COMMISSION OF THE EUROPEAN COMMUNITIES

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Working Document for

Draft

COMMISSION DIRECTIVE

on foods intended to meet the expenditure of intense muscular effort, especially for sports people

(Text with EEA relevance)
EXPLANATORY MEMORANDUM


2. On the basis of the opinion adopted by the Scientific Committee on Food (SCF) on 22 June 2000 (Report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. Adopted by the SCF on 22/6/2000, corrected by the SCF on 28/2/2001)) it is appropriate to lay down detailed compositional rules for the certain groups of foods with nutrient adaptation to meet the particular requirements associated with expenditure of intense muscular effort, especially for sports people.

3. The benefits of foods intended to satisfy the requirements associated with intense muscular effort can be useful not only for the sports people who are taking regular prolonged muscular exercise but also for other groups of the population, for example people in occupational jobs with hard physical work or extreme environmental conditions (people in the armed forces, miners, and mountaineers), as well as for people with irregular high intensity physical activities or fatiguing leisure activities.

4. The SCF note that a well-balanced diet is the basic nutritional requirement for athletes. However, aspects of physical activity (intensity, duration and frequency) and constraints of time mean there can be benefit from foods for particular nutritional purposes to satisfy the requirements associated with intense muscular effort. The increased energy needs of athletes are the most obvious difference in their nutritional requirements so their food intake is usually increased. This can affect food choice and eating patterns as well as having gastrointestinal effects.

5. Foods which give an increase in fluid, energy or nutrient availability in a short period of time can help to optimise performance directly or indirectly, through improved rate of recovery from intense muscular effort. Specially adapted nutritious foods or fluids which are easily digestible and rapidly absorbable may be useful to overcome the difficulty of providing high energy intakes when digestion and absorption can be impaired because of the intense muscular effort.

6. The metabolic capacity and power output of muscles depend on the energy source used. Maximal muscle performance depends almost entirely on carbohydrate as a substrate. People who take part in physical activity that involves intense muscular activity but who have low energy intakes need adequate carbohydrate intake to replace the carbohydrate used during the physical activity.
7. The scientific review of the SCF began in 1998. The report was published in 2000 and assessed the scientific evidence available at the end of 1990s relating to the particular nutritional requirements associated with activities involving intense muscular effort. At the time of the SCF review the following types of specific foodstuffs for sports people were on the market: rehydration drinks; energy drinks or energy powders and tablets; protein concentrates; supplements with specific vitamins, minerals and trace elements, and supplements with other substances such as creatine, choline and antioxidants; and, sports bars or meal replacement products.

8. On the basis of the available scientific evidence and the food products on the market at the time the SCF evaluated four groups of products intended to meet the particular nutritional requirements associated with the expenditure of intense muscular effort:

- carbohydrate-rich energy food products;
- carbohydrate-electrolyte solutions;
- protein and protein components; and,
- supplements – containing essential nutrients or other food components.

9. The SCF report indicates that the effect of high carbohydrate intake on physical performance has been extensively studied. The nutritional strategies to prepare for participation in and recovery from sport and exercise can be divided into pre-exercise meals, food intended to be consumed during exercise and food intended to be consumed after exercise. In terms of pre-exercise meals the method of “carbohydrate loading” during the week prior to competition is to gradually reduce the level of training during the week and to increase the carbohydrate intake to 9-10 grammes of carbohydrate per kilogramme bodyweight per day during the last days before the competition. It is possible to eat during participation in only a few sports. Easy to digest carbohydrate snacks or carbohydrate-electrolyte solutions are often eaten during such events. Regarding nutrition to aid recovery following exercise the SCF noted that research showed that a high carbohydrate diet during the post exercise period restored endurance performance during subsequent exercise. Therefore, carbohydrate-rich energy food products are useful when an athlete has a limited period of time for recovery between periods of prolonged physical activity.

10. With respect to carbohydrate-electrolyte solutions the SCF explain that the two factors that have been considered to contribute most to the onset of fatigue in exercise are the depletion of the body’s carbohydrate reserve and the onset of dehydration. The SCF report indicates that compared to water during prolonged physical activity drinks containing carbohydrates and electrolytes improve performance. However, the optimum carbohydrate concentration depends on a number of factors, among others the need for water and the intensity and type of exercise, intestinal absorptive capacity, osmolarity and type of carbohydrates. High carbohydrate concentrations delay gastric emptying, reducing the amount of fluid that is available for absorption but increasing the rate of carbohydrate delivery. The SCF advised an energy range of 80-350 kilocalories per litre for carbohydrate-electrolyte solutions with at least 75 % of energy provided by carbohydrate. The SCF noted that the addition of sodium stimulates carbohydrate and water uptake and helps to
maintain extracellular fluid volume and they recommended a minimum level of sodium in such products.

