



Potential pitfalls of health claims from a public health nutrition perspective

François Mariotti, Esther Kalonji, Jean-François Huneau, Irène Margaritis

► To cite this version:

François Mariotti, Esther Kalonji, Jean-François Huneau, Irène Margaritis. Potential pitfalls of health claims from a public health nutrition perspective. *Nutrition Reviews*, 2010, 68 (10), pp.624 - 638. 10.1111/j.1753-4887.2010.00322.x . hal-01761204

HAL Id: hal-01761204

<https://hal.science/hal-01761204v1>

Submitted on 9 Apr 2018

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Article type: *Nutrition Science ↔ Policy*

A review of the potential pitfalls of health claims from a public health nutrition perspective.

François Mariotti, Esther Kalonji, Jean François Huneau, and Irène Margaritis.

F Mariotti and *JF Huneau* are with AgroParisTech, CRNH-IdF, UMR914 Nutrition Physiology and Ingestive Behavior, F-75005 Paris, France and with INRA, CRNH-IdF, UMR914 Nutrition Physiology and Ingestive Behavior, F-75005 Paris, France. *E Kalonji* and *I Margaritis* are with the Direction of Risk Assessment for Nutrition and Food Safety, French Food Safety Agency, Maisons-Alfort, France.

Correspondence: *F Mariotti*, AgroParisTech, UMR914 Nutrition Physiology and Ingestive Behavior, 16 rue Claude Bernard, F-75005 Paris, France. E-mail: francois.mariotti@agroparistech.fr, Phone: +33-1-44-08-72-86, Fax: +33-1-44-08-18-58.

Keywords: Health Claims, Public health, Food Labeling, Perception, Diet, Human Nutrition, Consumers.

Disclaimer: The views expressed here are those of the individual authors and not those of their respective government agencies or organization.

ABSTRACT

The European Union is implementing a new regulatory framework for nutrition and health claims (HC) that will greatly impact communication on food. In particular, approved HC will be included in a positive register of generic claims. In the literature, assessment of the relevance of HC has mainly been related to scientific substantiation, and the issue of relevance in terms of public health has tended to be overlooked. Interestingly, however, the new regulation states that claims must be well understood by the average consumer. In this article we have gone beyond the issue of the scientific substantiation of claims and have reviewed the possible mismatches between consumer perception and understanding of HC, and the public health nutrition reality, which can result in misleading the consumer and ultimately impact public health nutrition. We have identified six pitfalls, and finally propose a comprehensive overview of the critical examination of any HC.

INTRODUCTION

The European Union (EU) is facing a period of dramatic regulatory change regarding health communication on foodstuffs. After years of discussion,¹ the European Parliament and Council issued a regulation in December 2006 (No. 1924/2006) on the nutrition and health claims made on foods,² including most food supplements.³ The purpose of this regulation was two-fold. On the one hand, the EU authority was aiming to rationalize communication on foodstuffs, in line with worldwide regulatory shifts during previous decades,^{1, 4-6} by prohibiting claims that are insufficiently precise or insufficiently substantiated. All nutrition and health claims that have not been approved by the EU Commission after scientific review by the European Food Safety Authority (EFSA) will be banned. On the other hand, if the effects of products, ingredients, nutrients and other components in a foodstuff are strongly substantiated, that food product will be allowed to carry a health claim (Figure 1.). In this article, and in line with the regulations, a health claim is defined as a claim of a relationship between a food category, a food or one of its constituents and health (Table 1, Fig.1.). At the same time, a companion regulation (No. 1925/2006) has opened the possibility in the EU of adding nutrients and various substances to commonly used foodstuffs.⁷ A product fortified with nutrients naturally has access to nutrition claims, which are mainly based on the "source of" or "rich in" levels of the nutrient content in the foodstuff (as defined in R. 1924/2006), and also to health claims. Lastly, if the association is relevant and strong enough from a scientific viewpoint, products could even claim that they can reduce the risk of a disease (or a risk factor for a disease), this having been prohibited previously in most EU countries.^{2, 8}

The relevance of health claims has been widely studied, primarily from a standard nutritional science standpoint, and many efforts have been dedicated to analyzing the systems that should be used to determine the level of evidence required to substantiate claims. Building on previous projects in the EU,^{9, 10} the "PASSCLAIM" project ("Process for the Assessment of

Scientific Support for Claims on Foods”) aimed to reach consensus on criteria to assess scientific support for claims on foods.^{11, 12} Briefly, under the EU system, claims are based on scientific evidence and their assessment takes account of all available scientific data; this system uses an evidence-based rating system that is similar to that applied in the US.¹³⁻¹⁵ The preamble to the European Regulation states that “Scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims”.² Several comprehensive reviews have addressed the issue of the scientific substantiation of claims, and the reader is directed to these papers.^{11, 12, 16-26} These key points necessary to substantiate health claims are briefly shown as included in the final figure that we propose to draw a complete picture of the analysis of health claims (Figure 2, Left part, “true” box, “classic claim scientific substantiation” arrow).

By contrast, relevance to public health (Table 1) has been somewhat overlooked.²⁵ In this regard, however, one important prerequisite for a health claim under the new European regulation is that the product and its composition must meet certain specific criteria related to its nutrient profile.² Under these conditions, the regulation aims to guarantee that the nutrient content of the product will not render it intrinsically unhealthy and therefore that the specific health claim will not be misleading when compared to the basic nutritional composition of the food product.²⁷⁻²⁹ Likewise, the regulation lays down an obligation to display an extended list of nutrient information on foods bearing a health claim.² A draft of the “nutrient profile” rules was issued recently, and they consist of a series of thresholds for saturated fatty acids, sugar and sodium contents per 100g of product, these being specific to each food category.³⁰ Lastly, and importantly, the new regulation is designed to ensure that the claims will have a realistic impact, by stating that they need to be “well understood by the average consumer”.²

Nevertheless, whether the regulation will successfully achieve its initial goals will depend on the practical implementation of authorizations and restrictions on claims. Some parts of the

90 rules have been published or drafted very recently (as regards the “nutrient profile”) and the
91 remainder, which concern the authorization of health claims and related conditions, are
92 presently under scrutiny by the EFSA at the request of the European Commission. Indeed,
93 apart from claims relative to the reduction in disease risk, those specifically directed at
94 children’s development and health (referred to as “Article 14”, Fig. 1), and product-specific
95 claims that are based on new, specific scientific data (referred to as “Article 13.5”, Fig. 1), all
96 other health claims (referred to as “Article 13.1”, Fig. 1) are to be determined by the European
97 Commission and listed in a register.² This register will constitute a “positive list” of claims,
98 supplemented by specific conditions of use (including the quantity of food and the pattern of
99 consumption, together with instructions or warnings, if necessary).² This creates an original
100 provision when compared with the regulations in other countries.³¹ Likewise, all claims that
101 have been rejected will constitute a “negative list”. Under the EU system, “Article 13 health
102 claims” (Fig. 1) mean all those related to a food category, a food or one of its constituents and
103 connected with health in the broadest sense, and include (i) traditional “function claims”
104 (known as “structure-function claims” in the US), as well as behavioral functions or the
105 control of body weight (e.g. *“Calcium is needed for the maintenance of normal bones and
106 teeth”*³²; *“Lutein is deposited naturally in the eye / helps support eye health”*; *“conjugated
107 linoleic acid supports lean body mass”*; *“Calcium helps promote a healthy body weight”*;
108 *“Vitamin B6 contributes to the regulation of hormonal activity”*³³ – Please note that all quotes
109 in italics that do not bear a specific reference are claims extracted from the list currently under
110 examination by the EFSA; quotes with references are the proposed wording as found in recent
111 scientific opinions issued by the EFSA or final claims authorized by recently adopted EU
112 regulations), and (ii) what the US system, and others, would consider as “dietary guidance”,
113 i.e. a claim regarding a relationship between a food (independently of its components) or a
114 diet, and health (e.g. *“The food product 'X' fits in a Mediterranean diet. A Mediterranean style*

diet helps maintain heart health”), inasmuch as this claim is made in a commercial communication^{2, 6, 14} By contrast, the Regulation does not apply to claims that are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies.² Finally, although Article-13 “health claims” group different types of claims with diverse implications from a public health nutrition (Table 1) perspective, the evaluation framework is the same, with considerable focus on the weight of evidence substantiating the claim on basic scientific grounds, and without any specific criteria that assess the potential adverse effects of those types of claims on public health nutrition.

