alliance for natural health

"Good Science, Good Law"

ANH INNOVATORS CLUB BULLETIN

February/March 2006

News

*** URGENT CALL *** World Health Organization request to ANH re avian influenza*

We have very recently been contacted directly by the World Health Organization (WHO) which has specifically asked us to compile a report on possible candidate natural products that have potential for use in the event of a highly pathogenic Avian Influenza H5N1 pandemic. **We urgently request inputs from companies who believe they may have products that are suitable to help mitigate the effects of H5N1 infection.** There needs to be a fairly strict requirement for eligibility of products (generic or proprietary) owing to the very short time frame available for research to establish or verify potential for use. Generally speaking the eligibility requirements would be a) evidence of *in-vitro* and/or *in-vivo* studies involving direct challenges with H5N1; b) evidence of efficacy in human studies with severe respiratory infections eg influenza, viral pneumonia but *not* the common cold. The deadline for the report is Monday 20th March so any products and supporting data are required by 12 noon GMT on Friday 17th March.

European Union

Seven Seas withdraws fish oil supplements in UK

The UK Food Standards Agency announced on 14th March 2006, that Seven Seas Ltd (owned by pharmaceutical giant Merck) has withdrawn a number of batches of its own-brand food supplements because of the presence of dioxins. Affected products are as follows:

Product Lot Numbers Expiry Date
Seven Seas Extra High Strength Cod Liver Oil Capsules 60s 351224 351369 May 2007 Jun 2007
Seven Seas Extra High Strength Cod Liver Oil Capsules 30s 351458 351380 Jul 2007 Jun 2007
Seven Seas High Strength Cod Liver Oil Capsules 60s 351176 351328 May 2007 Jun 2007
Seven Seas High Strength Cod Liver Oil Capsules 120s 351187 351629 351413 May 2007 Jul 2007 Jun 2007
Seven Seas JointCare Glucosamine Sulphate Capsules 30s 351834 351353 Aug 2007 Jun 2007
Seven Seas JointCare Glucosamine & Chondroitin Capsules 30s 351705 351701 Jul 2007 Jul 2007
Seven Seas JointCare ProJoint Capsules 30s 351464 351289 351075 Jun 2007 Jun 2007 May 2007
Seven Seas ProBrain Capsules 30s 351122 360401 May 2007 Jan 2008

Key questions asked in UK Parliament

Stephen O'Brien, appointed Shadow Minister for Health (9/12/2005) in the reshuffle following election of new Conservative Party Leader David Campbell, has been active this month in the UK Parliament asking key written questions of the UK Secretary of State for Health, Patricia Hewitt. The questions include what further steps are planned for securing continued market presence beyond 2009 of supplements containing nutrients not included in FSD annexes; timing of expected European Commission consultation with EU member states about setting of maximum permitted levels under Article 5 of the Food Supplements Directive (FSD); the relevance of the World Trade Organization (WTO) case in relation to barriers to trade in GMO's in relation to development of maximum permitted levels of vitamins and minerals; what impact assessment was carried out by the EU Commission on the proposed EU Nutrition and Health Claims Regulation.

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Increased levels of enforcement by MHRA

It has become apparent at the ANH, that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has considerably stepped up its surveillance of the UK natural products industry. Many companies are being hauled over the coals over claims that are considered by the MHRA as medicinal. ANH Consultancy is assisting several of these companies with re-positioning of its claims, labeling and marketing materials so that they are compliant with current laws, whilst making the most of the available science.

Important Note: we urge companies to consider carefully claims on products. Under DSHEA, structure/function claims allowed by the FDA are often unacceptable to European competent authorities. ANH Consultancy can assist with reviews of claims if required (see contact information at end of Bulletin for further information).

USA

Omega 3 oils influence mood, impulsivity and personality

A new study from Pittsburgh says people who have high intakes of omega-3 fatty acids are more agreeable and less impulsive. Previous studies have linked low levels of omega-3 to several neuro-behavioral disorders, while rowdy British kids who supplemented with omega-3s showed improvements in behaviour and learning after only five months. The new results show that people with low blood levels of EPA and DHA were more likely have mild-to-moderate depression (as scored by using the Beck Depression Inventory). High serum levels of DHA were related to more 'agreeableness' while people with low linolenic acid (LNA) levels were linked to being more 'impulsive'. The Pittsburgh results were presented last week at the 64th Annual Scientific Meeting of the American Psychosomatic Society.

