

# Health Claims Rejected by EFSA Naturalalpha's Opinion

*EFSA has issued a negative opinion for almost 80% of the health claims submitted by agro-food companies. Naturalalpha proposes a better understanding of EFSA's expectations, based on its scientific and regulatory expertise.*

Naturalalpha, an R&D/consulting company in the nutrition and health sector, and a privileged partner to the agro-food and the pharmaceutical industrials, examines the health claims dossiers that have recently been reviewed by EFSA (European Food Safety Authority). Most of the opinions published by EFSA are unfavourable: the nature of these conclusions highlights the difficulties faced by the companies and organizations that are trying to develop new and innovative products claiming health benefits according to Articles 13 and 14 (European Regulation 1924/2006) on nutrition and health claims made on foods.

Eighty per cent of the 70 health claims recently evaluated by EFSA have been rejected (Table I). Whatever the indication or the health benefit involved (gastrointestinal disorders, anxiety, cardiovascular risks, cognitive vitality, etc.), the health claims submitted to EFSA have been rejected because of a lack of the relevant scientific evidence that is required by the European rules. The only health claims that have been approved by EFSA concern phytosterols and phytosterols for their proven effects on the reduction of cholesterol levels and on the reduction of coronary disease incidence. Other health claims have also been accepted in the area of child development or health — those highlighting a relation between calcium and bone growth, between xylitol and the reduction of tooth decay, between DHA and the development of visual function and, finally, the health claims showing a correlation between omega-3 fatty acids and the development/maintenance of healthy cerebral function in children.

Naturalalpha believes that the high rate of health claims refusals derives from a lack of

knowledge concerning the expectations of regulatory agencies. Food industries now have to provide solid scientific evidence to justify their claimed effects — both at a preclinical (animal studies) and clinical (human studies) level. On the whole, agro-food industrials do not prepare for this level of complexity early enough in their R&D strategy. Virginie Coste, Regulatory Affairs Manager, Naturalalpha, says: "Amongst all the dossiers submitted to EFSA according to the common authorization procedure targeted by Articles 13-5 and 14, only 30.6% of them have been accepted for

products have also received unfavourable opinions. Those refusals not only spotlight the value of the intrinsic quality of support studies, but also the way that the science is communicated in the dossiers, which requires a transversal approach to the problem of, for example, including contradictory data. The role and the added value that Naturalalpha offers is in the study methodology of laboratory models and/or clinical trials in humans, performed meticulously and specifically to support the health benefits of the products tested. Moreover, Naturalalpha's expertise

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	6	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	8	4	2	2
	Oral health	1	1	1	
	Bone health	2	1		1
Claim referring to children's development and health (Art.14)	Growth	3	2		2
	Bone growth	5	5	3	2
	Cognitive/mental development	20	18	1	17
	Development of the CNS	9	9	3	6
	Ocular development	8	8	3	5
	Immunity	3	2		2
	Gut health	5	5		5
	Oral health	1	1		1
	<b>TOTAL</b>		<b>70</b>	<b>61</b>	<b>11</b>

**Table I:** Health claims recently evaluated by EFSA (status on 22 May 2009).

evaluation. In addition, in some cases, this selection phase of the application can vary from 15 days to 10 months. Such figures clearly demonstrate that most of the dossiers do not meet EFSA's standards, which are, indeed, very strict. Beyond the basic problem (the suitability of scientific proof), we have to confess that another factor — quality — is also missing from some dossiers. Naturalalpha's team is fully aware of the agency's requirements and takes them into account when developing applications for health claim authorizations."

Christophe Ripoll, Scientific Director, Naturalalpha, adds: "We should point out that major companies with well known

is based on its consulting activity, with dual experience in both the science and regulatory environments."

## Food and Health Claims Regulation 1924/2006/EC


This regulation, in force since 1 July 2007, aims to harmonize regulatory submissions at a European level by dealing with the use of food and health claims to ensure a high level of consumer protection and guarantee an effective (and efficient) internal market. Indeed, before the implementation of this regulation, health claims were governed by divergent national rules that impeded the free movement of foods within the European



Union. In addition, this regulation has facilitated the completion of general principles regarding the labelling of food, which is defined in Europe by Directive 2000/13/EC. Several specific labelling rules concerning the use of food and health claims have been established to help the consumer to make informed food choices and to protect them from any misleading information.

Currently, any claim that states that a food has beneficial nutritional properties or suggests that a relationship exists between the food and a health condition requires justification by scientific proof. This regulation applies to all and any statements and presentations made in commercial communications (using labelling, symbols, pictures and/or advertising) regarding any foodstuff offered to the end-consumer and stating, suggesting or implying that the food has particular characteristics, such as beneficial nutritional properties and/or could contribute to health or well-being (functional properties, reduction of a disease risk, development and child health).

Each category of health claim is put under a specific administrative procedure. The "functional" health claims (Article 13)

would only be allowed if their formulation and instructions for 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) must go under the close scrutiny of an authorization procedure based on a scientific dossier that will be evaluated by EFSA. A similar procedure exists for health claims based on newly developed scientific evidence and/or that include a request for the protection of proprietary data (Article 13-5). Applications for health claim authorizations are evaluated by EFSA within 5–6 months; the European Commission, on the basis of EFSA's opinions, makes the final acceptance decision. 

#### For more information

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