



## British Food Journal

Health claims regulations: Comparison between USA, Japan and European Union

Fiona Lalor, Patrick G. Wall,

### Article information:

To cite this document:

Fiona Lalor, Patrick G. Wall, (2011) "Health claims regulations: Comparison between USA, Japan and European Union", British Food Journal, Vol. 113 Issue: 2, pp.298-313, <https://doi.org/10.1108/00070701111105358>

Permanent link to this document:

<https://doi.org/10.1108/00070701111105358>

Downloaded on: 28 August 2018, At: 08:58 (PT)

References: this document contains references to 26 other documents.

To copy this document: [permissions@emeraldinsight.com](mailto:permissions@emeraldinsight.com)

The fulltext of this document has been downloaded 1322 times since 2011\*

### Users who downloaded this article also downloaded:

(2011),"Impact of nutrition knowledge on behaviour towards health claims on foodstuffs", British Food Journal, Vol. 113 Iss 6 pp. 753-765 <a href="https://doi.org/10.1108/00070701111140098">https://doi.org/10.1108/00070701111140098</a>

(2012),"Nutritional knowledge, nutritional labels, and health claims on food: A study of supermarket shoppers in the South East of England", British Food Journal, Vol. 114 Iss 6 pp. 768-783 <a href="https://doi.org/10.1108/00070701211234318">https://doi.org/10.1108/00070701211234318</a>

Access to this document was granted through an Emerald subscription provided by emerald-srm:126269 []

### For Authors

If you would like to write for this, or any other Emerald publication, then please use our Emerald for Authors service information about how to choose which publication to write for and submission guidelines are available for all. Please visit [www.emeraldinsight.com/authors](http://www.emeraldinsight.com/authors) for more information.

### About Emerald [www.emeraldinsight.com](http://www.emeraldinsight.com)

Emerald is a global publisher linking research and practice to the benefit of society. The company manages a portfolio of more than 290 journals and over 2,350 books and book series volumes, as well as providing an extensive range of online products and additional customer resources and services.

Emerald is both COUNTER 4 and TRANSFER compliant. The organization is a partner of the Committee on Publication Ethics (COPE) and also works with Portico and the LOCKSS initiative for digital archive preservation.

\*Related content and download information correct at time of download.



# Health claims regulations

## Comparison between USA, Japan and European Union

Fiona Lalor and Patrick G. Wall

*School of Public Health and Population Science, University College Dublin,  
Dublin, Ireland*

### Abstract

**Purpose** – The purpose of this paper is to review and compare the scientific and regulatory environments for nutrition and health claims on foodstuffs in the USA, Japan and the European Union.

**Design/methodology/approach** – A review of the literature and the relevant legislation in the three different countries is conducted. Regulations are reviewed and scientific evidence requirements are outlined in each country.

**Findings** – Full regulatory approval for claims across all three countries requires the support of robust scientific evidence. To obtain this, companies must submit comprehensive dossiers and detailed applications to the regulators with full descriptions of the tests and studies completed during product development. However in the USA and Japan, an alternative process exists. A health claim that is suggested but not supported by scientific evidence is known as a qualified health claim and is permitted in the USA and Japan, but not in the EU.

**Practical implications** – The paper demonstrates the difference in regulatory requirements in different countries which leads to different claims being permitted in different countries. It also leads to different levels of scientific support for similar claims which causes consumer confusion and develops an uneven playing pitch for the industry. Given that the industry operates in a global market place, it is imperative that a consensus is reached as to the level of scientific evidence required to approve a health claim. In that way, consumers can be safeguarded from being misled, consumer confusion will not be a concern and products can be globally distributed in line with the increasing liberalisation of trade.

**Originality/value** – This paper is of value to regulators and the food industry.

**Keywords** Food controls, Regulation, Japan, United States of America, European Union

**Paper type** General review

### Part I. Introduction

Nutrients with health enhancing properties, over and above those of conventional foods, provide immense commercial opportunities and possible could have huge public health implications. The food and drink (and recently the pharmaceutical sector) industry has spent millions of dollars in research and development of foods that contain added, technologically developed, ingredients with specific health benefits (Niva, 2007). These foods are known as functional foods. They were first marketed in Japan in the 1980s, where the term “functional food” was first used by the industry. These foods were intended for consumption as part of a normal diet but were to have a health benefit with a clear and nutritional basis (No-seong Kwak, 2001). Essentially functional foods bring science into everyday eating by promising particular and targeted health effects.

In 1990 in Japan, the Ministry for Health and Welfare initiated a policy approving the commercialization of functional foods. In Japanese legal terms, under the Nutrition Improvement Law, the term “Foods for specified health use”, or FOSHU, was created and hypoallergenic rice was the first product approved. However different countries



have different approaches to food legislation and in the USA there is no definition of functional, or health enhancing foods. Despite this lack of a legal position, the Institute of Medicine of the US National Academy of Sciences defined functional foods as those that, “to encompass potential healthful products, include any modified food, or food ingredient, that may provide a health benefit beyond the traditional nutrients it contains”.

Across the European Union the term functional food is rarely used. Instead, in December 2006, the European Union finally agreed, and published, EU Regulation 1924/2006 on nutrition and health claims (European Parliament and Council, 2006).

Despite the early acceptance in Japan of what a functional food was intended to be, there remains globally no generally accepted legal or scientific definition.

#### *What are nutrition and health claims?*

In addition to there being no consensus on the definition of what constitutes a functional food, the term “health claim” is also defined differently in different countries. The meaning of the word “claim” itself (as opposed to “health claim”) is, however, generally well understood. A widely accepted definition of a “claim” is that of Codex Alimentarius where it is defined as: “any representation, which states, suggests, or implies that a food has certain characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality”(Codex Alimentarius Commission, 1991).

