

SNE | GUIDANCE ON MEAL REPLACEMENTS FOR WEIGHT CONTROL

JANUARY 2017

TABLE OF CONTENTS

1 INTRODUCTION	3
Disclaimer	
Background	
2 MEAL REPLACEMENT FOR WEIGHT CONTROL CATEGORY	5
Definition and legal name	
3 LABELLING (Food Information to Consumers)	7
Mandatory labelling (FIC)	
Reference per 100g or 100ml and recommended portion	
Polyols	
Labelling particulars (Nutrition and Health Claims Regulation - NHCR)	
Health Claims	
Reference to the term “dietetic”	
Rate or amount of weight loss	
4 MEAL REPLACEMENT FOR WEIGHT CONTROL COMPOSITION	10
Riboflavin instead of Vitamin B2 and Thiamine instead of Vitamin B1	
Essential Amino Acids profile (g/100g protein)	
Transitional period	
Fibre	
Other nutrients and substances	
Notification	
List of vitamin and mineral sources – former regulation for PARNUTS fortification	
5 QUESTIONS & ANSWERS	16
Is a Meal Replacement for weight control a fortified food?	
Which additives are authorised for the Meal Replacement Category?	
6 TERMINOLOGY	19

1 INTRODUCTION

Disclaimer
Background

DISCLAIMER

This guidance document is intended to provide SNE members and Food Business Operators with information on the regulatory changes to ***Meal replacement for weight control*** legislation and is for general information purposes only. Whilst every effort is made to ensure that the information contained herein is reliable, the information contained does not constitute legal or other professional advice. No member of SNE accepts any responsibility or liability to users or any third parties in relation to the use of the information contained in this guidance.

The content of this guidance is the copyright of SNE. You may not republish or distribute any information available in this guidance or create a link to any part of this guidance for any commercial purpose without prior written consent which can be requested by contacting SNE at secretariat@specialisednutritioneurope.eu.

BACKGROUND

The Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (so-called Regulation on Foods for Specific Groups (FSG Regulation) has repealed inter alia Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction on 20 July 2016. ***Meal replacements for weight control*** are now considered as general food, covered by the general EU food law and bearing specific health claims.

2 MEAL REPLACEMENT FOR WEIGHT CONTROL CATEGORY

Definition and legal name

MEAL REPLACEMENT FOR WEIGHT CONTROL CATEGORY

As of 24 August 2016, the **Meal Replacement for weight control** category is defined within the framework of the Nutrition and Health Claims Regulation as published in Commission Regulation (EU) 2016/1413 of 24 August 2016 amending Regulation (EU) 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and children's development and health.

The food category is defined in this regulation as products bearing a weight loss and/or a weight maintenance health claim.

Only the products meeting the criteria defined by the EU regulation can:

- *Make a weight loss and/or weight maintenance claim*
- *Use the term **Meal replacement for weight control** as legal name*

Definition and legal name

'Meal replacements for weight control intended for partial replacement of the diet' are products presented as a replacement for one or two of the **main** meals of the daily diet.

The legal name under which the product is sold should be: **'Meal replacement for weight control'**.

The specifications for **Meal replacements for weight control** refer to the products ready for use, marketed as such or reconstituted as instructed by the food business operator responsible for the food information.

3 LABELLING (Food Information to Consumers)

Mandatory labelling (FIC)

Reference per 100g or 100ml and recommended portion

Polyols

Labelling particulars (Nutrition and Health Claims Regulation - NHCR)

Health Claims

Reference to the term “*dietetic*”

Rate or amount of weight loss

LABELLING (Food Information to Consumers)

Mandatory labelling (FIC):

The mandatory labelling elements are established by Regulation (EU) 1169/2011 on the provision of Food Information to Consumers (FIC) and include among others:

- *The name of the food*
- *The list of ingredients (decreasing order)*
- *Any Ingredient or processing aid causing allergies or intolerance*
- *The quantity of certain ingredients or categories of ingredients*
- *The net quantity (with appropriate unit)*
- *The date of minimum durability or the 'use by' date*
- *Any special storage conditions and/or conditions of use*
- *The name or business name and address of the food business operator*
- *The country of origin or place of provenance when relevant*
- *Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions*
- *A nutrition declaration*

MANDATORY
Elements

Reference per 100g or 100ml and recommended portion

FIC makes the labelling **per 100g or 100ml mandatory** and the labelling per recommended portion optional.

