alliance for natural health

"Good Science, Good Law"

ANH INNOVATORS CLUB BULLETIN

Amalgamated issue Sept/Oct & Nov/Dec 2006

Regulatory Developments

Codex Alimentarius

Report from meeting of Codex Committee on Nutrition and Foods for Special Dietary uses (CCNFSDU), 31st Oct – 3rd Nov, Chiang Mai, Northern Thailand

Dr Robert Verkerk sat in the Committee as scientific advisor to the National Health Federation, the only health freedom group in Codex with delegate status. Meleni Aldridge attended as an observer. Dr Verkerk's involvement within the Electronic Working Group (EWG) which meets separately from the main Committee, meant that some of the ANH's key concerns regarding existing, 'classical' risk assessment methodologies were brough to the fore and are being tabled as major discussion points as the principles evolve.

It was disappointing that so little time was given over to critical issues such as risk assessment, nutrient reference values and health claims in the main CCFNSDU meeting, and it seems that the Secretariat might be quite happy to see advancement of EU work in this area so that it might act as a template for the Codex.

An interesting observation made by both ANH members attending the meeting, was that there seemed to be a lot of harmony between the US government's delegation (led by Barbara Schneeman) and that of the European Commission (headed by Basil Mathioudakis). This, in our minds, rings alarm bells in terms of future plans of the FDA and should be considered in the light of what emerges from the FDA's consultation on functional foods.

For a summary of what went on at the Chiang Mai meeting, please go to the following link on the ANH website news pages:
http://www.alliance-natural-health.org/index.cfm?action=news&ID=257

Codex Committee on Food Labelling (CCFL). 35th session – definition of advertising

Summary: The ANH has made a direct submission to the UK government delegation following its request for input from the ANH as an interested party. We have identified a number of problems with the proposed definition (see p. 2).

The greatest concerns relate to how such a definition affects what presentations constitute an advertisement and it could have significant bearings on both EU legislation (e.g. EU medicinal law and the proposed nutrition and health claims regulation) as well as laws in other countries. The problems would be greatest if the definition itself was incorporated into a given country's legislature.

We have addressed this issue both by identifying a series of problems, as well as by presenting what we believe to be a workable solution, which is by providing specific exclusions to the definition. We have proposed exclusions for peer reviewed science, journalism/opinion and education.

The text of the ANH submission follows:

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ANH submission to UK Food Standards Agency re Codex Committee on Food Labelling

The ANH foresees a number of very substantial problems with the proposed definition, these being of such significance that in our view they effectively make the proposed definition unworkable.

The Proposed Draft Definition of Advertising in relation to nutrition and health claims about which interested parties have been invited to input is:

> *"Advertising: any representation to the public, by any means other than a label, that is intended or is likely to influence and shape attitude, beliefs and behaviours in order to promote directly or indirectly the sale of the food."*

The other definitions of direct relevance are:

> *"the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods and services, including immovable property, rights and obligations".*
> - Council Directive 84/450/EEC on misleading advertising defines advertising

> *"includes any notice, circular, invoice or other document, and any public announcement made orally or by any means of producing or transmitting light or sound, but does not include any form of labelling"*
> - UK Food Labelling Regulation 1996

We summarise some of the problems we anticipate with the proposed definition below:

- **Remit of the definition**. Any advertising suggesting particular nutritional uses for a product will effectively be viewed as a health claim, meaning that if the health claim is not approved, any advertising containing an unapproved health claim would be illegal. It also means that any advertisements containing health claims (approved or unapproved) may well cause the food product(s) in question to fall under the definition of a medicinal product under EU law. This is of particular concern given the widening of the scope of EU medicinal law under the latest amendment of Directive 2001/83/EC via Directive 2004/27/EC (Article 2(2))

- **Emerging science**. Advertising, based on the proposed definition, would include all verbal statements. This would mean, for example, that a presentation made by a company to potential customers in which findings from a scientific study were presented would be viewed as advertising. This would block any dissemination of emerging science if the dissemination were to occur in a commercial context, given that emerging science is unlikely to be sufficient to allow scientific substantiation of health claims (in the context of the current proposal for the EU Regulation on nutrition and health claims for foods)

- **Advertisements including scientific references**. Any advertisement that attempted to inform consumers of the value it places on science, would be prevented from including reference to peer-reviewed scientific journals if the implied health claim made in the journal, or, in the advertisement as a whole, was not (yet) an approved health claim

