Regulatory Environment and Claims – Limits and Opportunities

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Abstract

During the past decade, the use of claims became more and more important in many countries in relation to the increased awareness of consumer about the link between foods and health, offering to industry a valuable opportunity to differentiate and valorize their products and to promote innovation. However, more and more stringent regulations are developed, all based on the general principles adopted by the Codex Alimentarius Commission. In addition to the different regulatory processes and administrative requirements according to the country, the high level (and cost) of scientific substantiation of claims, the constraints introduced by nutrient profiles and the poor knowledge of the impact on consumer depending on the cultural contexts may limit these opportunities or, at least complicate their use. All these issues are briefly analyzed, highlighting some striking convergences and differences between countries.

Since more than a decade, there has been a sharp increase in the use of nutrition and health claims not only on the food labels, but also in industry communication and advertising. At a worldwide level, food products claiming a nutrition or health effect represented one third of the new food products put on the market in the mid-1990s, and currently could represent about three quarters. In most of the countries, the progression rate is larger for this food segment than for traditional foods: as an example, in Japan, which was a pioneering country in this field, the authorizations for FOSHU products grow linearly from some units in the mid-1990s to around 100 per year in 2006 [1], and the annual value of this market has increased from around one billion USD in 1997 to more than 5 billions in 2005 [2].

The reasons for such an increase are certainly diverse and probably rely on the convergent, though diverse, interests of the four major stakeholders: consumers, industry, researchers and public health authorities:
− Consumers are more and more aware of the links between nutrition and health. Though skeptical, they are influenced by claims in their food purchases [3].

− For industry, especially in Europe, after the food crises occurring in the last decade of the 20th century, it was also an opportunity to claim that food does not constitute only a risk. In addition, using nutrition and health claims constitutes an opportunity for product differentiation and valorization in a mature and saturated food market, and to promote innovation, allowing in many cases an increase in profit margins.

− For researchers, unraveling the health effects of food and nutrients was always the final challenge; since public funding is limited or decreasing in many countries, funding by industry for research supporting claim substantiation became a growing alternative source of financial support. This cooperation between industry and academic research is encouraged by public authorities in many parts of the world.

− For public health managers, it could represent a tool for decreasing the growing health costs. In some countries, medical societies also support some products or claim types.

The major issues limiting such an attractive opportunity relate to the regulatory environment for the different types of claims, the scientific substantiation of claims, the conditions of use for claims (especially the nutrient profile issue), and finally the consumer perception of claims on which depends their economic and health impact.

**Regulatory Environment**

Many countries regulate claims, with more or less specific regulations. However, they are all based on the initial principles agreed upon at the international level by the Codex Alimentarius Commission as early as 1979 [4]. Claims are defined as ‘any representation which states, suggests or implies that a food has particular characteristics’. The general principle was to not mislead the consumer, completed by specific mentions: prohibiting claims stating that a food can provide all essential nutrients, claims stating that a balanced diet cannot supply adequate amounts of nutrients, claims that cannot be substantiated or could raise doubt about the safety of similar food products. These characteristics were detailed in a following Codex guidelines adopted in 1997 [5] which may relate to nutrient content (nutrient content claims and nutrient comparative claims) or to a health relationship, comprising nutrient function claims, other function claims and reduction of disease risk claims. In addition to the claim, additional information is required: nutritional labeling, the target group, warnings and/or maximum safe intakes, and a general statement on the importance of maintaining a healthy diet. These texts should be read also in the context of the general
standards for the labeling of prepackaged foods [6] or foods for specific medical purposes [7].

Due to the long time needed for the adoption of Codex standards, many national authorities have developed their own regulations [review in 8]. No systematic comparisons of the different systems have been published, with the exception of the comparison between China and Japan [9] for the whole process, and a comparison of USA, Canada and Europe for the scientific substantiation [10, 11]. A systematic review is outside the scope of this paper, but some striking differences are highlighted in the following sections.

