SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to taurine and protection of DNA, proteins and lipids from oxidative damage (ID 612, 1658, 1959), energy-yielding metabolism (ID 614), and delay in the onset of fatigue and enhancement of physical performance (ID 1660) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to taurine and the following claimed effects: protection of DNA, proteins and lipids from oxidative damage, energy-yielding metabolism, and delay in the onset of fatigue and enhancement of physical performance. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is taurine (2- amino-ethanesulfonic acid), which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that taurine is sufficiently characterised.

Protection of DNA, proteins and lipids from oxidative damage

The claimed effects are "antioxidant activity, detoxifying properties, and protection of body cells from oxidative damage". The Panel assumes that the target population is the general population. The Panel considers that protection of DNA, proteins and lipids from oxidative damage is beneficial to human health

One human intervention study, which investigated the effects of taurine on the prevention of exercise-induced oxidative damage, was presented. The Panel notes that the small number of subjects, the lack

1 On request from the European Commission, Question No EFSA-Q-2008-1399, EFSA-Q-2008-1401, EFSA-Q-2008-2394, EFSA-Q-2008-2396, EFSA-Q-2008-2692 adopted on 02 July 2009.

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For citation purposes: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to taurine and protection of DNA, proteins and lipids from oxidative damage (ID 612, 1658, 1959), energy-yielding metabolism (ID 614), and delay in the onset of fatigue and enhancement of physical performance (ID 1660) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9):1260. [17 pp.]. doi:10.2903/j.efsa.2009.1260. Available online: www.efsa.europa.eu

of control group, the high doses of taurine used, and the lack of appropriate methods to assess oxidative damage limit the conclusions that can be drawn from this study in relation to the claimed effect under the proposed conditions of use.

On the basis of the data available, the Panel concludes that cause and effect relationship has not been established between the consumption of taurine and the protection of DNA, proteins or lipids from oxidative damage.

Energy-yielding metabolism

The claimed effect is "energy metabolism". The Panel assumes that the target population is the general population. The Panel considers that normal energy-yielding metabolism is beneficial to human health.

Although a role of taurine on glucose absorption and metabolism has been suggested in animal and *in vitro* experimental studies, the clinical studies available in type 1 diabetic subjects are too small and too short in duration to draw conclusions. In addition, taurine supplementation had no effect on insulin secretion/action in non-diabetic overweight subjects.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and the normal energy-yielding metabolism.

Delay in the onset of fatigue and enhancement of physical performance

The claimed effect is "ergogenic role in sports and exercise". The Panel assumes that the target population is sports men and women. The Panel considers that delaying the onset of fatigue and enhancing physical performance might be beneficial for sports men and women.

Three human interventions and one animal study investigated the relationship between the consumption of taurine and the claimed effect. In weighing the evidence the Panel took into account the small number of subjects included, the lack of measurements related to physical performance in one of the studies, the difficulty in attributing any effects to the consumption of taurine alone in two of the studies, and the high doses of taurine used in one human intervention and in the animal study, which limit the conclusions that can be drawn in relation to the consumption of taurine and the claimed effect under the proposed conditions of use.

On the basis of the data available, the Panel concludes that a cause an effect relationship has not been established between the consumption of taurine and the delay in the onset of fatigue or the enhancement of physical performance.

KEY WORDS

Taurine, antioxidants, oxidative damage, energy metabolism, fatigue, physical performance, health claims.

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ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group on claims for the preparation of this opinion: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is taurine (2- amino-ethanesulfonic acid), which is a well recognised nutrient and is measurable in foods by established methods.

Taurine occurs naturally in foods of animal origin and is practically absent from foods of plant origin.

The Panel considers that the food constituent, taurine, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Protection of DNA, proteins and lipids from oxidative damage (ID 612, 1658, 1959)

The claimed effects are "antioxidant activity, detoxifying properties, and protection of body cells from oxidative damage". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effects relate to the protection of body cells and tissues from oxidative damage caused by free radicals.

Reactive oxygen species including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation, pollutants). These reactive intermediates damage biologically relevant molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network which includes free radical scavengers like antioxidant nutrients.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage is beneficial to human health.

