IADSA NEWSFLASH
JUNE 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.

AFRICA

◆ SOUTH AFRICA

STALLED REGULATIONS, BUT ALSO SOME POSITIVE PROGRESS

Complementary and Alternative Medicines (CAMS) regulation negotiations in South Africa have once again stalled. Despite the fact that the Health Products Association of Southern Africa (HPA) has been in discussion on the subject with the Department of Health (DoH) for ten years, there is still no clarity on the situation. The draft regulations and guidelines are in the possession of the DoH but there is no indication as to when they may be published. The HPA has been seeking legal representation for advice on the matter.

On a more positive note, progress has been achieved by the inception of the Health Shops Association of Southern Africa (HSASA) which was launched in July 2012 under the

auspices of the HPA umbrella body. Managed by the HPA's Executive Secretary, Deirdre Allen, the HSASA is an official body prepared to address all issues relating to health shops countrywide and it aims to address issues that retailers may have in relation to CAMS, to keep them updated on legislation, regulations and advertising, and to guide appropriate staff training.

Additionally, the HPA Survey for 2012 is currently being prepared and is due for completion in July. The survey aims to ascertain the status of the CAMS market in South Africa as accurately as possible.

Source: HPA

ASIA

- **JAPAN**

GOVERNMENT APPROVES PROPOSALS FOR CLAIM REFORM

The Health and Medication Working Group of the Regulatory Reform Committee (RCC) of the Japanese Cabinet has reported its conclusions for the dietary/food supplement field to the Diet (Parliament) and their proposals have now been accepted. Issues for further development (which must take into account international research) by the relevant Government authorities, include:

- *The development of a system that allows structure-function claims for general dietary supplements, including processed food and agricultural and marine (fishery) products containing health-promoting ingredients. Timescale: to be reviewed in 2013, for conclusion and action in 2014*.

  Foods with health promoting ingredients include general dietary supplements, (at present, an undefined descriptor) as well as processed food and agricultural and fishery products. However, structure function claims for health benefits are not currently allowed for foods except for authorized food with health claims (Foods for Special Health Uses FOSHU, and Foods with Nutrient Function Claims FNFC), even if the food is intended for self-medication. In addition, while existing FNFC are allowed, under the business operator's responsibility, to claim their nutrient functionality based on the standards established by the government, FOSHU requires review by the government for each final product. This difference is a burden to the business operator and it has been argued that it compromises the implementation of the system. Therefore, with the exception of already authorised FOSHU and FNFC, a novel approach is proposes that permits structure function claims to be reviewed so as to obtain an outcome for foods with health promoting ingredients, including general dietary supplements, processed food, agricultural and fishery products. To optimise use of industry knowledge, it is proposed that structure function claims for functionality should be permitted according to the availability of substantiating scientific evidence, the provision of which is the responsibility of the business operator. This proposal is to be considered using the United States structure function claims system as a reference whereby the business operator evaluates the scientific substantiation and the function of the product, rather than the government. In addition, it is proposed

that, having taken into account all relevant factors, discussions be opened with the aim of establishing a system which also incorporates food safety (production, manufacturing and quality management, gathering information on adverse events) for processed food, agricultural and fishery products.

- *As part of the guidance for food structure function claims, to raise awareness of the types of product 'apparently recognized as food' that are excluded from the target of regulation for unapproved/unauthorised drugs. Timescale: for action in 2013.*

  Products are classified as pharmaceutical drugs by considering their ingredients, effect/efficacy, shape, dosage and administration in a comprehensive manner. However, there have been instances where products 'apparently recognized as food' by their appearance and shape receive regulatory guidance. Therefore, with the aim of clarifying the scope of "products apparently recognized as food" which are not included in the remit for the "regulation of unapproved/unauthorised drugs" in the guidance for food structure function claims, it is proposed that the Ministry of Health, Labour and Welfare (MHLW) should work to increase awareness of the scope/type of such food products. In addition, the Consumer Affairs Agency (CAA) should explain the range/scope of "products apparently recognized as food" and the bases for guidance for products where label wording may be false or exaggerated, (prohibited under the food structure function claims regulation). The CAA should also increase awareness of this guidance in the relevant local prefectural government departments, in city health centres, etc. so as to avoid discordances with guidance under Pharmaceutical Affairs Act.

