# ESSNA

**European Specialist Sports Nutrition Alliance**

*Representing manufacturers and distributors of specialist sports nutrition products in Europe*


## ESSNA POSITION PAPER ON THE PROPOSED DIRECTIVE ON FOODS INTENDED TO MEET THE EXPENDITURE OF INTENSE MUSCULAR EFFORT, ESPECIALLY FOR SPORTS PEOPLE (UNDER PARNUTS)

### 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 previous reports on its members' response to the SCF proposals in this area and a document giving examples of how products currently being marketed by its members might fit into the proposed SCF categories.

ESSNA want to ensure that products falling under this proposed Directive are adequately defined and that the requirements do not stifle future product development emanating from evolving nutritional science.

This document gives ESSNA's position on what it wishes to be included in the proposed Directive based on changes to the Working Document (SANCO D4/HL/mm/D440182), particularly taking into account the footnotes to the text.

### Key issues:

The key issues that ESSNA wishes to have addressed in the Directive are:

1. **The ability to use Creatine at up to 5g/day for maintenance.**
2. **The ability to use Creatine at a loading dose of 20g/day for up to a maximum of 5 days.**
3. **The allowance of addition of Amino Acids to be added to Protein concentrates & Protein-enriched foods other than for improving the quality of the nutritional value of protein.**
4. **The allowance of an additional category for creatine powder products.**
5. **The allowance of an additional category to allow mixed carbohydrate/protein powder products not separately satisfying the criteria in any of the four categories listed in the Working document.**
6. **The allowance of an open category depending on a notification procedure with the notifying company retaining a file of information supporting the marketing of the product for the intended uses and its compliance with the requirements of Article 1(2) of Council Directive 89/398/EEC.**
7. **The recognition that 'banned substances' should not be included in Sports Nutrition products but that it is impractical to directly include the WADA banned substances list that may change from time to time.**
8. **The allowance of 'Performance' claims related to the functional benefit of the product, that are excluded from the controls of the proposed 'Nutrition & Health Claims Regulation'.**


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**List of proposals by ESSNA, based on the content of the working document on the proposed Directive on foods intended to meet the expenditure of intense muscular effort, especially for sports people.**

**1. Creatine maintenance dose at 5g/day (Agree with IDACE)**

The Working Document recognises the use of creatine in foods intended to meet the expenditure of intense muscular effort but proposes a limit of 3g/day. We do not believe that this recognises the benefits of creatine to physical activity nor its proven safety in use, nor does it allow for proportionately higher levels to be used according to body mass. Further supporting information is referred to in Appendix 1.

**2. Creatine loading dose at up to 20g/day for up to 5 days**

The SCF provide no scientific rationale for avoiding creatine loading, which involves consuming 10-20g of creatine daily over a period of up to 5 days. This is a popular practice with many athletes as it has a number of advantages over consuming a smaller 'maintenance dose' of 3g per day, which the SCF suggests.
Further supporting information is referred to in Appendix 1.

**3. Addition of Amino Acids**

We believe that amino acids should be allowed to be added to Protein concentrates & Protein-enriched foods other than for improving the quality of the nutritional value of protein and to any other categories defined in the Directive. For example, Glutamine may be added to improve immune support, or branch-chain amino acids to help muscle recovery after intense exercise and/or training. During very prolonged endurance amino acids may also be an important source of energy.

The SCF's review of amino acids only includes the branched chain amino acids (BCAAs) and even then only in the context of central fatigue. There is a wealth of peer reviewed literature showing beneficial effects of BCAA supplementation of relevance to exercising populations. These effects include reducing the incidence of infection, improving aspects of immune function, reducing muscle injury and increasing muscle protein accretion- vital for muscle recovery after exercise. It is of some concern that none of these important studies on BCAAs were cited by the SCF in their review. Furthermore the SCF report does not extend to other amino acids and compounds with similar properties. Such compounds include tryptophan, tyrosine, N-acetyl-cysteine, ornithine, arginine glutamine, carnitine and taurine, which can all produce beneficial effects for exercising populations. Although it is clearly not possible for the SCF to review every study on amino acids of relevance to exercise, it certainly brings into question the following directive statement, which is not acceptable.

*'The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins and only in the proportions necessary for that purpose.*

The term nutritional value is not clearly defined and is open to misinterpretation as simply meaning increasing the 'Protein quality' or 'Net Protein Utilisation' (NPU) of a protein in a product. If this is the case, there is certainly no rationale for this viewpoint and no scientific basis for this comment is presented. It is clear that individual amino acids can exert positive effects on the body in the absence of protein i.e. they can produce effects independent of changes in 'Protein quality'. One example is the ability of glutamine to increase glycogen synthesis after exercise.

