

## **Understanding the impact of legislation on ‘reduction of disease risk’ claims on food and drinks: the REDICLAIM project**

Monique M. Raats<sup>1</sup>, Rosalind N. Malcolm<sup>1</sup>, Liisa Lähteenmäki<sup>2</sup>, Igor Pravst<sup>3</sup>, Heather Gage<sup>1</sup>, Amanda Cleary<sup>4</sup>, Anastasia Karatzia<sup>5</sup>, Anita Kušar<sup>3</sup>, Wei Yang<sup>6</sup>, Daniel L. Jackson<sup>1</sup>, Charo E. Hodgkins<sup>1</sup>, Marija Klopčič<sup>7</sup>, the REDICLAIM Consortium

<sup>1</sup>Food, Consumer Behaviour and Health Research Centre, University of Surrey, Guildford, Surrey, GU2 7XH, United Kingdom

<sup>2</sup>Aarhus University, Department of Management, Bartholins Allé 10, 8000 Aarhus C, Denmark

<sup>3</sup>Nutrition Institute, Tržaška cesta 40, 1000 Ljubljana, Slovenia

<sup>4</sup>ECIT Foundation, 40, Rue Washington, B-1050 Brussels, Belgium

<sup>5</sup>Department of International and European Law, Erasmus School of Law, Erasmus University Rotterdam, NL-3000 DR Rotterdam

<sup>6</sup>University of Kent, Centre for Health Services Studies, Canterbury, Kent CT2 7NF, United Kingdom

<sup>7</sup>University of Ljubljana, Department of Animal Science, Groblje 3, 1230 Domžale, Slovenia

### **Keywords**

disease risk reduction claims; food labelling; legislation; innovation; claim substantiation; health economics

### **Abstract**

The Nutrition and Health Claims Regulation (EC No. 1924/2006) has established a common framework for the regulation of nutrition and health claims used on foods across the European Union. This regulation aims to provide the European food industry opportunities for product innovation whilst protecting consumer interests with respect to controlling misleading advertising and promoting public health. However, in order to satisfy the approval of new health claims procedure particularly for new ‘reduction of disease risk’ claims [Article 14(1)(a) claims], significant research activity is required by industry to scientifically substantiate the claims they wish to make. There is a need to establish whether the implementation of this legislation is in fact driving product innovation and the development of healthy foods or whether it forms a barrier to such developments. The EU-funded REDICLAIM project is currently considering these issues. This article describes the project’s preliminary results and outlines the further programme of work.

### **Introduction**

Differences in legislation related to providing health-related information have varied widely before the common European Union (EU) legislation on claims. This has acted not only as barrier against free movement of goods and fair competition, but has also as a potential barrier to investing in health-related research to produce products that have specific health outcomes, including those contributing to disease risk reduction. Reports of studies investigating labelling of pre-packaged foods in EU countries showed that while 7-14% of foods was labelled with health claims, reduction of disease risk’ claims were present on less than 1% of the investigated items (Hieke et al. 2016, Pravst et al. 2015). The European Regulation on nutrition and health claims on foods [Nutrition and Health Claims Regulation (hereafter NHCR) (European Commission (EC) No. 1924/2006; EC 2006,

2008a,b,c, 2009a; European Parliament and the Council of the European Union 2007, 2008) is a harmonising law allowing health claims (Commission of the European Communities 2003) on foods to be made in a uniform manner throughout the Member States of the European Union (EU). Upon its introduction, the EC (2009b) stated that the main objectives of the proposed Regulation were to:

- achieve a high level of consumer protection by providing further voluntary information, beyond the mandatory information foreseen by EU legislation;
- improve the free movement of goods within the internal market; increase legal security for economic operators;
- ensure fair competition in the area of foods; and
- promote and protect innovation in the area of foods.

The REDICLAIM (Understanding the impact of legislation on 'REduction of Disease risk' CLAIMs on food and drinks) project aims to analyse whether these set goals have been achieved and whether they are regarded as achievable by stakeholders based on their opinions on how the legislation has been implemented.

The NCHR (EC 2006) aims to safeguard that claims made on are substantiated by scientific evidence (EC 2008a,b,c, 2009b). The European Food Safety Authority (EFSA) is responsible for verifying the scientific substantiation of the claims submitted for authorisation in the EU. The EC then use EFSA's opinions to decide whether to authorise the claims.

