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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight (ID 577) and maintenance of body weight after weight loss (ID 1553) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight (ID 577) and maintenance of body weight after weight loss (ID 1553) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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 formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight and maintenance of body weight after weight loss. 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 formulated palm and oat oil emulsion. The Panel considers that formulated palm and oat oil emulsion is sufficiently characterised.

Contribution to the maintenance or achievement of a normal body weight

The claimed effect is “weight control”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance or achievement of a normal body weight through a satiating effect. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

¹ On request from the European Commission, Question No EFSA-Q-2008-1364, EFSA-Q-2008-2290, adopted on 25 March 2011.

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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 Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjødin and Inge Tetens.

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

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight.

Maintenance of body weight after weight loss

The claimed effect is “weight management”. The target population is assumed to be overweight individuals in the general population who wish to maintain their body weight after significant weight loss. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of body weight after weight loss. The Panel considers that maintenance of body weight after weight loss is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the one human intervention study from which conclusions could be drawn for the scientific substantiation of the claim had some methodological limitations, and did not show a statistically significant effect of formulated palm and oat oil emulsion consumption on maintenance of body weight after weight loss.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of formulated palm and oat oil emulsion and maintenance of body weight after weight loss.

KEY WORDS

Palm and oat oil emulsion, body weight, weight loss, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ 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 out⁵. 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 constituents that are the subject of the health claims are “palm/oat oil fatty acid” and “formulated palm and oat oil emulsion”.

From the references provided, the Panel assumes that the food constituent which is the subject of the health claims is a mixture of fractionated palm oil (about 47 %) and fractionated oat oil (about 2.5 %) in a proportion 95:5 dispersed in water to give a total fat content of about 42 % (w/w). Five grams of the emulsion provide about 2 g fat. The fatty acid composition of the emulsion is known (Burns et al., 2002).

The Panel considers that the food constituent, formulated palm and oat oil emulsion, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Contribution to the maintenance or achievement of a normal body weight (ID 577)

The claimed effect is “weight control”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance or achievement of a normal body weight through a satiating effect.

Weight control can be interpreted as contribution to the maintenance of a normal body weight. In this context, weight loss in overweight individuals without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that contribution to the maintenance or achievement of a normal body weight is 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.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

2.2. Maintenance of body weight after weight loss (ID 1553)

The claimed effect is “weight management”. The Panel assumes that the target population is overweight individuals in the general population who wish to maintain their body weight after significant weight loss.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of body weight after weight loss.

Maintenance of weight loss can be interpreted as contribution to the maintenance of a normal body weight after significant weight loss. In this context, the maintenance of weight loss in overweight subjects without having achieved a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that maintenance of body weight after weight loss is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The references provided for the scientific substantiation of the claims included narrative reviews, human intervention studies and animal studies on foods/food constituents other than palm and oat oil emulsion and/or effects other than body weight (e.g. appetite and intestinal transit), and human intervention studies on the short-term effects of the food constituent on appetite ratings and energy intake (up to 36 hours). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

3.1. Contribution to the maintenance or achievement of a normal body weight (ID 577)

No human studies which addressed the effects of consumption of formulated palm and oat oil emulsion on body weight during weight loss were provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight.

3.2. Maintenance of body weight after weight loss (ID 1553)

Diepvens et al. (2007) designed a randomised, placebo-controlled, double-blind and parallel intervention study to assess the effects of a formulated palm and oat oil emulsion (i.e. with the characteristics described in section 1) on body weight maintenance after weight loss. Fifty overweight or obese women (age range: 18-58 years, BMI: 25-32 kg/m²) received a very-low-energy diet (2.1 MJ/day) for six weeks (weight loss period) and then consumed a yoghurt (250 g) containing either 3 g of milk fat plus 2 g of the formulated palm and oat oil emulsion or 5 g of milk fat (control) twice daily (at breakfast and in the afternoon) for 18 weeks during which the women were asked to restore their habitual eating patterns (weight maintenance period). The composition of the intervention and control yoghurts was matched for energy (2.0 MJ/500g) and macronutrient content (carbohydrates, protein and fat = 69, 12 and 19 E%, respectively). Subjects were stratified for age, BMI, weight, height, waist, and hip circumference, and then randomised to the intervention (n=22) or control (n=28) group at the beginning of the weight loss phase. Multiple primary outcomes were identified in the study (e.g. body weight after weight loss, body composition, resting energy expenditure, and fat oxidation). However, power calculations were not reported and multiplicity of outcomes was not taken into account in the statistical analysis. Statistical significance was set at $p < 0.05$ for all variables. During the weight loss phase, the test and placebo groups lost 7.76 ± 1.5 kg

