European Food Safety Authority

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to taurine and "immune system protection" (ID 611), "metabolism processes" (ID 613), contribution to normal cognitive function (ID 1659), maintenance of normal cardiac function (ID 1661), maintenance of normal muscle function (ID 1949) and delay in the onset of physical fatigue during exercise (ID 1958) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

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 (EC) No 1924/2006. This opinion addresses the scientific substantiation of a health claim in relation to taurine and "immune system protection", "metabolism processes", contribution to normal cognitive function, maintenance of normal cardiac function, maintenance of normal muscle function and delay in the onset of physical fatigue during exercise. 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. The Panel considers that taurine is sufficiently characterised.

[1] On request from the European Commission, Question No EFSA-Q-2008-1398, EFSA-Q-2008-1400, EFSA-Q-2008-2395, EFSA-Q-2008-2397, EFSA-Q-2008-2682, EFSA-Q-2008-2691, adopted on 12 November 2010.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens. The members of the Claims Sub-Working Group on Mental/Nervous System: Jacques Rigo, Astrid Schloerscheidt, Barbara Stewart-Knox, Sean (J.J.) Strain, and Peter Willatts.

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"Immune system protection"

The claimed effect is "for immune system protection". The target population is assumed to be the general population. The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

"Metabolism processes"

The claimed effect is "for metabolism processes (glucose/caffeine uptake)". The target population is assumed to be the general population. The claimed effect is not sufficiently defined and no further details were provided in the proposed wording or the clarifications provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Contribution to normal cognitive function

The claimed effect is "cognitive function/mental health". The target population is assumed to be the general population. The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and contribution to normal cognitive function.

Maintenance of normal cardiac function

The claimed effect is "for cardiovascular system health". The target population is assumed to be the general population. In the context of the proposed wording and the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal cardiac function. The Panel considers that maintenance of normal cardiac function is a beneficial physiological effect.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and maintenance of normal cardiac function.

Maintenance of normal muscle function

The claimed effect is "fonctionnement musculaire". The target population is assumed to be the general population. The Panel assumes that the claimed effect refers to the maintenance of normal muscle function. The Panel notes that from the information provided it is unclear which aspect of muscle function is the subject of the health claim, and that none of the references provided for this claim addressed any aspect of muscle function.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Delay in the onset of physical fatigue during exercise

The claimed effect is "tonus/vitality". The target population is assumed to be active individuals in the general population. In the context of the proposed wordings and clarifications provided by Member States, and in the context of the references provided, the Panel assumes that the claimed effect refers to a delay in the onset of physical fatigue during exercise. The Panel considers that a delay in the onset of physical fatigue during exercise is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and a delay in the onset of physical fatigue during exercise.

KEY WORDS

Taurine, immune system, metabolism, cognitive function, heart, muscle, fatigue, exercise, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of 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). Taurine is a well recognised nutrient and is measurable in foods by established methods.

Taurine occurs naturally in foods of animal origin and is generally 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. "Immune system protection" (ID 611)

The claimed effect is "for immune system protection". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were given in the proposed wording or the clarifications provided by Member States. Given the multiple roles of the immune system, the specific aspect of immune function that is the subject of the health claim needs to be specified, but it has not been indicated in the information provided.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.2. "Metabolism processes" (ID 613)

The claimed effect is "for metabolism processes (glucose/caffeine uptake)". The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no further details were given in the proposed wording or the clarifications provided by Member States.

[4] 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.

[5] Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.3. Contribution to normal cognitive function (ID 1659)

The claimed effect is "cognitive function/mental health". The Panel assumes that the target population is the general population.

Cognitive function includes memory, attention (concentration), learning, intelligence and problem solving, which are well defined constructs and which can be measured by validated psychometric cognitive tests.

The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

2.4. Maintenance of normal cardiac function (ID 1661)

The claimed effect is "for cardiovascular system health". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal cardiac function.

The Panel considers that maintenance of normal cardiac function is a beneficial physiological effect.

2.5. Maintenance of normal muscle function (ID 1949)

The claimed effect is "fonctionnement musculaire". The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect refers to the maintenance of normal muscle function. The Panel notes that from the information provided it is unclear which aspect of muscle function is the subject of the health claim, and none of the references provided for this claim addressed any aspect of muscle function.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.6. Delay in the onset of physical fatigue during exercise (ID 1958)

The claimed effect is "tonus/vitality". The Panel assumes that the target population is active individuals in the general population.

