Update of the annex of the Regulation 1924/2006

The annex of the Regulation 1924/2006 listing the nutrition claims allowed and the conditions applying to them can be amended following the new comitology procedure with EP scrutiny. First discussion is needed on new nutrition claims based on EFSA opinion and possible revisison of existing conditions for the use of nutrition claims. Stakeholders also need to be consulted in order to ensure the transparency of this process, and before any amendment is proposed. This document is a basis for the preliminary discussion on such amendment.

New nutrition claims

During the Council first reading of the Regulation 1924/2006, some MS asked for the addition in the annex of nutrition claims related to the content in omega 3 fatty acids and unsaturated fatty acids (UFA, MUFA and PUFA), for which EFSA provided a scientific opinion http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/1096.html

Claims referring to omega 3 content.

The conditions below were proposed:

Omega-3 fatty acid source: The food must contain more than 15% of the Recommended Nutritional Intake (with RNI set at 2 g/day for an adult male) for an adult male of the omega-3 fatty acids concerned per 100 g or 100 mL or 100 kcal.

High in omega-3 fatty acids: The food must contain more than 30% of the Recommended Nutritional Intake for an adult male of the omega-3 fatty acids concerned per 100 g or 100 mL or 100 kcal.

In its scientific opinion, EFSA commented on the conditions allowing the claims:

- The RNI proposed in the claim (2 g/day) is in the same range as intakes of ALA recommended by some national and international authorities to meet dietary requirements in adults (1-3 g/day). However, it is much greater than intakes recommended by some authorities for LC n-3 PUFA (EPA and DHA) in adults for cardio-protective effects (200-500 mg/day). In many EU populations intakes of both ALA and LC n-3 PUFA are typically lower than these recommendations.

- Some foods would qualify for the claim on a weight/volume, but not energy basis (e.g. safflower oil, soy bean, peanut, butter) while other foods (e.g. radish, cod) would qualify on an energy, but not weight/volume basis. Some foods qualify although a typical serving provides little n-3 PUFA (e.g. radish, safflower oil, butter). These anomalies arise because the reference food quantity (100 g, 100 mL, 100 kcal) is not linked to the typical intake of the food.

Amendments tabled by the EP in first reading were proposing the following conditions

SOURCE OF OMEGA 3 FATTY ACIDS:
A claim that a food is a source in omega 3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where at least one of the following conditions are met:
- Minimum 0,3g alpha-linolenic acid per 100g/100ml product
- Minimum 30mg very long chain omega 3 fatty acids per 100g/100ml product
as long as at least 15% of the dietary recommendation is met per average daily intake of product

HIGH OMEGA 3 FATTY ACIDS:
A claim that a food is high in omega 3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where at least one of the following conditions are met:
- Minimum 0,6g alpha-linolenic acid per 100g/100ml product
- Minimum 60mg very long chain omega 3 fatty acids per 100g/100ml product
as long as at least 30% of the dietary recommendation is met per average daily intake of product.

These conditions distinguish between the two types of omega 3 fatty acids, following the EFSA advice. They are also based on recommended intakes of the two types of omega 3 fatty acids. However, the notion of "average daily intake of product" is difficult to accept. It would imply a definition of portion of every food bearing the claims, and supposes a common understanding of portion size at the communityt level.

The reference to the "average daily intake of product" could be deleted from the conditions, and reference to 100g, and / or 100 kcal could be considered. A reference to 100 kcal would take account of the energy density of the product, but favour high water content products, such as vegetables, whose average daily portion would not deliver a significant amount of omega-3 (radish would be allowed to bear the "source of omega 3" claim). A reference per 100g would favour energy dense products, and lead to some other anomalies (butter would be allowed to bear the "source of omega 3" claim). The combination of both requirements may solve this problem. The conditions would be the following:

SOURCE OF OMEGA 3 FATTY ACIDS:
A claim that a food is a source in omega 3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where at least one of the following conditions are met:
- Minimum 0,3g alpha-linolenic acid per 100g and per 100kcal product
- Minimum 30mg very long chain omega 3 fatty acids per 100g and per 100kcal product