11. The SCF noted that endurance athletes have a modest increase in protein requirements. The Committee considered that a diet containing 10-11% energy from protein would meet the protein requirements of athletes who have an increased energy requirement. The SCF noted, however, that the increased requirement for protein might not be met if the total energy intake is relatively low. The SCF made recommendations for the protein content of protein concentrates and protein enriched foods.

12. The SCF noted that with an adequate dietary intake there is no need for additional essential micronutrients. Although in the case of restricted food intake, as seen in weight related sports, micronutrient intake could become marginal or deficient and under certain circumstances some athletes may not be able to reach their daily micronutrient requirements during periods of regular training. The SCF conclude that scientific evidence was lacking or inconsistent in supporting recommendations for nutrient intakes beyond population reference intakes.

13. The SCF reviewed a number of food components that had been related to physical performance; caffeine, creatine, carnitine, medium-chain triglycerides and branch chain amino acids. The SCF considered that there was scientific data of an ergogenic effect for only caffeine and creatine.

14. In a separate opinion adopted on 7 September 2000 the SCF reviewed the safety aspects of creatine supplementation (Opinion of the Scientific Committee on Food on safety aspects of creatine supplementation. (Adopted on 7 September 2000)). The Committee noted that certain intakes of creatine are effective in increasing total muscle creatine and improving performance of short term high intensity exercise. The SCF recommended that high loading doses of creatine should be avoided. On the basis of this opinion it is appropriate that products containing added creatine should have detailed instructions for use.

15. The proposed rules would contribute to a high level of protection of consumer interests by ensuring that the foods marketed as satisfying the particular nutritional requirements associated with expenditure of intense muscular effort have an appropriate composition, are safe and labelled in an adequate and clear manner, allowing consumers to make informed choices.

Note

The World Anti-Doping Agency (WADA) was established in 1999. Its mission is to promote and co-ordinate at international level the fight against doping in sport in all forms. WADA co-operates with intergovernmental organisations, governments, public authorities and other public and private bodies fighting against doping in sport. WADA is entitled to make proposals to the Olympic Movement, to international sports organisations and to public authorities on measures that could be taken to ensure further harmonisation and equity in anti-doping questions.

In 2003 WADA published the World Anti-doping Code (World Anti-Doping Agency, The World Anti-Doping Code, March 2003). The Code refers to the “Prohibited list” which includes a list of prohibited classes of substances whose use is regulated or proscribed in sport, in particular sports associated with the Olympic Movement. The list is published in
January each year and updated as necessary, the last updated list was published on 17 March 2004 and it came into effect on 26 March 2004.

The Commission considers that foods intended to satisfy the specific nutritional requirements associated with intense muscular effort, especially for sports people, should not contain prohibited substances included in the WADA prohibited list. However, the way to effectively ban such substances by a Commission Directive is not obvious. The compilation of such a list by the Commission is not considered possible at this stage. Whilst it is not possible to introduce in EU legislation a prohibition on the addition of substances on a list which is not under EU legislative control.

Member States are invited to consider this issue and views on the possible ways forward would be welcome.
COMMISSION DIRECTIVE

on foods intended to meet the expenditure of intense muscular effort, especially for sports people

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,


After consulting the European Food Safety Authority,

Whereas:

(1) Foods intended to meet the expenditure of intense muscular effort should meet the particular nutritional requirements of people who participate in activities that involve intense muscular effort, in particular professional sports people but also other people for example those in the armed forces, mountaineers, and manual workers such as miners. Such products may also be used by individuals who participate in activities that involve intense muscular expenditure during their leisure time.

(2) The foods covered by this Directive are intended to be consumed in addition to or as a partial substitute for a normal diet.

(3) The opinions adopted by the scientific advisory body concern foods intended to satisfy the particular nutritional requirements associated with intense muscular activity, namely carbohydrate-rich energy foods, carbohydrate-electrolyte solutions, protein concentrates and protein enriched foods. (Report of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. Adopted by the SCF on 22/6/2000, corrected by the SCF on 28/2/2001 and the Opinion of the Scientific Committee on Food on safety aspects of creatine supplementation. (Adopted on 7 September 2000.).)

(4) Given the nature of these products it is appropriate to lay down detailed compositional rules for foods with nutrient adaptation to meet the particular requirements associated with expenditure of intense muscular effort, especially for sports people.

