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ANH INNOVATORS CLUB BULLETIN

July 2007

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Key EU/US Regulatory Developments:

EU: EFSA and FDA strengthen cooperation in food safety science

The European Food Safety Authority (EFSA) and the U.S. Food and Drug Administration (FDA) are today signing the first U.S./European agreement in the area of assessing food safety risk.

Catherine Geslain-Lanéelle, EFSA Executive Director., said: *'I am delighted to be signing this agreement today with the FDA. Food safety knows no national boundaries and the food chain is today truly a global one.'*

Source: *DeHavilland, Tue, 03 Jul 07*

ANH Comment:
The ANH is deeply concerned that this will provide a mechanism for the transfer of onerous EFSA and/or FAO/WHO risk assessment procedures (as proposed for Codex Alimentarius) to be transported into the US and North American Regulatory Regimes.

Food Supplements Directive (DIR 2002/46/EC) Update

The Directive is still restricted primarily to vitamins and minerals. Under the provisions of the Directive (Article 4.8), the European Commission (EC) is meant of issued its intention for dealing with ingredients other than vitamins and minerals (e.g. botanicals, amino acids, essential fatty acids, fibre, etc.) by 12 July 2007, but the EC appears to have missed its deadline.

Links to European Commission website

Some important links to bookmark are:

European Commission website on food supplements
http://europa.eu/scadplus/leg/en/lvb/l21102.htm

Derogation list (as per article 4.6)
http://www.ec.europa.eu/food/food/labellingnutrition/supplements/food_supplements.pdf

ANH Comment:
It is imperative that companies who are reliant on derogation dossiers to maintain sale of non-Positive List forms need to be considering conducting bioavailability studies. Derogation dossiers can be rejected any time and if rejected, to remain listed on Annexe II the company will need to prove safety and bioavailability of nutrient form. We caution strongly against delay.

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Maximum Permitted Levels (MPLs)

In the meantime, the EC is still in the process of developing, following consultation with stakeholders (including the ANH), its methodologies for the setting of maximum permitted levels (MPLs) of vitamins and mineral food supplements. We believe these MPLs could potentially significantly impact higher dose, notably practitioner-type, products. On July 13th, the UK issued its views on the EC's recent consultation, to which the ANH made a major submission. Download the UK government (Food Standards Agency) report at the following link: http://www.foodstandards.gov.uk/multimedia/pdfs/vitsminslevelsresp.pdf

You will see the primary beneficial recommendations is to avoid using the procedure indicated in Article 5 of the Directive (where food intakes are subtracted from the USL levels) in the case of vitamins or minerals where there is no evidence of risk of harm in normal use. This would be a valuable step forward, but you will appreciate we are still concerned about, and are working to influence, the risk assessment methods that give rise to USLs. Of particular importance is to get the EC and the European Food Safety Authority (EFSA) to recognise the importance of vitamin or form (which has already been acknowledged by EFSA in its 6th colloquium (on risk/benefit assessment of foods), following the raising of this (and many other key issues) by Dr Robert Verkerk of the ANH at the colloquium.

Nutrition and Health Claims Regulations (Reg No 1924/2006) Update

On 1 July, the NHCR came into force EU-wide. We cannot emphasise the importance of considering applications for as many Article 13 (generic, non-disease risk reduction) claims as possible, as the opportunity to submit claims to the positive list of claims closes after September this year. We would be very happy to facilitate this process and are able to provide assistance to Innovators Club members on how to set up your applications, as well as offerings views on the acceptability of the scientific evidence accompanying the application.

On 17th June, the ANH made a submission to EFSA in response to its consultation on Article 14 claims (provided as an attachment to this Bulletin), which allow claims for disease risk reduction and children's health. In the draft guidance issued by the European Food Safety Authority

The Standing Committee on the Food Chain and Animal Health released on 20 July 2007 their opinion on certain key areas of interpretation of the Regulation. Some of the key points to emerge are:

- "source of" [a given nutrient] claims will be allowed as nutrition claims
- "contains" claims may be either nutrition claims or health claims, the latter applying if there is any implication of a health effect. Therefore "contains antioxidants" will be regarded as a health claim and will necessitate approval through the claims authorisation procedure. The claim "contains lycopene" on the other hand will be regarded as a nutrition claim. An extract from the guidance is given below:

