Regulatory Toxicology and Pharmacology 68 (2014) 475–487

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Implementation of the nutrition and health claim regulation – The case of antioxidants

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ARTICLE INFO

Article history:
Received 30 October 2013
Available online 10 February 2014

Keywords:
EFSA
European Commission
Food law
Scientific substantiation
Functional ingredients
Oxidative stress
Antioxidants
Nutrition research
Multifactorial

ABSTRACT

This article analyses the consequences of the implementation of the nutrition and health claim regulation in the field of food products containing antioxidants or food products claiming antioxidant activity. To this end, it first examines the origin and creation of the regulation and the involvement of EFSA in assessing scientific substantiation of health claims. Three criteria are regarded as critical in EFSA's opinions on the scientific substantiation of a health claim: the claimed effect (i) is well defined; (ii) is a clear beneficial physiological effect; and (iii) shows a cause effect relationship with the consumption of the food or functional ingredient. These criteria have implications for the research requested to substantiate health claims, although these implications do not all seem to fit nutrition research as it is currently executed. Looking at antioxidants, the complexity of the mechanisms and actions of antioxidants is not recognised by the criteria used to evaluate proposed health claims, nor by the methodologies used to assess the effects of antioxidants. These criteria should be adjusted with novel scientific insights after consulting stakeholders.

1. Introduction

After several Europe-wide food scares in the 1990s, there was a call to reform European food law (Hoad, 2011; Levidow and Carr, 2007; van der Meulen and van der Velde, 2008a; van der Meulen, 2009). Different advisory papers from the European Commission (EC) as the Green Paper (1997) and White Paper on Food Safety (2000), describing the vision on food law followed (European Commission, 1997, 2000). In 2002 the 'Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety', also called the General Food Law (GFL), entered into force (European Parliament and the Council, 2002; Levidow and Carr, 2007). This GFL is seen as the cornerstone of the European food law today (Szajkowska, 2009).

In addition to the GFL, the EU has adopted a great number of specific rules dealing with various aspects of the food chain and specific food components, as the use of flavourings (European Parliament and the Council, 2008), microbial criteria for food products (European Commission, 2010), or food information to consumers (European Parliament and the Council, 2011). Importantly, one of these specific rules deals with claims and statements made on food products about the effect of the product after intake: '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', also called the Nutrition and Health Claim Regulation (NHCR) (European Parliament and the Council, 2006). This regulation requires the information on the label provided to consumers to be based on scientific evidence, to prevent consumers from being misled by unclear or incorrect information and false claims (Hoad, 2011; Moors, 2012). The use of a claim is allowed or refused by the EC, after consulting the expert opinion of the European Food Safety Authority (EFSA) on the submitted claim (European Food Safety Authority, 2013a).

The NHCR entered into force on 1 July 2007, regulating all communications about nutritional content and health benefits of a product. All proposed claims were assessed by EFSA and documented in the so-called 'EFSA opinions'. Remarkably, the opinions gave negative advices on almost all suggested health claims in the field of food products or functional ingredients containing antioxidants or claiming antioxidant activity as shown in Table 1 below. This table provides an overview of proposed, authorised and non-authorised claims on antioxidants. Only eight claims out of 230 on antioxidant activity were assessed positively and subsequently

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http://dx.doi.org/10.1016/j.yrtph.2014.01.014
0273-2300/

Table 1
Claims on antioxidants in EU Register on nutrition and health claims (European Commission, 2012b).

Search term in register	Proposed claims	Authorised claims	Non-authorised claims
Antioxida[a,b]	156	0	156
Phenol[a]	26	1	25
Oxida[a]	230	8[c]	222

[a] Search term as entered in register.
[b] Both as substance and effect.
[c] Includes the positive opinions within phenol[a] as search term.

authorised by the EC to be used on products, *viz.* seven claims on vitamins and minerals, one claim on olive oil polyphenols (European Commission, 2012b).

EFSA's negative opinions led to a denial of proposed claims on antioxidants as property, ingredient, protector against oxidative damage or in maintaining the immune system (European Commission, 2012b). The positive opinions from EFSA on water-soluble tomato concentrate I and II (NDA Panel EFSA, 2009b, 2010a) and on cocoa flavonoids (NDA Panel EFSA, 2012b) are not taken into account here. The claimed health benefits of these products are not associated with antioxidant activity, and are not specifically regarded as a consequence of antioxidants as the active ingredient.

