

Health Claims Success

Fi-Conference
Legislation & Regulation
For NPD & Reformulation
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NutriClaim

Outline

- Health Claims that made it through the net?
- Authorization issues
- Max. & min. levels vitamins & minerals
- Marketing to consumers - Guidance on use authorized health claims

Health claims process

- Many have been rejected or will be rejected!
- Some are EC-authorized as yet
- Some more have received positive opinion by EFSA

EC-authorized

Article 14 health claims referring to the reduction of a risk factor in the development of a disease

Ingredient	Health Claim	CoU
Plant sterols Plant stanol esters	reduction of blood cholesterol - High cholesterol is risk factor of CHD	1.5-2.4 g/day
Xylitol 100%	reduction of dental plaque - high level dental plaque is risk factor dental caries in children	2-3 g gum/3 x day

EC-authorized

Article 14 health claims referring to children's development and health

Nutrient	Health Claim	CoU
ALA	Normal growth and development	Information to the consumer that the beneficial effect is obtained with a daily intake of 2 g of α -linolenic acid (ALA) and a daily intake of 10 g of linoleic acid (LA).
Protein	Bone development	at least 12% of energy value of food provided by protein

EC-authorized

Article 14 health claims referring to children's development and health

Nutrient	Health Claim	CoU	RDA Annex Dir. 90/496/EEC Annex II Reg. 1925/2006	15% RDA
Calcium	Bone development	at least source of - 15% of RDA	800 mg	120 mg
Vitamin D	Bone development		5 µg	0.75 µg
Phosphorus	Bone development	Expressed as per 100 g/ 100 ml or per package (single portion)	800 mg	120 mg
Iodine	Normal growth & development		150 µg	22.5 µg
iron	Normal cognitive development		14 mg	2.1 mg

EC-authorized

Article 13.5 health claim Article 13(5) health claims based on newly developed scientific evidence and/or including a request for the protection of proprietary data

Ingredient	Health Claim	CoU
Water soluble tomato concentrate	helps maintain normal platelet aggregation, which contributes to healthy blood flow	3g WSTC I or 150mg WSTC II in up to 250ml of either fruit juices, flavoured drinks or yogurt drinks (unless heavily pasteurized) or with a daily consumption of 3 g WSTC I or 150 mg WSTC II in food supplements when taken with a glass of water or other liquid.

Positive verdict by EFSA

Art. 14 health claims pertaining to vitamins and minerals

Calcium + Vitamin D	“Calcium may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures”	1000 mg Ca/20 µg D <ol style="list-style-type: none"> 1. no CoU could be established; 2. at least 1200 mg of calcium from all sources or at least 1200 mg of calcium and 800 I.U. of vitamin D from all sources
Thiamin	Neurological development	For infants and young children: compliant with Directives on follow-on formulae, FSMP, and processed cereal-based foods. All other foods: 15% RDA
Thiamin	Energy-yielding metabolism	For infants and young children: compliant with Directives on follow-on formulae, FSMP, and processed cereal-based foods. All other foods: 15% RDA
Iron	Cognitive development	At least 15% RDA (source of)

Positive verdict by EFSA

Art. 13.1 health claims

Vitamin A (beta-carotene)*	cell differentiation, immune system, skin and mucous membranes, vision, metabolism of iron
Thiamin (B1) *	energy-yielding metabolism, cardiac function, nervous system
Riboflavin (B2)	Energy-yielding metabolism, iron metabolism [#] , skin and mucous membranes [#] , vision [#] , red blood cells [#] , protection DNA, proteins and lipids, tiredness and fatigue, nervous system [#]
Niacin (B3)*	Tiredness and fatigue, energy-yielding metabolism, psychological function, skin and mucous membranes

Positive verdict by EFSA

Art. 13.1 health claims

Pantothenic acid (vitamin B5) *	Tiredness and fatigue, energy-yielding metabolism, mental performance, synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters.
Vitamin B6	Tiredness and fatigue, protein and glycogen metabolism *, nervous system *, red blood cell formation *, immune system *, regulation of hormonal activity *, homocysteine metabolism #, cysteine synthesis #
Folate	blood formation, homocysteine metabolism, immune system, cell division, maternal tissue growth during pregnancy, psychological functions #, tiredness and fatigue #, amino acid synthesis,