NEW
Elements

Recommendation

SNE recommends as best practice to use a nutrition labelling per recommended portion in addition to the labelling per 100g or 100ml.

SNE
Recommendations

Polyols

Foods containing more than **10% added polyols** must indicate that '*excessive consumption may produce laxative effects*'.

NEW
Elements

Labelling particulars (Nutrition and Health Claims Regulation - NHCR)

Based on Regulation (EU) 2016/1413 information shall be provided to the consumer:

- On the importance of maintaining an adequate daily fluid intake
- On the fact that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet.

MANDATORY
Elements

In order to achieve the claimed effect, one or two of the main daily meals (depending of the claim used) should be substituted with **Meal replacements for weight control**.

Health Claims

- Substituting one of the **main** daily meals of an energy restricted diet with a meal replacement contributes to the maintenance of weight after weight loss
- Substituting two of the **main** daily meals of an energy restricted diet with meal replacements contributes to weight loss

NEW
Elements

NEW
Elements

Recommendation

SNE recommends adapting the wording of the claims on the labels to reflect the new reference to “main” daily meals.

SNE
Recommendations

Reference to the term “dietetic”

SNE interpretation

Article 10.3 of NHCR stipulates that reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14 of NHCR.

Without prejudice of national interpretations to be confirmed by Food Business Operators before marketing, SNE considers that **Meal replacement for weight control** can use the term ‘dietetic’ at least in marketing material if not on the label, as long as the relevant claim is available in the same field of vision.

SNE
Interpretation

Recommendation

Please note however that some Member States like Spain prohibit at this stage the use of the term ‘dietetic’ in reference to Meal replacements for weight control. Other Member States prohibit its use at least on the label.

SNE
Recommendations

Rate or amount of weight loss

Claims which make reference to the rate or amount of weight loss are not authorised.

MANDATORY
Elements

4 MEAL REPLACEMENT FOR WEIGHT CONTROL COMPOSITION

Riboflavin instead of Vitamin B2 and Thiamine instead of Vitamin B1

Essential Amino Acids profile (g/100g protein)

Transitional period

Fibre

Other nutrients and substances

Notification

List of vitamin and mineral sources – former regulation for PARNUTS fortification

MEAL REPLACEMENT FOR WEIGHT CONTROL COMPOSITION

Essential Composition	Directive (EC) 96/8 ¹ Energy-restricted diets (ERD)	Regulation (EU) 2016/1413 ² Nutrition and Health Claims (NHCR)	
Energy	200 - 400kcal	200 ≤ MR ≤ 250kcal or 840 ≤ MR ≤ 1046kJ	New
Protein	25 - 50% of the total energy of the product	25 - 50% of the total energy of the product	
Protein quality	<p>A protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein given in Annex 2.</p> <p>If the chemical index is lower than 100% of the reference protein, the minimum protein levels shall be correspondingly increased.</p> <p>In any case the chemical index of the protein shall at least be equal to 80% of that of the reference protein.</p>	<p>A protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein given in Annex 2.</p> <p>If the chemical index is lower than 100% of the reference protein, the minimum protein levels shall be correspondingly increased.</p> <p>In any case the chemical index of the protein shall at least be equal to 80% of that of the reference protein.</p>	
Fat	≤ 30% energy of product	≤ 30% energy of product	
Essential fatty acids from linoleic acid	≥1g (in the form of glycerides)	≥1g (in the form of glycerides)	

¹Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction

²Commission Regulation (EU) 2016/1413 of 24 August 2016 amending Regulation (EU) 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health

Vitamins and minerals (minimum amounts, unless stated otherwise)	Directive (EC) 96/8 ¹ Energy-restricted diets (ERD)		Regulation (EU) 2016/14132 ² Nutrition and Health Claims (NHCR)		
	RI	≥ 30%	RI	≥ 30%	
Vitamin A (µg)	700	210	800	240	New
Vitamin D (µg)	5	1,5	5	1,5	
Vitamin E (mg)	10	3	12	3,6	New
Vitamin K (µg)	NA	NA	75	22,5	New
Vitamin C (mg)	45	13,5	80	24	New
Thiamine (mg)	1,1	0,33	1,1	0,33	
Riboflavin (mg)	1,6	0,48	1,4	0,42	New
Niacin (mg)	18	5,4	16	4,8	New
Vitamin B6 (mg)	1,5	0,45	1,4	0,42	New
Folic acid (µg)	200	60	200	60	
Vitamin B12 (µg)	1,4	0,42	2,5	0,75	New
Biotin (µg)	15	4,5	50	15	New
Pantothenic acid (mg)	3	0,9	6	1,8	New
Potassium (mg)	3100	500 instead of 930	2000	500 instead of 600	
Chloride (mg)	NA	NA	800	NA	
Calcium (mg)	700	210	800	240	New
Phosphorus (mg)	550	165	700	210	New
Magnesium (mg)	150	45	375	112,5	New
Iron (mg)	16	4,8	14	4,2	New
Zinc (mg)	9,5	2,85	10	3	New
Copper (mg)	1,1	0,33	1	0,3	New
Manganese (mg)	1	0,3	2	0,6	New
Fluoride (mg)	NA	NA	3,5	NA	
Selenium(µg)	55	16,5	55	16,5	
Chromium (µg)	NA	NA	40	NA	
Molybdenum (µg)	NA	NA	50	NA	
Iodine (µg)	130	39	150	45	New
Sodium (mg)		172,5		172,5	

