



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

KEY ISSUES FOR DISCUSSION AT THE CODEX NEXT MEETING

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) will meet in early November in Düsseldorf, Germany to discuss a number of key issues for the food supplement industry, including:

- Methods of analysis for Dietary Fibre:

While the definition of dietary fibre has been adopted, the CCNFSDU still needs to discuss the methods of analysis of dietary fibre. In the interests of international harmonisation, IADSA supports the use of AOAC methodologies.

- Revision/Addition of nutrient reference values (NRVs) for vitamins and minerals:

An electronic working group (eWG) led by the government of Korea, of which IADSA is a member, is revising the draft General Principles that are being developed for establishing NRVs of vitamins and minerals for the general population. Whilst it has a number of comments on specific issues on the revised draft, IADSA supports the proposal to update and extend the current list of vitamins and mineral NRVs to include 13 vitamins and 6 minerals and the inclusion of other nutrients such as chromium, copper, fluoride, potassium, manganese, molybdenum and phosphorus.

- Revision of Principles for the Addition of Essential Nutrients to Foods: IADSA's Scientific Group has drafted comment on the Discussion Paper and Proposal developed by the government of Canada to amend the Codex Principles for the Addition of Essential Nutrients to Foods. Although primarily concerning fortified foods, in terms of total intake the discussions on this issue could impact on future discussions on maximum levels for food supplements.

An IADSA delegation will be participating at the meeting. For more information on any of the above, contact: secretariat@iadsa.be

Source: IADSA

FOOD ADDITIVES USED IN SUPPLEMENTS

In recent years IADSA has been very successful in preventing the deletion from Codex of valuable technological additives and colours used in food supplements and in getting them adopted by the Codex Alimentarius Commission and included in the General Standard for Food Additives, the Codex positive list.

However, there many more additives used in supplements, and therefore IADSA's work must be on-going because the Codex Committee on Food Additives (CCFA) will consider a further batch in 2010. For this reason, IADSA has prepared a questionnaire for its members, seeking information on the usage and importance of the additives that Codex will review.

For more information, and a copy of the questionnaire, contact :
secretariat@iadsa.be

Source: IADSA

ASIA

▫ JAPAN

REVISED DIETARY REFERENCE INTAKES IN JAPAN

Public consultation on the Japanese 2010 Dietary Reference Intakes (DRIs) closed in the middle of July, and from April 2010 to March 2014 official nutritional advice - school lunch menus, health centre advice to consumers, etc. - will follow these revised levels

The main changes from existing DRIs are the following:

- The requirements for the over 70s are increased
- The recommended daily intake of sodium was decreased for adult males and females to 9g and 7.5g respectively
- 3. The recommended daily intake of calcium was increased for adult males and females to 778mg and 666mg respectively.

Source: AIFN

SURVEY ON FOOD SUPPLEMENT INTAKE OF CHILDREN UNDER 6

A survey of the food supplement intake of Japanese children under 6, carried out in 2007 by the Japanese Institute of Nutrition and funded by the Ministry the Ministry of Health, Labour and Welfare (MHLW), has recently been published

The survey, which had the secondary objective of assessing whether there was cause for concern about excessive intake, found that of 1533 children under 6

who attended nursery schools/kindergartens, 15% took supplements. Vitamin and mineral products accounted for 68% of the supplements consumed, which were primarily taken with the object of nutritional supplementation but also for health promotion and disease prevention.

Source: AIFN

INDIGESTIBLE DEXTRIN AS A FOSHU INGREDIENT

The MHLW will soon accept indigestible dextrin as a functional ingredient for Standardized FOSHU (food for specified health use) with the health claim of '*Good for those concerned about blood glucose levels*'. Standardized –FOSHU (S-FOSHU) is one of the FOSHU categories and its functional ingredients are decided by the MHLW when more than 100 products have been approved as existing FOSHU products with the same health claim. It is six years since the first approval in this health claim category and the products concerned were developed by at least two companies.

Indigestible dextrin has also been approved as a functional ingredient for S-FOSHU with the health claim of '*good for maintaining gastro-intestinal condition*'. The dosage is 3-8g/day for '*gastro-intestinal condition*' and 4-6 g/day for '*blood glucose level*'.

