



View Point

International legislation on nutrition and health claims



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ABSTRACT

The increasing public interest in dietary health benefits led to the development of different legislative texts on nutrition and health claims worldwide. Following a review of legislation of 28 jurisdictions, three prominent differences were discerned, concerning (i) the labelling of different types of nutrition and health claims and their permission; (ii) variations arising in the (pre-marketing) authorisation procedures; and (iii) the use of the scientific minority opinion in substantiating claims. By discussing these legal differences with findings from literature concerning consumer and industry effects, this review puts these pieces of legislation into a broader perspective. The studied pieces of legislation show critical differences and although various approaches have positive points, no optimal approach to regulate nutrition and health claims has been implemented yet. It would be preferable to permit similar types of claims throughout jurisdictions, permit claims that have a lower probability of misleading consumers e.g. nutrition claims to use emerging evidence and to require pre-marketing approval of claims with higher impact. International harmonisation in these aspects should globally lead to improved pieces of legislation, stimulate industrial efforts in functional foods and enhance consumers' opportunity to use health-enhancing products.

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Introduction

The increasing public interest in possible health benefits of foods has created an attractive opportunity for the food industry, *i.e.* developing functional foods. Functional foods are foods which are consumed within a normal dietary pattern, with health-enhancing properties beyond adequate nutritional effects (Diplock *et al.*, 1999; Howlett, 2008; Lalor and Wall, 2011; Moors, 2012). Japan was the first jurisdiction to regulate functional foods and their commercial outings by means of the FOSHU (Foods for Specified Health Use), which was based on research initiated in 1984 on the effects of these foods (Jones *et al.*, 2008; Lalor and Wall, 2011; Ohama *et al.*, 2006). FOSHU described the requirements for scientific substantiation of a claim on the health effect elicited by such a functional food product (Ohama *et al.*, 2006). Currently, several pieces of legislation dealing with nutrition and health claims are enforced throughout the world (Jones *et al.*, 2008).

The international market of functional foods is growing, even though consumers in countries affected by the economic turmoil are less willing to pay premium prices (Euromonitor

International, 2015a). The growth of the market is higher in countries less affected by this economic turmoil: the United States of America (USA) reported a market growth of functional foods of 0.9% over the years 2008–2013, where the growth reported in China was 21.1%, 21.3% in Argentina and even 33.8% in Venezuela in the same period (Euromonitor International, 2015b). Growth forecasts show that the market is expected to grow in almost all countries in the upcoming years, but are most optimistic for Asia, varying from an expected growth of 0.6% in Japan up to 13.4% in China (Euromonitor International, 2015c). Still, the market share of functional foods is rather small in numerous countries (Euromonitor International, 2015b). This increases the interest of the food industry to operate on an international level. However, global variations in legislative requirements on nutrition and health claims complicate the marketing of functional foods across jurisdictions (Aschemann-Witzel and Hamm, 2010; Jew *et al.*, 2008; Jones *et al.*, 2008; Kwak and Jukes, 2000; Lalor and Wall, 2013; Richardson *et al.*, 2003).

This paper reviews current international pieces of legislation on nutrition and health claims in an attempt to show the diverse approaches and to envision ways to optimise procedures from a scientific perspective. The similarities and differences in required scientific substantiation and their review processes can be found elsewhere (e.g. (Jew *et al.*, 2008; Malla *et al.*, 2013)) and will therefore not be discussed thoroughly in this paper.

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Methods

The jurisdictions described in the 2004 WHO report on the global regulatory environment of nutrition labels and health claims were the starting point of this review (Hawkes, 2004). The 22 jurisdictions from this report on which English information was available were included in this research and an additional six jurisdictions were identified where information on nutrition and health claim legislation was available in English.

Information from various sources was used to identify permitted and prohibited types of claims, as well as upon the authorisation procedure and the norm of scientific substantiation for claims by studying legislation of the various jurisdictions and scientific literature describing legislation concerning nutrition and health claims in different jurisdictions. Guidance documents from regulatory bodies dealing with nutrition and health claims were studied. Documents describing the interpretation of pieces of legislation were critically assessed to provide additional information on various jurisdictions. This created the opportunity to compare the different pieces of legislation upon nutrition and health claims and their surrounding procedures.

Results

Where the 28 identified jurisdictions are all seen to regulate nutrition and health claims, variations were found in the different pieces of legislation: (i) the different types of nutrition and health claims are described; (ii) whether or not authorisation is required and which shape it takes; and (iii) the possibility of using emerging scientific evidence.

