

Capitalizing on existing research to push your health claim

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Module 6A - Cardio Health
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Agenda

- Cardio health - product launch - ingredients
- Heart healthy claims vitamins & minerals
- Heart healthy claims other substances
- Perspectives for ingredients that didn't make it
- Capitalizing on existing research

Cardio health

Maintenance of good cardiovascular health is one of the most-desired and highly demanded health benefits from functional foods world-wide.

- Cholesterol
- Blood pressure
- Blood circulation
- Blood clotting
- Triglycerides

Heart Health Product launches

- Highest heart health F&B product launch activity in US (60%).
- In Europe, new product launch on the decline - coinciding with NHCR

Product landscape

Dominated by 4 product categories:

1. Bakery & cereals (23.1%)
2. Soft drinks (23.1%)
3. Dairy (10.3%)
4. Hot drinks (7.9%)

Source: Business Insights 2011

Drinks

Hot and soft drinks combined one-third of heart health market (2008-2010)

- Fruit juices
- Tea
- Dairy drinks

Source: Business Insights 2011

Ingredients

- Omega-3 fatty acids
- Phytosterols
- Dietary fibres (beta-glucans)
- Soy protein
- Vitamin E
- Magnesium
- Grape seed extract
- Coenzyme Q10

Regulatory landscape in Europe

- An improvement in cardiovascular health is one of the most-desired and highly demanded health benefits from functional foods world-wide.
- Reflective of this demand, the first health claims authorized by the European Commission, pertained to health benefits related to the cardiovascular system.

Plant sterols/stanols

Art. - 14 Reduction of disease risk:

- Plant sterols, plant stanol and their esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.

Water-Soluble Tomato Concentrate

Art. - 13.5 New function/evidence:

- Water-Soluble Tomato Concentrate (WSTC) I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow

EU health claims

Art. 13(1)

16 May 2012:

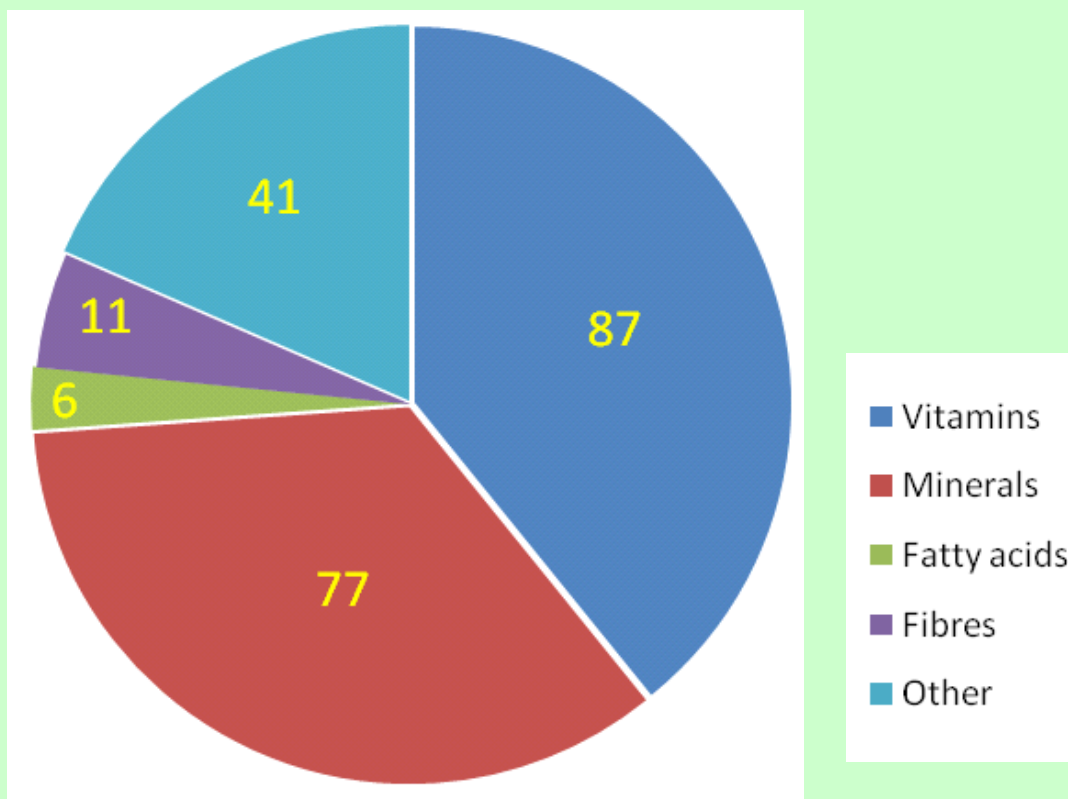
- EP adopted Regulation (EC) no. 432/2012 establishing a list of permitted health claims made on foods

14 December 2012

- All non-authorized health claims have to be taken off the market!

