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Commentary

Recommendations for successful substantiation of new health claims in the European Union

Igor Pravst[a,*], Anita Kušar[a], Katja Žmitek[a], Krista Miklavec[a], Živa Lavriša[a], Liisa Lähteenmäki[b], Viktorija Kulikovskaja[b], Rosalind N. Malcolm[c], Charo Hodgkins[d], Monique M. Raats[d], the REDICLAIM Consortium

[a] Nutrition Institute, Tržaška cesta 40, 1000 Ljubljana, Slovenia
[b] Aarhus University, MAPP Centre, Fuglesangs allé 4, 8210 Aarhus V, Denmark
[c] School of Law, University of Surrey, Guildford, Surrey, GU2 7XH, United Kingdom
[d] Food, Consumer Behaviour and Health Research Centre, University of Surrey, Guildford, Surrey, GU2 7XH, United Kingdom

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ABSTRACT

Background: While functional foods offer promise for public health and innovation in the food industry, the efficiency of such foods should be assured to protect consumers from misleading claims. Globally, many countries regulate the communication of the health effects of such foods to final consumers.

Scope and approach: In the European Union (EU), the use of health claims was harmonized in 2006. All claims need to be scientifically assessed by the European Food Safety Authority (EFSA) and pre-approved. Implementing the regulation has involved a steep learning curve for stakeholders, resulting in many health claims being rejected. The EU-funded REDICLAIM project used existing guidance documents, analyses of Scientific Opinions on new health claim applications, and a series of interviews with experts involved in such applications to identify key points in the process of authorizing new health claims.

Key findings and conclusions: Recommendations for the successful substantiation of new health claims in the EU were prepared. The substantiation of health claims is primarily based on human efficacy studies, and greater resources are required to authorize more innovative claims. The reported recommendations should be seen as a starting point for researchers in the area of nutrition and food technology, and for those dealing with functional foods, including the food industry.

1. Introduction

Nutrition is recognized as an important modifiable factor influencing human health. While overconsumption of energy-dense foods results in high energy intakes and growing incidence of obesity and a series of non-communicable diseases, specific populations are still at risk of nutrient deficiencies. Foods are a source of nutrients for the human body, but can also support body functions beyond adequate nutritional effects – providing health benefits. Discussions regarding functional food as a regulatory concept originated in Japan in late 1980s (Kwak & Jukes, 2001; Weststrate, van Poppel, & Verschuren, 2007). The development of functional foods was later particularly affected by regulations related to the use of health claims on foods (Ashwell, 2002; Weststrate et al., 2007). In the USA, evidence-based health or disease prevention claims have been allowed since 1990, when the Nutrition Labelling and Education Act was adopted (Arvanitoyannis & Houwelingen-Koukaliaroglou, 2005). In the European Union (EU), harmonization was achieved in 2006 with Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (NHCR) (EC, 2006), which requires health claims to be authorized before market entry (Verhagen & van Loveren, 2016). There is evidence of substantive use of health claims in EU countries, particularly in certain food categories (Hieke et al., 2016; Kaur et al., 2016; Kaur et al., 2015; Lalor, Kennedy, Flynn, & Wall, 2010; Lopéz-Galán & De-Magistris, 2017; Pravst & Kušar, 2015; Storcksdieck genannt Bonsmann et al., 2010). In a 2013 study, about 7–14% of pre-packed foods in selected EU countries were found to carry health claims (Hieke et al., 2016).

While functional foods with health claims provide opportunity for fostering innovation in the food sector and improving public health, there are also potential risks associated with their use, for example the lack of beneficial health effects or even health concerns which may

* Corresponding author.
E-mail address: igor.pravst@nutris.org (I. Pravst).

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arise from the regular consumption of these foods. Therefore many countries carefully regulate the use of health claims (de Boer & Bast, 2015).

The rationale behind the requirement for pre-approval of all specific health claims is ensuring fair competition and effective functioning of the internal EU market, as well as protection of consumers from misleading claims (EC, 2006). The latter is particularly important because health benefits are credence attributes, that is qualities that cannot be observed by a consumer. After a scientific assessment by the European Food Safety Authority (EFSA), the NHCR requires all health claims to be authorized by the European Commission (EC) through the comitology procedure (EC, 2017c). The Commission must act in line with the principles of good administration, and this imposes a duty of care on the Commission to act in good faith ("Demo-Studio Schmidt v Commission," 1983), to give due consideration to all the arguments presented ("Nolle v HZA Bremen-Freihafen," 1991), and to the task in hand ("Commission v Estonia," 2012). In particular, Recital 16 of the NHCR requires the Commission to ensure that the claim can be well understood by consumers.