- *A label review aimed at achieving easier language for consumers to understand. Timescale: to be reviewed and concluded in 2013, for action in the first half of 2014*

  The current system of FOSHU and FNFC allows only very limited and fixed wording which can be difficult for consumers to understand. Therefore, it is proposed that there should be discussion on the appropriate wording for structure function claims that is easy to understand and contributes to the consumer's choice and encourages appropriate consumption of the product. In addition, to enable business operators to more easily understand the rules on structure function claims and how such claims should be made (including how they differ from advertising), guidelines and brochures based on the various current laws and legal systems should be integrated into one category covering food structure function claims as a whole.

- *Rationalising and expediting the process of FOSHU applications. Timescale: a progress schedule to be developed and published in first half of 2013, reviewed and conclusion made in 2013, for action in 2014.*

  FOSHU product applications are approved by the Secretary General of the CAA, after being reviewed by the agency, the Consumer Commission, the Food Safety Commission, the MHLW, and the National Health and Nutrition Research Institute (or registered evaluating body). The standard evaluation period is supposed to be 6 months, but has sometimes taken more than 2 years. In addition, particularly for small and medium-sized enterprises, permissions are difficult to obtain for cost

reasons, and, overall, the system is seen as not working effectively. Therefore, it is proposed that the burden for companies be reduced by rationalising and expediting the review process - on the assumption that the efficacy and safety of the product are assured. For this purpose, a concrete schedule for the accomplishment of the revision, including disclosure of the process and the subject matter of examination, must be developed and published. This process must incorporate determination of the number of past applications which failed to reach approval (including the cases withdrawn by the applicants), and evaluation of the cases for which the failure was attributed to the burden of the procedure (costs, length of evaluation period etc.).

- *The expansion of targets for food with nutrient function claims (FNFC). Timescale: to be reviewed in 2013, for conclusion and action in 2014*

  Currently, only 12 vitamins and 5 minerals can be labelled with nutrient function claims (FNFC). The aim, therefore, is to expand the number of target ingredients for function structure function claims by taking into account examples from countries outside Japan, whilst maintaining consistency with national nutrient structure function claims standards and dietary reference intakes.

Source: AIFN

EUROPE

◆ EUROPEAN UNION

NEW PARNUTS RULES VOTED THROUGH

The European Parliament, in Plenary has now voted through new rules on the composition and labelling of food for infants and for special medical purposes (Products for Particuar Nutritional Uses, PARNUTS, Framework Directive). The Regulation will be published in the EU Official Journal during the coming weeks and will apply for businesses from 2016.

Over the next two years, the Commission will adopt detailed rules (delegated acts) on food covered by the Regulation, and will also present two reports on the necessity to develop specific rules in the future for 'growing up milks' for young children and food for sports people. The Commission also intends to adopt specific rules on the use of statements in the absence or reduced presence of lactose in foods.

Welcoming the Parliament's decision, Tonio Borg, the EU Commissioner for Health, is quoted as saying: *"… we need to make sure that EU rules on food for specific groups are fit for purpose and evolve at the same speed as market developments".*

More information on the regulation can be found here:
http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm

Source: EHPM

HEALTH CLAIMS UPDATE

- Claims Register: the European Union Health Claims register has now been updated to include 6 new approved claims. The list of non-authorised claims, including the remaining glucosamine/joint health claims, has also been updated, with an expiry date for the transitional period for these claims of 02/01/2014). See http://ec.europa.eu/nuhclaims/
- Botanical claims: there has been no further information from the European Commission as to the methodology or timescale for the review of botanical claims, so they remain 'on hold'.
- Generic Descriptors: it is understood that the European Commission shortly intends to adopt a draft proposed Regulation setting the rules for applications for the use of generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on health, which may be exempted from the application of that Regulation following an application by the food business operators concerned. (Sectors of the supplement industry have been particularly interested in this proposal which is likely to determine, for instance whether a term such as 'probiotic' used on a product label would be regarded as a generic descriptor, or as a health claim.)

Source: ERNA

FOOD COLOURINGS

Following a review of new data, EFSA has concluded that there is currently no reason to revise the Acceptable Daily Intake (ADI) for the food colour Allura Red AC. This recommendation applies to the so-called 'sulphonated mono azo dyes', a group of six chemically-related food colours including Allura Red AC. Based on the results, EFSA's experts will, if necessary, reconsider existing ADIs for these substances.

Dr Alicja Mortensen, Chair of EFSA's Panel on Additives and Nutrient Sources Added to Food (ANS Panel), stated: "In the light of all the data evaluated in this review, the Panel considers that these structurally related dyes could share a pattern of effects that deserve further investigation. However, currently the overall weight of evidence does not warrant a revision of the existing ADIs for these substances. These substances, as all other food additives will be kept under continuous observation and will be re-evaluated in the light of new scientific information arising from the additional testing requested."

