TECHNICAL REPORT

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Scientific and technical assistance on food intended for sportspeople

European Food Safety Authority

Abstract

The European Commission asked the European Food Safety Authority (EFSA) to compile existing scientific advice in the area of nutrition and health claims and Dietary Reference Values for adults that is relevant to sportspeople and to inform the Commission on how such scientific advice relates to the different conclusions and specifications of the report of the Scientific Committee on Food (SCF) of 2001 on the composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportspeople. The scientific advice provided by the SCF and the subsequent scientific advice of EFSA do not differ regarding: a) the essential role of carbohydrate intake in relation to physical performance, and particularly in relation to the recovery of normal muscle function after strenuous exercise, and the role of vitamin B1 on carbohydrate metabolism; b) the role of hydration and carbohydrate supply in the maintenance of physical performance during endurance exercise, as well as on the role of electrolytes (particularly sodium) in the maintenance of adequate hydration during exercise and in post-exercise re-hydration; c) the essential role of protein in the growth and maintenance of muscle mass, and the role of vitamin B6 in protein metabolism; d) the essential role of micronutrients and long-chain polyunsaturated fatty acids on body functions which may impact either athletic performance or specific health risks for athletes; e) the ergogenic properties of caffeine in endurance exercise; and f) the ergogenic effects of creatine in physical performance during short-term, high-intensity, repeated exercise bouts (i.e. in sports that require explosive, high-energy output activities especially of a repeated nature). In addition, EFSA completed the task of establishing Tolerable Upper Intake Levels for vitamins and minerals initiated by the SCF and provided advice on the safety of caffeine, also when consumed prior to intense physical exercise.

Key words: essential nutrients, ergogenic aids, sports, physical activity, physical performance, safety

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Summary

In accordance with Article 31(1) of Regulation (EC) No 178/2002, the European Commission asked the European Food Safety Authority (EFSA) for scientific technical assistance on food intended for sportspeople. More specifically, EFSA was requested to compile the outcomes of scientific advice in the area of nutrition and health claims and Dietary Reference Values (DRVs) for adults that is relevant to sportspeople and that was provided by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) to the Commission after the adoption of the report of the Scientific Committee on Food (SCF) on the composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportspeople. EFSA was also requested to inform the Commission on how such scientific advice relates to the different conclusions and specifications of the SCF report.

All published Scientific Opinions of the EFSA NDA Panel in the area of health claims were screened to identify scientific evaluations of Art. 13(1) claims or claim applications under Art. 13(5) or Art. 14 of Regulation (EC) No 1924/2006 for which:

- the target population was either active individuals in the general population or subjects performing physical exercise, and/or
- the claimed effect was related to aspects of exercise performance, such as: i) physical performance, endurance capacity, endurance performance, muscle mass, muscle strength, lean body mass; ii) muscle fatigue, water absorption, or the rated perceived exertion/effort during exercise; iii) recovery from muscle fatigue, restoration of muscle glycogen stores, and skeletal muscle tissue repair after exercise; iv) energy-yielding metabolism;
- the claimed effect was related to certain health risks for athletes, such as: i) upper respiratory tract infections, ii) exercise-induced inflammation, iii) oxidative stress, iv) joint function.

All published Scientific Opinions of the EFSA NDA Panel in the area of DRVs (for energy, water, macronutrients and micronutrients), including Scientific Opinions on Tolerable Upper Intake Levels (ULs) for nutrients, were also reviewed in order to gather relevant information for the present report.

The scientific advice provided by the SCF and subsequent scientific advice of the EFSA NDA Panel do not differ regarding:

- the essential role of carbohydrate intake in relation to physical performance, and particularly in relation to the recovery of normal muscle function after strenuous exercise, and the role of vitamin B1 (thiamine) on carbohydrate metabolism;
- the role of hydration and carbohydrate supply in the maintenance of physical performance during endurance exercise, as well as on the role of electrolytes (particularly sodium) in the maintenance of adequate hydration during exercise and in post-exercise re-hydration;
- the essential role of protein in the growth and maintenance of muscle mass, and the role of vitamin B6 (pyridoxine) in protein metabolism;
- the essential role of micronutrients and long-chain polyunsaturated fatty acids on body functions which may impact either athletic performance or specific health risks for athletes;
- the ergogenic properties of caffeine in endurance exercise; and
- the ergogenic effects of creatine in physical performance during short-term, high-intensity, repeated exercise bouts (i.e. in sports that require explosive, high-energy output activities especially of a repeated nature).

Whereas the SCF referred specifically to the quality of glycaemic carbohydrates (i.e. with a high glycaemic index) when advising on the composition and specifications of carbohydrate-rich foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, the conditions of use for the claim evaluated by EFSA were established for all glycaemic carbohydrates. The reason is that claim related to the role of all glycaemic carbohydrates on the recovery of normal muscle function (contraction) after strenuous exercise and not to the relative efficacy of different types of glycaemic carbohydrates in achieving the claimed effect, and therefore this aspect was not assessed by the NDA Panel. A health claim application on a combination of glucose and fructose and improves performance

in active individuals performing endurance exercise compared to the intake of glucose alone was submitted to EFSA and then withdrawn during the evaluation.

The two bodies concluded that protein requirements of athletes could be covered by established dietary guidelines, since higher energy needs would result in higher protein intakes on a body weight basis if the protein contribution to total energy intake is kept at about 10–12 %. Neither the SCF nor the EFSA NDA Panel considered that particular protein sources or protein components could have a beneficial effect for athletes on muscle mass or performance beyond what could be expected from high quality protein or protein in mixed diets.

Neither the SCF nor the EFSA NDA Panel considered that athletes may have specific requirements for micronutrients or n-3 LC-PUFA (e.g. beyond the requirements established for the general population), or that athletes would benefit from supplementation with these nutrients. The only health claim related to essential micronutrients specifically addressed to sportspeople (and not to the general population) which was evaluated by the Panel with a positive outcome related to vitamin C and the function of the immune system during and after intense physical exercise. Higher doses of vitamin C (beyond the Population Reference Intakes) were considered by the EFSA NDA Panel to be required for such benefit. The task of establishing ULs (or safe levels of intake) for vitamins and minerals initiated by the SCF has been already completed by EFSA and may serve as guidance to judge whether the intake of high levels of some vitamins and minerals through supplementation, a practice that is particularly popular among athletes, may pose a risk to health.

Whereas the SCF considered that caffeine ingestion prior to exercise enhanced performance in short-term intense exercise lasting approximately five minutes, the EFSA NDA Panel found no convincing evidence for such an effect. The safety of caffeine consumption in conjunction with intense physical exercise, which was not evaluated by the SCF, was considered in an EFSA opinion following a request from the European Commission during the process of authorisation of health claims on caffeine and physical performance.

The SCF warned about consuming creatine in hot conditions prior to exercise and notes the lack of robust data regarding the safety of long-term creatine supplementation, particular at doses higher than recommended. The EFSA NDA Panel did not assess the safety of long-term creatine supplementation because safety assessments are not foreseen in the framework of Regulation (EC) No 1924/2006 and no safety concerns were raised by risk managers regarding the long-term supplementation with creatine at doses of 3 g per day in the health claim authorisation process.

Neither the SCF nor the EFSA NDA Panel found a solid basis for the use of other food constituents as nutritional ergogenic aids to meet the expenditure of intense muscular effort and especially for sportspeople.

Whereas the SCF only considered health risks for athletes in relation to the intake of essential nutrients, EFSA assessed several health claims on the relationship between food constituents other than essential nutrients and health outcomes which have been linked to specific health risks for athletes, including the reduction of the risk of URTI, the reduction of systemic inflammation, the protection of cells and molecules against oxidative damage, and the maintenance of normal joints. All these claims have been evaluated by EFSA with negative outcomes. The target population for the majority of these claims was the general population. Physically active subjects or subjects performing sports were only mentioned specifically within the target population of claims on glucosamine and collagen hydrolysate and maintenance of normal joints.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Background

Food intended for sportspeople before Regulation (EU) No 609/2013

Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (so called "dietetic foods") lays down general rules on such foods. Their special composition or manufacturing process are clearly distinguishable from foodstuffs for normal consumption, are suitable for their claimed nutritional purposes and are marketed in such a way as to indicate such suitability.