Positive verdict by EFSA

Art. 13.1 health claims

Vitamin B12	red blood cell formation, cell division, energy-yielding metabolism, immune system, Reduction of tiredness and fatigue [#] , homocysteine metabolism [#] , neurological and psychological functions [#]
Vitamin C	Tiredness and fatigue [#] , psychological function [#] , regeneration vit. E, immune system (extreme exercise - 200 mg), nervous system, energy-yielding metabolism, protection DNA, lipids and proteins, collagen formation, non-haem iron absorption
Vitamin D	bone and teeth, absorption and utilisation of calcium and phosphorus, blood calcium concentrations, cell division, immune system and inflammatory response, muscle function

Positive verdict by EFSA

Art. 13.1 health claims

Vitamin E	DNA, proteins and lipids
Vitamin K	Bone, blood coagulation

Positive verdict by EFSA

Art. 13.1 health claims

Calcium	Bones and teeth, muscle function and neurotransmission, blood coagulation, energy-yielding metabolism, function of digestive enzymes, normal cell division and differentiation
Magnesium	Tiredness and fatigue, psychological function, muscle contraction
Potassium	Muscular and neurological function, blood pressure
Phosphorus*	Function of cell membranes, energy-yielding metabolism, maintenance of bone and teeth.

Positive verdict by EFSA

Art. 13.1 health claims

Iron	Red blood cells and haemoglobin, oxygen transport, energy-yielding metabolism, fatigue and tiredness
Zinc*	Immune system#, hair#, nails#, skin#, DNA synthesis and cell division, protection of DNA, proteins and lipids, bone, cognitive function#, fertility and reproduction, metabolism of fatty acids, normal acid-base metabolism, vitamin A metabolism, vision, testosterone production
Manganese*	Connective tissue, energy-yielding metabolism

Positive verdict by EFSA

Art. 13.1 health claims

Copper	Nervous system, immune system, energy-yielding metabolism
Selenium	Hair [#] , nails [#] , immune system, thyroid function, protection DNA, proteins, lipids,
Chromium [*]	Macronutrient metabolism, blood glucose metabolism
Fluoride	Tooth mineralization
Molybdenum [*]	Sulphur amino acid metabolism

Positive verdict by EFSA

Art. 13.1 health claims related to intestinal health

Lactulose	Reduction of intestinal transit time CoU: at least 10 g in a single serving
Wheat bran	Increase in faecal bulk CoU: at least high fibre
Wheat bran	Reduction of intestinal transit time CoU: at least 10 g/day in ≥ 1 servings

Positive verdict by EFSA

Art. 13.1 health claims related to immune system

Vitamins	Minerals
Vitamin A	Zinc
Vitamin B6	Copper
Folate	Selenium
Vitamin B12	
Vitamin C	
Vitamin D	

Issues (1)

Formats opinions of batch 1 & 2 (Oct. 2009/Feb. 2010) and batch 3 (Oct. 2010) differ

- 1st & 2nd batch: health benefits just listed
- 3rd batch: evaluation explained -

*The evidence provided does not establish that inadequate intake of **vitamin A, thiamine, niacin, zinc, manganese, chromium and phosphorus** leading to impaired function of the mentioned health relationships occurs in the general EU population.

Q: Will claims be allowed when intake is adequate?

Note:

- Low zinc status
- Decline in magnesium status
- Chromium depletion

Issues (2)

Positive verdict of claims based on symptoms of deficiency!
Legal validity? - deficiency syndromes are classified in ICD-10
(WHO_2007)

Diseased populations!

Claim: reduction of tiredness and fatigue

The claimed effect is “vitamin/mineral supplementation to reduce fatigue and tiredness in situations of inadequate micronutrient status”.

Cf. intake of *Pantothenic acid*, *vitamin B6*, *folate*, *vitamin B12*, *vitamin C*

Positive EFSA opinion - only half the battle

Member states:

- concerns over choking regarding glucomannan & guar gum
 - Glucomannan - blood cholesterol - 4 g/d
 - Glucomannan - reduction body weight - ≥ 3 g/d
 - Guar gum - blood cholesterol - ≥ 10 g/d
- Lactulose (transit time) and melatonin (alleviation of subjective feelings of jet lag) are considered medicines in some MS

Positive EFSA opinion - only half the battle

Member states:

- ‘Toothkind’ drink (≥ 4 drinks/day) - such consumption pattern should not be encouraged and is in conflict with national dietary guidelines in EU MS.
- High dose DHA +EPA (2-3 g/d) - blood pressure & triglycerides
 - No UL established - BfR recommends a max. of 1.5 g/d

Positive EFSA opinion - only half the battle

Members European Parliament (MEPs):

- Attempts to veto DHA health claim for normal visual development for infants up to 12 mo of age (supported by lobby from Baby Milk Action, BEUC, Unicef)

Vote:

- 328 in favour of rejection
- 323 against
- 26 abstentions

Claim **not rejected** because no majority (368)

Case shows willingness of MEPs to use their powers of scrutiny under comitology rules

Vitamin A intake

The evidence provided does not establish that inadequate intake of **vitamin A** leading to impaired function of the mentioned health relationships occurs in the general EU population.