The scope for the application of “health claims” is therefore huge, and the amount and nature of the claims allowed will have a dramatic impact on global health communication on food in the EU. By early 2009, the European call for applications for inclusion on the register had resulted in about 10,000 health claims, based on 4185 main relationships, which all need to be reviewed. The database can be found at http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article13.htm.³³ The EFSA has recently started to issue scientific opinions on these health claims, and a few of them (mostly Article 14 claims) have recently been authorized. The EU is now starting to implement the regulation and impact assessment in the years to come will help to clarify the extent to which the initial overall objectives of the regulation are being met. In this context, the present review is also designed to anticipate the future and formulate some recommendations.

The assessment of health claims has mostly been based on scientific substantiation, in order to determine whether the stated effect is “true”. The Regulation has also introduced a series of safeguards of public health relevance, which include (i) the nutrient profile system, (ii) mandatory “expended” nutrient labeling, (iii) a mandatory statement of importance of a varied and balanced diet and a healthy lifestyle, (iv) the prohibition of claims that encourage or condone the excessive consumption of any food or disparage good dietary practice and (v) a

requirement that the stated effect is beneficial.^{2, 33, 34} Nevertheless, one might contest that the issue of public health relevance has been explored in full and it is therefore uncertain that the system is intrinsically robust enough to guarantee practical implementation that will meet public expectations. On a more general level, whatever the regulatory system (except for a prohibition system), health claims can engender potentially adverse repercussions in terms of public nutrition (Table 1), and public health.²⁵ This review was based on the rule that a claim should be truthful and not misleading.³⁵ As mentioned above, the scientific substantiation of claims, which determines their truthfulness, has been already largely explored.^{11, 12, 16-26} By contrast, general reviews have generally overlooked possible mismatches between the understanding of consumers and the public health nutrition reality, which may mislead consumers and generate adverse effects on public nutrition.¹ Beyond the context of the European regulatory framework, the aim of this prospective review was thus to analyze the different characteristics of a claim that, in light of its relevance for public health nutrition, may result in misleading the consumer, and generating adverse effects on public nutrition. Having reviewed these pitfalls, we briefly considered some potential regulatory and practical options that could prevent the formulation of misleading claims. Finally, we propose a comprehensive, overview of the issue of health claims.

Will most food products be advertised as being healthy?

In order to limit the current widespread use of vague claims related to health, the regulation states that “Reference to general, nonspecific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14”.² However, under this regulation, all claims, except those of a purely nutritional nature, are “health claims”, including classical nutrient-function claims (Fig. 1). It is highly likely that at least one standard function claim (e.g. “*Proteins are essential for growth, development & maintenance of the body/body tissues/body function*”) will be allowed for most nutrients (e.g. proteins, lipids and carbohydrates, vitamins and minerals, and water). Therefore, virtually all food products that satisfy the nutrient profile and contain (before or after fortification) a significant amount of a given nutrient, will be authorized to use a “health claim” (article 13.1 claims), and hence unregistered “vague claims”, such as “This product is good for your health”. The specific nutrient-function claim could simply be used as an easy pass to a vague claim, and products could focus communication on the vague claim, disconnected from the specific generic claim. Thus unfortunately, for practical reasons, the objective of reducing the burden of vague claims will potentially not be achieved.

“Health claims” with differing degrees of importance to public health

Under the EU regulation, “health claims” include claims “regarding the role of a nutrient or other substance in [...] the functions of the body”, i.e. “function claims”, whatever the function.⁸ It should be noted that the regulation also clearly states that any claimed effect should be “beneficial” to health, which is a basic and important guarantee in terms of public health.^{2, 34} However, if “health” is considered in its broadest sense (i.e. complete physical, mental and social well-being, as defined by the WHO),³⁶ virtually all functions can be considered as relating to health, and many claims can refer to a “beneficial” effect on these

functions. But the importance of these functions to public health varies considerably. For instance, when prioritized in terms of the prevalence of dysfunctions and public health consequences, the importance of cardiovascular functions (e.g. “*n-3 LC-PUFA have a beneficial effect on the function of the arteries*”) is superior to that of the immune system (“*Copper is needed for the function of the immune system*”) and far ahead of physical and mental performance (e.g. “*Morinda citrifolia is an ergogenic aid*”, “*Phenylalanine helps to maintain mental health and stimulates mental alertness*”) and cosmetic functions (“*Beta-carotene promotes the onset of tanning by providing a slight coloring of the skin*” ; “*Silicon helps reduce hair brittleness*”). A multiplication of health claims of differing importance to public health would naturally be expected to add noise and impair the correct prioritization of claims by consumers in terms of their true significance. In addition, public communication targeting important risks to the health of the population (e.g. cardiovascular risk) may be understood less clearly.

Should dietary guidance be addressed as food-related “health claims”?

As stated above, Article 13.1 “health claims” include what the US system would appropriately consider as dietary guidance, in particular because a statement relates to the effect of a whole food or food category (Fig. 1). Most consumers will not distinguish such a claim from a regular specific health claim,³⁷ but because such a (food or diet-related) claim is more general, they are likely to understand it as forming part of dietary guidelines for the general public, and its impact may extend beyond the selection of a specific food that bears this claim to overall dietary choices.³⁸ It is therefore critical that such claims should be closely examined in a public health nutrition perspective. These statements should therefore constitute clear and useful general guidance that can be endorsed by the authorities and will comply with general public dietary guidelines. From a more practical point of view, the wording should provide consumers with clues as to implementation of the guidance. For instance: “*Regular*

consumption of fruits and vegetables (At least 400 g/day or 5 portions/day) supports the heart and cardiovascular health.” can be considered as guidance that public health nutrition policies would like to promote, and is already an important message in French and European communication to the public. The message goes beyond just one foodstuff and targets other products that may not choose to make any claim. Lastly, consumers can easily understand and implement the recommendation by simply including more fruits and vegetable in their diet. By contrast, “*The food product 'X' fits in a Mediterranean diet. A Mediterranean style diet helps maintain heart health*” is also scientifically sound, given the body of evidence concerning the health benefits of a Mediterranean diet, but may conflict with other general dietary guidelines endorsed by public health authorities (e.g. a food pyramid), and, of course, cannot be implemented practically if consumers are not taught what constitutes a Mediterranean diet. Lastly, claims such as “*Meat, poultry and fish promote the absorption of non-haem iron*” and “*Coffee contributes to maintain your fluid balance*” are likely to be read as guidance concerning the consumption of meat and coffee whereas general dietary guidelines are not likely to focus on meat and coffee consumption. Lastly, these types of claims could be accompanied by statements that specify food quantities and consumption patterns. However, these form part of the specific conditions that must be met to achieve the claimed effect.^{2, 34} Therefore, although the regulation states that the quantity of food should “reasonably” be achieved as part of a balanced diet,^{2, 34} such claims are not constructed to match general dietary guidelines.

Indeed, the preamble to the European regulation states that “A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet”.² General dietary guidelines, based the total diet approach, are the most robust^{39, 40} and are useful to the consumer for the practical application of food selection and promoting positive lifestyles.^{41, 42}

How will the “average consumer” understand these claims?

Claims on foods must be understood by consumers and must not be misleading. The benchmark for an "average consumer" used in the regulation is someone who is “reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors [...]”.² It should be noted that the European regulation, as stipulated in the preamble to R.1924/2006, also intends to "prevent the exploitation of consumers whose characteristics make them particularly vulnerable to misleading claims".² The EFSA also notes that the final wording of a claim may need to take account aspects other than agreement with the scientific evidence, e.g. understanding by consumers.³³

Pitfall #1 – the lexical issue

The EFSA assesses the wording of a health claim relative to its scientific truthfulness.¹³ However, this wording can be expected to raise several issues with respect to consumer understanding.

Firstly, the "average" consumer may find it difficult or impossible to understand some of the lexical terms employed, which should disqualify a claim (e.g. “*Copper helps build connective tissues*”, “*X is useful for the prophylaxis of recurrent infection of the upper respiratory tract*”, “*L-arginine increases nitric oxide production*”). When a consumer has heard a word many times, but is still unable to comprehend its precise meaning, this issue becomes more problematic. A good example concerns the word “metabolism”. To what extent does the average consumer really understand “*Phosphorus contributes to energy metabolism*”,⁴³ or “*Caffeine supports resting metabolic rate and thermogenesis*”? Considerable care must therefore be taken to prevent claims from being misleading because they are not correctly understood, or are too vague for the "average consumer".