The Directive foresaw that specific provisions should be adopted by the Commission for certain categories of dietetic foods (listed in Annex to the Directive) and established a notification procedure for other foods not listed in the Annex that complied with the definition.

One category for which the Directive foresaw adoption of specific rules was that of foods intended to meet the expenditure of intense muscular effort, especially for sportspeople. With a view to establishing specific provisions for this category of food, the Commission asked the Scientific Committee on Food to issue a report, adopted in 2001, on "the composition and specification of foods intended to meet the expenditure of intense muscular effort, especially for sportsmen" (hereinafter SCF report of 2001).

The SCF report of 2001 concluded that "the concept of a well-balanced diet is the basic nutritional requirement for athletes. Nevertheless, taking the aspects of intense muscular exercise in consideration such as intensity, duration and frequency as well as specific constraints like time and convenience, individuals can benefit from particular foods or food ingredients beyond the recommended dietary guidelines for the general population. As the increased energy need of these individuals is the most apparent difference, the food intake is higher. This can lead to differences in food choice and eating pattern as well as gastro-intestinal distress. Specially adapted nutritious foods or fluids may help to solve specific problems so that an optimal nutritional balance can be reached."

In the context of the SCF report, four food categories were identified, and, where applicable, essential compositional requirements were proposed.

The SCF report of 2001 also stressed that the "report is dealing with the physiological needs and appropriate uses of food and food ingredients to meet the expenditure of intense muscular effort. The safety aspects of high level of intake of certain compounds (…) are not taken into consideration".

On the basis of the SCF report of 2001, the Commission services carried out work to prepare specific provisions as requested by Directive 2009/39/EC. However, minimal progress was achieved and no specific legislation could be adopted due to divergent views amongst the Member States and stakeholders.

In the absence of such specific legislation, certain products intended for sportspeople may have been considered as dietetic food, under the framework applicable to dietetic foods, or marketed as "normal" food and, therefore, covered by other pieces of EU legislation, in particular those on food supplements, fortified foods, and nutrition and health claims. Meanwhile, EFSA provided scientific advice that is relevant to sportspeople in the context of the implementation of the above-mentioned legislations (e.g. in the evaluation of health claims on specific food constituents of interest to sportspeople) or in the context of other Commission's requests for scientific opinions such as for nutrition and food safety (e.g. the work on dietary reference values for energy, water, macronutrients and micronutrients or on the safety of caffeine).

The classification mentioned above is under Member States' responsibility, giving rise to divergent approaches that may have led to difficult situations on whether a specific food product had to be considered as a dietetic food intended for sportspeople, or as a fortified food/food supplement with a health claim targeting sportspeople. One of the objectives of the new legislative framework, set by Regulation (EU) No 609/2013, is to clarify this issue.

Regulation (EU) No 609/2013

With the evolution of the food market and EU food law, an increasing number of food products were developed to cater for the needs of specific population's sub-groups. Food marketed under the dietetic food legislation may have been questioned for its classification, as the "sub-group concept" might have been used inappropriately. Therefore, it has been considered necessary to review and clarify the scope of the dietetic food legislation.

Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (hereinafter FSG Regulation) repeals the framework of Directive 2009/39/EC and abolishes the concept of dietetic foods. It foresees that specific requirements should only be maintained for a limited number of product categories for which such requirements are needed.

The FSG Regulation does not include in its scope food intended for sportspeople. Nevertheless, its Article 13 requires the Commission to further assess the issue and to present a report "after consulting the Authority (…) to the European Parliament and to the Council (…) on the necessity, if any, of provisions for food intended for sportspeople. Such a report may, if necessary, be accompanied by an appropriate legislative proposal."

Recital 33 of the FSG Regulation further explains that "The consultation of the Authority should take into account the report of 28 February 2001 of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. In its report, the Commission should, in particular, evaluate whether provisions are necessary to ensure the protection of consumers."

In order to comply with the above-mentioned requirement of the FSG Regulation, the Commission requests EFSA to provide scientific assistance on foods intended for sportspeople in line with the terms of reference specified below.

Terms of reference

In accordance with Article 31(1) of Regulation (EC) No 178/2002, the European Commission asks EFSA for scientific technical assistance on food intended for sportspeople. More specifically, the Commission requests EFSA to:

- compile the outcomes of scientific advice that is relevant to sportspeople and was provided to the Commission after the adoption of the Report of the SCF on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportspeople, in particular in the area of nutrition and health claims and dietary reference values (DRVs) for adults; and
- inform the Commission on how such scientific advice relates to the different conclusions and specifications of the SCF report.

1.2. Interpretation of the Terms of Reference

EFSA interprets the Terms of Reference as a request to:

- compile the outcomes of scientific advice provided by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) to the European Commission in the areas of health claims made on food and Dietary Reference Values (DRVs) that is relevant to sportspeople; and
- compare the scientific advice provided by the SCF in 2001 regarding the composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportspeople, with the scientific advice provided by the EFSA NDA Panel in this area.

2. Data and Methodologies

2.1. Data

- The SCF report on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen, published in 2001 (SCF, 2001)

- Scientific Opinions of the EFSA NDA Panel in the area of health claims made on food and DRVs which have addressed:
  - specific nutritional requirements of athletic training and intense muscular effort
  - the impact of nutrients and other substances on energy-yielding metabolism, muscle function and physical performance;
  - the impact of nutrients and other substances on adverse effects associated to athletic training and intense muscular effort.
- Scientific Opinions of the EFSA NDA Panel which have addressed safety aspects of nutrients (Tolerable Upper Intake Levels), or the safety of non-nutrient food constituents proposed as ergogenic aids.

2.2. Methodologies

All published Scientific Opinions of the EFSA NDA Panel in the area of health claims were screened to identify scientific evaluations of Art. 13(1) claims or of claim applications under Art.13(5) or Art.14 of Regulation (EC) No 1924/2006 for which:

- the target population was either active individuals in the general population or subjects performing physical exercise, and/or
- the claimed effect was related to aspects of exercise performance, such as: i) physical performance, endurance capacity, endurance performance, muscle mass, muscle strength, lean body mass; ii) muscle fatigue, water absorption, or the rated perceived exertion/effort during exercise; iii) recovery from muscle fatigue, restoration of muscle glycogen stores, and skeletal muscle tissue repair after exercise; iv) energy-yielding metabolism;
- the claimed effect was related to certain health risks for athletes, such as: i) upper respiratory tract infections, ii) exercise-induced inflammation, iii) oxidative stress, iv) joint function.

All published Scientific Opinions of the EFSA NDA Panel in the area of DRVs (for energy, water, macronutrients and micronutrients), including Scientific Opinions on Tolerable Upper Intake Levels (ULs) for nutrients, were also reviewed in order to gather relevant information for the present technical report.

The conclusions of the SCF in 2001 (SCF, 2001) for the different categories of foods for sportspeople considered in the report (i.e. carbohydrate-rich energy food products, carbohydrate-electrolyte solutions, protein and protein components, and supplements, which comprise essential nutrients and other components) will be summarised first. This will be followed by a summary of the scientific advice provided by the EFSA NDA Panel in that area, clearly indicating the context in which such advice was provided and how it relates to the SCF report.