HIGH OMEGA 3 FATTY ACIDS:
A claim that a food is high in omega 3, fatty acids and any claim likely to have the same meaning for the consumer, may only be made where at least one of the following conditions are met:
- Minimum 0,6g alpha-linolenic acid per 100g and per 100kcal product
- Minimum 60mg very long chain omega 3 fatty acids per 100g and per 100kcal product

The following table provides a indication of the food eligible to the claims following the different conditions (per 100g and/ or per 100kcal)

	Omega 3 claims	**Criteria**
	Source of	alpha-linolenic acid (ALA)
	High in	alpha-linolenic acid (ALA)
	Source of	very long chain omega 3 fatty acids (LC n-3 PUFA)
	High in	very long chain omega 3 fatty acids (LC n-3 PUFA)

Energy value and fat composition of some foods typically high or low in ALA and/or LC n-3 PUFA (values per 100 g and per 100 kcal, respectively)

Food	Energy kcal	Total fat g	ALA g/100 g	ALA g/100 kcal	Total n-3 PUFA g/100 g	Total n-3 PUFA g/100 kcal	EPA g/100 g	EPA g/100 kcal	DHA g/100 g	DHA g/100 kcal	DPA g/100 g	DPA g/100 kcal	Total LC n-3 PUFA g/100 g	Total LC n-3 PUFA g/100 kcal
Rapeseed oil	900	100.0	9.2	1.0	9.2	1.0	-		-		-		-	
Soybean oil	900	100.0	7.7	0.86	7.7	0.86	-		-		-		-	
Linseed oil	900	100.0	54.0	6.0	54.0	6.0	-		-		-		-	
Walnut oil	900	100.0	12.9	1.4	12.9	1.4	-		-		-		-	
Wheat germ oil	900	100.0	7.8	0.87	7.8	0.87	-		-		-		-	
Safflower oil	*900*	*100*	*0.47*	*0.05*	*0.47*	*0.05*	-		-		-		-	
Soybean	327	18.3	0.9	0.28	0.9	0.28	-		-		-		-	
Soybean flour	347	20.6	1.4	0.4	1.4	0.4	-		-		-		-	
Linseed	376	30.9	16.7	4.4	16.7	4.4	-		-		-		-	
Walnut	663	62.5	7.5	1.1	7.5	1.1	-		-		-		-	
Peanut	564	48.1	0.53	0.09	0.53	0.09	-		-		-		-	
Pecan nut	703	72.0	0.79	0.11	0.79	0.11	-		-		-		-	
Kale	37	0.9	0.36	0.97	0.36	0.97	-		-		-		-	
Radish	*15*	*0.15*	*0.055*	*0.370*	*0.055*	*0.370*	-		-		-		-	
*Human milk**	*69*	*4.0*	*0.03*	*0.04*	*0.08*	*0.116*	*0.02*	*0.03*	*0.02*	*0.03*	*0.01*	*0.014*	*0.05*	*0.079*
Egg whole	*155*	*11.3*	*0.1*	*0.06*	*0.1*	*0.06*	-		-		-		-	
Egg yolk	353	31.9	0.26	0.07	0.5	0.142	-		0.18	0.05	0.06	0.017	0.24	0.0022
Pork liver	131	4.9	0.02	0.02	0.43	0.328	0.18	0.14	0.2	0.15	0.03	0.023	0.41	0.313
Chicken	*166*	*9.6*	*0.11*	*0.07*	*0.24*	*0.143*	*0.007*	*0.004*	*0.11*	*0.07*	*0.01*	*0.006*	*0.127*	*0.080*
Herring	233	17.8	0.06	0.03	2.86	1.227	2.0	0.86	0.7	0.3	0.1	0.04	2.8	1.2
Tuna	226	15.5	0.21	0.09	3.96	1.752	1.39	0.62	2.1	0.93	0.26	0.12	3.75	1.67
Salmon	202	13.6	0.36	0.18	3.34	1.653	0.75	0.37	1.85	0.92	0.38	0.19	2.98	1.48
Mackerel	182	11.9	0.25	0.14	2.11	1.159	0.63	0.35	1.1	0.60	0.13	0.07	1.87	1.02
Eel	281	24.5	0.66	0.23	1.86	0.662	0.26	0.09	0.57	0.20	0.37	0.13	1.2	0.42
Cod	*77*	*0.64*	*0.004*	*0.005*	*0.28*	*0.36*	*0.07*	*0.09*	*0.19*	*0.25*	*0.009*	*0.012*	*0.28*	*0.36*
Margarine, vegetable	722	80	2.58	0.36	2.56	0.36	-		-		-			
Butter	751	83.2	0.44	0.06	0.48	0.06	-		0.01	0.001	0.031	0.004	0.041	0.005