- **Disproportionate impacts on small businesses**. If a company is prevented from promoting its emerging science to potential customers, it is very difficult for them to fund further studies to allow the development of more conclusive findings that would be accepted in the 'scientific substantiation of claims' process. Given the current consultation by the European Food Safety Authority (EFSA) on the feasibility/advisability of receiving fees for processing authorisation files, small to medium-sized enterprises (SMEs) will find it increasingly difficult to meet the regulatory burden. SMEs, it should be appreciated, are effectively being asked not only to provide greater amounts of scientific evidence to substantiate claims, which it appears they cannot communicate to support sales until such time that any claims implied are approved by the EFSA, they may also find that fees required for substantiation itself act as major constraint

- **Education**. Any educational literature or website which refers to published scientific research that was used directly or indirectly by a company commercially would come under the remit of the proposed advertising definition. This would mean that the UK Medicines and Healthcare products Regulatory Agency's (MHRA) advice summarised in their document 'Borderline Section and the Internet' (see MHRA Technical Guidance Note 8) would be illegal unless the implied claims suggested by the science were claims approved by the EFSA

- **Freedom of opinion and expression.** Most of the work of the Alliance for Natural Health (ANH), and other non-governmental organizations with similar interests in the promotion and protection of natural healthcare, could be perceived (given the proposed definition) as advertising for the companies which are listed as supporting the ANH's work. This is clearly nonsense and a major infringement of Article 19 of the UN's Universal Declaration of Human Rights, viz: "Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers."

Following from this, we see that the main way of resolving these problems is not so much by modifying the proposed definition, or using any of the alternate definitions (above) which in themselves provide no resolution, but rather by including **comprehensive exclusions**, which would include:

- **Peer-reviewed science.** Any reference to or inclusion of data from peer-reviewed scientific research must be fully excluded from the definition (although we accept that interpretations of the research by the advertiser may be perceived as advertising and be subject to health claims regulation)

- **Journalism and opinion.** Journalistic articles and other opinion pieces must be excluded, even if these are used on advertising materials (including websites) that involve commerce, as any restriction on these is an infringement of individual freedom of opinion and expression

- **Education**. Written, oral or other information which is of an educational nature, on the condition that this information does not also include directly in its presentation the commercial sale of food products, should be exempt from the definition.

We hope that the Food Standards Agency will consider these concerns in its submission to the Codex Committee on Food Labelling (**closing date 15th December 2006**) as the proposed definition, without any modification, would lead to very serious problems, both for SMEs, but also for regulatory enforcers.

However, it is ironic that it is the consumer who is set to be the ultimate loser if the proposed definition is not amended, the very group that Codex guidelines seek to protect.

We would ask all companies to lobby their competent authority, trade associations and/or consumer associations on this issue as a matter of urgency. Should you require a separate copy of the ANH submission for forwarding, please email mel@anhcampaign.org

European Union

Commission invites consultation on proposal for European Food Safety Authority (EFSA) fees

The Commission is carrying out a consultation to gather the views of interested parties on the feasibility and advisability of presenting legislative proposal enabling the EFSA to receive fees for processing authorisation files. Please click here for the full explanatory document, making special note of the questions posed in 4.3 and 5.3 which form the basis for the submission.

Of some considerable concern is the fact that the proposal appears to be using the European Medicines Agency (EMEA) fees as an example, with fees in ranging from €232,000 down to a €90,000 for applications relating to human medicinal products, however they do offer discounts of up to 90% for SMEs. The two main options that are being considered for EFSA are i) every applicant pays a set fee for an authorisation file or ii) only applicants with profits specifically vested in the authorisation must pay a fee. The second option is only viable if the following distinctions can be made:

- Those in which the marketing authorisation is granted to a specific person who is the authorisation holder. In these cases the instrument of the individual decision issued to the holder is essentially used to grant the authorisation, and it can be assumed that the holder gains a particular benefit

- Those in which a substance or product would be authorised generically (placed on a positive list). Here there is essentially no holder of the authorisation, and legislation with general scope is used to authorise the substance or product. Once the conditions for the marketing and use of the authorised substance or product have been set up, it can be marketed and/or used by anyone provided that it appears on the positive list and the conditions of use laid down in law are complied with. In such a situation, since the authorisation is general, there would seem to be no clearly identified individual beneficiary and the applicant could be one of several who might profit from the authorisation.

The second option looks like a potentially safe haven on the surface, but on deeper consideration does not offer any real protection as the Commission goes on to identify the original holder of the intellectual property rights as being the overall beneficiary of authorisation files. Even the Commission realises the impracticability of following this route and brings the argument back to charging set fees for applying for authorisation files.