(5) The scientific advisory body noted that certain levels of intakes of creatine could have an impact on certain types of exercise, however, it considered that high
loading doses of creatine should be avoided. It is appropriate that labelling
requirements for food products containing added creatine covered by this
Directive should be introduced.

(6) Pursuant to Article 7 of Directive 89/398/EEC, the products covered by that
Directive are subject to the general rules laid down in Directive 2000/13/EC of
the European Parliament and of the Council on the approximation of the laws of
the Member States relating to the labelling, presentation and advertising of
foodstuffs. The present Directive adopts and expands upon the additions and
exceptions to those general rules, where appropriate. (OJ L 109, 6.5.2000, P. 29. as

(7) In particular, in view of the nature and destination of foods intended to meet the
expenditure of intense muscular effort it is necessary to provide information
concerning the energy value and principal nutrients contained in such foods and,
where appropriate, the origin and nature of the protein and/or protein hydrolysates
and the osmolality or osmolarity.

(8) Electrolyte solutions that are “isotonic” have specific characteristics, therefore, it
is appropriate to specify certain criteria for the use of the term if it is included in
the labelling of these products.

(9) In accordance with the principle of proportionality, it is necessary and appropriate
for the achievement of the basic objective of approximating the laws of the
Member States relating to foodstuffs intended for particular nutritional uses to lay
down rules on foods intended to meet the expenditure of intense muscular effort,
especially for sports people. This Directive does not go beyond what is necessary
in order to achieve the objectives pursued in accordance with the third paragraph
of Article 5 of the Treaty.

(10) The measures provided for in this Directive are in accordance with the opinion of
the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 4 (1) of Directive
89/398/EEC and lays down compositional and labelling requirements for foods intended
to meet the expenditure of intense muscular effort as defined in Article 2 (1) and
presented as such.
Article 2

1. For the purpose of this Directive, the following definition shall apply:

“foods intended to meet the expenditure of intense muscular effort” means a category of foods for particular nutritional uses specially processed or formulated and intended to meet the nutritional requirements for the expenditure of intense muscular effort, including but not limited to requirements associated with sporting activities.

2. Foods intended to meet the expenditure of intense muscular effort are classified in the following four categories: See note 1

(a) carbohydrate-rich energy food products with a specific nutrient adapted formulation to meet the particular energy requirements associated with the expenditure of intense muscular effort;

(b) carbohydrate-electrolyte solutions with a specific nutrient adapted formulation to meet the particular energy and electrolyte requirements associated with maintaining

Note 1 – The SCF evaluated the scientific evidence on the nutritional requirements for the expenditure of intense muscular effort and considered the specific food products that existed on the market at the end of the 1990s. The SCF recommended specific compositional requirements for 4 categories of foodstuffs. The SCF noted that the scientific evidence supported an ergogenic effect of caffeine and creatine but no specific compositional requirements were specified in their report for such products.

During the last few years there have been further developments in the area of products intended for use before, during and after sporting activities. For example there are now drinks intended for sports people specifically designed for hydration but with an energy content of less than 80 kcal/l. In addition, interested parties have asked for clarification of the situation of other product categories such as supplements, weight gain or body building powders and meal replacements with respect to the Directive.

The additional categories of products that need to be considered are not well defined. There are two options to include other categories of products in the scope of the Directive:

a) With the involvement of stakeholders the different categories that exist on the market at the present time could be described. The European Food Safety Authority could then be asked to give a scientific opinion on the specific compositional requirements for the different categories that have been identified.

b) The Directive could include a category of products that would be open and that would allow existing products and new products to be marketed subject to a notification procedure. When placing a product on the market the manufacturer or importer of a product would notify the competent authority of the Member State by forwarding a model of the label used for the product. The manufacturer or importer would be expected to keep a file supporting the marketing of the product for the intended uses as they could be required to produce for the competent authority the scientific work and the data establishing the product’s compliance with the requirements of Article 1 (2) of Council Directive 89/398/EEC.
hydration before and during the expenditure of intense muscular effort or restoring hydration after the expenditure of intense muscular effort;

(c) protein concentrates with a specific nutrient adapted formulation to meet the particular nutritional requirements for protein associated with the expenditure of intense muscular effort;

(d) protein enriched foods with a specific nutrient adapted formulation to meet the particular nutritional requirements for protein associated with the expenditure of intense muscular effort;

Article 3

Member States shall ensure that the products referred to in paragraphs 1 and 2 of Article 2 may be marketed within the Community only if they conform to the definition and rules laid down in this Directive.

Article 4

1. The formulation of foods intended to meet the expenditure of intense muscular effort shall be based on sound nutritional principles. Their use, in accordance with the manufacturer’s instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.

