

	THE INTERNATIONAL ALOE SCIENCE COUNCIL	
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International Update

To: IASC Members

From: Devon Powell, IASC

Please find below a list of current international and US items which may be of relevance or interest to your business. As the international organization representing the interests of suppliers, manufacturers, distributors and growers of *Aloe vera* and its related products, we are dedicated to maintaining a focus on the issues that may be of concern to your business, including dietary supplement and other similar regulations.

If you have any questions please feel free to contact me.

Best regards,

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CODEX

ADOPTION OF FOOD ADDITIVES

At its March meeting in Shanghai, China, the Codex Committee on Food Additives agreed the adoption into the General Standard for Food Additives (GSFA) of nine colors as proposed by IADSA for use in food supplements: Allura Red AC, Caramel Color Class IV, Carotenoids, Chlorophylls Copper Complexes, Erythrosine, Fast Green FCF, Grape Skin Extracts, Indigotine and Iron Oxides.

The final adoption of these colors will be considered by the Codex Commission, the decision-making body in Codex, at its next meeting at the end of June. A delegation of the International Alliance of Dietary/Food Supplement Associations (IADSA) of will be

participating at the meeting to support the levels agreed and recommended by the Committee.

The Committee, however, did not have time to discuss this year all the additives under consideration for inclusion in the GSFA. A questionnaire will be circulated to IADSA members to request further information on the use of those additives in food supplements for which there is very little information available. This information will then be provided to the Committee for consideration at its next meeting in 2010.

CLAIMS SUBSTANTIATION, RISK ANALYSIS AND GUM ARABIC FOR ADOPTION

IADSA has provided comments to the Codex Alimentarius Commission, the decision-making body in Codex, actively supporting the final adoption of three key texts:

- The Recommendations on the Scientific Substantiation of Health Claims, which take into account the totality of the available relevant scientific data and weighing of the evidence to substantiate a health claim.
- The Nutritional Risk Analysis Principles, which share the principles and recommendations of the 2006 FAO/WHO nutrient risk assessment report and are a solid framework for the potential future application of the risk assessment method by Codex for the use of vitamins, minerals and other substances in food supplements.
- The Provisions on Gum Arabic as a carrier at the proposed level of 10 mg/kg.

The final adoption of these texts will be considered by the Codex Commission at its next meeting at the end of June and a delegation of IADSA will be participating at the meeting to support their adoption as recommended by the Codex Committee on Nutrition and Foods for Special Dietary Uses.

ISSUES RELATED TO MANDATORY NUTRITION LABELLING

The Codex Committee on Food Labeling (CCFL) will be considering at its next meeting on the first week of May a Discussion Paper on Issues Related to Mandatory Nutrition Labeling prepared by an electronic working group led by Australia and of which IADSA is a member.

According to the current Codex Guidelines on Nutrition Labeling, the declaration and listing of nutrient content in a food is voluntary. However, this is mandatory for foods for which nutrition claims are made.

The CCFL agreed last year to identify and address the issues and concerns relating to mandatory nutrition labeling, which would mean that nutrition labeling would be present regardless of whether or not a nutrition claim is made.

IADSA has provided written comments to the CCFL providing information regarding the additional costs involved if mandatory nutrition labeling would be applied and indicating in particular that an exemption from mandatory nutrition labelling should be considered for food supplements where the energy content is less than 50 kcal per day.

FAO/WHO

MEETING ON NANOTECHNOLOGY

In response to concerns raised by member countries on the possible food safety implications of the application of nanotechnology to food and agriculture, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) are to hold an expert meeting to address the issue.

The aims of the meeting will be to:

- summarize actual and anticipated nanotechnology applications in the food and agriculture sectors, and develop a common view of their implications for food safety
- review current risk assessment procedures and evaluate their adequacy for the assessment of nano-particles in relation to foods,
- consider issues related to communication with all stakeholders, and overall agree on priority research to fill information gaps related to potential food safety issues and to develop guidance on the possible roles of FAO and WHO in addressing food safety issues linked to nanotechnology applications.

