

Why do health professionals need to know about the nutrition and health claims regulation? Summary of an Academy of Nutrition Sciences' Position Paper

INTRODUCTION

Claims about the nutritional and health benefits of foods and drinks crop up everywhere. But are all claims authorised, thereby based on robust scientific evidence, and compliant with legislation? For example, such claims cannot be associated with alcoholic drinks.¹ And what regulatory processes exist to protect the public? The regulation of nutrition claims and health claims is the subject of a new Position Paper from the Academy of Nutrition Sciences.²

The Academy was established in 2019 (Box 1) to provide a collective voice for the nutrition science discipline, including those engaged in research, education and training, clinical practice and nutrition science communication. It seeks to reduce the levels of misinformation on nutrition and health and improve understanding of how evidence is scrutinised and evaluated to produce dietary recommendations.

The Academy has a strong interest in nutrition research excellence, development of the nutrition science discipline and application of the outcomes of rigorous nutrition science for public benefit. The main audience for the Academy's work is the nutrition science community/profession and its stakeholders (e.g., government/policy makers and research funding agencies).

Its first Position Paper, published in December 2020 in the *British Journal of Nutrition*³ (<https://doi.org/10.1017/S0007114520005000>), with accompanying editorials in *Nutrition Bulletin*⁴ (<https://onlinelibrary.wiley.com/doi/full/10.1111/nbu.12480>) and the *Journal of Human Nutrition and Dietetics* (<https://doi.org/10.1111/jhn.12863>),⁵ focused on the nature of the evidence base used in nutrition science and frameworks underpinning dietary recommendations for prevention of non-communicable diseases such as cancers and cardiovascular diseases.

The focus of the Academy's second Position Paper, published in 2022 in the *British Journal of Nutrition*,² is the global regulation of nutrition and health claims but with a specific focus on Europe. The European Union's (EU) Nutrition and Health Claims Regulation (NHCR) was first published in 2006⁶ and has since been adopted

for use in Great Britain (GB) after the UK's exit from the EU⁷ (claims made in Northern Ireland still fall under the auspices of the EU). The Position Paper summarises current regulations for the EU and GB, with comparisons to approaches used by other countries where different levels of claims are permitted (e.g., so-called qualified claims that require less robust substantiation). The Position Paper emphasises the learnings gained through the implementation of the European Food Safety Authority evidence-based process for assessment of proposed claims. A corresponding risk assessment process is now undertaken independently in GB by the UK Nutrition and Health Claims Committee.

The Position Paper is not intended to be a comprehensive or systematic review of the health claims literature; there are a number of recently published, authoritative reviews available for those seeking deeper insight into this complex area of regulation.^{8–10} Instead, the aim is to help non-specialists appreciate the frameworks in place to protect the public and the progress that has been made in recent years. It also makes recommendations that focus on remaining challenges for nutrition science, consumer understanding and key stakeholders, including practising health professionals. Indeed, as discussed later, it may come as a surprise to discover that the regulations that apply in the EU and GB include a clause that governs the activity of health professionals in certain circumstances.

WHY DO HEALTH PROFESSIONALS NEED TO KNOW ABOUT HEALTH CLAIMS LEGISLATION?

Health professionals (especially dietitians and nutritionists with formal training in the topic) are well placed to provide consistent and evidence-based advice on the effects of foods or food constituents on health and on risk markers for disease and to encourage responsible use of authorised claims on food labels to support healthier dietary choices. They are also in a position to provide reassurance about the rigorous processes used to assess

BOX 1 What is the Academy of Nutrition Sciences?

The Academy is the result of a long-standing collaboration between four founding member organisations: the Association for Nutrition (AfN), the British Dietetic Association (BDA), the British Nutrition Foundation and the Nutrition Society.

Further information is available at <https://www.academynutritionsciences.org.uk/faqs>. To date the main outputs from the Academy have been blogs (available via its website, <https://www.academynutritionsciences.org.uk/news>) and externally published position papers.

the strength and quality of evidence required before a health claim is authorised. There are particular settings in which dietitians and nutritionists may work, where knowledge of the NHCR and its associated guidance^{7,11} is of particular importance. Examples are (i) working in the media or with patients or the general public to help with identification and understanding about potential benefits of foods that carry authorised health claims; (ii) guiding food and drink businesses on the responsible use of rigorously authorised health claims in marketing or advertising, or providing support for businesses wishing to submit a new health claim application; (iii) academic research or clinical efficacy trials on behalf of industry partners seeking independent verification of a product's efficacy in relation to a health claim.

The NHCR covers all claims about food and drink products in commercial (marketing) communications, and Article 12(c) (see Box 2) regulates what health professionals can say and do in this context.

The context of Article 12(c) is specifically for commercial communications. Guidance in support of the regulation, published by GB government,⁷ explains that 'commercial communications' include

'any form of product labelling or packaging to be delivered as such to the final consumer, product specific advertising in any form, including in print, broadcast, internet or direct mail, promotional features in print media, in-store promotions and food business social media'. The guidance makes a clear distinction between commercial (health professionals not allowed to recommend) and non-commercial communications (health professionals allowed to recommend). The latter are dietary guidelines or advice issued by public health authorities and bodies, such as

BOX 2 What is Article 12 (c) in the NHCR?

Article 12(c) in NHCR

'prohibits health claims that make reference to recommendations of individual doctors or health professionals (or to an association other than a national association of medical, nutrition or dietetic professionals or a health-related charity)'.

advice to eat at least five portions of fruits and vegetables a day. Also, health professionals are able to provide information on a specific product to patients or clients during one-to-one consultations and information in scientific publications; textbooks and lectures; or 'business to business' content, such as press releases, brochures or websites where the final recipient is a business, healthcare professional or journalist rather than the general public.