Therefore, the directive should be rewritten with provision for the addition of dipeptides and any one or more of the 22 naturally occurring amino acids (and their associated metabolites). These changes should be applicable to all categories of food products, including the additional categories proposed in this document. See Appendix 2 for more details.

**4. Creatine Powder category**

There are a number of sports nutrition products on the market that provide creatine powder in bulk for addition to drinks or solid foods to improve performance.

The current working document appears to allow the addition of creatine to any of the four categories currently defined. We would propose creatine powder products as an additional product category. The compositional requirement of this category would limit the use of creatine in products to a recommended maximum daily dose of 20g/day for 5 days and a recommended maximum maintenance dose of 5g/day thereafter.

The product category would be defined as:

'Creatine bulk powder or powder sachet products containing at least 75% by weight of the creatine source and carrying a recommended maximum daily dose of 20g/day for 5 days and a recommended maximum maintenance dose of 5g/day thereafter'.

**5. Carbohydrate / protein category**

We are aware of products on the market that do not satisfy the requirements of any of the four defined categories, but are targeted directly at the Sports market and are aimed at that specific, definable group of persons with a 'disturbed metabolism' due to their sports activities.

These are products that contain carbohydrates, protein/amino acids or other macronutrients that are consumed to improve muscular physique, physical performance, recovery or other similar attributes by committed athletes, weight-lifters or sportsmen. They do not, however, fit within the criteria listed for any of the four defined carbohydrate or protein products

As the Commission has stated that it does not wish to 'upset existing markets', we would ask that it attempts to accommodate these exceptions by creating an additional category:

'Carbohydrate/protein powder mixtures containing at least 15% of available energy from protein and at least 50% of available energy from carbohydrate'.

**6. General category**

We are also concerned that a limited number of product categories based on strict compositional requirements would stifle product development in food products "intended to meet the expenditure of intense muscular activity, especially for sports people.

There are many products on the market sold specifically to sportsmen that do not meet the compositional requirements of the four categories of products given in the Annex of the proposed Directive. Some of the range of products marketed are similar to the products in the Annex and aimed at similar users, but vary in their use of

certain ingredients or have a different proportion of energy macronutrient supply. Other products are sold as Sports supplements and may be categorised as food supplements or as energy bars that have been formulated specifically for sportsmen and are better categorised as 'fortified' foods". Option a) of this note would allow the current position of existing Sports nutrition products to be catered for but may be inflexible for the accommodation of products developed in the future.

We would therefore support an option allowing an open category depending on a notification procedure with the notifying company retaining a file of information supporting the marketing of the product for the intended uses and its compliance with the requirements of Article 1(2) of Council Directive 89/398/EEC.

**7. WADA list**

We accept the need for professional competitive sportsmen to be able to identify any prohibited substances in specialist sports products but there are a number of issues related to the adoption of the WADA 'prohibited list' in dictating the contents of products intended to be controlled by this proposed Directive.

As has been the recent experience with caffeine, substances may be listed and de-listed in a relatively short time with little notice. Thus if substances on the WADA list were immediately banned for use under the proposed Directive, then stocks of product in the supply chain from manufacture to those on the shelf could become redundant or illegal and the industry would face large costs in recall and replacement. The industry therefore seeks either a single non-changeable list at the time of the publication of the proposed Directive or at least a significant [24 month] period notification of change.

**8. 'Performance' and other Claims**

Sports nutrition products contain ingredients that are included to improve or maintain performance in advance or during intense muscular activity or to expedite recovery following intense muscular activity.

These products are currently labelled with 'Performance claims' related to preparation for exercise, maximising exercise output, increasing exercise endurance and aiding recovery following exercise. These are not considered to be 'health claims' and should be allowed on products sold under this proposed Directive and excluded from the requirements of the proposed Nutrition & Health Claims Regulation.

Some nutrition and health claims are specific to sports products and a pre-approved list should be authorised by the Commission for use in PARNUTS sports products under the Nutrition and Health Claims Regulation.

**9. Product name**

We agree with the proposed name under which the products should be sold as: "dietary food/drink for physical activity".

**10. Tonicity**

We would wish "hypotonic" & hypertonic" to be used as terms to be applied to drinks below and above the "Isotonic" range.