Conversely, although giving details of an exact function in a claim may impair its correct understanding by a consumer, it is important that the claim should not refer to too general a

bodily function. A good example concerns Lutein and Zeaxanthin: “*Helps support eye health / helps maintain healthy eyes / nutrition for eyes / promotes healthy eye function/helps maintain macular and retinal health*”. There exists a body of literature that suggests (but does not conclude) that consuming Lutein and Zeaxanthin may reduce the risk of Age-Related Macular Degeneration, which is a specific eye disease.⁴⁴ Any broader wording may make the function more comprehensible to the average consumer but would render the claim misleading because many consumers might understand that the product could be of value for other components of eye health, e.g. visual acuity.

In EFSA opinions, when the scientific relationship stated in a claim is considered to be truthful, appropriate wording is proposed to describe this relationship. The EFSA considers that the clarity and the specificity of wording is important,⁴⁵ and warns that consumer understanding may need to be taken into account in the final wording of claims as adopted by the European Commission during authorization.³³ In addition, the wording of a claim, like any part of an EFSA opinion, is open to comments from the public for 30 days after its publication, before a final decision is taken on authorization.² However, it is not the intention of the regulator to propose a detailed and rigid list of all possible wordings for a claim, and the EFSA is not asked to comment in details the possible wordings.⁴⁵ Thus the possibility that a lexical term may be insufficiently clear or specific to enable consumer understanding remains an important practical issue that requires impact assessment and further specific study on the grounds of consumer understanding.

Pitfall#2 – Beyond scientific trueness

In addition to lexical understanding, other mismatches may occur between the understanding (and perception) of a claim by consumers and the scientific evidence assessed by expert panels. In an expert committee, nutritionists would first of all consider that the claim “*lipids provide energy to the body*” relies on the strongest scientific evidence, because lipids are a

source of metabolizable energy. However, further discussion may make it clear to members that many consumers could understand (or perceive) “provides energy” as meaning “is energizing”. In this example, the wording may thus generate a misleading, attractive perception of the product that goes beyond its truthful, unexciting, basic meaning. Is a company likely to use a claim with unequivocal wording, such as: “lipids provide energy (“calories”) to the body”?

Clearly, this type of pitfall makes it even more difficult to assess the wording of claims because this requires considerable insight into how consumers may specifically understand and perceive the wording. If we are to advance in our analysis of how claims are understood by consumers, it is necessary to develop studies in the fields of psycho-sociology and consumer science.^{1, 37, 46-53} Whether a claim is misleading depends on the complex perception that naturally emerges from wording of the message. This field is largely under-developed but several approaches are available and should be implemented systematically in order to determine whether actual consumer perceptions are compatible with a claim being “well understood by the average consumer”.^{37, 49, 54} Nutrition experts need to work far beyond their strict disciplinary area and enter other fields if they are successfully to address all the points at issue.⁵⁵

Pitfall #3 – Matching consumer understanding and reality – The confusion between food and diet

Article 13.1 health claims, and particularly “function claims”, are generally built on a broad association between the consumption of a nutrient (or substance) in the diet and a function or health-related parameter. The effect may actually be related to the overall diet, but be claimed for a specific foodstuff. Accordingly, the food is only expected to exert this effect if it forms a significant part of the diet.²⁵ This condition is usually met by specifying that the food is a source of the nutrient/substance. However, for nutrients with Dietary Recommended Values,

the threshold for the nutrient in the food is based on the amount required, and does not take account of the actual, spontaneous level of the nutrient/substance in the diet. When the spontaneous dietary intake of a nutrient far exceeds the nutritional requirement, this can lead to a serious mismatch between the consumer's understanding of the claim and the true effect expected from including a given food in his diet. Protein is one example. In Western countries, the average protein intake in the general population is high (e.g. ~1.4g/kg in France and the US),^{56, 57} and far higher than the safe level of intake (0.83g/kg) defined as the 97.5th percentile of the population distribution of requirement.⁵⁸ Thus, in this regard, virtually all the general population is at no risk of inadequate intake.^{56, 57} Many foods currently on the market are promoted using claims such as "a source of protein; protein is needed for muscle function". However, because the mean protein intake in Western countries is around 16 %, ^{59,} ⁶⁰ choosing a food that is a "source of protein" (i.e. 12% or higher) will only marginally increase (or even decrease) the level of protein in the diet. Thus any associated health claim (e.g. for muscle function) would be misleading. From a more general standpoint, a health claim associated with a food that is "a source of/rich in" nutrient X is only meaningful if this food can replace another that contains low levels of nutrient X, and only when the overall dietary intake of nutrient X is low. When the latter condition is not met, function/health claims become misleading.

Interestingly, EFSA opinions lay considerable importance on the relevance of claims in light of the nutritional status of the European population. Indeed, in the two examples above, the EFSA has issued opinions (on nutrition and health in children, relative to an Article 14 claim application) stating that children and adolescents in the EU very probably consume sufficient protein and phosphorus, and there is no evidence for an effect above the required level.^{61, 62} Regarding protein, the opinion stated that "Recommended intakes of protein to meet the requirements for growth and development of children, including normal growth and

development of bone, have been established. [...] There is no evidence of benefit of additional protein above the amount found in otherwise nutritionally complete diets. [...] No evidence of inadequate intakes of protein in European children has been provided".⁶¹ However, unfortunately, this important point was apparently not retained subsequently during the decision procedure, and although reference was made to these specific EFSA opinions, the EU recently decided that the following constituted authorized claims: "Protein is needed for normal growth and development of bone in children" and, likewise, "Phosphorus is needed for the normal growth and development of bone in children".^{62, 63}

Pitfall #4 – Matching consumer understanding and reality – Is more better?

The relationship between the intake of a nutrient/food and a biological function is well known to be almost always curvilinear/quadratic in nature.^{64, 65} Indeed, most basic relationships between dose and response in nutritional science display a threshold upon which nutritional requirement is usually based. Increasing intake up to the nutritional requirement will enhance the associated function, and this part of the relationship can be viewed as being virtually linear, whereas for intakes above the requirement, the relationship will plateau rapidly, yielding no clear further benefit (but potential risk).⁶⁵ By contrast, the simplest way to represent a relationship between a nutrient/substance/food and the related function referred to in a claim is clearly linear, which would naturally be the perception of the “average consumer”. To put it in a nutshell, consumers most often adhere to the basic wrong premise of “the more, the better”. This is an extension of pitfall#3. Examples of such clearly misleading claims are numerous, and indeed virtually all claims are concerned (e.g. “*The body needs manganese to produce energy*”, “*Biotin helps release energy from fat*”, “*Polyols help keep teeth healthy*” ; and “*Vitamin C contributes to the protection of cell constituents from oxidative damage*”,⁶⁶ “*Copper contributes to normal function of the immune system*”,⁶⁷

"Iodine contributes to the normal growth of children",⁶⁸ "Sugar-free chewing gum helps neutralise plaque acids"⁶⁹).

This is a widely acknowledged pitfall. Regulations in Japan require that all nutrient-function claims be accompanied by a disclaimer stating that "Excessive intake of this product neither cures any disease nor improves health – keep with the optimal intake". Similarly, a specific disclaimer is added to claims on folic acid and fetal growth: "Folic acid is a nutrient that contributes to normal growth of the fetus but does not improve growth of the fetus with excess intake".⁷⁰ In the EU, the EFSA usually words the generic article 13.1 claims using the adjective "normal" (e.g. "Pantothenic acid contributes to normal mental performance"⁷¹ ; "Vitamin C contributes to the normal function of the nervous system"⁶⁶). This choice is of great importance to the present pitfall. However, it remains to be determined whether this subtle wording performs as well as a dedicated disclaimer in terms of helping average consumers to avoid the pitfall.