Source: JIHFS

EUROPE

EUROPEAN UNION

NUTRIENT SOURCES UPDATE

The European Food Safety Authority (EFSA) has completed the first comprehensive assessment of substances used as sources of vitamins and minerals in food supplements which are currently sold in the European Union. Since 2005, EFSA has examined 533 applications for 344 different substances. 186 applications were withdrawn at various stages during the evaluation process and around half of the remainder could not be assessed because insufficient safety data was provided by the applicants. There were possible safety concerns in relation to 39 applications.

The draft Commission Regulation amending Directive 2002/46/EC No 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements, will now be subject to 3 months' scrutiny by the European Parliament before being published in the Official Journal of the European Union.

Nutrient sources currently used in food supplements but not positively reviewed by EFSA will no longer be permitted for use from 2010 onwards.

Source: EHPM

HEALTH CLAIMS UPDATE

The European Food Safety Authority (EFSA) initially assured stakeholders that they would publish their opinions on Article 13.1 (generic) health claims in one batch, probably towards the end of 2010, at the end of the assessment process. However, EFSA has now said that they are bound by the terms of the General Food Law Regulation to publish their opinions as soon as possible after their adoption. Thus the first batch of opinions on 13.1. claims is expected in September of this year, and the European Commission will propose risk management conclusions to Member States after each batch of opinions is published.

It is also understood that EFSA will shortly be sending out to member states a list of claims which they are unable to assess. It is expected that EFSA will seek the withdrawal of these claims from the list of those submitted.

In respect of EFSA's review process for article 13.1 claims, despite the wording of the Nutrition and Health Claims regulation which suggests that the process should be particularly tailored to these claims, EFSA continues to say that the same stringency of process as for disease risk reduction claims will be used. For this reason, the European Federation of Associations of Health Product Manufacturers, (EHPM), the European Responsible Nutrition Alliance (ERNA) and the European Botanical Forum (EBF) have submitted to EFSA an extremely detailed model for the review of Article 13.1 claims, and, following urgent representations to Commissioner Vassiliou, have been promised a meeting after the summer break to discuss their concerns.

It is also understood that EFSA is to organise a meeting between EFSA Panel members, Member State representatives and the European Commission to discuss technical issues. The European supplement industry will be seeking, via their national representatives, for attendance at this meeting to be extended to a wider stakeholder group, including industry representation.

In the meantime, EFSA's review of children claims and of disease risk reduction claims continues, with the majority receiving adverse opinions. Particularly in the UK, this has resulted in unwarranted and 'scare-mongering' adverse media comment on the validity of health claims in general, which, with the assistance of scientific experts, the supplement industry is currently endeavouring to address.

Source: EHPM

NOVEL FOODS UPDATE

The European Food Safety Authority (EFSA)'s Panel on Dietetic Products Nutrition and Allergies (NDA) has recently carried out additional assessment of an application to use Glucosamine Hydrochloride from *Aspergillus niger* (RGHN) as a food ingredient, taking account of comments/objections of a scientific nature raised by Member States.

The applicant wants to add glucosamine hydrochloride to fruit juices and 'smoothies', dehydrated instant fruit mixes, sports drinks and iced tea drinks. Target consumers are older people and sportspeople.

The panel concluded that RGHN is safe as a food ingredient at an intake level of 750mg per day, but that consumers with diabetes or glucose intolerance should seek medicinal advice before consumption.

Antarctic Krill, *Euphausia superba* has obtained authorisation for use as a novel food at 200mg/day in food supplements, as it has a number of other applications including Lucerne leaf extract and chia seed. However, an opinion on the status of the puree and concentrate of Noni fruit, *Morinda citrifolia*, has been delayed because of questions on the consistency of proposed maximum limits with those approved with the authorisation of Noni juice.

In November of this year EFSA is to hold a Scientific Colloquium in Amsterdam, Netherlands, provisionally entitled 'What's New in Novel Foods'. The aim will be to stimulate expert debate on key issues related to the foreseen revision of the Novel Food Regulation that will serve as input to the preparation of an EFSA Guidance for applicants.