**11. Minimum Carbohydrate in Carbohydrate-rich foods**

We agree that the minimum carbohydrate in 'Carbohydrate-rich energy food' products should be at least 60% of total energy.

**12. Minimum Carbohydrate in Carbohydrate-rich food drinks**

We agree with IDACE that the minimum carbohydrate level in carbohydrate-rich energy food drinks should be 15% of weight by volume.

**13. High Glycaemic Index**

We agree that 'High Glycaemic Index' is difficult to define and should be removed to allow other sugars such as fructose (with a low Glycaemic Index) as part of the formulation to achieve slower release of energy from the product.

**14. Maximum energy in Carbohydrate-electrolyte drinks**

We would wish to allow the maximum energy content of carbohydrate-electrolyte solutions to be up to 1100kcals/l for combined energy provision & rehydration.

**15. Osmolalities**

Osmolality influences gastric emptying which in turn affects fluid uptake. There are technical limitations to producing high energy, high sodium content, carbohydrate electrolyte solutions with protein, that have an osmolality between 200mOsml/kg and 330 mOsml/kg. However, the SCF conclude that *'The composition of the drinks and the nature of the solutes is, however of greater importance that the osmolality itself*'. For this reason, osmolality restrictions relating to the proposed categories of 'carbohydrate electrolyte and protein drinks', and 'carbohydrate electrolyte and amino acid drinks' should be removed.

**16. Minimum protein in Protein-enriched foods**

For Protein-enriched foods, we agree that there could be a minimum protein level in the food of 10g/100g as well as a minimum 25% of the total energy being provided by the protein (to prevent low-calorie products being described as 'protein enriched' when they contain insignificant levels of protein.

**Other Comments:**

The Directive refers throughout to 'intense' but not prolonged exercise. This may be acceptable as a 'catch all' term, but if it applied in a strict scientific sense it could result in some food products falling foul of the directive. Scientific terms and definitions must be used appropriately in the draft to minimise the risk of future disputes and misinterpretation.

We do not believe that it is intended that all products aimed at sportsmen by inclusion of the word 'Sport' or inclusion of sports imagery on the label or in advertising should fall under this proposed Directive. Many products are aimed at recreational sportsmen or individuals on general fitness regimes. There is a risk that all Sports products might be considered as being included in the PARNUTS category, when the framework definitions are obviously directed at a particular, identifiable group who, because of their intensity of muscular activity have a disturbed metabolism requiring the intake of certain foods.

There must be provision for the inclusion of lipids, such as medium chain triglycerides (MCTs) in carbohydrate electrolyte solutions. Inclusion of these lipids can increase energy delivery without resorting to the use of high carbohydrate concentrations, which can cause gastrointestinal problems during exercise in some individuals. Addition of MCTs can also provide the customer with very high-energy isotonic drinks. The SCF suggests that MCTs are

unlikely to improve performance and have stated that they can cause gastrointestinal cramping. However, the studies presented can be criticised at a number of levels. Firstly, the experimental designs were such that there was insufficient statistical power to observe statistically significant treatment effects. In addition, many studies used exercise tests of insufficient duration to observe an increase in performance with MCT ingestion and perhaps most importantly, none of the studies allowed a sufficiently long habituation period for any detrimental effects of MCTs to subside. After an appropriate habituation period (typically several weeks or months), athletes anecdotally report no adverse effects to high levels of MCT ingestion.

The working document relies heavily upon the Scientific Committee on Foods (SCF) report. This failed to review relevant peer reviewed placebo controlled studies on amino acids and antioxidants that were published before the SCF report. As a consequence, the authors incorrectly concluded that these compounds were not of benefit to sportsmen. The SCF is now many years out of date and a substantial body of evidence has accumulated demonstrating the effectiveness of compounds other than carbohydrates, electrolytes and creatine for sportsmen.

ESSNA
10th December 2004

## Appendix 1

## Justification for the use of Creatine at up to 5g/day and at a loading dose to a maximum of 20 g/day for up to 5 days.

Report:

A separate scientific report has been written by Dr Robert Child to justify the use of Creatine by sports persons at a maintenance dose of 5g/day and a loading dose of up to 20g/day for up to 5 days:

**Child R, (July 2004), Scientific justification for creatine maintenance and creatine loading doses proposed by ESSNA.**

Summary:

This document reviews the current state of scientific understanding regarding creatine safety. In response to creatine loading at 20g per day and long term creatine use, supplementing in excess of 5g per day for over 5 years produced no adverse health effects. A scientifically based rationale to support the use of 5g of creatine daily as a maintenance dose and evidence for creatine loading at 20g per day over 5 days is provided. These popular and safe practices are efficacious at improving both physical and mental performance and also provide some health benefits.