2.2. Energy-yielding metabolism (ID 614)

The claimed effect is "energy metabolism". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the conversion of energy from foods into energy in the form of ATP which may be readily used by the body.

The Panel considers that normal energy-yielding metabolism is beneficial to human health.

[3] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

2.3. Delay in the onset of fatigue and enhancement of physical performance (ID 1660)

The claimed effect is "ergogenic role in sports and exercise". The Panel assumes that the target population is sports men and women.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the delay of the onset of fatigue and to enhanced physical performance.

The Panel considers that delaying the onset of fatigue and enhancing physical performance might be beneficial for sports men and women.

3. Scientific substantiation of the claimed effect

Taurine is synthesised in the body from sulphur containing amino acids, especially from cysteine, by oxidation of the sulphur function and decarboxylation. This last step is rate limiting. Compensatory mechanisms for dietary taurine deprivation (e.g. in vegans) include alteration of the bile salt glycine/taurine ratio, decrease in whole body taurine turnover and reduction of urinary excretion of taurine (Kendler, 1989). Taurine concentrations in tissues, particularly in the brain, are largely independent of taurine intakes. However, endogenous synthesis and usual consumptions can be insufficient to meet the metabolic needs in certain pathological conditions, so that taurine is considered to be a conditionally indispensable amino acid, particularly in preterm infants (Lourenço and Camilo, 2002).

3.1. Protection of DNA, proteins and lipids from oxidative damage (ID 612, 1658, 1959)

The references provided for the substantiation of the claimed effect include general reviews on the role of taurine in human nutrition, on the role of antioxidants in free-radical scavenging, on the role of oxidative stress in the development of chronic disease; studies on the role of taurine in the prevention/treatment of hypoxia and oxidative stress-induced tissue injury in animal models; and human intervention studies on taurine supplementation, both orally and intravenously, for the treatment of various disease conditions.

The Panel considers that no conclusions can be drawn from these references in relation to the claimed effect. The Panel also considers that the evidence provided in the animal studies does not predict an effect of taurine consumption on the protection of body tissues from oxidative damage in humans.

One human intervention study which investigated the effects of taurine supplementation on the prevention of exercise-induced oxidative damage was presented (Zhang et al., 2004). In an open label, single arm intervention, 11 young men (18-20 years of age) underwent an identical exhaustive test procedure using a bicycle ergometer before and after taurine supplementation (6 g/d for 7 days). Single cell gel assay was used to study DNA damage in white blood cells (WBC). Plasma lipid oxidation products were assessed using the plasma thiobaribituric acid reactive substance (TBARS) assay. Pre-supplementation of taurine, a significant negative correlation was found between plasma taurine concentrations before exercise and TBARS 6 hr after exercise. WBC showed a significant increase in DNA strand breakage 6 hr and 24 hr after exercise. Seven-day taurine supplementation reduced serum TBARS before exercise and resulted in a significantly reduced DNA migration 24 hr after exercise. The Panel notes that the small number of subjects studied, the lack of an appropriate control group, the high doses of taurine used in the study as compared to those proposed in the conditions of use, and the lack of appropriate methods to assess either lipid or DNA oxidative damage limit the conclusions that can be drawn from this study in relation to the claimed effect under the proposed conditions of use.

The Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and the protection of DNA, proteins and lipids from oxidative damage.

3.2. Energy-yielding metabolism (ID 614)

One monograph was provided for the substantiation of the claimed effect (Jellin et al., 2000).

The role of taurine on carbohydrate metabolism is mentioned in some of the references provided to substantiate other claims on taurine (Huxtable, 1992; Birdsall, 1998; Bouckenooghe et al., 2006). Although a role for taurine on glucose absorption and metabolism has been suggested in animal and *in vitro* experimental studies via interactions with the insulin receptor, the clinical studies, which were performed in patients with type 1 diabetes mellitus, are too small and too short duration to draw any conclusions (Franconi et al., 2006). In addition, taurine supplementation has no effect on insulin secretion/action in non-diabetic overweight subjects (Bouckenooghe et al., 2006).

The Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and normal energy-yielding metabolism.

3.3. Delay in the onset of fatigue and enhancement of physical performance (ID 1660)

The ergogenic effect of taurine in sports and exercise is not mentioned in any of the reviews and textbooks provided for the substantiation of the claimed effect.

