alliance for natural health
good science and good law

ANH INNOVATORS CLUB BULLETIN

December 2007

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URGENT: calls for action - please see page 6.

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Happy New Year!

Here's wishing all the members of our Innovator's Club a peaceful and productive start to 2008. Thank you for your support in 2007 and we hope to continue working with you in 2008. Your support is invaluable and helps us to continue our pioneering and unique work to help establish more appropriate scientific and legal frameworks for the natural health industry, while also protecting consumer freedom of choice in healthcare.

2007 has been a very full year in which we've seen the Regulators step up a gear in what appears to be a concerted movement orchestrated worldwide towards international harmonisation. There is more and more evidence to support the view that the European model of regulation of natural products is providing the template for global regulation, with both Codex guidelines and elements of proposed US regulation (most recently, in the area of health claims) mirroring the European regulatory model. 2008 holds a wide range of challenges in Europe (e.g. maximum permitted levels, proposed bans on 60 herbal ingredients), in the US (e.g. GMPs, AERs, health claims), in New Zealand (e.g. continued pressure from Australia re Trans-Tasman harmonisation), and elsewhere. We assure you that the ANH will, with your continuing help, be rising to the challenges as they emerge, as well as acting proactively to help create a workable and fitting regulatory framework.

The new ANH website, to be launched in January 2008, will, we believe, make an important contribution to the overall campaign. The website will allow us to much better publicise the range of activities in which we are involved, ranging from natural health, through to organic foods and farming, and drinking water quality. The site will allow strong graphics and multimedia capabilities, as well as forums and a specific members-only area for Innovators Club members.

We have annexed the ANH campaign end of year eBlast to this Bulletin (p. 8), for those of you who do not receive the eBlasts directly.

We thought it pertinent to share the festive season message from the UK Food Standards Agency's Chief Scientist, Andrew Wadge, because it rather starkly serves to remind us why none of us can give up on what we do and the reasons why we're doing it!

> ***Dump the detox***
>
> Posted by Andrew Wadge (Chief Scientist, Food Standards Agency, UK) on December 27, 2007 in *Science, safety and healt*
>
> *Been overdoing the feasting and tempted by the latest 'detox' diet or supplements? Well here's a good idea to help you recover and save you money at the same time. First, drink a glass or two of water (tap is fine, cheaper and more sustainable than bottled); second, get a little exercise - maybe a walk in the park - and third, enjoy some nice home-cooked food. There's a lot of nonsense talked about 'detoxing' and most people seem to forget that we are born with a built-in detox mechanism. It's called the liver. So my advice would be to ditch the detox diets and supplements and buy yourelf something nice with the money you've saved. Personally, I would recommend the new Neil Young and Steve Earle albums. What about you? Happy New Year!*

…… Happy New Year indeed!

We have submitted a response to Andrew Wadge's piece, which is presently being considered by moderators on the FSA website. Why don't you post your own comment at http://www.fsascience.net/2007/12/27/dump_the_detox

Key EU/US Regulatory Developments:

EFSA safety assessment of botanicals and botanicals preparations intended for use as food supplements

The next step in the harmonisation of food/food supplement regulations across the European bloc has been released by the European Food Safety Authority (EFSA) in the form of a draft guidance document on how botanicals and botanical preparations in food supplements should be classified. You will recall that the product and data requirements, as well as very high costs, of accessing the Traditional Herbal Medicinal Products Directive (Directive 2004/24/EC), effectively a fast-track for medicinal licensing of 'traditional' herbal medicinal products with more than 15 years history of EU usage, have meant that most companies are still reliant on selling herbal products, especially poly-herbal products, as food supplements. Not unsurprisingly the assessment hinges on safety and risk assessment, with around 860 plants having been categorised into two lists.