and 7.65 ± 1.4 kg, respectively. No statistically significant differences in body weight regain during the 18-month maintenance phase were observed between the intervention and placebo groups (1.13 ± 3.4 vs. 2.95 ± 3.1 kg, respectively, $p=0.05$). Weight regain as percentage of weight loss was not significantly lower in the intervention (15 %) compared to the placebo (40 %) group ($p=0.055$). The Panel notes that multiple primary outcomes were identified in the study, that multiplicity of outcomes was not taken into account in the statistical analysis, and that this study does not show a statistically significant effect of the food constituent on body weight maintenance after weight loss.

In weighing the evidence, the Panel took into account that the one human intervention study from which conclusions could be drawn for the scientific substantiation of the claim had some methodological limitations, and did not show a statistically significant effect of formulated palm and oat oil emulsion consumption on maintenance of body weight after weight loss.

The Panel concludes that a cause and effect relationship has not been established between the consumption of formulated palm and oat oil emulsion and maintenance of body weight after weight loss.

CONCLUSIONS

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

- The food constituent, formulated palm and oat oil emulsion, which is the subject of the health claims, is sufficiently characterised.

Contribution to the maintenance or achievement of a normal body weight (ID 577)

- The claimed effect is “weight control”. The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight.

Maintenance of body weight after weight loss (ID 1553)

- The claimed effect is “weight management”. The target population is assumed to be overweight individuals in the general population who wish to maintain their body weight after significant weight loss. Maintenance of body weight after weight loss is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of formulated palm and oat oil emulsion and maintenance of body weight after weight loss.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1364, EFSA-Q-2008-2290). 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>.

REFERENCES

- Burns AA, Livingstone MB, Welch RW, Dunne A and Rowland IR, 2002. Dose-response effects of a novel fat emulsion (Olibra) on energy and macronutrient intakes up to 36 h post-consumption. *European Journal of Clinical Nutrition*, 56, 368-377.
- Diepvens K, Soenen S, Steijns J, Arnold M and Westerterp-Plantenga M, 2007. Long-term effects of consumption of a novel fat emulsion in relation to body-weight management. *International Journal of Obesity*, 31, 942-949.

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 foods⁶ (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 FOOD⁷

Foods are commonly involved in many different functions⁸ 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 formulated palm and oat oil emulsion, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
577	Palm/oat oil fatty acid.	Weight control.	In studies found to increase and prolong the sense of satiety. Helps to control appetite during the day. Increases the feeling of satiety.
			<p>Conditions of use</p> <ul style="list-style-type: none"> - Meal replacement containing 3.8 mg/100 g, 12.5 g/serving of plam/oat oil fatty acids. - Väidet kasutava toidukäitleja andmete põhjal avaldub FabulesTM-i täiskõhutunnet pikendav toime, kui tarbida korraga üks portsjon toodet (150 g jogurtit), milles sisaldub 5 g FabulesTM lisandit.
ID	Food or Food constituent	Health Relationship	Proposed wording
1553	Formulated palm and oat oil emulsion.	Weight management.	Helps to eat less. Helps to reduce weight regain after dieting.
			<p>Conditions of use</p> <ul style="list-style-type: none"> - 5-12.5 g per day

GLOSSARY AND ABBREVIATIONS

BMI Body mass index