



NATURALPHA PROVIDES SPECIFIC EXPERTISE IN A NEW EVALUATION ERA OF NUTRITION AND HEALTH CLAIM DOSSIERS

- **The European Food Safety Authority (EFSA) has issued unfavorable opinions for 71% of the submitted health claims**
- **Naturalpha has established specific tools to identify the key issues to address for health claim dossier validation by the Authorities**

Lille (France), Cambridge (Massachusetts - USA), November 17, 2009, Naturalpha an international scientific and regulatory Consulting and R&D Company in Nutrition and Health and a privileged partner for functional foods and ingredients industries, suggests in-depth analysis of recent dossier review by EFSA for successful health claims strategy. The European Nutrition and Health Claims Regulation (1924/2006/EC) has introduced a new regulatory environment to make Health Claims in the European Union. One of the main innovations introduced by this regulation was the pre-approval required for the use of health claims. The latest release of generic health claim opinions (art 13/1), mainly refused by the Authority, gave new insights in the strategy to gain EFSA approval.

71 % of the 417 health claims evaluated to date by the EFSA have been rejected, 14 % were considered as not relevant in EU and 15 % were accepted

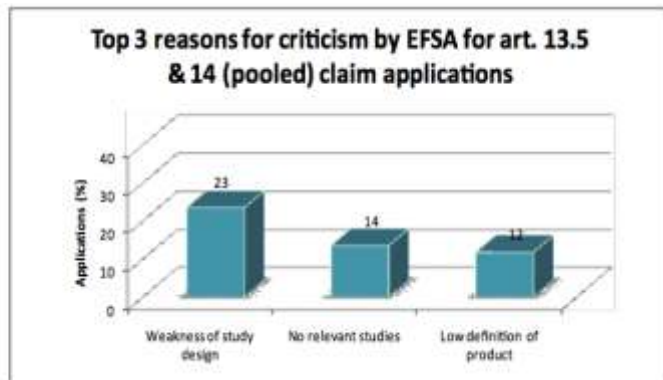
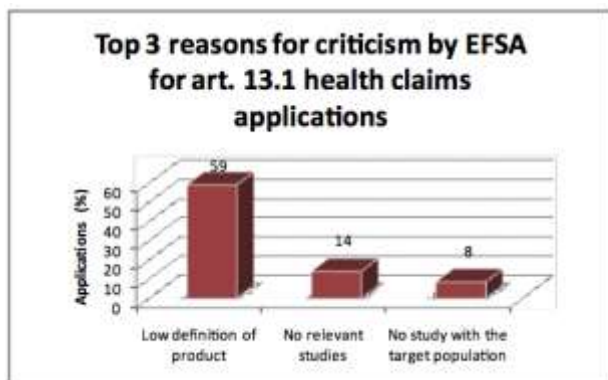
Since one year the European Food Safety Authority evaluated 417 "nutrient/product-health benefit" relationships: 349 generic claims under the Article 13.1 of the European Regulation (1924/2006/EC) that can be used by all companies; 13 claims based on newly developed scientific evidence and/or which include proprietary data protection (Article 13.5); 13 disease risk reduction claims (Article 14) and finally, 42 claims referring to children's health and development (Article 14). All claims are not evaluated in the same way. Generic health claims (Art.13.1) are evaluated through a consensus method whereas claims within Articles 13.5 and 14 need to be substantiated with interventional data on the product. This evaluation process has a huge impact on the opinions released by EFSA, but the global rate of unfavorable opinions with no difference between claim types is about 80-85 %.

Health Claim opportunities in the EU Framework – Naturalpha's tools & recommendations

The released EFSA opinions constitute an interesting tool for Naturalpha allowing the company to identify opportunities for claim dossier approval by the Authority. Naturalpha performs an in-depth analysis of each opinion released by EFSA, and has constituted powerful tools to analyze how dossiers are handled by the EFSA.

Analysis of the causes of criticism by EFSA in the released opinions shows that the high rate of refusal results from a lack of knowledge concerning the expectations of regulatory agencies and towards their strict evaluation process.

- When considering article 13.1 generic health claims, the main cause of criticism comes from the low definition of the product, found in almost 60 % (*source: Naturalpha*) of evaluated relationships. For instance, claims regarding probiotics have been rejected due to this cause. The second most common cause of health claim rejection is the lack of relevant studies (in 14 % of dossiers).
- On the contrary, concerning product health claims under articles 13.5 and 14, the problem often comes from the weakness of the study design especially in the human clinical studies.