Background

In a Discussion Paper adopted in 2004, the EFSA Scientific Committee expressed the need for improving the quality and safety of botanicals and botanical preparations that have become widely available to consumers through several distribution channels in the EU. They feel that as the market volume and the variety of products expands, so does the need for a better characterisation of the range of botanicals and botanical preparations on the market, and for harmonising the risk assessment and consumer information approaches for these products. The Discussion Paper was brought to the attention of the EFSA Advisory Forum whose members confirmed that the issue was from moderate to high priority for their respective countries. As a consequence, EFSA asked its Scientific Committee (SC):

- To prepare a guidance document on how to assess the safety of botanicals and botanical preparations to be used in food supplements
- To establish a list of main categories of botanicals and botanical preparations and to prioritise the products to be considered for a safety assessment

The guidance document

The EFSA SC has now adopted for public consultation a guidance document for safety assessment, in which botanicals or botanical preparations, for which an adequate body of knowledge exists, could benefit from a "presumption of safety". Issues they feel that should be carefully considered in order to reach such a conclusion are discussed in detail in the recent draft guidance document (attached). According to EFSA, safety assessment of botanicals and botanical preparations for which a "presumption of safety" is not possible, would require additional data according to an approach described in the attached guidance document.

EFSA's SC has compiled two Compendia of botanicals (also attached) that have been used in food and that have been reported by some European Member States as of possible concern regarding safety:

- A Compendium of botanicals that have been reported to contain toxic or addictive or psychotropic substances
- A Compendium of botanicals that have been reported to have also a medicinal use.

In addition, criteria for prioritising botanicals and botanical preparations for safety assessment have been developed. EFSA want it known that the inclusion of a botanical in one of the attached compendia cannot be interpreted as being classified by EFSA as foodstuffs and therefore does not prejudge the classification of those botanicals by the Member States in accordance with the relevant legal framework. Similarly, these compendia list botanicals without any judgment on whether these are safe or not safe for food / feed applications.

ANH Comment:

The Consultation is open until 15 February 2008 and we believe that its outcome will be pivotally important to the way in which regulatory authorities around the world deal with botanicals in food or dietary supplements. We will be submitting a strong response to the consultation but would welcome any inputs that any members of the Innovators Club might have. We would urge you to pass the attached, 28-page, EFSA draft guidance on botanicals to your regulatory specialists within your company with a view to them providing feedback to us for inclusion in our submission. Please email Meleni Aldridge, Innovators Club coordinator, at mel@anhcampaign.org). Your comments on the consultation should be sent to us by 8 February 2008.

International Developments

Codex Alimentarius

Dr Rob Verkerk participated, for the third year running, in this year's annual meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), held at Bad Neuenahr, Germany between 11 and 17 November 2007. Dr Verkerk acts as scientific advisor to the US-based National Health Federation, which is the only delegation officially present at Codex meetings to have a health freedom manifesto. The highlights from this year's meeting were the progress made in terms of understanding by members of the Electronic Working Group on risk assessment of problems with conventional risk assessment methods, as raised by Dr Verkerk during the meeting, as well as the strengthening of the relationship with the New Zealand government delegation.

You will appreciate that given that Codex committee decision-making procedure is based on consensus voting by country delegations, with INGOs (International Non-Governmental Organisations) only able to influence voting, it is imperative to have country delegations that are able to champion the natural health cause. Although the South African delegation was a supporter of these issues for a number of years, a change in the delegation membership for 2007, as well as an apparent shift in its priorities (including relinquishing heading up the Electronic Working Group on Nutrient Reference Values [NRVs]) has meant that we have needed to find a new champion.

Over the last year, the ANH has coordinated an effort with its new affiliate in New Zealand, the New Zealand Health Trust, to build a relationship with the New Zealand government's representatives at Codex. This has involved lengthy education and discussions on a wide range of issues, especially risk assessment, health claims and NRVs. Physical meeting, plenty of dialogue during the November meeting, and a dinner meeting, has cemented the relationship and we are confident that the New Zealand government will become an increasingly important champion of natural health and freedom of choice issues in future meetings.

It is also evident that the ANH's position paper on EU Maximum Permitted Levels [MPLs] (released on 24 October 2007) has become the key basis for discussion of limitations of existing methodologies about risk assessment, even within the context of Codex. The document on 'Establishment and Application of Risk Analysis Principles' by the CCNFSDU has moved to Step 5 (out of 8-steps) in the Codex procedure.

