SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to melatonin and alleviation of subjective feelings of jet lag (ID 1953), and reduction of sleep onset latency, and improvement of sleep quality (ID 1953) 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 health claims in relation to melatonin and alleviation of subjective feelings of jet lag, reduction of sleep onset latency, and contribution to sleep quality. 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 melatonin. The Panel considers that melatonin is sufficiently characterised.

Alleviation of subjective feelings of jet lag

The claimed effect is "sleep-wake cycle regulation". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that "sleep-wake cycle regulation" encompasses subjective feelings of jet lag. The Panel considers that alleviation of subjective feelings of jet lag might be a beneficial physiological effect.

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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

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In weighing the evidence, the Panel took into consideration the conclusions of the Cochrane review, which indicated that melatonin was effective in alleviating the subjective symptoms of jet lag.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of melatonin and alleviation of subjective feelings of jet lag. In order to bear the claim, the melatonin dose should be between 0.5 and 5 mg and should be taken close to bedtime on the first day (and any subsequent day) of travel and on the following few days after arrival at the destination. The target population is the general population.

Reduction of sleep onset latency and improvement of sleep quality

The claimed effect is "sleep-wake cycle regulation". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that "sleep-wake cycle regulation" encompasses helping to reduce sleep onset latency and helping to improve sleep quality. The Panel considers that reduction of sleep onset latency and improvement of sleep quality might be beneficial physiological effects.

In weighing the evidence, the Panel accepted the conclusions of the meta-analysis with respect to the outcomes of sleep onset latency and sleep quality.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of melatonin and reduction of sleep onset latency or improvement of sleep quality.

KEY WORDS

Melatonin, jet lag, sleep onset latency, sleep quality, 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 from similar health claims. The information provided in the consolidated list for the health claims which are the subject of this opinion is given in Table 1.

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

ID	Food or Food component	Health Relationship	Proposed wording
1953	Melatonin	Sleep-wake cycle regulation	Helps to reduce jet lag effects Helps to reduce sleep onset latency Helps to regulate circadian rhythm Improves sleep-wake cycle Contributes to improve sleep quality Helps to fall asleep in a natural way
	Conditions of use - At least 5 mg per day		

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is melatonin, which is a hormone produced by the pineal gland during the hours of darkness. Melatonin can be measured by established methods.

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

2. Relevance of the claimed effect to human health

2.1. Alleviation of subjective feelings of jet lag (ID 1953)

The claimed effect is "sleep-wake cycle regulation". The Panel assumes that the target population is the general population.

"Sleep-wake cycle regulation" is not sufficiently defined. In the context of the proposed wordings, the Panel assumes that "sleep-wake cycle regulation" encompasses subjective feelings of jet lag.

The Panel considers that alleviation of subjective feelings of jet lag might be a beneficial physiological effect.

[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.

2.2. Reduction of sleep onset latency and improvement of sleep quality (ID 1953)

The claimed effect is "sleep-wake cycle regulation". The Panel assumes that the target population is the general population.
"Sleep-wake cycle regulation" is not sufficiently defined. In the context of the proposed wordings, the Panel assumes that "sleep-wake cycle regulation" encompasses helping to reduce sleep onset latency and helping to improve sleep quality.

The Panel considers that reduction of sleep onset latency or improvement of sleep quality might be beneficial physiological effects.

3. Scientific substantiation of the claimed effect

The references cited to substantiate the claim included a total of 17 publications. Seven were reviews, including a Cochrane Systematic Review, and one was a comparison of circadian characteristics between healthy elderly people and young adults. The Panel notes that, of these seven references, only the Cochrane Systematic Review (Herxheimer and Petrie, 2002, reviewed 2008) is suitable for substantiating the claimed effect. The remaining 11 references reported on intervention studies with melatonin. Four of these intervention studies (Dahlitz et al., 1991; Nagtegaal et al., 1998; Kayumov et al., 2001; Mundey et al., 2005) were undertaken in patients who were diagnosed with delayed sleep phase syndrome, one (Haimov and Lavie, 1997) was undertaken in melatonin deficient elderly people, one (Siegrist et al., 2001) in sleep-disturbed middle-aged and elderly patients, most of whom were also on benzodiazepine treatments and one (Kunz et al., 2004) reported on two trials in patients with unselected neuropsychiatric sleep disorders and reduced rapid-eye-movement (REM) sleep duration. The Panel considers that the evidence provided does not establish that patients with various forms of sleep disorders, such as primary or secondary sleep disorders, are representative of the general population or that results obtained in studies on subjects with various forms of sleep disorders relating to the treatment of symptoms of this condition can be extrapolated to the general population.