A key aspect of any health claim application is the provision of evidence regarding the cause-effect relationship between consumption of the food (constituent) and the claimed health outcome (Martínez & Siani, 2017; Navas-Carretero & Martinez, 2015). Implementing the NHCR has involved a steep learning curve for different stakeholders, including policy makers and authorities in the EU member states, the EFSA, and the food industry (Martin, 2015; Vero & Gasbarrini, 2012), with several suggestions having been made to improve it (Cappuccio & Pravst, 2011; de Boer, Urlings, & Bast, 2016; Kaur et al., 2016; Pravst, 2011). In many cases, health claim applications were evaluated with a negative outcome by the EFSA – often because they were not supported by sufficient scientific evidence (Verhagen & van Loveren, 2016). While an important objective of the NHCR was to foster innovation in the food sector, some evidence suggests that the opposite might be the case (Bröring, Khedkar, & Ciliberti, 2017; Khedkar, Ciliberti, & Bröring, 2016).

The challenges associated with the use and substantiation of health claims have been recognized by the European Commission (EC), resulting in the funding of specific projects in the EC's Seventh Framework Programme on topics including the role of health claims in consumer behaviour [CLYMBOL project (Hieke et al., 2015)] and food constituents that show potential [FIBEBIOTICS project (Mes, 2013), BACCHUS project (Buttriss, 2015)]. The REDICLAIM project was funded, with the aim to assess the NHCR, where a particular emphasis was on "reduction of disease risk" (RDR) claims (so called Art 14.1.a claims), and also new function claims (so called Art 13.5 claims). The project's focuses are: (1) understanding the main issues and hurdles concerning the substantiation and use of health claims on foodstuffs, and the level of awareness about legal obligations regarding the use of claims among the relevant stakeholders; and (2) to produce a three-fold study of the NHCR's impact on the claim substantiation process, health research and/or innovation in the food chain, and nutrition economic models – to determine the health impact (Raats et al., 2015). Another key project objective was to support the food business in the enhanced development of innovative and competitive products, and their better compliance with the regulation.

2. Methodology and approaches

One of the REDICLAIM's work streams ascertained the interaction between legislation and the claim substantiation process, and on prepared key recommendations for the successful substantiation of new health claims in the EU – covering new function claims, as well as and RDR claims.

The health claims legislation in selected developed countries/regions (EU, USA, Canada and Australia/New Zealand) was compared, focusing on the advantages and disadvantages of different solutions from a research and development perspective (Raats et al., 2016). In all selected jurisdictions, RDR claims must be pre-approved before being used in the market. Applicants are usually food companies or producers of food ingredients and the application procedures are well defined. The strength of scientific evidence needed to substantiate such health claims is typically described as "generally accepted scientific evidence of beneficial physiological effect in humans" (EU), "significant scientific agreement" (USA and Canada), and an "established food-health relationship based on the totality and weight of evidence" (Australia and New Zealand) (Raats et al., 2016).

Health claim applications receiving an unfavourable evaluation from EFSA are either a result of poor quality available scientific data, or poor presentation of such data (i.e. the quality of the application) (Martínez & Siani, 2017; Pravst, 2010). In order to understand this in more detail, existing EFSA Opinions on new health claim applications were analysed, and interviews were conducted with experts experienced in preparing health claim dossiers, mostly from the food industry and research consultancy service providers specialized in the health claim authorization process. Analysis of the EFSA's Opinions focused on all, favorable and unfavorable, applications for RDR claims after the NHCR was introduced in 2007. Critical issues were identified and coded. Interviews were conducted with successful and unsuccessful RDR claim and new function health claim applicants. In practice, these claims can result in the authorization of company-specific, proprietary health claims, and may therefore represent a driving force for innovation in the food industry. Interviewees found the health claim application process to be either easy or challenging, depending on the novelty of the claimed health benefit and/or underlying science. The process was perceived as straightforward for food constituents for which existing knowledge can be exploited (e.g. for various well investigated types of dietary fibre in relationship to cholesterol lowering), while the process was regarded as much more challenging for health claims based on emerging scientific findings (i.e. less investigated types of fibre, plant extracts and their specific constituents, probiotics).

Based on the results of the above mentioned literature review of EFSA Opinions and interviews, key recommendations for the successful substantiation of new health claims in the EU (Fig. 1) were identified and a draft document containing the recommendations was prepared

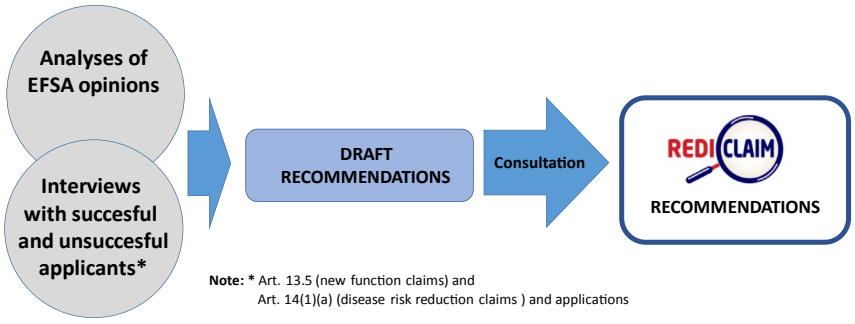

Fig. 1. Schematic approach to identifying key recommendations for the successful substantiation of new health claims in the European Union.