The European Union, in its recently published Regulation on the subject (European Parliament and Council, 2006), defines a health claim as “any claim that states, suggests or implies that a relationship exists between a food category, a food, or one of its constituents and health” (European Parliament and Council, 2006).

In the USA, a health claim refers to any statement “that expressly, or by implication characterises, the relationship of any substance to a disease or health-related condition” (US FDA Centre for Food Safety and Applied Nutrition, 2008).

The term functional food may have no internationally agreed definition but this is not preventing the market for this category of products from growing and expanding in individual countries. According to the Food Marketing Institute, 65 per cent of grocery shoppers try to manage or treat health conditions through diet (Food Marketing Institute, 2004). The potential exists for global distribution of similar products if agreement on the regulations for “health claims” existed. This article highlights the differences in the requirements in the USA, the EU and Japan and relevant documentation was identified by searching electronic databases including PubMed, Google Scholar and Food Science and Technology Abstracts.

## **Part II. Regulation and scientific requirements**

### *II.1 Japan*

*II.1.1 Regulation of claims in Japan.* The results of research and development on the physiological function of foods prompted the Japanese Ministry of Health, Labour and Welfare (MHLW) to establish a regulatory system regarding foods that claim health benefits. This system was aimed at informing the public of health information concerning specific foods. “Foods for specified health use” (FOSHU) was set up by the MHLW in 1991 as the regulatory system to approve statements contained on a label regarding the effects of foods on the human body (Schimizu, 2003).

FOSHU was enacted under the Nutrition Improvement Law and is based on the requirement for scientific evidence to support applications. However, ten years later, in April 2001, the Japanese government enacted a new regulatory system called “Foods with Health Claims” (FHC). This new system integrated FOSHU and revised it to make capsules, tablets or other dosage forms which were commonly consumed as supplements, permissible (Ohama *et al.*, 2006). It created two different categories FOSHU; and Foods with nutrient function claims (FNFC) (Schimizu, 2003):

- (1) *FOSHU*. FOSHU labelled food (or products) contain ingredients that have positive effects on human physiological function. It is intended that these products be consumed for the maintenance, or promotion of health, or specifically by people who wish to control certain health conditions. These products must not make medical claims such as “prevent”, “cure”, “treat” or “diagnose”. Examples of existing FOSHU claims are “This product helps to maintain normal blood pressure, blood sugar or cholesterol”. A prohibited claim would be “This product cures hypertension”. In order to receive FOSHU approval, scientific evidence supporting the claim must be provided by the food business operator. Since December 2007, 755 items had been granted FOSHU status (Yamada *et al.*, 2008). Existing health claims on FOSHU are classified into eight groups:

- gastro intestinal conditions;
- blood pressure;
- serum cholesterol;
- blood glucose;
- absorption of minerals;
- blood neutral fat;
- dental health; or
- bone health (Schimizu, 2003).

To gain approval, the design of the product must be accompanied by the rationale as to how the product makes a contribution to the improvement of the Japanese diet and also the maintenance of good health (Ohama *et al.*, 2006).

- (2) *Foods with nutrient function claims (FNFC)*. FNFC is the category of “health foods” which permit the use of functional claims for nutrients according to their scientific evidence. Nutrient function claims have been widely accepted by scientific experts, based on scientific evidence and applied to existing foods or supplements internationally. Such claims are readily understood by the general public (Yamada *et al.*, 2008) and when enforced in April 2001, this category permitted the use of 12 vitamin claims, a beta-carotene claim and five mineral claims. These claims are standardized according to conclusions drawn by the Japanese MHLW and the list is continuously expanding.

In February 2005, the regulatory system in Japan was reviewed and altered once more. This was with a view to making it easier for applicants to obtain approvals for distributing FOSHU products in the marketplace. With the additional aim of promoting the provision of accurate information to consumers, it was decided to allow health claims with some conditions (qualified) under the FOSHU system. These are

known as “qualified FOSHU” and were created for products that do not meet the scientific evidence requirements under current licensing examination procedures but are considered to have some benefits.

### *II.1.2 Scientific requirements for claim approval in Japan*

Based on the principles of satisfactory scientific agreement, the documentation that must be supplied when applying for FOSHU approval are (Yamada *et al.*, 2008):

- A sample of the entire package including labels and health claims.
- Documentation that demonstrates the clinical and nutritional proof of the product and/or its functional components aimed at the maintenance of health.
- Documentation that demonstrates clinical and nutritional proof of the intake amount of the product and/or its functional component.
- Documentation concerning the safety of the product and its functional component, including additional human studies regarding the eating experience.
- Documentation concerning the stability of the product and its functional component.
- Documentation of the physical and biological characteristics of the product and its functional component.
- Details of methods of qualitative and quantitative analytical determination of its functional component and the analytical results regarding the components of the product.
- A report describing the analysis of the designated nutrient constituents and the product’s energy content.
- A statement of the method and equipment used in the food’s production and an explanation of the quality control system.

These can be summarized into three essential requirements:

- (1) Effectiveness based on scientific evidence (including clinical evidence).
- (2) Safety of product (including safety studies in human subjects).
- (3) Analytical determination of the effective components.

After validation, and assessment of all the scientific data supplied, the MHLW makes a decision whether to grant approval for the product under FOSHU. However, with the establishment of Qualified FOSHU in 2005, where the scientific evidence may not be sufficient for full standardized FOSHU these products can be placed on the market with a qualifying statement that “evidence has not necessarily been established”. In addition, the term “possibly” must be included in the description of the health claim.

## *II.2 United States of America*

*II.2.1 Regulation of claims in the USA.* The United States Congress passed the Nutrition Labelling and Education Act (NLEA) in 1990 (US Food and Drug Administration, 1990). This gave the FDA clear authority to require nutrition labelling of most foods; and to require that all nutrient content claims, e.g. “high fibre”, “low fat” etc. and health claims be consistent with agency regulations. Under this Act, foods with approved

health claims are not considered drugs but rather foods for general consumption. To use such a claim in association with food, the FDA was authorised to issue specific regulations describing the permitted claim. This was to enable consumers to “understand the information provided in the claim and the relative significance of such information in the context of a total daily diet”.