The full report from November's meeting can be downloaded from:
http://www.codexalimentarius.net/download/report/687/al08_26e.pdf

Europe

EU vitamin and mineral derogations

We strongly urge all manufacturers and suppliers selling products into any EU market to keep a close eye on the EU derogation list of vitamins and mineral forms at http://europa.eu.int/comm/food/food/labellingnutrition/supplements/food_supplements.pdf given the stated intention of EFSA and the European Commission to withdraw as many as 300 nutrient forms from the list by 31 December 2007. At the time of release of the present Bulletin (on the same date), these deletions have yet to occur, but they are likely imminent. The key reason for any withdrawals will be lack of data within the dossiers. See Action Point 4 (p. 7) for how ANH Consultancy can help with compilation of dossiers. **Remember: it will be an offence to continue marketing any food supplement product in any of the EU's 27 Member States if the product contains any vitamin and mineral forms which are not listed either on Annex II of the Directive (2002/46/EC) or the derogation list.**

EU Maximum Permitted Levels (MPLs)

The Irish Association of Health Stores continues its campaign, which is now fuelled heavily by the ANH's October 2007 position paper on MPLs, to lobby the Irish government to consider consumer interests in its inputs to the development of the proposed EU-wide regulation of maximum levels for food supplements and fortified foods.

Dr Robert Verkerk from the ANH spoke together with Green Party Senator Deirdre de Burca, also Health Spokesperson for the Greens, at a press conference in Dublin on 12 December 2007. The press conference signalled the handing over of 60,000 signatories of the IAHS's rolling petition against this proposed regulation. It is worth considering a point made in the joint IAHS/ANH press release on 12 December that if the opposition across the EU was found to be similar to that in Ireland, this would represent 6.5 million Europeans opposing the proposed regulation of maximum levels.

For press release and related media coverage in Ireland (including leading national newspapers, the Irish Times and the Irish Independent, please refer to:

http://www.alliance-natural-health.org/index.cfm?action=news&ID=305 (or search for 'Irish Association of Health Stores' on new ANH website, at www.anhcampaign.org, which will go live by end of January 2008).

It is expected that the European Commission will issue final amounts in 2009 as it submits its proposal for an amendment to the Food Supplements Directive (Directive 2002/46/EC), or an entirely new Directive or Regulation for consideration by the Council of Ministers and the European Parliament.

USA

FDA petition to irradiate dietary supplements

US based Steris Corp filed a petition with the FDA in 2003 and proposed that the food additive regulations "be amended to provide for the safe use of ionizing radiation for the control of microbial contamination on dietary supplements, and ingredients used in the manufacture of dietary supplements, up to a maximum absorbed dose of 30 kGy" (kiloGray). So far, the FDA has not denied the petition and American Herbal Products Association (AHPA) became aware of the petition when it was referenced in the preamble to the FDA's final rule on current good manufacturing practice for dietary supplements on June 25, 2007.

The ANH and the AAHF strongly support the AHPA petition. If there were ever an approach that could, in a single swoop, lessen the potency of herbs and other dietary supplements, then it is irradiation.

There is good evidence now that almost any dosage of ionizing radiation does some damage (if it can kill pathogens, it can damage other cells and molecules), and any dosage above 10kGy is considered very high. 30 kGy is excessive in anyone's book, especially when exposure is likely to be to particularly sensitive molecules such as vitamins or enzymes. The danger for the nutraceutical industry is that vitamins and enzymes, as well as other nutrients or cofactors, are much more prone to break down when not present in a food matrix, as is typically the case in dietary supplements. In real terms this may mean that consumers could seriously be misled if the stated label content is different from the actual content which has been reduced as a result of irradiation.

There are other risks as well: the formation of radiolytic products which can be harmful and the increased risk of migration of components in packaging materials (e.g. plasticizers like bisphenol-A) into the food or dietary supplement product.

AAHF is planning a campaign to educate Congress and is working on an appropriate report language request (due by Feb 14th) for House and Senate encouraging the FDA to reconsider its stance on irradiation of food.

Please send any comments to Meleni Aldridge (mel@anhcampaign.org) for onward submission to AAHF.

New FDA docket set to re-categorise health claims for dietary lipids, soy, antioxidant vitamins and selenium

The US Food and Drug Administration (FDA) has just announced an opportunity for public comment on its intent to re-evaluate the scientific evidence for two previously authorized health claims (dietary lipids (fat) and cancer; soy protein and risk of coronary heart disease) and two qualified health claims that were the subject of letters of enforcement discretion (antioxidant vitamins and risk of certain cancers; selenium and certain cancers). The agency is undertaking a re-evaluation of the scientific basis for these authorized health claims and qualified health claims because of new scientific evidence that has emerged for these substance-disease relationships. The new scientific evidence may have the effect of weakening the substance-disease relationship for these authorized health claims and either strengthening or weakening the scientific support for the substance-disease relationship for these qualified health claims.

