EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to very low calorie diets (VLCDs) and reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), reduction in body fat mass while maintaining lean body mass (ID 1412), reduction of post-prandial glycaemic responses (ID 1414), and maintenance of a normal blood lipid profile (1421) 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 very low calorie diets (VLCDs) and reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), reduction in body fat mass while maintaining lean body mass (ID 1412), reduction of post-prandial glycaemic responses (ID 1414), and maintenance of normal blood lipid profile (1421) 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 very low calorie diets (VLCDs) and reduction in body weight, reduction in the sense of hunger, reduction in body fat mass while maintaining lean body mass, reduction of post-prandial glycaemic responses, and maintenance of normal blood lipid profile. 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 diet that is the subject of the claims is "very low calorie diet (VLCD) program". The Panel considers that whereas the diet that is the subject of the claim, very low calorie diet, is sufficiently characterised in relation to the following claimed effects: reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), and reduction in body fat mass while maintaining lean body mass (ID 1412), very low calorie diet is not sufficiently characterised in relation to: reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile

[1] On request from the European Commission, Question No EFSA-Q-2008-2147, EFSA-Q-2008-2148, EFSA-Q-2008-2149, EFSA-Q-2008-2151, EFSA-Q-2008-2158, adopted on 08 April 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 Sjödin and Inge Tetens.

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(ID 1421), mainly owing to the lack of standardisation of the type of available carbohydrates and of most of the fatty acids that formula foods for use in very low calorie diets should contain.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of a very low calorie diet and reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile (ID 1421).

Reduction in body weight

The claimed effect is "safe and effective weight loss, long term weight maintenance". The target population is assumed to be obese adults who wish to reduce their body weight. The Panel considers that reduction in body weight is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the evidence provided consistently showed a greater reduction of body weight in obese subjects on very low calorie diets compared to other dietary interventions aimed at weight loss.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of a very low calorie diet and reduction in body weight.

The Panel considers that in order to bear the claim, a diet should comply with the specifications and conditions of use laid down in CODEX STAN 203-1995. The target population is obese adults who wish to reduce their body weight.

Reduction in the sense of hunger

The claimed effect is "reduced hunger". The target population is assumed to be obese adults in the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to a reduction in sense of hunger mediated by the induction of ketogenesis during a sustained energy deficit. The Panel considers that reduction in the sense of hunger during a sustained energy deficit is a beneficial physiological effect.

No references were provided which addressed the effects of very low calorie diets on sense of hunger.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of a very low calorie diet and reduction in the sense of hunger during a sustained energy deficit.

Reduction in body fat mass while maintaining lean body mass

The claimed effect is "burning fat for energy, preserving lean tissue". The target population is assumed to be obese adults in the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the loss of fat mass while maintaining lean body mass during weight loss. The Panel considers that reduction in body fat mass while maintaining lean body mass is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the evidence provided does not consistently show a greater reduction in body fat mass relative to lean body mass in obese subjects on very low calorie diets compared to other dietary interventions aimed at 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 a very low calorie diet and reduction in body fat mass while maintaining lean body mass.

KEY WORDS

Very low calorie diets, VLCD, weight loss, hunger, body fat mass, lean body mass, post-prandial glycaemic response, lipid profile, 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 diet that is the subject of the claims is "very low calorie diet (VLCD) program".

Very low calorie diets (VLCDs) or very low energy diets are diets which contain energy levels between 450 and 800 kcal per day, and 100 % of the recommended daily intakes for vitamins and minerals. They should contain not less than 50 g of high-quality protein (protein-digestibility-corrected amino acid score of 1), should provide not less than 3 g of linoleic acid and not less than 0.5 g alpha-linolenic acid with a linoleic acid/alpha-linolenic acid ratio between 5 and 15, and should provide not less than 50 g of available carbohydrates (CODEX STAN 203-1995[6]). VLCDs are typically used for 8-16 weeks.

The Panel notes that the nutritional composition and use of VLCDs is not regulated in the European Union.