The six colours included in a review performed by ANS Panel are: Allura Red AC (E 129), Amaranth (E 123), Ponceau 4R (E 124), Sunset Yellow FCF (E 110), Tartrazine (E 102) and Azorubine/Carmoisine (E 122). These substances have previously been assessed by

Source: ERNA

UPDATED RULES FOR SILICON DIOXIDE AND SILICATE

Updated EU regulations on the limits for silicon dioxide and silicate in food supplements have been welcomed by the supplement Association, Food Supplements Europe (FSE) after the members of the trade body spotted an error in legislation.

The amendment of Regulation (EU) No 438/2013 corrects a mistake in the regulation that would have limited the use of silicon dioxide and silicate in food supplements to 1% - considerably below the levels that are currently safely used in food supplements. The error occurred when the additives were transposed into the new Regulation that comes in to force on June 1st.

Source: ERNA

EFSA TO HOLD INFO. SESSION ON SCIENTIFIC EVALUATION CRITERIA

The European Food Safety Authority (EFSA) has announced an information session to be held in Parma, Italy on 20 November 2013. The objective of the meeting is to "*discuss with scientists the information required for a full scientific evaluation of human studies submitted for the scientific evaluation of health claims.*"

However, the announcement makes clear that the event "*will NOT address the scientific requirements for the substantiation of health claims, either in general or in relation to selected areas.*"

Registration for the event will open after the summer break and further details can be found on the following link: http://www.efsa.europa.eu/en/events/event/131120.htm

Source: EHPM

NEW APP EXPLAINS HOW LEGISLATION WORKS

A new interactive app. which explains how the majority of European Union (EU) legislation is created is now available. The application takes the user through the ordinary legislative procedure step by step. Under the procedure proposals are adopted jointly by the European Parliament and national governments sitting in the Council of the European Union and it is used for the vast majority of legislation.

The application explains the ordinary legislative procedure using graphics with short explanations. It is also possible to get longer and more detailed descriptions by clicking on the links and the tabs. In addition the application shows how long each step in the procedure takes, how the user can influence what is being decided and how the votes take place.

For further information, see:

http://www.europarl.europa.eu/news/en/headlines/content/20130508STO08098/html/EU-laws-made-easy-new-app-explains-how-majority-of-legislation-gets-created

Source: EHPM

LEGISLATION FOR TWO MORE APPROVED SUPPLEMENT INGREDIENTS

The European Commission Regulation is currently consulting on legislation which proposes to:

- Amend Annex II of Directive 2002/46/EC by adding “chromium enriched yeast” to the list of mineral substances which may be used in the manufacture of food supplements
- Amend Annex II of Regulation (EC) No 1925/2006 by adding “chromium (III) lactate tri-hydrate” to the list of mineral substances which may added to foods.

The intention of the Commission is to submit this proposal to a Standing Committee meeting for discussion and ultimately a vote.

Source: ERNA

EFSA FOOD COMPOSITION DATABASE

The final report of EFSA contract CFT/EFSA/DCM/2011/03 has recently been announced. The aim of the project was to provide EFSA with an updated food composition database covering approximately 1750 foods in combination with additional FoodEx2 facet descriptors included in the EFSA FoodEx2 classification system, and to expand the dataset to include harmonised information on the most common composite recipes of European countries and harmonised information on food supplements.

Nutrient information was provided according to nutrient data available in each European Union national food composition database and varied depending on relevance to each food. All datasets provided data for energy, protein, total fat and carbohydrates. Values for fatty acids were provided in all datasets but coverage across the range of foods was limited in some datasets and coverage of specific isomers varied. Data for vitamins B1, B2, B3, B6, B12, A, C, D, E and folate were provided by a minimum of 10 countries. Biotin and pantothenic acid data were provided by 6 countries. All countries provided values for minerals and trace elements but coverage varied by country and food. Amino acid data was available from 2 countries but only for a limited selection of foods.

The outcomes of the report included:

- The FoodEx2 food list and facet descriptors should be reviewed for use with food composition data and further clarifications, scope notes, and examples provided to facilitate improved accuracy and consistency of matching food composition data to FoodEx2 codes.

- Procedures for providing data when values for a food are not available for a particular country should be reviewed. There are limitations to the approach of borrowing values from another dataset because it cannot be guaranteed that borrowed values are directly comparable to foods consumed within a country. Published food composition datasets do not always take into account recent changes in food production that may impact on nutrient content. Further additional evaluation is possible now that the final dataset is complete and borrowed data can

be easily identified. In particular guidelines should be considered for foods where nutrient content may differ due to processing practices, e.g. fortification.

