

EUROPEAN COURT OF JUSTICE ON FOOD SUPPLEMENTS

THE ALLIANCE FOR NATURAL HEALTH SHINES LIGHT ON THE SILVER LINING

After detailed analysis of the European Court of Justice (ECJ) judgment with its expert EU barrister Paul Lasok QC, ANH anticipates that following the ECJ verdict:

- **The vast majority of vitamin and mineral food supplements will not be banned on 1 August**
- **Gaining admission on to the 'positive list' will now be a much simpler, less time consuming and more affordable process than was previously the case**
- **The burden of proof for showing an ingredient to be unsafe will now lie with the regulator and not the manufacturer**
- **The Directive now does not apply to natural forms of vitamins and minerals normally found in the diet**

This outcome is in effect what ANH has been working towards for over three years.

The initial reaction on 12th July to the judgment of the ECJ on the Food Supplements Directive (FSD) was one of disappointment. Yet the ANH hailed it as a success. ANH's specialist EU lawyers have now given a more considered interpretation and still maintain it has achieved the key objectives the ANH has been working towards.

It is not a simple question of whether the FSD was lawful or not. ANH challenged the lawfulness of the FSD because to ANH it appeared to have draconian and unnecessary consequences for the food supplements industry and for consumers. In upholding the lawfulness of the FSD, the ECJ has clarified what the FSD actually means and has clearly restricted the scope of the application of the ban on non-FSD compliant nutrients. There is a clear 'silver lining' within the judgment that will be beneficial to the millions of consumers who use vitamin and mineral supplements for their health and are key to everything that ANH has been campaigning for all along.

At the heart of the FSD is the 'positive list' of vitamin and mineral ingredients that are permitted. On 5 April 2005 the ECJ's Advocate General described the procedure by which ingredients are added to the positive list as being "as transparent as a black box." It was widely understood that to get an ingredient onto the 'positive list', manufacturers would have to go through a very time consuming and costly process for them to prove that each nutrient was safe. This might have cost more than £250,000 per ingredient. With many innovative, supplements containing sometimes upwards of 30 ingredients each, this burden upon many manufacturers, typically being small companies, would effectively lead to them being put out of business. This would be the case even if the products included natural sources of vitamins and minerals that had been part of the human diet for thousands of years.

However, the judgment of the ECJ has now gone a long way to make the process more transparent, and to require (although not define) simplified procedures for getting ingredients onto the 'positive list'. In summary, the analysis of the ECJ's judgment by ANH's legal and scientific team indicates:

1. There must be a greater degree of clarity on what information companies need to submit to admit an ingredient on to the positive list. This is likely to be simpler, shorter and less expensive than previously feared.

2. Once an ingredient is submitted for inclusion in the positive list, it cannot be refused unless the regulator finds the ingredient to be unsafe. If the regulator believes the ingredient should be rejected, it will have to undertake a full risk assessment based on “the most reliable scientific data available and the most recent results of international research,” that will then prove the ingredient (or dosage) to be unsafe. This transfers the burden of proof from the manufacturer to the regulator, principally the European Food Safety Authority. Any rejection can then be challenged in the courts.
3. Bans of natural vitamins and minerals not on the positive list that are “normally found in or consumed as part of the diet” will now *not* occur. This coupled with the natural health industry’s response in submitting large numbers of ‘simplified dossiers’, the wide-reaching bans that were anticipated to come into force on 1 August 2005, are unlikely to occur.

Commenting, **Dr Robert Verkerk**, Executive Director of ANH, said:

“The fact that the necessary requirements for admission to the positive list have been fundamentally changed means that the vast majority of high quality and innovative vitamin and mineral food supplements will now, with relative ease and limited expense, be able to join the positive list and thus not face a ban. These changes have been at the heart of what the ANH has been campaigning for over the last three and a half years and indeed, formed the major part of its legal challenge to aspects of the FSD.”

While some organisations have relied more on emotional outcry, calling for an all-or-nothing annulment of the FSD, this has never been the case with ANH. All it has wanted is sensible regulation, which is why it has worked ‘at the coalface’ in Brussels, Strasbourg and Luxembourg, with leading scientists, medical doctors and experts in EU law.

ANH has always been committed to the FSD doing its job properly as it provides a ‘safe harbour’ for food supplements that maintains them as a category of foods and prevents them from being considered as medicines.

In light of the judgment, ANH is willing to work closely with the European Union Institutions and Competent Authorities in Member States, providing its professional expertise to ensure that the processes in the FSD are based on good law and good science, central to ANH’s approach from the outset.

On the basis of this interpretation of the ECJ ruling, the ‘David and Goliath’ challenge brought by the ANH should have a positive outcome for the millions who choose the leading edge in natural healthcare.

ENDS

Contact

For further information contact Adrian Shaw at Ikon Associates. Tel +44 (0)1483 535 102 or email adrian@ikonassociates.com

Notes for editors:

1. The Alliance for Natural Health is a Europe-wide association of consumers, complementary practitioners, distributors, retailers, and leading-edge manufacturers who have an interest in food supplements and natural health. More information, including details of members, can be found at www.anhcampaign.org

Good science and good law underpin all of the ANH's work, and the scientific reports produced by the ANH are endorsed by many of the world's leading doctors and scientists working in the field of nutrition.

2. Had the ban on vitamins and minerals been implemented without the restrictions imposed now by the ECJ:
 - Over 5000 products would have disappeared from the shelves of UK health stores as a result of the ban removing access to over 300 vitamin and mineral ingredients (out of a total of about 420). These include, among others, the main natural forms of Vitamin E, several forms of vitamin C, the key natural form of folic acid, MSM and a range of minerals such as vanadium, silicon and boron, all being products which millions of consumers choose to take as part of their regular health regime and have done so without any ill effects for many years.
 - An individual's freedom of choice to take safe natural health products would have been removed – 40% of the UK's population take vitamins and minerals.
 - Products would have been banned with absolutely no scientific justification. Many of the world's leading scientific and medical experts in nutrition support the absence of any proper basis for the proposed bans.
 - Further legislative proposals by the EU are due to be considered by the European Parliament later this year and next. These include restrictions on herbal products, on maximum dosages of vitamins and minerals and restrictions on health claims of foods. Again, the ANH is working to help positively shape such legislation using its mantra of 'good science and good law'.