2. Products referred to in points (a) to (d) of Article 2 (2) shall comply with the compositional criteria specified in the Annex.

Article 5

1. The name under which products covered by this Directive are sold shall be “dietary food for physical activity” or, if appropriate, “dietary drink for physical activity”. If the product is intended to satisfy the nutritional requirements associated with a specific type of physical activity then the type of physical activity may be also included in the name of the product. Where the physical activity is associated with a sport then the name of the sport for which the product is intended may be indicated in association with the name of the product.
2. The labelling shall bear, in addition to those provided for in Article 3 of Directive 2000/13/EC, the following mandatory particulars:

a) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or 100 ml of the product ready for use in accordance with manufacturer’s instructions. This information may in addition be provided per serving as quantified in the label or per portion, provided that the number of portions contained in the package is stated;

b) for products specified in points (c) and (d) of Article 2 (2) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product;

c) for creatine and products with added creatine detailed instructions for use shall be provided. Such instructions shall result in intakes of not more than 3 g per day;

d) where appropriate, information on the osmolality or the osmolarity of the product.

3. The following description may be included in the labelling of drinks according to their osmolarity:

- drinks with an osmolality not less than 270 mOsm/kg water and not greater than 330 mOsml/kg water may be described as “isotonic” or an equivalent description.

4. The labelling shall bear instructions for the appropriate preparation, the use and the storage of the product after opening of the container, as appropriate.

Article 6

1. Member States shall permit trade in products which comply with this Directive from [...] at the latest.

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Note 2 – Interested parties have requested that the maximum permitted level of regular creatine supplementation be 5g/day with the possibility for higher levels during periods of creatine loading.
2. Member States shall prohibit trade in products which do not comply with this Directive from […] at the latest.

Article 7

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by […] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 8

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 9

This Directive is addressed to the Member States.

Done at Brussels, […]

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*Note* 3 – The SCF report proposed the term “isotonic” may be applied to products with an osmolality of 270 – 330 mOsm/l kg water. The need to define criteria of terms for drinks with other ranges of osmolalities may need to be considered.
ESSENTIAL COMPOSITION OF FOODS INTENDED TO MEET THE EXPENDITURE OF INTENSE MUSCULAR EFFORT

Note - The specifications refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

CARBOHYDRATE-RICH ENERGY FOOD PRODUCTS

1. Products referred to in point (a) of Article 2 shall contain:

Carbohydrate: Carbohydrates shall provide at least 75 % of total energy See note 4

in the case of drinks the product must have a carbohydrate concentration of at least 10 % of weight by volume See note 5 and, metabolisable carbohydrates See note 6 shall provide at least 75 % of total energy.

If vitamin B₁ (thiamin) is added, the product shall contain at least 0.2 mg vitamin B₁ per 100 g carbohydrates.

Note 4 – Interested parties have suggested that the minimum energy from carbohydrate should be 60 % or 65 %. They indicate that in addition to carbohydrate the raw materials used in the manufacture of solid food products contain protein and lipids that make it difficult to meet the minimum threshold of 75 % energy form carbohydrate. They also suggest that this threshold will reduce the range of acceptable, palatable products for sports people.

Note 5 – Interested parties have suggested that the minimum level of carbohydrate in carbohydrate-rich energy drinks should be greater than 10 % weight by volume. They suggest that a higher level of carbohydrate would enable the drink to provide more energy rather than optimal fluid replacement. They suggest that the minimum carbohydrate content should be 15 % weight by volume or should be at least 50% greater than standard soft drinks and juices which contain 10-12 % weight by volume carbohydrate.

Note 6 – The SCF proposed that the carbohydrate source should be metabolisable carbohydrate characterised by a high glycaemic index and gave as examples glucose, glucose polymers and sucrose. It should be noted that the definition of a “high” glycaemic index carbohydrates and the control of it in food products, if it were to be specified in a legal provision, would pose numerous problems. In addition, the characterisation of carbohydrates by high glycaemic index excludes fructose and interested parties have indicated fructose has been shown to be useful in foods intended for sports people.
CARBOHYDRATE-ELECTROLYTE SOLUTIONS  See note 7

2. Products referred to in point (b) of Article 2 shall contain:

**Energy:** The energy content shall be at least 340 kJ/l (80 kcal/l) See note 8 and not greater than 1488 kJ/l (350 kcal/l) See note 9.

**Carbohydrate:** Metabolisable carbohydrates shall provide at least 75 % of total energy. See note 10

**Sodium:** The sodium content shall be at least 20 mmol/l (460 mg/l) as sodium ions (Na\(^+\)) See note 11 and not greater than 50 mmol/l (1150 mg/l) as sodium ions (Na\(^+\)).