**Different Types of Claims**

In Japan [1, 2], a specific category was created in 1991 for regulating claims, the FOSHU (Food for Specified Health Use); the regulation evolved in 2001 and 2005, to consist now in several categories of FHC (foods with health claims), including FNFC (food with nutrient function claims), ordinary FOSHU and new type FOSHU (standardized, qualified and disease risk reduction). In Europe [12], there is a very general regulation (regulation 1924/2006/CE), covering all the products falling into the field of food law, including dietetic products and dietary supplements, but distinguished different procedures for generic claims (Article 13.1 claims), newly emerging or proprietary claims (Article 13.5 claims), and claims on children growth and development and disease risk reduction (Article 14 claims). In the USA [13], the Nutrition labeling and education Act (NLEA), implemented in 1994, regulates health claims made on foods; in parallel, the Dietary Supplement and Health Education Act (DSHEA, adopted in 1994) regulates claims on nutrient functions. Additional information on the regulatory environment can be found elsewhere for Australia New Zealand [14], China [15], and Korea [16].

In line with these differences in the regulatory status, there are also differences in the requirements for different types of claims. In the USA under the DSHEA regulation [13], nutrient function claims do not require preapproval by the FDA before being used on labels, but must be accompanied by a disclaimer. In Europe, such claims will be used only after scientific evaluation by the European Food safety Authority (EFSA), authorization by the Standing Committee of the Food Chain and Animal Health (SCFCAH), and inscription in the European register of claims. More than 44,000 claims have been collected at the European level, which, after elimination of redundancies, of claims not conform to the legislation, such as medicinal claims, led to a consolidated list of 4,185 entries corresponding to around 10,000 claims for around a thousand of substances. A first series of opinions on these generic nutrient function claims has been released in October 2009.

Since a food which would prevent, treat or cure a disease would be classified as a drug everywhere, the concept of ‘disease risk reduction claim’ has
been developed and agreed upon at the international level in the Codex guidelines [5]. These claims are always considered as high-level claims and require preapproval before use. The extent to which such claims are approved or used largely varies between countries. Today, there are fifteen claims authorized in USA [13], five proposed in Australia-New Zealand [14], four in China [15] and only two in Japan [1]; two disease risk reduction claims have been approved in Europe, but more applications are still currently under scrutiny. The regulation in Europe (and China) focuses not on disease risk reduction per se, but on the reduction of a disease risk factor, although what is a risk factor is not clearly defined in the European regulation. This has led to an apparently paradoxical situation, where claims on phytosterols were accepted despite the fact that there is no actual demonstration of the efficacy in decreasing the risk of cardiovascular disease but only serum LDL cholesterol, whereas claims on xylitol, for which EFSA recognized the efficacy in decreasing the risk of dental caries, could not be legally accepted, since no clear risk factor was identified.

**Scientific Substantiation of Claims**

If there is a general agreement on the need for scientific substantiation, the exact interpretation on what constitutes substantiation has given rise to many debates, and different wordings, reflecting different approaches, are included in regulations. The Codex recommendations for the substantiation of health claims have been adopted only in 2009 [17]. Originally, in the USA, there was a request for a ‘significant scientific agreement’, some experts choosing the word ‘consensus’. Since this was contested in justice courts, as opposed to the First Amendment of the US Constitution [8], the concept of ‘qualified claims’ has now been adopted in this country: the wordings of claims should reflect the scientific evidence, from level A claims (the strongest) to level D (‘there is little scientific evidence supporting this claim’). This approach has partly been adopted by Japan, with the category of ‘qualified FOSHU’, but not in Europe. However, all the regulations require the strongest scientific evidence to support disease risk reduction claims. All the regulations, including Codex guidelines, favor well-designed human intervention studies, but may accept less stringent study types on a case-by-case basis, the assessment being based on the consideration and weighing of the totality of the available evidence. China and Japan request that some of the submitted studies are performed on Chinese or Japanese populations [1, 15]. Like in Europe, ‘generally accepted scientific evidence’ can be used. In some countries, and especially in the USA, authoritative statements from public scientific authorities can be used; by contrast, in Europe and other countries, specific assessment made by the competent authority is required. Guidelines for the preparation and submission of the dossiers are available on the websites of these authorities.
The European regulation has introduced the concept of proprietary data, covering the studies funded by the applicant. If the EFSA positive opinion could not have been reached without the use of such proprietary data, then these data cannot be used by another applicant (unless the first one agrees with this use). This form of protection of claims was laid down in the regulation ‘in order to stimulate research and development within the agri-food industry’; this protection is limited in time (5 years from the official approval) ‘in order to avoid the unnecessary repetition of studies and trials, and to facilitate access to claims by small and medium-sized enterprises’. Today, only one dossier received a favorable opinion from EFSA.

