

ABOUT THE NUTRITION AND HEALTH CLAIMS REGULATION

- * Regulation No 1924/2006 applies to foods (and food supplements), and seeks to harmonise commercial nutrition and health claims made on labels and in advertising throughout the European Community, in order to ensure the effective functioning of the internal market, whilst providing a high level of consumer protection.
- * The NHCR came into force on 1 July 2007 (Article 28). Transitional measures (Article 27) are in place until 31 July 2009 for foods labelled prior to the date of enforcement, that do not comply with the Regulation, and for products on sale before 1 January 2005 bearing brand names or trademarks that do not comply, until 19 January 2022. Nutrition claims made before 1 January 2005, that have been made under the proviso of Member States statutory instruments, can continue to be made until 19 January 2010.
- * NHCR offers two distinct pathways to companies wishing to make health claims—Article 13 generic claims based on individual nutrients in a product and Article 14 product-specific, disease-risk-reduction (and children's health) claims.
- * The European Food Safety Authority (EFSA) is currently evaluating Article 13 generic claims submitted by Member States in January 2008. The first 500 opinions on these claims were published by EFSA on 1 October 2009. The approved list is due for publication in 2010, whereby companies will be required to alter their current claims to those that use an approved claim for a specific generic ingredient. No product-specific claims will be allowed unless approved under the very onerous Article 14 application process.

ANH KEY CONCERNS

- * **Threat to freedom of speech.** The Regulation applies equally to verbal, pictorial and written statements or presentations. *Unless* 'authorised' by the Commission on the basis of EFSA approval, all suggestions or implications that a food or nutrient has specific beneficial nutritional properties, or that a relationship exists between a food/nutrient and health, are banned even if scientific evidence for such claims exists.
- * **Unfair impact on small businesses.** The NHCR regime disproportionately benefits large corporations and has the potential to cripple SMEs, because a) many previously allowed claims will be lost; b) the 'me-too' environment of Article 13 will make it harder for smaller companies to differentiate products, and; c) Article 14 product-specific claims applications are highly onerous and require evidence from extensive and prohibitively expensive randomised clinical trials (RCTs). This regime creates what we describe as 'a passport system for big business'.
- * **High level of consumer protection?** The NHCR is intended to offer a high level of consumer protection, but since all products containing the same ingredients will be forced to make the same claims, and claims will only be allowed where EFSA has established a causal relationship (very difficult in the case of most foods and ingredients), consumers will find it very difficult to distinguish between different products and make informed choices that are personally relevant.
- * **Legal basis for substantiation of Article 13 claims.** Of the more than 44,000 Article 13 (generic) claim applications submitted, all but some 4,500 were culled by a subsequent stipulation that claims could be substantiated using human studies. This requirement is not made clear in the Regulation and therefore it is imperative that the legal basis of this decision is challenged or clarified.
- * **The scientific basis for establishing health claims is inadequately specified and unnecessarily onerous.** The Regulation indicates that claims must be substantiated using "generally accepted scientific data" (Recital 25 and Article 6), but specific measures detailing the requirements for this substantiation have not been given. EFSA are currently requiring proof of a causal relationship via human studies, relying mainly on RCTs, which sets the bar unnecessarily high. Such studies may not be appropriate for nutrients and are generally conducted on diseased rather than healthy persons. Health relationships or benefits can be established more than adequately through the use of observational (including epidemiological) studies as well as non-human studies.
- * **Have the principles of sound administration been ignored or inadequately followed?** Interested parties have not been given the necessary level of guidance over the requirements for applications for health claims under Article 13, as per the measures of general application laid out in Articles 15 through to 18, leading to a lack of transparency as well as a shifting of 'goalposts' after the dossier submission deadline.