It should also be noted that, beyond issues regarding the truthfulness and relevance of claims, the disclaimers referred to above should also be helpful in limiting excessive intake, which is important to public health. Indeed, the risks of a chronic over-consumption of nutrients and dietary substances are clearly more difficult to assess than the benefits,^{65, 72, 73} and a correct definition of the actual window of optimum intake still requires the development of appropriate risk-benefit markers and methods.^{74, 75}

In this regard, the European regulation states that health claims shall not encourage excess consumption of a food and shall be accompanied by appropriate warnings on products that are likely to present a health risk if consumed to excess. The first health claim authorizations (under Article 14) and the first series of EFSA opinions under Article 13 were not accompanied by any specific disclaimers of that type,^{e.g.76, 77} The rationale is that most nutrients and substances are not considered to be potentially hazardous to health at the

expected level of consumption, based on current risk assessments for these substances, or that little or no data are available to characterize the danger.^{e.g.76, 77}

Pitfall #5 – Matching consumer understanding and reality – Multifactoriality

Another well-known error in the understanding of a claim relates to the belief that because nutrient/substance X is important for function Y, the latter will be guaranteed by an appropriate intake of X, which simply conceals the fact that function Y (and physiological functions in general) is impacted by numerous genetic and environmental factors, including dietary parameters.⁷⁸ One may argue that if multifactoriality is not spelled out in the claim, the “average consumer” will lose sight of prioritizing different factors, and only believe in the decontextualized relationship.⁷⁸ Interestingly, it has been shown that the less a consumer is able to find alternative causes for an effect stated in a claim and disabling conditions for the claimed (cause-effect) relationship, the more this increases the absolute believability of the claim, thus misleading the consumer as to the multifactorial reality of the relationship mentioned.⁷⁹ Nieves & Lindsay⁸⁰ recently concluded their comments on the negative results of a meta-analysis concerning calcium and fracture risk by stating: “This meta-analysis highlights the importance of not segmenting nutrition into heterogeneous populations and isolated nutrients. Bone is not just calcium, and calcium does not function in isolation”. Calcium and bone can be considered as one of the most typical, consensual, relationships in nutritional science, yet it may not be strong enough to be demonstrated significantly when all other factors are taken into account, i.e. when the true situation of consumers is addressed. One may therefore argue that other claimed single relationships, which are not as strong or typical as calcium & bone, may be largely misleading if the consumer is not provided with clear information about the other factors also thought to impact (and potentially more strongly) the health-related parameter.

At the request of the European Commission, the EFSA issued an initial series of opinions on nutrients in relation to bone health in adults, and children and adolescents.^{32, 43, 81-83} Regarding all relationships where the EFSA stated that "a cause and effect relationship has been established",⁸² the EU then issued regulations authorizing related claims, namely "*Calcium is needed for normal growth and development of bone in children*", "*Protein is needed for normal growth and development of bone in children*".⁶³ Other recent EFSA opinions have also proposed claim wordings for other nutrients in relation to bone health, e.g. "*Vitamin K contributes to maintenance of normal bone*".⁸⁴ Is a consumer supposed to determine the relative importance of these different links to bone health? Are calcium, protein and vitamin K supposed to exert similar benefits on bone health? Furthermore, how can a given claim be understood when it is decontextualized from other nutritional, physiological or environmental (and genetic) factors. Finally, it remains unclear how the average consumer can integratively understand a series of claims for the same benefit when the information is fragmented between different food products, and how this can be expected to facilitate relevant food choices.

It should nonetheless be noted that, according to the European regulation, if a health claim is made for a product the labeling must also include a statement indicating the importance of a varied and balanced diet and a healthy lifestyle.² This information, which could be read as a disclaimer, is important in that it can prevent the complete decontextualization of a health claim. However, it remains unclear how far this very general information is able to appropriately balance the specific relationship highlighted by the health claim. This issue is considered in greater depth below.

Pitfall #6 – Matching consumer understanding and reality – For which consumers?

One crucial final point with respect to public health is that the population cannot be considered as homogenous. Because nutritional status varies considerably, tailoring

432 dietary/nutritional strategies to specific (sub)populations has become a major prerequisite for
433 effective health policies.⁸⁵ When nutritional status and the importance of the health-related
434 outcome vary, the health message must target the specific, relevant population. In the future,
435 the expanding area of nutrigenomics is expected to lead to a more detailed identification of
436 the precise populations to which a health claim is relevant.⁸⁶ However, this goal is still far
437 off⁷⁵ and our current knowledge of nutritional science is already sufficient to enable the
438 partial refinement of some health claims. For instance, because iron status tends to be low in
439 women of childbearing age but is usually correct or high in men,⁸⁷⁻⁹⁰ health claims regarding
440 iron may not be really applicable to adult men, and unless otherwise stated, such a claim
441 would be misleading in most of this population. Taking the example of protein again, and as
442 explained previously, it is currently thought that protein-muscle claims are irrelevant in the
443 majority of the population, but they may be important for the frail elderly.⁹¹ Specifying a
444 target population may be the only way to prevent a claim from being misleading for the
445 majority.

446 EU regulations do not lay down special requirements regarding the definition of target
447 populations (except for claims related to children),^{2, 8} but the EFSA requires the definition of a
448 target population for an intended health claim¹³. However, if the applicant proposes that the
449 claim should be assessed in the context of the general population, it remains unclear whether
450 full consideration will be given to the present pitfall. As for the example of iron, the recent
451 EFSA opinion states that a general cause and effect relationship has been established between
452 the dietary intake of iron and a series of iron-related functions, but does not comment on the
453 fact that the claim may not apply similarly to men and women.⁹²

454
455 **Implementation of health claims and the public health nutrition perspective.**

Given the new opportunities available to fortify foods, it is expected that the numbers of foods bearing generic “health claims” (under Article 13.1), will increase rapidly and markedly. This increase would be a challenge for the present system. Although the EU nutrient profile procedure/concept remains provisional, it could be hypothesized that the system ultimately chosen may be highly permissive, inasmuch as in practice it could be insufficiently discriminatory.

Whereas a limited number of appropriate nutrition and health claims for a limited number of food products may be useful to consumers when they make healthy dietary choices, and could also be considered as an opportunity for public health,^{19, 22, 26} an uncontrolled proliferation of health claims has long been acknowledged as confusing or even a danger to the public^{25, 93} because it usually generates false perceptions and inappropriate behavior.⁹⁴ This includes (i) the “halo” and “integrative” effects, which discourage consumers from looking for other (more) critical information regarding the value of different foodstuffs to their overall diet, such as lists of ingredients or nutrition facts,^{54, 95, 96} and (ii) other erroneous perceptions of a product's properties (e.g. the “magic bullet” effect), which may induce the overselection of foods (e.g. when feelings of guilt are lost with respect to foods that should only be consumed in limited quantities in the diet).^{52, 54, 97} As a result, the more a consumer selects foodstuffs according to the attractiveness of claims, the less they will be sensitive to official guidelines when choosing foods to achieve a balanced diet.^{16, 52} Public health communication on diet and health may be blurred in the noise and confusion generated by possibly overwhelming advertising/marketing campaigns by the food industry^{16, 41, 93, 98} and based on a proliferation of Article 13.1 (or US “structure-function”) claims. In this respect, these claims constitute the greatest risk, because Article 14 claims relative to reducing disease risk (or US “health claims”) are more specific and far more relevant to public health, and are required to mention

the multi-factorial nature of a disease (or health-related condition); more importantly, as for Article 13.5 claims, large numbers of such Article 14 claims are not anticipated.

Given the huge impact of health claims on food choice,^{42, 98} the growing number of health claims in the EU may soon result in important changes to the selection of foodstuffs. As has been shown in the US, the prioritization of health messages by consumers changes over time, and food labels have an increasingly important impact.^{38, 98} The risk is that such practices may hasten the current, dramatic dietary transition from the cultural/historical diets that continue to be followed (particularly in European Mediterranean countries) and have proven importance in public health nutrition (e.g. the Mediterranean diet)⁹⁹ to a poorly reasoned diet, i.e. mostly composed of foods that benefit from the strongest health marketing campaigns.

In the last part of this article, we will consider the potential practical ways (and difficulties), to prevent claims from being misleading because of the series of pitfalls we have presented.

Where do we go from here? – Restricting claims, controlling their wording, adding disclaimers?

Witnesses in court must swear to tell “the truth, the whole truth and nothing but the truth”; in the same way, health claims must not avoid “the whole truth”. It can be argued that public health nutrition policy should aim to increase general knowledge on nutrition and health (the “internal characteristics” of consumers) so that these consumers can make informed choices based on limited information (the truth, but not the whole truth). However, only a minority of the population have sufficient knowledge of nutrition and health to enable them to understand “the whole truth” when information is not supplied on a product.^{25, 37, 100} Thus the direct provision of all the information they require to consumers (using disclaimers), in a well-balanced manner, constitutes a powerful option for the public health authorities.