**Nutrient Profiles**

The Codex guidelines of 1997 [5] require that claims ‘should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition’. This possibility has been implemented in the USA in 2002: it is a threshold scheme with an ‘across the board’ approach. FDA takes into account ten nutrients, four considered as ‘disqualifying’ (total fat, saturated fatty acids, cholesterol and sodium: no more than 20% of the daily value per serving) and one out of six as ‘qualifying’ (vitamin A, vitamin C, iron, calcium, protein, or fiber prior to any fortification: at least 10% of the daily value per serving). The introduction of such nutrient profiles in the European regulation is also in line with the Codex recommendation and led to many research works and debates at the European level [18, 19] in order to answer the questions laid down in the regulation: system ‘across the board’ or by food category, choice of nutrients, reference basis, calculation (threshold or score) and validity testing. In European Member States, the first system was proposed and implemented in the UK [20] and is known as the ‘traffic light’ scheme; this system has been slightly modified for use in Australia-New Zealand. Comparative testing has been published [21, 22]. Though the different systems reach agreement for ‘extreme’ foods’ (such as fruits and vegetables or ‘junk foods’ at the two ends of the continuum), very large differences in results are obvious for ‘intermediate’ foods, with important practical consequences for industry. Therefore, the validity of the results of a system should be assessed by more objective techniques than the comparison with expert consensus, the only method used so far [23]: comparison with dietary surveys [21], with the Healthy Eating Index or food-based dietary guidelines [24]; more recently, we proposed to use linear programming to verify whether a balanced diet can be built by using only foods eligible to bear claims [25]. In Europe, the issue is complicated by the fact that the regulation requires that
the various dietary habits across Europe should be taken into account. The initial proposal of the European Commission was a mixed system (across the board, with a few number of specific categories), consisting in thresholds for three nutrients (sodium, fat, sugars). Today, what should have been a technical issue, managed by the traditional European Comitology procedure at the level of the SCFCAH, has become a very sensitive political issue, having led to debates in some national Parliaments and to a direct management by the President of the European Commission, and for which the final result cannot be predicted.

**Conclusion**

Though science is universal, claim perception, acceptance and impact on individual and public health vary considerably according to the cultural context of the country where a food is sold, constituting an important limit to the success of a claim [26]. Much less research works have been devoted to these issues [27]. Claims do not stand alone, but are inserted into a complex network of information, linking in the consumer’s mind, according to the prominent model used by social scientists, values (for health), attitudes (toward functional foods, including hedonic expectations and perception of the food healthiness) and behavior (intention to purchase). Some (still rare) works suggest that there could be a negative impact of health claims on consumers [13] and especially children [28, 29] for whom health and pleasure could be mutually exclusive. Some experimental research with actual foods also shows the relatively low acceptance of disease risk reduction claims for foods as compared to other claim types, which questions the industry interest to fund high-cost research necessary to substantiate this type of claims in the context of more and more stringent regulations [28].

**References**

Regulatory Environment and Claims


Discussion

Dr. Spieldenner: If industry has to prove that a product acts on a risk factor and contributes to disease reduction, how can an animal model be sufficient to prove this?

Dr. Martin: Clearly in China, as you know, it’s an issue of risk factor, but in my opinion it’s not mandatory that the risk factor should be clearly identified and demonstrated in human. In human, you can demonstrate, for example, that Xylitol reduces
the disease (caries) itself and you can provide supportive animal studies demonstrat-
ing what the risk factor could be. So it’s the totality of the evidence which is taken into
account and not only one type of study; thus, if you cannot demonstrate what could
be the risk factor in human and you have only supportive studies in animal, it can be
accepted.