Claims referring to unsaturated fat content

The conditions below were proposed to EFSA:

High monounsaturated fat: A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that saturated fat must not provide more than 10% of energy.

High polyunsaturated fat: A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from polyunsaturated fat and saturated fat must not provide more than 10% of energy.

High unsaturated fat: A claim that a food contains high amount of unsaturated fat and any claim likely to have the same meaning for the consumer may only be made where the amount of unsaturated fat is 70% of the total fat content in the product.

In its scientific opinion, EFSA commented on the conditions allowing the claims:

The claims could be made for some foods which provide only low amounts of unsaturated fat a typical serving. These anomalies arise because the thresholds are expressed as % of total fatty acids content which is not directly related to the typical intake of the food. In addition, some foods which provide significant amounts of unsaturated fatty acids may not qualify for the claim e.g. foods that are naturally high in MUFA such as olive oil and fatty fish (e.g. herring, salmon) and some margarines. This anomaly arises because the saturated fat content of these foods may exceed the disqualifying threshold of 10 E%.

The following table show for some foods how these criteria perform the selection for the claim "high monounsaturateed fatty acid" :

ORIGINAL MUFA CLAIM

Food in green cells can bear the claim high in MUFA
conditions: MUFA are 45% of total fatty acids
Disqualifying claims >10% energy from saturated fat

Name	ENKJ	FAT g/100g	MUFA g/100g	PUFA g/100g	SAFA E%	MUFA % of TFA
Almonds dried	2490	52	33,9		7%	68%
Avocado	669	15,3	11,5		10%	79%
Bacon	1441	32,8	14,8		35%	47%
Cashew nuts	2431	46,5	27,3		14%	61%
Cereal mix fruits nuts sugar or honey	1534	5,9	3,3		2%	62%
Chicken breast meat and skin	621	6,9	3,2		13%	49%
Chicken meat and skin	713	11	5,1		18%	49%
Egg	612	10,1	4,5		17%	54%
Fat spread fat 35 % fortified Becel	1329	35	11		25%	31%
Fat spread fat 70% Flora	2602	70	27		46%	39%
Fat spread fat 75% Milda	2782	75	32		44%	43%
Goose meat and skin	1514	33,6	17,7		24%	56%
Grill sausage fat c 18%	1029	18,2	8,8		24%	51%
Hazelnuts	2695	62,6	48,8		6%	82%
Hen meat	590	6,3	2,7		9%	45%
Herring Atlantic	965	18,5	7,7		16%	46%
Mackerel Atlantic	891	16	6,5		15%	45%
Mackerel fillets in tomato sauce canned	467	6	2,5		10%	46%
Margarine liquid fat 80 % fortified	2970	80	45,4		9%	59%
Mustard French	377	5	3,2		2%	67%
Olive oil	3700	100	72,1		14%	75%
Olives green in brine drained	499	12,7	8,9		13%	73%
Peanuts dried	2388	49	24,5		11%	52%
Pecan nuts	2805	68	42,2		7%	65%
Pistachio nuts	2517	48,5	32,7		9%	71%
Pork chops fat removed	430	1,7	0,8		5%	52%
Pork fillet	446	2,6	1,2		8%	51%
Pork loin smoked	442	2,2	1		7%	50%
Rapeseed oil fortified	3700	100	58,6		7%	61%
Reindeer shoulder	455	2,5	1,7		12%	75%
Salmon Atlantic	757	12	5		13%	46%
Veal shank	410	1,9	0,8		6%	46%
White bread fibre c 3% e.g. loaves rolls	1060	2,4	1,1		1%	51%
White bread liquid milk fibre c 4% e.g. hamburger buns hotdog rolls	1161	4,1	2,1		1%	57%
Whiting	333	0,6	0,2		1%	48%

