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European Union

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No. Cion doc.:	D043783/03 - Annex 1

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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... amending Regulation (EU) No 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
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Delegations will find attached document D043783/03 - Annex 1.

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Encl.: D043783/03 - Annex 1



Brussels, **XXX**  
SANTE/12273/2015 ANNEX Rev. 2  
(POOL/E4/2015/12273/12273R2-EN  
ANNEX.doc) D043783/03  
[...] (2016) **XXX** draft

ANNEX 1

**ANNEX**

**to the**

**COMMISSION REGULATION (EU) .../...**

**amending Regulation (EU) No 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**

ANNEX

In the Annex to Regulation (EU) No 432/2012 the entries for food categories "Meal replacement for weight control" are replaced by the following:

Nutrient substance, food or food category	Claim	Conditions of use of the claim	Conditions, and/or restrictions of use of the food, and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
'Meal replacement for weight control	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	<p>In order to bear the claim, a food should comply with the following requirements:</p> <p><b>1. Energy content</b></p> <p>The energy content shall not be less than 200 kcal (840 kJ) and shall not exceed 250 kcal (1046 KJ) per meal.*</p> <p><b>2. Fat content and composition</b></p> <p>The energy derived from fat shall not exceed 30% of total available energy content of the product.</p> <p>The linoleic acid (in the form of glycerides) shall not be less than 1 g.</p> <p><b>3. Protein content and composition</b></p> <p>The protein contained in the food shall provide not less than 25 % and not more than 50% of the total energy content of the product.</p>	<p>In order to bear the claim, information shall be provided to the consumer on the importance of maintaining an adequate daily fluid intake and 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.</p> <p>In order to achieve the claimed effect, one main meal</p>	2010; 8(2):1466 2015; 13(11):4287	1418

		<p>The chemical index of protein shall be equal to that set by the World Health Organization in 'Energy and protein requirements'. Report of a Joint WHO/FAO/UNU Meeting. Geneva: World Health Organisation, 1985 (WHO Technical Report Series, 724):</p> <p style="text-align: center;"><b>Amino acid requirement pattern</b></p> <table border="1" data-bbox="496 1012 1294 1489"> <thead> <tr> <th></th> <th><b>g/100g protein</b></th> </tr> </thead> <tbody> <tr> <td>Cystine + methionine</td> <td>1,7</td> </tr> <tr> <td>Histidine</td> <td>1,6</td> </tr> <tr> <td>Isoleucine</td> <td>1,3</td> </tr> <tr> <td>Leucine</td> <td>1,9</td> </tr> <tr> <td>Lysine</td> <td>1,6</td> </tr> <tr> <td>Phenylalanine + tyrosine</td> <td>1,9</td> </tr> <tr> <td>Threonine</td> <td>0,9</td> </tr> <tr> <td>Tryptophan</td> <td>0,5</td> </tr> </tbody> </table>		<b>g/100g protein</b>	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	<p>should be substituted with one meal replacement daily.</p>		
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Meal replacement for weight control	Substituting two of the main daily meals of an energy restricted diet with meal replacements contributes to weight loss	<p>In order to bear the claim, a food should comply with the following requirements:</p> <p><b>1. Energy content</b></p> <p>The energy content shall not be less than 200 kcal (840 kJ) and shall not exceed 250 kcal (1046 KJ).*</p> <p><b>2. Fat content and composition</b></p> <p>The energy derived from fat shall not exceed 30% of total available energy content of the product.</p> <p>The linoleic acid (in the form of glycerides) shall not be less than 1 g.</p> <p><b>3. Protein content and composition</b></p> <p>The protein contained in the food shall provide not less than 25 % and not more than 50% of the total energy content of the product.</p> <p>The chemical index of protein shall be equal to that set by the World Health Organization in 'Energy and protein requirements'. Report of a Joint WHO/FAO/UNU Meeting. Geneva: World Health Organisation, 1985 (WHO Technical Report Series, 724):</p>	<p>In order to bear the claim, information shall be provided to the consumer on the importance of maintaining an adequate daily fluid intake and 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.</p> <p>In order to achieve the claimed effect, two of the main daily meals should be substituted with meal replacements daily.</p>	2010; 8(2):1466 2015; 13(11):4287	1417
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			<p><b>Amino acid requirement pattern</b></p> <table border="1" data-bbox="327 1019 1216 1496"> <thead> <tr> <th></th> <th><b>g/100g protein</b></th> </tr> </thead> <tbody> <tr> <td>Cystine + methionine</td> <td>1,7</td> </tr> <tr> <td>Histidine</td> <td>1,6</td> </tr> <tr> <td>Isoleucine</td> <td>1,3</td> </tr> <tr> <td>Leucine</td> <td>1,9</td> </tr> <tr> <td>Lysine</td> <td>1,6</td> </tr> <tr> <td>Phenylalanine + tyrosine</td> <td>1,9</td> </tr> <tr> <td>Threonine</td> <td>0,9</td> </tr> <tr> <td>Tryptophan</td> <td>0,5</td> </tr> <tr> <td>Valine</td> <td>1,3</td> </tr> </tbody> </table>		<b>g/100g protein</b>	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			
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\* From 21 July 2016 until [OPOCE please insert the exact date – 3 years after the entry into force of this Regulation] the energy content of the food shall not be less than 200 kcal (840 kJ) and shall not exceed 400 kcal (1 680 kJ).

\*\* From 21 July 2016 until [OPOCE please insert the exact date – 3 years after the entry into force of this Regulation] the food shall provide at least 30% of the amounts of vitamins and minerals specified in the below Table per meal:



Vitamin A	(µg RE)	700
Vitamin D	(µg)	5
Vitamin E	(mg)	10
Vitamin C	(mg)	45
Thiamin	(mg)	1,1
Riboflavin	(mg)	1,6
Niacin	(mg-NE)	18
Vitamin B <sub>6</sub>	(mg)	1,5
Folate	(µg)	200
Vitamin B <sub>12</sub>	(µg)	1,4
Biotin	(µg)	15
Pantothenic acid	(mg)	3
Calcium	(mg)	700
Phosphorus	(mg)	550

Iron	(mg)	16
Zinc	(mg)	9,5
Copper	(mg)	1,1
Iodine	(µg)	130
Selenium	(µg)	55
Sodium	(mg)	575
Magnesium	(mg)	150
Manganese	(mg)	1

From 21 July 2016 until [OPOCE please insert the exact date – 3 years after the entry into force of this Regulation] the amount of potassium per meal provided by the food shall be at least 500 mg.