However, “What is simple is wrong and what is complex cannot be understood”, and nutrition and health is clearly a highly complex issue.¹⁰¹ Consumer science has developed information

processing theories in order to understand and analyze how a message is understood and dealt with.^{49, 102} When applied to nutrition and health claims, the general picture is that a consumer will make inferences beyond what is actually stipulated in words, and that this process is important to the final integration and choice model.^{49, 103} More specifically, a correct understanding of a health claim means that the average consumer will make inferences that are correct, but various types of erroneous inferences also exist.^{49, 95, 104} One obvious option is to secure against erroneous inferences by using a complete statement. If X is a nutrient/substance and Y is a body function, the sentence “The product is rich in X; X is good for Y” may be true but very misleading, as explained in the sections above on pitfalls. In order to guarantee that a text is not misleading, this sentence should in fact read: “The product is rich in X; if you use this product instead another one that supplies less X in your diet, it should help you to achieve a sufficient intake of X (provided that your present intake is not already sufficient), and therefore, given the importance of X as regards Y, this may help Y, but may not be useful for other functions. However, other factors influence Y, so that an adequate consumption of X does not guarantee the satisfactory functioning of Y. It is likely that you already consume enough X [unless you belong to the specific population P] and in this case, there is no evidence that consuming this food product will benefit you, and indeed you should be aware that there is always a risk that if you consume more X than required, this may harm your health. Do not forget to follow government guidelines on diet and health, as these are more important and more likely to be true than the specific benefit claimed by this product”.

Clearly, it is not practicable to explain the issue in such detail, simply because consumers would not be able to understand the whole truth,^{37, 48} or, to use the terminology adopted by perception scientists, the average consumer will not, or cannot, process this information in order to come to a decision.⁴⁹

In the preamble to the European regulation, mention is made of the difficulty in conveying a message that is both short, comprehensive, truthful and meaningful, but the extent of this problem is restricted to functions that are the most likely to be complexly influenced by many factors: "There are many factors, other than dietary ones, that can influence psychological and behavioural functions. Communication on these functions is thus very complex and it is difficult to convey a comprehensive, truthful and meaningful message in a short claim to be used in the labelling and advertising of foods".²

One interesting option is to resort to a limited number of appropriate disclaimers, inasmuch as they may effectively counterbalance a claim and prevent it from being misleading. Some countries (e.g. the USA and Japan) have adopted such a disclaimer policy. The EU regulation does not actually require any disclaimer, but only a statement "indicating the importance of a varied and balanced diet and a healthy lifestyle".² However, it is not stipulated how this statement should be included in the labeling of a health claim, and it is essential that the disclaimer (as in the USA) should form an integral part of the claim, otherwise consumers will skip the full, non-product-specific information and concentrate on short product-specific claims, which have now become the most attractive and best understood information.^{37, 105} Alternatively, when the health claim combines many of the aforementioned pitfalls, another – and arguably the best – option is to refuse authorization of the claim.

Suggestions for a general policy that addresses health claims on a case-by-case basis

Finally, the ideal arrangements from a public health perspective probably consist in identifying and implementing an optimum mix of different options, tailored to reduce as far as possible any risk of misleading consumers, generating inappropriate food choices and impairing practical compliance with official guidelines,⁵² while retaining a message that can be understood and is relevant to public health nutrition. These options may be: (i) to ban or limit the type of claims, (ii) to restrict the wording of claims, and (iii) to include general

disclaimer statements. For instance, it could be argued that, firstly, only structure-function claims (or generic Article 13.1 claims) relevant to public health nutrition should be allowed. This would imply banning claims regarding nutrients that are already consumed in sufficient quantities, and always describing in detail the specific target populations at risk of deficiency. Secondly, any “health claim” (ranging from structure-function claims to disease-reduction claims) should always be accompanied by a disclaimer that states that (a) the function or health-related condition is also influenced by many other factors, (b) more is not necessarily better, and (c) consumers should first of all select foodstuffs that comply with general dietary guidelines.

Indeed, this general strategy should be adapted on a claim-by-claim basis that precisely determines the public health relevance of each claim, the importance and political/scientific relevance of the different options available, and any specific provisions that need to be included. For example, the FDA applies precise weighting to the importance of disclaimers with respect to claims for a reduction in disease risk.^{e.g., 106} The final objective is to finely tune the length of the claim and the number of disclaimers, thus preventing, on the one hand, claims that are short, readable and comprehensible but misleading, and, on the other hand, claims that are precise and correct, but too long and intricate and therefore difficult to understand.³⁷ Lastly, because the perceptions and intentions generated by a given message are generally affected by the individual/sub-group characteristics of consumers, attention must also be paid to the specific population covered by the scope of a claim and to practical aspects regarding implementation.^{107, 108} Finally, whereas examination of the scientific substantiation of a claim will merely result in a "yes" or "no", full examination of the characteristics of a claim, ensuring that it is not misleading and remains relevant to public health, will probably result in a variety of provisions, including rewording and the addition of disclaimers (Fig. 2,

Right part, "not misleading" box). This process can be expected to be iterative, as the wording and disclaimer policy will feed back from an impact assessment of the wording of the claim.

CONCLUSION

This review presents a schematic framework for a comprehensive analysis of health claims that would integrate important points from a public health perspective (Fig. 2). The regulation is now being implemented in the EU, and impact assessment is foreseen in the coming years. In this regard, the present work may be helpful if efforts are to be made to reduce the adverse and confusing effects that may arise from an insufficiently controlled and intense proliferation of misleading/irrelevant health claims. The points raised by the present review, however, go beyond the European context, as they concern all stakeholders in health claims under different regulatory frameworks. In Europe, and in all other countries, considerable efforts are still necessary to analyze the perception and understanding of "health claims" relative to their relevance to nutritional science and public health nutrition. More generally, and given the ongoing rapid transition in diet and health problems, any food product and its related claims should be contextualized in diets and analyzed from a bio-psychosocial standpoint.

References

1. Przyrembel H. Food labelling legislation in the EU and consumers information. Trends Food Sci Tech. 2004;15(7-8):360-365.
2. Corrigendum to 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. 18 January 2007; 2007:L 12/13.
3. 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: Official Journal of the European Union. 18 February 2002; 2002:L 31/25.
4. Taylor CL, Wilkening VL. How the nutrition food label was developed, Part 2: the purpose and promise of nutrition claims. J Am Diet Assoc. 2008;108(4):618-623.
5. Taylor CL. Regulatory frameworks for functional foods and dietary supplements. Nutr Rev. 2004;62(2):55-59.
6. Kwak NS, Jukes DJ. Current international approaches to food claims. Nutr Rev. 2000;58(12):370-377.
7. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods: Official Journal of the European Union. 30 December 2006; 2006:L 404/426.
8. European Commission. Guidance on the implementation of Regulation N° 1924/2006 on Nutrition and Health Claims made on food. Conclusion of the standing committee on the food chain and animal health 2007.
9. Roberfroid MB. Global view on functional foods: European perspectives. Br J Nutr. 2002;88 Suppl 2:S133-138.
10. Contor L. Functional Food Science in Europe. Nutr Metab Cardiovasc Dis. 2001;11(4 Suppl):20-23.
11. Aggett PJ, Antoine JM, Asp NG, et al. PASSCLAIM: consensus on criteria. Eur J Nutr. 2005;44 Suppl 1:i5-30.
12. Asp NG, Bryngelsson S. Health claims in Europe: new legislation and PASSCLAIM for substantiation. J Nutr. 2008;138(6):1210S-1215S.
13. EFSA Scientific Panel on Dietetic Products Nutrition and Allergies. Scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim. EFSA J. 2007;530.
14. Rowlands JC, Hoadley JE. FDA perspectives on health claims for food labels. Toxicology. 2006;221(1):35-43.
15. Food and Drug Administration. Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims - Final; 2009.
16. Hasler CM. Health claims in the United States: an aid to the public or a source of confusion? J Nutr. 2008;138(6):1216S-1220S.
17. Schneeman B. FDA's review of scientific evidence for health claims. J Nutr. 2007;137(2):493-494.
18. Jew S, Vanstone CA, Antoine JM, Jones PJ. Generic and product-specific health claim processes for functional foods across global jurisdictions. J Nutr. 2008;138(6):1228S-1236S.
19. Jones PJ, Asp NG, Silva P. Evidence for health claims on foods: how much is enough? Introduction and general remarks. J Nutr. 2008;138(6):1189S-1191S.

