

ESSNA

European Specialist Sports Nutrition Alliance

Representing manufacturers and distributors of specialist sports nutrition products in Europe

ESSNA COMMENTS ON A PROPOSAL FOR A REGULATION ON NUTRITION & HEALTH CLAIMS MADE ON FOODS 2003/0165 (COD)

Introduction:

ESSNA is a Trade Association representing the specialist product sector of the Sports Nutrition industry in Europe. It comprises members who have sales & marketing interests in specialist sports nutrition products in most of the Member States of Europe. ESSNA has written a previous report on its members' response to the proposed Directive on 'products intended to meet the expenditure of intense muscular effort, especially for sports people' (under PARNUTS). This document reviews the Council Document on the proposed Regulation on Nutrition & Health Claims made on foods - with particular consideration of sports foods.

General Comments on the proposed Regulation:

We are disappointed that the wording of the Council document 2003/0165(COD) of 30th June 2004 on the proposed Regulation on Nutrition & Health Claims is little changed from the earlier Commission document COM (2003) 424 of July 2003. This is despite two major principles within the proposed Regulation that have caused widespread and deep concern within the food industry and caused many hundreds of amendments put forward for the EP First Reading which was planned in April 2004 but held over until the new parliament has been reformed.

Sports Products, targeted at sports people in Europe, may be categorised either under the proposed PARNUTS category of 'Sports Nutrition' products (if they conform to certain requirements including product compositional requirements), as Food Supplements, as 'fortified foods' (under proposed "Addition of Nutrients to foods" legislation) or sold as general foods.

None of the specific legislative food categories above allow specifically for claims to be made on the products included except, to a very limited extent, where PARNUTS allows certain terms to indicate the particular nutritional properties of the product concerned.

There are two major concerns that apply to Sports Products sold under PARNUTS, Food Supplements or general food legislation. They are:

- the principle of nutrient profiling (*Article 4*)
- the prohibited claims (*Article 11*)

The specific difficulties caused by these Articles on Sports Products (to be detailed later) are in addition to the requirement for companies to substantiate all Health Claims and receive approval before they may be used. This is seen to be a restrictive and costly exercise particularly for the many SME sports product companies in the industry.

There are also a number of nutrition & health claims that are specific to sports nutrition products and do not fit easily with the limitations and constraints of nutrition & health claims applied to general food products. These will be dealt with later in detail

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Objectives of the European Specialist Sports Nutrition industry in relation to this proposed Regulation on Nutrition & Health Claims:

- Sports Nutrition products falling under PARNUTS (Directive 89/398) should be exempted from the scope of the Nutrition and Health Claims Regulation but be subject to national notification to ensure attached claims are not unreasonable.
- Sports Nutrition products that are not exempt from the Nutrition and Health Claims Regulation should be allowed to make claims that may be substantiated with wording appropriate to the level of scientific data to allow for emerging science and to encourage further research.
- The average targeted user should assess claims on the basis of the understanding of them. In the specialist sports sector, the targeted user may have a significant scientific understanding of the physiological effects of the products that carry the claim.
- A list of 'generally acceptable health claims' should be drawn up and approved for a transitional period (say three years) during which they could be assessed for 'approved use' by EFSA. This 'grand-fathering' of claims could also apply to 'Company' & 'Brand' names with an implicit health claim without a time limit
- There should be no category of 'Prohibited Claims' (Article 11). All claims are subject to an approval process, making this prohibition unnecessary.
- The effect of 'Nutrient Profiling' (Article 4) would need to take into account products with specific beneficial purposes for sports people that may be related to adverse health effects in the general population (eg the need for raised sodium levels in recovery drinks).
- The process of substantiation and approval of claims should be simple, quick and inexpensive. SMEs should not be disadvantaged in this process where Health claim approval could be restricted to large companies with the necessary resources.

Specific comments on the contents of the proposed Nutrition and Health Claims Regulation

Article 1.4:

The wording should be changed to: *"This Regulation shall not apply to products within the following Community legislation:"*

Article 2.5:

To the definition: "health claim" means....and health,

Add: *"but does not include statements concerning the maintenance of normal physiological function;"* .

Article 2.8:

To the definition: "average consumer" means....circumspect

Add: *"within the target group of consumers at which the claim is directed"*

(eg sports product users who, on average, have a high understanding of the physiological need and the claimed effect of the product concerned).

Article 3c

Sports people have increased demands of nutrients such as protein, amino acids, carbohydrate, water, sodium and some micronutrients that are not provided in optimal amounts for health and performance by a 'balanced and varied diet'.

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Article 4:

The purpose of this Article is understandable but there are many exceptions and there is a concern that 'within the 18 months' the Commission will create rules that will not allow health claims on products that are intended to maintain or restore a normal physiological function because they have an apparently poor Nutrient Profile. An example might be a sports rehydration product with additional salt to replace that lost during extended exercise or a Cod Liver Oil capsule consisting of 95% fat but containing the RDA of Vitamins A & D.

We would want to know more about the procedure that the Commission would use to create these adverse nutrient profiles and particularly which products may be excepted from the category of products prohibited from making these claims if they fall within these adverse profiles.

Article 5

Insert

Article 5.1a:

"The use of qualified nutrition and health claims shall also be permitted if the presence, absence or reduced content in a food or food category of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect as included in accepted scientific data."

This would allow the development of food research to be applied in health claims assuming the science was acceptable (peer reviewed publications). The wording of the claim would be qualified using words such as "It has been shown in recent studies that X **may** have a certain benefit...."