Note:

In addition to the changes in minimum levels:

- The addition of Vitamin K becomes mandatory
- The unit for Vitamin E is mg instead of mg-TE
- Folate becomes Folic Acid
- Thiamine and Riboflavin should be expressed under these names in the nutrition table
- For some vitamins, it is possible to add synonym known in brackets, for example, “Thiamine (Vitamin B1)” instead of “Thiamine”
- Salt & Sodium:
 - o Salt must be indicated in the nutrition information table, as FIC requires the labelling of salt.
 - o Regulation (EU) 2016/1413 provides for a minimum mandatory level of sodium in **Meal replacements for weight control**. The Annex XIII of the Regulation EU 1169/2011 does not require the labelling of the nutrient Sodium in the table of micronutrients.

Riboflavin instead of Vitamin B2 and Thiamine instead of Vitamin B1

Recommendation

Vitamins B1 and B2:

Some Member States give the possibility to reference Vitamins B1 and B2 instead of Thiamine and Riboflavin. Food Business Operators should confirm the position of national authorities before using those references on the label. In this case SNE recommends using those as synonyms: Thiamine (Vitamin B1), Riboflavin (Vitamin B2).

SNE
Recommendations

Essential Amino Acids profile (g/100g protein)

Essential Amino Acids	Minimum Required (in g / 100 g Protein)
Cystine + Methionine	1,7
Histidine	1,6
Isoleucine	1,3
Leucine	1,9
Lysine	1,6
Phenylalanine + Tyrosine	1,9
Threonine	0,9
Tryptophan	0,5
Valine	1,3

The conditions of use of the **Meal replacement for weight control** health claims refer to the World Health Organisation (WHO), energy and protein requirements. Report of a joint FAO/WHO/UNU Meeting. Geneva: World Health Organisation, 1985. (WHO Technical Report Series, 724)

Transitional period

Recital 18 of Regulation (EU) 2016/1413 states: “To enable food business operators to adapt to the necessary changes regarding the conditions of use of health claims for meal replacement for weight control in particular regarding the energy content and the vitamin and mineral content, a transitional period should be provided”.

To adapt smoothly the compositional criteria and labelling in accordance with the new Regulation particularly in terms of energy, vitamins and minerals, a 3 year transition period has been established (until 14 September 2019). During this period, either transition rules (Option A) or new rules (Option B) established by Regulation (EU) 2016/1413 can be followed for placing **Meal replacements for weight control** on the market:

