



## PRESS RELEASE

For immediate release

Loosdrecht - 2 May 2007

EU BOTANICAL FORUM'S MAXIMUM LEVEL FOR BOTANICALS  
CHALLENGED AS BARRIER IN INTERNAL MARKET

International Nutrition Company (INC) has taken the initiative to challenge a model recently proposed by the EU Botanical Forum as a way to distinguish foods from medicines. The Forum's model, which was presented in the article *Use of Botanicals in Food Supplements* was widely interpreted as a safety model for "botanicals". INC feels that EBF's proposal harbors a largely unnoticed maximum level criterion which, if implied, would seriously upset botanical food supplement markets not only in the liberal Member States, but in the entire internal European market as well.

In cooperation with co-authors professor Aalt Bast of Maastricht University and independent researcher Dr. Jaap Hanekamp, and in collaboration with two prominent attorneys, both well versed in EU food law, INC reviewed the scientific and legal merits of the Forum's proposal. The result of this joint research effort can be found in the article *The European Regulation of food supplements and food fortification* (\*) as recently published in issue 19 of *Environmental Law & Management*. The Forum's proposal, so conclude the authors, conflicts with the European regulations that currently organize and regulate the internal European markets of foods and food supplements and the products' free movement therein.

The entire issue boils down to the correct and unconditional implication of the principle of "Intended Normal Use" (INU). In the Forum's proposal, so state the authors of *The European Regulation of food supplements and food fortification*, the INU principle has been seriously crippled because, although INU is presented as the decisive principle in organizing and defining the use of botanicals in food supplements, the Forum actually endows overriding power to a criterion that squarely conflicts with INU: "therapeutic dosage". In a model that organizes markets and products on the basis of products' intended use, there is no room for criteria that organize things in a fundamentally different way.

"In fact," so says leading author and INC director Bert Schwitters, "the Botanical Forum neglects the fact that European food legislation as it stands today forms the very framework that organizes the conventional and fortified foods and food supplement markets. An informed food business operator does not require anyone's decision tree



or other template to make before-market-entry considerations. Designing the intended normal use for a product immediately and unconditionally defines that product's recommended dosage, market and the concomitant European legal framework. In the consequent application of the INU principle, dosage will naturally follow intended use. The Forum's suggestion that use should follow dosage distorts the natural and logical flow in the INU system."

"The Forum," so continues Schwitters, "has made an effort to reach a redundant compromise via à vis vested interests who seek to maintain their dominant position in the field of botanicals intended for medicinal use. Apparently, these vested interests do not like the fact that EU food law provides entitlement to entry and free movement throughout the entire internal European market for botanicals and other 'other substances' intended by their manufacturers for nutritional use and marketed for instance as food supplements. Recently, the EU Commission made its approach quite clear by bringing before the European Court of Justice the issue that Spain has been continuously obstructing the free movement of botanical food supplements."

The publication of the *The European Regulation of food supplements and food fortification* is quite timely, now that the EU Commission is on the threshold of publishing its report on the advisability of setting specific rules for botanicals and other so called 'other substances'. "In organizing the 'other substances'," so concludes Schwitters, "the EU Commission can simply continue to place emphasis on safety within the existing legal framework that already rests on intended normal use. The Forum's 'therapeutic dosage' criterion is extraneous to all this, it is not a safety criterion and has no place in today's internal European foods and food supplement markets."

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(\* ) *The European Food regulation of food supplements and food fortification. Intended normal use – the ultimate tool on organising level playing field markets and regulations, or how to break the fairy ring around 'other substances'*. Bert Schwitters, Geetha Achanta, Dennis van der Vlies, Hervé Morisset, Aalt Bast, Jaap Hanekamp; *Environmental Law & Management*, issue 19, 2007, pp 19-29.

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