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PRESS RELEASE
For immediate release

16 March 2007, Dorking, United Kingdom

ANH puts spotlight on EU procedures for food supplements following European Court judgment

The Alliance for Natural Health has today informed the European Commission that it will scrutinise its procedures and those of the European Food Safety Authority on food supplements, in accordance with a European Court of Justice (ECJ) judgment.

On 12 July 2005 the European Court of Justice (ECJ) in Luxembourg delivered its judgment on a case brought by the EU-wide Alliance for Natural Health (ANH), along with two UK health food associations. The case challenged the EU Food Supplements Directive potential ban on thousands of food supplement products on the EU market that contain nutrient forms not listed on the 'positive list' of the Directive.

ANH files applications to create legal precedent

The ANH has filed 15 applications to the Directive's positive list as a means of testing the European Commission and European Food Safety Authority's procedures, which were referred to as having the "transparency of a black box" by the ECJ's Advocate General Geelhoed in April 2005. This flaw was regarded as being of such a profound nature that the Advocate General made a recommendation to the ECJ that the Directive be invalidated.

When the ECJ delivered its ruling some three months later, the Directive was upheld – but on the condition that the procedures for adding vitamin and mineral ingredients to the Directive's limited positive lists were made fully transparent and carried out within a reasonable time frame.

The ANH has been engaged in correspondence with the relevant authorities, including the UK Food Standards Agency, the European Commission and the European Food Safety Authority, on all aspects of the procedure and time lines for applications to the positive list and has yet to receive adequate, clear responses.

"*The European Commission and European Food Safety Authority appear to be ignoring the ECJ's ruling and continue to be operating within their black box*," says Dr Robert Verkerk, Executive & Scientific Director of the ANH. "*It's critically important now that we establish proper procedures for permanently adding vitamins and minerals to the Directive's positive list, using the clarified procedures set up by the European Court, especially as derogation dossiers, some of which were very brief, could be rejected at any stage.*"

The Directive only lists 15 minerals, when scientific research has shown that many more are needed for optimum health, at dosages greater than those found in most contemporary diets. Among the ANH's 15 applications, nine are applications to have additional minerals, including sulphur, strontium, vanadium, boron and lithium added to Annex I of the positive list.

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The European Court clarifies the criteria required for positive list applications

The ECJ also spelled out the criteria required for applications to the positive list. The ECJ made it clear that the only criterion required to have a vitamin or mineral added to the positive list (Annex I) was that it be normally found in and consumed as part of the diet. In its nine test applications to Annex I of the Directive, the ANH has demonstrated, using peer reviewed, published scientific research or government nutrient intake statistics, that all these substances are normally found in the diet. However, scientific research shows that their concentration is often insufficient for optimum health, hence the value of supplements containing these substances.

The ECJ also stipulated that two criteria were required for applications to Annex II of the positive list, which contains the vitamin and mineral forms which may be used in the manufacture of food supplements. The current list contains only 114 forms, while more than 400 forms have been used safely for decades. A ban has yet to occur since the fate of the additional 400 or so vitamin and mineral forms has yet to be decided following the submission of derogation dossiers to the European Food Safety Authority prior to 12 July 2005. In fact, only two of these submissions have been evaluated and approved since this time. The fate of the vast majority may not be known until closer to the end of the derogation phase in December 2009. Any dossier that is rejected will immediately make illegal any sale of products containing the relevant ingredient.

ANH applications prioritise natural forms of vitamins and minerals

The ANH has filed six applications to Annex II including generic and proprietary forms of mixed carotenoids, wheatgerm oil containing natural forms of vitamin E (mixed tocopherols and tocotrienols) and palm fruit vitamin E tocotrienols. These sorts of natural complexes are conspicuously absent from the Directive's positive lists and, at the proposed dosages, are considered to be free of harmful effects sometimes associated with isolated, synthetic vitamin forms. Scientific studies also suggest that these natural forms of vitamins are of greater benefit to health.

ANH intends to challenge any refused applications in the courts

Robert Collins, Legal Director of the ANH said, "*With so much uncertainty about, it is essential that clear, workable and transparent procedures are established – and of course the European Court has made this abundantly clear. The European Food Safety Authority can only reject applications if the criteria they have given are not met or they can prove that the proposed use is unsafe. Moreover, the Court has indicated that if the procedure results in a refusal, the refusal must be open to challenge through the courts. Since, in our test applications, we believe we have met the required criteria and have demonstrated the safety of the proposed uses, we will be taking any refusals to the courts so that proper precedents can be developed according to the procedure made law by the European Court.*"

The ANH will continue to maintain very close scrutiny over the European Commission and European Food Safety Authority procedures. It is hoped, assuming the ECJ's ruling is taken into account, that this will pave the way towards a more rational and transparent approach towards regulation of all categories of food supplements over the coming years.

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EDITOR'S NOTES

About the Alliance for Natural Health (ANH) - www.anhcampaign.org

The ANH is a UK-based, EU-focused, international, legal-scientific, non-governmental organisation that is working on behalf of consumers, medical doctors, complementary health practitioners and food manufacturers and distributors, to protect and promote natural healthcare, using the principles of good science and good law.