There is a tiered system of claims authorised in the USA:

(1) As mandated under the NLEA, since 1993 the FDA have authorised the following health claims (US Food and Drug Administration, 2007):

- calcium and reduced risk of osteoporosis;
- sodium and reduced risk of hypertension;
- dietary saturated fat and cholesterol and reduced risk of coronary heart disease;
- dietary fat and reduced risk of cancer;
- fruits, vegetables and grain products that contain fibre, particularly soluble fibre, and reduced risk of coronary heart disease;
- fruits and vegetables and reduced risk of cancer;
- folate and reduced risk of neural tube defects;
- dietary noncariogenic carbohydrate sweeteners and reduced risk of dental caries;
- soluble fibre from certain foods and reduced risk of coronary heart disease;
- soy protein and reduced risk of coronary heart disease;
- plant sterol/stanol esters and reduced risk of coronary heart disease.

In accordance with the NLEA, in order to make a new claim, companies had to apply to the FDA and authorisation was granted provided specific requirements were met. First, the claim had to characterise the relationship of any substance to a disease, or health related condition, for which most people, or a specific group of people, such as the elderly are at risk. Second, for a claim to be valid, the rules required significant agreement among qualified experts that the claim was supported by the “totality of publicly available scientific evidence”.

(2) In 1997, with a view to speeding up the authorisation procedure, the US Congress passed the FDA Modernization Act (FDAMA) (US Food and Drug Administration, 1997) which specifically provided for the use of health claims based on authoritative statements from a scientific body of the US Government or the National Academy of Sciences. In addition, the FDAMA gave the FDA 120 days to respond to the companies’ notification. If they did not act to prohibit or modify the claim within that time, the claim could be used. In accordance with this procedure, the following claims have been approved for use (US Food and Drug Administration, 2008):

- wholegrain foods and a reduction in the risk of heart disease and certain cancers;
- potassium and a reduction in the risk of high blood pressure and stroke;
- flouridated water and a reduction in the risk of dental caries;

- saturated fat, cholesterol and trans-fat and a reduction in the risk of heart disease.

Claims approved under this system are known as “Health claims based on authoritative statements”.

- (3) In a further attempt to accelerate the authorisation process, in 2003 the FDA *Consumer Health Information for Better Nutrition Initiative* (US Food and Drug Administration, 2003) was published. This concluded that consumers would benefit from more information on food labels concerning diet and health. In addition, past court decisions clarified a need to provide for health claims based on less scientific evidence rather than just on the standard of significant scientific agreement, as long as the claims do not mislead the consumer. As a result, qualified health claims were introduced. For these claims, the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. It permits the use of a health claim where there is emerging evidence for a relationship between a food and reduced risk of a disease or health related condition. In these cases, a qualifying statement is required as part of the claim to indicate that the evidence supporting the claim is limited. Qualified health claims currently in use in the USA are:

- *Qualified claim about cancer risk:* tomatoes and/or tomato sauce and reduced risk of prostate, ovarian, gastric and pancreatic cancer; calcium and colon/rectal cancer and calcium and reduced risk of recurring colon/rectal polyps; green tea and reduced risk of cancer; selenium and reduced risk of cancer; antioxidant vitamins and reduced risk of cancer.
- *Qualified claims about cardiovascular disease risk:* nuts and reduced risk of heart disease; walnuts and reduced risk of heart disease; Omega-3 fatty acids and reduced risk of coronary heart disease; B vitamins and reduced risk of vascular disease; mono-unsaturated fatty acids from olive oil and reduced risk of coronary heart disease; unsaturated fatty acids from canola oil and reduced risk of coronary heart disease; corn oil and reduced risk of heart disease.
- *Qualified claims about cognitive function:* phosphatidylserine and cognitive dysfunction and reduced risk of dementia.
- *Qualified claims about diabetes:* chromium picolinate and reduced risk of diabetes.
- *Qualified claims about hypertension:* calcium and reduced risk of hypertension, pregnancy induced hypertension and reduced risk of pre-eclampsia.
- *Qualified claims about neural tube defects:* 0.8 mg folic acid and reduced risk of neural tube defects.

*II.2.2 Scientific requirements for claim approval in USA.* There have been regulatory requirements for health claims in the USA since 1990 and as outlined above, a number of changes since then. These changes have produced alternative procedures for different types of claims. These alternative procedures have resulted in a relaxation of the scientific requirements, and a distinct reduction in the levels of scientific evidence, required to support a claim. NLEA authorised claims are most rigorously assessed by the FDA,

FDAMA claims are reviewed and supported by organisations external to the FDA and finally qualified health claims, where emerging science can be considered satisfactory.

NLEA or Significant Scientific Agreement (SSA) Claims (US Food and Drug Administration, 1999). As outlined above, under NLEA, a manufacturer must first apply to the FDA for authorisation prior to using a particular claim. On foot of receiving a petition from a manufacturer, the FDA will evaluate among other considerations, whether the evidence supporting the relationship that is the subject of the claim meets a “significant scientific agreement” standard.

The scientific review process FDA uses to evaluate health claims is comprehensive and focuses first on a review of individual studies. After identifying relevant, good quality studies and assessing their strengths and weaknesses, the agency conducts a more comprehensive review based on the body of evidence as a whole.

The assessment of scientific validity for a health claim includes two components:

- (1) that the totality of the publicly available evidence supports the substance/disease relationship that is the subject of the claim; and
- (2) that there is significant scientific agreement among qualified experts that the relationship is valid.

The FDA has published guidance to the industry on the level of data required and the calibre of studies that should be conducted (US Food and Drug Administration, 1999). This guidance also outlines the assessment criteria the FDA use to establish whether, or not, significant scientific agreement exists and authorisation of the claim can be granted.