The REDICLAIM project focusses on new general function claims [Article 13(5)] which were not in use before 2006 or are based on newly developed scientific evidence, and 'reduction of disease risk' claims [Article 14(1)(a) claims] that state, suggest or imply that the consumption of a food or food constituent significantly reduces a risk factor in the development of a human disease. It should be noted that 'Reduction of disease risk' claims are different from medicinal claims that relate to the prevention a disease. For both new general function claims and reduction of disease risk claims, applicants can request for 5 years of protection of proprietary data. This gives companies time to differentiate their products from those of other companies and is thus create a competitive advantage through product innovation.

Food products with health claims, particularly 'reduction of disease risk' claims require multidisciplinary research efforts from identifying the potential risk factors through to applying the gained knowledge in concrete food applications. An increased prevalence of life style-related non-communicable diseases has fuelled the interest in the associations between food and health, resulting not only in higher public funding of multidisciplinary science projects, but also higher private investment.

REDICLAIM is an EU-funded project which started in 2013 and ends in October 2016. The project seeks to assess the NCHR (2006). REDICLAIM will: (1) Seek to understand the (a) main issues and hurdles concerning substantiation and use of 'reduction of disease risk' claims on food and drinks; (b) level of awareness about legal obligations with regard to 'reduction of disease risk' claims on food and drinks among the relevant stakeholders; and (2) Produce a three-fold study of the impact of nutrition and health claims legislation specific to 'reduction of disease risk' claims on food and drinks on: (a) The claim substantiation process, (b) Health research and/or innovation in the food chain, and (c) Nutrition economic models to determine health impact. An overview of the project structure and research plans can be found in Raats et al. (2015).

## **Results and discussion**

### ***Work package 1: Stakeholder engagement and dissemination***

REDICLAIM's community of interested stakeholders (e.g. industry, regulatory bodies, clinical trial specialists, scientists, health professionals and civil society) is being brought together to reflect on project findings.

### ***Work package 2: Establish the regulatory frameworks for 'reduction of disease risk' claims on food and drinks***

A desk-based exercise coupled with interviews at government level, mapped the regulatory framework and decision-making process for health and nutrition claims at EU level; and mapped and analysed the implementation of the regulatory framework for 'reduction of disease risk' claims at Member State level. It is clear that there are significant problems relating to the operation of the Nutrition and Health Claims Regulation (EC) No 1924/2006 (hereafter NHCR). These arise from a variety of factors including:

- the clash between the twin aims of consumer protection and trade;
- the inevitable centring of the NHCR on Article 114 of the Treaty for the Functioning of the European Union;
- the lack of a clear legal basis in the Treaty for the Functioning of the European Union for public health and nutrition matters;
- the uneasy fit of NHCR into the food safety context when it is in fact based on the medicines evaluation model whereby proof of efficacy rests upon the link between active ingredient and health and the health outcome which is likely to be achieved;
- the role of EFSA in the evaluation of claims under the NHCR where EFSA's primary function is in assessing risk rather than in the evaluation and analysis of the benefit of an ingredient;
- the lack of a clear mandate and basis for EFSA to act in NHCR claims;
- the lengthy delays in processing claims; and
- legal aspects of the regulation, particularly the 'comitology' procedures which pertained at the time of implementation of NHCR.

A second task mapped the top-level implementation of 'reduction of disease risk' claims at Member State level. The purpose was to identify and illustrate the role of the Member States in the authorisation and enforcement process, as well as potential differences between the approaches of each Member State regarding the use of 'reduction of disease risk' claims on food. In most cases the national framework was concerned with the implementation of Directive 2000/13 EC (now replaced by Regulation 1169/2011) on food labelling. All member states had national legislation supplementing NHCR but in varying degrees.

### ***Work package 3: Exploring the interaction between legislation and health research and/or innovation in the food chain***

Health claim substantiations are performed by taking the totality of the available pertinent scientific data into account and by weighing it, in particular as to whether: (1) the effect is relevant for human health; (2) there is an established cause and effect relationship between the consumption of the food and the claimed effect in humans; (3) the effect has been shown on a study group which is representative of the target population; and (4) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet.

The first task identified the kind of research used to support health claim applications based on new knowledge (13.5 claims) and 'reduction of disease risk' claims (14.1a claims). Claim substantiation is mainly based on relatively new but not the most recent peer-reviewed and published research.

Companies have a role in partly funding the research in co-operating with the academic researchers, but the use of unpublished data is limited in claim applications. EU's role as a funding body is very limited in the cardiovascular health claim applications submitted by the end of 2013. Further work will explore food manufacturers' willingness/capability to exploit new research findings in cardiovascular health related innovation processes; and the role of health claim regulation as a facilitator or barrier to research-based innovation aimed at developing products based on new findings and risk reduction of diseases.