3. Assessment

In 2001, the SCF examined the requirements of different categories of foods intended to meet the demands of intense muscular effort, especially for sportspeople (SCF, 2001). The starting point of the evaluation was that a well-balanced diet is the basic nutritional requirement for athletes, and that specific requirements may arise depending on particular physiological conditions which are the consequence of athletic training and performance. The questions addressed by the SCF were, therefore: i) whether (and the extent to which) sportspeople (and other target groups involved in regular or irregular intense muscular exercise) have specific nutritional requirements which may not be adequately covered by dietary guidelines intended for the general population, and ii) whether specific nutrients and/or other food constituents could positively affect physical performance when consumed in amounts beyond what could be expected from such dietary guidelines.

The SCF provided conclusions for four categories of foods for sportspeople (i.e. carbohydrate-rich food products, carbohydrate-electrolyte solutions, protein and protein components, and supplements, comprising essential nutrients and other components) plus energy. The safety aspects of a high level of intake of specific foods or food constituents were not taken into consideration.

This report summarises the main conclusions of the SCF in relation to the four food groups mentioned above plus energy, as well as the advice of the EFSA NDA Panel provided to risk managers thereafter.

3.1. Energy requirements

3.1.1. SCF 2001

The first and clearest difference in nutritional needs between individuals who are engaged in intense muscular exercise and the general population was related to energy expenditure, and therefore to energy requirements. Whereas energy expenditure of a sedentary adult female/male amounts to approximately 8.5–12.0 MJ (1 825–2 580 kcal) per day, physical activity by means of training or competition will increase the daily energy expenditure by 2 to 4 MJ (430–860 kcal) per hour of exercise, depending on physical fitness and on duration, type and intensity of sport.

The SCF noted that individuals with a substantial increase in their daily physical activity must adapt the energy intake by an increased food consumption to meet the energy needs according to the level of daily energy expenditure, and that this increased energy demand could be achieved by an increased intake of selected normal foods. However, compensating for such high energy expenditure by ingesting normal solid meals will pose a problem for any athlete involved in intense competitions or trainings, since the digestion and absorption processes will be impaired during intense physical activity, and thus this population group could benefit from specially adapted nutritious foods/fluids which are easily digestible and rapidly absorbable.

3.1.2. EFSA's NDA Panel

The Scientific Opinion on DRVs for energy provides Average Requirements (ARs) for specified age, sex and physical activity level (PAL) groups (EFSA NDA Panel, 2013c). PALs of >2 characterise highly active lifestyles, including subjects performing physical exercise several hours per day and several days per week, whereas a PAL value of 1.4 was considered to reflect a low active (sedentary) lifestyle. Differences in energy expenditure estimates associated with differences in PAL between sedentary and highly active subjects were high. Adult subjects with a PAL of 2.4 were estimated to spend, on a daily basis, up to twice the energy spent by subjects with a PAL of 1.4 of the same age and sex.

3.1.3. Conclusions

Physical activity increases energy expenditure and energy requirements. For athletes and other subjects with very high levels of physical activity, energy requirements may be very high. The advice of the EFSA NDA Panel regarding the increased energy requirements of highly active individuals (PAL values > 2) is in line with the advice provided by the SCF with respect to sportspeople. Although this increased energy demand could be achieved by an increased intake of selected normal foods, specially adapted foods or fluids may help this population group to cover the increased energy needs while avoiding gastrointestinal distress.

3.2. Carbohydrate-rich energy food products

3.2.1. SCF 2001

Beneficial effects

The SCF acknowledged consensus on the essential role of carbohydrate intake in relation to physical performance during all types of exercise, generally lasting longer than one hour. This knowledge was based on the importance of increased body glycogen stores in liver and muscle for sustaining prolonged heavy exercise, as well as the direct relationship between the level of carbohydrate intake and the re-synthesis of muscle glycogen after exhausting exercise. It was recommended that carbohydrate-rich foods with a high glycaemic index should provide 10 g of carbohydrate per kg bw during the 24-h recovery. Athletes should consume up to 1 g/kg bw of carbohydrate immediately after the exercise bout and then about 0.5 g/kg bw at hourly intervals until the next meal, which should be made up of high glycaemic index carbohydrate foods. In this respect, it was found that, although all types of carbohydrates that increase blood glucose concentrations effectively were suitable, specially developed carbohydrate-rich food products could be of benefit in reaching an adequate carbohydrate intake for sportspeople.

Composition and specifications

Such carbohydrate-rich food products should supply at least 75 E % (solid foods), or 10 % of weight by volume (drinks), as carbohydrates. These should be carbohydrates with a high glycaemic index (e.g. glucose, glucose polymers, sucrose), which are rapidly absorbed and induce a high increase in blood glucose concentrations. In addition, these products may contain at least 0.05 mg vitamin B1 (thiamine) per 100 kcal provided by carbohydrates (i.e. at least 0.2 mg thiamine per 100 g of carbohydrates).

3.2.2. EFSA's NDA Panel

Beneficial effects

In several health claim evaluations, the EFSA NDA Panel concluded that glucose is an energy-containing macronutrient which contributes to energy-yielding metabolism, and that energy-yielding metabolism is needed for all functions and activities of the body, including physical activity and exercise (EFSA NDA Panel, 2012e, 2012d).

A health claim related to glycaemic carbohydrates and recovery of normal muscle function (contraction) after strenuous exercise pursuant to Article 13(5) of Regulation (EC) No 1924/2006 was also evaluated by EFSA's NDA Panel with a positive outcome (EFSA NDA Panel, 2013a). As previously noted in the Scientific Opinion on DRVs for carbohydrates and dietary fibre (EFSA NDA Panel, 2010f), the NDA Panel acknowledged that glucose, which is mainly provided to body cells from glycaemic carbohydrates, can be stored as glycogen in muscles, and that muscle glycogen is used primarily as a source of energy within the muscles. The Panel also found it well established that strenuous exercise depletes skeletal muscle glycogen stores, that low glycogen stores limit energy production in muscles and limit skeletal muscle contraction, and that glycaemic carbohydrates, consumed especially in the first hours following strenuous exercise, stimulate glycogen re-synthesis in muscle and contribute to the replenishment of skeletal muscle glycogen stores to a greater extent than other energy-containing macronutrients, and which leads to the recovery of normal skeletal muscle function (contraction). The claim related to the role of all glycaemic carbohydrates on the recovery of normal muscle function (contraction) after strenuous exercise and not to the relative efficacy of different types of glycaemic carbohydrates (e.g. carbohydrates with a high glycaemic index *vs* carbohydrates with a low glycaemic index, combinations of different types of sugars *vs* glucose alone) in achieving the claimed effect, and therefore this aspect was not assessed by the NDA Panel. A health claim application on a combination of glucose and fructose and improves performance in active individuals performing endurance exercise compared to the intake of glucose alone was submitted to EFSA in 2014 pursuant to Article 13(5) of Regulation (EC) No 1924/2006. The application was withdrawn during the evaluation.

The EFSA NDA Panel also concluded that thiamine has a central role in energy-yielding metabolism, and especially in the metabolism of carbohydrates and branched-chain amino acids (BCAA) (EFSA NDA

Panel, 2009a). The Panel is currently preparing a scientific opinion on DRVs for vitamin B_1 (EFSA-Q-2011-01225).

Conditions of use

In order to achieve the claimed effect, glycaemic carbohydrates (e.g. glucose and fructose, sucrose and lactose, malto-oligosaccharides and starch) should be consumed at doses of 4 g per kg bw in the first 4 to 6 hours following strenuous exercise. The target population was subjects who had performed strenuous exercise. The conditions of use for the claim on thiamine and energy-yielding metabolism were linked to nutrition claims in the Annex of Regulation (EC) No 1924/2006 and assumed that any amount would contribute to the function.