Significant scientific agreement means that the validity of the relationship is not likely to be reversed by new and evolving science. To assess this for each claim, the following is required:

- *Identification of data for review.* Human studies, both interventions and observational studies, animal and in vitro studies should be provided.
- *Performance of reliable measurements.* The use of biomarkers, suitable measurement of the food substance, dietary intake and the ability to distinguish the effects of diet from other variables should be documented.
- *Evaluation of individual studies.* Details of study design, conduct analysis and interpretation of each individual study should be included.
- *Evaluation of the totality of the evidence.* Assessment of all individual studies taken together, i.e. the number of studies, consistency of results, magnitude of effects etc. should be provided.
- *Assessment of significant scientific agreement.* SSA depends on the strength and consistency of the evidence. It cannot be reached without a strong, relevant and consistent body of evidence on which experts in the field may base a conclusion that a substance/disease relationship exists.

FDAMA claims (US Food and Drug Administration, 1997). As outlined above, in accordance with FDAMA, it was permitted to use health claims provided they were based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences. It became no longer essential to supply all comprehensive scientific data to the FDA in order to apply for authorisation of a claim.

Now a much simpler notification, based on authoritative statements from acceptable organisations became satisfactory. Once sanctioned by a reputable scientific body, the FDA will not object to the use of a particular claim. The FDA will no longer gather and assess the data in support of a FDAMA claim but has surrendered the responsibility for that to other organisations.

However, while the FDA does not conduct a comprehensive scientific evaluation of the data under FDAMA, it does uphold the “significant scientific agreement” standard for health claims. Based on the notification procedure, if the FDA believes that the totality of publicly available evidence does not support a claim, they can issue a regulation to prohibit its use.

Qualified health claims (US Food and Drug Administration, 2006). Qualified health claims differ from Significant Scientific Agreement (SSA) claims in that they must be accompanied by a disclaimer or otherwise qualified (see Table I). In the case of qualified health claims, as with SSA claims, a petition must be submitted to the FDA for approval. Qualified health claims are still based on the totality of publicly available evidence but, based on an interim procedure, the scientific support does not have to be as strong as that for significant scientific agreement.

Table II identifies the total number of claims now available on the US market.

### II.3 European Union

II.3.1 Regulation of claims in the European Union. In Europe, claims that a food will cure a disease, or will reduce the risk of a disease, were not permitted under Regulation 2000/13 on the labelling, presentation and advertising of foodstuffs. Article 2:

The labelling and methods used must not . . . b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating, or curing a human disease, or refer to such properties (European Parliament and Council, 2000).

Level of scientific agreement	Suggested qualifying statement
Moderate	Although there is scientific evidence supporting . . . the evidence is not conclusive
Low	Some scientific evidence suggests. . . however, FDA has determined that this evidence is limited and not conclusive
Extremely low	Very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim. Petitions falling below this level of evidence will be denied

Source: Falk (2004)

**Table I.**  
Levels of scientific agreement required below SSA and qualifying statements

	<i>n</i>
NLEA authorised claims	10
Claims based on Authoritative statements by scientific bodies	4
Claims permitted with proviso of qualifying statement (qualified health claim)	22
Total permitted claims available in the USA	36

**Table II.**  
Total number of claims permitted in the USA

With a changing market and consumer demands, coupled with additional public health requirements and different Member State rules on the subject, the European Union was forced to review this area and published EU Regulation on Nutrition and Health Claims (European Parliament and Council, 2006) in December 2006. The aim of this Regulation is to ensure that any claim made on a food label in the EU is clear, accurate and substantiated to enable consumers to make informed and meaningful choices when it comes to food and drinks. For the first time, it will be permitted to make a claim that a food will reduce the risk factors for a disease.

EU Regulation 1924/2006 on nutrition and health claims. Claims such a “fat free”, “low in salt” etc. have been on the EU market for years but have not been legislated for. However, this system is addressed by EU Regulation 1924/2006, which clearly divides claims into 2 categories:

- (1) *Nutrition claims.* A nutrition claim is one which states, suggests, or implies that a food has particular beneficial nutritional property due to the energy, nutrients, or other substances provided, not provided or produced in reduced/increased amounts. The appendix to this legislation provides a list of permitted claims and the conditions applying to them. For example to claim that a product is “low energy”, the product must have less than 40 kcal/100 g for solids and less than 20kcal/100 ml for liquids.
- (2) *Health claims.* A health claim is one that states, suggests, or implies that a relationship exists between a food category, a food, or one of its constituents, and health.

This Regulation establishes a new system for operators to apply to have their health claim approved. No non-approved health claims will be permitted. Each EU Member State had to compile and submit to the Commission, a list of claims currently on their market along with references to the relevant scientific justification, before 31 January 2008. Following consultation with the European Food Safety Authority, the Commission will adopt a Community list of permitted claims and all necessary conditions, by 31 January 2010. The different types of health claims as outlined in EU Regulation 1924/2006 are:

Article 13: Health Claims other than those referring to the reduction of disease risk and to children’s development and health:

- 13.1 Health claims describing or referring to:
  - a. the role of a nutrient or other substance in growth, development and the functions of the body;
  - b. psychological and behavioural functions;
  - c. without prejudice to Directive 96/8/EC, slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.
- 13.5 Claims based on newly developed scientific evidence and/or that which includes a request for proprietary data.

Article 14: Reduction of disease risk claims and claims referring to children’s development and health.

Article 13.1 claims are based on “generally accepted scientific evidence” and only “*references* to the relevant scientific justification” are required when suggesting such claims. However claims based on newly developed scientific evidence, Article 13.5 claims, require the submission of an extensive dossier. In a similar vein, because disease risk reduction claims were previously prohibited and claims relating to the children’s development and growth were deemed to be targeting a particularly vulnerable population, an extensive dossier is now required for their application (Article 14 claims).