Source: EHPM

FOOD LABELLING UPDATE

The main area of debate of interest to food supplements is the proposal for a mandatory font size for mandatory product information. The latest proposal for a size of 1.2mm remains unacceptable for food supplement products, often

marketed in relatively small packages which contain a large number of ingredients, (multivitamins, etc.).

The Swedish Presidency of the European Union has said that they would like to agree most issues by the end of the year and intend to hold regular meetings to enable this. (EHPM) are being encouraged to continue dialogue with their national officials to demonstrate the impractical nature of this requirement for food supplements, and the need for a special exemption to cover their needs. A further important argument is the very considerable impact this legislation will have in terms of costs to operators.

Source: EHPM

EC REPORT ON THE IMPLEMENTATION OF THE EU HYGIENE RULES

The Hygiene Package contains different articles requiring a report of the Commission to the European Parliament and to the Council, reviewing the experience gained from the application of the hygiene package. It has now been published and concludes that overall Member States have taken the necessary administrative and control steps to ensure compliance with the hygiene package. However, there is still room for improvement in relation to implementation.

In general, Member States consider that the legislation requires slight adjustments, but not a fundamental overhaul - but Member States and private stakeholders clearly expressed the view that at present they do not want to extend the requirement for HACCP-based procedures to food business operators carrying out primary production.

According to the report, the main difficulties identified are in relation to:

- Certain exemptions from the scope of the hygiene Regulations
- Certain definitions laid down in the Regulations and the procedure for adapting those definitions
- Certain practical aspects concerning the approval of establishments handling foods of animal origin and the marking of such foods
- The import regime for certain foods
- The implementation of HACCP-based procedures in certain food businesses and the implementation of official controls in certain sectors.

The report does not suggest any detailed solutions to these difficulties and the Commission will therefore consider the need for any proposals to improve the food hygiene package.

For further information, contact Secretariat@EHPM.be

Source: EHPM

LRVs FOR n - 3 AND n – 6 PUFAs

The European Food Safety Agency (EFSA) has given its opinion on the reference labelling values of omega 3 fatty acids.

EFSA has agreed the proposed Reference Labelling Value (RLV) for n-3 Polyunsaturated Fatty acids (PUFAs) of 2 g. However, it has put forward higher values for the RLA of long chain n-3 PUFA (mainly eicosapentaenoic acid and docosahexaenoic acid [EPA and DHA]) respectively of 250mg instead of the proposed 200mg. For the RLV of n-6 PUFA, (linoleic acid and a α -linoleic acid [LA and ALA]) 10g respectively is proposed, instead of the 6 g originally suggested by the European Commission.

Source: EHPM

EU HEAVY METAL LIMITS FOR SUPPLEMENTS

European Commission Regulation 629/2008 which sets limits for heavy metals in food supplements came into effect throughout the European Union in July of this year.

The Regulation sets the following limits for food supplements:

- lead: 3 mg/kg
- cadmium: mg/kg except for seaweed products (3 mg/kg)
- mercury: 0.1 mg/kg

Following concerns about the difficulty in meeting these limits for cadmium in supplements derived from fish, the European Federation of Associations of Health Product Manufacturers (EHPM) has contacted its members to try to determine the extent of this problem.

For further information, contact secretariat@ehpm.be

Source: EHPM

COMMISSION CONSULTS ON GMs

The European Commission's Director General for Environment has launched an evaluative study to look at reactions to genetically modified (GM) crops in Europe.

The aim of the project is to '*...assess how far the implementation of the legislative framework has achieved its objectives*', which include the protection of human and animal health, defence of consume and environmental interests, and the functioning of the internal market.

Unlike the USA, considerable resistance to genetic modification remains in the European Union (EU), and there are currently a number of court cases concerning the interpretation of EU regulation.

The evaluation, which will involve a questionnaire for broad range of stakeholders, is due for completion by early 2010.