A call for data and call for experts for the Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications have been issued and are available at:

http://www.fao.org/ag/agn/agns/meetings_consultations_en.asp

Source: IADSA

EUROPE

EUROPEAN UNION

PARLIAMENTARY ELECTIONS SPELL REGULATORY DELAY

It is confirmed that progress on the proposed new food information legislation will be delayed until after the European Parliamentary elections which take place in June of this year. As the elections are likely to mean a number of new members of the European Parliament, a new round of lobbying can be expected, resulting in a delay of at least 6 months.

A similar delay is expected to the proposed revision of the Novel Foods Regulation because the European Commission, the Council and the European Parliament have been unable to reach agreement on a common text. This means that the whole text will be subject to a second reading after the European Parliament elections.

It is anticipated that a number of other pieces of legislation currently going through the European Union regulatory process will also be delayed until much later in 2009.

Source: EHPM

HEALTH CLAIMS UPDATE

The approximately 42,000 generic health claims under Article 13 of the Nutrition and Health Claims Regulation originally received by the European Food Safety Authority (EFSA), were consolidated down to about 4,000 substance/health relationships. These have now been screened by EFSA prior to the review process, and placed in three categories:

- 1,024 with a review deadline of 31/07/09.
- 486 with a review deadline of 30/11/09.
- 2693 with no deadline.

For those not yet given an assessment date deadline, EFSA has assigned an assessment category 3, meaning that they are too vague. It has therefore instructed the Member States which submitted the claims to advise the companies that prepared the applications that further data to include measurable clearly defined health effects, as opposed to health maintenance claims, is required. Short deadlines for the provision of this information have been given.

The industry associations EHPM, ERNA and the European Botanical Forum (EBF) have held meetings with and made strong representations to EFSA in relation to the nature of the further information required and the deadlines. In particular they are contesting the standards of evaluation that EFSA intends to apply to Article 13 generic claims, which are essentially the same as those for disease risk reduction claims. Thus EHPM, ERNA and the EBF members are being encouraged to deliver the following key messages to their Member State authorities, asking them to ensure that they are brought to EFSA's attention:

- There should be a reassessment of the process followed for the development and evaluation of article 13.1 claims (generic claims).
- All evidence should be taken into account by EFSA, and all evidence should be weighed to assess its ability to substantiate a claim, i.e. there should not be a total focus on human intervention studies, double blind clinical trials, etc.

In addition, EHPM and ERNA are working together with the European Food and Drink Association (CIAA) compiling the submission of clarifications that will be sent to the Member States, and collecting comments and concrete examples highlighting that the information requested by EFSA is very confusing.

Separately, EFSA continues to assess claims for children and disease risk reduction claims. A small number have been approved, but the majority have been rejected.

Source: EHPM

EBF WELCOMES JUDGEMENT ON BOTANICALS

The European Botanical Forum (EBF) has welcomed a recent European Court of Justice judgment against Spain for not applying the principle of mutual recognition in relation to botanical food supplements as a further example of the legal co-existence of botanical food supplements and herbal medicinal products.

Spain's practice has been to consider products that contain herbs as medicinal, despite the fact that they are marketed legally in other Member States as food supplements – a practice seen by the Court as incompatible with the principle of the free movement of goods.

However, the ECJ decision was that substances which, while having a physiological effect on the body, do not have a significant effect, should not 'automatically' be classified as medicinal products by function: *'The mere fact that one or more medicinal herbs are among the constituents of a product is not sufficient to permit the conclusion that that product contributes to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action'*.

Source: ERNA

MAXIMUM PERMITTED LEVELS UPDATE

A European Commission Working Group continues to discuss proposals for setting Maximum (and Minimum) permitted Levels of Vitamins and Minerals under the EU Food Supplements Directive and is testing the assessment models provided by EHPM and ERNA for food supplements and that provided by the food industry for fortified foods.

It is anticipated that, like a number of other pieces of proposed legislation, the long-awaited concrete proposals for maximum and minimum levels will not appear until after the European Parliament elections in June of this year.

