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

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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

rules have been published or drafted very recently (as regards the “nutrient profile”) and the remainder, which concern the authorization of health claims and related conditions, are presently under scrutiny by the EFSA at the request of the European Commission. Indeed, apart from claims relative to the reduction in disease risk, those specifically directed at children’s development and health (referred to as “Article 14”, Fig. 1), and product-specific claims that are based on new, specific scientific data (referred to as "Article 13.5", Fig. 1), all other health claims (referred to as “Article 13.1”, Fig. 1) are to be determined by the European Commission and listed in a register.[2] This register will constitute a “positive list” of claims, supplemented by specific conditions of use (including the quantity of food and the pattern of consumption, together with instructions or warnings, if necessary).[2] This creates an original provision when compared with the regulations in other countries.[31] Likewise, all claims that have been rejected will constitute a "negative list". Under the EU system, “Article 13 health claims” (Fig. 1) mean all those related to a food category, a food or one of its constituents and connected with health in the broadest sense, and include (i) traditional “function claims” (known as “structure-function claims” in the US), as well as behavioral functions or the control of body weight (e.g. "*Calcium is needed for the maintenance of normal bones and teeth*"[32]; “*Lutein is deposited naturally in the eye / helps support eye health*”; "*conjugated linoleic acid supports lean body mass*"; “*Calcium helps promote a healthy body weight*”; "*Vitamin B6 contributes to the regulation of hormonal activity*"[33] – Please note that all quotes in italics that do not bear a specific reference are claims extracted from the list currently under examination by the EFSA; quotes with references are the proposed wording as found in recent scientific opinions issued by the EFSA or final claims authorized by recently adopted EU regulations), and (ii) what the US system, and others, would consider as “dietary guidance”, i.e. a claim regarding a relationship between a food (independently of its components) or a 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 & Lindsay[80] 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

dietary/nutritional strategies to specific (sub)populations has become a major prerequisite for effective health policies.[85] When nutritional status and the importance of the health-related outcome vary, the health message must target the specific, relevant population. In the future, the expanding area of nutrigenomics is expected to lead to a more detailed identification of the precise populations to which a health claim is relevant.[86] However, this goal is still far off[75] and our current knowledge of nutritional science is already sufficient to enable the partial refinement of some health claims. For instance, because iron status tends to be low in women of childbearing age but is usually correct or high in men,[87-90] health claims regarding iron may not be really applicable to adult men, and unless otherwise stated, such a claim would be misleading in most of this population. Taking the example of protein again, and as explained previously, it is currently thought that protein-muscle claims are irrelevant in the majority of the population, but they may be important for the frail elderly.[91] Specifying a target population may be the only way to prevent a claim from being misleading for the majority.

EU regulations do not lay down special requirements regarding the definition of target populations (except for claims related to children),[2, 8] but the EFSA requires the definition of a target population for an intended health claim[13]. However, if the applicant proposes that the claim should be assessed in the context of the general population, it remains unclear whether full consideration will be given to the present pitfall. As for the example of iron, the recent EFSA opinion states that a general cause and effect relationship has been established between the dietary intake of iron and a series of iron-related functions, but does not comment on the fact that the claim may not apply similarly to men and women.[92]

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

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

564 Indeed, this general strategy should be adapted on a claim-by-claim basis that precisely
565 determines the public health relevance of each claim, the importance and political/scientific
566 relevance of the different options available, and any specific provisions that need to be
567 included. For example, the FDA applies precise weighting to the importance of disclaimers
568 with respect to claims for a reduction in disease risk.[e.g., 106] The final objective is to finely tune
569 the length of the claim and the number of disclaimers, thus preventing, on the one hand,
570 claims that are short, readable and comprehensible but misleading, and, on the other hand,
571 claims that are precise and correct, but too long and intricate and therefore difficult to
572 understand.[37] Lastly, because the perceptions and intentions generated by a given message are
573 generally affected by the individual/sub-group characteristics of consumers, attention must
574 also be paid to the specific population covered by the scope of a claim and to practical aspects
575 regarding implementation.[107, 108] Finally, whereas examination of the scientific substantiation
576 of a claim will merely result in a "yes" or "no", full examination of the characteristics of a
577 claim, ensuring that it is not misleading and remains relevant to public health, will probably
578 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.

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925 **Figure legends**

926 **Figure 1. The nutrition and health claims system under the new EU regulation**
927 **N°1925/2006.[2]**