Overseas companies risk losing products from EU market

American companies selling nutraceuticals into Europe risk having their products removed from the market through apparent confusion over correct regulatory procedure, says Dr John Wilkinson from Herbal Sciences International. Dr Wilkinson correctly asserts that the most important EU directives for nutraceuticals are the Food Supplements Directive (FSD), the Novel Foods Directive and the Traditional Herbal Medicinal Products Directive (THMPD), and he states that the need for evidence of safety and history of use in the EU is important to all three. He, however, has not signaled that two proposed regulations (see below), the Nutrition & Health Claims Regulation and the Addition of Nutrients to Foods Regulation, due to be finalized this year, are likely to be equally significant.

Regulatory Developments

European Union

ANH pursues final phase of EU Food Supplements Directive legal challenge

The ANH has confirmed its intention with the High Court in London to continue and finalise its legal challenge against the EU Food Supplements Directive (FSD). Through this process, the ANH intends to ensure changes are made to the UK regulation (statutory instrument) so that it is brought into line with the improved clarification and narrowing of scope offered by the European Court of Justice ruling last July. Following such a change, the other EU Member States will be forced to make similar changes to their national laws reflecting the EU Directive.

The UK Food Standards Agency confirms addition of nutrients to FSD positive list

The Commission's proposals to amend the annexes of the Food Supplements Directive 2002/46/EC (FSD), to include additional vitamin and mineral substances (boron, boric acid, sodium borate, calcium-L-methyl folate and ferrous bisglycinate) have received a favourable scientific evaluation from the European Food Safety Authority (EFSA).

The Commission proposals for the addition of these substances to the annexes of the FSD were discussed at the Standing Committee on the Food Chain and Animal Health meeting on 9 February 2006.

1) **Draft Commission Directive amending Annex II of Directive 2002/46/EC as regards the inclusion of calcium-L-methyl folate and ferrous bisglycinate.**

   The Committee unanimously delivered a favourable opinion on this Draft Commission Directive (SANCO/168/2006). This amending Directive will be transposed into UK law following appropriate consultation with UK stakeholders.

   With respect to calcium-L-methyl folate, the Foods Standards Agency is consulting with the Commission to confirm whether a novel foods authorization will be required before it can be placed on the market as a food supplement.

2) **Draft Commission Directive amending Annex I to Directive 2002/46/EC as regards the inclusion of boron and Annex II of Directive 2002/46/EC as regards the inclusion of boric acid and sodium borate (SANCO167/2006).**

   The German authorities have provided the Commission with the opinion of the Federal Institute for Risk Assessment (BfR) on the addition of boron and of some of its sources to food supplements, issued on 16 November 2005.

   At the Standing Committee meeting of 2 December 2005, some Member States objected to the inclusion of boron and its sources in the Annexes of Directive 2002/46/EC, claiming safety concerns in the absence of the establishment of a maximum level and indicating that boron had not been established as an essential nutrient. In order to allow for (further) consideration of the above scientific opinion submitted by the German authorities by the EFSA the draft Commission Directive was not discussed further.

The Foods Standards Agency will consult with UK stakeholders when the Commission publishes further amendments to the Directive on the remaining substances under assessment by EFSA.

Important Note: *ANH wishes to stress that it is critical that companies wishing to maintain sale of nutrients which are not presently on the positive list should apply, with minimum of delay, for submission to the positive list, even if derogations by way of dossiers presently allow sale. This is because the European Food Safety Authority could come forward with a negative opinion on any derogation dossier at any time before the end of the derogation period (31 December 2009). We are presently awaiting confirmation from the UK Government or the European Commission that the European Court of Justice ruling (12 July 2005) on the ANH's legal challenge of the FSD allows for a simplified application procedure to the positive list. This view may be cemented only after the ANH takes its case back to the High Court in London.*

MEP's table amendments to proposed Nutrition and Health Claims Regulation

Ministers for the EU Parliament have reasserted their position over the proposed EU regulation on nutrition and health claims, tabling 269 amendments at second reading in response to a common position that did not take on board the majority of the opinions expressed at first reading. Amendments were tabled at a meeting of the Environment, Public Health and Food Safety Committee and will be voted on later this month, with a final plenary vote scheduled for May 2006. If the final plenary vote does not arrive in a consensus between parliament and the council, the 25 MEP's and 25 representatives from Member States will enter into a private conciliation process. Miguel Fernandez da Silva, an advisor for European Advisory Services, is quoted as saying that this process seems very likely now as the situation is tense and mutual agreement seems remote.

