

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (ID 1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

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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 meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in 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 that is the subject of the health claims is “meal replacement for weight control”, which is defined in Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction. The Panel considers that “meal replacement for weight control” is sufficiently characterised in relation to the claimed effects.

1 On request from the European Commission, Question No EFSA-Q-2008-2154, EFSA-Q-2008-2155, adopted on 4 December 2009.

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Reduction in body weight

The claimed effect is “safe, effective & healthy weight loss; greater weight loss than with conventional calorie counting”. The target population is assumed to be overweight subjects in the general population 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 in the first meta-analysis provided, weight loss achieved with meal replacement products was significantly greater (almost double) than with conventional energy restricted diets prescribed with the same calorie content, and that in another meta-analysis provided, both weight loss strategies were equally effective, although the intensity of the intervention was three times higher for the conventional energy restricted diets than for meal replacements. The Panel also took into account that all the meal replacement studies included in the meta-analyses used commercial products for the replacement of meals that usually contain up to 250 kcal/serving and generally comply with the characterisation described in this opinion, except for a lower protein content expressed on energy basis (generally 18-25 % energy as protein), and that biologically plausible mechanisms have been proposed by which meal replacements could exert the claimed effect, mostly in relation to their controlled energy content and relatively high protein, low fat content.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of meal replacements in substitution of regular meals in the context of energy restricted diets and reduction in body weight.

In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid down in Directive 96/8/EC in relation to food products under Article 1 (2b) of that Directive. In order to achieve the claimed effect, two meals should be substituted with meal replacements daily. The target population is overweight subjects in the general population who wish to reduce their body weight.

Maintenance of body weight after weight loss

The claimed effect is “maintenance of weight loss”. The target population is assumed to be overweight subjects in the general population who wish to maintain their body weight after significant 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 most of the studies presented report significantly better weight maintenance after weight loss when meal replacements are used in the maintenance phase, that all the meal replacement studies presented used commercial products for the replacement of meals that usually contain up to 250 kcal/serving and generally comply with the characterisation described in this opinion, except for a lower protein content expressed on energy basis (generally 18-25 % energy as protein), and that biologically plausible mechanisms have been proposed by which meal replacements could exert the claimed effect, mostly in relation to their controlled energy content and relatively high protein, low fat content.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of meal replacements in substitution of regular meals and the maintenance of body weight after weight loss.

In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid down in Directive 96/8/EC in relation to food products under Article 1 (2b) of that Directive. In order to achieve the claimed effect, one or two meals should be substituted with meal replacements daily. The target population is overweight subjects in the general population who wish to maintain their body weight after significant weight loss.

KEY WORDS

Meal replacement, body weight, weight loss, weight maintenance, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

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 from similar health claims. The information provided in the consolidated list for the health claims which are subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claims is “meal replacement for weight control”, which is defined in Directive 96/8/EC⁵ on foods intended for use in energy-restricted diets for weight reduction. Briefly, the energy provided by a meal replacement shall not be less than 840 kJ (200 kcal) and shall not exceed 1 680 kJ (400 kcal) per meal. Meal replacements for weight loss shall provide not less than 25 % and not more than 50 % of the total energy of the product as protein, not more than 30 % of the total available energy as fat, not less than 1 g of linoleic acid (in the form of glycerides), at least 30 % of the dietary reference values for adults of vitamins and minerals, and at least 500 mg of potassium per meal.

The Panel considers that the food, “meal replacement for weight control”, which is the subject of the health claims is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Reduction in body weight (ID 1417)

The claimed effect is “safe, effective & healthy weight loss; greater weight loss than with conventional calorie counting”. The Panel assumes that the target population is overweight subjects in the general population who wish to reduce their body weight.

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

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

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

2.2. Maintenance of body weight after weight loss (ID 1418)

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

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 Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction. OJ L 55, 6.3.1996, p. 22.

Maintenance of weight loss can be interpreted as the 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 achieving a normal body weight is considered beneficial to health.

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

3. Scientific substantiation of the claimed effect

3.1. Reduction in body weight (ID 1417)

A total of 25 references were submitted for the substantiation of the claimed effect. These include two meta-analyses of randomised controlled trials (RCT) in humans (Heymsfield et al., 2003; Anderson et al., 2004) covering most of the pertinent studies cited in relation to this claim and therefore the assessment will be based on these.