Dr. Greer: You had a number of slides about the US where the situation I would
describe it is schizophrenic, and I don’t think a lot of people in the audience appreciate
that. We have two sets of regulations, one is for qualified health care claims on food
and the other is for dietary supplements. Essentially, the one for dietary supplements
is uncontrolled. Take something like DHA; if you want to market DHA for pregnant
women and put it into food marketed to pregnant women or even encourage pregnant
women to eat more fish with DHA in it you have a problem with the FDA. However,
if you put it into a pill and market it as a dietary supplement with no control of how
much is in there and no control of how you are supposed to take it, that’s not a prob-
lem. I assume you don’t have the situation in Europe, is that correct?

Dr. Martin: We don’t, since the regulation is the same for staple food and dietary
supplements.

Dr. Greer: The other interesting thing is nutrient profiling, just to take a nutrient
like calcium. It is possible to add calcium to foods in the US and claim that it builds
stronger bones. You can add it to cookies for children, you can add it to sugar-coated
breakfast cereals for children, and even add it to sweetened fruit drinks for children
and claim that it builds stronger bones. This is how schizophrenic the system is as
none of these products is in the best interest of children. More recently, the dairy
industry in the US tried to get a qualified health-care claim for milk (a good source of
calcium and vitamin D in the US), that it prevents osteoporosis and builds stronger
bones. It took them almost 3 years to get the FDA to approve the qualified health care
claim for a whole food like milk. You mentioned that the US has nutrient profiling.
This is a schizophrenic process as well as we have at least four different systems. The
systems are not government regulated. You can take an unhealthy food product like
sugar-coated cereals. Add multiple vitamins and minerals to it and raise its nutrient
profile score to the ‘smart choice’ product. So it’s really driven by the marketing pro-
cess and is not in the best interest of children.

Dr. Martin: Of course, it was not my intention to give a very exhaustive picture:
there are public regulations but there are also private logos which complexify this
issue too, but as far as I understood, here we were concerned with public regulation of
the access to the authorization of claims linked to an innovation. Of course, I am aware
of the problem with dietary supplements. In one of my papers 10 years ago, we were
asked for 1,000 reprints by a small enterprise in the US which sold the type of sugars
we were studying in humans, and clearly it was used to support the claims for dietary
supplement in which these sugars were introduced, so it’s clear. But the only point I
wanted to emphasize for you is the fact that depending on the market you target you
have to take all these issues into account. For big companies like Nestlé who work all
around the world, of course it’s additional work for each region of the world.

Dr. B. Koletzko: I am rather puzzled by the list of Article 14 health claims that
the EU has published in October and I wonder whether you could enlighten us on
the underlying wisdom. The Commission has decided to approve claims that linoleic,
α-linolenic acid, calcium, vitamin D and protein are needed for a normal growth and
development of children. Clearly that is scientifically correct. However, if you consider
the practical implications, it may be beneficial to enhance the average intake of calcium
and vitamin D if a large part of the European population has a low intake of these nutri-
ents. With regard to protein, I cannot image any benefit of a health claim on protein-rich
foods in the European population which already has a protein intake clearly far above
the requirements. Thus, consumers will be misled into thinking that increasing protein intake even further would benefit bone health, for which we have no evidence whatsoever. If the Commission has accepted these claims, one would logically expect that they should accept claims for any single essential nutrient. There is scientific evidence that, like protein, also salt is essential for growth and development of children, and energy, which can be provided by sugar and fat, is essential for growth and development of children. Do we really want a health claim that indicates salt is needed for the growth and development of children, and hence encourage people to buy more salty foods?

Dr. Martin: I fully agree. We have discussed that endlessly, but it's a policy decision and not a scientific decision. In terms of reference we received from the commission, it was clearly indicated that the fact that there is no public health concern about a nutrient should not be taken into account and cannot be an argument to reject a claim. Of course, for protein we cannot not say anything else, but claims are useful for commercial reasons; it's not a nutritional health policy. So, for me, claims could be very dangerous if there is no national or European nutrition policy in order to give clear references to consumers. If a consumer is hesitant about claims that are true but useless, he should consider also this public, official information into account when he analyzes that claim to decide if he purchases a product or not.