- 641 20. Lupton JR. Determining the strength of the relationship between a food, food
642 component, or dietary supplement ingredient and reduced risk of a disease or health-
643 related condition. *J Nutr.* 2005;135(2):340-342.
- 644 21. Kwak NS, Jakes D. Issues in the substantiation process of health claims. *Crit Rev*
645 *Food Sci Nutr.* 2001;41(6):465-479.
- 646 22. Tapsell LC. Evidence for health claims: a perspective from the Australia-New Zealand
647 region. *J Nutr.* 2008;138(6):1206S-1209S.
- 648 23. AFSSA (French Food Safety Agency). Opinion of 10 January 2007 on guidelines for
649 the constitution and assessment of dossiers concerning nutrition and health claims for
650 foods: Request no. 2006-SA-0182; 2007.
- 651 24. AFSSA (French Food Safety Agency). Opinion of 23 January 2008 on the assessment
652 of generic claims for drawing up a register as provided for in the European regulations
653 on health and nutrition claims: Request no. 2005-SA-0169; 2008.
- 654 25. Lawrence M, Rayner M. Functional foods and health claims: a public health policy
655 perspective. *Public Health Nutr.* 1998;1(2):75-82.
- 656 26. Clydesdale FM. A proposal for the establishment of scientific criteria for health claims
657 for functional foods. *Nutr Rev.* 1997;55(12):413-422.
- 658 27. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific opinion on the
659 setting of nutrient profiles for foods bearing nutrition and health claims pursuant to
660 article 4 of the Regulation (EC) ° No 1924/2006 on request from the European
661 Commission. *EFSA J.* 2008;644.
- 662 28. Drewnowski A, Fulgoni V, 3rd. Nutrient profiling of foods: creating a nutrient-rich
663 food index. *Nutr Rev.* 2008;66(1):23-39.
- 664 29. Kennedy E, Racs P, Dallal G, et al. Alternative approaches to the calculation of
665 nutrient density. *Nutr Rev.* 2008;66(12):703-709.
- 666 30. European Commission. Working document on the setting of nutrient profiles;
667 Prepared by the Commission services - Brussels, 22 October 2008. 2008.
- 668 31. L'Abbe M R, Dumais L, Chao E, Junkins B. Health claims on foods in Canada. *J Nutr.*
669 2008;138(6):1221S-1227S.
- 670 32. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
671 substantiation of health claims related to calcium and maintenance of bones and teeth
672 (ID 224, 230, 231, 354, 3099), muscle function and neurotransmission (ID 226, 227,
673 230, 235), blood coagulation (ID 230, 236), energy-yielding metabolism (ID 234),
674 function of digestive enzymes (ID 355), and maintenance of normal blood pressure
675 (ID 225, 385, 1419) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on
676 request from the European Commission. *EFSA J.* 2009;7(9).
- 677 33. EFSA Panel on Dietetic Products Nutrition and Allergies. Briefing document for
678 Member States and European Commission on the evaluation of Article 13.1 health
679 claims on request of EFSA. *EFSA J.* 2009;7(11).
- 680 34. Commission regulation (EC) No 353/2008 of 18 April 2008 establishing
681 implementing rules for applications for authorisation of health claims as provided for
682 in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament: Official
683 Journal of the European Union. 19 April 2008; 2008:L 109/111.
- 684 35. Codex Alimentarius. Guidelines for the use of Nutrition and Health Claims. CAC/GL
685 23-1997. 1997.
- 686 36. WHO. Constitution of the World Health Organization, adopted by the International
687 Health Conference, New York, 19 June–22 July 1946, and entered into force on 7
688 April 1948. 1946.
- 689 37. Food and Drug Administration. Transcript of Public Meeting: Assessing Consumer
690 Perceptions of Health Claims. College Park, Maryland 2005.

- 691 38. International Food Information Council. 2005 Consumer Attitudes toward Functional
692 Foods/Foods for Health—Executive Summary 2006.
- 693 39. Imamura F, Jacques PF, Herrington DM, Dallal GE, Lichtenstein AH. Adherence to
694 2005 Dietary Guidelines for Americans is associated with a reduced progression of
695 coronary artery atherosclerosis in women with established coronary artery disease. *Am*
696 *J Clin Nutr.* 2009;90(1):193-201.
- 697 40. Estaquio C, Castetbon K, Kesse-Guyot E, et al. The French National Nutrition and
698 Health Program score is associated with nutritional status and risk of major chronic
699 diseases. *J Nutr.* 2008;138(5):946-953.
- 700 41. Nitzke S, Freeland-Graves J. Position of the American Dietetic Association: total diet
701 approach to communicating food and nutrition information. *J Am Diet Assoc.*
702 2007;107(7):1224-1232.
- 703 42. International Food Information Council. 2007 Food & Health Survey—Consumer
704 Attitudes toward Food, Nutrition & Health 2007.
- 705 43. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
706 substantiation of health claims related to vitamin D and maintenance of bone and teeth
707 (ID 150, 151, 158), absorption and utilisation of calcium and phosphorus and
708 maintenance of normal blood calcium concentrations (ID 152, 157), cell division (ID
709 153), and thyroid function (ID 156) pursuant to Article 13(1) of Regulation (EC) No
710 1924/2006 on request from the European Commission. *EFSA J.* 2009;7(9).
- 711 44. Trumbo PR, Ellwood KC. Lutein and zeaxanthin intakes and risk of age-related
712 macular degeneration and cataracts: an evaluation using the Food and Drug
713 Administration's evidence-based review system for health claims. *Am J Clin Nutr.*
714 2006;84(5):971-974.
- 715 45. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
716 substantiation of health claims related to *Armoracia rusticana* P. Gaertn. and
717 improvement of diuretic function (ID 2224, 2719) pursuant to Article 13 (1) of
718 Regulation (EC) No 1924/2006 on request from the European Commission. *EFSA J.*
719 2009;7(9).
- 720 46. Urala N, Arvola A, Lähteenmääki L. Strength of health-related claims and their
721 perceived advantage. *Int J Food Sci Technol.* 2003;38:815-826.
- 722 47. van Trijp HC, van der Lans IA. Consumer perceptions of nutrition and health claims.
723 *Appetite.* 2007;48(3):305-324.
- 724 48. Cowburn G, Stockley L. Consumer understanding and use of nutrition labelling: a
725 systematic review. *Public Health Nutr.* 2005;8(1):21-28.
- 726 49. Leathwood PD, Richardson DP, Strater P, Todd PM, van Trijp HC. Consumer
727 understanding of nutrition and health claims: sources of evidence. *Br J Nutr.*
728 2007;98(3):474-484.
- 729 50. Kapsak WR, Schmidt D, Childs NM, Meunier J, White C. Consumer perceptions of
730 graded, graphic and text label presentations for qualified health claims. *Crit Rev Food*
731 *Sci Nutr.* 2008;48(3):248-256.
- 732 51. Hooker NH, Teratanavat R. Dissecting qualified health claims: evidence from
733 experimental studies. *Crit Rev Food Sci Nutr.* 2008;48(2):160-176.
- 734 52. Moorman C, Diehl K, Brinberg D, Kidwell B. Subjective Knowledge, Search
735 Locations, and Consumer Choice. *J Consum Res.* 2005;31(3):673-680.
- 736 53. van Kleef E, van Trijp HCM, Luning P. Consumer research in the early stages of new
737 product development: a critical review of methods and techniques. *Food Qual Pref.*
738 2005;16:181-201.
- 739 54. Williams P. Consumer understanding and use of health claims for foods. *Nutr Rev.*
740 2005;63(7):256-264.

