

## ALLIANCE FOR NATURAL HEALTH OBTAINS REFERENCE TO EUROPEAN COURT ON FOOD SUPPLEMENTS BAN

**An English High Court judge ruled yesterday that the legislative powers of the European Commission should be examined by the European Court of Justice in Luxembourg.**

The landmark cases brought by the **Alliance for Natural Health** and two UK industry associations have been successful both in getting permission for Judicial Review and obtaining a reference to the European Court of Justice in their challenge to the legality of the Food Supplements Directive ban on nutrients.

Mr Justice Richards gave decisive judgment yesterday afternoon after having examined the voluminous evidence and complex legal arguments. He emphasised that the reference to the European Court should be made without delay given that the ban on up to 5000 vitamin and mineral products as of 1 August 2005 in the UK alone, as proposed by Brussels legislators, would impact manufacturers, retailers, practitioners and consumers reliant on these products across Europe.

This is a test case on the proper scope of the legislative powers of the Community Legislator over member states and has far reaching implications for health as well as freedom of choice.

The industry and complementary health organisations around Europe are hopeful that the European Court of Justice will give its ruling prior to the imposition of the ban which comes into on 1 August 2005, on up to 270 forms of vitamins and minerals that are currently available in food supplements sold in markets such as the UK, Sweden, Ireland and The Netherlands.

Dr Robert Verkerk, Executive Director of the Alliance for Natural Health says: "This court decision is a victory for millions of consumers of advanced food supplements, many of which have found good health using nutrition as the central approach. We are hopeful that the European Court in Luxembourg will invalidate the unnecessary ban on the wide range of natural, food-derived ingredients that comprise most of the advanced food supplements. The proposed ban is wholly unnecessary and works counter to health policy where nutrition is increasingly seen as a key way forward."

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**For further information** please see attached press release **ANH landmark legal challenge** released on the day of the court hearing (Friday 30 January 2004); see below:

## ANH LANDMARK LEGAL CHALLENGE TO EU FOOD SUPPLEMENTS BAN

**Dame Judi Dench, Dame Joan Plowright and Bianca Jagger** are among thousands of consumers all over Europe supporting the *Alliance for Natural Health* (“ANH”) in its application for Judicial Review of the **Food Supplements Directive**, which is to be heard in the High Court on **Friday 30 January**. Unless challenged successfully, the Directive will ban, from 2005, thousands of safe products which have been available for years.

**ANH Executive Director, Dr Robert Verkerk**, says: “People have had enough – this Directive is *supposed* to be promoting trade in food supplements in the EU but actually has the reverse effect. It will prohibit from sale many of the more advanced, safe supplements currently available in the UK, Sweden, Ireland and Holland, forcing these countries to comply with a much more restrictive regime more typical of the existing regimes in countries like Germany and France. The governments of these countries are openly hostile to advanced food supplements. We go to court next Friday to commence a test case to address this anomaly with a goal of obtaining a legal regime which befits the 21<sup>st</sup> Century. We want to ensure that the Directive supports the role of nutrition at the heart of healthcare policy.

We readily endorse the notion of reasonable and proportionate legislation for natural products. But moves to ban around 300 of the 420 or so vitamin and mineral forms currently on the market must be resisted, particularly when this will prevent the sale of some of the most beneficial food supplements that have a long and unblemished track record of safety.”

The ANH is supported by consumers, practitioners, and manufacturers and retailers of innovative food supplements, across 43 countries. Over 80% of funds raised to-date for the challenge have come from the end-users of these innovative food supplements, who are greatly concerned that the Directive will deprive them of access to advanced, bioavailable and effective products of their choice.

**David Hinde, Solicitor and Legal Director of the ANH** adds: “We have lined up a legal team of the highest calibre with barristers from *Brick Court Chambers* and solicitors at *the Simkins Partnership*. ANH’s challenge is based on EU constitutional law grounds. We say that the ban on food supplements imposed by the Directive is quite unnecessary in order to facilitate the internal market and thus goes beyond the legal powers of the Community legislator. This case may well prove to be a landmark decision on the interface between EU legislative powers, the sovereignty of Member States and the protection of individual and companies’ rights. We support appropriate legislation but the Directive in its present form is unworkable and will have a catastrophic effect on the emerging market for advanced high potency and effective food supplements.”

**Erica Murray** of the *Irish Association of Health Stores* who has worked closely with ANH gathering commercial data from Ireland, comments: “This Directive needs to be modified if it’s going to deal fairly with the thousands of smaller businesses involved with innovative natural health products across Europe. Otherwise it will give a huge competitive advantage to the big companies, which dominate mass-market sales of lower potency vitamin and mineral supplements from supermarkets and pharmacies. We have lodged voluminous evidence from the UK, Sweden, Ireland and Italy to show that the Directive – if unchallenged – will have dire consequences for hundreds of smaller businesses in the UK and other parts of Europe.”