The meta-analysis (and pooled analysis) by Heymsfield et al. (2003) is based on six randomised controlled trials where subjects were instructed to replace one (usually for the weight maintenance phase) or two meals (usually for the weight loss phase) with meal replacement products as part of a conventional energy restricted diet (>800 and <1600 kcal per day) or to follow a conventional energy restricted diet providing the same calorie content with durations ranging between three and 51 months. All the studies included in the meta-analysis used commercial products for the replacement of meals, which usually contain up to 250 kcal/serving and generally comply with the characterisation described in section 1 except for a lower protein content expressed on energy basis (generally 18-25 % energy as protein). A total of almost 500 subjects with initial BMI ranging between 25 and 40 kg/m² (average 31 kg/m²) of which 249 were randomised to receive meal replacements (including a small portion of subjects with type 2 diabetes) where evaluated for their weight loss after 3 and 12 months respectively. The drop out rate was equivalent between groups at 3 months and significantly lower in the meal replacement group at one year. Weight loss was significant at both time points in all studies (one study including 75 subjects reported only 3-month data) for both interventions, with significantly greater weight loss in subjects receiving the meal replacement plan (about 7-8 % of initial body weight) compared to the conventional energy-restricted diet (about 3-7 % of initial body weight). When subjects with type 2 diabetes were omitted from the analyses, the weight loss difference between groups was slightly more pronounced. A random effects meta-analysis estimate indicated a significantly greater weight loss in the meal replacement group than in the conventional diet group at three months and one year (weight loss difference between groups=2.54 kg and 2.43 kg, respectively). The Panel notes that the majority of studies evaluated data on completers only (per protocol analyses), and not on the intention-to-treat population, and that the most plausible explanation for the observed effects is a better compliance with the weight reduction program in the meal replacement intervention group.

The meta-analysis by Anderson et al. (2004) is based on 47 intervention studies conducted in adult obese but otherwise healthy subjects (BMI at least 30 kg/m² at baseline) assessing the effects of meal replacements (at least two meal replacements per day, four studies), energy restricted diets (providing >1500 kcal per day, six studies), low-energy diets (providing 800-1500 kcal per day, 10 studies), very low-calorie diets (providing up to 800 kcal per day, 19 studies), and soy diets (providing up to 800 kcal per day, eight studies) and reporting weight loss data after 24 weeks of treatment. Participants in the four studies on meal replacements were overweight and obese subjects who received at least two meal replacement servings daily as part of an energy restricted diet. All the studies included in the meta-analysis used commercial products for the replacement of meals, which usually contain up to 250 kcal/serving and generally comply with the characterisation described in section 1 except for a lower protein content expressed on energy basis (generally 18-25 % energy as protein). They involved more than 600 subjects of both sexes (470 women and 133 men) with average

BMI ranging from 28 to 34 kg/m². Two of the studies had been included in the meta-analysis by Heymsfield et al. (2003) described above (Ditschuneit et al., 1999; Ashley et al., 2001), whereas one was published after the end date for the literature search (Bowerman et al., 2001). In these studies, women lost an average of 9.3 % of their initial weight while men lost 8.6 %. These effects were comparable to intensive lifestyle interventions including conventional energy-restricted diets with an intensity factor (integrating number of visits with a doctor, clinic visits, and class hours) three times lower. Body weight loss with meal replacements was only about 50 % of that found in populations with slightly higher BMI receiving VLCD treatments with an intensity factor four times higher. The Panel notes that the majority of studies evaluated present data on completers only (per protocol analyses), and not on the intention-to-treat population.

Reference was made in the consolidated list to the recommendations of the American Dietetic Association (ADA) on meal replacements for weight loss and weight maintenance (http://www.adaevidencelibrary.com/template.cfm?template=guide_summary&key=625&auth=1).

The ADA reports that the evidence for that recommendation is strong and based on eight RCTs, three nonrandomised clinical trials, and good-quality meta-analysis reporting equivalent or greater weight loss in subjects receiving a diet containing 1–3 daily meal replacements (Ahrens et al., 2003; Allison et al., 2003; Ashley et al., 2001; Ditschuneit et al., 1999; Ditschuneit et al., 2001; Flechtner-Mors et al., 2000; Hannum et al., 2004; Heber et al., 1994; Heymsfield et al., 2003; Mattes, 2002; Noakes et al., 2004; Rothacker, 2000; Rothacker et al., 2001; Winick et al., 2002).

Different mechanisms have been proposed by which replacing one or two meals per day by meal replacements could promote weight loss as compared to traditional energy-restricted diets. Meal replacements appear to increase compliance with energy-restricted programs for weight loss (Anderson et al., 2004). This finding could be explained in part because they offer an easy and “ready-to-eat” way of restricting energy intake using calorie-controlled meals, in part because their (protein-rich, low-fat) macronutrient composition may induce sustained satiety to a greater extent. On the other hand, the (protein-rich, low-fat) macronutrient composition of the meal replacements may induce energy inefficiency during negative energy balance by several mechanisms (increasing energy expenditure, sparing lean body mass), which may explain in part their effects on weight loss and maintenance (Krieger et al., 2006; Westerterp-Plantenga et al., 2009).