NHCR - The Harvest

- 222 authorized claims



Winner Vitamins

Vitamin	# authorized claims	% of total authorized
Vitamin C	15	7%
Vitamin B6	10	5%
Vitamin B2 (Riboflavin)	9	4%
Vitamin B12	8	≈4%

4 Vitamins - 20% of total authorized claims

Winner Minerals

Mineral	# authorized claims	% of total authorized
Zinc	18	8%
Magnesium	10	5%
Calcium	8	≈4%
Copper	8	≈4%

4 Minerals - 20% of total authorized claims

Winner Minerals

4 Vitamins + 4 Minerals - 40% of total authorized claims

222 authorized claims:

8 vitamin & mineral claims related to heart health

Heart healthy!

vitamins & minerals

Nutrient	Health Benefit			
	Blood pressure	Homocysteine	Blood Coagulation	Heart Muscle
Vitamin B6		+		
Vitamin B12		+		
Vitamin K			+	
Choline		+		
Betaine		+		
Magnesium				+
Potassium	+			
Reduction of sodium	+			
Vitamins ACE	-	-	-	-

Nutrient	Conditions of Use			
	Blood pressure	Homocysteine	Blood Coagulation	Heart Muscle
Vitamin B6		15% RDA		
Vitamin B12		15% RDA		
Vitamin K			15% RDA	
Choline		82,5 mg of choline per 100 g or 100 ml		
Betaine		1,5 g of betaine (500 mg/portion)		
Magnesium				15% RDA
Potassium	15% RDA			
Reduction of sodium [≤ 0.12 g/100 g-100 ml]	Foods low in sodium/ reduced sodium			

Heart healthy!

Other substances

Nutrient	Health Benefit				EDV*
	Cardiac function	Blood pressure	Cholesterol	Triglycerides	
EPA/DHA	+	+		+	
Beta-glucans			+		
Glucomannan			+		
Alpha-Linolenic acid			+		
Plant sterols/stanols			+		
Monacolin A			+		
Walnuts					+

* Endothelium-dependent vasodilation

Nutrient	Conditions of Use				
	Cardiac function	BP	Cholesterol	Triglycerides	EDV*
EPA/DHA	40 mg/100 g-kcal - 250 mg	2-4 g/d		3 g/d	
Beta-glucans			3 g/1 g per portion		
Glucomannan			4 g		
Alpha-Linolenic acid			0.3 g/100 g-kcal - 2 g		
Plant sterols/stanols			0.8 g		
Monacolin A			10 mg		
Walnuts					30 g

Ingredients

- Omega-3 fatty acids
- Phytosterols
- Dietary fibres
- Soy protein
- Vitamin E
- Magnesium
- Grape seed extract
- Coenzyme Q10

Soy Protein - why not?

Pubmed: 'Soy protein' AND 'cholesterol' (limits 'human' and 'RCT')

- 141 hits
- 8 meta-analyses - all positive
- Claim application
- Apparent wealth of data (32 RCTs; 8 observational trials).

(Isolated) soy protein

Food constituent

Meta-analyses Soy protein and lowering of LDL-cholesterol (43 RCTs)

Conclusion:

Regular consumption of 1 to 2 servings of soy protein daily (15 to 30 g) has a significant favorable impact on serum lipoprotein risk factors for CHD.

Anderson & Bush. J Am Coll Nutr. 2011 Apr;30(2):79-91.

(Isolated) soy protein

Food constituent

EFSA opinions:

(Isolated) Soy protein and lowering of LDL-cholesterol

Cause and effect relationship **not established**


EFSA J. 2010;8(7):1688

EFSA J. 2012;10(2):2555

Meta-analyses may wrong-foot you!