- Further consideration should be given to the use of retention factors in recipe calculations. Recommendations exist but practices are very different between countries and some countries do not use them. The applicability of retention factors could be assessed by reviewing differences between calculated and analysed values.

- Information on food supplements is not consistently collected or maintained. Collection of data from manufacturers on a regular systematic basis should be investigated to allow maintenance of a more comprehensive database.

- Member states and candidate countries should be encouraged to provide additional resources for generation of new analytical data on food to improve the quality of national datasets and avoid the necessity to calculate values or borrow values from another country.

Source: ERNA

◆ **FRANCE**

THE FRENCH NATIONAL DECREE ON BOTANICALS

Certain plants were withdrawn from the original version of the French national decree on botanicals:

- *Hypericum perforatum* L. (Millepertuis),
- *Humulus lupulus* L. (Houblon) pour la présence de prénylnaringénine,
- *Curcuma longa* L-
- *Curcuma zedoaria* (Christm.) Roscoe,
- *Garcinia mangostana* L.,
- *Garcinia gummi-gutta* (L.) Roxb.,
- *Ocimum tenuiflorum* L. (basilic sacré),
- *Commiphora mukul* (ajout ce jour)

Now, the revised version has been returned to the French authorities by the European Commission and must now be signed off by various French government ministers.

However, the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) has asked the supplement association Synadiet to make comments in respect of Annex I, the main list, because small modifications could still be introduced in the columns “Restrictions” or “Substances under surveillance”. However, new plants cannot be added.

Source: SYNADIET

◆ **GERMANY**

GERMAN COURT RULING ON STEVIA CONTESTED.

As the result of a complaint from a regional Consumer Association, a German court has ruled that manufacturers must not suggest on product labels that the sweetener Steviolglycoside (E 960) is 'natural'. The consumer group brought the case on the grounds that images of stevia leaves on product packaging were misleading because the processed sweetener product obtained had "nothing to do with a natural extract or even the stevia plant". The group also said that steviol glycosides do not occur naturally in foods.

The European Stevia Association (EUSTAS) and the International Stevia Council (ISC) has since strongly criticised the consumer group, arguing that it is their comments that are misleading: the statement that steviol glycosides have nothing to do with the actual plant misleads consumers to believe that that steviol glycosides are synthetic compounds, whereas in fact Steviol glycosides are the sweet compounds that occur originally in the leaves of the stevia plant and that are extracted using conventional plant extraction techniques as described in the Regulation (EU) No 231/2012.

Source: BLL

- **IRELAND**

IRELAND HOSTS EUROPEAN RISK SUMMIT

Ireland recently hosted a European Risk Summit Meeting held in Trinity College, Dublin, and attended by European regulators, agencies, companies, and academics associated with the food, healthcare, and chemicals industries. The subject under debate was the advantages of evidence and risk-based rulemaking.

Particular policy issues covered included:

- Promoting science based regulation in Europe – challenges and opportunities
- Hazard classifications and risk assessments: How do we best regulate?
- The role of smart and better regulation: Lessons from the Member States and beyond
- Risk based policy making and the precautionary principle.

Source: IADSA

- **ITALY**

REDUCTION OF THE DAILY LEVEL OF MELATONIN IN SUPPLEMENTS

The Italian Ministry of Health have recently announced the re-evaluation of melatonin maximum level allowed in food supplements, specifically stating the reduction of the previous maximum level of 5 mg to a 1 mg per daily dose.

The Ministry puts forward the reasoning that more than 1mg would be sufficient to support

the claimed effects and that there are on the EU market authorized medicines with daily doses of 2 mg melatonin. By reducing the level the Ministry wants to ensure 'the level in food supplements has a physiological effect rather than a therapeutic effect.'

A very short transition period - until 30 September 2013 - is given to companies to comply with the new requirements.

- **SPAIN**

AMENDMENT TO ROYAL DECREE ON FOOD SUPPLEMENTS

Spain has recently issued a proposal of amendment to the Spanish Royal Decree 1487/2009 on food supplements.

The draft includes a new Annex III: "*Other substances with nutritional or physiological purposes permitted to be used in the manufacture of food supplements*". The current list includes 53 ingredients with maximum daily doses for certain substances. It does not cover botanicals. It also includes a clause of mutual recognition for food supplement products not compliant with the Spanish legislation but already lawfully manufactured or sold in another EU or EEA country.

Spanish trade associations are currently drafting their comments to be sent to the Spanish Food Safety and Nutrition Authority, AESAN.