For clarification, the following processes, related to the dietary supplement industry sector, fall under EFSA's remit:

- Applications for the FSD Positive List (only applies to vitamins and minerals currently, but will apply to botanicals in 2007)
- Applications for the FSD Derogation List (which is open until December 2009) and any rejections based on unfavourable reviews
- Applications for product specific health claims as per Nutrition and Health Claims Regulations (NHCR) which is due to come into force in May 2007

The closing date for this consultation is 15th February 2007 and we would be grateful for input from the Innovators to include in the ANH submission. We would also urge any companies considering applications for both the Positive List and NHCR, to do so as soon as possible. We feel that the writing is pretty much on the wall with regard to an EFSA fee structure and as such, applications should be made before this comes into force.

The ANH view on the future of selling dietary supplements into the medical community in the EU

Many people wonder what effect future EU laws will have on the ability of doctors to prescribe nutrients. The question was recently raised again by a Board member of our affiliate in the USA, the American Association of Health Freedom, and as it has a direct relevance for both US and EU companies selling into the medical community in Europe, we've included the answer in this issue of the bulletin.

Question:
Under the new EC legislation relating to supplements, if a supplement or supplement potency is not allowed to be sold to the general public, could a licensed doctor prescribe it? If so, could the doctor prescribe it at will or only if the supplement or potency had been prior approved as a drug?

Answer:
Medical doctors need to abide by what is euphemistically described as "good clinical practice" and if they don't, they run the risk of being struck off the medical register in the country in which they practice. In general terms, this means in the UK for example, that they need to adhere to the guidelines set by the NHS (see http://www.prodigy.nhs.uk/). These guidelines are influenced heavily by those produced by the National Institute for Health and Clinical Excellence (NICE).

In many areas in which any good clinical nutritionist would prescribe nutrients (e.g. atherosclerosis), there are no indications for use of nutrients in this guidance. Then when you look for very obvious areas such as osteoporosis, you will see that the guidance is heavily tilted towards drugs (biphosphonates and strontium ranelate, both actually derived originally from natural products), and any references to nutrients such as vitamin D and calcium can only be found in supporting evidence and the recommendations are far from cutting-edge:

e.g.
http://www.prodigy.nhs.uk/osteoporosis_treatment_and_prevention_of_fragility_fractures/extended_information/management_issues

In the few areas where there is limited clinical guidance offered for specific conditions such as osteoporosis or alcohol abuse, high dose, licensed vitamin and/or mineral preparations are available in the UK on the NHS (and elsewhere in the EU given central licensing through the European Agency for the Evaluation of Medicinal Products [EMEA]), but ironically - and very importantly - these do not generally match the latest nutritional/nutrigenomic science. The nutrient therapies are also frequently adjuncts to drug therapies and the nutrients supplied by the NHS in the UK and elsewhere in the EU are produced and marketed by drug companies.

Saying this, a range of licensed nutrients are available for intravenous use and these are used by some 'alternative' doctors, but should the doctor make a claim that these nutrients are being used as a component of chelation therapy for heart disease, this could be viewed as a breach of 'good clinical practice' and could result in an enquiry, which in turn may lead to a suspended or revoked medical license.

A medical doctor, at his/her medical discretion, particularly in the private sector, can go outside this guidance, but - crucially - any significant departure from the guidance increases his/her exposure for a malpractice enquiry or prosecution by the relevant medical governing body, the General Medical Council (GMC) in the UK. I have included a couple of UK cases for your perusal:

Vitamins/natural products in cancer therapy:

http://www.gmc-uk.org/concerns/decisions/search_database/ftp_panel_schreiber_20060504.asp

Prosecution for using natural thyroid hormone (T3/T4 combination) rather than the synthetic drug thyroxine (T4 only) (T3 is the active form in the body and some people have difficulty with the T4 to T3 conversion):

http://news.independent.co.uk/uk/health/story.jsp%3Fstory=73194

Once international risk assessment procedures have agreed upper/maximum safe levels for vitamins (and subsequently other nutrients), it will provide medical authorities with more leverage to regard a 'high dose' recommendation or prescription as unsafe, unless it is specifically licensed or approved.

I know this outlook is rather bleak, but it emphasises why it is of such key importance to completely review risk assessment procedures which you will know is one of the central projects in ANH's remit. Furthermore, it is imperative that further nutritional research is undertaken and positioned to challenge medical guidance in favour of nutrient-based therapies where there is appropriate evidence.

URGENT: calls for action Please Respond!