Case: UK vitamin A intake

- Mean intakes of all vitamins were above the Reference Nutrient Intakes (RNI) for men and women overall (taking all ages together)
- The Lower Reference Nutrient Intake (LRNI) represents the amount of a nutrient which is likely to meet the needs of 2.5% of the population
- The Estimated Average Requirement (EAR) is the intake which is likely to meet the needs of 50% of the population
- The Reference Nutrient Intake (RNI) is the intake which is considered sufficient to meet the requirements of 97.5% of the population

Table 20 (continued) : Mean intakes of vitamins from food as a percentage of Reference Nutrient Intake (RNI) and percentage below the Lower Reference Nutrient Intake (LRNI), by age and sex.

Vitamin	Males aged (years)							
	19-24		25-34		35-49		50-64	
	Mean intake as % RNI	% below LRNI	Mean intake as % RNI	% below LRNI	Mean intake as % RNI	% below LRNI	Mean intake as % RNI	% below LRNI
Vitamin A (retinol equivalents) (µg)	80	16	103	7	141	5	164	4
Thiamin (mg)	160	2	232	0	204	0	230	1
Riboflavin (mg)	129	8	163	1	168	2	169	3
Niacin equivalents (mg)	232	-	272	-	270	0	279	0
Vitamin B ₆ (mg)	189	-	211	0	206	2	201	1
Vitamin B ₁₂ (µg)	296	1	395	-	465	0	485	0
Folate (µg)	151	2	173	-	171	0	181	-
Vitamin C (mg)	162	-	185	0	221	-	236	-
Vitamin D (µg) ¹	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Number of subjects (unweighted)</i>	61		160		303		242	
Vitamin	Females aged (years)							
	19-24		25-34		35-49		50-64	
	Mean intake as % RNI	% below LRNI	Mean intake as % RNI	% below LRNI	Mean intake as % RNI	% below LRNI	Mean intake as % RNI	% below LRNI
Vitamin A (retinol equivalents) (µg)	78	19	98	11	112	8	136	5
Thiamin (mg)	181	-	194	2	190	1	200	1
Riboflavin (mg)	126	15	131	10	151	5	159	6
Niacin equivalents (mg)	246	2	240	-	263	1	270	0
Vitamin B ₆ (mg)	165	5	158	1	170	2	177	2
Vitamin B ₁₂ (µg)	266	1	264	1	325	1	378	0
Folate (µg)	114	3	117	2	128	2	134	2
Vitamin C (mg)	170	1	181	-	200	0	236	0
Vitamin D (µg) ¹	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Number of subjects (unweighted)</i>	78		211		379		290	

¹ Vitamin D is also obtained from the action of sunlight on the skin. No DRV is set for adults.

