



NATURALPHA'S OPINION ON THE HEALTH CLAIMS REJECTED BY THE EFSA (European Food Safety Authority)

- **The EFSA has issued negative opinion for almost 80% of the health claims submitted by agro food companies**
- **Naturalpha proposes a better understanding of the EFSA expectations thanks to their scientific and regulatory expertise.**

Lille (France), Cambridge (Massachusetts - USA), March 24th 2009, Naturalpha, which is a Consulting and R&D Company in Nutrition and Health, and a privileged partner for the agro food and the pharmaceutical industrials, presents its analysis about health claims dossiers recently reviewed by the EFSA. Most of the opinions published by the EFSA are unfavorable. The nature of the conclusions issued by the EFSA highlights the difficulties faced by the industrials and the organisms which try to develop new and innovative products claiming health benefits under the articles 13 and 14 of the European Regulation 1924/2006 on nutrition and health claims made on foods.

80% of the 50 health claims recently evaluated by the EFSA have been rejected.

Whatever the area or the health benefit involved (esthetics, gastrointestinal disorders, anxiety, cardiovascular risks, cognitive vitality...), the health claims submitted to the EFSA have been rejected because of a lack of relevant scientific evidences required by the European rules.

The only health claims approved by the EFSA concern the phytosterols and the phytostanols for their proven effects on the reduction of the cholesterol level and on the reduction of coronary diseases incidence.

Other health claims have also been accepted in the area of child development or health; those ones highlighting a relation between calcium and bone growth, between the xylitol and reduction of the risk of tooth decay, also between DHA and the development of the visual function, and finally the health claims highlighting a relation between omega 3 fatty acids combination and the development or the care of healthy cerebral function in children.

Naturalpha estimates that the high rate of refusal of health claims results from a lack of knowledge concerning the expectations of regulatory agencies. Food industries have now to provide solid scientific evidences to justify claimed effects both at pre-clinical (animal studies) and clinical (human studies) level. Mostly, agro food industrials do not take into account this level of expectations early enough in their R&D strategy.

Virginie Coste, Regulatory Affairs Manager of Naturalpha: "Amongst all the dossiers submitted to the EFSA regarding the common authorization procedure targeted by the articles 13-5 and 14, only 28% of them have been accepted for evaluation. In addition, this selection phase of the application, can vary from 15 days to 10 months in some cases. Those figures clearly demonstrate that most of the dossiers do not meet the standards of the EFSA, which are, indeed, very severe. Beyond the basic problem (especially linked to the suitability of scientific proofs), we do have to confess that quality is also missing in some dossiers. Naturalpha's team is fully aware of the agencies requirements and takes them into account while elaborating the applications for authorization of health claim."

Christophe Ripoll, Scientific Director of Naturalpha: "We have to point out that, even big companies with famous products have also received unfavorable opinions. Those refusals spotlight the question of the intrinsic quality of the support studies, but also the methodology of the scientific writing of the dossiers, which require an transversal approach of the problematic for example the inclusion of contradictory data. The role and the added value of Naturalpha consist in the methodology of the studies in laboratory models and/or clinical trials in humans, performed meticulously and specifically in order to support the health benefits of the products tested. Moreover Naturalpha's expertise is based on its consulting activity with a double skill in science and regulatory environments."

Health claims recently evaluated by the EFSA – Status on March 13th, 2009

Type of Allegation	Category	Claim submitted	Claim evaluated	Approval	Denial
Health claim based on newly developed scientific data and/or which include a request for the protection of proprietary data (Art.13-5)	Gut health	3	1		1
	Weight management / obesity	2	2		2
	Cognitive sphere	2	2		2
Claim regarding referring to the reduction of disease risk (Art.14)	Cardiovascular health	6	4	2	2
	Oral health	1	1	1	
	bone health	1	1		1
Claim referring to children's development and health (Art.14)	Growth	2	1		1
	Bone growth	5	5	3	2
	Cognitive/mental development	18	17	1	16
	Development of the CNS	9	5	2	3
	Ocular development	8	4		4
	Immunity	2	2		2
	Gut health	5	4		4
	Oral health	1	1		1
TOTAL		65	50	9	41

Source: Web portal Nutrialpha - <http://www.nutrialpha.com/>

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" (article 13) would only be allowed if their formulation and their instructions of use appear in the community register (list of authorized claims) that will be published in January 2010.

The claims referring to the reduction of disease risk and those regarding children's development and health (article 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 (article 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, a Biotechnology Company specialized in consulting and R&D in Nutrition and Health, offers the pharmaceutical and food industries solutions allowing them to build an effective research strategy. Naturalpha helps shortening the process of R&D and to launch their product on the market. Naturalpha supports its industrial partners in the building of the proofs of "health effect" of their innovative products at every stage of their developments: strategic and scientific intelligence, preclinical and clinical studies, registration of their product on the market.

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>

Contacts:

NATURALPHA

Emilie GAZO - Communication Manager

Ph: 03 20 95 95 09

emilie.gazo@naturalpha.com

MILESTONES – PR

Jacques-Olivier COSTA / Bruno ARABIAN

Ph: 01 75 44 87 42 / 40

jocosta@milestones.fr / milestones@milestones-fr.com