Source: EHPM

WORKING PAPER ON OPTIONS FOR REVISION OF PARNUTS

From a recent meeting of the Working Group of the Advisory Group on the review of PARNUTS (Products intended for Particular Nutritional Uses) legislation, it has emerged that there are many current difficulties with the application of the 20 year old existing Framework legislation, including definition, scope, inconsistencies relating to notification, and product categories for which no decisions have been made on specific rules.

As a result, serious consideration is being given to a number of options which include:

- to take no action and maintain the status quo. (Borderline problems between food supplements, fortified foods and dietetic foods would remain, and the same products could potentially still be classified differently in Member States).
- To adopt informal guidelines at Community level. (Provides the possibility of issuing guidance on standards for diabetic, sports and lactose-free foods, but would not provide legal certainty as it is not legally binding.)
- The revision of the Framework Directive and the adoption of a new dietetic food Framework regulation.
- The repeal of the PARNUTS Directive. Either, replacing it with a new Framework Regulation, initially covering only the categories of foods already covered by specific Directives/Regulation. Or, no replacement but the maintenance of certain existing specific Directives. Or, the repeal of all legislation on dietetic foods.

The various options will be further discussed with stakeholders.

Source: EHPM

THE SAFETY ASSESSMENT OF BOTANICALS: UPDATE

For some months now a European Scientific Cooperative Working Group (ESCO) composed of experts identified by the European Food Safety Authority (EFSA) and the Member States has been testing the approach to the safety assessment of botanicals that was proposed in their EFSA's draft guidance document, published last year.

The task comprised a number of case studies of the practical application of the guidance to various herbs, and the preparation of a comprehensive compendium of herbs with safety concerns. Now, this work has been completed and EFSA's Scientific Committee is considering the ESCO Group's suggestions for a possible update of the guidance.

Most recently, EFSA has announced that it is working on the programme of a Workshop, expected to be held in November in Athens, Greece, to present its work to stakeholders and to discuss a possible way forward.

Source: ERNA

STAKEHOLDERS DISCUSS PUBLIC CONSULTATIONS AND RISK ASSESSMENT

A recent meeting of the European Food Standards Agency (EFSA)'s Stakeholder Platform endorsed a document which gives 'general guidelines' for undertaking EFSA public consultations on scientific outputs. The document lays out EFSA's integrated approach and outlines the criteria for identifying the need for a public consultation, the types of scientific outputs on which such consultations can be launched, and how the outcome should be reported.

Participants also discussed EFSA's opinion on transparency in scientific aspects of risk assessment. With the aim of ensuring that EFSA scientific outputs are clear, understandable and reproducible, the document outlines general principles such as the identification of data sources, criteria for inclusion and exclusion and confidentiality of data.

Source: ERNA

BfR/EFSA WORK ON THE ASSESSMENT OF ISOFLAVONES

The safety and benefits of Isoflavones used in food supplements have been the subject of a number of reports and a focus of interest in several member states in the recent past. In particular, in April 2007, the German Risk Assessment Institute (BfR) published a report which questioned the safety of isoflavones.

In response, The European Food Safety Authority (EFSA) created an ad-hoc scientific co-operation (ESCO) working group to collect together all the relevant scientific information. The ESCO working group is now reviewing this data through a structured search strategy, with the aim of completing the task by end 2009.

The BfR report is potentially of considerable significance to the supplement industry, and in May of this year a conference, supported by IADSA member

CRNUSA, was held in Milan, Italy, to address the issue of soy isoflavones and the risk assessment work of Bfr and EFSA.

The CRN USA has now prepared comment the issue and is asking the European Federation of Associations of Health Product Manufacturers (EHPM) whether its members would be willing to endorse and support these comments and the Minutes of the Milan conference. Such endorsement would enable them to be both considered as part of the available data for consideration by EFSA, and used in dialogue with Member States, some of whom, it is feared, may take action not in line with the risk assessment principles described in the documents and before the EFSA assessment is complete.

For further information contact secretariat@EHPM.be

Source: EHPM

UNITED KINGDOM

WARNING ON WEIGHT LOSS SUPPLEMENTS

Some six weeks after their recall from the US market because of a suspected connection of a weight loss product with serious liver damage, the UK Food Standards Agency has warned against the consumption of Hydroxycut products.