Ms Murray adds: “We are pleased to see that other associations have now also seen the light. In particular, we welcome the decision of the UK trade associations – *the National Association of Health Stores* and the *Health Food Manufacturers Association* – to mount a parallel challenge. We hope Europe gets the message that people want their advanced supplements. More and more people are choosing natural products and this freedom of choice should not be denied.”

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## BACKGROUND INFORMATION

### Micronutrient deficiencies in the 'typical diet'

Although many health authorities continue to claim that it is possible to obtain all the nutrients required in a "balanced and varied diet,"<sup>1</sup> there is a rapidly growing body of scientific evidence that demonstrates that large groups of people do not meet the minimum nutritional requirements established through reference intakes, let alone those needed for optimum health. Micronutritional status has been shown to be particularly inadequate for particular groups such as the young, elderly, vegans or patients with malabsorption.<sup>2,3</sup>

Many factors contribute to reduced micronutrient intake. These include inadequate consumption of fresh fruit and vegetables, increased consumption of processed foods, poor dietary choices, lower food intake caused by less active lifestyles and inappropriate cooking methods. Furthermore, intensive training regimes, stress, smoking and exposure to environmental chemicals places additional demands on the body and increases the requirement for particular micronutrients. For

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<sup>1</sup> Statements made in the media, including by Sir John Krebs (Chair, Food Standards Agency), following release of the UK Expert Group on Vitamins and Minerals *Draft Report on Upper Safe Levels of Vitamins and Minerals*, 8 May 2003: see media references on NHS Online ([http://www.nelh.nhs.uk/hth/vitamin\\_warning.asp](http://www.nelh.nhs.uk/hth/vitamin_warning.asp))

<sup>2</sup> Krebs-Smith SM, Cook A, Subar AF, Cleveland L, Friday J. US adults' fruit and vegetable intakes, 1989 to 1991: a revised baseline for the Healthy People 2000 objective. *Am J Public Health*, 1995; 85 (12): 1623-9.

<sup>3</sup> Krebs-Smith SM, Cleveland LE, Ballard-Barbash R, Cook DA, Kahle LL. Characterizing food intake patterns of American adults. *Am J Clin Nutr*, 1997; 65 (4 Suppl): 1264S-1268S.

example, that a smoker needs to consume 4 times the RDA of Vitamin C in order to have the same plasma level of Vitamin C as a non-smoker.<sup>4</sup>

National nutrition surveys undertaken in the UK have shown that that large minorities are not reaching their dietary targets for Reference Nutrient Intakes (RNIs).<sup>5,6,7</sup> In the case of the elderly, inadequate intake of vitamin D, magnesium, Vitamin K and copper have been of particular concern.<sup>9</sup>

In a major UK survey of dietary habits of 4 to 18 year-olds,<sup>8</sup> it has been shown that *the most commonly consumed foods* are white bread, savoury snacks, chips, biscuits, potatoes and chocolate confectionery. Additionally, it was found that boys eat, by weight, nearly four times as many biscuits than leafy green vegetables, while girls eat, by weight, more than four times as much sweets and chocolate than leafy green vegetables. The same survey also revealed that 91% of girls aged 4-6 years failed to reach the RNI for zinc (a key mineral required for the immune system); while 97 % of girls aged 15 to 18 years did not reach the RNI for magnesium, 73% did not reach the RNI for zinc, and 53 % did not reach the RNI (200 µg) for folic acid, despite recent studies that demonstrate that intakes well over 400 µg are likely to be required to minimise risk of neural tube defects.<sup>9</sup>

### **The case for supplementation**

There has been a rapid recent expansion of the body of scientific evidence in peer-reviewed journals which demonstrates that use of food supplements can improve overall nutritional status and key bio-markers for health as well as reduce risk of chronic diseases.<sup>11</sup>

However, many of the large scale clinical studies carried out to investigate the effects of nutrient supplementation have involved single or limited numbers of nutrients, often at suboptimal doses. Such studies are likely to underestimate the benefits of supplementation, given that many nutrients function synergistically.

A major review of studies on the relationships between vitamin intake and various diseases published between 1966 and 2002 demonstrated that suboptimal levels of vitamin intake are associated with increased risk of contracting a variety of chronic diseases, including cancer, heart disease and osteoporosis.<sup>10</sup> The authors of this study concluded that many physicians may be

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<sup>4</sup> Losonczy KG, Harris TB, Havlik RJ. Vitamin E and vitamin C supplement use and risk of all-cause and coronary heart disease mortality in older persons: the Established Populations for Epidemiologic Studies of the Elderly. *Am J Clin Nutr*, 1996; 64 (2): 190-6.