#### ***Work package 4: Ascertaining the interaction between legislation and the claim substantiation process***

The first task compared NHCR with health claims legislation in other developed countries (USA, Canada, Australia, New Zealand), focusing on advantages and disadvantages of different solutions from a research and development perspective. In all selected jurisdictions, 'reduction of disease risk' claims need to be pre-approved before being used on the market. Food businesses have the possibility to apply for authorization of new 'reduction of disease risk' claims and procedures are well defined. Applicants are fully responsible for preparation of application dossiers. The process of evaluation of the submitted proposals and authorization of new health claims is not subject to fees, however it is likely that fees will be implemented in Australia and New Zealand. Typical description of the strength of scientific evidence needed for approval of such health claims is 'generally accepted scientific evidence of beneficial physiological effect in humans' in the EU, 'significant scientific agreement' in the USA and Canada, and 'established food-health relationship based on the totality and weight of evidence' in Australia and New Zealand. Further work will include an investigation of known assessments of health claim applications and reasons for rejections; and case studies on applicants' experiences of the health claim application process with focus on positively and negatively assessed applications.

#### ***Work package 5: Nutrition economic models for food constituents associated with 'reduction of disease risk' claims***

Based on a review of the relevant literature, a decision analytic model has been built and parameters have been assembled to appraise the cost-effectiveness of plant sterol/stanols in the management of people with hypercholesterolemia. Based on the English population, the model is being used to calculate cardiovascular disease risk reduction associated with plant sterols/stanols incorporated in dairy products/margarine spreads, when compared to a normal diet. The number of avoided events, and the associated savings to the British National Health Service, are being simulated over 20 years under varying assumptions about compliance rates. This will show whether promotion of sterol/stanol enriched functional foods are cost effective, and for which age and sex groups in the population.

### **Conclusions**

One of the central aims of the NCHR is to ensure a high level of consumer protection through requiring that all health claims be scientifically substantiated and approved before use; thus creating a positive list of claims for use in the European market. REDICLAIM results will contribute to the:

- Development of an evidence base of the process by which health claims are made and controlled by regulatory frameworks.
- Effectiveness of the control of health claims by regulation.

- Establishment of recommendations for government, industry and the scientific community with a view to conducting the necessary research and development of products carrying health claims.

In order to achieve both effective compliance with better regulation and, to contribute to the enhancement of innovative and competitive products REDICCLAIM will:

- Enable the identification of regulation as a barrier or driver to the use of 'reduction of disease risk' claims and their scientific basis.
- Identify regulatory gaps and will develop guidelines for the effective regulation of health claims which enable and enhance innovation while meeting the consumer and ethical perspectives. Support tools will be developed for stakeholders to inform issues concerning the substantiation and use of 'reduction of disease risk' claims on food and drinks.
- Provide the European legislator with a proposal for issues relating to the enforcement of legislation specific to substantiation and use of 'reduction of disease risk' claims on food and drinks.

### **Acknowledgements**

REDICCLAIM has received funding from the EU's Seventh Framework Programme for research, technological development and demonstration (contract number FP7-603036).

### **Conflict of interest**

The authors have no conflict of interest to disclose.

### **REDICCLAIM project partners**

- Aarhus University (Denmark)
- University of Surrey (UK)
- University of Ljubljana (Slovenia)
- Nutrition Institute (Slovenia)

### **References**

Commission of the European Communities, 2003. Commission Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods; COM (2003) 424 final COD 2003/0165 of 18 July 2003.

EC, 2006. Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union L404: 9–25.

EC 2008a. Regulation (EC) No. 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission. Official Journal of the European Union L39: 8–10.

EC 2008b. Regulation (EC) No. 109/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods. Official Journal of the European Union L39: 14–5.

EC 2008c. Regulation (EC) No. 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in article 15 of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council. Official Journal of the European Union L109: 11–6.

EC 2009a. Regulation (EC) No. 1169/2009 of 30 November 2009 amending Regulation (EC) No. 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in article 15 of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council. Official Journal of the European Union L314: 34–5.

EC 2009b. Community register of health claims. Available at: <http://ec.europa.eu/nuhclaims> (accessed 25 March 2016).

European Parliament and the Council of the European Union, 2007. Official Journal of the European Union L404: 3–18.

European Parliament and the Council of the European Union, 2008. European Commission Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 Text with EEA relevance.

Hieke, S. et al. 2016. *Nutrients* 8, 137; doi:10.3390/nu8030137

Pravst, I et al. 2015. *Nutrients* 7(11), 9353; doi:10.3390/nu7115474

Raats, MM et al. 2015. *Nutrition Bulletin* 40(4), 340-348; doi: 10.1111/nbu.12179