- 741 55. Garrett JL. Improving results for nutrition: a commentary on an agenda and the need
742 for implementation research. *J Nutr.* 2008;138(3):646-650.
- 743 56. Fulgoni VL, 3rd. Current protein intake in America: analysis of the National Health
744 and Nutrition Examination Survey, 2003-2004. *Am J Clin Nutr.* 2008;87(5):1554S-
745 1557S.
- 746 57. AFSSA (French Food Safety Agency). Report "Protein Intake: Dietary Intake,
747 Quality, Requirements and Recommendations". 2007.
- 748 58. WHO/FAO/UNU. Protein and amino acid requirements in human nutrition. World
749 Health Organ Tech Rep Ser. 2007(935):1-265, back cover.
- 750 59. Elmadfa I, ed. European nutrition and health report 2009: Karger; 2009. Forum of
751 Nutrition.
- 752 60. Dubuisson C, Lioret S, Touvier M, et al. Trends in food and nutritional intakes of
753 French adults from 1999 to 2007: results from the INCA surveys. *Br J Nutr.* 2009;1-
754 14.
- 755 61. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion of the
756 Panel on Dietetic Products, Nutrition and Allergies on a request from the Association
757 de la Transformation Latière Française (ATLA) on the scientific substantiation of a
758 health claim related to animal protein and bone growth. *EFSA J.* 2008;858.
- 759 62. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion of the
760 Panel on Dietetic Products, Nutrition and Allergies on a request from Danone S.A on
761 the scientific substantiation of a health claim related to dairy fresh cheese and bone
762 growth. *EFSA J.* 2008;895.
- 763 63. Commision Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation
764 and refusal of authorisation of certain health claims made on food and referring to the
765 reduction of disease risk and to children's development and health: Official Journal of
766 the European Union. 22 october 2009; 2009:L 277/273.
- 767 64. Desquilbet L, Mariotti F. Dose-response analyses using restricted cubic spline
768 functions in public health research. *Stat Med.* 2010. DOI: 10.1002/sim.3841.
- 769 65. Bier DM. Amino acid pharmacokinetics and safety assessment. *J Nutr.* 2003;133(6
770 Suppl 1):2034S-2039S.
- 771 66. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
772 substantiation of health claims related to vitamin C and protection of DNA, proteins
773 and lipids from oxidative damage (ID 129, 138, 143, 148), antioxidant function of
774 lutein (ID 146), maintenance of vision (ID 141, 142), collagen formation (ID 130, 131,
775 136, 137, 149), function of the nervous system (ID 133), function of the immune
776 system (ID 134), function of the immune system during and after extreme physical
777 exercise (ID 144), non-haem iron absorption (ID 132, 147), energy-yielding
778 metabolism (ID 135), and relief in case of irritation in the upper respiratory tract (ID
779 1714, 1715) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request
780 from the European Commission. *EFSA J.* 2009;7(9).
- 781 67. EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
782 substantiation of health claims related to copper and protection of DNA, proteins and
783 lipids from oxidative damage (ID 263, 1726), function of the immune system (ID
784 264), maintenance of connective tissues (ID 265, 271, 1722), energy yielding
785 metabolism (ID 266), function of the nervous system (ID 267), maintenance of skin
786 and hair pigment (ID 268, 1724), iron transport (ID 269, 270, 1727), cholesterol
787 metabolism (ID 369), and glucose metabolism (ID 369) pursuant to Article 13(1) of
788 Regulation (EC) No 1924/2006 on request from the European Commission. *EFSA J.*
789 2009;7(9).

- 790 **68.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
791 Substantiation of a health claim related to Iodine and necessary for the growth of
792 children pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA J.
793 2009;7(11).
- 794 **69.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
795 substantiation of health claims related to sugar-free chewing gum and dental and oral
796 health, including gum and tooth protection and strength (ID 1149), plaque acid
797 neutralisation (ID 1150), maintenance of tooth mineralisation (ID 1151), reduction of
798 oral dryness (ID 1240), and maintenance of the normal body weight (ID 1152)
799 pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the
800 European Commission. EFSA J. 2009;7(9).
- 801 **70.** Shimizu T. Health claims on functional foods: the Japanese regulations and an
802 international comparison. Nutr Res Rev. 2003;16(2):241-252.
- 803 **71.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on
804 substantiation of health claims related to pantothenic acid and energy-yielding
805 metabolism (ID 56, 59, 60, 64, 171, 172, 208), mental performance (ID 57),
806 maintenance of bone (ID 61), maintenance of teeth (ID 61), maintenance of hair (ID
807 61), maintenance of skin (ID 61), maintenance of nails (ID 61) and synthesis and
808 metabolism of steroid hormones, vitamin D and some neurotransmitters (ID 181)
809 pursuant to Article 13 of Regulation (EC) No 1924/2006 on request from the European
810 Commission. EFSA J. 2009;7(9).
- 811 **72.** Renwick AG. Toxicology of micronutrients: adverse effects and uncertainty. J Nutr.
812 2006;136(2):493S-501S.
- 813 **73.** Vanderveen JE. Gap analysis guidelines for assessing acute, chronic, and lifetime
814 exposures to high levels of various nutrients. J Nutr. 2006;136(2):514S-519S.
- 815 **74.** Elliott R, Pico C, Dommels Y, Wybranska I, Hesketh J, Keijer J. Nutrigenomic
816 approaches for benefit-risk analysis of foods and food components: defining markers
817 of health. Br J Nutr. 2007;98(6):1095-1100.
- 818 **75.** Hesketh J, Wybranska I, Dommels Y, et al. Nutrient-gene interactions in benefit-risk
819 analysis. Br J Nutr. 2006;95(6):1232-1236.
- 820 **76.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
821 substantiation of health claims related to vitamin A and cell differentiation (ID 14),
822 function of the immune system (ID 14), maintenance of skin and mucous membranes
823 (ID 15, 17), maintenance of vision (ID 16), maintenance of bone (ID 13, 17),
824 maintenance of teeth (ID 13, 17), maintenance of hair (ID 17), maintenance of nails
825 (ID 17), metabolism of iron (ID 206), and protection of DNA, proteins and lipids from
826 oxidative damage (ID 209) pursuant to Article 13(1) of Regulation (EC) No
827 1924/2006 on request from the European Commission. EFSA J. 2009;7(9).
- 828 **77.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific opinion on the
829 substantiation of health claims related to biotin and energy-yielding metabolism (ID
830 114, 117), macronutrient metabolism (ID 113, 114, 117), maintenance of skin and
831 mucous membranes (ID 115), maintenance of hair (ID 118, 2876) and function of the
832 nervous system (ID 116) pursuant to Article 13(1) of Regulation (EC) No 1924/2006
833 on request from the European Commission. EFSA J. 2009;7(9).
- 834 **78.** Hasler CM. Functional foods: benefits, concerns and challenges-a position paper from
835 the american council on science and health. J Nutr. 2002;132(12):3772-3781.
- 836 **79.** Chandon E, Janiszewski C. The influence of causal conditional reasoning on the
837 acceptance of product claims. J Consum Res. 2009;35(6):1003-1011.
- 838 **80.** Nieves JW, Lindsay R. Calcium and fracture risk. Am J Clin Nutr. 2007;86(6):1579-
839 1580.