In weighing the evidence, the Panel took into account that in the meta-analysis by Heymsfield et al. (2003), weight loss achieved with meal replacement products was significantly greater (almost double) than with conventional energy restricted diets prescribed with the same energy content, and that in the meta-analysis by Anderson et al. (2004), both weight loss strategies were equally effective, albeit the intensity of the intervention was three times higher for the conventional energy restricted diets than for meal replacements. The Panel also took into account that all the meal replacement studies included in the meta-analyses used commercial products for the replacement of meals that usually contain up to 250 kcal/serving and generally comply with the characterisation described in section 1, except for a lower protein content expressed on energy basis (generally 18-25 % energy as protein), and that biologically plausible mechanisms have been proposed by which meal replacements could exert the claimed effect, mostly in relation to their controlled energy content and relatively high protein, low fat content.

The Panel concludes that a cause and effect relationship has been established between the consumption of meal replacements in substitution of regular meals in the context of energy restricted diets and reduction in body weight.

3.2. Maintenance of body weight after weight loss (ID 1418)

A total of 14 references were submitted for substantiation of the claimed effect. A number of these references were not considered as pertinent to the claim because of their short follow-up (Anderson et al., 2004; Heber et al., 1994; Winick et al., 2002), were based on pharmacologically treated type 2

diabetic subjects, which are not representative of the target population (Redmon et al., 2003; Yip et al., 2001), did not report on original data (e.g., duplicates, letters and comments), or were limited to abstracts with no sufficient information available for a full scientific evaluation.

The meta-analyses by Heymsfield et al. (2003) described in section 3.1. included most of the single studies cited in relation to the claim on the effects of meal replacements on weight loss. As the greatest weight loss with this strategy is achieved during the first three months of the intervention, during which at least two meals are substituted with meal replacements, the Panel considers that data on further weight loss achieved after this period (from three months to one year in the meta-analysis by Heymsfield et al., 2003), during which usually one meal and one snack are substituted with meal replacements, can be taken into consideration for the substantiation of a claim on body weight maintenance after weight loss.

Three additional references reporting longer follow-ups of some of the studies included in the meta-analysis by Heymsfield et al., (2003) were also considered pertinent to the claimed effect (Ditschuneit et al., 1999; Flechtner-Mors et al., 2000; Rothacker, 2000). These references reported sustained weight loss after a total of 27 months (Ditschuneit et al., 1999) that was maintained after 4 years (-8.4 % of initial body weight) (Flechtner-Mors et al., 2000) with one meal and one snack replacements. Rothacker (2000) also reported that 84 overweight women and 50 overweight males who received a self-managed meal replacement weight control program for 5 years lost 4.2 and 5.8 kg (respectively) in that period, compared to matched controls who gained 6.5 and 6.7 kg, respectively, during the same period of time.

Reference was made in the consolidated list to the recommendations of the American Dietetic Association (ADA) on meal replacements for weight loss and weight maintenance (for link see item 3.1.). The ADA reports that the evidence for that recommendation is strong and based on eight RCTs, three nonrandomised clinical trials, and good-quality meta-analysis reporting equivalent or greater weight loss in subjects receiving a diet containing 1–3 daily meal replacements (Ahrens et al., 2003; Allison et al, 2003; Ashley et al, 2001; Ditschuneit et al, 1999; Ditschuneit et al, 2001; Flechtner-Mors et al, 2000; Hannum et al, 2004; Heber et al, 1994; Heymsfield et al, 2003; Mattes, 2002; Noakes et al, 2004; Rothacker, 2000; Rothacker et al., 2001; Winick et al, 2002).

Different mechanisms have been proposed by which replacing one or two meals per day by meal replacements could promote the maintenance of body weight after weight loss as compared to traditional energy-restricted diets. Meal replacements appear to increase compliance with energy-restricted programs for weight maintenance after weight loss (Anderson et al., 2004). This finding could be explained in part because they offer an easy and “ready-to-eat” way of restricting energy intake using energy-controlled meals, in part because their (protein-rich, low-fat) macronutrient composition may induce sustained satiety to a greater extent. On the other hand, the (protein-rich, low-fat) macronutrient composition of meal replacements may induce energy inefficiency during negative energy balance by several mechanisms (increasing energy expenditure, sparing lean body mass), which may explain in part their effects on weight maintenance after weight loss (Krieger et al., 2006; Westerterp-Plantenga et al., 2009).