- If in the naming of the “substance” or category of substances, there is a description or indication of a functionality or effect on health, the "contain" claim is a health claim. In other words, if the function is mentioned - even in the naming of a substance or substances - this relates to a **health claim**.
Examples: “contains antioxidants” ; “contains probiotics/prebiotics” ;

- As an extension, claims which make an indication of a functionality in the description of a nutrient or a substance (for instance as an adjective to the substance) should also be classified as a **health claim**.
Examples: “with prebiotic fibres” or “contains prebiotic fibres”; “with functional bacteria” or “with functional enzymes”

- If in the naming of the “substance” or category of substances, there is only factual information [of the content of the active ingredient and not claimed effect], this must be classified as a **nutrition claim**.
Examples: “contains lycopene” ; “contains lactic acid bacteria” ; “contains lutein”

- The Standing Committee reminds us that all claims are subject to the general principles laid down in Articles 3 and 5 of the Regulation. In the case of the “contains” claims, this means notably that the substance subject to the claim is present in significant quantity *and* has been shown to have a beneficial nutritional or physiological effect.

- The Standing Committee has also provided clarification on the borderline between a functional (Article 13) and a health claim. Functional claims refer to normal, vital functions of the body whereas reduction of disease risk claims refer to reduction of specific disease risk factors. When the function claims mentions a disease risk factor generally recognised by scientific evidence, it is considered as an article 14 claim if a reduction of this risk factor is mentioned.

  Examples:

  Function claims – Article 13: maintains healthy cholesterol *or* helps to control blood pressure

  Disease risk reduction claims – Article 14: lowers blood cholesterol *or* reduces blood pressure

International Developments

Codex Alimentarius

Work has continued in the Codex Committee for Nutrition and Foods for Special Dietary Uses (CCNFSDU) on key areas such as risk assessment, still headed by Australia and now headed by Korea, NRVs (Nutritional Reference Values).

We believe this is a critical time to influence risk assessment in particular given the increased collaboration that will now occur between EFSA and the FDA (see first item in bulletin). In addition to this it appears highly likely that the Reagan-Udall Foundation in the US, proposed for establishment under Bill S.1082, which has a specific remit for safety and risk assessment, will also follow internationally agreed methodologies proposed by Codex.

The ANH continues to play an active part in both Electronic Working Groups (EWGs) and continues to propose methodologies that are scientifically rational. It is important to recognise that poor scientific methodology presently characterises risk assessment and NRV methodologies, but it is becoming apparent that many of the related issues that the ANH has identified over the last 3 years are now receiving increasing support given the strength of their scientific basis.

USA

Using Dietary Supplements in Patient Care Congressional Briefing

On September 26, 2007, our US affiliate, the American Association for Health Freedom will be presenting a Congressional Briefing entitled, 'Using Dietary Supplements in Patient Care'.

Background:
According to the 129-page annual report of the American Association of Poison Control Centers published in the journal Clinical Toxicology (Feb 2007), the National Poisoning and Exposure Database showed that there was not even one death caused by vitamins in 2005, yet dietary supplements are increasingly attacked and scrutinized.

The media, allopathic medicine, and Quackbusters, among others, continue to criticize, mislead, and misinterpret the safety, effectiveness, and even regulations of dietary supplements.

Several well-respected practitioners and scientists will be briefing US Congress and the public on the use of dietary supplements in treating patients in the United States.

Whether it's using dietary supplements as an alternative to drugs or surgery, finding relief when there is no other option, or saving the patient or taxpayer money, dietary supplements are misunderstood, but vital components of the healthcare system.

For more information, please email them direct at office@healthfreedom.net or telephone on +1.800.230.2762.

Ireland

EU Directive violates consumer's right to choose

On 19th July 2007 the Irish Association of Health Stores (IAHS) has announced the launch of a major consumer campaign to counter moves within the EU

which would radically reduce the strength of all vitamin and mineral products (food supplements), via the proposed Maximum Permitted Levels.