Additional components or interventions included in a "very low calorie diet (VLCD) program", however, are not sufficiently characterised; these may vary between programs and may affect both initial weight loss and long term weight maintenance. Similarly, the types of available carbohydrates (e.g. their chemical composition and physical properties) which formula foods for use in VLCDs should contain, are not specified. The Panel also notes that the fatty acid composition of formula foods for use in VLCDs is only partially specified (CODEX STAN 203-1995).

The Panel considers that whereas the diet which is the subject of the claim, VLCD, is sufficiently characterised in relation to the following claimed effects: reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), and reduction in body fat mass while maintaining lean body mass (ID 1412), VLCD is not sufficiently characterised in relation to: reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile (ID 1421), mainly owing to the lack of standardisation of the type of available carbohydrates and of most of the fatty acids that formula foods for use in VLCDs should contain.

[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.

[6] CODEX STAN 203-1995. CODEX STANDARD for Formula Foods for Use in Very Low Energy Diets for Weight Reduction

The Panel concludes that a cause and effect relationship cannot be established between the consumption of a VLCD and reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile (ID 1421).

The Panel considers that the diet which is the subject of the claim, VLCD, is sufficiently characterised in relation to the following claimed effects: reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411) and reduction in body fat mass while maintaining lean body mass (ID 1412).

2. Relevance of the claimed effect to human health

2.1. Reduction in body weight (ID 1410)

The claimed effect is "safe and effective weight loss, long term weight maintenance". The Panel assumes that the target population is obese adults who wish to reduce their body weight.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to a reduction in body weight.

Weight loss can be interpreted as the achievement of a normal body weight in previously obese subjects. In this context, weight loss in obese subjects without the achievement of a normal body weight is considered a beneficial physiological effect.

The Panel considers that reduction in body weight is a beneficial physiological effect.

2.2. Reduction in the sense of hunger (ID 1411)

The claimed effect is "reduced hunger". The Panel assumes that the target population is obese adults in the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to a reduction in sense of hunger mediated by the induction of ketogenesis during a sustained energy deficit.

The Panel considers that reduction in the sense of hunger during a sustained energy deficit is a beneficial physiological effect.

2.3. Reduction in body fat mass while maintaining lean body mass (ID 1412)

The claimed effect is "burning fat for energy, preserving lean tissue". The Panel assumes that the target population is obese adults in the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the loss of fat mass while maintaining lean body mass during weight loss.

The Panel considers that reduction in body fat mass while maintaining lean body mass is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Reduction in body weight (ID 1410)

The references provided for the scientific substantiation of the claim included abstracts with insufficient information for a scientific evaluation, narrative reviews, and human intervention studies on diets other than VLCDs (e.g. low carbohydrate diets and low fat diets) and/or effects other than body weight changes (e.g. body composition and snoring). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Four reviews (Ayyad and Andersen, 2000; Jebb and Goldberg, 1998; Miura et al., 1989; Mustajoki and Pekkarinen, 2001) and two meta-analyses (Anderson et al., 2004; Gilden Tsai and Wadden, 2006) including most of the original human intervention studies presented on the effects of VLCDs on body weight loss were provided.

The two meta-analyses were based on 19 individual studies including more than 2,500 overweight or obese subjects (the majority of whom were obese) of both sexes (the majority of whom were females) treated with VLCDs for between eight and 28 weeks (median 22 weeks), and with a follow-up period of between one and five years.