Source: AFINUR

- **UNITED KINGDOM**

NOVEL FOOD APPLICATION FOR CHIA OIL

As part of a Novel Food application, Chia oil is being proposed for use in food supplements.

For further detail, see: http://www.food.gov.uk/multimedia/pdfs/chiaoildoss2013

Source: CRNUK

FOOD INFORMATION TO CONSUMERS REGULATION:

The UK food supplement sector continues to wait for the national guidance relating to the FIC. The Department for Environment, Food & Rural Affairs (DEFRA) is currently drafting detailed information offering further interpretation/guidance for industry. Although the guidance was anticipated ahead of the summer it is now further delayed until the autumn.

The UK Department of Health has now published new guidance on nutrition labeling. Supplements do not follow this scheme but Nutrition Guidance also launched alongside the main guidance is relevant; it relates to the nutrition aspects of the Food Information to Consumers regulation. (Technical guidance on the nutrition-related aspects of EU

Regulation No.1169/2011 on the provision of food information to consumers (EU FIC).

The new technical guidance will eventually form part of the wider joint Defra/ DH/FSA guidance. This information has been produced to ensure that companies are fully compliant with the EU FIC nutrition labelling provisions. The document will be combined with guidance on general and allergens labelling in due course. This technical guidance can be found at:

https://www.gov.uk/government/publications/technical-guidance-on-nutrition-labelling

Source: CRNUK

UK LAUNCHES FOP NUTRITION LABELLING SCHEME

The UK Department of Health has now officially launched its new national front of pack (FoP) nutrition labelling scheme. The scheme combines the use of red, amber and green colour coding and percentage reference intakes, alongside the amounts of energy, fat, saturated fat (saturates), sugars and salt in a defined portion of food.

In accord with the terms of the European Union Food Information to Consumers Regulation (FIC), provision of a FoP nutrition label is voluntary. However, the Regulation sets out requirements that must be met if companies choose to provide FoP information. In addition, under Article 35, it allows Member States to recommend to businesses the adoption of "additional forms of expression" which help consumers to interpret the nutrition information and apply it to the food choices that they make.

The nutrition labelling rules apply to prepacked food and foodstuffs for particular nutritional uses (PARNUTS), only if there are not separate nutrition labelling provisions in the PARNUTS directives that take precedence over the EC FIC requirements. The labelling rules do not apply to food supplements that fall within the scope of Directive 2002/46/EC. Guidance on the scheme can be found at:
https://www.gov.uk/government/publications?departments[]=department-of-health

While European consumer bodies have generally approved the UK scheme, and are advocating its extension throughout the EU, this UK development it has attracted some criticism from those European Food Trade organisations who would prefer an EU-wide scheme.

Source: HFMA

LATIN AMERICA

- **MERCOSUR**

MERCOSUR AND FOOD LABELLING

Mercosur, the "Common Market of the South," is an economic and political agreement among certain Latin American countries with the aim of promoting the free movement of goods, services and people among member states.

Current full members of Mercosur, Argentina, Brazil, Venezuela and Uruguay (in its draft standard) set out in their national regulations RTM 26/2003 that food labelling will also be applicable to dietary supplements.

The Mercosur Working Subgroup on Technical Regulations and Conformity Assessment has now set a target date of December 2013 to agree on a common text for a new Technical Regulation on food labelling. The objective is to provide the requirements of mandatory information and determine how information should be presented, including topics such as the declaration of allergens and quantitative declaration of ingredients.

After the revision of the text by the Working Subgroup, the regulation will be submitted to the Common Market Group, the executive body, for approval and subsequent adoption by each of the Member States. Member States must then adopt the resolution made by the Common Market Group within a period of no more than 180 days.

Source: ALANUR

- **ARGENTINA**

MODIFICATION TO THE FOOD CODE FOR SOFT DRINKS

The Soft Drink definition in the Argentine Food Code has been modified. The changes are related to the increase of the maximum levels of caffeine from 20 to 32 mg/ 100 ml and the inclusion of warning phrases such as:

- "Do not use in case of pregnancy, breastfeeding, children and elderly people".
- "It is suggested not to be consumed with alcohol".
- "High in caffeine", (when the caffeine content exceeds 20mg/100ml).

The advertising of these drinks must comply with the Argentine Food Code specifications:

- They must not be directly or indirectly associated with alcohol consumption.
- They should not be introduced as contributing to health or welfare
- Consumption should not be linked to ideas or images of success in the emotional and / or sexual lives of people, or highlight social prestige, masculinity or femininity.
- The advertising message must not contain images or sounds of children under eighteen years old.