The ANH's principal objective is to help develop an appropriate legal-scientific framework and environment for the development of sustainable approaches to healthcare. Within this setting, consumers and health professionals should be able to make informed choices about a wide range of health options, and in particular those that relate to diet, lifestyle and non-drug-based or natural therapies, so that they may experience their benefits to the full while not exposing themselves to unnecessary risks.

About the Press Release

Judgment of the ECJ on the ANH case (12 July 2005) can be downloaded from:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62004J0154:EN:HTML

The ANH's key grievance

The ANH's greatest concern over the EU Food Supplements Directive (2002/46/EC), which affects millions in Europe who consume food supplements containing vitamins and minerals, as well as other nutrients to support their diets, is the absence from the positive list of many key *natural* forms and complexes of vitamins and minerals. None of this would be a problem if it was reasonably easy to have a nutrient added to the list – but, unfortunately, the data requirements set by the European Commission are so onerous that only the largest companies have the capacity to conduct the studies required.

The Advocate General's 'black box'

Worse than this, the exact procedure, data requirements and time lines required to gain access have not been clearly set out. This was in fact the major stimulus for the opinion of the Advocate General, Leendert Geelhoed, handed down on 5 April 2005, which recommended that the Directive be invalidated. He rather famously pronounced the procedure as 'transparent as a black box'. Extracts from the Advocate General's opinion are given below:

> "In short, this procedure, in so far as it may exist and in so far as it may deserve this title, has the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken. The procedure therefore lacks essential guarantees for the protection of the interests of private applicants….. Thus, lacking appropriate and transparent procedures for its application, the Directive infringes the principle of proportionality. It is, therefore, invalid."

Directive upheld by the ECJ, but….

Three months later, when the ECJ delivered its judgment, many were surprised to find that the 13 judges in the case did not follow the Advocate General's recommendation to invalidate the Directive. Rather, the judges decided to uphold the Directive, yet at the same time, through the 25-pages of their ruling, they provided key clarification that went a very long way to remove the black veil from Advocate General Geelhoed's box.

The unveiling of the Advocate General's 'black box' by the ECJ

The ECJ makes very clear in paragraph 82 of its ruling that transparency must be maintained, as well as clarifying the European Commission's responsibilities to interested parties, viz:

> "The absence of any such provisions cannot, however, be regarded as such as to jeopardise the proper functioning of the procedure for modifying the positive lists within a reasonable time. It is none the less the responsibility of the Commission, by virtue of the implementing powers conferred on it by Directive 2002/46 concerning, inter alia, the way the procedure is operated, to adopt and make accessible to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out transparently and within a reasonable time."

The European Court clarifies the criteria required for applications to the positive list

Many companies have understandably feared that they cannot afford to make applications to the positive lists because of onerous data requirements stipulated by the European Commission. Others have been given the impression that they cannot make an application for a specific vitamin or mineral form (Annex II) because the group to which the form belongs is not listed in Annex I of the positive list. However, the ECJ made clear in its judgment the criteria required to gain access to both Annexes of the Directive's positive list, as well as indicating that the procedure needs to be fully transparent and must be carried out "within a reasonable time".

Criterion required for applications to Annex I of the positive list

The Court specifies only one criterion required for applications to Annex 1, which presently contains 13 vitamins, and only 15 minerals. The criterion is as follows, as demonstrated in paragraph 85 of the judgment:

> "….the criterion that the vitamin or mineral be normally found in, and consumed as part of, the diet is the only relevant criterion for the purposes of the list in Annex I to the directive."

Criteria required for applications to Annex II of the positive list

Also in paragraph 85, the Court clarifies the two criteria required for applications to Annex II:

> "As regards the list in Annex II to the directive, it is apparent……that the only relevant criteria are those relating to the safety and bioavailability of the chemical substance in question."

ECJ clarifies basis for refusals

Paragraph 73 of the ruling re-states that the procedure for applications to the positive list must be completed in a "reasonable time" and applies the burden of proof for lack of safety on the competent authorities in cases where applications are refused:

> "Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorised substances may be refused by the competent

> authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts (see, by analogy, Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraphs 26, 27 and 36, and Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraphs 35, 36 and 50)."

Conclusion

The European Court, in its ruling of July 2005, appeared to go a very long way towards addressing the claimants' main concerns, while at the same time avoiding the severe option of invalidating the Directive. This approach may have been developed to provide as much of a win-win situation to all parties as could be mustered, while at the same time saving the European institutions the embarrassment of an over-turned Directive.

The difficulty for many leading-edge, innovative manufacturers has been that since the ruling, almost two years ago, the European Commission appears to be ignoring the ECJ's ruling. Geelhoed, who has now retired, may be surprised to find that his 'black box' has yet to be made transparent.

The ANH's strategy to test the ECJ ruling will, it is hoped, apply the pressure needed to ensure transparent, clear and proportionate procedures for applications to the Directive's positive list. It will likely set a precedent which will then be applied to other groups of nutrients such as botanicals, essential fatty acids, amino acids and probiotics.