Dr. Ferruzzi: I want to follow up on Dr. Greer's comment because what I think is also interesting is that the multiple 'claims' systems that are in place in the US are in some ways providing a disincentive to true innovation. On one hand you see 'calcium builds strong bones'. This is not a health claim, these are in fact structure/function claims, and it's clearly important to differentiate those tools from the standpoint of innovation. However the consumer does not differentiate those tools. In fact, structure/function claims for the most part require no pre-market approval from the FDA and all you have to do is have your studies in a dossier put together in a case, so when you see a barrier to entry to this health market as a company you are more likely to take the structural function side because you can communicate on it in a way that the consumer understands. The shorter simpler message is preferred by marketing. What has that done to the state of innovative science? It's an interesting debate.

Dr. Martin: If you say calcium is needed for bone it's a nutrient function claim which requires no approval in the US, but which requires approval in Europe; it's on a list of claims on which we are working now. If you say calcium strengthens your bones, it's quite different, it's a health claim which requires a specific dossier.

Dr. Ferruzzi: Not in the US. In the US, a health claim relates to a disease state, but 'strong bones' is not; it has to say osteoporosis.

Dr. Martin: Strengthened bones is a health benefit.

Dr. Ferruzzi: In the US, it's a structure/function claim. You are right, it's a benefit, but not in the US legally.

Dr. Martin: The last point, I saw this paper which was published some time ago that indicates that claim perception clearly is culturally related and depends on the country in which you perform the study [1].

Dr. Haschke: My question is related to intellectual property, which is normally regulated by patents. In Europe, as you have mentioned, there's a 5-year protection of so-called proprietary data. This has caused fundamental confusion in the associations and companies because let's say you have a patent protection and 12 years later you publish a clinical study with some data which can result in a claim, you have an extension of the patent which is not justified. This probably has to go to court and has to be clarified. The European Commission is not so clear on whether this 5-year protection proposal is illegal or not. Could you comment on this?

Dr. Martin: It's clearly an innovation in the regulation, and I remember I gave a talk at the European Commission with the Head of the Units in 2001, and I talked about
the possibility to have some form of protection of claims. At that time, the answer was: no, it's not possible, it would create a distinction and inequalities in the food sectors, but some years later they have accepted the issue. For the moment, only one claim has been accepted in this condition, so we'll have to wait and see what the actual interpretation and management of this issue could be. For us, the only thing we have to do as scientists is to say if without the studies which are identified by the applicant as proprietary, the claim could have been justified. I am very much in favor of that, even if there are some difficulties in implementation and interpretation, because as scientists we can expect that this type of protection could lead to more investment in higher quality studies. But I agree, at the moment it's just a beginning of a new process, of an innovative regulatory issue and, we have to wait for clearer indications because we don't know exactly if a published study can be considered as proprietary. For some people, the best result of this regulation will be to give a huge amount of work to lawyers.

Dr. Solomons: I just want to get back to what Dr. Greer discussed earlier as smart choices. In Europe, we have the Choices International Foundation. This is a new concept that I think many people here in the room are just getting their heads round of front labeling as opposed to back labeling, and the back label is mostly about the adequacy of nutrients in a serving. Front labeling, which Dr. Greer partially characterized, is a formula for the lack of damage or overconsumption of risky elements from a serving of a food, that's what it's about. In your data about how consumers feel, I think there is a very interesting thing we need to begin to look at which is: they seem to be skeptical. They first want pleasure, second they don't want to be harmed, and third they want that a product is healthy or nutritious. If the consumer is skeptical about it because it might cause harm, it puts in a way a priority for the front label over the back label. I think we need to understand what front labeling is about because in terms of driving innovation as soon as front labeling is understood it can be optimally exploited in issues relevant to product, production, marketing and so forth.

Dr. Martin: I agree with that, there is little consumer research studies on these types, and unfortunately they are generally published in journals which are not read by nutritionists, i.e. Journal of Consumer Research or Journal of Marketing Research. As an example, there has been some indication in consumer studies [2] that the existence of a claim on the front label can divert the consumer to read the true information on the back, the nutrition information; so, it's necessary to regulate the correspondence between front labeling and back information.

References