3.2.3. Conclusions

The advice of the EFSA NDA Panel regarding the essential role of carbohydrate intake in relation to physical performance, particularly in relation to the recovery of normal muscle function after strenuous exercise, and the role of thiamine on carbohydrate metabolism, is compatible with, and complementary to, the advice provided by the SCF in 2001. Whereas the SCF referred specifically to the quality of glycaemic carbohydrates (i.e. with a high glycaemic index) when advising on the composition and specifications of carbohydrate-rich foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, the conditions of use for the claim evaluated by EFSA were established for all glycaemic carbohydrates because the claim related to the role of all glycaemic carbohydrates on the recovery of normal muscle function (contraction) after strenuous exercise and not to the relative efficacy of different types of glycaemic carbohydrates in achieving the claimed effect, and therefore this aspect was not assessed by the NDA Panel. A health claim application on the differential effects of a combination of glucose and fructose *vs* glucose alone on endurance performance was submitted to EFSA pursuant to Article 13(5) of Regulation (EC) No 1924/2006. The application was withdrawn during the evaluation.

3.3. Carbohydrate-electrolyte solutions

3.3.1. SCF 2001

Beneficial effects

The SCF considered that the two factors which contribute most to the onset of fatigue in exercise were the depletion of the body's carbohydrate reserve and the onset of dehydration, as a consequence of the loss of water and electrolytes in sweat. Compared to water as a control drink, a substantial body of scientific evidence supported the hypothesis that, during prolonged exercise, drinks containing carbohydrates and electrolytes, in particular sodium, improve performance. Sodium was found to be the only electrolyte added to drinks consumed during exercise that is known to confer a physiological benefit. There were no good scientific reasons for the addition of potassium or magnesium to sports drinks.

Composition and specifications

The SCF highlighted that the optimum carbohydrate concentration in the drinks would depend on a number of factors, such as the need for water (hot/cold conditions), the intensity and type of exercise (gastrointestinal absorptive capacity), osmolality (rate of gastric emptying as well as water absorption in the small intestine), and type of carbohydrate (simple vs. polymers). Therefore, a range from 80–350 kcal (335–1470 kJ) carbohydrates/1000 ml in carbohydrate-electrolyte solutions was advised. A sodium concentration of 20–50 mmol/l (460–1150 mg/l) was found to stimulate carbohydrate and water uptake maximally in the small intestine and will help to maintain extracellular fluid volume. The evidence to support the inclusion of other components as essential ingredients was not convincing.

3.3.2. EFSA's NDA Panel

Beneficial effects

In its Scientific Opinion on DRVs for water (EFSA NDA Panel, 2010g), the NDA Panel acknowledged fundamental differences between athletes and the general adult population regarding water requirements and the risk of water balance disorders.

Total body water, about 60 % (range 45 to 75 %) of body mass, varies with body composition and is higher in subjects with low fat mass and high skeletal muscle glycogen, such as in athletes. In this population subgroup, body weight, which is a sensitive, accurate and easily measured indicator of hydration status when measured regularly and under standard conditions, may not accurately reflect changes in hydration status since carbohydrate loading in athletes will increase body weight by retaining water with glycogen stored in muscle.

Overconsumption of water that exceeds the kidney's maximal excretion rate of 0.7-1.0 L/hour is not easy to achieve under normal conditions and with normal dietary habits. However, both heat stress and exercise can reduce renal water excretion. Water intoxication with potentially life-threatening hyponatraemia through overconsumption of water, a very rare event under normal conditions, has been observed as a consequence of excessive electrolyte-free water consumption in rehydration of athletes during and after prolonged physical exercise.

The NDA Panel defined Adequate Intakes (AIs) of water for men (2.5 L per day) and women (2.0 L per day) based on observed intakes and on considerations of achievable or desirable urine osmolarity. These AIs apply only to conditions of moderate environmental temperature and moderate PAL (1.6). The Panel noted, however, that water losses incurred under extreme conditions of external temperature and physical exercise, which could be up to about 8 L per day, had to be replaced together with concomitant losses of electrolytes to avoid hypo-osmolar disturbances (EFSA NDA Panel, 2010g).

The NDA Panel assessed health claims on carbohydrate-electrolyte solutions and reduction in rated perceived exertion/effort during exercise, enhancement of water absorption during exercise, and maintenance of endurance performance (EFSA NDA Panel, 2011b). Based on consensus opinions/reports from authoritative bodies, which included the SCF (SCF, 2001), but also the American College of Sports Medicine (Sawka et al., 2007; Rodriguez et al., 2009), the Panel concluded that beverages containing carbohydrates and electrolytes (in particular sodium) contribute to the maintenance of physical performance during prolonged endurance exercise, relative to plain water, and that the consumption of beverages containing electrolytes and carbohydrates during exercise can help maintain fluid and electrolyte balance, as well as endurance exercise performance. The Panel also noted that sodium stimulates carbohydrate and water uptake in the small intestine, and helps to maintain extracellular fluid volume. No evidence was provided to establish a cause and effect relationship between the consumption of carbohydrate-electrolyte solutions and reduction in rated perceived exertion/effort during exercise.

A health claim related to carbohydrate solutions and maintenance of physical performance during endurance exercise (EFSA NDA Panel, 2014a) was evaluated by the Panel with a negative outcome. Upon a request by EFSA for clarification on whether the claim submitted could be covered by the health claim already authorised on carbohydrate-electrolyte solutions, the applicant indicated that the food constituent that was the subject of this claim was carbohydrate solutions that do not include electrolytes. The applicant failed to provide the specifications of the intervention and control solutions used in the human intervention studies submitted for the substantiation of the claim.

Conditions of use

The conditions of use for claims on carbohydrate-electrolyte solutions and water absorption during exercise and endurance performance were set by the Panel on the basis of the specifications given by the SCF in 2001. The target population for these claims was active individuals performing endurance exercise.

3.3.3. Conclusions

The scientific advice provided by the SCF and by the EFSA NDA Panel regarding the role of hydration and carbohydrate supply in the maintenance of physical performance during endurance exercise, as well as on the role of electrolytes (particularly sodium) in the maintenance of adequate hydration during exercise and in post-exercise re-hydration, do not differ. The compositional requirements for carbohydrate-electrolyte solutions given by the two bodies are the same.

3.4. Protein and protein components

3.4.1. SCF 2001

Beneficial effects

The SCF acknowledged that strength athletes having trained for years, novice athletes involved in strength training and endurance athletes may have a modest increase in protein requirements compared to low and moderately active subjects. Protein requirements for these categories of subjects were estimated as 1.0–1.2, 1.3–1.5 and 1.2–1.4 g/kg bw, respectively, from nitrogen balance studies. However, owing to the increased energy requirements of athletes (see section 3.1), which in elite endurance athletes can be as much as two to three-fold higher than that of moderately active subjects, diets containing 10–12 % of total energy as protein of mixed quality were deemed adequate to meet the protein requirements of sportspeople. The SCF also noted that acute and long-term increases in the protein content of the diet do not, *per se*, lead to increases in muscle protein mass or whole body protein mass when the protein content exceeds the dietary requirement, and that the use of supplements of protein hydrolysates or free amino acids had no beneficial effects on the whole body or muscle protein synthesis when compared to the intake of protein from different sources in a mixed meal.

The only potential beneficial effect of increased protein intake by athletes was related to the timing of intake of the extra protein, rather than to the total amount on a daily basis. The SCF considered that the use of protein-carbohydrate solutions or protein-carbohydrate rich solid food products in the post-exercise period could help the rapid re-synthesis of glycogen stores that were lost during the exercise. However, it was unclear for how long after exercise the increased protein intake was required.

Composition and specifications

The SCF recommended that the protein source of protein supplements for sportspeople should have a minimal protein quality level (NPU) of 70 %. Protein should be at least 70 % of the dry matter for protein concentrates, and 25 % of the total energy for protein-enriched foods. Addition of amino acids was only allowed to improve the nutritional quality of protein, if needed. If added, these products should contain at least 0.02 mg vitamin B_6 (pyridoxine) per gram of protein, based on the concept that the requirement for vitamin B_6 is closely related to protein intake.