To date, EFSA has published opinions on 41 different Article 14 claims, the majority of which pertain to children’s development and health. EFSA has approved eight of these claims, the details of which are outlined in Table III.

*II.3.2 Scientific requirements in European Union.* One of the most important parts of the Regulation 1924/2006 on nutrition and health claims is that scientific substantiation is the major cornerstone on which authorisation for the use of health claims will be granted. In this regards, the regulation acknowledges and references, the Process for the Assessment of Scientific Support for Claim on Foods (PASSCLAIM) project (Asp and Bryngelsson, 2008). This project engaged more than 160 scientists from academia, industry, research institutes, public interest groups and the regulatory environment and its primary objective was to produce a generic tool for assessing the scientific support for health claims in foods (Asp and Contor, 2003). It concluded the following generally applicable criteria for the scientific support of claims. These criteria:

Category	Claims	Exact text approved by EFSA
Reduction of disease risk	Plant sterols and blood cholesterol	Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of CHD
Reduction of disease risk	Plant stanols and blood cholesterol	Plant stanol esters have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of CHD
Reduction of disease risk	Xylitol chewing gum/pastilles and tooth decay	Xylitol chewing gum reduces the risk of caries in children
Children’s development and health	ALA and LA and growth and development of children	Essential fatty acids are needed for normal growth and development of children
Children’s development and health	Vitamin D and Bone growth in children	Vitamin D is needed for normal growth and development of bone in children
Children’s development and health	Calcium and bone growth in children	Calcium is needed for normal growth and development of bone in children
Children’s development and health	Calcium and Vitamin D and bone strength in children	Calcium and vitamin D are needed for normal growth and development of bone in children

**Note:** The exact text provided is that which, according to EFSA, reflects the scientific evidence

**Table III.**  
Article 14 claims approved by EFSA (until 16 January 2009)

- emphasised the need for direct evidence of benefits to humans;
- recognised the usefulness of markers or intermediate effects; and
- emphasised that effects should be both statistically and biologically meaningful.

PASSCLAIM is used as guidance for EFSA in scientifically assessing claims. In accordance with EU Regulation 1924/2006, the EU Commission forwards all Article 13 and Article 14 claims to EFSA. The principle questions asked by the EFSA are:

- Has the product been sufficiently characterised?
- Is the product/claimed effect beneficial for health?
- Has a cause and effect relationship been established?

Parallel to PASSCLAIM, EFSA published *Scientific and Technical Guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim*, in June 2007 (European Food Safety Authority, 2008). This document outlines in great detail the level of scientific and support material required when making an application. Comprehensive scientific data is necessary, including tabulated, and written, summaries of data from pertinent human and non human, studies whether they are interventions or observational studies, experimental or quasi experimental, randomised, controlled etc. The application form is very specific and detailed and it specifies the requirement to provide both published and unpublished data.

Table IV provides a summary of the regulatory systems across the different countries.

#### **Part IV. Comparison across countries**

Different countries view claims differently, employ different standards for levels of scientific evidence and different processes for evaluation. The level of evidence required in one country may not meet the requirements in another so claims that are permitted in one location may be prohibited elsewhere.

##### *High level of scientific evidence*

As outlined above, the requirement for SSA claims in the USA, the FOSHU claims in Japan and Article 13 (5) and Article 14 health claims in Europe all require detailed scientific assessment and review. There are similar rules in different countries but claims are categorised differently, which can result in different outcomes.

##### *Lower level of scientific evidence*

Qualified health claims in the USA and Qualified FOSHU in Japan are similar in nature. Both accept that a food or product may have some beneficial effect, without all the science to support it. In Europe there is no such claim category for those with weaker levels of scientific evidence.

Table V clearly outlines the different type of claims and the different levels of scientific agreement required in each jurisdiction.

#### **Part V. Discussion**

Science has taken enormous steps in understanding the relationship, both positive and negative between diet and health. Nevertheless, diet related diseases are increasing in

Type of claim	Legislation	Conditions for approval
<i>USA</i>		
NLEA authorised claim	Nutrition, Labelling and Education Act, 1990	FDA must be petitioned and authorisation granted provided specific conditions are met Nutrient or food substance had to be related to a disease or health condition for which most people or a specific group of people, such as the elderly are at risk For a claim to be valid, the rules require significant agreement among qualified experts that the claim was supported by the "totality of publicly available scientific evidence"
Health claims based on authoritative statements	Food and Drug Modernization Act, 1997	Health claims based on authoritative statements from a scientific body of the US Government or of the National Academy of Science [FDA not formally petitioned]
Qualified health claims	FDA Consumer Health Information for Better Nutrition Initiative, 2003	Provides for qualified health claims where the evidence (both quality and strength) fall short of that required for FDA to issue an authorising Regulation. Emerging evidence is sufficient and a qualifying statement must be used to indicate that the evidence is limited
<i>European Union</i>		
Article 13.1 claims are claims other than those referring to reduction of disease risk and to children's development and health	European Union Regulation 1924/2006 on nutrition and health claims	Claims may be made, without detailed approval, provided they are: based on generally accepted scientific evidence well understood by the average consumer
Article 13.5 claims are those based on newly developed scientific evidence Article 14 claims are reduction of disease risk claims and claims referring to children's development and health	European Union Regulation 1924/2006 on nutrition and health claims	Claims are reviewed and approved or rejected by EFSA. EFSA verifies that the health claim is substantiated by the scientific evidence as supplied (taking into account the totality of the available scientific data and by weighing the evidence) and the wording of the claim would be understood by the average consumer
<i>Japan (Yamada et al., 2008)</i> FOSHU	Nutrition Improvement Law, 1991	These are allowed to use labels that inform consumers who ingest the food for specific health purposes that their purpose may be achieved by consuming the product

(continued)