In weighing the evidence, the Panel took into account that most of the studies presented reported significantly better weight maintenance after weight loss when meal replacements are used in the maintenance phase, that all the meal replacement studies presented used commercial products for the replacement of meals that usually contain up to 250 kcal/serving and generally comply with the characterisation described in section 1, except for a lower protein content expressed on energy basis (generally 18-25 % energy as protein), and that biologically plausible mechanisms have been proposed by which meal replacements could exert the claimed effect, mostly in relation to their controlled energy content and relatively high protein, low fat content.

The Panel concludes that a cause and effect relationship has been established between the consumption of meal replacements in substitution of regular meals and maintenance of body weight after weight loss.

4. Panel's comments on the proposed wording

4.1. Reduction in body weight (ID 1417)

The following wording reflects the scientific evidence: "Substituting two daily meals with meal replacements helps to lose weight in the context of energy restricted diets."

4.2. Maintenance of body weight after weight loss (ID 1418)

The following wording reflects the scientific evidence: "Substituting one or two daily meals with meal replacements helps to maintain body weight after weight loss."

5. Conditions and restrictions of use

5.1. Reduction in body weight (ID 1417)

In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid down in Directive 96/8/EC in relation to food products under Article 1 (2b) of that Directive. In order to achieve the claimed effect, two meals should be substituted with meal replacements daily. The target population is overweight subjects in the general population who wish to reduce their body weight.

5.2. Maintenance of body weight after weight loss (ID 1418)

In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid down in Directive 96/8/EC in relation to food products under Article 1 (2b) of that Directive. In order to achieve the claimed effect, one or two meals should be substituted with meal replacements daily. The target population is overweight subjects in the general population who wish to maintain their body weight after significant weight loss.

CONCLUSIONS

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

- The food, "meal replacement for weight control", that is the subject of the health claims is sufficiently characterised in relation to the claimed effects.

Reduction in body weight (ID 1417)

- The claimed effect is "safe, effective & healthy weight loss; greater weight loss than with conventional calorie counting". The target population is assumed to be overweight subjects in the general population 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 meal replacements in substitution of regular meals in the context of energy restricted diets and reduction in body weight.

- The following wording reflects the scientific evidence: “Substituting two daily meals with meal replacements in the context of energy restricted diets helps to lose weight.”.
- In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid down in Directive 96/8/EC⁶ in relation to food products under Article 1 (2b) of that Directive. In order to achieve the claimed effect, two meals should be substituted with meal replacements daily.

Maintenance of body weight after weight loss (ID 1418)

- The claimed effect is “maintenance of weight loss”. The target population is assumed to be overweight subjects 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 been established between the consumption of meal replacements in substitution of regular meals and maintenance of body weight after weight loss.
- The following wording reflects the scientific evidence: “Substituting one daily meal and one snack with meal replacements helps to maintain body weight after weight loss.”.
- In order to bear the claims, a food should contain a maximum of 250 kcal/serving and comply with specifications laid down in Directive 96/8/EC in relation to food products under Article 1 (2b) of that Directive. In order to achieve the claimed effect, one or two meals should be substituted with meal replacements daily.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2154, EFSA-Q-2008-2155). 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 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

Main entry health claims related meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss), including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1417	Meal replacement for weight control (as defined in Directive 96/8/EC energy restricted diets for weight reduction)	Safe, effective & healthy weight loss. Greater weight loss than with conventional calorie counting	Scientifically/clinically proven as a safe and effective weight loss programme A healthy way to lose weight and keep it off Losing weight with meal replacement plans can maintain healthy lipid profile/blood glucose and insulin/blood pressure Reaching and maintaining a healthy weight is important in helping healthy lipid profile/blood glucose and insulin levels/blood pressure People losing weight with meal replacements have shown healthier biomarkers than people dieting on a conventional calorie controlled diet Removes the need for calorie counting at mealtimes – Substituting one or two daily meals or snacks with meal replacements is a successful weight loss and weight maintenance strategy
<p>Conditions of use</p> <ul style="list-style-type: none"> - For weight loss - Use to replace one or more meals of the daily diet - Mahlzeitenersatz (gemäß Definition in Richtl. 96/8/EG) - Replace two meals a day - Replace two meals a day as part of a weight loss programme 			
1418	Meal replacement for weight control (as defined in Directive 96/8/EC energy restricted diets for weight reduction)	Maintenance of weight loss	Safe and effective for long term use for weight maintenance Meal replacements have been shown to be more successful in helping people maintain weight loss than conventional calorie controlled diets Using meal replacements for weight loss and weight maintenance
<p>Conditions of use</p> <ul style="list-style-type: none"> - Replace one meal a day as a weight maintenance strategy/to keep the weight off 			

GLOSSARY / ABBREVIATIONS

BMI	Body mass index
LDL	Low density lipoproteins
RCT	Randomised controlled trials
VLCD	Very low calorie diet