<sup>5</sup> Gregory J, Foster K, Tyler H, Wiseman M. *The Dietary and Nutritional Survey of British Adults*. 1990. HMSO, London.

<sup>6</sup> Bates CJ, Prentice A, Cole TJ, van der Pols JC, Doyle W, Finch S, Smithers G, Clarke PC. Micronutrients: highlights and research challenges from the 1994-5 National Diet and Nutrition Survey of people aged 65 years and over. *Br J Nutr*, 1999; 82 (1): 7-15.

<sup>7</sup> Finch S, Doyle W, Lowe C, Bates CJ, Prentice A, Smithers G, Clarke PC. *National Diet and Nutrition Survey: people aged 65 years and over. Volume 1: Report of the diet and nutrition survey*. 1998. TSO, London.

<sup>8</sup> Gregory JR, Lowe S, Bates CJ, Prentice A, Jackson LV, Smithers G, Wenlock R, Farron M. *National Diet and Nutrition Survey: young people aged 4 to 18 years. Volume 1: Report of the diet and nutrition survey*. 2000. TSO, London.

<sup>9</sup> Wald MJ, Law MR, Morris JK, Wald GS. Quantifying the effect of folic acid. *Lancet*, 2001; 358: 2069-2073.

<sup>10</sup> Fairfield KM, Fletcher RH. Vitamins for chronic disease prevention in adults: scientific review. *JAMA*, 2002; 287 (23): 3116-26.

unaware of common food sources of vitamins or may be unsure which vitamins they should recommend for their patients and given the current status of scientific knowledge it may be prudent for most adults to supplement their diet with a daily multivitamin.<sup>11</sup>

A study which followed 11,178 people between the ages of 67 and 105 over the period 1984 - 1993 concluded that the overall risk of death was reduced by 42% for those who took higher dose supplements of vitamins C and E.

It was demonstrated conclusively following a randomised double-blind prevention trial across 7 countries that women who took supplements containing 400 µg folic acid reduced the risk of having babies with neural tube defects such as spina bifida by some 72%.<sup>11</sup>

In a very large study of 88,756 women from the Nurses' Health Study who were free of cancer in 1980 and provided updated assessments of diet, including multivitamin supplement use, from 1980 to 1994, were followed through for colon cancer. It was found that long term use (over 15 years use), but not short-term use (less than 4 years use) of multivitamins containing folic acid markedly reduced (ca. 5-fold) the frequency of colon cancer.<sup>12</sup>

In a further epidemiological study involving 87,245 female nurses, it was found, after adjustment for age and smoking, that long-term Vitamin E supplementation alone was associated with a 9% reduction in heart disease.<sup>13</sup> Vitamin C (1000 mg /day) and E (800 IU /day) supplements have been shown to significantly reduce the development of arteriosclerosis.<sup>14</sup>

In a clinical intervention study (CHAOS) of 2002 coronary patients by Cambridge University scientists, supplementation of up to 800 IU vitamin E (in the α-tocopherol form) per day for over two years was associated with reductions in the frequencies of heart attacks by as much as 75%.<sup>15</sup>

It has been shown that long-term micronutritional deficiencies cause damage to DNA much in the same way as radiation and such oxidative stress is likely to contribute to the development of cancer.<sup>16</sup>

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<sup>11</sup> MRC Vitamin Study Research Group. Prevention of neural tube defects: results of the Medical Research Council Vitamin Study. *Lancet*, 1991; 338 (8760): 131-7.

<sup>12</sup> Giovannucci E, Stampfer MJ, Colditz GA, Hunter DJ, Fuchs C, Rosner BA, Speizer FE, Willett WC. Multivitamin use, folate, and colon cancer in women in the Nurses' Health Study. *Ann Intern Med*. 1998; 129 (7): 517-24.

<sup>13</sup> Stampfer MJ, Hennekens CH, Manson JE, Colditz GA, Rosner B, Willett WC. Vitamin E consumption and the risk of coronary disease in women. *N Engl J Med*, 1993; 328 (20): 1444-9.

<sup>14</sup> Fang JC, Kinlay S, Beltrame J, Hikiti H, Wainstein M, Behrendt D, Suh J, Frei B, Mudge GH, Selwyn AP, Ganz P. Effect of vitamins E and C on progression of transplant-associated arteriosclerosis: a randomised trial. *Lancet*, 2002; 359 (9312): 1108-13.

<sup>15</sup> Stephens NG, Parsons A, Schofield PM, Kelly F, Cheeseman K, Mitchinson MJ. Randomised controlled trial of vitamin E in patients with coronary disease: Cambridge Heart Antioxidant Study (CHAOS). *Lancet*. 1996; 347 (9004): 781-6.

<sup>16</sup> Ames BN. Micronutrient deficiencies - A major cause of DNA damage. *Ann New York Acad Sci*, 1999; 889: 87-106.