Following the opinion of EFSA, the conditions for such claims could be modified as follows:

HIGH MONO UNSATURATED FAT
A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that monounsaturated fat provides more than 10% of energy of the product.

HIGH POLY UNSATURATED FAT
A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 10% of energy of the product.

HIGH UNSATURATED FAT
A claim that a food contains high amount of unsaturated fat and any claim likely to have the same meaning for the consumer may only be made where the amount of unsaturated fat is 70% of the total fat content in the product under the condition that unsaturated fat provides more than 10% of energy of the product.

These modifications would ensure that a significant amount of unbsaturated fat is provided by the foods bearing the claims. The disqualifying criterion on saturated fat is deleted. The content in satuarted should however be of first importance for the setting of nutrient profiles that will govern the use of such claims.

The following table show the effect of the modification of the conditions for MUFA claim:

PROPOSED MODIFICATION FOR MUFA CLAIM

Food in green cells can bear the claim high in MUFA
conditions: MUFA 45% of total fatty acids + MUFA 10% energy

Name	ENKJ	FAT g/ 100g	MUFA g/ 100g	PUFA g/ 100g	SAFA E%	MUFA % of TFA	MUFA kcal for 100g	MUFA E%
Almonds dried	2490	52	33,9	11	7%	68%	305,1	12,3
Avocado	669	15,3	11,5	1,3	10%	79%	103,5	15,5
Bacon	1441	32,8	14,8	2,8	35%	47%	133,2	9,2
Cashew nuts	2431	46,5	27,3	7,9	14%	61%	245,7	10,1
Cereal mix fruits nuts sugar or honey	1534	5,9	3,3	1,4	2%	62%	29,7	1,9
Chicken breast meat and skin	621	6,9	3,2	1	13%	49%	28,8	4,6
Chicken meat and skin	713	11	5,1	1,6	18%	49%	45,9	6,4
Egg	612	10,1	4,5	1,2	17%	54%	40,5	6,6
Fat spread fat 35 % fortified Becel	1329	35	11	8,6	25%	31%	99	7,4
Fat spread fat 70% Flora	2602	70	27		46%	39%	243	9,3
Fat spread fat 75% Milda	2782	75	32		44%	43%	288	10,4
Goose meat and skin	1514	33,6	17,7	3,8	24%	56%	159,3	10,5
Grill sausage fat c 18%	1029	18,2	8,8	1,9	24%	51%	79,2	7,7
Hazelnuts	2695	62,6	48,8	6,5	6%	82%	439,2	16,3
Hen meat	590	6,3	2,7	0,9	9%	45%	24,3	4,1
Herring Atlantic	965	18,5	7,7	4,7	16%	46%	69,3	7,2
Mackerel Atlantic	891	16	6,5	4,4	15%	45%	58,5	6,6
Mackerel fillets in tomato sauce canned	467	6	2,5	1,6	10%	46%	22,5	4,8
Margarine liquid fat 80 % fortified	2970	80	45,4	23,4	9%	59%	408,6	13,8
Mustard French	377	5	3,2	1,2	2%	67%	28,8	7,6
Olive oil	3700	100	72,1	9,1	14%	75%	648,9	17,5
Olives green in brine drained	499	12,7	8,9	1,4	13%	73%	80,1	16,1
Peanuts dried	2388	49	24,5	15,5	11%	52%	220,5	9,2
Pecan nuts	2805	68	42,2	16,7	7%	65%	379,8	13,5
Pistachio nuts	2517	48,5	32,7	7,3	9%	71%	294,3	11,7
Pork chops fat removed	430	1,7	0,8	0,2	5%	52%	7,2	1,7
Pork fillet	446	2,6	1,2	0,3	8%	51%	10,8	2,4
Pork loin smoked	442	2,2	1	0,2	7%	50%	9	2,0
Rapeseed oil fortified	3700	100	58,6	30,2	7%	61%	527,4	14,3
Reindeer shoulder	455	2,5	1,7	0,2	12%	75%	15,3	3,4
Salmon Atlantic	757	12	5	3,3	13%	46%	45	5,9
Veal shank	410	1,9	0,8	0,2	6%	46%	7,2	1,8
White bread fibre c 3% e.g. loaves rolls	1060	2,4	1,1	0,7	1%	51%	9,9	0,9
White bread liquid milk fibre c 4% e.g. hamburger buns hotdog rolls	1161	4,1	2,1	1,3	1%	57%	18,9	1,6
Whiting	333	0,6	0,2	0,2	1%	48%	1,8	0,5

