

ECJ RULING SECURES FUTURE FOR VITAMINS AND MINERALS

WHY THE ALLIANCE FOR NATURAL HEALTH MAINTAINS THAT THE EUROPEAN COURT RULING ON THE FOOD SUPPLEMENTS DIRECTIVE IS A VICTORY

After further detailed analysis of the 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
- The Directive now does not apply to natural forms of vitamins and minerals normally found in the diet
- Where it is necessary to be on the positive list, gaining admission 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

This successful outcome is, effectively, what ANH has been working towards for over three years.

The initial media reaction on Wednesday to the judgment of the European Court of Justice (ECJ) on the Food Supplements Directive (FSD) was one of disappointment. Yet the Alliance for Natural Health hailed it as a victory. ANH's specialist EU lawyers have now given a more considered interpretation of the ruling and still maintain that ANH has achieved the key objectives it has been working towards in relation to the FSD over the past three years. Crucially, it is highly likely that most vitamin and mineral supplements will continue to be available. Here's why....

It is not a simple question of whether the FSD was lawful or not. The devil, as always, is in the details. ANH challenged the lawfulness of the FSD because to ANH it appeared to have draconian and quite unnecessary consequences for the food supplements industry and for consumers. In upholding the lawfulness of the FSD, the ECJ has clarified what exactly the FSD actually means and has clearly restricted the scope of the application of the ban on non-FSD compliant nutrients. There are very significant and positive details 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." Because of the FSD's lack of clarity and restrictive interpretation by regulators, it was widely understood that to get an ingredient onto the positive list, manufacturers would have to go through a very time consuming, onerous 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, leading-edge supplements containing sometimes upwards of 30 ingredients each, this burden upon many leading-edge 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 black box 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. 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 now unlikely to occur.
2. 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 considerably simpler, shorter and less expensive than previously feared, making it easily viable for companies to get ingredients on to the approved list.
3. 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/safety 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 a considerable burden of proof from the manufacturer to the regulator, principally the European Food Safety Authority. Furthermore, any rejection can then be challenged in the courts.

ANH is very confident of the validity of its view, but is aware that as a result of the ECJ's judgment, a controversy about the scope of the FSD has emerged. ANH says that the ECJ has limited the scope of the FSD to vitamins and minerals obtained from non-natural sources, while some other bodies maintain that naturally sourced vitamins and minerals are covered by the FSD.

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 now 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 to the positive list 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 Food Supplements Directive.

"In achieving this, ANH has therefore gained a very significant victory for consumers, practitioners, retailers and manufacturers in protecting their right to buy, supply and produce safe, innovative and leading-edge food supplements across Europe."

While some organisations have relied more on emotional outcry, calling for an all-or-nothing annulment of the Food Supplements Directive, 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 Food Supplements Directive properly doing its job as it provides a safe harbour for food supplements that maintains them as a category of foods and prevents them from being considered medicines.

In light of the judgment, ANH is ready and 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 Food Supplements Directive are indeed based on good law and good, leading-edge science, which have been central to ANH's approach from the outset.

A quick reminder on why ANH has been the driving force in challenging this legislation.

- ANH was formed in 2002 specifically to contest the Food Supplements Directive, two weeks before it was due to be approved in the European Parliament. Few even knew of this controversial EU legislation at this time
- ANH raised media awareness of the issues at the time, including the positive list and the prospect that thousands of food supplements could disappear
- ANH brought the landmark legal challenge to the FSD in the European Courts
- ANH provided the technical, scientific and nutritional data in support of its challenge, also sharing its information with other parties involved in mounting a parallel challenge

Without the efforts of this small, spirited organisation, the situation we are in today, where most food supplements should remain freely available, would not have happened, as the Directive would have been misunderstood and applied incorrectly.

On the basis of this interpretation of the ECJ ruling, the David and Goliath challenge brought by the Alliance for Natural Health 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'.