3.4.2. EFSA's NDA Panel

In its Scientific Opinion on DRVs for protein (EFSA NDA Panel, 2012a), the NDA Panel proposed a Population Reference Intake (PRI) for protein of 0.83 g/kg bw per day for adults and older adults of both sexes, a quantity which should meet the requirement of most (97.5 %) of the healthy adult population. This PRI was applicable both to high quality protein (i.e. with a protein digestibility-corrected amino acid score ≥1) and to protein in mixed diets. The criterion of adequacy for the protein intake was the lowest intake that is sufficient to achieve body nitrogen equilibrium (zero balance) during energy balance. When expressed as % of energy intake (E %), average total protein intakes in EU countries range from about 12 to 20 E % in adults. Within population ranges vary from about 10–15.5 E % at the lower (2.5–10th percentile) end to about 17–27 E % at the upper (90–97.5th percentile) end of the intake distributions.

The Panel noted that the major anabolic influences on muscle were contractile activity and feeding, and that ingestion of sufficient dietary energy and protein was a prerequisite for muscle protein synthesis and maintenance of muscle mass and function. However, there were no data showing that an additional intake of protein (i.e. beyond protein requirements) would increase muscle mass in

different age groups who are in nitrogen balance, including subjects undertaking endurance or resistance exercise. In addition, the Panel noted that BCAA (leucine, valine, isoleucine), and particularly leucine, have been demonstrated to act as a signal for muscle protein synthesis *in vitro* and in animal models, whereas limited information was available on the influence of leucine alone on muscle protein synthesis in humans. There was no convincing evidence at the time that chronic leucine supplementation above the requirement of 39 mg/kg bw per day was efficient in promoting an increase in muscle mass when the intake of protein is at the PRI based on nitrogen balance, and when amino acid requirements are met.

The NDA Panel evaluations of health claims submitted under Art.13(1) and Art.13(5) of Regulation (EC) No 1924/2006 are consistent with this advice. Whereas the Panel acknowledged that protein contributes to the growth and maintenance of muscle mass, it considered that protein intakes within the DRVs allow for normal protein turnover and muscle recovery after physical exercise (EFSA NDA Panel, 2010k). No evidence was provided that the consumption of specific protein sources (e.g. bovine colostrum, casein protein hydrolysates, whey protein), of specific amino acids which are incorporated into proteins (e.g. BCAA, β-alanine, L-glutamine), or of compounds derived from protein amino acids (L-carnitine, L-carnosine) had an effect on whole body lean mass, muscle mass, or other outcomes considered as beneficial for sportspeople (e.g. endurance capacity and/or performance, muscle strength, restoration of muscle glycogen stores after strenuous exercise, skeletal muscle tissue repair, and recovery of muscle fatigue after exercise) beyond what could be expected from the consumption of mixed dietary protein within the DRV when other energy and nutrient requirements are met (EFSA NDA Panel, 2009a, 2010l, 2010m, 2010k, 2010a, 2011o, 2011p, 2011a, 2014b).

Claims on the potential beneficial effects of consuming protein-carbohydrate solutions or protein-carbohydrate rich solid food products in the post-exercise period have not been evaluated by EFSA.

The Panel also acknowledged that vitamin B_6 functions as a coenzyme in a variety of enzymatic reactions in the metabolism of amino acids, one-carbon units, lipids, and the pathways of gluconeogenesis, among others, and that vitamin B_6, as pyridoxal phosphate (PLP), contributes to energy-yielding metabolism since PLP-dependent transaminases convert gluconeogenic amino acids to alpha-keto acids to create substrates for the production of glucose (EFSA NDA Panel, 2009h, 2010o). EFSA's NDA Panel is currently preparing a Scientific Opinion on DRVs for vitamin B_6 (EFSA-Q-2011-01228).

Conditions of use

The conditions of use for health claims on protein and growth and maintenance of muscle mass, and on vitamin B_6 and energy and macronutrient metabolism, were linked to nutrition claims in the Annex of Regulation (EC) No 1924/2006 and assumed that any amount would contribute to the function.

3.4.3. Conclusions

The scientific advice provided by the SCF and the subsequent scientific advice of the EFSA NDA Panel regarding the essential role of protein in the growth and maintenance of muscle mass, and on the role of vitamin B_6 in protein metabolism, do not differ. The two bodies considered that protein requirements of athletes could be covered by established dietary guidelines, since higher energy needs would result in higher protein intakes on a body weight basis if the protein contribution to total energy intake is kept at about 10–12 %. Average protein intakes (as E %) in virtually all EU countries are beyond these values. Neither the SCF nor EFSA considered that particular protein sources or protein components could have a beneficial effect for athletes on muscle mass or performance beyond what could be expected from high quality protein or protein in mixed diets.

3.5. Supplements: essential nutrients

DRVs for essential nutrients in healthy adults published by various national and international bodies, including the SCF and EFSA thereafter, do not distinguish between nutrient requirements for normal healthy *versus* physically active subjects. However, it has been argued that intense physical exercise and regular training may influence the balance of and requirements for some essential nutrients. In addition, there are potential hazards from the intake of high levels of some vitamins and minerals through supplementation, a practice that is particularly popular among athletes (SCF, 2001).

3.5.1. SCF 2001

Beneficial effects

Besides the obvious side effects of irregular or inadequate training, the SCF identified the following health risks for athletes which could be further influenced by the inadequate intake of essential nutrients: i) upper respiratory tract infections, ii) exercise-induced inflammation, and iii) oxidative stress.

The SCF considered that, for sportspeople with an adequate dietary intake, there was no further need for additional supplementation with essential micronutrients such as minerals, trace elements and vitamins. This was also the case for vitamins involved in energy-yielding metabolism, such as vitamins B_1 (thiamine), B_2 (riboflavin), niacin, B_6 (pyridoxine) and B_{12} (cobalamin); and for minerals involved in muscle function (contraction), such as potassium, magnesium and calcium; for vitamins (C and E) involved in the endogenous defence against oxidative damage, and for carotenoids (β-carotene). For essential fatty acids and trace elements involved in the regulation of the immune function, such as long-chain polyunsaturated fatty acids (LC-PUFA) and zinc, respectively, and for trace elements playing a role in energy and free radical metabolism, such as copper, selenium, and manganese, experimental data in athletes was not available.

In the case of restricted food intake, as is frequently observed in weight related sports (i.e. sports in which athletes are on negative energy balance or need to maintain a low body weight), the SCF noted that micronutrient intake could become marginal or deficient, which would justify supplementation. However, scientific evidence was lacking or inconsistent in supporting recommendations for nutrient intakes beyond the accepted dietary guidelines.

Safety

The ULs of vitamins and minerals were at the time under consideration by the SCF and were not covered in the report.

3.5.2. EFSA's NDA Panel

Beneficial effects

The PRIs for vitamins and minerals set by the SCF for the general healthy population and subgroups thereof are currently being revised and updated by the EFSA NDA Panel (on-going mandate). In common with the SCF, the NDA Panel does not establish nutrient requirements specifically for subjects performing intense muscular effort or for sportspeople (e.g. athletes).

The NDA Panel has evaluated health claims regarding the role of vitamins of the B group on energy-yielding metabolism (EFSA NDA Panel, 2009a, 2009i, 2009j, 2009k, 2009h, 2010o, 2010p, 2010q); the role of vitamins C and E in the endogenous defence of cells and molecules against oxidative damage (EFSA NDA Panel, 2009l, 2010n); the role of minerals such as potassium, magnesium and calcium on muscle function (contraction) (EFSA NDA Panel, 2009e, 2009f, 2010h); and the role of trace elements on the maintenance of immune function, energy-yielding and macronutrient metabolism, and defence of cells and molecules against oxidative damage (EFSA NDA Panel, 2009g, 2009d, 2009c, 2009b, 2010j, 2010i, 2010e, 2011c), all with a positive outcome. The target population for all these claims was the general population and the conditions of use were set on the basis of nutrient claims in the Annex of Regulation (EC) No 1924/2006, which refer to the labelling reference values for these nutrients. Labelling reference values have been established on the basis of nutrient requirements (PRIs) set by the SCF. Although the Panel acknowledged that intakes of n-3 LC-PUFA may have an impact on functions partially regulated by eicosanoids, including inflammatory and immunological reactions, neither immune function nor inflammation were considered appropriate health outcomes to set DRVs (EFSA NDA Panel, 2010d) or a safe level of intake (EFSA NDA Panel, 2012f) for these fatty acids.

