



Council of the
European Union

Brussels, 29 July 2014
(OR. en)

12284/14
ADD 1

DENLEG 138
AGRI 520
SAN 304

COVER NOTE

From:	European Commission
date of receipt:	24 July 2014
To:	General Secretariat of the Council
No. Cion doc.:	D034099/02 - Annexes 1 to 2
Subject:	ANNEXES to the COMMISSION REGULATION (EU) No .../.. authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk.

Delegations will find attached document D034099/02 - Annexes 1 to 2.

Encl.: D034099/02 - Annexes 1 to 2



Brussels, **XXX**
SANCO/10121/2014 Rev. 2 ANNEX
(POOL/E4/2014/10121/10121R2-EN
ANNEX.doc) D034099/02
[...](2014) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) No .../..

authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk.

ANNEX I

Permitted health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	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 opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Abtei Pharma Vertriebs GmbH, Abtei 1, 37696, Marienmünster, Germany.	Calcium	Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food which provides at least 400 mg of calcium per quantified portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1200 mg of calcium from all sources.	For foods with added calcium the claim may be used only for those targeting women 50 years and older	Q-2008-721 Q- 2009-00940
Article 14(1)(a) health claim referring to a reduction of a disease risk	Abtei Pharma Vertriebs GmbH, Abtei 1, 37696, Marienmünster, Germany.	Calcium and vitamin D	Calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures	The claim may be used only for food supplements which provide at least 400 mg of calcium and 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the claim is specifically intended for women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1200 mg of calcium and 20 µg of vitamin D from all sources.	For food supplements with added calcium and vitamin D the claim may be used only for those targeting women 50 years and older	Q-2008-721 Q- 2009-00940

<p>Article 14(1)(a) health claim referring to a reduction of a disease risk</p>	<p>DSM Nutritional Products Europe AG, P.O. Box 2676, 4002 Basel, Switzerland.</p>	<p>Vitamin D</p>	<p>Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness. Falling is a risk factor for bone fractures among men and women 60 years of age and older.</p>	<p>The claim may be used only for food supplements which provide at least 15 µg of vitamin D per daily portion. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 20 µg of vitamin D from all sources.</p>	<p>For food supplements with added vitamin D the claim may be used only for those targeting men and women 60 years and older</p>	<p>Q-2010-01233</p>
---	--	------------------	---	---	--	---------------------

ANNEX II

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Glucosamine hydrochloride	Slowing down/reduce the destruction process of cartilage of the musculoskeletal system and consequently reduce the risk of osteoarthritis.	Q-2009-00412
Article 14(1)(a) health claim referring to a reduction of a disease risk	Isolated soy protein	Protein-rich soybean component has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease.	Q-2011-00784
Article 14(1)(a) health claim referring to a reduction of a disease risk	Plant sterols in combination with Cholesteronorm®mix	Actively lowers cholesterol.	Q-2009-00237 Q-2011-01114
Article 14(1)(a) health claim referring to a reduction of a disease risk	Eicosapentanoic acid (EPA)	EPA has been shown to reduce the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour.	Q-2012-00573
Article 14(1)(a) health claim referring to a reduction of a disease risk	Plant stanols (as plant stanol esters)	Consuming 2 g/day plant stanols (as plant stanol esters) as part of a diet low in saturated fat results in a 2-fold greater reduction in LDL-cholesterol than consuming a low saturated fat diet alone. High cholesterol is a risk factor in the development of coronary heart disease.	Q-2012-00915