**Table IV.**  
Regulating claims in Japan, USA and Europe

Type of claim	Legislation	Conditions for approval
“Qualified” FOSHU	Reclassification of FOSHU by the Office of Health Policy on newly developed foods, 2005	These are allowed to use qualified or conditional labels that inform consumers who ingest the food for specific health purposes that their purpose may be achieved by consuming the product. With the aim of promoting the provision of proper information to people, it was decided to allow health claims with some conditions (qualified) under the FOSHU system for food products that do not have sufficient scientific evidence required in the course of current licensing examination procedures but are considered to have certain efficacy
“Standardised” FOSHU	Reclassification of FOSHU by the Office of Health Policy on newly developed foods, 2005	These of the FOSHU for which a license/approval is granted on the basis of compliance with the separately prescribed standards
“Reduction of disease risk” FOSHU	Reclassification of FOSHU by the Office of Health Policy on newly developed foods, 2005	A FOSHU with a label containing any indication of a reduction of risks of developing certain diseases. At this moment, food containing calcium (reducing risk of osteoporosis) or folic acid (reducing risk of neural tube defects) are permitted. However, in issuing an approval, the label will be required to contain a sufficient warning that the relevant disease has many risk factors and that sufficient exercise is also required for healthy life. The label also will be required to contain a sufficient warning for excessive intake

Table IV.

incidence in all countries and are a major burden on all health services. Functional foods may potentially have a role in improving public health while also providing a commercial opportunity for many companies (Van Assema *et al.*, 1996; Williams, 2005, 2006; Dwyer, 2007). The regulatory systems worldwide are charged with the responsibility of ensuring consumer health is protected and that they are not being misled and also with creating an environment for industry to grow and develop. The European system for this category of foods is still in its infancy (the Regulation was only published in 2006) whereas in Japan and the USA and health claims have been regulated for almost 20 years. Within all three countries, the systems have both similarities and differences. The categories of claims may be different and the regulatory approach completely dissimilar in each country but, for a fully authorised claim, with complete regulatory support, in all cases, comprehensive scientific evidence is required.

Type of claim	Level of science required
<i>USA</i>	
NLEA/SSA claims	Significant scientific agreement required
FDAMA claims	Based on authoritative statements by authorised federal scientific bodies
Qualified health claims	Weaker scientific support is satisfactory provided qualifying statement is also provided
<i>European Union</i>	
Articles 13 (5) and 14 Health Claims	Must meet detailed scientific requirements for examination by EFSA's Panel on Dietetic products, Nutrition and Allergies (NDA)
<i>Japan</i>	
Standardised FOSHU	Detailed determination and validation of scientific evidence must be supplied
Qualified FOSHU	Weaker scientific evidence is satisfactory provided qualifying statement is also provided

**Table V.**  
Comparison of levels of scientific evidence required in three different countries

In the USA and Japan, there is a view that there are benefits from an approach alternative to full authorisation for claims. It was considered that industry would benefit by getting their products to market sooner and there could be a public health benefit when consumers have access to a wider range of products. Qualified health claims were introduced in both countries whereby and when relevant, a statement to the effect that all the science may not be available to support a specific claim but there may be an effect, must be made. This statement is designed to enable consumers distinguish between these claims and those approved as a result of substantial scientific evidence of efficacy. However, some studies have indicated that consumers do not make this distinction. A study in the USA by the International Food Information Council showed that 78 per cent of consumers could not correctly sort different claims as to the different level of supporting scientific evidence (International Food Information Council, 2007). These findings were corroborated by Hooker and Teratanavat in 2008 where their study suggests that consumers are not yet able to distinguish between the different types of health claims and the strength of science on which the claim is based (Hooker and Teratanavat, 2008).

This complicated situation leaves us with the question as to the appropriate degree of regulation that is required. It is important that the consumer be protected but also that they are offered choices which may benefit their health. In addition, it is also important that the industry be allowed to grow, develop and compete internationally. The consumer must be supplied with the information in a manner where they understand and ultimately believe what they read. Clearly regulated health claims are the route to achieving this aim. The challenge to the regulators is how to strike a balance between preventing false and misleading information from reaching consumers while encouraging the use of foods to attain a healthy lifestyle.

The regulatory systems in the USA and Japan have accepted that there may be potential in permitting the use of claims where the supporting scientific evidence is not significant. However even in cases where full authorisation for a claim is applied for, the level of evidence required for foods with health claims extends only as far as dietary intervention. If, as is the case in the USA and Japan, there's a weakening of the

evidence required for health claims and a “qualified claim” alternative, then we are moving towards complete deregulation and a market where claims with no scientific support and no regulatory assessment, are freely in use. To gain regulatory approval for a medicine requires extensive clinical trials. Foods are not medicines but nevertheless, a certain level of regulation is essential to ensure consumer safety. The use of qualifying statements may serve to confuse the consumer who may believe the products definitely rather than possibly improve their health. European consumers are protected from this confusing situation by the regulatory requirements within the European Union.