It is understood that the UK formula for the product may be different from its US counterpart. However, the FSA has not yet identified the specific problematic ingredient and both US and UK formulae can be found on the UK market - hence the need for an official public warning.

Source: HFMA

'MIRACLE BERRIES'; BEE VENOM – NOVEL FOOD STATUS?

Because of a lack of evidence of consumption in the European Union (EU) to a significant degree before May 1997, it is probable that the UK Food Standards Agency (FSA) will accord Novel Food status to 'Miracle Berries', (*Synsepalum dulcificum*.) This would mean that the safety of the berries would have to be demonstrated to and approved by the European Food Standards Agency (EFSA) before further sale in the EU.

Separately, a New Zealand company has applied to the FSA for approval to market the venom from the honeybee as a novel food ingredient. The venom, which is extracted by a 'milking' process is added to honey with the aim of helping alleviate symptoms of arthritis.

Source: HFMA

CONSULTATION ON IRON AND HEALTH LAUNCHED

The Scientific Advisory Committee on Nutrition (SACN) has issued a scientific consultation on its draft report that reviews the evidence on iron and health and considers the health effects of both iron deficiency and iron excess.

The main reasons for the SACN review are:

- National dietary survey have consistently shown that some people in the UK have iron intakes below those currently recommended, with a consequent risk of conditions such as anaemia.
- Concerns about possible links between red and processed meat intake (both good sources of iron) and colorectal cancer.

Source: CRN

UK WARNED ON COMPLIANCE WITH IRRADIATION REGULATIONS

The UK has received a second warning from the European Commission that its rules governing imports of irradiated food from third countries do not comply with EU legislation.

Directive 1999/2/EC says that European Union (EU) countries can only accept food and food ingredients treated with irradiation from outside the EU if that treatment has taken place in a processing plant on a Community approved list.

It is understood that new UK regulations due to come into force shortly, will resolve this situation.

Source: HFMA

FSA TO SET UP NEW ASPARTAME STUDY

The UK Food Standards Agency is to set up a pilot study on possible adverse reactions to the sweetener Aspartame, commonly used in diet and low calorie food products.

Currently there is only anecdotal evidence of adverse effects such as headaches and upset stomachs apparently caused by aspartame. The 18 month study, which will take place in a clinical setting and under medical supervision, will ask people who have suffered such reactions to eat, on two occasions a product which may or may not contain aspartame. Any symptoms will then be recorded and a blood sample taken to measure biochemical parameters.

The Agency still consider aspartame to be safe, but, as Andrew Wadge, FSA's chief scientist said, '*... we know that some people consider they react badly to consuming this sweetener so we think it is important to increase our knowledge about what is happening*'

Source: HFMA

NORTH AMERICA

CANADA

CHFA AND NHPD HOLD BILATERAL MEETING

The Canadian Health Food Association (CHFA) and the Natural Health Products Directorate (NHPD) held a bilateral meeting on June 24, 2009. The meeting provided an opportunity to discuss in more depth the work that has been done on Standards of Evidence & Testing. The NHPD has confirmed that it will use these documents as the basis for the work that will be taking place with its newly established Program Advisory Committee (PAC) this summer and early fall.

The CHFA expressed major concerns to the NHPD: the lack of consistency in the review of applications; the need to ensure that standards of evidence are appropriate to the nature of the generally low-risk nature of natural health products; and, the need to enable appropriate testing of products.

NHPD also provided a number of status updates on various issues, including generalized health claims, Schedule F, E-IRN initiative and an update on the backlog. The NHPD reiterated its commitment to complete the review of the "backlog" – now defined as those applications received prior to April 1, 2008 – by March 31, 2010.

The CHFA will continue to lobby for changes to the interpretation and implementation of the Natural Health Product Regulations.

Source: CHFA

NEW MONOGRAPHS

Health Canada has released five new updated monographs for Gingko Biloba, Borage Oil, Iron, Cranberry and Fluoride. <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/new-neuf-eng.php>

These monographs are intended to serve as a guide to industry for the preparation of Product Licence Applications and labels for natural health product market authorization.