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**Note 7** – The SCF discusses carbohydrate-electrolyte solutions which are intended for rehydration. However there exists on the market today a range of drinks produced to satisfy particular needs associated with intense muscular activity. Interested parties have suggested that 3 electrolyte solutions should be included in the Directive:

a) Carbohydrate-electrolyte solutions: designed to provide optimal hydration and carbohydrate energy before, during and after the expenditure of intense muscular effort. It has been suggested that these products may provide energy between 80-350 kcal/l and contain 20-50 mmol sodium/litre.

b) Low calorie carbohydrate-electrolyte solution: designed to provide optimal hydration before, during an after the expenditure of intense muscular effort. It has been suggested that these products could provide a more limited amount of energy between 60-100 or 200 kcal/l and contain 20-50 mmol sodium/litre.

c) Electrolyte solutions: designed to provide fluid and electrolytes for thirst quenching, general hydration and help to top up the electrolytes lost in sweat, before, during and after the expenditure of intense muscular effort. It has been suggested that these could be energy free or have a minimum energy content of 60 kcal/l and contain 6.5-20 mmol sodium/litre.

**Note 8** – As indicated in note 7, it has been suggested that the minimum energy content of drinks should be lower to permit specially adapted drinks to be produced which promote hydration but which are not calorific for use by individuals who are being physically active to help reduce their weight or for individuals who need to maintain a relatively low body weight. Certain interested parties have suggested that the electrolyte solutions might be energy free whilst others have proposed a minimum energy content of carbohydrate-electrolyte solutions of 60 kcal/l.

**Note 9** – It has been suggested that the maximum energy content should be up to 1100 kcal/l as the maximum of 350 kcal/l is too low for recovery drinks formulated for both energy provision and hydration.

**Note 10** – There are some carbohydrate-electrolyte solutions that contain peptides, amino acids, or triglycerides and may contain less than 75 % of energy from metabolisable carbohydrates.

**Note 11** – The SCF report noted that carbohydrate electrolyte solutions should contain 460-1150 mg (20-50 mmol) sodium/l. Interested parties have indicated that there are products on the
Osmolality: The osmolality shall be at least 200 mOsml/kg water and not greater than 330 mOsml/kg water. See note 12

market that are specially formulated for general hydration rather than optimal hydration and can help top up electrolytes lost in sweat. Such products have a sodium content of 150-460 mg (6.5-20 mmol) sodium/l which interested parties have indicated will help avoid hyponatraemia.

Note 12 – The Commission services has interpreted the SCF report comment on osmolalities of carbohydrate-electrolyte drinks as being an essential requirement. The wording of the SCF report is not clear on this point and it states that carbohydrate electrolyte solutions “…may be formulated to cover a range of osmolalities between 200 and 330 mOsml/kg water.”. It is not clear if the wording means that the stated range of osmolalities is an essential requirement for carbohydrate-electrolyte drinks or is optional.

Interested parties have requested that the osmolality of electrolyte solutions should not be specified in the Directive.
**PROTEIN CONCENTRATES**

3. Products referred to in point (c) of Article 2 shall contain:

**Protein content:** At least 70 % of dry matter shall be protein.

**Protein quality:** The Net Protein Utilisation (NPU) should be at least 70 %. See note 13

If vitamin B₆ is added the product shall contain at least 0.02 mg vitamin B₆ per g protein.

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.

See note 14

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**Note 13** – In the SCF report on the revision of the essential composition of infant formulae and follow-on formulae it was proposed that protein quality should not be based on Net Protein Utilisation. In the report it is proposed that protein quality should be based on the chemical index or amino acid score of a protein in comparison with a reference protein.

**Note 14** – Interested parties have suggested that addition of amino acids should also be permitted for reasons other than improving the nutritional value of protein, for example for ergogenic and performance improving reasons. In addition, they have indicated that in certain circumstances when carbohydrates are in short supply amino acids may be used as a source of energy and that some amino acids are used more heavily so some deficiency may occur. It has been suggested that there should also be provision for the addition of dipeptides.
**PROTEIN ENRICHED FOODS**

4. Products referred to in point (d) of Article 2 shall contain:

**Protein content:** At least 25\% of total energy shall be from protein. See note 15

**Protein quality:** The Net Protein Utilisation (NPU) shall be at least 70\%. See note 13

If vitamin B\(_6\) is added the product shall contain at least 0.02 mg vitamin B\(_6\) per g protein.

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. See note 14

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**Note** 15 – The criteria of 25\% of energy from protein could mean that low calorie products that provide nutritionally insignificant amounts of protein could be described as a “protein enriched food”.

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16