

Understanding the impact of European regulation on the substantiation and use of claims on food & drinks

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AIMS

Redicclaim seeks to understand the way in which the European 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 and associated legislation has had and continues to have an impact on the substantiation and use of "reduction of disease risk" claims on food and drinks.

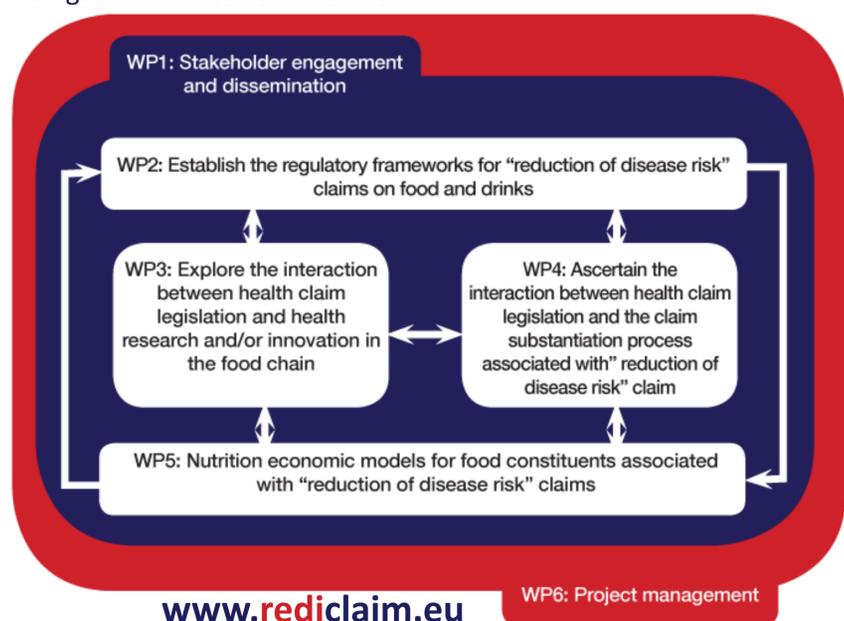
METHODS

Establishing the regulatory frameworks

- mapping the regulatory framework and decision-making process for health and nutrition claims at EU level
- mapping and analysing the implementation of the regulatory framework for 'reduction of disease risk' claims at Member State level
- mapping and analysing the evidence of compliance to enable research into impacts of legislation on innovation

Exploring the interaction between legislation and health research and/or innovation in the food chain

- identifying research carried out on beneficial interactions between the presence or absence of a food component and cardio-vascular function(s) in the body
- exploring food manufacturers' willingness/capability to exploit new research findings in cardio-vascular health related innovation processes
- exploring 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



Ascertaining the interaction between legislation and the claim substantiation process

- comparison of legislation of EU with that in other developed countries
- investigation of known assessments of health claim applications and reasons for rejections
- case studies on applicants' experiences of the health claim application process with focus on positively and negatively assessed applications

Nutrition economic models

Nutrition economic modelling methods are used to calculate the potential health and economic impact of 'reduction in disease risk' claims on the general population by establishing the:

- proportion of the population with suboptimal consumption of the food (constituent) of interest
- impact of optimal consumption levels on disease burden and health care costs

PRELIMINARY RESULTS

Table 1. Analysis of 33 cardiovascular function-related claim dossiers decisions across submitted through 10 member states

	13.5 claims <i>Function claims based on newly developed scientific data</i>		14.1a claims <i>Reduction of disease risk claims</i>		All claims
	Negative	Positive	Negative	Positive	
Mean impact factor	2.7	7.2	6.5	5.6	5.5
Authors' affiliation					
University	41	28	80	105	254
Company	36	8	19	44	107
Hospital	10	12	15	33	70
Research centre	11	1	19	25	56
NGOs	1	0	3	12	16
Government	3	2	11	18	34
Other	4	0	7	7	17
Total	106	51	154	224	554

Table 2. Types of publications used in cardiovascular function-related claim substantiation dossiers

	13.5 claims <i>Function claims based on newly developed scientific data</i>	14.1a claims <i>Reduction of disease risk claims</i>	All claims
Peer-reviewed journals	94	250	344
Reports, not peer-reviewed articles	2	4	6
References, standards & guidelines	0	4	4
Scientific opinions	2	20	22
Non-published documents	19	21	40
Patent applications	2		2
Total	119	299	418

Structural issues identified (EU level)

- Legal base
 - scope of legislation
 - aim of legislation
- Legislative overlap
 - breach of general principles of law
 - application of *lex specialis*, i.e. where two laws govern the same factual situation, a law governing a specific subject matter overrides a law which only governs general matters
- Institutional deficiencies
 - Commission, EFSA, national agencies
- Methods of delegation of decision-making powers
 - comitology, i.e. a process by which EU law is modified or adjusted and takes place within "comitology committees" chaired by the European Commission

Litigation issues identified (EU level)

- Potential for challenges before the Court of Justice of the European Union
 - preliminary references (Art. 267, Treaty on the Functioning of the European Union (TFEU))
 - direct actions (Art. 263 TFEU)
- Potential for challenges before the World Trade Organization
 - 3rd country complaints to the Dispute Settlement Body