- 840 **81.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
841 substantiation of health claims related to calcium and vitamin D and maintenance bone
842 (ID 350) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from
843 the European Commission. EFSA J. 2009;7(9).
- 844 **82.** EFSA Panel on Dietetic Products Nutrition and Allergies. Opinion of the Panel on
845 Dietetic Products, Nutrition and Allergies on a request from Transformation Laitière
846 Française (ATLA) on the scientific substantiation of a health claim related to calcium
847 and bone growth. EFSA J. 2008;826.
- 848 **83.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion of the
849 Panel on Dietetic Products, Nutrition and Allergies on a request from the Association
850 de la Transformation Laitière Française (ATLA) on the scientific substantiation of a
851 health claim related to animal protein and bone growth. EFSA J. 2008;858.
- 852 **84.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
853 substantiation of health claims related to vitamin K and maintenance of bones (ID 123,
854 127, 128 and 2879), blood coagulation (ID 124 and 126), and function of the heart and
855 blood vessels (ID 124, 125 and 2880) pursuant to Article 13(1) of Regulation (EC) No
856 1924/2006 on request from the European Commission. EFSA J. 2009;7(9).
- 857 **85.** Hercberg S, Chat-Yung S, Chaulia M. The French National Nutrition and Health
858 Program: 2001-2006-2010. Int J Public Health. 2008;53(2):68-77.
- 859 **86.** Ferguson LR. Nutrigenomics approaches to functional foods. J Am Diet Assoc.
860 2009;109(3):452-458.
- 861 **87.** Expert Scientific Working Group. Summary of a report on assessment of the iron
862 nutritional status of the United States population. Am J Clin Nutr. 1985;42(6):1318-
863 1330.
- 864 **88.** Milman N. Serum ferritin in Danes: studies of iron status from infancy to old age,
865 during blood donation and pregnancy. Int J Hematol. 1996;63(2):103-135.
- 866 **89.** Milman N, Rosdahl N, Lyhne N, Jorgensen T, Graudal N. Iron status in Danish
867 women aged 35-65 years. Relation to menstruation and method of contraception. Acta
868 Obstet Gynecol Scand. 1993;72(8):601-605.
- 869 **90.** Fairweather-Tait SJ. Iron nutrition in the UK: getting the balance right. Proc Nutr Soc.
870 2004;63(4):519-528.
- 871 **91.** Morais JA, Chevalier S, Gougeon R. Protein turnover and requirements in the healthy
872 and frail elderly. J Nutr Health Aging. 2006;10(4):272-283.
- 873 **92.** EFSA Panel on Dietetic Products Nutrition and Allergies. Scientific Opinion on the
874 substantiation of health claims related to iron and formation of red blood cells and
875 haemoglobin (ID 249, ID 1589), oxygen transport (ID 250, ID 254, ID 256), energy-
876 yielding metabolism (ID 251, ID 1589), function of the immune system (ID 252, ID
877 259), cognitive function (ID 253) and cell division (ID 368) pursuant to Article 13(1)
878 of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA
879 J. 2009;7(9).
- 880 **93.** Anon. Control of health claims in foods. Lancet. 1998;351(9103):609.
- 881 **94.** Sims SS. Federal trade commission study on food health claims in advertising:
882 implications for nutrition education and policy. J Nutr Educ. 1999;31:355-359.
- 883 **95.** Roe BE, Levy AS, Derby BM. The impact of health claims on consumer search and
884 product evaluation outcomes: results from FDA experimental data. J Public Policy
885 Mark. 1999;18:89-115.
- 886 **96.** Murphy D, Hoppock TH. Generic Copy Test of Food Health Claims in Advertising -
887 A Joint Staff Report of the Bureaus of Economics and Consumer Protection: Federal
888 Trade Commission; 1998.

- 889 97. Chandon P, Wansink B. The biasing health halos of fast-food restaurant health claims:
890 lower calorie estimates and higher side-dish consumption intentions. *J Consum Res.*
891 2007;34(301-314.).
- 892 98. International Food Information Council. 2007 Consumer Attitudes toward Functional
893 Foods/Foods for Health—Executive Summary 2007.
- 894 99. Martinez-Gonzalez MA, Bes-Rastrollo M, Serra-Majem L, Lairon D, Estruch R,
895 Trichopoulou A. Mediterranean food pattern and the primary prevention of chronic
896 disease: recent developments. *Nutr Rev.* 2009;67 Suppl 1:S111-116.
- 897 100. Andrews JC, Netemeyer RG, Burton S. The nutrition elite: Do only the highest levels
898 of caloric knowledge, obesity knowledge, and motivation matter in processing
899 nutrition ad claims and disclosures? *J Public Policy Mark.* 2009;28(1):41-55.
- 900 101. Looker AC. Interaction of science, consumer practices and policy: calcium and bone
901 health as a case study. *J Nutr.* 2003;133(6):1987S-1991S.
- 902 102. Weber EU, Johnson EJ. Mindful judgment and decision making. *Annu Rev Psychol.*
903 2009;60:53-85.
- 904 103. Andrews JC, Netemeyer RG, Burton S. Consumer generalization of nutrient content
905 claims in advertising. *J Marketing.* 1998;62:62-75.
- 906 104. Snyder R. Misleading characteristics of implied-superiority claims. *J Advert.*
907 1989;18(4):54-61.
- 908 105. Geiger CJ. Health claims: history, current regulatory status, and consumer research. *J*
909 *Am Diet Assoc.* 1998;98(11):1312-1322; discussion 1323-1314.
- 910 106. Food and Drug Administration - HHS. Food labeling: health claims; calcium and
911 osteoporosis, and calcium, vitamin D, and osteoporosis. Final rule. *Fed Regist.*
912 2008;73(189):56477-56487.
- 913 107. Keller PA, Lehmann DR. Designing effective health communications: a meta-
914 analysis. *J Public Policy Mark.* 2008;27(2):117-130.
- 915 108. King JC. An evidence-based approach for establishing dietary guidelines. *J Nutr.*
916 2007;137(2):480-483.
- 917 109. Hughes R. Definitions for public health nutrition: a developing consensus. *Public*
918 *Health Nutr.* 2003;6(6):615-620.
- 919 110. Hughes R. Public health nutrition--moving from rhetoric to results. *Public Health*
920 *Nutr.* 2008;11(11):1091-1092.

Acknowledgements

922 We would like to thank Isabelle Bordes and Raphaëlle Ancellin for their useful input and
923 discussions on this topic. The authors have no conflict of interest to report.

924

Figure legends

Figure 1. The nutrition and health claims system under the new EU regulation N°1925/2006.²

Figure 2. A comprehensive schematic overview of what is necessary to analyze health claims while integrating important public health aspects. This Figure presents the different

points that need to be examined when assessing any “health claim”. The items are placed on the figure as a function of their classic acceptance (horizontal axis) and their importance to public health (vertical axis). Examination of the trueness of the basic relationship stated in a claim is a standard scientific procedure, based on an established system that weighs the evidence. The points at issue are figured in the “true” box and indeed constitute a classic substantiation process, which has been comprehensively studied and reviewed. Criteria may vary with the type of claim (e.g. nutritional epidemiology for generic nutrient-function claims vs. randomized-controlled trials for specific claims), but the level of confidence should be the same whatever the claim. Relevance based on supportive epidemiological data may make a more definite contribution to public health. More advanced regulatory systems include the question “is the food otherwise healthy?” this more global examination is of value to public health and is a first point to be considered in order to ensure that the claim is not misleading. However, a full assessment of a health claim should go far beyond this standard examination to encompass all issues connected with public health. If a claim reads like dietary guidance and could be confused with official guidelines, this is another item to be included in the “Not misleading” box, in that it could impact the public health significance of a claim. Lastly, possible mismatches between consumer perception/understanding and the reality of public nutrition and health (i.e. the misleading character of a claim) are numerous. Such sources of misunderstanding could have a dramatic impact on food consumption and overall diet in the population, and hence important implications for public health nutrition. Six pitfalls have

950 been identified by the present review. They are usually overlooked, presumably because they
951 are difficult to apprehend, standing at the crossroads between nutritional science, public
952 health nutrition and psychosocial consumer science, i.e. related to the complex field of Public
953 Nutrition. When taken into account, these points call for a case-by-case analysis of claims,
954 and action by public authorities would consist in the complex fine tuning of the wording of a
955 given claim in order to ensure that it does not mislead consumers (“reject / reword / add
956 disclaimers” box).
957

958 Table 1. Definitions of terms used in the present review.
959

Health Claim	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 regulatory definition). ²
Public health	The science and practice of protecting and improving the health of a community
Public Health Nutrition	Application of Nutrition (and physical activity) to the promotion of good health of a community. ¹⁰⁹
Public Nutrition	Field encompassing the range of factors known to influence nutrition in populations, including diet and health, social, cultural, and behavioral factors; and the economic and political context. ¹¹⁰

960

CLAIMS

" Message or representation stating, suggesting or implying that a food has particular characteristics "

NUTRITION CLAIMS

" A food has particular beneficial nutritional properties concerning energy, nutrients, substances "

Article 8; permitted if they are listed in the Annex of the regulation

REDUCTION OF DISEASE RISK CLAIMS

" The consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease "

CHILDREN'S DEVELOPMENT AND HEALTH CLAIMS

Application for **authorization** based on a scientific dossier; the procedure is effective since 1st July 2007
Concerns health claims based on new scientific evidence and/or on data which should be regarded as proprietary

OTHER HEALTH CLAIMS

" Referring to
a) the role of nutrient/substance in growth, development and function of the body,
b) physiological and behavioural functions,
c) slimming, weight control, reduction of hunger, increase of satiety or reduction of diet energy "

- **Article 13.1**: Based on generally accepted scientific evidence; **Positive list of accepted claims which can be used without authorization**
- **Article 13.5**: Based on new scientific data and/or data which should be regarded as proprietary; Application of the **authorization procedure**

« Article 14 »
claims

« Article 13 »
claims

HEALTH CLAIMS

" A relationship exists between a food category, a food or one of its constituents and health "

P
O
S
I
T
I
V
E

L
I
S
T

O
F

C
L
A
I
M
S

Fig.2