In the context of the proposed wordings and clarifications provided by Member States, and in the context of the references provided, the Panel assumes that the claimed effect refers to a delay in the onset of physical fatigue during exercise.

The Panel considers that a delay in the onset of physical fatigue during exercise is a beneficial physiological effect.

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 (Lourenco and Camilo, 2002).

3.1. Contribution to normal cognitive function (ID 1659)

The references cited for the substantiation of the claimed effect included a website from a government body and narrative reviews on taurine metabolism and outcomes not related to the claimed effect. The majority of papers addressed outcomes unrelated to the claimed effect such as the management of alcohol dependence, chlorination of taurine by human neutrophils, epilepsy, taurine transport in the heart, heart failure, cell volume regulation, taurine requirements in infants or during long-term parenteral nutrition, insulin-dependent diabetes, fat malabsorption in cystic fibrosis, taurine and exercise in humans and rats, liver injury in rats, hamster sperm, age-related reduction in plasma taurine in rats, retinal degeneration in mice, growth in infant monkeys and nitrogen dioxide lung injury in hamsters. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Two studies investigated the effect of a drink containing taurine, glucuronolactone and caffeine on reaction time, concentration, memory, subjective alertness and physical endurance (Alford et al., 2001), and on cognitive function and mood (Seidl et al., 2000). The Panel considers that no conclusions can be drawn from studies on a fixed combination for the scientific substantiation of a claim on taurine alone.

The Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and contribution to normal cognitive function.

3.2. Maintenance of normal cardiac function (ID 1661)

Fourteen references have been provided for the substantiation of the claim; five of them were not available to the Panel despite reasonable efforts made to retrieve them. Among the available references there were four narrative reviews in which the health relationship was stated without providing original data, two animal studies, two *in vitro* studies and one human study. Among them, only the human study (Azuma et al., 1992), one *ex vivo* animal study (Raschke et al., 1995) and one *in vitro* study (Takahashi et al., 1997) addressed the claimed effect.

The study by Azuma et al. (1992) was an uncontrolled intervention in 10 patients suffering from congestive heart failure who received 3 g/day of taurine (above the proposed condition of use of 75 to 500 mg/day) for 6 weeks while continuing their usual pharmacological treatment. The Panel considers that no conclusion can be drawn from this small uncontrolled study.

The study by Raschke et al. (1995) used a model of ischemia-reperfusion injury in the isolated guinea pig heart, and the study by Takahashi et al. (1997) assessed the effect of taurine on calcium overload in cultured cardiomyocytes. The Panel considers that evidence provided in *ex vivo* animal studies and in *in vitro* studies is not sufficient to predict the occurrence of an effect of taurine consumption on maintenance of normal cardiac function in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of taurine and maintenance of normal cardiac function.

3.3. Delay in the onset of physical fatigue during exercise (ID 1958)

The references provided for the substantiation of the claim include two narrative reviews on the health effects of taurine, all unrelated to the claimed effect, and a number of human intervention studies using taurine in combination with other food constituents, including caffeine and glucuronolactone. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

In one single arm, uncontrolled study (Zhang et al., 2004), the effect of taurine supplementation on exercise time to exhaustion was studied in 11 young men (aged 18-20 years). Subjects performed a bicycle ergometer test (rate of 60 rpm with an increased workload of 20 W/min) until exhaustion. After the first exercise test, subjects received supplemental taurine powder at a daily dose of 6 g (2 g three times a day) for 7 days prior to the second exercise test, which was identical to the first test. Maximal oxygen uptake, the exercise time to exhaustion and maximal workload were assessed after each test. The Panel notes that this study was not controlled, and that the study design does not allow controlling for a possible training effect between the first and second cycling tests. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

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

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.

"Immune system protection" (ID 611)

- The claimed effect is "for immune system protection". The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

"Metabolism processes" (ID 613)

- The claimed effect is "for metabolism processes (glucose/caffeine uptake)". The target population is assumed to be the general population.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Contribution to normal cognitive function (ID 1659)

- The claimed effect is "cognitive function/mental health". The target population is assumed to be the general population. Contribution to normal cognitive function is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of taurine and contribution to normal cognitive function.

