

ANH INNOVATORS CLUB BULLETIN

May/June 2006

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News - *EU derogation dossiers under threat*

In this issue we have decided to focus on one main area due to its extreme importance and the potential ramifications for companies selling dietary supplements into countries in the European Union.

There have been some recent approaches by the UK Food Standards Agency (FSA) to leading-edge companies (in turn passed on to the ANH) which suggest that the UK government (read: Dept of Health, FSA, Medicines and Healthcare products Regulatory Agency [MHRA]) is buckling under pressure from the European institutions to move towards the ‘original plan’ for food supplements in the EU, as depicted in the Food Supplements Directive (FSD).

This is very concerning, albeit somewhat predictable, and suggests that European Member States are ignoring the gains made by way of the European Court Judgement (ECJ) ruling in July 2005.

It appears there is now a significant risk that key dossiers will be withdrawn at very short notice. We know that the UK FSA is actually making recommendations to the European Commission to have particular dossiers withdrawn. For example, in a letter to an Innovators Club Gold Member, dated 6 June, the FSA recommend withdrawal of several dossiers relating to safe, food form ingredients. Quoting from Dr Clair Baynton (Head of Novel Foods, Additives and Supplements Division, UK FSA):

“ I am writing to inform you that the Food Standards Agency will inform the Commission that the dossiers submitted by you for the substances listed above in paragraphs 2, 3 and 4 should be withdrawn.”

The letter demonstrates that the FSA is using a very simplistic, nomenclature-driven approach to accepting nutrient forms under either the positive list or derogations via dossiers. The likely inference from this is that all ‘simplified dossiers’ will likely be withdrawn. They often have not appreciated the chemical form of the substance and we have had to demonstrate the different names for single substances to prevent substances from being withdrawn.

One area that is promising is that the FSA is accepting vitamin and mineral forms that are altered following their reaction in vegetable cultures, on the condition the nature of the vegetable cultures is explicit and the forms added to the cultures are positive list or derogated forms.

This cooling off of the UK position provides a stronger reason than ever to ensure that the ANH is able to go back to the High Court to finalise its legal challenge and we are presently awaiting the allocation of a Court date. It is imperative that clarification be obtained through the Court for the lack of transparency that continues to be an issue with the ECJ Ruling on the FSD. This case will set a key precedent not only for vitamins and minerals, but almost more importantly, for other nutrient forms such as botanicals, amino acids, essential fatty acids, enzymes, probiotics, etc.

The most pressing problem for companies is that now not only are substances for which dossiers were accepted after the 25th July 2005 cut-off period, on the market illegally, but substances currently protected by earlier dossiers may be at risk if those dossiers are subsequently refused.

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ANH Recommendation:

We ***strongly urge*** companies to begin the process of applying to the vitamins and minerals Positive List without delay in order to safeguard the products currently enjoying sales across the UK and rest of Europe. Please find attached to this email the current data requirements for application to the positive list. Central to our case in the High Court, will be agreement that these requirements go beyond the legal requirement of the Directive and we will be submitting a proforma which we and our lawyers believe is compliant with the Directive. We have been asked by the UK government to keep this proforma confidential for the present time.

Following the detailed Opinion from Paul Lasok QC on the ECJ Ruling, the ANH has been instrumental in developing a new framework for a classification system of vitamins and minerals, including natural sources, based on the natural sources arguments used by the ANH in its challenge as well as the response in the ECJ ruling. Like the proforma application, we have also been asked to not release this publicly while it is considered by the opposing party, in this case, the UK government.

So, although we cannot release this information widely, through the ANH Consultancy Ltd, we are able to use these data to assist you in making your applications to the positive list which will be forwarded to the European Food Safety Authority (EFSA), should you require it.

Please note that Gold Members are entitled to a 20% discount on consultancy fees, in addition to two free hours of our consultancy a month.

The key issue facing the ANH is making sure we have sufficient funds (ca. £40 k) to proceed once we have a date and we would welcome any creative suggestions for a funding drive through your respective networks. Please contact Meleni Aldridge (mel@anhcampaign.org) to discuss this further.

A call for action

..... as highlighted in last month's bulletin:

Nutrition and Health Claims Regulation avoids conciliation

In the last issue of the bulletin we put out a call for companies to assist us by submitting a list of generic claims for specific nutrients. To date I have not received any inputs and would remind you of the following and request your assistance:

“Probably of equal significance to the Food Supplements Directive in the EU, the Nutrition and Health Claims Regulation has been voted through the European Parliament via a compromise package. This deal at least has avoided the fate of the Regulation being decided by the European Commission and Council of Ministers in Conciliation, behind closed doors.”

For a detailed briefing on the Regulation, please refer to ANH's public affairs briefing on the Regulation [published on the ANH website on 16 May 2006](#).

Critically important now is for the natural products industry, particularly the innovative sector, to determine the range of generic claims that may be of interest to the industry over the coming years.”

CALL TO COMPANIES: We ask that companies submit by **end of June** a list of all generic claims for specific nutrients (not just vitamins and minerals, but also essential fatty acids, amino acids, phytonutrients, herbals, probiotics, prebiotics, etc.) about which they are interested. These will be used in ANH submission's to the EU to widen as far as possible SME (small to medium sized enterprise) generic claims. **Please email mel@anhcampaign.org with your proposed generic claims by end of June at the latest.**

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