The meta-analysis by Anderson et al. (2004) was based on 47 intervention studies conducted in obese but otherwise healthy adult subjects (BMI at least 30 kg/m^2 at baseline) which assessed the effects of meal replacements (at least two meal replacements per day, four studies), energy restricted diets (providing >1,500 kcal per day, six studies), low-energy diets (providing 800-1500 kcal per day, 10 studies), VLCDs (providing up to 800 kcal per day, 19 studies), and soy diets (providing up to 800 kcal per day, eight studies), and reported weight loss data after 24 weeks of treatment. Participants in the 19 studies on VLCDs were 1,968 obese subjects of both sexes with an average initial BMI of 39.6 kg/m^2 (range 36.1 to 41.9 kg/m^2). The mean drop-out rate in these studies was 35.3 %. Data were reported for 1,347 women and 396 men. Subjects lost an average of 22.6 % of their initial body weight over the 24 weeks of intervention; such weight loss was significantly higher than the weight loss achieved with any other weight loss strategy considered, and this significant difference with respect to other weight loss strategies was maintained after one year. However, no significant differences in body weight loss were observed between weight loss strategies at longer follow-ups. Subjects on VLCDs maintained an average weight loss of 16.1 %, 9.7 %, 7.8 %, 7.0 % and 6.2 % of their initial body weight at follow-up after one, two, three, four and five years, respectively. Large individual differences were observed in long-term effectiveness depending on the initial amount of weight loss, additional (behavioural) interventions, and level of physical activity. VLCDs and low-energy-diet programs were the weight loss strategies which required more aggregated medical visits, clinic visits and class hours (e.g. intensity score about four times higher than meal replacements). The Panel notes that the majority of studies presented data on completers only, and not on the intention-to-treat population.

The meta-analysis by Gilden Tsai and Wadden (2006) included only randomised controlled trials (RCTs) comparing the efficacy of low calorie diets (LCDs) *vs.* VLCDs, and which included follow-up data of at least one year after maximum weight loss. Six RCTs including 233 subjects met the inclusion criteria. Initial VLCD treatment for 8-12 weeks followed by an LCD containing 1,000 to 1,600 kcal/day and behavioural treatment for additional 12 to 104 weeks was compared to LCD and behavioural treatment of similar durations. Maximal weight loss for subjects in the VLCD group ranged between 13.4 and 19.9 % of initial body weight, which was approximately 6.5 % more than that observed for subjects in the LCD group. Body weight at 1.5-2 years of follow-up in the VLCD group was -12.3 to -7.6 % of initial body weight, which was slightly but still significantly (1.5 % difference) lower than in the LCD group.

The remaining references and reviews, which addressed the effects of VLCDs on weight loss compared to other dietary strategies aimed at weight loss, are in agreement with these two meta-analyses. Compared with other non-surgical interventions for weight loss, VLCDs in the context of intense supervision (e.g. by physicians and other health professionals) lead to greater weight loss (ranging from 12 to 20 % of initial body weight or about 12 to 35 kg) after 8-16 weeks of treatment, although considerable weight regain occurs when follow-up is extended for a number of years, particularly in the absence of behavioural modifications at follow-up. However, about one third of women and about 28 % of men still had 10 % lower body weight after five years. Those subjects had generally been more successful during the weight loss phase (Jebb and Goldberg, 1998; Mustajoki and Pekkarinen, 2001; Pekkarinen et al., 1996).

Although VLCDs appear to be superior in producing large initial weight loss compared with other dietary interventions, long-term success is highly dependent on additional interventions including long-term life-style changes and active follow-up (Ayyad and Andersen, 2000). Miura et al. (1989) assessed the effects of combining VLCDs and behavioural modifications *vs.* the effects of either VLCD alone or behavioural modification alone in 70 obese subjects refractory to other weight loss interventions. VLCD alone or in combination with behavioural modifications showed no significant differences in initial weight loss (7.5±2.1 *vs.* 8.3±2.3 kg/month). However, after 2 years, the group on VLCD only had regained on average 4.3±3.5 kg (>50% of their initial weight loss) while the group receiving the combination of VLCD plus behavioural modification had lost one additional kg (-1.0±0.7 kg) and the group on behavioural therapy only had lost an additional 1.3±2.2 kg. Compared to the group receiving behavioural therapy only, the total weight loss at two years was not significantly different in the group on VLCD only (approximately -5 kg in both groups).

In weighing the evidence, the Panel took into account that the evidence provided consistently showed a greater reduction of body weight in obese subjects on VLCDs compared to other dietary interventions aimed at weight loss.

The Panel concludes that a cause and effect relationship has been established between the consumption of a VLCD and reduction in body weight.

