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eBULLETIN

Quarterly Bulletin **Issue No1 - 1st quarter 2009**

Technical Issues: End of FSD Derogation Period

The EC Food Supplements Directive 2002/46/EC, Article 4(6) derogation period ends on 31st December 2009 and companies need to prepare their product lines accordingly.

Vitamin and mineral substances permitted for use in food supplements are subject to changes from the end of this year given the upcoming end of the derogation period. Substances have been classified into three groups, as follows:

1. Substances benefiting from derogation

Which receive a favourable opinion from the European Food Safety Authority (EFSA) and, subject to a decision by the European Standing Committee on the Food Chain and Animal Health (SCoFCAH), will be added to the list in Annex II to the Directive. This will permit their continued use after 31/12/09.

2. Substances without favourable opinion from EFSA

Will not be added to the list in Annex II of the Directive and will not be permitted for use in Food Supplements after 31/12/09. Any food supplements containing these substances which are on the market after this date will no longer comply with the FSD and must be removed from the market.

3. Substances with negative opinion from EFSA

For example the six vanadium substances which were given a negative opinion and no longer fulfil a legal condition for maintaining the derogation. It is now an offence under the Food Supplements Directive (refer to individual Member State statutory regulations) to sell any products containing substances which have received a negative opinion.

A number of vitamin and mineral substances subject to the derogation have already received EFSA opinions. The European Commission has indicated that it expects that EFSA will have completed their assessment of remaining dossiers by the end of May 2009. ***No extension of the derogation period is planned.***

Please see Annex A for substances which SCoFCAH consideration is pending.

Annex B lists 145 individual substances no longer permitted in food supplements (dossiers withdrawn).

Annex C lists 76 substances no longer permitted unless new dossiers are submitted.

(See ANH analysis on p. 3)

EU Court Ruling infringes speech

On Thursday 2nd April a landmark ruling was issued by the European Court of Justice which will dramatically influence reporting about the benefits of natural products used in healthcare. The ruling on Case C-421/07 relates to the Danish government's criminal proceedings against a journalist, Frede Damgaard, regarding "dissemination of information about a medicinal product by a third party acting on his own initiative".

Read the full ANH opinion.

What it means for companies:

1. In recent years, within Europe, companies have been able to grow their businesses faster by allowing third parties and journalists to write independently about their products.
2. Previously the term 'advertising' has been something that only a commercial operator such as a manufacturer or retailer can engage in.
3. This case which effectively turns what we consider to be a wayward ruling by a Danish regional court, into European law, which is technically effective immediately. It means that any suggestion given by a third party, such as a journalist/PR, that a particular product (not generic ingredient) can be used to prevent or treat a disease, can be construed both as advertising and as a medicinal claim.

(*Continued p. 3*)

EFSA approves forms of Ca, Mg & Zn

The European Food Safety Authority (EFSA) has found calcium ascorbate, magnesium ascorbate and zinc ascorbate safe for use in food supplements.

After a request from the European Commission to EFSA's Panel on Food Additives and Nutrient Sources added to Food (ANS), the sources of calcium, magnesium, zinc and vitamin C were found to present no safety issues at typical doses across the 27 Member States in the EU.

The ANS noted a minor concern that "*when dietary intake is taken into consideration, in the case of food supplements providing 66.5 mg zinc ascorbate or above, the Tolerable Upper Intake Level (TUL) for zinc established by the SCF will be exceeded.*"

Suggested intake levels of 1500mg of calcium ascorbate per day were within established limits of 2500mg. Levels of 1120.8 mg for magnesium ascorbate were well within a TUL of 2500mg per day. Zinc ascorbate, only those above the 97.5th percentile of all adults and children of all ages would exceed the TUL.

The dossiers on magnesium and zinc were submitted by Natuur- & gezondheids Producten in the Netherlands. The calcium dossier was submitted by Solgar in the UK.

EU Regulatory Overview

A full ANH summary to the key areas of EU legislation: FSD; MPLs; NHCR, THMPD and key actions for companies selling food supplement products.

We are reaching a key time in company decision making when it comes to ensuring compliance of high-end, specialist foods/dietary supplements sold within the EU market as it is subjected to a series of EU Directives and Regulations applying to the sector. Of particular concern are a) food supplements containing vitamins, minerals and botanicals; b) herbal products that are potentially eligible under the simplified medicinal registration scheme offered by the Traditional Herbal Medicinal Products Directive, and; c) health claims under the Nutrition and Health Claims Regulation, including both claims that can benefit from transitional measures and implied claims contained in brand names.

For those of you that missed the Special Bulletin in December last year, we detail some key areas of EU regulation relating to food supplements, after which can be found (Section 5) a key list of urgent actions required by companies to help ensure compliance of particular food supplement products, ingredients and supporting marketing material and websites.

Download the Special Bulletin.

EU Court Ruling infringes speech

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4. Such breaches of Directive 2001/83/EC bring with them potential criminal prosecution.

5. The case has a direct bearing on third party websites which have up until now been important sources of information for consumers about 'medicinal effects' of food supplements.

6. The Advocate General's opinion in the case takes a much more balanced view on the importance of the freedom of the press and recommends that where there is no connection between the journalist and the commercial operator, the publication is not viewed as advertising. However, many of the Advocate General's sensible views were ignored in the final ruling.

7. The case is apparently going to be appealed by Frede Damgaard and we would hope that more of the Advocate General's viewpoints are taken on board.