### References

- Asp, N.-G. and Bryngelsson, S. (2008), “Health claims in Europe: new legislation and PASSCLAIM for substantiation”, *The Journal of Nutrition*, Vol. 138 No. 6, pp. 1210S-121.
- Asp, N. and Contor, L. (2003), “Process for the assessment of scientific support for claims on foods (PASSCLAIM): overall introduction”, *European Journal of Nutrition*, Vol. 42, supplement 1, pp. 1/3-1/5.
- Codex Alimentarius Commission (Ed.) (1991), *Codex Alimentarius Commission Codex General Guidelines on Claims*, Vol. CAC/GL 1-1979 (Rev. 1 1991).
- Dwyer, J.T. (2007), “Do functional components in foods have a role in helping to solve current health issues?”, *Journal of Nutrition*, Vol. 137 No. 11, pp. 2489S-249.
- European Food Safety Authority (2008), “Scientific and technical guidance for the preparation and presentation of an application for authorisation of a Health Claim”, available at: [www.efsa.europa.eu/cs/BlobServer/DocumentSet/claim\\_guidance\\_format\\_applicant\\_part1-4\\_SURVEY.doc?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/claim_guidance_format_applicant_part1-4_SURVEY.doc?ssbinary=true)
- European Parliament and Council (2000), *European Parliament and Council Directive 2000/13 of the European Parliament and of the Council Relating to the Labelling, Presentation and Advertising of Foodstuffs*, Vol. O.J. L 109 6.5.2000.
- European Parliament and Council (2006), *European Parliament and Council Regulation No. 1924/ of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods (2006)*, Vol. OJ L 404 30.12.2006, p. 12.
- Falk, M. (2004), “The impact of regulation on informing consumers about the health promoting properties of functional foods in the USA”, *Journal of Food Science*, Vol. 69 No. 5, pp. R143-5.
- Food Marketing Institute (2004), “Shopping for health: making sense of nutrition news and health claims”, available at: [www.fmi.org/news\\_releases/index.cfm?fuseaction=mediatext&id=684](http://www.fmi.org/news_releases/index.cfm?fuseaction=mediatext&id=684)
- Hooker, N. and Teratanavat, R. (2008), “Dissecting qualified health claims: evidence from experimental studies”, *Critical Reviews in Food Science and Nutrition*, Vol. 48, pp. 160-76.
- International Food Information Council (2007), available at: [www.ific.org/research/funcfoodsres07.cfm](http://www.ific.org/research/funcfoodsres07.cfm)
- Niva, M. (2007), “‘All foods affect health’: understandings of functional foods and healthy eating among health-oriented Finns”, *Appetite*, Vol. 48, pp. 384-93.
- No-seong Kwak, D.J.J. (2001), “Functional foods. Part 1: the development of a regulatory concept”, *Food Control*, Vol. 12, pp. 99-107.
- Ohama, H., Ikeda, H. and Moriyama, H. (2006), “Health foods and foods with health claims in Japan”, *Toxicology*, Vol. 221 No. 1, pp. 95-111.

- 
- Schimizu, T. (2003), "Health claims on functional foods: the Japanese regulations and an international comparison", *Nutrition Research Reviews*, Vol. 16, pp. 241-52.
- US Food and Drug Administration (1990), *Nutrition Labelling and Education Act (1990) Public Law 101-553*, 104 Stat. 2353 codified at 21 USC 343 (1993).
- US Food and Drug Administration (1997), *FDA Modernization Act (FDAMA)*, available at: [www.cfsan.fda.gov/~dms/labfdama.html](http://www.cfsan.fda.gov/~dms/labfdama.html)
- US Food and Drug Administration (1999), *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, December, available at: [www.cfsan.fda.gov/~dms/SSAguide.html](http://www.cfsan.fda.gov/~dms/SSAguide.html)
- US Food and Drug Administration (2003), *Consumer Health Information for Better Nutrition Initiative Task Force Report*, available at: [www.cfsan.fda.gov/~dms/qhc-sum.html](http://www.cfsan.fda.gov/~dms/qhc-sum.html)
- US Food and Drug Administration (2006), *Implementation of 'Qualified Health Claims': Questions and Answers, Guidance for Industry*, available at: [www.cfsan.fda.gov/~dms/qhcqagui.html](http://www.cfsan.fda.gov/~dms/qhcqagui.html)
- US Food and Drug Administration (2007), *Qualified Health Claims Subject to Enforcement Discretion*, Updated April 2007, available at: [www.cfsan.fda.gov/~dms/qhc-sum.html](http://www.cfsan.fda.gov/~dms/qhc-sum.html)
- US FDA Centre for Food Safety and Applied Nutrition (2008), *Guidance for Industry: A Food Labelling Guide*, available at: [www.cfsan.fda.gov/~dms/21g-8.html](http://www.cfsan.fda.gov/~dms/21g-8.html)
- Van Assema, P., Glanz, K., Brug, J. and Kok, G. (1996), "Effects of health claims on eating habits of the Dutch population", *European Journal of Public Health*, Vol. 6 No. 4, pp. 281-7.
- Williams, P. (2005), "Consumer understanding and use of health claims for foods", *Nutrition Reviews*, Vol. 63 No. 7, pp. 256-64.
- Williams, P. (2006), "Can health claims for foods help consumers choose better diets?", *CML-Clinical Nutrition*, Vol. 15 No. 2, pp. 25-30.
- Yamada, K., Sato-Mito, N., Nagata, J. and Umegaki, K. (2008), "Health claim evidence requirements in Japan", *Journal of Nutrition*, Vol. 138 No. 6, pp. 1192S-19.

**Corresponding author**

Fiona Lalor can be contacted at: [Fiona.lalor@ucd.ie](mailto:Fiona.lalor@ucd.ie)