Source: ALANUR

- **BRAZIL**

***Functional Claims – ANVISA working group*:** The Brazilian Regulatory Agency of Health Surveillance, (ANVISA) has published notice of the intention of creating a working group to develop criteria to select foods and beverages that could use well-known and generally accepted functional health or nutrition claims.

The Working Group will be coordinated by the Division of Special Products of ANVISA´s Food General Management and will be composed of:

- ANVISA's Special Product Management

- General Coordination of Food and Nutrition (CGAN), Ministry of Health
- Department of Nutrition, Federal University of Minas Gerais
- Pan American Health Organization (PAHO)
- International Life Sciences Institute (ILSI)
- Policy Observatory on Food Security and Nutrition (OPSAN)
- Brazilian Association of Food Industries (ABIA)
- Brazilian Association of the Dietetic Food Industry and Food Special Uses (ABIAD)
- Brazilian Association of Nutritional Products Companies (ABENUTRI)
- Technical and Scientific Advisory Committee on Functional Foods and Novel Foods from ANVISA.

The Working group will have 24 months, from May 2013, to complete their task.

Bill to ban the use of Aspartame: earlier in the year a bill was presented at the State Legislature in San Pablo, Brazil, to forbid the marketing and use of aspartame in food, chewing gum and drink composition, etc.

In addition, information would be circulated in schools, health care centres and media centres on the health risks caused by the consumption of aspartame. The justification is based on the allegation of a possible link between aspartame consumption and the increase of risk of suffering from cancer.

The Legislature of the State of Sao Paulo has proposed a new public hearing to pursue the issue.

Titanium Dioxide Bill: a bill to ban the use of titanium dioxide in food was presented in 2012.

Since then, the industry has been working closely on this issue in order to avoid the bill's approval, and the Brazilian Food Industry Association (ABIA) has now met the politician who presented the to explain the main difficulties that the prohibition on the use of titanium dioxide as additive could cause.

The bill is now in the Social Security and Family Commission awaiting its vote.

Source: ALANUR

- **CHILE**

FOOD SUPPLEMENTS AND FOODS FOR ATHLETES

The Commission of Sanitary Regulation for Food (RSA), formed by Ministry of Health and industry representatives, is reviewing the Title XXIX of the Sanitary Regulation for Food (RSA) for food dietary supplements and foods for athletes.

The review on the dietary supplements section has been completed, and it includes changes on the definition, labelling and advertising of supplements. However, the Commission has not yet completed the review of the section on food for athletes, which currently focuses on the use of amino acids, among others.

Once the revision of Title XXIX is accomplished, authorities are expected to send it to public consultation, probably by the end of June, although this will depend on the discussions regarding the section of food for athletes, which is still ongoing.

ALANUR will evaluate the content of revised version of Title XXIX with the aim of offering comments.

Source: ALANUR

- **MEXICO**

AGENCY RECALLS OVER 32,000 SUPPLEMENTS

The Federal Commission for the Protection against Sanitary Risk (COFEPRIS) has reported the recall of 32,352 supplement units due to health violation in the state of Oaxaca, Mexico. They were marketed under the premise that they treated non-communicable chronic diseases such as diabetes, hypertension, arthritis and cancer.

1.5 tons of raw materials and 48,517 labels were also recalled and will be analyzed in order to determine their ingredients. Appropriate sanctions will be applied.

Source: ALANUR

NORTH AMERICA

- **CANADA**

GINSENG PRODUCT GRANTED NPN NUMBER AND COGNITIVE CLAIMS

The Canadian Natural Health Product Directorate (NHPD) has recently granted a Natural Health Number (NPN) to an American Ginseng product

The approval permits three health claims, related to a specified daily dose of the product:

- Helps to support cognitive function
- Helps to support cognitive performance
- Helps to support working memory

Source: IADSA

HEALTH CANADA WARNING ABOUT CAFFEINE

Health Canada has warned Canadians about the importance of managing the consumption of caffeine, especially by children, pregnant and breastfeeding women and women who are planning to become pregnant.

For further information, see: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/34021a-eng.php

Source: IADSA

- **UNITED STATES**

SUPPLEMENT USERS HAVE HEALTHY HABITS

When it comes to making lifestyle choices, those who take dietary supplements seem to make healthier choices overall compared to those who do not take dietary supplements, according to the most recent CRN Consumer Survey on Dietary Supplements conducted by a Public Affairs company on behalf of the Council for Responsible Nutrition (CRN). Consistent with years past, the survey, which has been run annually since 2000, found that 68% of US adults take dietary supplements, and they are more likely than non-supplement users to also engage in certain other healthy habits.