Types of claims

The 'Guidelines for Use of Nutrition and Health Claims' published by the Codex Alimentarius Committee defines two types of claims, viz. nutrition claims and health claims (Codex Committee on Food Labelling, 2013). Nutrition claims are defined as 'any representation which states, suggests, or implies that a food has particular nutritional properties'. These claims include three categories of claims: (i) nutrient content claims, describing the level of a nutrient contained in a food (e.g. 'contains calcium'); (ii) nutrient comparative claims, which compare the nutrient and/or energy levels of two or more foods (e.g. 'light'); and (iii) non-addition claims, describing that a specific ingredient has not been added to a food (e.g. 'fat free') (Codex Committee on Food Labelling, 2013).

The Codex guidelines define health claims as "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health", including three types of claims: (i) nutrient function claims, describing the physiological role of the nutrient in growth, development and normal functions of the body (e.g. 'vitamin C contributes to the normal function of the immune system'); (ii) other function claims, emphasising specific beneficial effects of the consumption of foods or their constituents, relating to a positive contribution to health or the improvement of a function or to modifying or preserving health ('cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow'); and (iii) claims on reduction of disease risk, which relate the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition ('Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures.') (Codex Committee on Food Labelling, 2013).

Although the studied jurisdictions label the types of claims differently, all claims can be categorised within these six categories.

Differences arise between the types of claims permitted for use within the various jurisdictions, as depicted in Table 1. Since most pieces of legislation do not further specify the specific types of nutrition claims permitted or prohibited, only the full category is presented in the table.

In all reviewed jurisdictions, nutrition claims are officially permitted for use (Agri-Food and Veterinary Authority of Singapore, 2015; Bureau of Food and Drugs, 1984; Centre for Food Safety, 2008; Consejo de Ministros de Integración Económica Centroamericana, 2012; Department of Health, 2010; European Parliament and Council of the European Union, 2006; Food and Drug Administration Taiwan, 2012; Food and Drug Administration, 2013; Food Standards Australia New Zealand, 2014; Giudice, 2013; Global Agricultural Information Network, 2011a; Government of Canada, 2013; Malla et al., 2013; Ministerio de la Protección Social, 2008; Ministerio de Salud, 2011; Ministry of Agriculture, Agricultural and Livestock Service, 2006; Ministry of Food and Drug Safety, 2011; Ministry of Health, 2013a, 2013b, 2001; National Agency for Food and Drug Administration and Control, 2005; National Agency of Drug and Food Control, 2011; Ohama et al., 2006; People's Republic of China, 2011; Republic of Ecuador, 2011a; Secretaría de Economía, 2010; Zawistowski, 2011). Generally this entails the use of both nutrient content claims and nutrient comparative claims, only legislation in Chile, Japan and Taiwan does not specifically address the use of nutrient comparative claims (Malla et al., 2013; Ministry of Agriculture, Agricultural and Livestock Service, 2006; Ohama et al., 2006; Zawistowski, 2011).

The use of nutrient function claims is allowed in almost all evaluated jurisdictions (Agri-Food and Veterinary Authority of Singapore, 2015; Bureau of Food and Drugs, 1984; Centre for Food Safety, 2008; Chan, 2011; Consejo de Ministros de Integración Económica Centroamericana, 2012; da Silveira et al., 2009; Department of Health, 2010; European Parliament and Council of the European Union, 2006; Food and Drug Administration Taiwan, 2012; Food and Drug Administration, 2013; Food Standards Australia New Zealand, 2014; Global Agricultural Information Network, 2011a; Government of Canada, 2013; Malla et al., 2013; Ministerio de la Protección Social, 2008; Ministerio de Salud, 2011; Ministry of Agriculture, Agricultural and Livestock Service, 2006; Ministry of Food and Drug Safety, 2011; Ministry of Health Labour and Welfare, Japan, 2015a; Ministry of Health, 2013a, 2013b; National Agency of Drug and Food Control, 2011; Ohama et al., 2006; People's Republic of China, 2011; Republic of Ecuador, 2011b; Secretaría de Economía, 2010; Zawistowski, 2011). Only Brunei Darussalam and Nigeria prohibit the use of nutrient function claims (Ministry of Health, 2001; National Agency for Food and Drug Administration and Control, 2005). In Nigeria food products bearing health claims are regarded and regulated as drugs and therefore claims are not permitted on regular food products (Global Agricultural Information Network, 2012). The legislation in most jurisdictions reviewed, considers nutrient function claims to be health claims, yet they are judged as nutrition claims in Malaysia and Thailand (Malla et al., 2013; Ministry of Health, 2013a; Ministry of Public Health, 1998).

Other or enhanced function claims are prohibited in, Brunei Darussalam, India, Nigeria, South-Africa and Thailand, although the new draft regulation on nutrition and health claims in India does permit these claims (Food Safety and Standards Authority of India, 2012; Gautier, 2012; Ministry of Health, 2001; Ministry of Public Health, 1998; National Agency for Food and Drug Administration and Control, 2005). Legislation in Hong Kong and Vietnam does not specifically describe nor prohibit other or enhanced function claims (Ministry of Health, 2013b; Public Health and Municipal Services Ordinance, 2008). Within the 21

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