Author:

Dr Robert Child is CEO of the nutritional consultancy Alimentarius Ltd. He has a BSc (Hons.) in Sports Science and an MSc in human metabolic diseases. He investigated exercise and free radical induced damage to human skeletal muscle to obtain a PhD and followed this with a government funded Post Doctoral research position in human nutrition. His second Post Doc. focussed on the physiological and biochemical demands of training and the nutritional requirements of elite athletes. In addition to scientific books, his research has been published in numerous clinical, medical, physiology, nutrition and sports journals. He is currently nutritional consultant to professional football and rugby teams, and Olympic and World Championship medallists from swimming, mountain biking and sailing.

## Appendix 2

# *Scientific justification for amino acid fortification of foods to meet the needs of intense or prolonged muscular effort.*

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## Introduction

There are numerous sports nutrition products currently marketed which benefit from the addition of specific amino acids. Under proposed EU legislation such practices will 'only be permitted solely for the purpose of improving the nutritional value of the proteins and only in the proportions necessary for that purpose'. The SCF (2001) has previously reported that there is no benefit from adding specific amino acids to the diet of sportsmen. However, these conclusions were not based on a thorough review of the scientific literature available at the time, or the data which has emerged subsequent to their original report.

This document provides the scientific rationale for the addition of amino acids to foods intended to meet the needs of intense muscular effort. Three essential amino acids (leucine, isoleucine and valine) and one non-essential amino acid (glutamine) have been chosen illustrate the potential benefits of adding amino acids to sports foods. These amino acids have been chosen to provide examples of potential benefits for the athlete, which can arise from amino acid supplementation. It should certainly not be misinterpreted to mean that these are the only amino acids of benefit to the athlete, as several others have also been shown to produce effects that counter physiological and environmental stressors and directly benefit physical and cognitive performance (Banderet et al. 1989, Owasoyo et al. 1992).

## Problems of defining protein and amino acid requirements of sportsmen

Consideration of the arguments for amino acid fortification of sports foods cannot be completely understood without a rudimentary understanding of the effects of exercise on protein metabolism. The SCF (2001) recognised that exercise increases protein requirements from around 1g to 1.4g per kg bodyweight. They proposed that nitrogen balance studies provided evidence that such protein intakes were adequate for athletes. However, Millward (1999) highlighted several problems with using nitrogen balance studies to determine protein needs in the general population. These include 'the absence of satisfactory, practical, nitrogen or amino acid balance methods' and the 'lack of quantifiable, unequivocal metabolic indicators of adequacy that can validate balance measures'. Such techniques may be even less valid in athletes due to nitrogen losses in sweat and may be further confounded by the complex relationship between substrate availability and amino acid oxidation. It is also well recognised that endurance exercise increases the requirement for branched chain amino acids (BCAAs), as a consequence of preferential oxidation during physical activity (Hood and Terjung 1990, Wagenmakers 1998). It has been estimated that even when consuming protein at the upper level suggested by the SCF the dietary

provision of leucine, could be oxidised in a single exercise session (Hood and Terjung 1990). Calculations based on steady state rates of leucine oxidation at rest and during exercise indicate that the recommended daily dietary intake of leucine is inadequate, since it is lower than the measured whole body rate of leucine oxidation (Hood and Terjung 1990). These authors concluded that this inadequacy is exacerbated in individuals who are physically active and this would clearly be detrimental to health and athletic performance. The complexity of amino acid metabolism makes such arguments difficult to substantiate purely on a theoretical basis. An alternative and arguably more valid approach is to evaluate the effects of supplementation with amino acid fortified foods, on meaningful endpoints for the sportsman. These could be considered to include cognitive and exercise performance, the incidence of infection and muscle damage. If dietary amino acid intakes were adequate then no benefits would be anticipated; in contrast, studies showing benefits from supplementation although not directly demonstrating deficiency, by definition would indicate sub-optimal dietary amino acid intakes. A large number of studies have been performed supplementing sportsmen with a variety of amino acids and a brief selection relating to the BCAAs and glutamine are outlined.