Source: EHPM

EFSA DOSSIER SUBMISSION UPDATE

Over 50 nutrient source ingredients have now received positive opinion from EFSA and over a hundred further positive opinions are possible from those yet to be assessed. For those EU member states where derogation has been granted, this means that the remaining 255 ingredients listed on the Commission website will not be allowed to be used at the end of the derogation period, January 2010.

For further information on the dossier list see:

http://ec.europa.eu/food/food/labellingnutrition/supplements/food_supplements.pdf

A searchable 'register of questions' which can be used to follow the progress of dossiers through the assessment process and view the final published opinions can be found on: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf?nocache=1232721334485>

A draft Commission proposal for a Regulation for the official addition to the list of sources of nutrients listed in Annex II of the Food Supplements Directive is currently under discussion.

Source: EHPM

NOVEL FOODS UPDATE

The European Food Safety Authority (EFSA)'s Panel on Dietetic Products, Nutrition and Allergies (NDA) has approved the safety of *Morinda citrifolia* (Noni) fruit puree and concentrate as a novel food ingredient.

In the opinion of the EFSA NDA the manufacturing procedure was similar to that of the already- approved Noni juice and was not expected to result in qualitative or quantitative compositional differences of nutritional relevance. The EFSA NDA did, however, note the increasing number of cases of particular sensitivity for hepatotoxic effects to noni fruit products.

Separately, a further synthetic form of fermented lycopene has been approved under the Novel Food Regulations for a number of different food uses, including food supplements. A proprietary, patented omega-3 rich extract of Krill (minute marine creatures) has also been granted Novel Food and PARNUTs (Products for particular nutritional uses) approvals. This means that it can be used in a number of food forms, including food supplements, fortified foods and foods for special medical purposes.

Source: EHPM

LOWER TOLERABLE LEVEL FOR CADMIUM

At the request of the European Commission, the European Food Safety Authority (EFSA)'s Panel on Contaminants in the Food Chain has recently assessed the risks to human health related to the presence of cadmium in foodstuffs.

Following the review of updated dietary exposure data, the Panel has set a reduced tolerable weekly intake for cadmium of 2.5 µg/kg b.w.

Source: EHPM

EU PROJECT ON MICRONUTRIENT LEVELS

A European Commission funded project, European micronutrient Recommendations Aligned (EURRECA), is aiming to design a methodology for assessing micronutrient requirements (such as folic acid, vitamin D and iron), and for devising nutrient recommendations covering the 27 member states of the European Union.

Currently such recommendations are disparate, with most countries using nationally derived values.

For further information, see: www.Eurreca.org/everyone/5653

Source: ERNA

ENERGY DRINK INGREDIENTS APPROVED

Following assessment by the European Food Safety (EFSA) Scientific Panel on Food Additives and Nutrient Sources added to Foods (ANS) of the safety of two popular energy drink ingredients, taurine and D-glucorono-y-lactone, EFSA has decided that they pose no safety concerns at average usage levels of 0.5 cans per day (average dosage of 500mg taurine and 300mg D-glucorono-y-lactone).

In the Panel's view, the acute adverse events, even death, that have been linked to high consumption of these substances are more probably linked to high caffeine consumption.

Source: EHPM

CONSULTATION ON ENZYME GUIDELINES

The European Food Safety Authority (EFSA) is consulting on its draft Guidelines on the safety of food enzymes.

The draft specifies the kind of information that industry must provide to enable the EFSA Panel on Food Contact Materials, Enzymes, Flavorings and Processing Aids (CEF) to assess enzymes.

In the UK, the recently adopted Food Improvements Agents Package (FIAP) means that enzymes used as processing aids must be approved, but prior approval has not previously been required in most other Member States of the European Union.

Further detail can be found at http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902439387.htm

Source: EHPM

FINAL NANO-RISK OPINION PUBLISHED

The European Food Safety Authority (EFSA) has finished assessing the potential risks of nano-technology for food and feed, and has concluded that because there are so many uncertainties that remain over its safe use, a cautious, case-by-case approach, should be adopted.

EFSA's Standing Committee has recommended further research on engineered nano materials (ENMs) to establish their stability and any interactions in food and feed, and in the gastro-intestinal tract and biological tissues. It also advocates the development and validation of methods of detecting, characterising and quantifying ENMs, and of assessing toxicity.