The only health claim related to essential micronutrients specifically addressed to sportspeople (and not to the general population) which was evaluated by the Panel with a positive outcome related to vitamin C and the function of the immune system during and after intense physical exercise (EFSA NDA Panel, 2009l). Most of the studies considered by the Panel indicated that vitamin C

supplementation with doses above the DRVs failed to reduce the incidence of colds in the normal population. However, evidence showed that persons exposed to brief periods of intense physical exercise and/or cold environments benefit in terms of duration and severity of the common cold from regular vitamin C intake above 200mg/d. The conditions of use for that claim (200 mg per day of vitamin C) clearly exceeded those established for the maintenance of a normal immune function for the general population (EFSA NDA Panel, 2009l), as well as the PRI for vitamin C for adults set by the SCF (60 mg per day) and recently revised by the EFSA NDA Panel (95 mg per day for women and 110 mg per day for men) (EFSA NDA Panel, 2013b).

Safety

The task of establishing ULs (or safe levels of intake) for vitamins and minerals initiated by the SCF was completed by EFSA in 2005[1]. In 2012, the EFSA NDA Panel revised the ULs for calcium and vitamin D (EFSA NDA Panel, 2009a, 2012g, 2012h), and established a safe level of intake for n-3 LC-PUFAs, upon request from the Commission. The last request was triggered by concerns raised by Member States during the authorisation of health claims evaluated with a positive outcome for these fatty acids. There were insufficient data to establish a UL for vitamin C. Supplemental daily doses of vitamin C up to about 1 g, in addition to normal dietary intakes, were not associated with adverse gastrointestinal effects, but these may occur at higher intakes (3–4 g per day). These amounts are several times above the 200 mg per day of vitamin C required to decrease the risk of common cold infections after strenuous exercise.

3.5.3. Conclusions

The scientific advice provided by the SCF and by the EFSA NDA Panel do not differ regarding the essential role of micronutrients and LC-PUFA on body functions which may impact either athletic performance or specific health risks for athletes. However, neither the SCF nor the EFSA NDA Panel considered that athletes may have specific requirements for these nutrients (e.g. beyond the requirements established for the general population), or that athletes would benefit from supplementation with these nutrients. The only health claim related to essential micronutrients specifically addressed to sportspeople (and not to the general population) which was evaluated by the Panel with a positive outcome related to Vitamin C and the function of the immune system during and after intense physical exercise. Higher doses of vitamin C (beyond the PRIs) were considered by the EFSA NDA Panel to be required for such benefit. The task of establishing ULs (or safe levels of intake) for vitamins and minerals initiated by the SCF has been already completed by EFSA and may serve as guidance to judge whether the intake of high levels of some vitamins and minerals through supplementation, a practice that is particularly popular among athletes, may pose a risk to health.

3.6. Supplements: other food constituents

Both the SCF and EFSA have considered constituents in food other than essential nutrients on the basis of their ergogenic properties.

3.6.1. SCF 2001

The SCF assessed the scientific evidence available at the time on the relationship between supplementation with caffeine, creatine, L-carnitine, medium-chain triglycerides (MCT) or BCAA and sports performance. Other food constituents were not assessed as ergogenic aids.

Caffeine

Beneficial effects

The SCF considered that caffeine ingestion prior to exercise enhanced performance of both prolonged endurance exercise and short-term intense exercise lasting approximately five minutes. The SCF noted that the ergogenic effects of caffeine were well known, and that caffeine was at the time considered as a doping substance by the International Olympic Committee at doses which exceeded 12 µg caffeine/ml of urine.

[1] http://www.efsa.europa.eu/en/ndatopics/docs/ndatolerableuil.pdf

Composition and specifications

The ergogenic effects of caffeine were observed at doses of about 3–8 mg/kg bw consumed prior to exercise.

Safety

The safety of caffeine consumed under the above-mentioned conditions was not assessed.

Creatine

Beneficial effects

The relative importance of CrP during exercise was found by the SCF to be dependent on the nature of the exercise. Creatine supplementation was considered to induce a small improvement in exercise performance in sport events that require explosive, high-energy output activities especially of a repeated nature, but it did not appear to enhance aerobic activities.

Composition and specifications

The SCF recommended five days of creatine loading (10–20 g per day in 2–4 equal portions), followed by a maintenance dose of 2–3 g per day.

Safety

The SCF considered that the information available regarding the safety of creatine supplementation was lacking or incomplete, particularly at doses exceeding the specifications above. Creatine ingestion prior to competition in the heat was discouraged, as it may interfere with water absorption and as there was no rationale for intake immediately before competition. The SCF found it unlikely that acute and long-term consumption of creatine supplements would impair kidney function in healthy individuals.

Other food constituents proposed as ergogenic aids

The SCF reviewed controlled scientific studies available at the time which had investigated the effect of carnitine, MCT and BCAA supplementation on exercise performance or on claimed mechanisms by which these food constituents could exert an effect on performance. Such studies provided no basis for the use of carnitine, MCT or BCAA intended as nutritional ergogenic aids to meet the expenditure of intense muscular effort and especially for sportsmen.

3.6.2. EFSA's NDA Panel

Caffeine

Beneficial effects

The effects of caffeine on physical performance were assessed by EFSA in the context of health claims submitted under Art. 13(1). EFSA concluded that a cause and effect relationship had been established between the consumption of caffeine prior to exercise and an increase in endurance capacity, an increase in endurance performance, and a reduction in the rated perceived exertion/effort during exercise, which was also considered a mechanism of action by which caffeine could exert an effect on endurance performance. The NDA Panel considered that a cause and effect relationship between caffeine consumption and an increase in physical performance during short-term high-intensity exercise was not established (EFSA NDA Panel, 2011d). Out of the 10 human intervention studies considered for the scientific substantiation of this claim, five were published in the year 2000 or after and were not available at the time the SCF opinion was adopted.

In the majority of the human studies which were considered for the scientific substantiation of these claims, volunteers were habitual caffeine consumers and caffeine was given at least one hour prior to exercise after at least 24 h of caffeine withdrawal.

Conditions of use

In order to achieve the claimed effects, the NDA Panel considered that caffeine should be consumed at doses of 3 mg/kg bw one hour prior to exercise for claims on endurance capacity and performance, which was the lowest effective dose in the studies submitted for the substantiation of these claims. For claims on the reduction in the rated perceived exertion/effort during exercise, caffeine should be consumed at doses of 4 mg/kg bw prior to exercise. This was the lowest dose tested in the human studies submitted for substantiation (EFSA NDA Panel, 2011d). The target population for these claims was adults performing endurance exercise.

Safety

In its Scientific Opinion on the substantiation of health claims related to caffeine and exercise performance (EFSA NDA Panel, 2011d), the EFSA NDA Panel did not assess the safety of caffeine consumption in conjunction with physical exercise because safety assessments are not foreseen in the framework of Regulation (EC) No 1924/2006. However, in the process of authorisation of the above-mentioned health claims, some Member States raised concerns regarding the safety of caffeine when consumed prior to intense physical exercise, either alone or through the so-called "energy drinks". In this context, EFSA received a mandate from the European Commission to assess the safety of caffeine from all dietary sources, including food supplements, in the general healthy population and in relevant specific subgroups thereof (e.g. children, adolescents, adults, the elderly, pregnant and lactating women, subjects performing physical exercise), when consumed either alone or in combination with other substances present in "energy drinks" (D-glucurono-γ-lactone and taurine), alcohol or *p*-synephrine.