Case: UK vitamin A intake

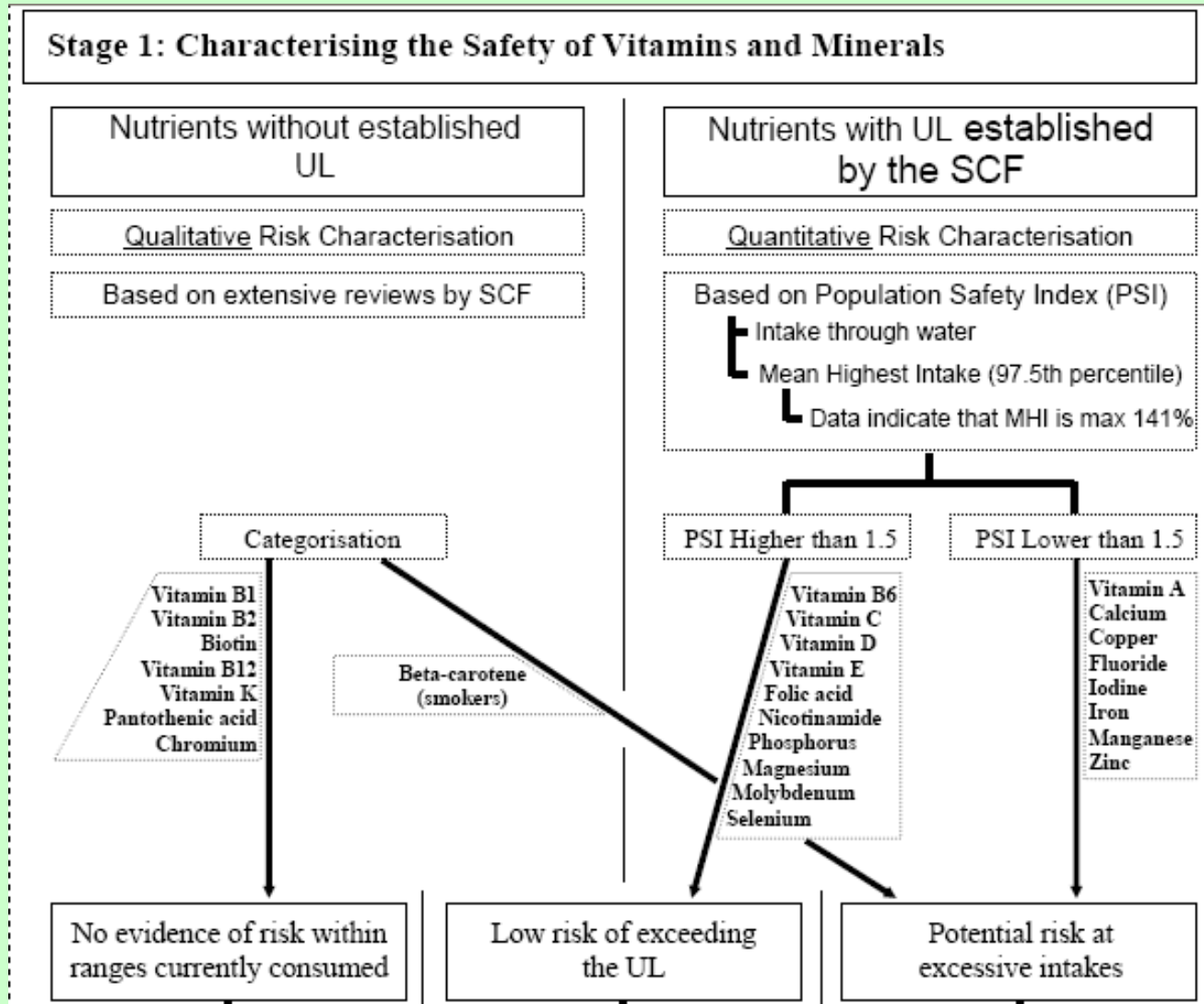
Implications?