Article 6.1

To: "Nutrition and....generally accepted scientific data."

Add: *"and qualified health claims shall be based on emerging scientific data".*

This allows the use of emerging science from food research by reflecting the lack of 'established' science by the use of qualified claims "may" or "might" connected with "possible evidence" or "in recent trials".

Article 6.3

To: "The competent authorities....with this Regulation."

Add: *"except where during the transitional period from... to... (3 years), a list of temporary claims are accepted by the Commission pending their review by EFSA".*

This could be legislated for in a similar manner to the claims for "generally accepted role of a nutrient or other substance" in Article 12.2a

Other comments related to the substantiation process:

- Dossiers submitted to EFSA to substantiate health claims should generally be within the capability and resources of Small & Medium Enterprises (SMEs).
- Health claims currently allowed or approved to be used by Member States should be placed on a fast-track approval scheme through EFSA.

Article 7

Currently food supplements are exempt from the full nutrient declaration (proposed to be extended under the Revision of Directive 90/496) and this exemption should continue to apply to them where a nutrition or health claim is being made. An exemption could be made here or a new Article 1.5 stating that *"This Regulation shall apply without prejudice to: The Food Supplements Directive 2002/46/EC"*.

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Insert

Article 8.3

“For food product presented in unit dose form (such as tablets, capsules, pastilles, lozenges etc.) consideration should be given to replacing the quantities /100g or /100ml by an appropriate quantity per recommended daily dose”

Article 10.2(d)

The phrase: “if consumed to excess” needs to be defined or reconsidered. Virtually all products are likely to be harmful if consumed to excess.

Article 11

ESSNA is against a prohibition on certain categories of health & nutrition claims as all claims are subject to a substantiation & approval process anyway and emerging science may create overwhelming evidence of the benefit of certain foods or nutrients in these areas of prohibited claims. This Article should therefore be removed in its entirety.

Further:

Slimming or weight-reduction claims: If there is no provision for these, slimming products such as meal replacement products or low-calorie alternative products – which are well understood by the consumer – would be lost from the market. This would be a disaster in the context of the growing obesity ‘epidemic’. There are a number of sports products that encourage loss of fat and its replacement by lean muscle that might be considered to be weight-reduction products. ESSNA is very much against the prohibition of this type of claim.

Psychological & behavioural claims: Again, there are definable scientific reasons for allowing these health claims in relation to sports and other products. Caffeine, ginseng and other mental stimulants are well known to improve mental alertness and aid concentration. Glucose has the ability to improve mental performance during endurance exercise. Recital (15) claims the reason for prohibiting psychological & behavioural claims is because there are many factors influencing these functions making communication difficult. This is true of many physiological functions also and is particularly true in ‘disease risk reduction’ claims, yet claims relating to these areas are not prohibited. Companies should be allowed to substantiate their claims and propose appropriate communication/wording.

Improving immune responses: We understand that this has been held up as an example of a “general well being” claim that is vague & meaningless. On the contrary, there is ample evidence that athletes exercising to their limits during a relatively short period suffer reduced immunity to infection and frequently suffer colds and other infections after a few days of intense activity. It is also an established and well-researched fact that the immune system can be improved by the optimal intake of certain nutrients and other natural foods.

Article 12

Health claims describing a generally accepted role of a nutrient or other substance should be allowed as proposed by the adoption of a Community list of commonly used and acceptable nutrient function claims. We should like to know more about the mechanism of adoption of the list and the flexibility in wording that we wish to be allowed in use.

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Article 13

We welcome this possibility of extending health claims to foods, the consumption of which, influences factors involved in disease risk reduction. However we see little benefit to Sports Nutrition product manufacturers.

Article 14

In Article 14.3(e) we do not agree with the provision of the wording of the claim "in all Community languages". This places an undue & disproportionate burden on companies that wish to market in only one Member State in their natural language.

We would also object to exact wording being approved and necessary in use. Often the context of the claim in other text or the need to address the wording to a different target group with a different level of understanding requires slight changes to the wording.

A strict application of exact wording would result in multiple submissions for approval by EFSA of essentially the same claim.

Article 15.3

As proposed earlier in the definitions (Article 2.8), the average sports product user has a high understanding of the physiological need and the claimed effect of the product concerned. We therefore propose that the words: "average consumer" are replaced by: *"the average consumer within the target group"*.

Article 26

Entry into Force:

We agree with the UK proposed amendment:

"Health claims, other than those referred to in Article 12(1), that are used for foods, categories of food or food constituents at the time this Regulation enters into force in compliance with existing provisions, can continue to be used provided an application is made pursuant to Article 14 within twelve months following the entry into force of this Regulation and until six months after a final decision is taken pursuant to Article 16."

There should be a paragraph that allows product labelled before the deadline for compliance with this Regulation to be allowed to sell-through without a time limit.

Annex Nutrition Claims

The following Nutrition Claims frequently used in Sports Nutrition products are not included in the list are:

- High Energy
- High Carbohydrate
- High Carb

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Other Nutrition Claims that may be used in Sports Nutrition products not included in the list are:

- Omega-6 fatty acid source
- High Omega-6 fatty acids
- Trans Fatty acid free
- Cholesterol free
- Low carbohydrate
- Low Carb

Other comments on Nutrition Claims:

The measurement of Fibre should be defined.

The measurement of 'Protein Quality' may need defining if included in the Protein claims.

ESSNA
19th October 2004