The Panel, however, considers that results obtained from sleep disorders accompanying sleep restriction as a result of lifestyle and work schedules, such as air travel and shift work, can be extrapolated to the general population.

3.1. Alleviation of subjective feelings of jet lag (ID 1953)

Three (Petrie et al., 1989; Petrie et al., 1993; Arendt and Marks, 1986) of the remaining four references, which were provided, reported on the chronobiotic effects of melatonin with respect to subjective feelings of jet lag in healthy adults after long-haul flights, as did the aforementioned Cochrane Systematic Review. The study of Pierard et al. (2001) investigated outcomes on hormonal rhythms.

The Cochrane Systematic Review (Herxheimer and Petrie, 2002, reviewed 2008) of randomised placebo-controlled trials with melatonin interventions for alleviating jet lag, which included the aforementioned two Petrie studies and the Arendt study along with eight other studies not included in the 17 references provided by Member States and stakeholders, had as primary measure subjective ratings of jet lag. The conclusions of this review were that melatonin (0.5 to 5 mg/day) is effective in preventing or reducing jet lag. The Panel considers that these findings indicate a role for melatonin in decreasing subjective ratings of jet lag scores.

In weighing the evidence, the Panel took into consideration the conclusions of the Cochrane review, which indicated that melatonin was effective in alleviating the subjective symptoms of jet lag.

The Panel concludes that a cause and effect relationship has been established between the consumption of melatonin and alleviation of subjective feelings of jet lag.

3.2. Reduction of sleep onset latency and improvement of sleep quality (ID 1953)

No data were provided on the effects of melatonin on sleep onset latency or on sleep quality. The Panel, however, notes that a meta-analysis (Buscemi et al., 2006; not provided by the Member States or stakeholders) on the efficacy of melatonin for secondary sleep disorders accompanying sleep restriction concluded that there is no evidence that melatonin is effective in treating sleep onset latency (data from nine studies with 508 participants) or measures of sleep quality (data from five studies with 386 participants) in people with sleep disorders accompanying sleep restriction, such as jet lag and shift-work disorder. Only one of the trials (Suhner et al., 1998) included in the Cochrane Review was common to the meta-analysis on the efficacy of trials with melatonin on people with sleep disorders accompanying sleep restriction and the Panel also notes that the meta-analysis did not examine the effect of melatonin on subjective feelings of daytime fatigue and the sleep disturbance aspects of jet lag.

In weighing the evidence, the Panel accepted the conclusions of the meta-analysis with respect to the outcomes of sleep onset latency and sleep quality.

The Panel concludes that a cause and effect relationship has not been established between the consumption of melatonin and reduction of sleep onset latency or improvement of sleep quality.

4. Panel's comments on the proposed wording

4.1. Alleviation of subjective feelings of jet lag (ID 1953)

The Panel considers that the following wording reflects the scientific evidence: "Melatonin contributes to the alleviation of subjective feelings of jet lag.".

5. Conditions and possible restrictions of use

5.1. Alleviation of subjective feelings of jet lag (ID 1953)

The Panel considers that in order to bear the claim, the melatonin dose should be between 0.5 and 5 mg and should be taken close to bedtime on the first day (and any subsequent day) of travel and on the following few days after arrival at the destination. The target population is the general population. Melatonin appears to be safe with short-term use (three months or less). There are no data on safety for children and older people.

CONCLUSIONS

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

- The food constituent, melatonin, that is the subject of the health claim is sufficiently characterised.

Alleviation of subjective feelings of jet lag (ID 1953)

- The claimed effect is "sleep-wake cycle regulation". The target population is assumed to be the general population. Alleviation of subjective feelings of jet lag might be a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of melatonin and alleviation of subjective feelings of jet lag.

- The following wording reflects the scientific evidence: "Melatonin contributes to the alleviation of subjective feelings of jet lag".

- In order to bear the claim, the melatonin dose should be between 0.5 and 5 mg and should be taken close to bedtime on the first day (and any subsequent day) of travel and on the following few days after arrival at the destination. The target population is the general population.

Reduction of sleep onset latency and improvement of sleep quality (ID 1953)

- The claimed effect is "sleep-wake cycle regulation". The target population is assumed to be the general population. Reduction of sleep onset latency and improvement of sleep quality might be beneficial physiological effects.

- A cause and effect relationship has not been established between the consumption of melatonin reduction of sleep onset latency or improvement of sleep quality.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2686). 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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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[5] (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[6]

Foods are commonly involved in many different functions[7] 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.

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