With respect to the safety of caffeine when consumed prior to physical exercise, the NDA Panel concluded that single doses of caffeine up to 200 mg, corresponding to about 3 mg/kg bw for a 70-kg adult, or the same amount consumed within a short period of time, are unlikely to induce clinically relevant changes in myocardial blood flow in the general healthy adult population, either at rest or when consumed less than two hours prior to intense physical exercise, under normal environmental conditions. These doses of caffeine were also unlikely to induce clinically relevant changes in blood pressure, hydration status or body temperature under the above-mentioned conditions. Single doses of caffeine up to 200 mg were unlikely to reduce the perceived exertion/effort during exercise, which in the context of the safety assessment targeting the general healthy adult population (not limited to adults performing endurance exercise willing to obtain such an effect) was considered a potential adverse health effect (EFSA NDA Panel, 2015).

Creatine

Beneficial effects

The effects of creatine on physical performance were assessed by EFSA in the context of health claims submitted under Art. 13(1). The NDA Panel concluded that a cause and effect relationship had been established between creatine supplementation and an increase in physical performance during short-term, high-intensity, repeated exercise bouts, whereas it had no effect on endurance capacity or endurance performance (EFSA NDA Panel, 2011e).

Conditions of use

The Panel considered that, in order to obtain the claimed effect, 3 g of creatine should be consumed daily. The target population was adults performing high-intensity exercise. No restrictions of use were noted.

Safety

In its Scientific Opinion on the substantiation of health claims related to creatine and exercise performance (EFSA NDA Panel, 2011e), the EFSA NDA Panel did not assess the safety of long-term creatine supplementation because safety assessments are not foreseen in the framework of Regulation (EC) No 1924/2006. No safety concerns were raised by risk managers regarding the long-

term supplementation with creatine at doses of 3 g per day in the process of authorisation of the above-mentioned health claim.

Other food constituents proposed as ergogenic aids

A number of food constituents proposed as ergogenic aids, including (but not limited to) L-carnitine and BCAA, have been assessed by EFSA in relation to different aspects of exercise performance in the context of health claims submitted under Art. 13(1) and Art. 13(5) (see Appendix A). All these claims have been assessed by the NDA Panel with a negative outcome. Additional claims related to exercise performance were submitted under the Art. 13(1) procedure for food constituents and combinations of constituents for which no human data were provided (EFSA NDA Panel, 2011f). No claims related to exercise performance for MCT have been submitted to EFSA so far.

Other food constituents proposed to reduce specific health risks for athletes

EFSA also evaluated a number of health claims under Art. 13(1) and Art. 13(5) for food constituents other than essential nutrients in relation to health outcomes which have been linked by the SCF (SCF, 2001) and other bodies to specific health risks for athletes. These include claims on the reduction of the risk of URTI, the reduction of systemic inflammation, the protection of cells and molecules against oxidative damage, and the maintenance of normal joints. All these claims were evaluated by the NDA Panel with negative outcomes. The target population for the majority of these claims was the general population. Physically active subjects or subjects performing sports were only mentioned specifically within the target population of claims on glucosamine and collagen hydrolysate and maintenance of normal joints (EFSA NDA Panel, 2011g, 2012b).

3.6.3. Conclusions

Caffeine

The SCF considered that caffeine ingestion prior to exercise enhanced performance of both prolonged endurance exercise and short-term intense exercise lasting approximately five minutes. The EFSA NDA Panel subsequently agreed on the ergogenic properties of caffeine in endurance exercise, but found no convincing evidence for an effect of caffeine on physical performance during short-term high-intensity exercise. Out of the 10 human intervention studies considered by EFSA for the scientific substantiation of this claim, five were published in the year 2000 or thereafter and were not available at the time the SCF opinion was adopted. Whereas the ergogenic effects of caffeine were observed at doses of about 3-8 mg/kg bw consumed prior to exercise, EFSA set the conditions of use for claims on endurance capacity and performance at the minimum effective dose of 3 mg/kg bw. The conditions of use for a claim on a reduction in the rated perceived exertion/effort during exercise, which was also considered a mechanism of action by which caffeine could exert an effect on endurance performance, were set at the minimum dose tested in the studies available.

The safety of caffeine consumption in conjunction with intense physical exercise, which was not evaluated by the SCF, was considered in an EFSA opinion following a request from the European Commission during the process of authorisation of health claims on caffeine and physical performance.

Creatine

Both the SCF and the EFSA NDA Panel concluded positively on the ergogenic effects of creatine in physical performance during short-term, high-intensity, repeated exercise bouts (i.e. in sports that require explosive, high-energy output activities especially of a repeated nature), whereas no effect of creatine supplementation was expected in aerobic sport activities of longer duration (i.e. on endurance capacity or endurance performance). Whereas the SCF recommended five days of creatine loading (10-20 g per day in 2–4 equal portions), followed by a maintenance dose of 2–3 g per day, EFSA set conditions of use for this claim addressed to adults performing high-intensity exercise at 3 g per day (maintenance dose). The SCF warned about consuming creatine in hot conditions prior to exercise and notes the lack of robust data regarding the safety of long-term creatine supplementation, particular at doses higher than recommended. The EFSA NDA Panel did not assess the safety of long-term creatine supplementation because safety assessments are not foreseen in the framework of Regulation (EC) No 1924/2006. No safety concerns were raised by risk managers regarding long-term

supplementation with creatine at doses of 3 g per day in the process of authorisation of the above-mentioned health claim.

Other food constituents proposed as ergogenic aids

Neither the SCF nor the EFSA NDA Panel found a solid basis for the use of other food constituents as nutritional ergogenic aids to meet the expenditure of intense muscular effort and especially for sportspeople.

Other food constituents proposed to reduce specific health risks for athletes

Whereas the SCF only considered health risks for athletes in relation to the intake of essential nutrients, the EFSA NDA Panel assessed several health claims on the relationship between food constituents other than essential nutrients and health outcomes which have been linked to specific health risks for athletes, including reduction of the risk of URTI, reduction of systemic inflammation, protection of cells and molecules against oxidative damage, and maintenance of normal joints. All these claims have been evaluated by EFSA with negative outcomes. The target population for the majority of these claims was the general population. Physically active subjects or subjects performing sports were only mentioned specifically within the target population of claims on glucosamine and collagen hydrolysate and maintenance of normal joints.

4. Overall conclusions

The scientific advice provided by the SCF and the subsequent scientific advice by the EFSA NDA Panel do not differ regarding:

- the essential role of carbohydrate intake in relation to physical performance, and particularly in relation to the recovery of normal muscle function after strenuous exercise, and the role of vitamin B_1 (thiamine) on carbohydrate metabolism;
- the role of hydration and carbohydrate supply in the maintenance of physical performance during endurance exercise, as well as on the role of electrolytes (particularly sodium) in the maintenance of adequate hydration during exercise and in post-exercise re-hydration;
- the essential role of protein in the growth and maintenance of muscle mass, and the role of vitamin B6 (pyridoxine) in protein metabolism;
- the essential role of micronutrients and LC-PUFA on body functions which may impact either athletic performance or specific health risks for athletes;
- the ergogenic properties of caffeine in endurance exercise; and
- the ergogenic effects of creatine in physical performance during short-term, high-intensity, repeated exercise bouts (i.e. in sports that require explosive, high-energy output activities especially of a repeated nature).