Proposed EU Addition of Nutrients to Foods Regulation

This is an important regulation, which has yet to go to second reading, which will affect all foods, including functional foods, to which nutrients such as vitamins and minerals, as well as other nutritional substances, are added. It proposes to not only control which ingredients can be added, using more or less exactly the same positive list system as the FSD, it also proposes to control maximum permitted levels as per Article 5 of the FSD. Therefore, any gains made via the ANH's legal challenge of the FSD are likely to set an important precedent for this Regulation.

As a Regulation, rather than a Directive, the provisions of the Regulation will come in to force immediately following its passage through second reading of the European Parliament. Unlike a Directive, the law does not need to be transposed into national laws of the Member States. The Regulation was proposed initially on 10 November 2003, and it was presented for first reading in the European Parliament on 26 May 2005. The

Common Position from Commission and Council was adopted on 8 December 2005. The date of the second reading has yet to be proposed.

See item below re ANH's work to lobby the European Parliament to vote against inclusion of fluorides from the positive list.

ANH Lobbying to remove fluorides from Annexes of Addition of Nutrients to Foods Regulation

The ANH has communicated the following to all members of the key ENVI Committee in the European Parliament which recently met to discuss the Common Position after receipt of comments from the Council of Ministers.

In line with Recital 9, to avoid *"*Controversy as to the identity of these essential nutrients that could potentially arise should be avoided", any reference to fluoride or fluorides should be deleted from the Annexes of the proposed Regulation. There are numerous reasons for this including:

- Most health authorities do not regard fluoride as an essential nutrient.
- Sodium and potassium fluoride have been included in Annex II (as per Directive 2002/46/EC), yet there is inadequate evidence of the safety of these ingredients when added to foods.
- Recital 12 states *'No claims about the nutritional or health benefits should be made'* yet the primary purpose for the addition of fluoride to foods is based on purported health benefits (i.e. reduction in incidence of dental caries). Such claims are clearly medicinal according to Directive 2004/27/EC (i.e. fluorides at the dosages delivered exert metabolic or pharmacological effects). Sodium or potassium fluoride, as well as fluorides added to drinking water, have not been subjected to safety and efficacy evaluation as required for medicinal product market authorisation in the EU.
- There is a growing body of evidence of the harmfulness of sodium fluoride in drinking water. Four recent references are given:

  Cicek E, Aydin G, Akdogan M, Okutan H. Effects of chronic ingestion of sodium fluoride on myocardium in a second generation of rats*. Hum Exp Toxicol.* 2005 Feb;24(2):79-87.

  Dabrowska E, Balunowska M, Letko R, Szynaka B. Ultrastructural study of the mitochondria in the submandibular gland, the pancreas and the liver of young rats, exposed to NaF in drinking water. *Rocz Akad Med Bialymst.* 2004;49 Suppl 1:180-1.

  Shivarajashankara YM, Shivashankara AR, Bhat PG, Rao SH. Lipid peroxidation and antioxidant systems in the blood of young rats subjected to chronic fluoride toxicity. *Indian J Exp Biol.* 2003 Aug;41(8):857-60.

  Aydin G, Cicek E, Akdogan M, Gokalp O. Histopathological and biochemical changes in lung tissues of rats following administration of fluoride over several generations. *J Appl Toxicol.* 2003 Nov-Dec;23(6):437-46.
- The inclusion of fluorides in the Annexes infringes Recital 10 since many forms of fluoride (e.g. the forms added to drinking water) have not been proven to be safe at the dose ranges ingested by the public (see above). Owing to the dose-dependent toxicity of fluorides, addition of fluoride to foods or drinking water does not provide sufficient control over dosage (e.g. a sports person may consume more than 6 L of water a day during intense training or competition).
- Given that the Commission has agreed deletion of sodium chloride (common salt) from Annex II, the inclusion of fluorides in Annex II also cannot be justified.

USA

S.722 (108th Congress) Dietary Supplement Safety Act (Not yet introduced)

A bill to amend the Federal Food, Drug, and Cosmetic Act to require that manufacturers of dietary supplements submit to the Food and Drug Administration reports on adverse experiences with dietary supplements, and for other purposes. Introduced by Sen. Durbin. Had 4 co-sponsors. Durbin's office recently told us that they will be re-introducing this bill in early 2006 and that they are adding new language. They also sent us the list of organizations that support it and are working on gaining more support. Sen. Durbin may not re-introduce this bill if he finds that Sen. Harkin & Hatch's "compromise" AER bill (see below) meets his requirements.