The guidance⁷ states in Section 4.5:

'Our understanding is that this prohibition was put in place due to concern that, in commercial communications, the added weight of perceived professional expertise might unduly influence consumers, and the objective of the Regulation is that consumers should not be misled in any way'.

The Academy considers that there has been insufficient attention paid to the complexity and implications of health claims legislation for professional practice in nutrition and dietetics and considers that nutrition, dietetic and potentially other health professionals, such as doctors and nurses, should ensure they are up to date in their knowledge concerning the use of health claims. These days, in the formal training received by registered dietitians and registered nutritionists, there is typically some inclusion of pertinent food legislation, such as the NHCR and the associated authorisation processes discussed here, but the extent is likely to vary between courses. Other types of health professionals and those working on the periphery of the food and health sectors are less likely to be familiar with the rigorous nature of the approval process and the complexity of the regulation and associated guidance. As detailed later, the Academy has made recommendations in relation to training programmes and also continuous professional development (CPD) provision for practitioners working

in this area (e.g., doctors and other health professionals giving dietary advice), to attain and maintain their knowledge and understanding of the NHCR, and implications for their professional practice.

A further issue that arises in the context of commercial communications is the wording in Section 10 of the current GB guidance,⁷ which states that *celebrity endorsements do not appear to fall within the scope of the prohibition in Article 12(c) (unless the celebrity is a doctor or health professional)*.

The Academy's Position Paper suggests that the current situation appears, by default, to allow non-professionals (e.g., 'influencers' and 'celebrities') with limited or no professional training in nutrition science to provide high-profile endorsements of authorised health claims within advertisements and marketing materials for foods and food supplements. The Position Paper states that 'at the very least, celebrity endorsement may give undue weight to an authorised health claim and the influence such individuals can have on the public is often far greater than any individual health professional. Even more seriously, lack of training in nutrition science and the associated legislation may risk influencer and celebrity endorsement being associated with non-authorised and potentially unsafe or misleading claims'.

Although it is clear that the legislation on health claims came into force prior to the full evolution of social media and associated marketing of products by influencers, it is also the case that diets, foods and dietary supplements have now become a major segment for income generation via social media. This presents the potential to undermine the main principles of the NHCR, which is precisely to help/protect the consumer by distinguishing fully evidenced authorised claims from those which have limited or no scientific validity. The legislation also creates a non-level-playing field where qualified nutrition/dietetic professionals, whose practice is governed by Codes of Practice and professional registration, are not permitted to communicate authorised health claims to consumers in commercial communications, whereas unqualified individuals can. This situation appears to be inconsistent with the aims and objectives of the regulation and potentially undermines the principles of evidence-based and proportionate regulation. The Academy considers that the current guidance associated with Article 12(c) needs to be reviewed to help ensure consistent interpretation and consumer protection. A growing number of nutritionists and dietitians work in commercial settings, such as with or in the food industry, and may wish to refer to authorised health claims to highlight health relationships or to inspire confidence in the processes outlined in the Position Paper. However, preliminary findings of a small survey of professionals working in the sector reveal widely differing interpretations of the current GB guidance in relation to interpretation of Article 12(c),¹² suggesting that further clarification is needed on what nutrition and dietetic professionals working in commercial communications settings are reasonably permitted to do.

STRENGTHS AND OTHER CHALLENGES OF HEALTH CLAIMS REGULATION

The regulation of health claims for foods and drinks is intended, primarily, to protect consumers from unscrupulous claims by ensuring claims are accurate and substantiated with high-quality scientific evidence. In its Position Paper, the Academy recognises the strengths of the transparent, rigorous scientific assessment by independent scientists of the evidence underpinning claims in the EU, an approach now independently adopted for GB after the UK's exit from the EU. Further strengths are the separation of risk assessment (evidence) from risk management (setting policy) and the extensive guidance for those submitting claims for potential authorisation. Nevertheless, four main challenges in assessing the scientific evidence and context in alignment with the regulation remain: (i) the added complexity of undertaking efficacy trials for foods in human subjects compared to protocols for drug trials; (ii) defining a 'healthy' population for these trials as specified in the regulation; (iii) developing clearly defined biomarkers for some outcomes, to support robust efficacy trials; and (iv) ensuring the composition of a food bearing a health claim is consistent with 'generally accepted nutrition principles'.

The Position Paper also illustrates the challenges experienced by consumers seeking to use health claims to identify diets and foods which may improve their health, including foods that can reduce risk factors for chronic illnesses, such as heart disease, osteoporosis or diabetes. Many consumers report finding the wording of health claims unclear or lacking sufficient motivational content. Others perceive health claims with scepticism, whereas some are positively influenced by the presence of a health claim on a product such that they mistakenly assume the product has nutritional benefits, in addition to the claimed effect, that are not warranted, sometimes referred to as a 'health halo' effect. Furthermore, consumer research concerning health claims is still at a relatively early stage, with findings reflecting the wide cultural and socio-economic variation that exists across Europe and globally.

RECOMMENDATIONS

The Academy's position paper concludes with some recommendations:

1. The academy considers that a clear consensus concerning the scientific classification of 'healthy' and 'unhealthy' individuals in efficacy trials has not yet been fully explored or agreed. Development of clearly defined biomarkers that can support such definitions and which may also be used as outcome

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