Source: ERNA

FRANCE

ASSOCIATIONS TAKE ACTION ON BOTANICAL LIST

Article 16 of the 2006 French Decree, which transposed the EU Food Supplement Directive, provides that an ingredient which is not authorized in France but which is authorized in a food supplement in another European Union Member State becomes legal on French territory after being declared according to the procedure put into place by this article. This provision is an application of the mutual recognition principle. In addition, after the procedure had been set up for six months, the Article states that botanicals and other substances and their conditions of use, authorized through the Article 16 procedure, should be listed in an Order, which would subsequently be updated as necessary.

However, this first Order 'Substances and Botanicals' has now been awaited for nearly three years. It is understood that this delay is caused by AFSSAPS (the French Health Products Safety Agency), which would like to maintain the majority of botanicals listed in the draft text for an exclusive use in medicines.

The delay in publishing this text creates serious legal insecurity for French stakeholders in the food supplements industry and the French supplements association, SYNADIET, is taking decisive action to try to remedy the situation, including top-level meetings with its Directorate-General for Enterprise (Ministry of Industry, Economy and Employment) and Directorate-General for Health (Ministry of Health) representatives.

The French supplement association SDCA has a similar action plan, but with particular emphasis on the conditions for publication of the Order. SDCA has advised the authorities that the supplement industry could not accept restrictions in regard to what has been accepted by individual notifications, if these restrictions on conditions of use:

- are not based on safety grounds, and assessed case by case
- do not meet the principle of proportionality (for example, the French authorities want to restrict the possibility of adding caffeine at a very low level but will not agree to the adoption of labeling rules to manage this kind of risk, despite the fact that a such a rule has already been adopted for beverages under EU labeling regulation).
- are not notified to the European Commission and other member states under Chapter III of EU Regulation on ‘Fortified Foods’.

Source: SYNADIET / SDCA

ITALY

BOTANICALS LIST PUBLISHED

A new list of several hundred botanicals which can be used in food supplements in Italy has recently been published on the Italian Ministry of Health website. However, the list is not definitive, and botanicals not included in the list should be considered as novel foods according to EU Regulation 258/97 – unless they have been used as foods in another Member State, when they will be accepted under the mutual recognition principle.

For further information see: www.ministerosalute.it/

Source: AIIPA / FederSalus

UNITED KINGDOM

FSA WARNING ON CONTAMINATED SUPPLEMENTS

The Food Standards Agency (FSA) has issued a Food Alert for Action warning concerning the recall of all batches of a food supplements because some of the supplements are contaminated with a banned drug, nimesulide.

The supplements are marketed as natural anti-inflammatory pain-killers for conditions such as arthritis and migraine.

Source: CRN

NEW FOOD & ENVIRONMENT RESEARCH AGENCY LAUNCHED

A new Food & Environment Research Agency (FERA) has recently been launched with the aims of supporting and developing a sustainable food chain and a healthy natural environment and of protecting the global community from biological and chemical risks.

The new agency brings together expertise in:

- the understanding of relevant policy and regulation issues
- the inspection services to protect seeds, crops, etc.
- the science necessary to horizon scan for issues, diagnose threats, trace contaminants, evaluate risk and inform policy
- responding to and recovering from accidental or deliberate contamination

For further information, see www.defra.gov.uk/fera

Source: HFMA

ASTAXANTHIN EXTRACT SEEKS NOVEL FOOD APPROVAL

An Indian company has applied to the Food Standards Agency for approval under the Novel Food Regulations to market an astaxanthin-rich extract obtained from the algae *Haemtococcus pluvialis* as a food supplement.

The company is seeking FSA's opinion on the equivalence of this extract to an astaxanthin oleoresin that it already manufactures and which is exported to a number of countries, including Member States of the European Union.

Source: HFMA

NORTH AMERICA

CANADA

NEW GUIDANCE ON PRODUCT CLASSIFICATION

Several hundred Product License Applications for products in food format which have characteristics of both natural health products (NHPs) and foods have been received by Health Canada. These applications have presented regulatory

challenges in classifying the products (commonly referred to as "food-like NHPs", or "NHPs in food format") since they could fall under either the Canadian *Natural Health Products Regulations* (NHPR) and/or Parts A, B and D of the *Food and Drug Regulations* (FDR).