Source: CHFA

UNITED STATES

GOVERNMENT BACKING FOR VITAMIN D AND OMEGA 3 STUDY

What is said to be the largest randomised trial ever of vitamin D and marine omega-3 and their impact on reduction of heart disease and cancer, is about to begin.

Funded by the National Institutes of Health and other institutes and agencies, the randomised double-blind, placebo-controlled clinical trial will take place over 5 years and will involve 20,000 participants, including women over 65 and men over 60 with no prior history of cancer, heart disease or stroke. It will seek to establish whether moderate to high doses of these supplements can have a preventative effect on these conditions.

Source: CRN US

IOM INVITES PUBLIC COMMENT ON VITAMIN D AND CALCIUM DRIs

The US Institute of Medicine has set up a committee to undertake a study to assess current relevant data and update as appropriate the dietary reference values (DRIs) for vitamin D and calcium. The review will include consideration of chronic and non-chronic disease indicators. It will incorporate systematic evidence-based reviews of the literature and an assessment of potential indicators of adequacy and excess intake, based on the strength and quality of the evidence and the public health significance, taking into consideration sources of uncertainty in the evidence.

The results of this two year study are due to be published in 2010, and the IOM is to hold an open meeting in August where the views of the general public will be sought.

Source: NPA

FDA GUIDANCE ON SUPPLEMENT AERs

Following industry comment on its draft guidance issued in 2007, the US Food and Drug Administration (FDA) has now issued updated guidance of its adverse event reporting (AER) system, including minimum data and recordkeeping requirements.

The minimum data which must be submitted for each serious AER (a reaction resulting in death, hospitalisation or the need for medical intervention) is:

- An identifiable patient
- An identifiable initial receptor
- Identity and contact information for the responsible person (the manufacturer, packer, or distributor submitting the AER)
- A suspect dietary supplement
- A serious adverse event or fatal outcome

The guidance also makes it clear that the submission of a serious AER will not be construed by the FDA as admission of a link between the product and the adverse event – rather, the submission should be considered a ‘safety report’ and the company can include a disclaimer that their product ‘*..involved, caused or contributed to the serious adverse event*’.

Source: NPA

ODS RELEASES 9 BIBLIOGRAPHIES ON SUPPLEMENT RESEARCH

Since 1999, the Office of Dietary Supplements (ODS) in the United States has released 9 annual bibliographies presenting significant dietary supplement research. Each year an international team of reviewers in the fields of nutrition, botanical sciences, and public health reviewed nominated articles from peer-reviewed journals and ranked them. ODS selected the top 25 for publication in the bibliographies.

For the 2007 issue of the Annual Bibliography, over 400 original scientific papers from 83 journals were initially identified for consideration. Of these, 223 papers relevant to dietary supplements were sent to 54 external scientific experts in the fields of nutrition, public health, medicine and pharmacognosy for evaluation. In scoring the papers, the expert reviewers considered each study’s design and statistical evaluation, public health significance, and potential to advance the field.

The Bibliography contains the 25 top-scoring papers and copies may be downloaded free of charge from the ODS website at http://ods.od.nih.gov/Research/Annual_Bibliographies.aspx.

Source: CRN US

ENFORCEMENT: FTC ADOPTS NEW ATTITUDE

From recent dialogue, it appears that rather than simply pursuing business to consumer (B2C) deception and false advertising, the Federal Trade Commission (FTC) intends to increase the scope and intensity of its enforcement activities.

In future FTC will actively pursue business to business (B2B) cases where the supplier of a raw material, a private label finished product who also provides Certificates of Analysis, ingredient specifications, advertising, promotional or other substantiation will be held to the same standards as companies that advertise directly to consumers.