The IAHS states that products have been available in Ireland and the UK at these dosages for decades without any serious side effects and the Association is urging consumers of these higher level food supplements to let their voices be heard.

Jill Bell, President of the Irish Association of Health Stores is quoted as saying, *"if, as we suspect, the EU authorities are contemplating the reduction of permitted levels to pathetically low RDA levels, people who depend on higher levels to optimise their health will be denied this right. In view of our creaking health service, it seems utter madness to deny people the right to do their utmost to stay well and to avoid dependence on the medical system, but in reality this Directive is going to ensure just that.*"

Under the Food Supplements Directive, the European Food Safety Authority is to set maximum permitted levels for every vitamin and mineral by the end of this year. It is of concern to the Irish Association of Health Stores that the Irish Department of Health has recommended to the EU Commission that only RDA levels (Recommended Dietary Allowance) be sanctioned. RDAs are simply the minimum level of a nutrient required to prevent a deficiency disease such as scurvy and have nothing to do with ensuring optimum health.

In keeping with the message of the AAHF's Congressional Briefing next month, Jill Bell states that "I*reland, along with the UK, has a tradition of higher level supplement usage, extending back more than 40 years. Not a single case of any serious side-effects has been recorded in that time"*.

The IAHS, like the ANH and AAHF would endorse regulation which is appropriate, however, as we have discussed above the risk assessment methodology used to determine MPLs is seriously flawed.

It is known that over 45% of the Irish population use food supplements on a regular basis to support and maintain their health.

ANH Comment
Companies selling into Ireland can support this campaign by asking their distributors and customers to sign the petition in health stores throughout the country. There is also an on-line petition at http://www.thepetitionsite.com/2/help-save-our-supplements that can be widely publicised.

New Zealand

NZ battle against Trans-Tasman harmonisation not yet over

Certain health advocates have claimed a stunning defeat of the planned Trans-Tasman harmonisation of complementary medicines

The New Zealand Parliament has most certainly rejected the bill which aimed to set in place plans to set up a joint Australian-New Zealand authority for medicines and therapeutic products, which would regulate all complementary medicine and natural health products using the onerous Australian pharmaceutically-based model.

Although there may be something to celebrate in the short-term, the group leading the battle against Trans-Tasman harmonisation in New Zealand, the New Zealand Health Trust, has a much more sober view on this.

Yesterday, Dave Sloan from the NZ Health Trust, told ANH that he is concerned that the new NZ health minister will use ministerial powers to bring in a regime for natural health products that is even more onerous than that expected under the Trans-Tasman harmonisation scheme. This, says Sloan, could force more support for the Trans-Tasman bill - and get it back

on the table. He told us that the NZ government will try to hang on to this issue regardless, and it would be utterly wrong to sit back thinking the bill was dead.

The following article supports Dave Sloan's concerns:
http://www.nzherald.co.nz/author/story.cfm?a_id=164&objectid=10451961

For further information, review the NEWS section on the NZ Health Trust website from 12 July 2007.

URGENT: calls for action
Company response required!

1. Companies wishing to apply for generic Article 13 Health Claims should do so immediately. Closing date for submission of Article 13 claims in the UK is September 2009. Please see letter from the UK Food Standards Agency attached. **Please make contact with us to discuss this further and ANH Consultancy Ltd is able to provide support for such applications on a consultancy basis. Alternatively make use of the 2 h free consultancy we offer every month for ANHIC Gold and Silver members (cannot be accumulated or carried forward to next month).**

2. **US Innovators:** Charitable tax deductible donations (for US individuals and companies) can be made to the ANH via our US affiliate the American Association for Health Freedom/Health Freedom Foundation. Donations should be sent to The Health Freedom Foundation clearly marked that the gift is in support of European or global work.

   The Health Freedom Foundation
   4620 Lee Highway, Suite 210
   Arlington, VA 22207
   Phone: 1800 230 2762 or 703 294 6244 or Fax: 703 624 6380

   Note to US companies: We would be extremely grateful if you could publicise this method of making charitable tax deductible donations to the ANH from within the US to your customers in any marketing literature you are about to send out.

For further information about the ANH, the ANH Innovators Club or ANH Consultancy Ltd, please contact:

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