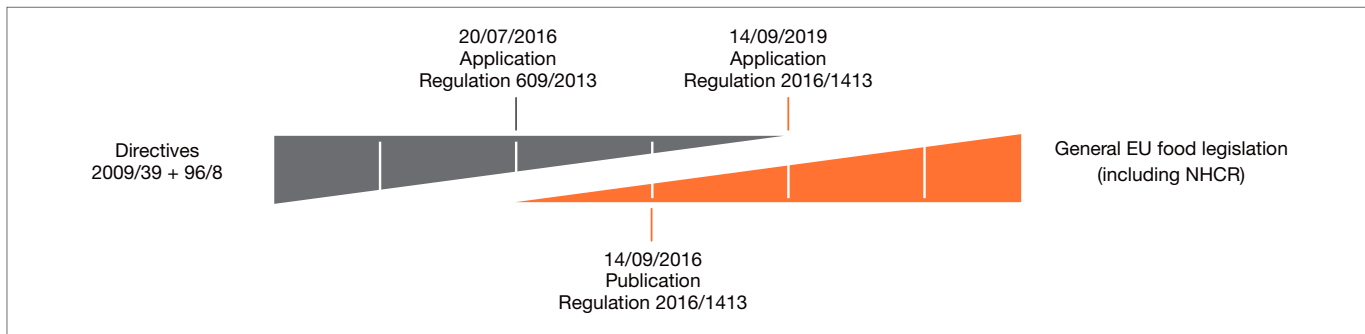
Option A – Transition Rules

- o From 21 July 2016 until 14 September 2019 the energy content of the food shall not be less than 200kcal (840kJ) and shall not exceed 400kcal (1680kJ).
- o From 21 July 2016 until 14 September 2019 the food shall provide at least 30% of the amounts of vitamins and minerals specified in the related transition table as established in Regulation (EU) 2016/1413.
- o From 21 July 2016 until 14 September 2019 the amount of potassium per meal provided by the food shall be at least 500mg.

OR (Please see next page)

Option B – New Rules

- From 21 July 2016 until 14 September 2019 the energy content of the food shall not be less than 200kcal (840kJ) and shall not exceed 250 kcal (1046kJ)
- From 21 July 2016 until 14 September 2019 the food shall provide at least 30% of the nutrient reference values of vitamins and minerals per meal as laid down in Annex XIII to Regulation (EU) No 1169/2011. This requirement does not apply to fluoride, chromium, chloride and molybdenum. The amount of sodium per meal provided by the food shall be at least 172,5mg. The amount of potassium per meal provided by the food shall be at least 500mg.



SNE interpretation

Members and Food Business Operators should note that Options A and B cannot be mixed and that between 14 September 2016 and 14 September 2019, Meal replacements for weight control shall comply to either Option A or Option B. Following 14 September 2019, all Meal replacements for weight control should be in compliance with Option B.

Food which complies with this regulation and which is placed on the market or labelled before 14 September 2019 may continue to be marketed after that date until stocks of such food are exhausted.

SNE
Interpretation

FIBRE

In the conditions of use for the Health Claims relating to **Meal replacement for weight control**, the Regulation (EU) 2016/1413 does not provide for a minimum amount of fibre, as fibre is present in the rest of the diet.

Meal replacements for weight control replace one or two main meals, so fibre can be provided by the rest of the diet.

Recommendation

SNE recommends to members and Food Business Operators to inform consumers on the importance of fibre in the diet. Food Business Operators can also choose to formulate **Meal replacements for weight control** with fibre. When a Food Business Operator chooses to formulate a **Meal replacement for weight control** with fibre, one could aim to meet the conditions of use for the nutrition claim “source of fibre” or “high in fibre”.

SNE
Recommendations

Nutrition claims

- **SOURCE OF FIBRE:** A claim that a food is a source of fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3g of fibre per 100g or at least 1,5g of fibre per 100kcal.
- **HIGH FIBRE:** A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6g of fibre per 100g or at least 3g of fibre per 100kcal.

When formulating with fibres, SNE recommends to members and Food Business Operators to confirm with relevant national authorities that this does not trigger a change of category reference (as fortified food) implying potential notification at national level.

Other nutrients and substances

Other nutrients and substances may be used to improve the nutritional quality and/or acceptability of the **Meal replacement for weight control** provided that they have been proven to be suitable and safe for their intended purpose.

Recommendation

When using other nutrients and substances, SNE recommends Food Business Operators to confirm with relevant national authorities that this does not trigger a change of category reference (as fortified food) implying potential notification at national level, in some Member States.

SNE
Recommendations

Notification

Recommendation

*Please note that the legal status of a **Meal replacement for weight control** can vary from one Member State to another, from general food to fortified food. SNE recommends to members and Food Business Operators to confirm with relevant national authorities if a notification of the **Meal replacement for weight control** is necessary before entering the market.*

SNE
Recommendations

List of vitamin and mineral sources – former regulation for PARNUTS fortification

Regulation (EU) 609/2013 repealed Regulation 953/2009 (PARNUTS fortification), including its list of authorised vitamins, minerals and other substances. After 20 July 2016 **Meal replacement for weight control** fall under the remit of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances.

The following mineral sources previously allowed in **Meal replacements for weight control** are no longer allowed:

- Calcium bisglycinate
- Calcium L-pidolate
- Magnesium bisglycinate
- Magnesium L-pidolate
- Ferrous L-pidolate

Also, Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances does not cover amino acids, meaning that Food Business Operators need to follow the EU and national rules related to fortification.

