

# Gateway to Claims Success

*The success of a health claim file depends on the quality of scientific evidence. The majority of negative EU health claim opinions relate to insufficient scientific justification for the claimed effect.*

by Thomas Pauquai

In nutrition, as in other market sectors, the commercial success of a product, functional food, dietary supplement or dietary product is linked to its quality and the benefits of health/well-being it brings to consumer, but first on its promise; the claim. Before testing a product, being satisfied (or not) and then buying it again (or not), the first contact that the consumer has with a product is the promise it bears, which will impact the purchasing mechanism of this product more than any other.

Beginning 2012, with the publication of the regulation of generic claims, the transitional period during which manufacturers can still communicate almost as they wish, will come to an end, and the rejected claims can no longer be used (joint, diuretic etc...).

We'll reach the new model of validation by the European Food Safety Authority (EFSA) and the European Commission of health claims submitted through a claim file.

### Upsetting the Rules

Article 2 of EC Regulation 1924/2006 states that "any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics," is a claim. Therefore, any communication regarding the health benefit of a food must comply with this regulation.

Regulation 1924/2006 has completely upset the rules of the game for communication on products. Until now, the

positioning and the benefit of a product were communicated by promises that were extremely striking and attractive to the consumer, based on more or less solid scientific evidence or traditional use. Now, the health claim must be substantiated by scientific evidence and validated prior to its use by scientific and regulatory authorities, EFSA and the European Commission.

While the claims contained in the positive list of approved generic claims can be used by manufacturers, with the sole condition of respecting the defined conditions of use, any generic claim not listed on this list will be prohibited. These generic claims will claim around a normal function of an ingredient or product. But the simple and low cost use of generic claims could quickly lead to a unified market and product standardization, of both compositions and claims.

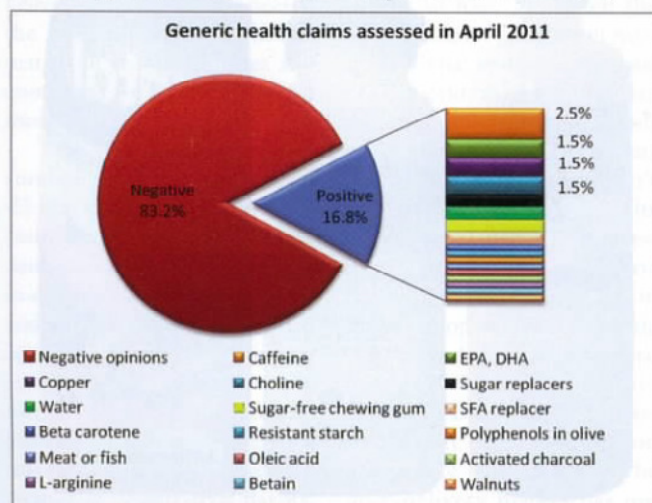
As opposed to generic claims, specific claims allow manufacturers to differentiate their product from their competitors with a claim which is unique, original and proper to the product. But this way of communication, specific to a product, requires experience and expertise, and undeniably significant costs in terms of time and money, to properly justify the claimed efficacy, by specific proprietary clinical evidence presented to EFSA,

in an application for the authorization of a health claim.

### Ingredient Characterization

The file format is the same for applications for authorization of a health claim in Article 13.5 (health claim not included in the Community list of permitted claims and based on newly developed scientific evidence and/or which include a request for the protection of proprietary data) or 14 (Reduction of disease risk claims and claims referring to children's development and health). Moreover, according to the guidelines of EFSA transmitted almost four years ago, the constitution is clear. Of the five parts that compose the health claim file, two are essential. One must provide the data for a perfect characterization of the product (characteristics, specifications, stability, variability, analytical methods, manufacturing process, quality system, bioavailability etc.) to justify that the product is always identical, with the same characteristics, specifications, etc. It must be the same product, clinically evaluated many years ago that will be sold to consumers supported by a health claim. The other essential part of the file must provide the scientific evidence (human data > non-human; published > unpublished, etc.) of the efficacy of the product. In summary, a health claim file

Generic health claims assessed in April 2011



can be defined as all the scientific evidence of the efficacy of a well characterized food/ingredient. A relationship must be established between the consumption of this food and the health benefits claimed. Characterization is justified by its specifications, data of stability, variability, bioavailability etc. The efficacy is justified by at least one clinical study on the product itself and must provide health benefits.