Out of the references provided, three human intervention studies (Yatabe et al., 2003; Baum and Weiss, 2001; Alford et al., 2001) and one animal study (Zhang et al., 2004) investigated the relationship between the consumption of taurine and the claimed effect.

In a crossover double blind intervention study (Baum and Weiss, 2001), 13 endurance trained athletes consumed 500 ml of a so-called "energy drink" containing 2 g taurine, 160 mg caffeine, 1.2 g glucuronolactone, 43 g saccharose, and 10.5 g glucose (and vitamins), 500 ml of a similar (control) drink without taurine and glucuronolactone, and 500 ml of a drink containing only saccharose and glucose (placebo) 40 minutes before a controlled intense exercise. Parameters of cardiac contractility were assessed by echocardiography before and after exercise. Some parameters of cardiac contractility (e.g., left ventricular end systolic diameter) improved after exercise following consumption of the "energy drink" compared to the control and placebo drinks. The Panel notes that no conclusions can be drawn from this study for the substantiation of the claim on taurine alone.

In the study by Alford et al. (2001), a total of 36 volunteers were included in three different small double-blind crossover studies comparing the effects of 250 ml of an energy drink containing 1 g taurine, 80 mg caffeine and 600 mg glucuronolactone to those of 250 ml of carbonated water (control) consumed before aerobic and anaerobic endurance testing. When compared to the control drink (carbonated water), the energy drink significantly improved aerobic endurance (maintaining 65–75% max. heart rate) and anaerobic performance (maintaining max. speed) on cycle ergometers. The Panel notes that no conclusions can be drawn from this study for the substantiation of the claim on taurine alone.

The study by Zhang et al. (2004) was an open label, single arm intervention which investigated the effects of taurine supplementation (6 g/d for 7 days) on exercise performance in 11 young men (18-20 years of age). Subjects were asked to undergo an identical exhaustive test procedure using a bicycle ergometer before and after the taurine supplementation period. Workload, VO2 max, and exercise duration before fatigue significantly increased after taurine supplementation compared with baseline (pre-treatment). The Panel notes that the small number of subjects studied, the lack of an appropriate control group, and the high doses of taurine used in the study (6 g/d, 60 times higher than the 100mg/d dose proposed in the conditions of use) limit the conclusions that can be drawn from this study in relation to the claimed effect under the proposed conditions of use.

In a rat study (Yatabe et al., 2003), a modest but significant increase in time to exhaustion was observed with very high doses of taurine (0.5 g/kg) that are not relevant for human nutrition.

In weighing the evidence, the Panel took into account the small number of subjects studied, the lack of measurements related to physical performance in one of the studies, the difficulty in attributing any effects to the consumption of taurine alone in two of the studies, and the high doses of taurine used in one human intervention study and in the animal study, which limit the conclusions that can be drawn from these studies in relation to the consumption of taurine and the claimed effect under the proposed conditions of use.

The Panel concludes that a cause an effect relationship has not been established between the consumption of taurine and the delay in the onset of fatigue or the enhancement of physical performance.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, taurine, which is the subject of the health claims, is sufficiently characterised.

Protection of DNA, proteins and lipids from oxidative damage (ID 612, 1658, 1959)

- The claimed effects are "antioxidant activity, detoxifying properties, and protection of body cells from oxidative damage". The target population is assumed to be the general population. Protection of DNA, proteins and lipids from oxidative damage is beneficial to human health.

- A cause and effect relationship has not been established between the consumption of taurine and the protection of DNA, proteins or lipids from oxidative damage.

Energy-yielding metabolism (ID 614)

- The claimed effect is "energy metabolism". The target population is assumed to be the general population. Normal energy-yielding metabolism is beneficial to human health.

- A cause and effect relationship has not been established between the consumption of taurine and normal energy-yielding metabolism.

Delay in the onset of fatigue and enhancement of physical performance (ID 1660)

- The claimed effect is "ergogenic role in sports and exercise". The target population is assumed to be sports men and women. Delaying the onset of fatigue and enhancing physical performance might be beneficial for sports men and women.