Revised conditions for nutrition claims already listed in the annex

Comparative claims

Codex guidelines for the use of nutrition and health claims mention that for comparative claims:

" The comparison should be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where a 10% difference in the NRV would be acceptable"

The current percentage used in the Regulation 1924/2006 is 30% for these compatrative claims. The advantage of an alignment with the Codex conditions is balanced by the less significant difference it would provide compared with the current situation. If an alignement with Codex would be proposed, it would consist in the following modifications:

The conditions should be replaced by the following:

INCREASED [NAME OF THE NUTRIENT]
A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, and any claim likely to have the same meaning for the consumer, may only be made where the product meets the conditions for the claim ‘source of’ and the increase in content is at least 25 % compared to a similar product.

REDUCED [NAME OF THE NUTRIENT]
A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 25 % compared to a similar product, except for micronutrients, where a 10 % difference in the reference values as set in Directive 90/496/EEC shall be acceptable.

ENERGY-REDUCED
A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 25 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

The current conditions for the claim "energy reduced" are in line with other community rules established (and under revision) for sweeteners. However, in the frame of the provisions of the Directive 94/35/EC on sweeteners for use in foodstuffs, the 30 % reduction is requested for the use of the sweeteners, and not for the use of a claim. Different reduction percentages can therefore be envisaged.

Low / very low sodium claim - adaption of threshold for waters

The conditions for the use of claims on sodium content were already revised during the first Council reading, in order to align the conditions with the one already laid down in the Community legislation on mineral water. Indeed, Directive 80/777/EEC provides for the possibility for mineral water to bear the claim "Suitable for a low-sodium diet" with a threshold of sodium of 20 mg/l.

The current conditions are the following:

LOW SODIUM/SALT
A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. For waters, other than natural mineral waters falling within the scope of Directive 80/777/EEC, this value should not exceed 2 mg of sodium per 100 ml.

VERY LOW SODIUM/SALT
A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. This claim shall not be used for natural mineral waters and other waters.

The prohibition for waters to use the "very low sodium" claim was introduced to avoid that waters other than those covered by Directive 80/777/EEC can circumvent the provisions of the "low sodium" claim (threshold 2 mg per 100ml) and use the "very low sodium" claim (threshold 40 mg per 100ml).

In order to align the "very low sodium" claim conditions with the one of the "low sodium" claim, a specific threhold could be provided for waters. The conditions could then be replaced by the following:

VERY LOW SODIUM/SALT
A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,04g of sodium, or the equivalent value for salt, per 100g or per 100ml. For mineral waters falling within the scope of Council Directive 80/777/EEC and other waters for human consumption falling within the scope of Council Directive 98/83/EC, this value should not exceed 0,7mg of sodium per 100ml.

The value of 0,7mg is obtained by applying the same reduction factor as for the other thresholds:

	Low sodium	Reduction factor	Very low sodium
other foods	12	/ 3	4
waters	2	/ 3	0,7