Whereas the SCF referred specifically to the quality of glycaemic carbohydrates (i.e. with a high glycaemic index) when advising on the composition and specifications of carbohydrate-rich foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, the conditions of use for the claim evaluated by EFSA were established for all glycaemic carbohydrates. The reason is that the claim related to the role of all glycaemic carbohydrates on the recovery of normal muscle function (contraction) after strenuous exercise and not to the relative efficacy of different types of glycaemic carbohydrates in achieving the claimed effect, and therefore this aspect was not assessed by the NDA Panel. A health claim application on a combination of glucose and fructose and improves performance in active individuals performing endurance exercise compared to the intake of glucose alone was submitted to EFSA and then withdrawn during the evaluation.

The two bodies concluded that the protein requirements of athletes could be covered by established dietary guidelines, since higher energy needs would result in higher protein intakes on a body weight basis if the protein contribution to total energy intake is kept at about 10–12 E %. Neither the SCF nor the EFSA NDA Panel considered that particular protein sources or protein components could have a beneficial effect for athletes on muscle mass or performance beyond what could be expected from high quality protein or protein in mixed diets.

Neither the SCF nor the EFSA NDA Panel considered that athletes may have specific requirements for micronutrients or n-3 LC-PUFA (e.g. beyond the requirements established for the general population), or that athletes would benefit from supplementation with these nutrients. The only health claim related to essential micronutrients specifically addressed to sportspeople (and not to the general population) which was evaluated by the Panel with a positive outcome related to vitamin C and the function of the immune system during and after intense physical exercise. Higher doses of vitamin C (beyond the PRIs) were considered by EFSA to be required for such benefit. The task of establishing ULs (or safe levels of intake) for vitamins and minerals initiated by the SCF has been already completed by EFSA and may serve as guidance to judge whether the intake of high levels of some vitamins and minerals through supplementation, a practice that is particularly popular among athletes, may pose a risk to health.

Whereas the SCF considered that caffeine ingestion prior to exercise enhanced performance in short-term intense exercise lasting approximately five minutes, the EFSA NDA Panel found no convincing evidence for such an effect. The safety of caffeine consumption in conjunction with intense physical exercise, which was not evaluated by the SCF, was considered in an EFSA opinion following a request from the European Commission during the process of authorisation of health claims on caffeine and physical performance.

The SCF warned about consuming creatine in hot conditions prior to exercise, and notes the lack of robust data regarding the safety of long-term creatine supplementation, particular at doses higher than recommended. The EFSA NDA Panel did not assess the safety of long-term creatine supplementation because safety assessments are not foreseen in the framework of Regulation (EC) No 1924/2006. No safety concerns were raised by risk managers regarding long-term supplementation with creatine at doses of 3 g per day in the health claim authorisation process.

Neither the SCF nor the EFSA NDA Panel found a solid basis for the use of other food constituents as nutritional ergogenic aids to meet the expenditure of intense muscular effort and especially for sportspeople.

Whereas the SCF only considered health risks for athletes in relation to the intake of essential nutrients, EFSA assessed several health claims on the relationship between food constituents other than essential nutrients and health outcomes which have been linked to specific health risks for athletes, including reduction of the risk of URTI, reduction of systemic inflammation, protection of cells and molecules against oxidative damage, and maintenance of normal joints. All these claims have been evaluated by EFSA with negative outcomes. The target population for the majority of these claims was the general population. Physically active subjects or subjects performing sports were only mentioned specifically within the target population of claims on glucosamine and collagen hydrolysate and maintenance of normal joints.

References

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neuromuscular function (ID 4250), contribution to normal cognitive function (ID 710, 1596, 1631, 1983) and maintenance of normal neurological function (ID 1596) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1741, 26 pp. doi:10.2903/j.efsa.2010.1741

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Abbreviations

AI	Adequate Intake
AR	Average Requirement
BCAA	Branched-chain amino acids
bw	Body weight
DRV	Dietary Reference Value
LC-PUFA	Long-chain polyunsaturated fatty acid
MTC	Medium-chain triglycerides
PAL	Physical Activity Level
PLP	Pyridoxal phosphate
PRI	Population Reference Intake
SCF	Scientific Committee on Food
UL	Tolerable Upper Intake Level

Appendix A – Food constituents and claimed effects related to exercise performance evaluated by EFSA in the context of health claims

Food constituent	Claimed effect	Type of claim	References
ATP	Maintenance of normal muscle function	Art. 13 (1)	(EFSA NDA Panel, 2011h)
B-alanine	Increase in physical performance during short-term high-intensity exercise	Art. 13 (1)	(EFSA NDA Panel, 2010l)
	Increase in time to exhaustion		
	Increase in physical performance during short-duration, high-intensity exercise	Art. 13(5)	(EFSA NDA Panel, 2014b)
Bovine colostrum	Improvement in exercise performance when combined with regular training	Art. 13 (1)	(EFSA NDA Panel, 2011i)
	Increase in lean body mass when combined with resistance exercise		
	Recovery following intense exercise		
BCAA	Growth or maintenance of muscle mass	Art. 13 (1)	(EFSA NDA Panel, 2010m)
	Attenuation of the decline in muscle power following exercise at high altitude		
	Faster recovery from muscle fatigue after exercise		
	Improvement of cognitive function after exercise		
	Reduction in perceived exertion during exercise		
Casein protein hydrolysates	Growth or maintenance of muscle mass	Art. 13 (1)	(EFSA NDA Panel, 2011j)
	Increase in endurance performance		
	Faster recovery from muscle fatigue after exercise		
Citruline malate	Faster recovery from muscle fatigue after exercise	Art. 13(5)	(EFSA NDA Panel, 2012c, 2014c)
Coenzyme Q10	Contribution to normal energy-yielding metabolism	Art. 13 (1)	(EFSA NDA Panel, 2010c)
	Increase in endurance capacity and/or endurance performance		
B-hydroxy B-methylbutyrate monohydrate (HBM) alone or in combination with α-ketoisocaproic acid (KIC)	Reduction of muscle tissue damage during exercise	Art. 13(1)	(EFSA NDA Panel, 2011l)
	Increase in lean body mass		
	Increase in muscle strength		
	Increase in endurance performance		
	Skeletal muscle tissue repair		
	Faster recovery from muscle fatigue after exercise		
L-carnitine	Faster recovery from muscle fatigue after exercise	Art.13(1)	(EFSA NDA Panel, 2011a)
	Skeletal muscle tissue repair		
	Increase in endurance capacity		
L-carnosine	Increase in muscle power	Art.13(1)	(EFSA NDA Panel, 2011p)
	Increase in endurance capacity		
	Maintenance of normal cardiac function		
L-glutamine	Growth or maintenance of muscle mass	Art.13(1)	(EFSA NDA Panel, 2011o)
	Faster restoration of muscle glycogen stores after strenuous exercise		
	Skeletal muscle tissue repair		

Food constituent	Claimed effect	Type of claim	References
Ribose	Faster recovery from muscle fatigue after exercise	Art.13(1)	(EFSA NDA Panel, 2011m)
Sodium phosphate	Increase in endurance performance	Art.13(1)	(EFSA NDA Panel, 2011n)
	Increase in endurance capacity		
Soy phosphatidyl choline	Faster recovery from muscle fatigue after exercise	Art.13(1)	(EFSA NDA Panel, 2010b)
	Improvement of neuromuscular function		
	Contribution to normal fat metabolism		
Superoxide dismutase (SOD)	Reduction of muscle fatigue during exercise	Art.13(1)	(EFSA NDA Panel, 2010r)
Taurine	Maintenance of normal cardiac function	Art.13(1)	(EFSA NDA Panel, 2009m, 2011k)
	Maintenance of normal muscle function		
	Delay in the onset of physical fatigue during exercise		
Whey protein	Growth or maintenance of muscle mass	Art.13(1)	(EFSA NDA Panel, 2010a)
	Increase in lean body mass during energy restriction and resistance training		
	Reduction of body fat mass during energy restriction and resistance training		
	Increase in muscle strength		
	Increase in endurance capacity during the subsequent exercise bout after strenuous exercise		
	Skeletal muscle tissue repair		
	Faster recovery from muscle fatigue after exercise		