Vitamin E

Antioxidant effects purported to be related to decrease in CV-risk

- protection of DNA, proteins and lipids from oxidative damage 
- maintenance of normal cardiac function **X**
- maintenance of normal blood circulation **X**

Grape seed extract

No claims listed for heart health

Heart health benefits inferred from in vitro/animal studies

Recent meta-analysis (Feringa, 2011):

- significantly lower systolic blood pressure
- significantly lower heart rate
- no effect on lipid or CRP levels

Coenzyme Q10

Well-known for heart healthy effects - studies primarily in patients

- maintenance of normal blood pressure **X**
- maintenance of normal blood cholesterol concentrations **X**
- protection of DNA, proteins and lipids from oxidative damage **X**

Walnuts & endothelium-dependent vasodilation

- One pertinent study in healthy human hypercholesterolemic volunteers (Ros et al., 2004)
- One supportive study in medicated type 2 diabetes patients (Ma et al., 2010)
- One supportive acute study (Cortès et al., 2006)

Cocoa Flavanols & endothelium-dependent vasodilation

- One pertinent study in healthy human hypercholesterolemic volunteers (Davison et al., 2008)
- One study showing dose-dependency (proprietary)
- 2 supportive RCTs in target population
- Two supportive study in medicated type 2 diabetes patients/CAD patients (Balzer et al., 2008; Heiss et al., 2010)
- 7 supportive adequately controlled acute studies & 7 studies with white chocolate-control/no control

Capitalizing on existing research

Article 13.5 route allows:

- Application stringent study selection criteria
- Development of concept health relationship - claimed effect (primary endpoint - biomarker)
- Rationales for choices made in relation to dose, duration, effect size, target population etc.
- decreased/no dependence on published meta-analyses
- submission of 'tailored' meta-analysis (proprietary)

Capitalizing on existing research

Relevant/sufficient(?) data may already be present in current science base

- Soy protein & lowering of LDL-cholesterol
- Olive polyphenols and maintenance of normal HDL-cholesterol
- Cocoa flavanols & blood pressure
- Grape seed extract & blood pressure
- IPP/VPP & blood pressure
- ALA & blood pressure

- Green tea & blood pressure/EDV
- Coenzyme Q10 and blood pressure
- Etc.

Walnuts & endothelium-dependent vasodilation

- One pertinent study in healthy human hypercholesterolemic volunteers (Ros et al., 2004)
- One supportive study in medicated type 2 diabetes patients (Ma et al., 2010)
- One supportive acute study (Cortès et al., 2006)

Acceptable for art. 13.5/14 claim?



Thank you!

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Plant sterols/stanols

Current CoU:

- 1.5-2.4 g/d
- Reduction of 7 to 11% LDL-Chol
- Duration to obtain claimed effect is 2-3 weeks
- yellow fat spreads, dairy products, mayonnaise and salad dressings

Plant sterols/stanols

New claim with extended CoU - EFSA verdict:

- 3 g/d **OK**
- Reduction of 12% LDL-Chol **No (11.4%)**
- Duration to obtain claimed effect is 1-2 weeks **No (2-3 weeks)**
- yellow fat spreads, dairy products, cheese, rye bread, oatmeal, fermented soy milk based products (drinkable and spoonable yoghurt-type products), and oat based milk drinks **No way**

Replacement TFA/SA

“Consumption of saturated fat increases blood cholesterol concentrations; consumption of mono and/or polyunsaturated fat in replacement of saturated fat has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease”.

Replacement TFA/SA

The Panel considers that in order to bear the claim, significant amounts of mixed SFAs should be replaced by cis-MUFAs and/or cis-PUFAs in foods or diets on a gram per gram basis as per Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010[1] and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods[2] (section 2.2.3). The target population is subjects who want to lower their blood cholesterol.

Replacement TFA/SA

The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006.

HIGH POLYUNSATURATED FAT

at least 45 % of the fatty acids present in the product derive from polyunsaturated fat under the condition that polyunsaturated fat provides more than 20 % of energy of the product.

Replacement TFA/SA

II.2.3. Significant comparison

Based on Article 9, paragraph 2, and in order not to mislead the consumer, it will not be possible for operators to make a "reduced" claim where the 30% reduction is achieved, but the difference between the standard and the light version would not have any significance for the overall intake of the nutrient in question. For example, it will not be possible to make a "reduced fat" claim on bread. For similar reasons of significant quantity, the conditions governing the claim "increased [name of the nutrient]" are that the food bearing the claim "increased [name of the nutrient]" should meet the conditions for the claim "source of".