- A cause an effect relationship has not been established between the consumption of taurine and the delay in the onset of fatigue or the enhancement of physical performance.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1399, EFSA-Q-2008-1401, EFSA-Q-2008-2394, EFSA-Q-2008-2396, EFSA-Q-2008-2692). The scientific substantiation is based on the information provided by the Members States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm

REFERENCES

Alford C, Cox H, Wescott R, 2001. The effects of red bull energy drink on human performance and mood. Amino Acids 21, 139-50.

Baum M and Weiss M, 2001. The influence of a taurine containing drink on cardiac parameters before and after exercise measured by echocardiography. Amino Acids 20, 75-82.

Birdsall TC, 1998. Therapeutic applications of taurine. Altern Med Rev 3, 128-136.

Bouckenooghe T, Remacle C, Reusens B, 2006. Is taurine a functional nutrient? Curr Opin Clin Nutr Metab Care 9, 728-733.

Franconi F, Loizzo A, Ghirlanda G, Seghieri G, 2006. Taurine supplementation and diabetes mellitus. Curr Opin Clin Nutr Metab Care 9, 32-36.

Huxtable RJ, 1992. Physiological actions of taurine. Physiol Rev 72, 101-163.

Lourenço R and Camilo ME, 2002. Taurine: a conditionally essential aminoacid in humans? An overview in health and disease. Nutr Hosp 17, 262-270.

Kendler BS, 1989. Taurine: an overview of its role in preventive medicine. Prev Med 18, 79-100.

Jellin JM, Gregory P, Batz F, 2000. Natural medicines comprehensive database. Stockton, CA: Therapeutic Research Faculty, Stockton, CA.

Yatabe Y, Miyakawa S, Miyazaki T, Matsuzaki Y, Ochiai N, 2003. Effects of taurine administration in rat skeletal muscles on exercise. J Orthop Sci 8, 415-419.

Zhang M, Izumi I, Kagamimori S, Sokejima S, Yamagami T, Liu Z, Qi B, 2004. Role of taurine supplementation to prevent exercise-induced oxidative stress in healthy young men. Amino Acids 26, 203-207.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[4] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[5]

Foods are commonly involved in many different functions[6] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[4] OJ L12, 18/01/2007
[5] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[6] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the consumption has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.

- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.

- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.

- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to taurine, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
612	Taurine	Antioxidant activity	- Helps to protect body cells; - Helps to protect from radicals which cause cell oxidation; - Helps to protect cells and tissues from oxidation; - Contributes to the total antioxidant capacity of the body.
	Conditions of use - 75-150 mg.		
	Food or Food component	**Health Relationship**	**Proposed wording**
614	Taurine	Energy metabolism	- Taurine is important for the energy metabolism; - the transformation of food into energy.
	Conditions of use - No conditions of use provided.		
	Food or Food component	**Health Relationship**	**Proposed wording**
1658	Taurine	Antioxidant properties	- Supports the protection of the body's cells; - Supports the protection from free radicals; - Supports the protection of cells and tissues from oxidation.
	Conditions of use - Tagesdosis > 40 mg. - 75-150 mg. - Taurin als Aminosäure, in Austernerzeugnissen oder in anderen Erzeugnissen. 300 mg pro kg Lebensmittel als Aminosäure. - 100 mg täglich–Nahrungsergänzung. - 500-3000 mg.		

	Food or Food component	Health Relationship	Proposed wording
1660	Taurine	Ergogenic role in sports and exercise	- Helps to delay the onset of fatigue; - helps to maintain energy levels for prolonged periods during intense competition / exercise; - enhances endurance and helps to maintain peak effort during times of high physical demand.
	Conditions of use - Sports foods and food supplements containing taurine and targeted at sports people. - 100 mg Taurin.		
	Food or Food component	**Health Relationship**	**Proposed wording**
1959	Taurine	Antioxidant/ detoxifying properties	- Possesses antioxidant and detoxifying properties; - can protect from free radical which cause cell damage, due to its antioxidant properties; - can protect cells and tissues from oxidative damages.
	Conditions of use - At least 500 mg/day.		

GLOSSARY / ABBREVIATIONS

TBARS	Thiobaribituric acid reactive substance
WBC	White blood cells