**Mass Rejection**

While some files, which were among the earliest submitted and assessed by EFSA, received positive opinions, a majority of assessed files/

claims were rejected. In the first batch of generic claims published in October 2009, of the 521 claims assessed in 94 opinions, 63% were negative. In February 2010, for the second batch of 416 claims assessed in 31 opinions, 98% were negative! This negative trend was maintained at 80% with the third batch delivered in October 2010, when over 808 claims were assessed in 75 opinions. In April, for the fourth batch of 442 claims assessed in 63 opinions, 83% were negative. Recently, in June 2011, for the fifth batch of 536 claims assessed in 73 opinions, 85% were negative. Regarding the specific claims,

the level of success is low, but it is also increasing steadily, going from only 17% positive opinion in November 2010, to 25% in June 2011. Note that these accepted claims mainly relate to nutrients, vitamins, minerals, phytosterols, omega 3, tomato concentrate and xylitol, but no plant extract or unexpected ingredient in providing an innovation to market. So what are the reasons that may explain such a low success rate?

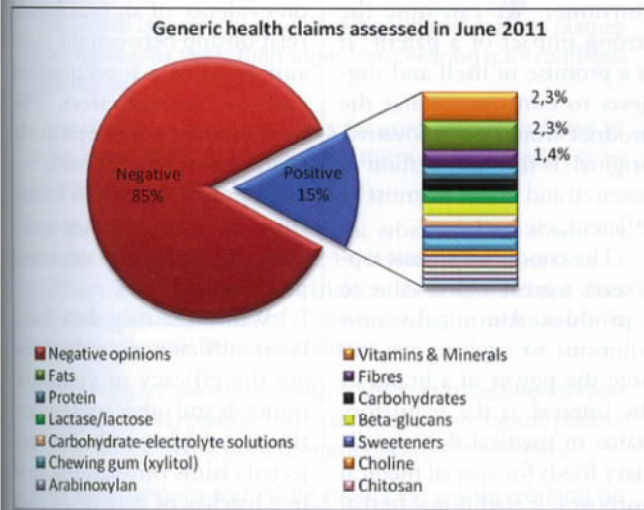
**Low Return**

Regarding the first criteria for evaluating a health claim file, experience shows that only a few of files had an insufficient characterization of the ingredient. It appears however that the majority of negative opinions are related to insufficient scientific justification for the claimed effect. The success of a health claim file depends on the quality of scientific evidence, that is to say the studies, justifying the efficacy of the product. In any case, a convincing study should be conducted on the ingredient or the product itself at the dosage and conditions of use, corresponding to the claim applied for. It seems that

the data on the various components cannot be extrapolated to support the product itself (e.g. Immune Balance Drink). The methodology must of course be randomized, double-blind, placebo-controlled (i.e. gold standard). Included subjects must be healthy, the results obtained in a population of patients cannot be extrapolated to the general population (e.g. glucosamine), and the sample size calculated *a priori*. Finally, markers and methods must be validated. Another key point in evaluating a claim is the health relationship. If a few health relationships such as breast enhancement, diuretic effect or antioxidant effect are not accepted, for the moment, the vast majority of applications and health relationships have been approved by EFSA.

**High Discrimination**

Besides these technical considerations of sufficient characterization of the ingredient, the health relationship and scientific evidence justifying the claimed effect, we nevertheless question the fact that vitamins and minerals are mainly positively evaluated relative to plants or other ingredients that are regularly



rejected. The recent positive opinion obtained by thiamine in Article 14 on children's health for the application: "Thiamin and maintenance of normal neurological development and function," is an example.

Why is there such discrimination between an evaluation reserved for vitamins/minerals, whose benefit is established on the fact that the deficiency is deleterious, and one made with other ingredients, whose benefit should be established on the fact that consumption provides real statistically significant effect?

Why is this, when the application of Regulation 1924/2006 should be strictly the same for all actives, subject to an application for a claim? Shedding light and providing a better understanding of the shortcomings of the files does help to understand the many negative opinions, but it does not solve the problem. How then can companies continue to communicate on the health benefits of their products?