More information can be seen at http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-24813.pdf.

The ANH's affiliate, the American Association for Health Freedom (AAHF) will be responding to this call with a submission to the FDA. You are invited to send your comments to Meleni Aldridge (mel@anhcampaign.org), who will be liaising with the AAHF prior to submission by 19th February 2008.

URGENT: calls for action
Company response required!

1. **Comments invited on EFSA draft Guidance for safety assessment of botanicals and botanical preparations:** Urgent comments are required from manufacturers and distributors regarding the EFSA draft guidance (attached) on botanicals and botanical preparations intended for use as food supplements by mid February 2008. Therefore, the ANH requires your comments no later than **Friday 8th February 2008** in order for us to include your position in our submission.

2. **Comments invited on FDA petition to irradiate dietary supplements:** In order to have your position included in the AAHF report to the House and Senate, please make sure you submit to the ANH by **Thursday 7th Feburary 2008**.

3. **Comments invited to FDA submission on re-categorisation of health claims:** Comments are required on the FDA's move to re-categorise allowed health claims for dietary lipids and cancer, soy and heart disease and antioxidant vitamins, selenium and certain cancers. The ANH will be collecting comments for onward submission to the AAHF by **Monday 11th February 2008**.

4. **Applications to Positive List of EU FSD called for**: Comments from the European Commission and AESGP at the AESGP conference in October 2007 highlight the risk to companies relying on derogation dossiers for product sales. The ANH strongly advises companies once again, to consider making applications to the FSD Positive List for nutrients whose sale is currently protected by derogation dossiers. The ANH can provide support through the IC membership for Gold and Silver members and through the ANH Consultancy Ltd if necessary. **Key action point for 2008**.

5. **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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Issued December 24, 2007

Seasons greetings to you—supporters and friends of the Alliance for Natural Health. Since our inception in 2002, every year has become more and more important with regard to key processes that have the potential to make or break our ability to maintain and heal our bodies using the fruits of nature.

2007 stands out in so many ways, and we can already see why 2008 is set to be so important for all of us who hold our rights to freedom of choice in healthcare so dear. But first and foremost, we'd like to extend our very warm thanks to all of our supporters for making it possible for us to continue our pioneering work—without your help, we would not be able to continue. This support is truly international, with supporters now originating from 98 different countries, covering every continent and region of the world.

Highlights of 2007

This year has again seen us extend the bounds of our work. A quick run through our archive of news items in 2007, via http://www.alliance-natural-health.org/index.cfm?action=news&ID=all, will give you a feel for what has been achieved this year, ranging from our work in places as contrasting as the US, Europe, New Zealand and the United Arab Emirates.

Almost exactly two years after the ruling on our case which challenged the EU's Food Supplements Directive, our actions forced the European Commission to reverse its 2006 position on natural sources of nutrients, which indicated that these vital nutrients would be banned unless comprehensive, cost-prohibitive dossiers were submitted to the European Food Safety Authority. The Commission's revised view was provided after we submitted a cluster of applications to the Directive's positive list, and it confirmed that natural, food sources of vitamins and minerals were indeed outside the scope of the Directive and would be regarded as foods, not supplement ingredients. They can therefore continue to be used without requiring costly applications to the positive list.

2007 saw more and more evidence of globalisation of laws, guidelines and standards on natural health. Such a trend could be a good thing if it meant 'harmonising' to liberal laws, but the real problem is that 'consumer safety' is being used, perversely, as a reason to apply highly restrictive standards on natural health products and claims about them. Codex Alimentarius is a central mechanism in this process, and after attending the last meeting of its nutrition committee in Bad Neuenahr in Germany in November, as part of the US-based National Health Federation, we were left in no doubt that our work in unpicking the irrational science that underpins these safety arguments is central to making gains against this tide of oppressive, anti-natural health regulation.