Now, a new Guidance document, the *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats*, has been issued, which is intended to facilitate decision-making on product classification by basing decisions on the following four criteria:

- Product composition
- Product Representation
- Product Format
- Public perception and History of Use.

For further details, see: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/food_nhp_aliments_psn-2009-eng.php

Source: CHFA

UNITED STATES

REPORT SEEKS IMPROVEMENTS IN SUPPLEMENTS REGULATION

A report by the US Government Accountability Office (GAO) suggests that the US Food and Drug Administration (FDA) should be much more rigorous in its regulation of dietary supplements, since consumers continue to experience side effects associated with the use of these products.

The report notes that reported side effects from supplements have increased three-fold since December 2007, the date from which companies were required to disclose to the FDA side effects reported by consumers.

For further details, see <http://www.gao.gov/products/GAO-09-250>

Source: NPA

FACT SHEET ON BIOTERRORISM

The Food and Drug Administration (FDA) and the US Customs and Border Protection (CBP) have recently published the 'Prior Notice of Imported Food Final Rule' and a draft compliance policy guide that outlines the agencies' enforcement policies.

The final rule takes effect in May of this year, and the types of food affected include dietary supplements and dietary ingredients and infant formula. For further detail, see: www.cfsan.fda.gov/~dms/fsbtac29.html

Source: CRN US

USDA DISCUSSES REVISION OF GE REGULATION

Following a high level of public interest in its initial consultation, the US Department of Agriculture (USDA) has invited interested parties to take part in a scoping session on the agenda for meetings discussing a proposed rule for genetically engineered (GE) organisms.

The proposed rule will revise the existing regulations introduced in 1987 for the importation, movement and environmental release of GEs. USDA's Animal and Plant Health Inspection Service is particularly interested in comment on which GE organisms should be included/excluded from the proposed regulations, and on the elimination of current notification requirements so as to expedite the introduction/transport of GE organisms.

Source: AHPA

INCREASE IN SUPPLEMENTS MADE WITH NANOTECHNOLOGY

An organization that tracks consumer products that claim to contain nanoscale substances has recently noted growth in the number of consumer products made with nanotechnology, particularly in the area of dietary supplements.

Project on Emerging Nanotechnologies (PEN), a non-profit body, says that it has 800 consumer products in its inventory, which was started in March 2006. At that time there were 11 dietary supplements, but that figure has now risen to 44.

Source: AHPA

GUIDE ON IMPORTED FOOD SHIPMENTS AVAILABLE

The Food and Drug Administration (FDA) has recently announced the availability of a small entity compliance guide (SECG) for the final rule on prior notice of imported food. The final rule issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was published in the US Federal Register of November 7, 2008.

The SECG is intended to help all entities, especially small businesses, better understand the prior notice regulation.

The SEGG can be found at: <http://www.cfsan.fda.gov/~acrobot/fsbtpn2.pdf>

Source: NPA

SOUTH WEST PACIFIC

AUSTRALIA & NEW ZEALAND

DRAFT GUIDELINES FOR WEIGHT LOSS PRODUCTS

The Australian Government Department of Health and Ageing Therapeutic Goods Administration has developed a *Draft Guideline for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss*. The draft is currently out for consultation.

The Guideline has been developed to assist sponsors of Listed complementary medicines in determining the level and kind of evidence to support indications and claims for weight loss. It aims to help ensure consistency in the type and level of evidence required to support indications and claims for weight loss in Listed medicines and give consumers confidence in the medicines they choose for self-care.

For further details see: <http://www.tga.gov.au/cm/consult/drweightloss.htm>

Source: CHC

FSANZ SEEK VIEWS ON GM FOOD

Food Standards Australia New Zealand (FSANZ) is currently seeking comment on an application for approval for a food derived from a genetically modified soyabean.

FSANZ 's assessment found no safety concerns. Individuals and stakeholders now have until May to comment on this assessment.

Source: CHC

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