Maximum and minimum levels

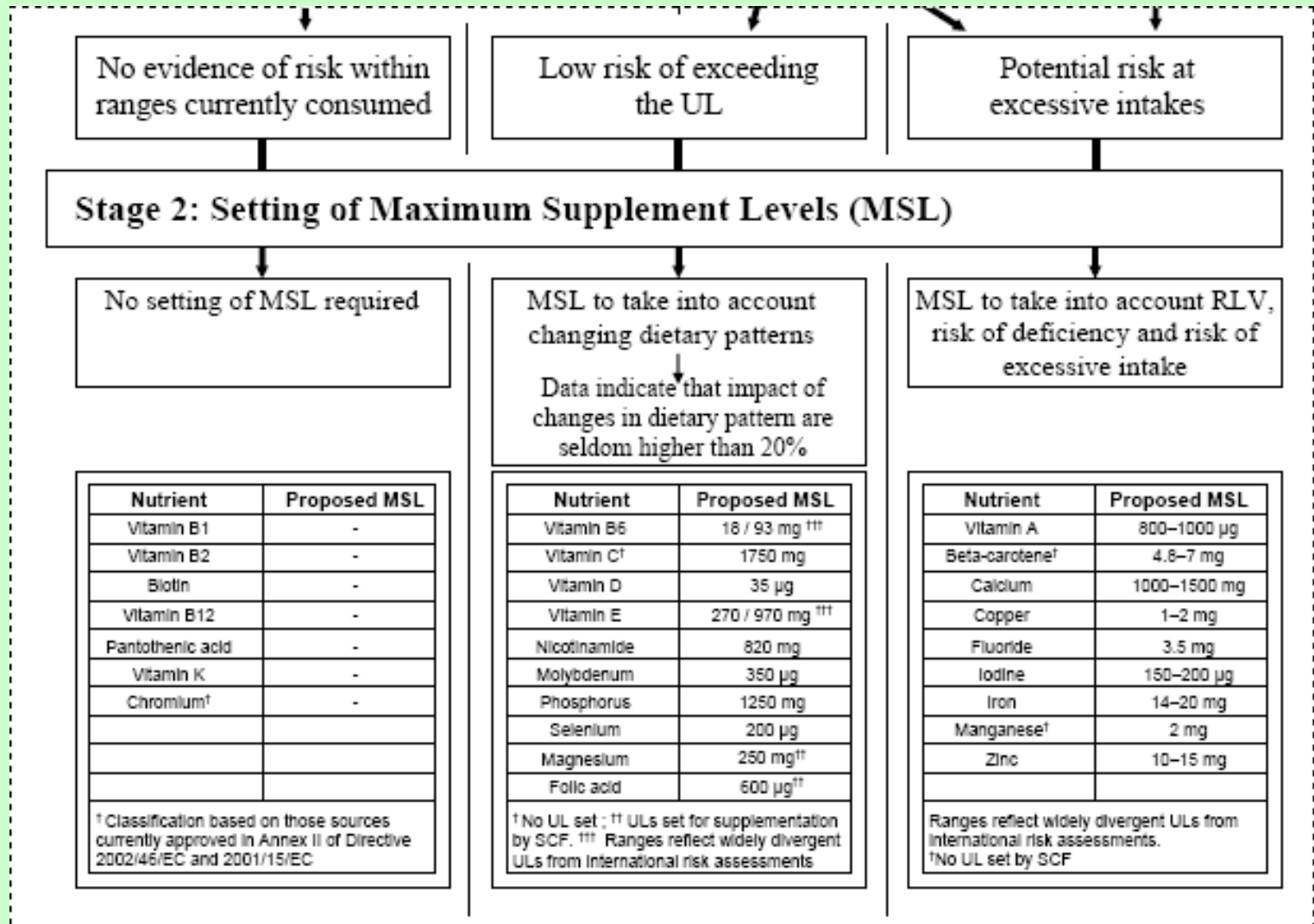
- Pertain to vitamins and minerals
 - Already announced in Dir. 2002/46/EC, reiterated in Reg. 1925/2006. However, not yet materialized
- Levels of Ingredients, for which health claim is authorized, are indicated in CoU.

To set maximum amounts of vitamins and minerals in fortified foods and food supplements, it is necessary to use the extrapolated ULs for children and to take into account nutrient intakes from all likely sources. Richardson_2010

Maximum and minimum levels



Maximum and minimum levels



Issues (3): art. 6(3) Reg. 1925/2006 ³¹

3. The maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 shall be set taking into account:

- (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different groups of consumers; and
- (b) intakes of vitamins and minerals from other dietary sources.

If there is no deficiency, will fortification (claims) be allowed?
Esp. when high consumption of particular food bearing the claim (is anticipated)!

Issues (4): art. 6(5) Reg. 1925/2006 ³²

5. When the maximum amounts referred to in paragraph 1 and the conditions referred to in paragraph 2 are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following shall also be taken into account, as necessary:

- (a) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;
- (b) the nutrient profile of the product established as provided for by Regulation (EC) No 1924/2006.