This work was possibly most clearly exposed in our October 2007 position paper which attacked the European Commission's proposed approach on setting maximum levels for vitamins and minerals EU-wide. We demonstrated that political and economic forces have distorted the model to such an extent that its flawed science threatens to limit our intakes to the point that we would not be able to purchase levels of nutrients generally associated with good health. For example, the model proposes that levels of the provitamin A carotenoid, beta-carotene, would be limited to the amount typically found in less than one-and-a-half carrots and that of selenium to less

than that present in just two brazil nuts. If you haven't yet had a chance to read our position paper— consider allocating 15 or 20 minutes over the New Year's break to inform yourself of one of the most central issues that will affect your ability to manage your own health over the coming years. It will help you to understand how one of the most powerful governments in the world hopes to foist a flawed risk management model on 450 million of its citizens, with further hopes of exporting the same system globally via Codex over the coming years.

Let's be reminded of the Irish people's concern over this issue. The ANH joined the Irish Association of Health Stores just two weeks ago in a press conference which preceded passing a rolling petition, presently with over 60,000 signatories, to the Irish Minister for Health, Mary Harney. If we assume that other Europeans feel the same way as the Irish, that would mean that 6.5 million or so European consumers oppose Europe's attempt to limit our vitamin dosages. 2008 is likely to be make or break when it comes to seeing whether a democracy still exists in Europe, and there's good reason to believe that these natural health issues might become pivotal to any referenda on ratification of the European constitution.

Let us also remember that although Europe represents the 'epicentre' of moves to restrict natural health, as well as the template for international regulation, especially through Codex, there are many other regions of the world where the outcome of the fight on natural health issues is pivotal. It would be remiss, in any summary of 2008, to not make mention of the struggle of the New Zealand people, spearheaded by ANH's New Zealand affiliate, the New Zealand Health Trust, to stop the medicalised model of Australia from finding a new home on the other side of the Tasman. The diverse natural products and raw materials industry of New Zealand, which is a major supplier to other parts of the world, including the US, would suffer dramatically if the Trans-Tasman harmonisation agreement was to eventuate. The recent success of the New Zealand Health Trust's campaign buys some much needed time, but the fight goes on.

Looking to 2008

While we stitch together our campaign strategy for 2008, we see another pivotal year ahead. We will see ever greater attempts to limit our access, internationally, to natural health, be it by attempts to impose impossibly high hurdles for players in the natural health market. These hurdles can typically only be negotiated by the multinational pharmaceutical and food corporations, the very organisations set to benefit if the competition from smaller companies, the real pioneers in natural health, is eliminated. But as we've demonstrated before, good science and good law, the central plank of ANH's approach, can be used to positively influence the process.

Following what will be a 12 month delay, caused by unforeseen technical issues and tight funds, we also aim to launch our new website in late January 2008. Our thanks go to our new web team at Embright who have now overcome the main technical problems hindering the development of the site. The ANH's new portal (at www.anhcampaign.org) will, we believe, allow us to drive our campaigns so much more effectively—as well as providing valuable information on issues as diverse as natural healing, organic foods, GM, drinking water quality and mobile phone radiation. It will also mean the end of these text-rich eBlasts (hooray, we hear you utter!) with which we have all persevered over the last four years! Apologies to those of you who have struggled with our eBlasts, especially to those whose systems don't allow the eBlasts to format properly and appear as a single paragraph of text!

A final thank you for 2007

The ANH is headed by a small, core team of very dedicated people. This team consists of Dr Rob Verkerk, our executive and scientific director, Meleni Aldridge, our development manager, Dr Damien Downing, our medical director, Rob Collins, our legal director and, last but not least, Paul Harris, our financial and administrative director. This team reaches out to dozens of specialists, including scientists, doctors, practitioners, lawyers and others, as well as other organisations around the world, to create a true global alliance of natural health interests.

Our work is supported entirely by donations, and the core team would like to thank all of you who financially supported our work in 2007. It is only with your support that we can continue our unique work.

Please help our 2008 campaign

We hope that you will see fit to make a generous donation to the ANH in 2008. Our legal team has indicated that a legal challenge to protect the great, non-European traditions, probably centring around the great Indian traditions of Ayurveda and Unani, would be very timely in 2008. With your help, such a challenge could be a real possibility in the coming year. Our new website will offer a much better perspective on the breadth of our work—and we hope you will consider donating to the ANH so that we might continue to work together to forge a healthcare system worthy of future generations.

Seasons greetings!

In peace—and in continuing health,

The ANH Core Team