The survey was conducted on-line and included a national sample of 2,006 adults aged 18 and older from Ipsos' U.S. on-line panel. 77% all adults believe that taking supplements is a smart choice for a healthy lifestyle. When asked why they take supplements, 53% of supplement users said they took dietary supplements for overall health and wellness; 35% said it was to fill in nutrient gaps in their diet. At 76%, the multivitamin was found to be the most popular dietary supplement among supplement users, again consistent with data from years past.

To quote Duffy MacKay, ND, Vice-president scientific and regulatory affairs at CRNUSA, '*A daily multivitamin is beneficial for almost everyone, at any stage in life, playing an important role in filling nutrient gaps, and serving as an affordable and convenient insurance policy for getting valuable nutrients*.'.

Source: CRNUSA

NIH LAUNCHES SUPPLEMENT DATABASE

Following the launch of the Dietary Supplements label database, researchers, health care providers and consumers can now see the ingredients listed on the labels of about 17,000 dietary supplements by looking them up on a website. Free of charge, the database is hosted by the National Institutes of Health and is available at www.dsld.nlm.nih.gov.

The Dietary Supplement Label Database provides product information in one place that can be searched and organized as desired. "*This database will be of great value to many diverse groups of people, including nutrition researchers, healthcare providers, consumers, and others,"* said Paul M. Coates, Ph.D., director of the NIH Office of Dietary Supplements (ODS). *"For example, research scientists might use the Dietary Supplement Label Database to determine total nutrient intakes from food and supplements in populations they study."*

For consumers, the My Dietary Supplements (MyDS) app from ODS is already available, at https://myds.nih.gov . The app offers an easy way to keep track of vitamins, minerals, herbs, and other products, and offers science-based, reliable information on dietary supplements.

Source: UNPA

ARE HERBAL TINCTURES ALCOHOLIC BEVERAGES?

Following reports received by The American Herbal Products Association (AHPA) that agents of the Florida Division of Alcoholic Beverages (ABT) had conducted inspections targeting the retail sale of herbal tinctures on the basis that these products are alcoholic beverages, resulting in warnings of non-compliance with Florida's alcoholic beverage laws, AHPA prepared a succinct guidance and suggestions for Florida retailers that sell herbal tinctures, available upon request from mmcguffin@ahpa.org

Now, AHPA's prompt action has resulted in Florida retailers receiving letters from the ABT that rescind the notices of non-compliance with the state's alcoholic beverage laws. This is because the relevant Florida law which defines alcoholic beverages to include "all beverages containing one-half of 1 percent or more alcohol," specifically exempts proprietary and other products that are "unfit for beverage purposes." Most herbal tinctures have long been considered under federal alcohol tax rules to be non-beverage products that are unfit for beverage use.

Source: AHPA

REACTION TO CISPI's CALL FOR A GINKGO PRODUCT BAN

The Food and Drugs Administration (FDA), has responded to a recent call to the FDA from the Centre for Science in the Public Interest (CISPI) for a ban on Gingko products

CSPI's request to FDA to ban ginkgo is based on a National Toxicology Programme (NTP) report examining high doses of ginkgo force-fed to mice and rats. As part of its response FDA say, *'…it is not scientifically valid to conclude with certainty that dietary supplement products containing Ginkgo biloba are unsafe based solely on data from the new NTP study. In the study, rats and mice were fed amounts of Ginkgo biloba extracts (by body weight) that may be considerably greater from those which a consumer would normally ingest from a dietary supplement product containing Ginkgo biloba. In addition, there may be differences in the extract used in these studies in contrast to what is available on the market for Ginkgo biloba dietary supplements*.'

Supplement trade associations have also commented promptly: Steven Dentali of AHPA is quoted as saying that if the study on which the CISPI comments are based had gone through a peer review process, it would have been rejected, and Steve Mister, President and CEO of CRNUSA said, '*Ginkgo biloba has literally been used for thousands of years, and this attempt by CSPI to discredit this safe and beneficial dietary supplement demonstrates an irresponsible misinterpretation of both the science and the intent of the National Toxicology Program (NTP) in reviewing ginkgo. This premature evaluation from CSPI reveals an abuse of its position, a lack of understanding about the regulation of food by FDA, and presents a true disservice to consumers.'*

Source: AHPA, CRNUSA

ASSOCIATION SPONSORS TOXICOLOGY FORUM SESSION

CRNUSA is sponsoring a scientific session at the 39th Annual Toxicology Forum Summer Meeting entitled, "Adverse Events and Causality Assessment: A Potential Framework for Dietary Supplements and Functional Foods."

