that a claim for a particular product warrants further investigation, and a summary of the evidence must be made publicly available

The next stage (third phase) is where the Bill is examined and discussed line by line and MPs may suggest amendments.

Source: NPNZ

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KEY EVENTS 2013

KEY EVENTS 2013 MAY – DECEMBER 2013

Date	Conference	Place
May 07 - 09	Food Ingredients Istanbul 2013 http://fi-istanbul.ingredientsnetwork.com	Istanbul, Turkey
May 14 - 16	Vitafoods Europe www.vitafoods.eu.com	Geneva, Switzerland
May 15 - 17	Codex Committee on Food Labelling http://www.codexalimentarius.org/meetings-reports/en/	Canada
June 25 – 27	Natural Products Association MarketPlace http://www.naturalmarketplaceshow.com/nm12/Public/enter.aspx	Las Vegas, NV, United States
June 25 - 28	Executive Committee of the Codex Alimentarius Commission http://www.codexalimentarius.org/meetings-reports/en/	Rome, Italy
June 26 - 28	Natural Ingredients / Health Ingredients China 2013 http://fiasiachina.ingredientsnetwork.com/home	Shanghai, China
June 26 - 28	Health Ingredients Philippines 2013 http://fiphilippines.ingredientsnetwork.com/	Manila, Philippines
July 01 - 05	Codex Alimentarius Commission http://www.codexalimentarius.org/meetings-reports/en/	Rome, Italy
July 14 - 16	Cosmoprof North America 2012 www.cosmoprofnorthamerica.com/	Las Vegas, NV, United States

Date	Conference	Place
August 06 - 08	Food Ingredients South America http://fi-southamerica.ingredientsnetwork.com/home	Sao Paulo, Brazil
August 26 - 29	13th International Nutrition & Diagnostics Conference http://www.indc.cz/en/	Olomouc, Czech Republic
August 29 - 31	Natural Products Expo Asia 2013 http://www.naturalproductsasia.com/ea13/public/enter.aspx	Hong Kong, China
September 07 - 10	25th SANA 2013 http://www.sana.it/en/	Bologna, Italy
September 11 - 13	Food Ingredients Asia - Thailand http://fiasia-thailand.ingredientsnetwork.com/	Bangkok, Germany
September 25 - 28	Natural Products Expo East http://www.expoeast.com/expoeast2013/public/enter.aspx	Baltimore, MD, United States
October 03 - 05	Food Ingredients India http://fiindia.ingredientsnetwork.com/	Mumbai, India
October 09 - 11	Health Ingredients Japan http://www.hijapan.info/eng/	Tokyo, Japan
October 30 - November 01	Worldfood Ukraine 2013 http://www.worldfood.com.ua/en/exhibition/about/	Kyiv, Ukraine
November 04 - 08	Codex Committee on Nutrition and Foods for Special Dietary Uses http://www.codexalimentarius.org/meetings-reports/en/	Germany
November 13 - 15	Cosmoprof Asia 2013 http://www.cosmoprof-asia.com/	Hong Kong, China
November 19 - 21	Food Ingredients Europe & Natural Ingredients http://fieurope.ingredientsnetwork.com/home	Frankfurt, Germany

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