1. We would be very grateful for your feedback on the consultation process regarding the possibility of EFSA charging fees for processing authorisation files and would ask that you reply no later than **25th January 2007**.

2. Companies wishing to apply for the Positive List regarding vitamin and mineral supplements, or for specific Health Claims approval, should do so immediately given the threat of potential EFSA fees. The ANH strongly recommends this course of action, rather than going for derogations, as they can be withdrawn at any stage if an unfavourable review is given by EFSA and this is only a safe haven until December 2009. **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.**

3. Urgent request for companies to get behind the ANH submission to the consultation regarding the proposed draft definition of advertising in relation to nutrition and health claims under consideration by the Codex Committee on Food Labelling. Deadline for submission **15th December 2006.** Submissions can be made to competent authorities, trade or consumer associations or to the Codex Committee at:

   Mr. Ron Burke, Director
   Bureau of Food Regulatory, International
   and Interagency Affairs,
   Health Products and Food Branch,
   Health Canada, Bldg No. 7, Room 2395,
   Tunney's Pasture, Ottawa K1A 0L2,
   Canada
   Fax No. 613.941.3537
   E-mail: codex_canada@hc-sc.gc.ca

   With a copy to:

   Secretary
   Codex Alimentarius Commission
   Joint FAO/WHO Food Standards
   Programme - FAO
   Viale delle Terme di Caracalla
   00100 Rome, Italy
   Fax: +39 (06) 5705 4593
   E-mail: codex@fao.org

4. **US Innovators:** With the fiscal year in the United States drawing to a close, we would like to remind companies that fully tax deductible donations 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 restricted to 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

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

Please email our Development Manager, Meleni Aldridge, at mel@anhcampaign.org or telephone +44 (0)1306 646 551, with your input on the consultation processes or for additional support on either Positive List or health claim applications.

USA

AER bill update

There has been a lot of buzz from activists in the past few days that Congress was going to be acting very fast on the AER bill.

American Association for Health Freedom (AAHF) feels that there is a (small) possibility that this bill could be acted on before the 109th Congress ends, but it is difficult to tell definitely at this time.

The Senate convened on Thursday Nov 16th and will not be back in session until December 4th, so nothing can be acted on until then. They will be in session approximately 12 days in December (zero days in October and only five days in November). They have agreed to work on certain bills (none of which are the AER bill) and of course there is the confirmation hearing of Robert Gates for Secretary of Defense.

The bill was introduced by Senator Hatch and currently has 5 co-sponsors (Senators Harkin, Durbin, Kennedy, Cornyn, and Enzi). There is also strong support from Democrats and from members of the health committee. AAHF has contacted a couple of Congressional offices and there appears to be no "knowledge" of activity on the bill yet, but we did hear that Senator Hatch was coming back on Monday 27th – a full week earlier than the session convenes. As lead sponsor, could he be coming in to work on votes?

On the House side, there are only two sponsors and there seems to be little interest in moving the bill forward (and the usual suspects are not on the bill – Waxman, Davis, Dingell, etc.).

There is concern that with Democrats gaining control of Congress, they will introduce an even worse bill. AAHF does not agree with the philosophy of supporting a bad bill, so an even worse bill will not be introduced. Work hard, then work harder to stop them both. AAHF is currently meeting with lobbyists in order to hire the best candidate to handle health freedom issues with the new Congress.

ANH/AAHF joint submission to FDA on Functional Foods debate

The Food and Drug Administration (FDA) has announced a public hearing on the regulation of certain conventional foods that companies are marketing as ''functional foods.'' The purpose of the hearing is for the agency to share its current regulatory framework and rationale regarding the safety evaluation and labelling of these foods, and to solicit information and comments from interested persons on how FDA should regulate these foods under the agency's existing legal authority.

Mike Ruggio, attorney from the Washington-based firm Manatt, has agreed to attend the meeting on Tuesday 5th December to make an oral presentation on behalf of the AAHF/ANH. The proposed approach and written inputs have been developed largely by Dr Rob Verkerk of the ANH and have been agreed by the Boards of both organizations. The full presentation will be published in the next IC bulletin.

For your information the public hearing will be held on Tuesday, 5th December 2006, from 9 am to 4.30 pm at the FDA Centre for Food Safety and Applied Nutrition in College Park, Maryland.

A summary of the oral presentation was made on 28th November, while full written or electronic comments need to be submitted until 5th January 2007. The administrative record of the hearing will remain open until 5th January 2007.

For further information, please find the full document attached to this email.

For further information about the ANH,
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