928 **Figure 2. A comprehensive schematic overview of what is necessary to analyze health**
929 **claims while integrating important public health aspects.** This Figure presents the different
930 points that need to be examined when assessing any “health claim”. The items are placed on
931 the figure as a function of their classic acceptance (horizontal axis) and their importance to
932 public health (vertical axis). Examination of the trueness of the basic relationship stated in a
933 claim is a standard scientific procedure, based on an established system that weighs the
934 evidence. The points at issue are figured in the “true” box and indeed constitute a classic
935 substantiation process, which has been comprehensively studied and reviewed. Criteria may
936 vary with the type of claim (e.g. nutritional epidemiology for generic nutrient-function claims
937 vs. randomized-controlled trials for specific claims), but the level of confidence should be the
938 same whatever the claim. Relevance based on supportive epidemiological data may make a
939 more definite contribution to public health. More advanced regulatory systems include the
940 question “is the food otherwise healthy?” this more global examination is of value to public
941 health and is a first point to be considered in order to ensure that the claim is not misleading.
942 However, a full assessment of a health claim should go far beyond this standard examination
943 to encompass all issues connected with public health. If a claim reads like dietary guidance
944 and could be confused with official guidelines, this is another item to be included in the “Not
945 misleading” box, in that it could impact the public health significance of a claim. Lastly,
946 possible mismatches between consumer perception/understanding and the reality of public
947 nutrition and health (i.e. the misleading character of a claim) are numerous. Such sources of
948 misunderstanding could have a dramatic impact on food consumption and overall diet in the
949 population, and hence important implications for public health nutrition. Six pitfalls have

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

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

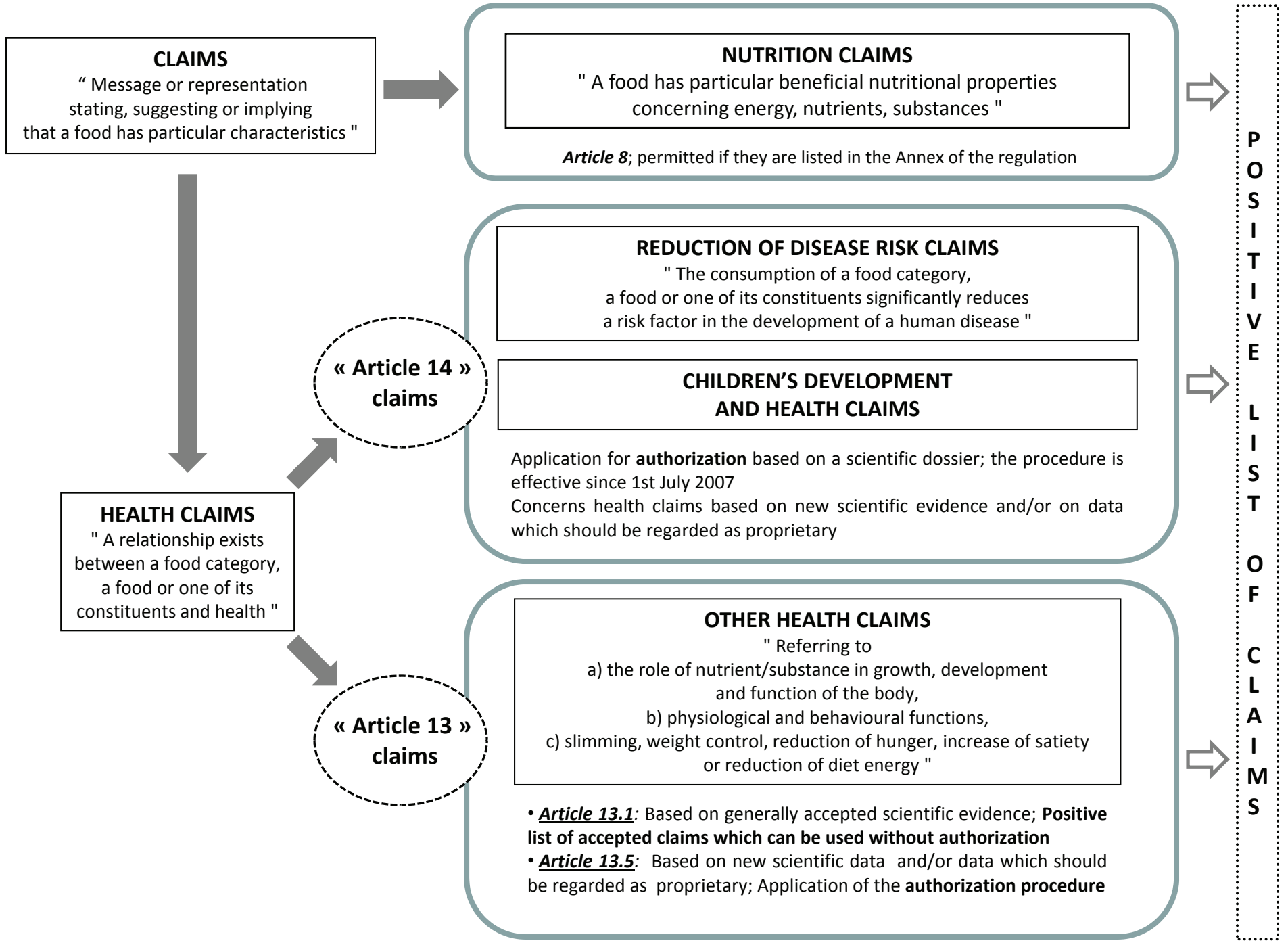
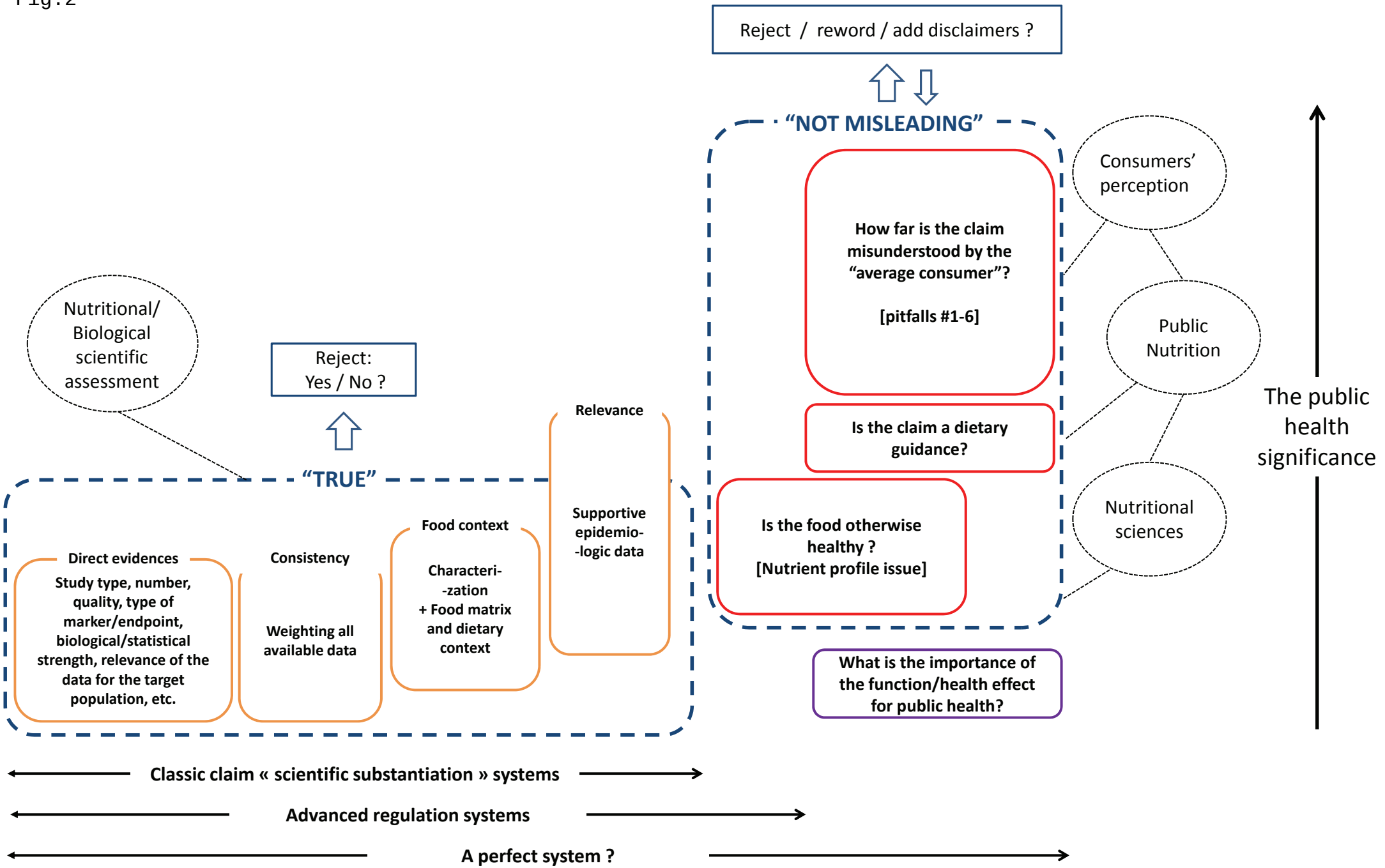