Adverse Event Reporting (AER) for Dietary Supplements Bill (Not yet introduced)

A June 21 2004 debate on the Senate floor between Sens. Richard Durbin (D-Ill.), Tom Harkin (D-Iowa) and Orrin Hatch (R-Utah) resulted in an agreement to collaborate on legislation during this session of Congress creating mandatory adverse event reporting (AER) for dietary supplements. Spurred by Durbin's introduction of a Department of Defense (DOD) authorization bill amendment which would require companies selling certain dietary supplements on military bases to report serious AERs to the government. Harkin and Hatch immediately introduced an alternative amendment that would have required the Department of Health and Human Services to develop a national AER reporting system and report back to Congress within six months. The debate went from Dietary Supplement Health and Education Act (DSHEA), enforcement by the Food and Drug Administration (FDA), to ephedra and androstenedione and then to other dietary supplement topics. The debate concluded with an agreement to withdraw the amendments and work together to add a mandatory AER system to pending legislation classifying steroid precursors as controlled substances. The promised "AER Compromise" bill never happened in the 108th session so Sen. Durbin kept introducing his amendment to DOD authorizing bills as leverage to get the AER compromise bill going.

Well that time is about now. Sen. Harkin & Hatch are drafting with the assistance of HELP (Health, Education, Labor And Pensions) Chairman, Enzi an Adverse Event Reporting bill. Why are long-time supporters of dietary supplements Hatch & Harkin working with one of our most vocal opponents? Sen. Durbin has gained a lot of power in Congress by becoming Minority Whip (Democrat's second in command). Durbin needs Hatch & Harkin because he's not on the HELP committee (and they are) and he needs their support to get ANY type of AER bill through the committee. Any HELP Committee mark-up on the Harkin, Hatch, Durbin, Enzi FDA AER for Supplements bill is off the agenda until next year. No further negotiations have been held. As soon as we have more information on this bill, we will let our members know.

Other Developments

Antioxidant Analysis

The ANH Consultancy has been directly involved in research with Knight Scientific Ltd (www.knightscientific.com), a world-leading, independent antioxidant and free radical research laboratory in the UK, analyzing the relative antioxidant capacities of a range of multivitamin and mineral supplements, as compared with 2 smoothies and a popular proprietary vegetable juice. Both product groups are increasing in popularity and it is important to appreciate their relative contribution to the daily antioxidant quota from our conventional diet. The results showed that the best vitamin and mineral supplements tested delivered similar antioxidant capacities to the best smoothies, but the best supplements, ironically, considering the processing required, turned out to be considerably more cost effective for an equivalent antioxidant ‘punch’. The Knight Scientific ABEL assay using challenges with peroxynitrite or superoxide are the only assays known which allow comparison of whole products, such as supplements or foods. ORAC assays and similar, involve extraction of specific antioxidants from foods or supplements so do not reflect the true antioxidant of the whole product. For further information, please contact ANH Consultancy on info@anhconsultancy.com or telephone +44 (0)1306 646 553.

UK Trade Shows

- ANH held a booth at the Natural Trade Show in Brighton, Sussex, 12-13 March, and Dr Robert Verkerk made a presentation in the Keynote Theatre entitled ***Let Thy Food Be Thy Medicine: Using Good Science to Stay the Right Side of the Law***.

  "Based on media reports and various utterings in the trade press you may have felt that the European Court ruling on food supplements achieved nothing. Nothing could be further from the truth. Find out in this presentation what's really going on and learn how manufacturers, distributors, retailers and practitioners can use the Court's ruling to their business' advantage. Directives affecting herbal products, novel foods and GMOs are perceived as obstacles for many products of therapeutic value. Although other legislation in the pipeline may create serious obstacles, discover how ANH is helping people to stay the right side of the law."

- ANH will be taking a booth at the Natural Products Trade Show in Olympia, London 9-10th April (14.30 h), and Drs Damien Downing and Robert Verkerk will be giving a lecture entitled ***Winter colds, influenza or bird flu: The use of natural products in immune system modulation.***

  "*Find out why so many people's immune systems struggle to cope with viral infections. Drs Damien Downing and Rob Verkerk present the latest evidence on how natural products can be used to modulate the immune system and show how some well known immune boosters can be counter-productive. A* ***must*** *for practitioners*."

US Institute for Functional Medicine

- Dr Robert Verkerk and Meleni Aldridge will be attending the 13th International Symposium on Functional Medicine in Tampa, Florida, 19-23 April - ***Managing Biotransformation: The Metabolic, Genomic and Detoxification Balance Points***. We look forward to meeting with any of you who intend to be present.

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

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