3.2. Reduction in the sense of hunger (ID 1411)

The references provided for the scientific substantiation of the claim included narrative reviews, and human intervention studies on diets other than VLCDs (e.g. low carbohydrate diets and low fat diets) and/or effects other than sense of hunger (e.g. body weight changes, body composition and snoring). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

No references were provided which addressed the effects of VLCDs on sense of hunger.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a VLCD and reduction in the sense of hunger during a sustained energy deficit.

3.3. Reduction in body fat mass while maintaining lean body mass (ID 1412)

The references provided for the scientific substantiation of the claim included narrative reviews, and human intervention studies on the effects of diets other than VLCDs (e.g. low carbohydrate diets, and low fat diets) on body composition. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Ryttig and Rossner (1995) assessed body composition changes in 60 obese subjects on a diet providing 330 kcal/day for 12 weeks using tetra polar bioelectrical impedance analysis. The Panel

notes that this diet does not comply with the minimum requirement of 450 kcal/day for VLCDs, and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Zahouani et al. (2003) reported on a study in 1,389 obese subjects who lost on average 10.3±5.5 kg fat mass and 2.2±2.05 kg fat free mass after 90 days on a VLCD. Body composition was assessed by leg-to-leg bioelectrical impedance analysis. Burgess (1991) found that fat mass contributed 75 % to total weight loss after 12 weeks of VLCD treatment assessed by hydro-densitometry as well as by bio-impedance analysis in 17 obese subjects (9 women). Coxon et al. (1989) randomised obese females to consume either a VLCD providing 405 kcal/day (n=12) or a VLCD providing 800 kcal/day (n=14) for eight weeks, each aimed at obtaining different rates of weight loss. Body composition was assessed by bioelectrical impedance analysis and by infrared interactance. A ratio of just over 0.4 between loss of fat free mass and total weight loss regardless of the rate of weight loss was observed. Hoie et al. (1993) assessed the quality of weight loss by near-infra-red interactance in 127 obese subjects on a VLCD for eight weeks. Mean weight reduction was 12.7 kg (12.6 % of initial weight) and mean body fat loss was 9.5 kg, which constitutes about 75 % of the weight loss. Mean reduction in lean body mass was 3.2 kg. No correlation was found between initial body mass index (BMI) and loss of lean body mass, or between initial body composition and weight loss. Morgan et al. (1992) assessed changes in body composition using total body nitrogen measured by *in vivo* neutron activation analysis in 11 females on a VLCD for 11 weeks. The mean loss of total body nitrogen was 125±57 g, equivalent to 781±356 g protein. The fat-free mass component of the weight loss was calculated by two different methods as 23.5 % (±3 % SEM) and 22.8 % (±2.7 % SEM), respectively.

The Panel notes that none of the studies provided assessed the effects of VLCDs on body composition compared to other dietary strategies for weight loss, that most of the studies provided used bioelectrical impedance analysis or infrared interactance for body composition analysis, both of which are not considered as reliable methods to assess changes in body composition in obese subjects during rapid weight loss, and that in most of the studies provided body fat accounted for about 70-78 %, and fat-free mass for about 22-30 %, of the total weight lost, which is, respectively, the approximate composition of the excess body weight in obese subjects and the approximate composition of the weight loss which could be expected by the use of other weight loss strategies.

In weighing the evidence, the Panel took into account that the evidence provided did not consistently show a greater reduction in body fat mass relative to lean body mass in obese subjects on VLCDs compared to other dietary interventions aimed at weight loss.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a VLCD and reduction in body fat mass while maintaining lean body mass.

4. Panel's comments on the proposed wording

4.1. Reduction in body weight (ID 1410)

The Panel considers that the following wording reflects the scientific evidence: "Replacing the usual diet with a very low calorie diet helps to lose weight".

5. Conditions and possible restrictions of use

5.1. Reduction in body weight (ID 1410)

The Panel considers that in order to bear the claim, a diet should comply with the specifications and conditions of use laid down in CODEX STAN 203-1995. The target population is obese adults who wish to reduce their body weight.