CLAIMS
“ Message or representation stating, suggesting or implying that a food has particular characteristics "
NUTRITION CLAIMS
" A food has particular beneficial nutritional properties concerning energy, nutrients, substances "
Article 8; permitted if they are listed in the Annex of the regulation
HEALTH CLAIMS
" A relationship exists between a food category, a food or one of its constituents and health "
« Article 14 » claims
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
« Article 13 » claims
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
POSITIVE LIST OF CLAIMS

Fig.2


Reject / reword / add disclaimers ?
"NOT MISLEADING"
How far is the claim misunderstood by the "average consumer"?
[pitfalls #1-6]
Is the claim a dietary guidance?
Is the food otherwise healthy ?
[Nutrient profile issue]
What is the importance of the function/health effect for public health?
Consumers' perception
Public Nutrition
Nutritional sciences
The public health significance
Nutritional/ Biological scientific assessment
Reject: Yes / No ?
"TRUE"
Direct evidences
Study type, number, quality, type of marker/endpoint, biological/statistical strength, relevance of the data for the target population, etc.
Consistency
Weighting all available data
Food context
Characteri--zation + Food matrix and dietary context
Relevance
Supportive epidemio--logic data
Classic claim « scientific substantiation » systems
Advanced regulation systems
A perfect system ?