Source: Health Claim Database from Nutrialpha Europe (web-based tool developed by Naturalpha)

To sum up, a high-quality and emphasized product characterization, no matter the claim typology combined with a efficient R&D strategy, with special attention to the clinical study design, are 2 of the most important key success factors for EFSA assessment. However, each demand must be assessed in a case-by-case approach in order to really address the specificity of each product and scientifically substantiate the targeted claim. Naturalpha performs tailor-based analyses for its customers, to identify major threats and opportunities regarding existing EFSA opinions.

Virginie Coste, Regulatory Affairs Manager of Naturalpha: "We can observe that the global rate of unfavorable opinions given by EFSA on all types of health claims is about 80-85 %. A majority of these unfavorable opinions come from the simple fact that agro food industrials ignore or underestimate the existing elements released by EFSA throughout guidelines and opinions. Regarding generic claims, the product characterization is essential but for other claims it is necessary to analyze accepted generic claims in order to have a differentiated wording on the benefit or health effect claimed. Besides, there are many reasons for criticism on a specific health topic and on an ingredient typology already given by the EFSA they sometimes just need to be integrated or checked out. Naturalpha's team is fully aware of these remarks and takes them into account while elaborating the health claim strategy and dossiers for its clients."

Christophe Ripoll, Research & Development Executive Vice-President, of Naturalpha: "In parallel with wording and ingredient typology awareness, building the scientific program in accordance with the targeted claim constitutes a crucial aspect of claim assessment. Firstly we need to identify the existing gaps between available science and EFSA claim requirements to make them match. Defining the relevant and most efficient preclinical and clinical studies to be performed corroborating benefit or health effect is also a very important aspect of dossier building. Finally, to avoid EFSA health claim rejection, the study design and more precisely the clinical trials concerning a future product have to be as pertinent as possible and to rely on well-established scientific evidence. Based on this consideration, Naturalpha can now propose its own clinical nutrition center, the CNCN, dedicated to clinical trials in nutrition to meet the growing needs of functional foods and ingredients producers and to accompany them in their product development."

Regarding the Regulation on food and health claims (1924/2006/EC)

This regulation, in force since July 1st 2007, aims to harmonize regulatory dispositions at a European level dealing with the use of food and health claims in order to ensure a high level of consumer protection and to guarantee a good internal market functioning. Indeed, before the implementation of this regulation, the health claims were governed by divergent national rules that impeded the free movement of foods within the European territory. In addition to that, this regulation has allowed completing the general principles regarding the labeling of food, which is defined in Europe by the Directive 2000/13/EC. Several specific labeling rules regarding the use of food and health claims have been established in order to help the consumer making food choices and to protect them from any misleading information

From now, any claim stating that a food has particular beneficial nutritional properties or suggesting that a relationship exists between the food and health, acquires justification by scientific proofs.

This regulation applies to all the messages and representations made in commercial communications, (using labeling, symbols, pictures or advertising...), from a food delivered to the final consumer and stating, suggesting or implying that the food has particular characteristics, meaning: beneficial nutritional properties and/or a relation with health (functional properties, reduction of a disease risk, development and child health).

Each category of health claim is put under a specific administrative procedure. The health claims called "functional" (Art. 13) or "generic" (Art. 13.1) article would only be allowed if their formulation and their instructions of use appear in the community register (list of authorized claims) that should be published in January 2010.

The claims referring to the reduction of disease risk and those regarding children's development and health (Art. 14) have to be put under close scrutiny of an authorization procedure on the basis of a scientific dossier that will be evaluated by the EFSA.

Similar procedure exists for health claims based on newly developed scientific evidence and/or which include a request for the protection of proprietary data (Art. 13.5).

The applications for authorization of health claims are evaluated by the EFSA within 5 to 6 months and their final acceptance is decided by the European Commission on the basis of opinion made by the EFSA.

Naturalpha

Naturalpha, specialized in scientific and regulatory consulting and R&D in Nutrition and Health, offers functional food and ingredients industries solutions to build an effective research strategy. Naturalpha helps shortening the process of R&D and time to launch their product on the market. Naturalpha supports its industrial partners in building the proof of "health effect" of their innovative products at every stage of their development: scientific and regulatory intelligence and consulting, health claim dossier audit, preclinical health benefit evaluation and validation, clinical studies.

Spin-off of the biotechnology company Genfit, Naturalpha is located in Lille with an office in Cambridge (Massachusetts, USA). Naturalpha employs 25 specialists (physicians, engineers, research scientists and dieticians) and is a member of the Pole of Competitiveness Nutrition Health Longevity. <http://www.naturalpha.com/index.php>

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