

REQUEST FOR COMMENTS FROM THE AMERICAN ASSOCIATION FOR  
HEALTH FREEDOM AND THE ALLIANCE FOR NATURAL HEALTH  
FOR PUBLIC HEARING ON  
CONVENTIONAL FOODS BEING MARKETED  
AS “FUNCTIONAL FOODS”

SUMMARY SUBMISSION

Prior to oral presentation on December 5, 2006

The American Association for Health Freedom (AAHF) and its European-based affiliate, the Alliance for Natural Health (ANH), represent the interests of the emerging, innovative functional food and dietary supplement sector, including large numbers of practitioners and consumers.

The present blurring caused by lack of adequate definition and clarity of scope of conventional foods, dietary supplements, functional foods and drugs is creating increasing legal uncertainty that compromises informed consumer choice, and creates unnecessary risk to business operators and lack of clarity for regulatory enforcers.

The functional food and dietary supplement industries have seen rapid growth in recent years, alongside scientific research which is increasingly demonstrating the pivotal role of nutrients and other dietary and natural components in disease risk reduction and the management and promotion of good health.

A new legislative framework for functional foods is urgently required which reduces legal uncertainty and caters for changes in the way in which scientific evidence is appraised. Accordingly, food companies can commercialize scientific findings born out of emerging science – and consumers can benefit without unnecessary delays.

The AAHF and the ANH uphold that functional foods should be regarded as a sub-category of conventional foods and thereby utilize all relevant aspects of food law, except in conditions where health claims are made.

We propose that there should be two distinct levels of health claim, one involving structure/function claims that utilize the same framework presently used under DSHEA (1994) for dietary supplements, the second being more specific, authorized by a relevant scientific body and involving a higher degree of scientific substantiation which would be categorized according to the three-tier WHO system (conclusive, probable or possible).

The former, structure/function claim category would require 30 days premarket notification, while the second, authorized health claim category would require 120 days premarket notification.

Authorizations would be agreed by consensus by a task force comprised of government, industry, consumer and academic representatives, affiliated with a recognized and

appropriate scientific body (e.g. National Academies of Science , National Institutes of Health).

Critical to the evaluation of health claims is consideration of the totality of evidence. This should emphasize human studies, but should not give undue weight to specific randomized controlled trials (RCTs) which may be less scientifically relevant than observational or epidemiological studies. Animal, cell and molecular studies should be used primarily as supporting evidence.

There should be new criteria for establishing both safety and benefit of ingredients to be used in functional foods. These would include categorization as follows:

- GRAS (existing category and new category/regime to cater for novel [post-1958] substances)
- GRAE (as proposed by the Institute of Food Technology)
- GRASIU (a specific category of potentially more dose-sensitive ingredients, as proposed by AAHF/ANH)
- Negative list (ingredients that should not be used in functional foods, as proposed by AAHF/ANH, an adaptation of existing FFDCA 402(f)(1)(B))

Functional foods provide a delivery system for functional ingredients within a food matrix and may potentially provide one of the most important tools in health management programs given their food base. They also are very well suited to health prevention as they can be used regularly by consumers, without specific advice from health professionals. We strongly support the development of government sponsored research programs to facilitate new research.

#### Conclusion

Owing to the “grey area’ that exists between functional foods with label claims and licensed drugs, also with distinct medicinal label claims, it is important to develop a regulatory framework that reduces legal uncertainty for functional food companies, so that they are able to work using clearly delineated criteria to avoid FDA drug classification of their products.