CONCLUSIONS

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

- Whereas the diet, very low calorie diet (VLCD), which is the subject of the claims is sufficiently characterised in relation to the following claimed effects: reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), and reduction in body fat mass while maintaining lean body mass (ID 1412), VLCD is not sufficiently characterised in relation to: reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile (ID 1421), mainly owing to the lack of standardisation of the type of available carbohydrates and of most of the fatty acids that formula foods for use in VLCDs should contain.

- A cause and effect relationship cannot be established between the consumption of a VLCD and reduction of post-prandial glycaemic responses (ID 1414) and maintenance of normal blood lipid profile (ID 1421).

Reduction in body weight (ID 1410)

- The claimed effect is "safe and effective weight loss, long term weight maintenance". The target population is assumed to be obese adults who wish to reduce their body weight. Reduction in body weight is a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of a VLCD and reduction in body weight.

- The following wording reflects the scientific evidence: "Replacing the usual diet with a very low calorie diet helps to lose weight".

- In order to bear the claim, a diet should comply with the specifications and conditions of use laid down in CODEX STAN 203-1995. The target population is obese adults who wish to reduce their body weight.

Reduction in the sense of hunger (ID 1411)

- The claimed effect is "reduced hunger". The target population is assumed to be obese adults in the general population. In the context of the proposed wordings, it is assumed that the claimed effect refers to a reduction in sense of hunger mediated by the induction of ketogenesis during a sustained energy deficit. Reduction in the sense of hunger during a sustained energy deficit is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of a VLCD and reduction in the sense of hunger during a sustained energy deficit.

Reduction in body fat mass while maintaining lean body mass (ID 1412)

- The claimed effect is "burning fat for energy, preserving lean tissue". The target population is assumed to be obese adults in the general population. In the context of the proposed wordings, it is assumed that the claimed effect refers to the loss of fat mass while maintaining lean body mass during weight loss. Reduction in body fat mass while maintaining lean body mass is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of a VLCD and reduction in body fat mass while maintaining lean body mass.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2147, EFSA-Q-2008-2148, EFSA-Q-2008-2149, EFSA-Q-2008-2151, EFSA-Q-2008-2158). 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

Anderson JW, Luan J and Hoie LH, 2004. Structured weight-loss programs: meta-analysis of weight loss at 24 weeks and assessment of effects of intervention intensity. Advances in Therapy, 21, 61-75.

Ayyad C and Andersen T, 2000. Long-term efficacy of dietary treatment of obesity: a systematic review of studies published between 1931 and 1999. Obesity Reviews, 1, 113-119.

Burgess NS, 1991. Effect of a very-low-calorie diet on body composition and resting metabolic rate in obese men and women. Journal of the American Dietetic Association, 91, 430-434.

Coxon A, Kreitzman S, Brodie D and Howard A, 1989. Rapid weight loss and lean tissue: evidence for comparable body composition and metabolic rate in differing rates of weight loss. International Journal of Obesity, 13 Suppl 2, 179-181.

Gilden Tsai A and Wadden TA, 2006. The evolution of very-low-calorie diets: an update and meta-analysis. Obesity (Silver Spring), 14, 1283-1293.

Hoie LH, Bruusgaard D and Thom E, 1993. Reduction of body mass and change in body composition on a very low calorie diet. International Journal of Obesity and Related Metabolic Disorders, 17, 17-20.

Jebb SA and Goldberg GR, 1998. Efficacy of very low-energy diets and meal replacements in the treatment of obesity. Journal of Human Nutrition & Dietetics, 11, 219.

Miura J, Arai K, Tsukahara S, Ohno M and Ikeda Y, 1989. The long term effectiveness of combined therapy by behavior modification and very low calorie diet: 2 years follow-up. International Journal of Obesity, 13 Suppl 2, 73-77.

Morgan WD, Ryde SJ, Birks JL, Thomas DW and Kreitzman SN, 1992. Changes in total body nitrogen during weight reduction by very-low-calorie diets. American Journal of Clinical Nutrition, 56, 262S-264S.

Mustajoki P and Pekkarinen T, 2001. Very low energy diets in the treatment of obesity. Obesity Reviews, 2, 61-72.