Thus it will no longer be a defence for a manufacturer/marketer to argue that the supplier failed to provide them with truthful, accurate and substantiated information. Instead, FTC's view is that the duty to independently verify covers the whole supply chain, and

- advertisers are held to a strict liability standard
- It is not a defence to rely on suppliers' representations/information
- The marketer has a duty to confirm and verify information from suppliers

Source: UNPA

HEAVY PENALTIES FOR FRAUDULENT MARKETING OF SUPPLEMENTS

A Michigan businessman has pleaded guilty to using his company to repackage and sell unapproved new drugs over the internet, marketed as dietary supplements for the prevention or treatment of various diseases including diabetes, high blood pressure and high cholesterol.

He faces a fine of \$12m and, potentially, a jail sentence of up to 25 years.

Source: AHPA

SELENIUM: ASSOCIATION RESPONDS ON HEALTH RISKS, MISLEADING ADVERTISING, A VERY QUALIFIED CLAIM

Association responds on health risks: Recently, the Centre for Science in the Public Interest (CISPI) has been quoted as saying that selenium products '*.....are dangerous of the health of men suffering from prostate cancer*' and '*.....may increase risk of diabetes and hypertension*'.

The US Council for Responsible Nutrition (CRN US) has strongly disputed the content and tone of CISPI's statements because they do not consider them to be substantiated by the available evidence.

Misleading advertising: CISPI has recently notified a major multi-national company that it will sue if it continues to claim that the selenium in its multivitamin product may reduce risk of prostate cancer. Currently, the company's radio

advertising poses the question '*Did you know that there are more new cases of prostate cancer each year than any other cancer?* It then says, '*Now there is something you can do*'.

CISPI's view is shared by leading researchers in the prostate cancer field, who find scant evidence to support such a claim, and are asking the Federal Trade Commission to take immediate action.

A very qualified claim: In response to a petition filed last year the Food and Drug Administration has said it could allow certain very qualified health claims in relation to selenium intake and reduced risk of bladder, prostate and thyroid cancer. However, the agency considers the evidence for such benefits to be '*very limited*' and any claim for prostate cancer would have to state that it is '*highly unlikely*' that selenium would reduce the risk.

Source: CRN US / AHPA / NPA

NATIONWIDE RECALLS OF SUPPLEMENT PRODUCTS

The Food and Drug Administration (FDA) has recently warned that 4 weight loss supplement products have been found contain an undeclared drug ingredient, sibutramine, known to increase blood pressure and presenting significant risk for people with heart problems. The company concerned has now instituted a voluntary nationwide recall.

In a separate incident, FDA found that samples of 6 male enhancement supplement products contained tadalafil, aminotadalafil or sildenafil, active ingredients of an FDA approved drug for erectile dysfunction, making the products unapproved drugs. None of the active drug ingredients, which may interact with nitrates found in prescription drugs often taken by consumers with diabetes, high blood pressure or heart disease, were declared on the product labels. Again, the company concerned has instituted a voluntary nationwide recall.

Source: AHPA

SOUTH WEST PACIFIC

AUSTRALIA

ASSOCIATION WORKS ON REFORM OF ADVERTISING POLICY

Following the failure of the Trans-Tasman Harmonisation (TTH) process and the non-realisation of an Australia New Zealand Therapeutic Products Authority, IADSA member The Complementary Healthcare Council has been lobbying to

bring to reality those aspects of the TTH scheme which were positive initiatives for industry.

Once such area is advertising, where CHC's Regulatory Policy Committee sees a number of key criteria. Advertising policy must:

- protect consumer health and safety
- provide accurate and adequate information about complementary medicines (CM) whilst preventing misleading claims and indications
- allow innovation in the CM industry to flourish
- be cost effective to both industry and regulator
- be consistent, yet flexible and enforceable
- be co-regulatory (in terms of self-regulation working in tandem with government regulation).

Source: CHC

TGA FEE INCREASES AND SUPPLEMENT PRICES

The Australian Therapeutic Goods Administration (TGA) is to increase its annual fees and charges for complementary medicines by 14.3%.

The Australian Complementary Healthcare Council (CHC) is opposed to the scale of the increase, which they fear will result in consumers paying more for popular supplements intended to assist them with improved health outcomes. To quote CHC Executive Director Dr. Wendy Morrow, *'It will inevitably impact businesses both big and small and consumers will end up having to foot the bill for doing their best to be healthy'*.

Source: CHC

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