**Benefits from amino acid supplementation**

The Scientific Committee on Food (SCF) reported that 'Controlled studies to improve performance by the administration of BCAA during exercise at ambient temperature all failed to demonstrate the claimed effect' (Berg et al. 2001). However the SCF did acknowledge that one study (Mittleman et al. 1998) 'observed an ergogenic effect in men and women exercising in the heat (34oC), but considered this 'an isolated finding in a special condition'. In fact, Blomstrand et al. (1991) also found improved running performance in slow marathon runners when consuming BCAA fortified drinks compared with ordinary carbohydrate electrolyte drinks. Interestingly, subjects who were provided with BCAAs also improved aspects of mental performance in response to both a marathon and a 30km cross country run; effects which were absent in the control groups (Blomstrand et al. 1991). Similarly, Hassmen et al. (1994) found cognitive performance was enhanced after a 30km cross country race by addition of BCAAs to carbohydrate drinks. During cycling exercise BCAA administration was found to lower perceived ratings of effort and fatigue (Blomstrand et al. 1997). Such changes and improvements in mental performance could clearly be beneficial for physically demanding sports with high cognitive demands, such as orienteering, sailing, cycling and football.

The SCF consider exercising in the heat (34$^{o}$C) to be a 'special condition', however it is important to remember that three of the last four summer Olympics were held at venues where temperatures regularly exceeded 34$^{o}$C (Barcelona, Sydney and Athens). Numerous sporting events conducted in central Europe between June and August also habitually expose competitors to temperatures in excess of 34$^{o}$C (e.g. Tour De France), so clearly these are not 'special conditions' for the sportsman! Therefore, in contrast the SCF's proposals it is appropriate to conclude that BCAAs can benefit sportsmen, by improving both mental and physical performance.

Recent studies have also demonstrated BCAAs can benefit exercising populations by countering the problems associated with prolonged and intense physical activity. Exercise increases tissue damage particularly to muscle (Child 1999) and BCAAs have been shown to reduce evidence of sarcolemmal injury (Coombes and McNaughton 2000), muscle protein breakdown (MacLean et al. 1994) and increase muscle protein synthesis (Blomstrand and Saltin

2001). These changes are not purely academic and are likely to be of benefit to all athletes involved in intense training, by helping to maintain muscle mass and power. Research on mountaineers (Schena et al. 1992) is consistent with this view, as BCAAs administration attenuated the decline in muscle loss and helped sustain muscle power, after three weeks trekking at altitudes of 2500 to 4000m.

Exercise increases the body's exposure to a greater number and variety pathogens and suppresses several aspects of immune function. Such effects are often manifest by the high incidence of infections in the days following strenuous physical activity (Castell et al. 1996) and this is a common phenomenon after participation in running, rowing and triathlon. Castell et al. (1996) found that glutamine supplementation reduced self reported infections in distance runners and rowers. Similarly Bassit et al. (2000) found that supplementation with BCCAs reduced the incidence of infections by 34% in triathletes. Non-supplemented controls suffered a 20% reduction in plasma glutamine levels after exercise, while those supplemented with BCAAs maintained plasma glutamine levels. Based on these findings and greater proliforative and cytokine responses following BCAA supplementation (Bassit et al. 2000), the authors concluded that these effects could be linked to the lower incidence of infection.

The gut and immune cells are also important for minimising and combating infection and achieve this using glutamine rather carbohydrate as the primary energy source (Reeds et al. 2001, Karinch et al. 2001). Under conditions of inflammation, which often arises in response to damaging exercise (Child 1999) and/or infection, glutamine availability can become rate limiting for key functions, such as phagocytosis and antibody production (Karinch et al. 2001). Supplementation with the non-essential amino acid glutamine has been shown to reduce the incidence of infections in athletes (Casell et al. 1996, Castell and Newsholme 1997). This could be considered surprising, as this amino acid can easily be synthesised in humans using BCAAs as precursors (Bassit et al. 2000, Wagenmakers 1998). However, for reasons which remain to be elucidated, glutamine levels fall after prolonged exercise and this event appears to increase susceptibility to infection (Bassit et al. 2000). Supplementation with BCAAs for several days, or acute glutamine supplementation, can maintain plasma glutamine levels after exercise and reduce infections (Bassit et al. 2000, Castell and Newsholme 1997).

## Summary

There is clearly evidence demonstrating that additional provision of BCAAs and glutamine can benefit health and performance in athletes. This finding should not be considered unique and similar evidence could also be provided for a variety of other amino acids. As such, it is appropriate for manufacturers to add amino acids to sports nutrition products to provide benefits for exercising populations.

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