### Communication Strategies

The simplest, quickest and cheapest solution, which, on the other hand, is less original, and does not allow the distinguishing of one product from another in a competitive mar-

ket, is the use of the so-called "generic claims."

With the only condition being the use of the correct ingredient (that is to say a vitamin or mineral because of the very small chances of success for other ingredients) at the right dose, any manufacturer may use a defined claim. As mentioned above, this could quickly lead to a homogenization of the market and product standardization, in terms of both compositions and claims.

The solution to use a proprietary and original claim, is to obtain approval by a procedure in Article 13.5 or 14. Even if this process is long (from 12 months to much more between the constitution of the file and the scientific opinion from EFSA) and very expensive (since it requires at least one good clinical study), such a claim can differentiate a product from its competitors. Note that once a claim receives a positive opinion, it will be applicable throughout the EU; i.e. 27 Member States.

This is the promise of powerful business development, also internationally, as the European system is becoming the point of reference, which has recently become clearer through an exchange with the US FDA. Another extremely important point is the data

protection for five years that exists for health claim files under Article 13.5.

While this new regulation restricts the communication to the public, what about the one made with health professionals? The regulation is ambiguous on this concept, which would leave an additional opportunity to communicate on the benefits and efficacy of products.

### Substantial Equivalence

Out of the Regulation 1924/2006 and the application for authorization of a health claim, there are not a lot of other ways to communicate and valorize a product to the consumer. We can note the strong impact of a patent. It is a promise in itself and suggests to consumers that the product would be innovative, original, is the culmination of research and therefore must be efficient, etc.

The concept of patent represents a great added value to a product. Among the new solutions to explore, we can note the power of a brand or the interest as the regulatory status in medical devices, dietary foods for special medical purposes or traditional herbal medicine products.

Moreover, innovation can also come from the use of

new ingredients. This implies a prior regulatory approval, a process that can be both time and money-consuming for a "novel food."

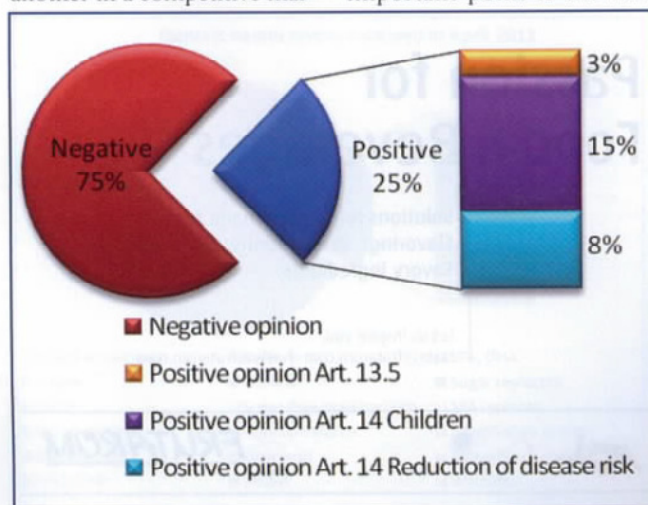
However, there still exists a certain period of time for a simplified procedure, which is much more simple and less expensive; the procedure of "substantial equivalence." This principle is to justify that the new ingredient being authorized is similar in several specific points to another already authorized and/or marketed ingredient.

### Winning Claims

Experience shows that a health claim file must be based on evidence of an established relationship between the consumption of a food/product and the claimed effect. The food/product must be properly characterized, the scientific evidence must support its health benefits, and the claim must be consistent with the evidence presented.

While existing data have been sufficient to substantiate the efficacy of vitamins, minerals and other substances, the very high number of rejected claims through the first five batches of generic claims proves that the situation is not the same for plants. Additional data and new clinical studies are needed to prove the claimed efficacy of the plants. Suppliers will have to invest a lot to prove the efficacy of their products, before they can claim on their efficacy. ♦

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Within its fifth batch of Scientific Opinions on health claims, EFSA has published a favorable opinion on the "Toothfriendly" claim for foods and beverages that are demonstrably non-cariogenic and non-erosive. EFSA's positive scientific opinion builds the basis for the continued use of the Toothfriendly quality seal, a registered trademark since 1982. The seal is coupled with the explanatory term "Toothfriendly" for use on foods which neither contain fermentable carbohydrates nor excessive amounts of food acids.