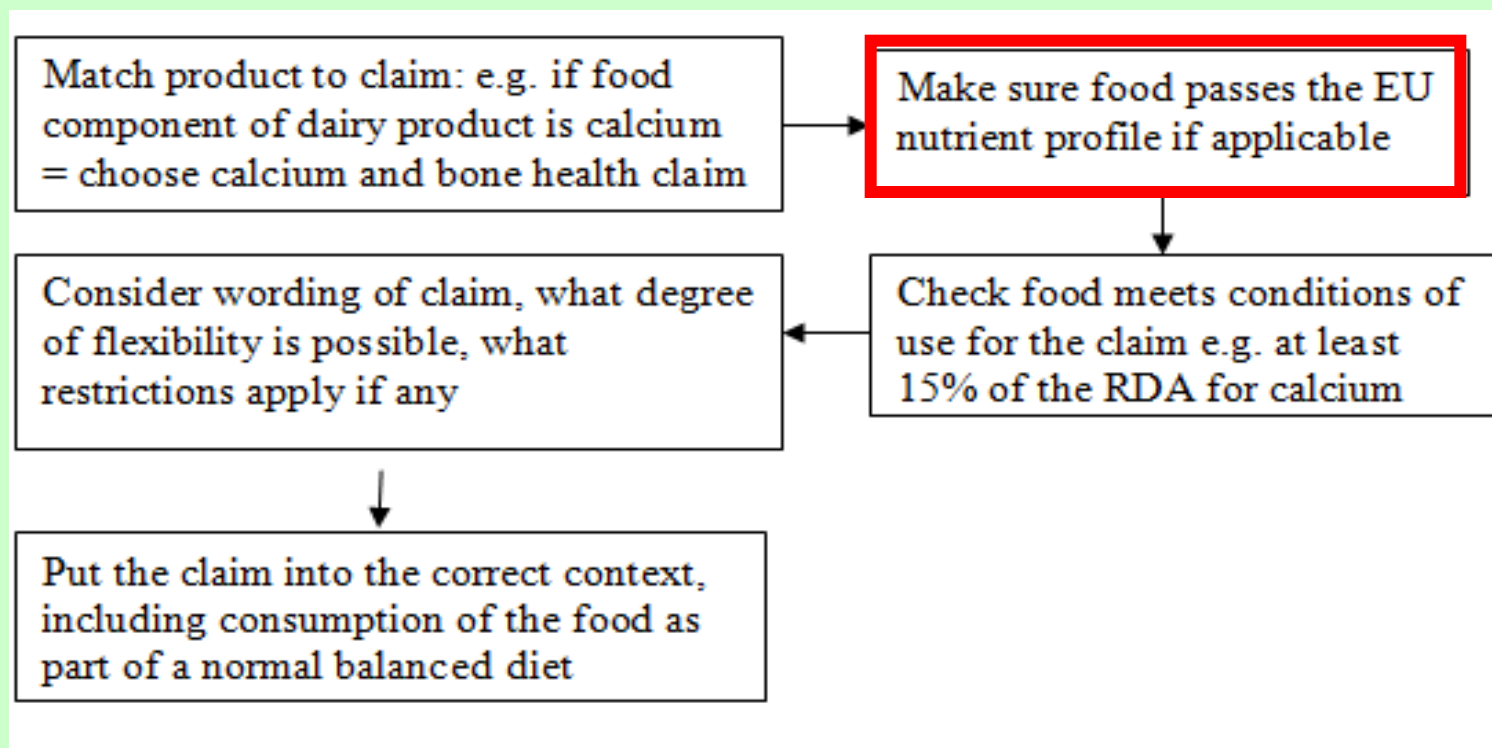
If there is no deficiency, will fortification (claims) be allowed?
Esp. when high consumption of particular food bearing the claim!

EC Guidance on use authorized health claims

Claim must be authorized and listed in:

- Annex of nutrition claims (Reg. 1924/2006 and Reg. 116_2010)
 - Union list of Art. 13 claims
 - Union list of Art. 14 claims
 - Annex of Health Claims authorized on basis of proprietary data
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- **Bear in mind - EFSA opinions are not legally binding!**

EC Guidance on use authorized health claims



Nutrient Profiles

- Not yet in place! (understatement?)

EC Guidance on use authorized health claims

- Target audience
 - Where products could be eaten by many different population groups, but the claim is only valid for one/some of these groups, this should be made clear to consumers (cf case UK vitamin A intake).
- ‘Good for you!’, ‘Keeps your body healthy!’ etc. must be accompanied by a specific authorized health claim.

However, final document is in preparation but will not be due until late this year, hopefully before list authorized art. 13(1) claims is published

Read this carefully before placing food with HC on the market!

New Food(s)?



- High in fiber
- Fat-free
- Salt-free
- High protein

Source of:

- Vitamin B2
- Vitamin B3
- Copper
- Potassium

Good for everything, good for all!



Contribution to/ maintenance of normal:

1. energy-yielding metabolism,
2. immune function,
3. muscle function,
4. blood pressure,
5. iron metabolism,
6. skin and mucous membranes,
7. vision,
8. red blood cells,
9. Protection DNA, proteins and lipids,
10. Reduction of tiredness and fatigue,
11. nervous system
12. psychological function

Reg. 1924/2006 introduces whole new class of miracle foods!

Thank you!