The over-arching abstract is; "*Post-market surveillance (adverse event reporting) is a critical component of monitoring the safety and quality of functional foods and dietary supplements. As requirements for the collection and reporting of post-market adverse events increase around the world, causality assessments (determining if a product or ingredient is causally linked to an adverse event) will become more critical in validating the safety of these products or identifying specific safety issues. Today however, there are examples in the literature of causality assessment criteria established for drugs being inappropriately applied to cases involving foods and supplements, frequently leading to inaccurate or premature conclusions of causality. There is an urgent need to establish an appropriate science-based and systematic framework to apply to cases involving foods and supplements to help assess causality. Such a framework needs to take into account the multi-ingredient nature of these products, including presence of multiple botanical ingredients, and the relatively short life-cycle of many products, patterns of use, including use of concomitant medications and predisposing conditions, among other items."*

The line-up of distinguished and knowledgeable experts who will present the current status, as well as suggested "blue sky" options going forward are:

- J. Navarro, MD, Chair, Division of Hepatology, Einstein Healthcare Network, Philadelphia, PA. "Established causality assessment frameworks and criteria for foods and/or drugs"
- Scott A. Jordan, BS, Dphil; Senior Evaluator, Toxicologist; Marketed Health Products Directorate; Health Canada. "Post-market surveillance: A Key Tool for Monitoring and Improving the Safety of Natural Health Products (NHP) in the Canadian marketplace'
- Richard Kingston, PharmD., President, Regulatory and Scientific Affairs, SafetyCall International & Clinical Professor of Pharmacy, College of Pharmacy, University of Minnesota. "Current approaches to causality assessment: Are they appropriate for dietary supplements?"
- Bill J. Gurley, PhD, Department of Pharmaceutical Sciences, University of Arkansas for Medical Sciences, College of Pharmacy, Little Rock, Arkansas. "Clinical Utility of Dietary Supplement Case Reports and Adverse Event Reports: A Pharmaceutical Scientist's Perspective."

The event is an open scientific meeting and interested parties are encouraged to attend. For further details contact: jgriffiths@crnusa.org

Source: CRNUSA

FDA WARNINGS: PRODUCT TESTING; GMP DEFICIENCIES

It would seem that the Food and Drug Administration (FDA) is increasing its testing of finished supplement products, as was demonstrated in a warning letter to a manufacturer that a product produced for an own label distributor contained only 5% of the nutrient levels declared on labels, and that the label is therefore false and misleading.

Other recent FDA letters regarding Good Manufacturing Practice (GMP) make the point that manufacturers cannot rely on a supplier's qualification to verify the identity of components that are dietary ingredients; promise written manufacturing method records for products, but not provide FDA a timeline for the completion of the record or documentation of what they will contain; and various other cGMP deficiencies.

Source: AHPA, UNPA

SOUTH WEST PACIFIC

◆ AUSTRALIA

THERAPEUTIC GOODS AMENDMENT BILL PASSED

The main amendment contained within the Australian Therapeutic Goods Amendment bill gives, via legislative instrument, the power to exclude goods from the scope of the Therapeutic Goods Act (TGA) regulatory scheme. Currently, any product that falls within the regulatory scheme because a therapeutic claim is made may be subject to regulation under the Act, even if no public health risk is likely.

The new power will only obtain in the cases where it is clear that the goods in question have little to do with managing public health and safety, but, due to a therapeutic claim made by the manufacturer, fall within the very broad definition of 'therapeutic goods'. Increasingly, more and more health and wellbeing claims are being made in relation to products where public health considerations are not likely to be an issue. Examples include 'power bands'—holographic wristbands that are claimed to improve balance, strength and flexibility—and mattresses which contain bacteria designed to reduce the effects of dust mites. Such products will now be excluded from the TGA regulatory regime, but will still be regulated under consumer protection laws.

In discussing the amendment, the Australian parliament noted that because the definition of therapeutic goods is so wide, goods that were perhaps not in contemplation when the legislation was enacted more than 20 years ago may now inadvertently be caught within its scope. It is hoped that these changes will benefit the sponsors of therapeutic goods by providing greater clarity about their obligations under the TGA and provide the Therapeutic Goods Administration with improved mechanisms for its monitoring and compliance

Source: CHC

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KEY EVENTS

KEY EVENTS 2013
KEY EVENTS 2013 JULY– DECEMBER 2013

Date	Conference	Place
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
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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