8. **Bottom line:** all companies need to urgently review all advertising and promotional material as well as other materials and websites used by third parties which contain information about their products to determine their exposure under the terms of this ECJ ruling. ANH Consultancy (email info@anhconsultancy.com) can facilitate this process where required.

ANH analysis of current status of Annex II applications to the FSD

With just 8 months left for the expiry of the derogation period, any company that is reliant on vitamin or mineral ingredients that have not yet received a positive opinion from EFSA, must take immediate action.

Here is a checklist for how to proceed:

1. Is you ingredient on Annex II of the FSD (Directive 2002/46/EC)? If so, the ingredient can continue to be used.

2. Is the ingredient on the subsequent amendment (amending Directive 2006/37/EC) which adds calcium L-methylfolate and ferrous bisglycinate to Annex II? Again, if so, the ingredient can continue to be used.

3. If neither of the above apply, check for the ingredient on Annexes A, B or C (see p. 1, column 3 of this Bulletin) to find out the status of the vitamin or mineral source. If it is neither on Annex II, nor on either Annex B or Annex C, and you have a strong interest in the ingredient, we would recommend strongly that you make an application to Annex II. There are specific requirements for this which includes characterisation data for the ingredient, as well as supplying evidence of safety and bioavailability. ANH (info@anhcampaign.org) can supply you with the data requirements or ANH Consultancy (info@anhconsultancy.com) can work in confidence with you and help you with the application.

There are a number of anomalies with Annexes A, B and C. Some of the obvious ones are:

Annex A

- 'Tocotrienol tocopherol' presumably relates to a form of vitamin E containing various tocopherol and tocotrienol isomers. However, if this dossier is unsuccessful, it would lead to a ban on tocotrienols, except those contained in natural sources, as clarified in 2007 between the ANH and the European Commission following the ANH's judicial review of the FSD.

Annex B

- The calcium salt of '5 methyl tetrahydrofolate' is already approved under the amending Directive of 2006.

- The most common form of coenzyme B12, namely methylcobalamin, has already been granted a positive opinion by EFSA.

- Natural sources of 'provitamin A carotenoids' are already permitted as food additives and as natural sources outside the scope of the Directive, as clarified by the ANH (as above).

Annex C

- 'Iodine from kelp' is outside the scope of the Directive and benefits from the natural source exclusions secured by the ANH (as above).

Other comments:

It is of paramount importance that new dossiers are assembled and submitted within the coming few months for particular nutrients which will otherwise be completely banned until such time that a successful dossier is submitted. One particular example is that of silver, which appears as 'colloidal silver' and 'silver hydroxide' in Annex C. Other examples include other minerals such as vanadium and strontium.

In order to minimise a company's risk, it is important to use as many forms of vitamin and mineral that have either already been approved for Annex II are are likely to be by 31 December 2009, namely those on Annex A. In addition, the use of natural sources derived from food plants is an alternative strategy.

Finally, it is important to recognise that Annex II of of the FSD is permanently open, so submissions can be made at any time, including after the expiry of the derogation period. However, this would mean that ingredients that are presently derogated would be banned as of 1 January 2010 until such time that EFSA had positively evaluated a new ingredient and the appropriate amendment had been made to the base directive (Directive 2002/46/EC) to allow addition of the ingredient to Annex II.

A personal message

from Dr Robert Verkerk, Executive & Scientific Director

We are approaching one of the most difficult transition phases in the regulatory environment for any natural health product selling in any of the 27 European Member States. The fact that regulations such as the Food Supplements Directive, the Traditional Herbal Medicinal Products Directive (an issue we will consider in detail in our next bulletin) and the Nutrition and Health Claims Regulation are all in transition means that it is difficult to predict in absolute terms exactly how the land will lie, say by 2012. This makes planning difficult but our continuous engagement with EU regulators and companies bringing new products to the EU market, as well as our actions in helping companies which are challenged by specific regulators, means that we are in a unique position to offer support to the 'leading edge' of the industry.

In addition to this we have been forging ever stronger links with organisations and practitioner associations throughout the world; this global involvement helps us to see the 'big picture' of where global regulations are going and how to influence it to ensure the scientific and regulatory framework is shaped optimally to support your business interest.

We have recently expanded our campaign to two issues of key importance to natural health: GM food and Vaccine Choice.

On 12th April I gave a keynote address on how GM issues are affecting the natural products sector at Natural Products Europe 2009 in London. There is a lot of work to be done in making this industry fully cognisant of the importance of GM to all of our futures.

We thank you for your support and hope you'll find our recent developments in the ANH Innovators Club a significant step in the right direction. We look forward to receiving any comment or feedback through our Exec. Coordinator, Meleni Aldridge, at mel@anhcampaign.org.

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The ANH Consultancy Ltd (ANHC) was established in 2005 as a sister company to the Alliance for Natural Health (ANH). The consultancy offers some of the leading experts worldwide in their respective fields to companies, government agencies and other organisations for confidential, project-specific consultancy services in the natural and sustainable health arena.

The ANHC benefits from the years of cumulative experience of its experts in the natural health or sustainable healthcare and food-related industries, and its association with the ANH. Key services include:

- Educational programs, information services and public awareness campaigns
- Food, food supplements, cosmetics and organic products regulatory compliance
- Assistance in avoiding medicinal product or novel foods classification
- of food and supplement products in the EU
- Reformulation advice, product enhancement and labelling advice
- Health claims advice and dossier preparation
- Design of human and other trials (including bioavailability and efficacy studies)
- Development of core claims documentation

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