

ANH PRACTITIONERS SUMMARY: NUTRITION AND HEALTH CLAIMS REGULATION

Official 'Europa EU' Summary of Legislation
<http://europa.eu/scadplus/leg/en/lvb/l21306.htm>

NB: It is important to recognise the difference between a Directive and a Regulation. Directives have a date when they come into force in the Member States (MS), but include a period of transposition where they are incorporated into the Statutory Instrument of the individual MS. There can therefore be small variations in how individual MS interpret the directive. Regulations on the other hand, are considered law in all MS from the date that they come into force—there is no period of transposition or variation in expression.

Nutrition and Health Claims Regulations (NHCR) constitutes one of the biggest risks to our freedom of speech and can prevent a practitioner from properly informing his/her patient/client about the known or even proven benefits of a particular food or food supplement product.

It is a passport to big business and has been set up with commercial promotion, advertising and labelling of food and health products in mind. It applies equally to both verbal and written statements. You cannot state, suggest or imply that a food or nutrient has particular characteristics or beneficial nutritional properties, or that a relationship exists between a food/nutrient and health, unless it is an 'Authorised Claim' included in the EU harmonised list approved by the European Food Safety Authority (EFSA). There are two types of allowed health claim: generic claims (under Article 13) and disease risk reduction (and childrens' health) claims (under Article 14).

'The legislation... protects consumers by prohibiting any information which is false, difficult to understand or misleading (e.g. which attributes medicinal properties to food wrongly or without scientific evidence);... encourages or condones excessive consumption of a product; encourages consumption of a product by stating or suggesting directly or indirectly that a balanced diet does not provide all the nutrients that are needed; attempts to scare consumers by mentioning changes in bodily functions'.

The bottom line: unless a product claim has been specifically approved by EFSA under Article 14, applications to which are extremely onerous and require evidence from randomised controlled trials, which are unaffordable to many smaller companies, the claim will not be allowed.

- A 'Napoleonic' System of Law. As of 2010, all health claims are banned unless specifically allowed by being included on the EFSA 'Approved List'. This is known as a 'Napoleonic' system of law. Hundreds of generic claims submitted

by manufacturers, associations and other bodies, including the ANH, are presently being considered by the EFSA.

- Scientific Substantiation Requirements. The scientific substantiation requirements have been set very high, and require evidence from human trials, which are probably often can prohibitively expensive for smaller companies.
- The two Types of Allowed Health Claim. This regulation will allow particular claims to be made for foods and food ingredients:

- Those that relate to generic ingredients – under Article 13.

Nutrition and Health Claim regulations are purported to be all about protecting consumers, but since all products containing the same ingredients will be forced to make the same claims, consumers will find it very difficult to distinguish between different products and make informed choices.

- Those that relate to disease risk reduction and children's health – under Article 14.

These types of claim in particular will require very high levels of scientific substantiation. Article 14 will be **product** not ingredient specific, and only the largest corporations will be able to afford the trials required for eligibility, yet it is the small to medium-sized businesses that have been the key pioneers and innovators within the natural health field. This is why the ANH considers Article 14 Health Claims to be a passport system for big business.