## This article has been cited by:

1. M. Bitzios, L. Jack, S.C. Krzyzaniak, M. Xu. 20. Dissonance in the food traceability regulatory environment and food fraud 375-393. [[Crossref](#)]
2. Alice B. Nongonierma, Richard J. FitzGerald. 2017. Strategies for the discovery and identification of food protein-derived biologically active peptides. *Trends in Food Science & Technology* **69**, 289-305. [[Crossref](#)]
3. Aristeia Baschali, Effie Tsakalidou, Adamantini Kyriacou, Nena Karavasiloglou, Antonia-Leda Matalas. 2017. Traditional low-alcoholic and non-alcoholic fermented beverages consumed in European countries: a neglected food group. *Nutrition Research Reviews* **30**:01, 1-24. [[Crossref](#)]
4. Tomas Lafarga, Maria Hayes. 2017. Bioactive protein hydrolysates in the functional food ingredient industry: Overcoming current challenges. *Food Reviews International* **33**:3, 217-246. [[Crossref](#)]
5. Oliver Todt, José Luis Luján. 2017. The role of epistemic policies in regulatory science: scientific substantiation of health claims in the European Union. *Journal of Risk Research* **20**:4, 551-565. [[Crossref](#)]
6. Jessica Aschemann-Witzel, Klaus G. Grunert. 2017. Attitude towards resveratrol as a healthy botanical ingredient: The role of naturalness of product and message. *Food Quality and Preference* **57**, 126-135. [[Crossref](#)]
7. Fook Yee Chye, Birdie Scott Padam, Seah Young Ng. Innovation and Sustainable Utilization of Seaweeds as Health Foods 390-434. [[Crossref](#)]
8. Hans Verhagen, Henk van Loveren. 2016. Status of nutrition and health claims in Europe by mid 2015. *Trends in Food Science & Technology* **56**, 39-45. [[Crossref](#)]
9. Tomas Lafarga, Dilip K. Rai, Paula O'connor, Maria Hayes. 2016. Generation of Bioactive Hydrolysates and Peptides from Bovine Hemoglobin with In Vitro Renin, Angiotensin-I-Converting Enzyme and Dipeptidyl Peptidase-IV Inhibitory Activities. *Journal of Food Biochemistry* **40**:5, 673-685. [[Crossref](#)]
10. Lorena Meléndez-Illanes, Cristina González-Díaz, Elisa Chilet-Rosell, Carlos Álvarez-Dardet. 2016. Does the scientific evidence support the advertising claims made for products containing *Lactobacillus casei* and *Bifidobacterium lactis* ? A systematic review. *Journal of Public Health* **38**:3, e375-e383. [[Crossref](#)]
11. Liran Christine Shan, Aine Regan, Frank J Monahan, Chenguang Li, Celine Murrin, Fiona Lalor, Patrick G. Wall, Aine McConnon. 2016. Consumer views on “healthier” processed meat. *British Food Journal* **118**:7, 1712-1730. [[Abstract](#)] [[Full Text](#)] [[PDF](#)]
12. M.J. Ruffell. Nutrition and Health Claims for Food: Regulatory Controls, Consumer Perception, and Nutrition Labeling 93-97. [[Crossref](#)]
13. Igor Pravst, Anita Kušar. 2015. Consumers' Exposure to Nutrition and Health Claims on Pre-Packed Foods: Use of Sales Weighting for Assessing the Food Supply in Slovenia. *Nutrients* **7**:12, 9353-9368. [[Crossref](#)]
14. Tomas Lafarga, Dilip K. Rai, Paula O'Connor, Maria Hayes. 2015. A Bovine Fibrinogen-Enriched Fraction as a Source of Peptides with in Vitro Renin and Angiotensin-I-Converting Enzyme Inhibitory Activities. *Journal of Agricultural and Food Chemistry* **63**:39, 8676-8684. [[Crossref](#)]
15. Karin Y.M. Tan, Eline M. van der Beek, M.Y. Chan, Xuejun Zhao, Leo Stevenson. 2015. Health claims on food products in Southeast Asia: regulatory frameworks, barriers, and opportunities. *Nutrition Reviews* **73**:9, 634-641. [[Crossref](#)]
16. Jessica Aschemann-Witzel, Klaus G. Grunert. 2015. Resveratrol and health from a consumer perspective: perception, attitude, and adoption of a new functional ingredient. *Annals of the New York Academy of Sciences* **1348**:1, 171-179. [[Crossref](#)]

17. Alie de Boer, Aalt Bast. 2015. International legislation on nutrition and health claims. *Food Policy* 55, 61-70. [[Crossref](#)]
18. Sura-at Supachaturat, Rath Pichyangkura, Achara Chandrachai, Duanghathai Pentrakoon. 2015. A Turning Point to Successful Entrepreneurship in Case Thai Functional Food Company. *International Journal of Social Science and Humanity* 5:9, 804-807. [[Crossref](#)]
19. Erfan Younesi, Mehmet Turan Ayseli. 2015. An integrated systems-based model for substantiation of health claims in functional food development. *Trends in Food Science & Technology* 41:1, 95-100. [[Crossref](#)]
20. L. Lähteenmäki. Consumer interpretation of nutrition and other information on food and beverage labels 133-148. [[Crossref](#)]
21. S. Grasso, N.P. Brunton, J.G. Lyng, F. Lalor, F.J. Monahan. 2014. Healthy processed meat products – Regulatory, reformulation and consumer challenges. *Trends in Food Science & Technology* 39:1, 4-17. [[Crossref](#)]
22. Amanda Berhaupt-Glickstein, Mary L. Nucci, Neal H. Hooker, William K. Hallman. 2014. The evolution of language complexity in qualified health claims. *Food Policy* 47, 62-70. [[Crossref](#)]
23. Miguel Márquez. Product Innovation 13-26. [[Crossref](#)]
24. Barbara Bigliardi, Francesco Galati. 2013. Innovation trends in the food industry: The case of functional foods. *Trends in Food Science & Technology* 31:2, 118-129. [[Crossref](#)]
25. Anna Arola-Arnal, Josep M. del Bas, Antoni Caimari, Anna Crescenti, Francesc Puiggròs, Manuel Suárez, Lluís Arola. How Does Foodomics Impact Optimal Nutrition? 303-349. [[Crossref](#)]
26. Liisa Lähteenmäki. 2013. Claiming health in food products. *Food Quality and Preference* 27:2, 196-201. [[Crossref](#)]
27. Mitsunori Hirogaki. 2013. Estimating Consumers' Willingness to Pay for Health Food Claims: A Conjoint Analysis. *International Journal of Innovation, Management and Technology* 4:6. . [[Crossref](#)]
28. Giuseppe Nocella, Orla Kennedy. 2012. Food health claims – What consumers understand. *Food Policy* 37:5, 571-580. [[Crossref](#)]