Recommendation

SNE recommends to members and Food Business Operators to reformulate when using the above-mentioned sources of nutrients that are no longer authorised and to confirm the status of amino acids with relevant national authorities.

SNE
Recommendations

5 QUESTIONS & ANSWERS

Is a *Meal replacement for weight control* a fortified food?

Which additives are authorised for *Meal replacement for weight control*?

QUESTIONS & ANSWERS

Is a *Meal replacement for weight control* a fortified food?

As of 20 July 2016, ***Meal replacement for weight control*** being general food, is covered by Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances.

It is the competence of the Member States to classify foodstuffs and the status of ***Meal replacement for weight control*** may vary from one Member State to another.

Current situation in the EU:

1. Some Member States consider ***Meal replacement for weight control*** as General food,
2. Other Member States consider them as Fortified food,
3. A number of Member States consider that when meeting the NHCR requirement, ***Meal replacements for weight control*** are general food. As soon as a ***Meal replacement for weight control*** is formulated with additional micronutrients or other substances, the ***Meal replacement for weight control*** falls into the Fortified food category.

Recommendation

SNE recommends to members and Food Business Operators to clarify the national rules with the relevant national associations or national authorities when marketing a product.

Which additives are authorised for *Meal replacement for weight control*?

Meal replacements for weight control fall under Category 13.3 - Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (whole or part of the total daily diet) as specified in Regulation (EC) 1333/2008.

E Number	Additive name	Maximum limit, restrictions / exceptions
Group I	Group I, Additives	ML = quantum satis; except E 425, ML = 10000 mg/kg; E 620 to E 625, ML = 10000 mg/kg individually or in combination, expressed as glutamic acid; E 626 to E 635, ML = 500 mg/kg individually or in combination, expressed as guanylic acid.
Group II	Group II, Food colours authorised at quantum satis	quantum satis
Group III	Group III, Food colours with combined maximum limit	ML = 50 mg/kg
Group IV	Group IV, Polyols	quantum satis
E 104	Quinoline Yellow	ML = 10 mg/kg
E 110	Sunset Yellow FCF/Orange Yellow S	ML = 10 mg/kg
E 124	Ponceau 4R, Cochineal Red A	ML = 10 mg/kg
E 160d	Lycopene	ML = 30 mg/kg
E 200 - 213	Sorbic acid - sorbates; Benzoic acid - benzoates	ML = 1500 mg/kg
E 338 - 341, E 343 and E 450 - 452	Phosphoric acid - phosphates - di - tri - and polyphosphates	ML = 5000 mg/kg
E 405	Propane-1, 2-diol alginate	ML = 1200 mg/kg
E 432 - 436	Polysorbates	ML = 1000 mg/kg
E 473 - 474	Sucrose esters of fatty acids, Sucroglycerides	ML = 5000 mg/kg
E 475	Polyglycerol esters of fatty acids	ML = 5000 mg/kg
E 477	Propane-1,2-diol esters of fatty acids	ML = 1000 mg/kg
E 481 - 482	Sodium and Calcium stearoyl-2-lactylates	ML = 2000 mg/kg
E 491 - 495	Sorbitan esters	ML = 5000 mg/kg
E 950	Acesulfame K	ML = 450 mg/kg
E 951	Aspartame	ML = 800 mg/kg
E 952	Cyclamic acid and its Na and Ca salts	ML = 400 mg/kg
E 954	Saccharin and its Na, K and Ca salts	ML = 240 mg/kg
E 955	Sucralose	ML = 320 mg/kg
E 959	Neohesperidine DC	ML = 100 mg/kg
E 961	Neotame	ML = 26 mg/kg
E 962	Salt of aspartame-acesulfame	ML = 450 mg/kg
E 960	Steviol glycosides	ML = 270 mg/kg
E 969	Advantame	ML = 8 mg/kg

TERMINOLOGY

TERMINOLOGY

ERD	Energy Restricted Diets - Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction
FIC	Food Information to Consumers - Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers
FSG	Foods for Specific Groups
MS	EU Member States
NHCR	Nutrition and Health Claims Regulation - Regulation (EC) 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
RI	Reference Intake
SNE	Specialised Nutrition Europe

For further information, please contact:



Avenue des Nerviens 9-31, 1040 Brussels, Belgium | T + 32 2 508 10 74 | F + 32 2 508 10 25
secretariat@specialisednutritioneurope.eu | www.specialisednutritioneurope.eu