As a result of the negative opinions of EFSA on antioxidant related health effects and subsequent declines of proposed health claims by the EC, today no statements about ingredients acting as antioxidants or their health effects are allowed to be made, except for claims based on the previously mentioned positive opinions (Europe Press Releases, 2006; European Commission, 2012b). For industrials in this field, who are not able to communicate the benefit of their product, this may be a reason to no longer focus their research on antioxidants (Ernst & Young, 2012; Hoad, 2011).

The EC as regulator considers the regulation of health claims a stimulation for the industry to innovate and to develop healthier foods or food products with functional benefits, thereby improving their competitiveness (Flynn, 2012; Moors, 2012). Nevertheless, several industrials view the NHCR suppresses creativity and innovations and notice flaws in the regulation and its implementation, with unclear criteria on the required scientific evidence to substantiate a claim. Other parties, critically following the regulation, however state that extensive guidance is offered to applicants by several guidance documents from EFSA (Ernst & Young, 2012; Flynn, 2012; Gilsenan, 2011; Hoad, 2011; Moors, 2012). These parties expect uncertainty on the evidence needed to substantiate a claim certainly will decrease even more with the list of approved claims published in December 2012 as annex to 'Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health' (Europe Press Releases, 2006; European Commission, 2012a; Gilsenan, 2011; Moors, 2012). Although many opinions and critiques on the regulation and the used assessment criteria were expressed, no critical evaluation has been written defining the problems that arise from the implementation of the NHCR.

This paper aims to fill that lacuna. Therefore, this paper analyses the implementation of the NHCR, taking food products containing antioxidants or claiming antioxidant activity as a case study. The mechanism of action of antioxidants is currently highly debated, which makes this case study very timely. Two research questions are put forward: (i) Which criteria are used to assess the scientific substantiation of health claims; and (ii) Whether these criteria are suitable to assess a claim.

In this paper, first the framework of the NHCR is described, followed by the establishment of EFSA and the role of EFSA in the NHCR. Subsequently different opinions on claims of antioxidants are analysed to answer the research questions, which is followed by the conclusions of this paper.

2. Nutrition and Health Claim Regulation: realisation and definitions

The Nutrition and Health Claim Regulation entered into force in 2007, and was preceded by scientific projects and advisory papers.

2.1. Creating regulation on claims

Increasing interest in the concepts of functional foods and health claims led the European Union and International Life Sciences Institute Europe (ILSI Europe) to start the FUFOSE (Functional Food Science) project in 1995, to create an approach for evidence needed to support the development of functional foods, based on science (Diplock et al., 1999; European Food Information Council). This research project also addressed the concept of health claims. The final document in 1999 defined two types of health claims: (i) enhanced function claims, claiming actions of a product going further then their established functions in the body and (ii) reduction of disease risk claims, claiming the consumption of a specific food or functional ingredient will help to decrease the risk of a specific condition (Diplock et al., 1999). To implement the conclusions and principles of the FUFOSE project, the PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods) project was started, to define criteria for studies to substantiate both types of claims (Aggett et al., 2005; European Food Information Council). The final document of PASSCLAIM, published in 2005, defined criteria for substantiation of a claim, although it was emphasised these criteria only serve as a template for the evaluation process and could provide guidance for applicants; there was still a need to include expert advice in development of regulation on health claims (Aggett et al., 2005). PASSCLAIM also proposed a third type of health claim, *viz.* the nutrient function claim, closely related to the enhanced function claim. Where enhanced function claims describe functions of the product beyond established functions in the body, a nutrient function claim describes the physiological role of a nutrient in growth, development and normal functions of the body, based on generally accepted and well-established knowledge (Aggett et al., 2005).

In the meantime, introducing specific provisions to manage nutrition and function claims was proposed in the White Paper on Food Safety, to harmonise legislation throughout the European Union and to ensure a high level of consumer protection (European Commission, 2000, 2001). In May 2001 this was followed by the discussion paper on nutrition claims and functional claims, describing issues from invited comments of over 90 stakeholders to take into consideration in upcoming legislative acts. These comments led to the inclusion of health claims in the same proposed regulation as nutrition claims, where the first idea was to create separate legislation for the different types of claims (European Commission, 2001, 2003a). In 2003 the final proposal to regulate nutrition and health claims in Europe was presented by the EC (European Commission, 2003b; European Food Information Council). The development of the NHCR is depicted in Fig. 1 below.

2.2. The Nutrition and Health Claim Regulation

Since 2006, claims on antioxidants and other active ingredients in food products are regulated by Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, also called the NHCR (European Parliament and the Council, 2006). The NHCR is a more