Maintenance of normal cardiac function (ID 1661)

- The claimed effect is "for cardiovascular system health". The target population is assumed to be the general population. In the context of the proposed wordings and the clarifications provided by Member States, the claimed effect is assumed to refer to the maintenance of normal cardiac function. Maintenance of normal cardiac function is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of taurine and maintenance of normal cardiac function.

Maintenance of normal muscle function (ID 1949)

- The claimed effect is "fonctionnement musculaire". The target population is assumed to be the general population. It is assumed that the claimed effect refers to the maintenance of normal muscle function. From the information provided, it is unclear which aspect of muscle function is the subject of the health claim, and none of the references provided for this claim addressed any aspect of muscle function.

- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Delay in the onset of physical fatigue during exercise (ID 1958)

- The claimed effect is "tonus/vitality". The target population is assumed to be active individuals in the general population. In the context of the proposed wordings and clarifications provided by Member States, and in the context of the references provided, the claimed effect is assumed to refer to a delay in the onset of physical fatigue during exercise. A delay in the onset of physical fatigue during exercise is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of taurine and a delay in the onset of physical fatigue during exercise.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1398, EFSA-Q-2008-1400, EFSA-Q-2008-2395, EFSA-Q-2008-2397, EFSA-Q-2008-2682, EFSA-Q-2008-2691). 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 full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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Alford C, Cox H and Wescott R, 2001. The effects of red bull energy drink on human performance and mood. Amino Acids, 21, 139-150.

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

Lourenco R and Camilo ME, 2002. Taurine: a conditionally essential amino acid in humans? An overview in health and disease. Nutricion Hospitalaria, 17, 262-270.

Raschke P, Massoudy P and Becker BF, 1995. Taurine protects the heart from neutrophil-induced reperfusion injury. Free Radical Biology and Medicine, 19, 461-471.

Seidl R, Peyrl A, Nicham R and Hauser E, 2000. A taurine and caffeine-containing drink stimulates cognitive performance and well-being. Amino Acids, 19, 635-642.

Takahashi K, Schaffer SW and Azuma J, 1997. Taurine prevents intracellular calcium overload during calcium paradox of cultured cardiomyocytes. Amino Acids, 13, 1-11.

Zhang M, Izumi I, Kagamimori S, Sokejima S, Yamagami T, Liu Z and 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[6] (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[7]

Foods are commonly involved in many different functions[8] 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.

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] 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 dietary intake 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 DISCLAIMER

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 constituent	Health Relationship	Proposed wording
611	Taurine	For immune system protection. Clarification provided It is necessary to build up white blood cells and therefore helps in a proper immune function.	Amino acid that plays an important role in the immune system.
	Conditions of use - 75 – 150 mg		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
613	Taurine	For metabolism processes (glucose/caffeine uptake) Clarification provided Stimulates the secretion/excretion or release of digestive juices and supports the excretory function of kidneys resulting in more frequent and voluminous urination	It supports proper metabolism (uptake of glucose/caffeine).
	Conditions of use - 75-150 mg		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1659	Taurine	Cognitive function/Mental health	-Helps physical and mental performance in cases of temporary stress
	Conditions of use - Energy drink with taurin content of 400mg/100g, 1,320mg/serving, 4,000mg/daily serving.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1661	Taurine	For cardiovascular system health Clarification provided Cardioprotective effect by regulating intracellular calcium level. Management of normal potassium levels in	It protects eye retina, for protection of liver cells from toxins, for proper heart function, proper cardio-vascular health

		heart tissues helps proper functioning of the heart.	
	Conditions of use - 75-150 mg - Tagesdosis Taurin: 500 mg–Erwachsene		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1949	Taurine	fonctionnement musculaire	effet relaxant sur le cœur et les muscles
	Conditions of use - 140mg/j		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1958	Taurine	Tonus/ Vitality Clarification provided Taurine delays the onset of fatigue. Taurine increases energy levels for prolonged period.	Helps to enhance tonus and vitality. Helps to support body's vitality. Helps to make you feel more energetic. Helps to improve physical well-being.
	Conditions of use - At least 500 mg/day		

GLOSSARY AND ABBREVIATIONS

Rpm Revolution per minute