

## 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 nutrition and 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 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 more onerous Article 14 application process.

## ANH KEY CONCERNS

- \* **Threat to freedom of speech.** The Regulation applies equally to both verbal 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 particular characteristics or beneficial nutritional properties, or that a relationship exists between a food/nutrient and health, all claims are banned even if scientific evidence for such a claim exists.
- \* **Disproportionate impact against small businesses.** The NHCR benefits large corporations in particular and has the potential to cripple SMEs, as Article 14 product-specific claims applications are excessively onerous and require evidence from randomised clinical trials (RCTs), which are prohibitively costly for the majority of smaller companies and not relevant for foods or food ingredients with many years, decades or even centuries of safe use.
- \* **High level of consumer protection?** Nutrition and Health Claim regulations are 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, consumers will find it very difficult to distinguish between different products and make informed choices that are personally relevant.
- \* **Legal basis for requiring human studies for substantiation of Article 13 claims.** The recent decision by the European Commission has allowed the over 6,000 claim applications to be culled to just 1,500. This requirement is not made clear in the regulation and therefore it is imperative that the legal basis of this decision is clarified.
- \* **The scientific basis for health claims is inadequately specified.** The Regulation indicates that claims are substantiated by "generally accepted scientific data" (Recital 25 and Article 6), but specific measures detailing the requirements for this substantiation do not appear to have been given. It may be quite possible to demonstrate scientifically the presence of a given health relationship or benefit through the use of non-human studies.
- \* **Have the principles of sound administration been ignored or inadequately followed?** In the opinion of ANH and IAHS, 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 and a shifting of 'goalposts' after the dossier submission deadline.