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## **European Court of Justice Ruling on EC Food Supplements Directive**

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### **The Ruling:**

In an opinion released today, the European Court of Justice (ECJ) reversed the April 5, 2005 opinion of the EC Advocate General (AG) regarding the validity of the European Commission's Food Supplements Directive 2002/46 (FSD). **The ECJ found that the FSD is valid.** The ruling allows the FSD to take effect on schedule on August 1, 2005. Specifically, it will allow maximum levels (still to be developed) to be set on the basis of risk assessment, and separately it leaves the positive lists of nutrients and nutrients sources in place. Only those ingredients that appear on the positive lists are permitted in vitamin and mineral food supplements for sale in the member countries of the EU. (Please note, however, that the lists are category-based, and in cases where the nutrient categories have not yet been addressed, each country within the EC is free to apply its individual national rules, the majority of which are very restrictive. To date, the EC directive has addressed only vitamins and minerals; there is no plan in place yet for the EC to look at other categories, but the language in the definition section will allow that in the future.)

### **CRN's Reaction:**

While CRN believes the ruling provides some positive news for industry and consumers, that reaction is tempered by the need to remain vigilant as the directive is implemented. The reality is that the FSD will provide consumers in the UK market with fewer product choices, while in most of the EC communities, product marketing will be liberalized.

Despite some concerns about the positive lists aspect of the FSD, our optimism is somewhat bolstered based on the Codex ruling last week to adopt the vitamin and mineral supplements guideline. In light of today's decision by the ECJ, CRN believes that the Codex guideline adopted last week takes on even more significance for the preservation of consumer choice. Approval of the Codex guideline will assure that the upper limits set by the FSD conform to sound scientific principles for upper limits, and in most cases will exceed the restrictive levels that are currently imposed by using population reference intakes (European term for Recommended Dietary Allowances, the RDAs) to establish these maximum values. Further, as the FSD is implemented, the Codex ruling and CRN's involvement in Codex proceedings will make it feasible for us to work within the Codex framework to ensure that the FSD moves forward in an open and scientifically valid manner on its nutrient lists and maximums.

### **Additional Background on FSD:**

The FSD includes administrative procedures for the amendment of the lists by submission of dossiers demonstrating the appropriateness and safety of the new nutrient or nutrient source being proposed. Many in the industry see the dossier requirement to be onerous, time consuming and expensive, but the ruling leaves the established dossier procedures as the only option for amendment of the positive lists. An encouraging note at the end of the Court's press release stated, "...the Court emphasized that it is the responsibility of the Commission to adopt and make accessible to interested parties the measures necessary to ensure generally that the

## CRN Comment on European Court of Justice Ruling on EC Food Supplements Directive

consultation stage within the European Food Safety Authority [for the addition of other food supplements] is carried out transparently and within a reasonable time."

### **Additional Background on Codex Guideline on Vitamin and Mineral Food Supplements:**

On July 4, the Codex Alimentarius Commission unanimously approved and adopted the Codex guideline on vitamin and mineral supplements that had been developed by the Codex Committee on Nutrition and Foods for Special Dietary Uses. The guideline section on maximum levels of vitamin and minerals in these products is similar to Article 5 of FSD, except that the Codex guideline goes further to specify that the second paragraph of the section on maximums does not allow limits to be set solely on the basis of population reference intakes (i.e., RDAs). As a result, the Codex guideline requires any maximums set should be based on risk assessment and not recommended intakes; it does not specify the risk assessment method or numerical outcomes. Determining maximums based on what constitutes safe upper limits is a more scientifically sound approach for determining the highest levels of dietary supplement ingredients that can be sold to consumers. Usually, this approach also results in more liberal and varied dosage regimens (and thus, more consumer choice) than RDAs, which are more subject to political determination and local variations of what a governing authority believes is the necessary levels to maintain health rather than what are the safe upper limits for a nutrient. Also, the Codex guideline does not establish any lists of nutrients or nutrient sources (chemical forms). If such lists are suggested at a later stage, CRN will work to help obtain reasonable, science-based lists and procedures.

### **Conclusion:**

The Codex guideline requires that risk assessment, rather than recommended dietary allowances be used to identify limits for vitamins and minerals in supplements in international trade. The Codex guideline goes beyond the FSD by overtly prohibiting the setting of limits based on recommended intakes. Codex does not list vitamins, minerals and their sources, or even require that lists should be established.

With the ECJ confirming the entire EC FSD, CRN and other industry groups will remain vigilant in Codex to guard against onerous lists and amendment procedures.