Pekkarinen T, Takala I and Mustajoki P, 1996. Two year maintenance of weight loss after a VLCD and behavioural therapy for obesity: correlation to the scores of questionnaires measuring eating behaviour. International Journal of Obesity and Related Metabolic Disorders, 20, 332-337.

Ryttig KR and Rossner S, 1995. Weight maintenance after a very low calorie diet (VLCD) weight reduction period and the effects of VLCD supplementation. A prospective, randomized, comparative, controlled long-term trial. Journal of Internal Medicine, 238, 299-306.

Zahouani A, Boulier A and Hespel JP, 2003. Short- and long-term evolution of body composition in 1389 obese outpatients following a very low calorie diet (Pro'gram18 VLCD). Acta Diabetologica, 40 Suppl 1, S149-150.

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[7] (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[8]

Foods are commonly involved in many different functions[9] 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.

[7] OJ L12, 18/01/2007
[8] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[9] 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 very low calorie diet (VLCD) including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1410	Very low calorie diet (VLCD) Programme	1) Safe and effective weight loss 2) long term weight maintenance	which ensures a rapid, yet controlled way of reaching a healthier weight The programme allows thousands of clients to lose their excess weight (VLCD is a ...) way of reaching a healthier weight (Foodpacks allow...) effective weight loss This is a unique opportunity for you to reshape your waist, your weight A fast safe and effective way to slim down to your target weight For fast weight loss as the sole source of nutrition For more gradual weight loss with additional food for long term weight maintenance Produces excellent weight loss in the desired timescale Will help you lose weight in a scientifically proven safe and healthy way A healthy way to reduce weight and keep it off Shrink your waist Lose weight from your waist 'Weight care' Scientific research confirms credibility and efficacy The low calorie levels of the diet mean that everyone will lose weight on the programme/sole source programme Nutritionally complete VLCD formula, which enables fast,

			safe and effective weight loss Lose weight safely and comfortably/shed weight quickly and safely/Look forward to a slimmer you/The low calorie levels of the diet mean that everyone will lose weight/You will re-shape waist/ lose inches off your waist
	Conditions of use - Nutritionally complete formula VLCD providing <800 kcal/day - Programme using initial nutritionally complete formula VLCD providing <800kcal/day. Weight management Programme providing counsellor support and/or behaviour modification		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1411	Very low calorie diet (VLCD) Programme	Reduced hunger	The composition of the Food packs means you wont be starving – once you're in ketosis your physical hunger is suppressed. With such formula food, clients experience little, if any hunger – as after around 3-4 days the body goes into a state of ketosis.
	Conditions of use - Nutritionally complete, ketogenic VLCD formula providing <800kcal/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1412	Very low calorie diet (VLCD) Programme	Burning fat for energy, preserving lean tissue	when you are on Food packs - your body uses its stored fat to make up the difference (of energy) ..evidence suggests that VLCDs do not accelerate the loss of lean tissue weight loss is 3 parts fat and 1 part lean during weight loss. the body breaks down fat to make up the deficit. When you lose weight it comes off in the ratio 3 parts fat to 1 part lean tissue – and that's true of any diet.
	Conditions of use - Nutritionally complete very low calorie diet formula providing <800kcal/day		

ID	Food or Food constituent	Health Relationship	Proposed wording
1414	Very low calorie diet (VLCD) Programme	Low glycaemic index	Low glycaemic index formula food Low glycamic index products
	Conditions of use - Nutritionally complete VLCD formula food providing <800kcal/day with GI measured to <55		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1421	Very low calorie diet (VLCD) Programme	VLCD/low carbohydrate diets helps to the maintenance of normal blood lipid profile	VLCD/low carbohydrate diets helps to the maintenance of normal blood lipid profile
	Conditions of use - Nutritionally complete VLCD formula <800kcal		

GLOSSARY AND ABBREVIATIONS

BMI	Body mass index
LCD	Low calorie diet
RCT	Randomised controlled trial
VLCD	Very low calorie diet