

Health claims in Europe

“The greatest challenge to commercial free speech ever seen in the natural health sector”



Relevant legislation

Nutrition and Health Claims Regulation (NHCR); Regulation 1924/2006, and amending acts



What are health claims all about?

- Health claims are statements on commercial food or natural health products that manufacturers use to inform consumers about the health benefits of their products
- They include claims like ‘magnesium reduces tiredness’ or ‘fish oil helps joint mobility’
- Even if they don’t recognise the term ‘health claims’, consumers have been using them for decades to make informed choices about the food they eat and feed their families. Health claims in the marketplace help the consumer to distinguish junk food from nutritious options
- Find out which claims have and have not been authorised using the EU’s Register of Nutrition and Health Claims (<http://ec.europa.eu/nuhclaims>)

What’s the problem?

- The European Union (EU) is imposing a Napoleonic – ‘illegal unless specifically allowed’ – legal framework to govern health claims
- From 14th December 2012, thousands of ‘general function’ (Article 13.1) claims about the health benefits of foods and food ingredients will disappear from commercial food and food supplement products in EU Member States
- The future of claims about plant ingredients (botanicals) is very uncertain. The process is currently on hold pending an EU decision, after objections were raised when the European Food Safety Authority (EFSA) initially rejected 97% of botanical health claims
- EFSA requires proof of a cause-and-effect relationship before health claims are authorised EU-wide– this requires very expensive clinical trials similar to those used for pharmaceutical drug approvals. Very few companies can afford these.



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What's the problem?

- The NHCR and EFSA's scientific substantiation methods create a 'passport system for big business'. The approval process for 'emerging science' (Article 13.5) claims, children's health and disease-risk reduction claims (Article 14) is too complex and expensive for anyone but the biggest corporations – and even these are struggling to get claims authorised



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What are some of the consequences?

- The EU-wide food and natural health products marketplace will become almost information-free: a disaster for disease prevention, as consumers will have little obvious guidance as to what foods and ingredients are good for them and why
- Less than 250 health claims are currently authorised and published in the official 'Community Register' (<http://ec.europa.eu/nuhclaims>). These only cover around 70 foods or ingredients
- Ironically, the NHCR evolved from the EU's 'Strategy on Nutrition, Overweight and Obesity-Related Health Issues', and Article 27 requires the European Commission to undertake an impact assessment of the NHCR and how it has affected, "Dietary choices...obesity and non-communicable diseases" – by 19th January 2013 at the latest
- Non-specific claims like 'oily fish is good for you' and 'superfood' will be banned unless accompanied with an authorised general function claim
- Not a single amino acid, prebiotic or probiotic claim has yet been authorised, despite copious evidence of benefit – but none within the narrow parameters required by EFSA.

Solutions

- In the short term, 'pending' health claims that have previously been used and are awaiting evaluation by EFSA must continue to be permitted under the 'transitional measures' outlined in Article 28
- EFSA must revise its scientific substantiation requirements and should adopt a non-hierarchical approach to evaluating evidence before re-evaluating botanical health claims
- A new regulatory framework allowing claims for traditional use of botanical products and ingredients should be developed, to bring it in line with traditional claims for herbal medicines (Directive 2004/24/EC)
- A graded approach to communicating the type of available evidence should be promoted to help inform consumers
- Legal action will be required if the EU is unwilling to amend the NHCR or methods of scientific substantiation – three legal cases are already in progress
- EU Member States should follow the Dutch example by allowing companies to 'interpret' the basic claims wording, significantly increasing the scope of claims