



Council of the
European Union

Brussels, 3 May 2016
(OR. en)

8611/16
ADD 1

DENLEG 38
AGRI 230
SAN 168

COVER NOTE

From:	European Commission
date of receipt:	3 May 2016
To:	General Secretariat of the Council

No. Cion doc.:	D043609/02 - Annex 1
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../.. refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

Delegations will find attached document D043609/02 - Annex 1.

Encl.: D043609/02 - Annex 1



Brussels, **XXX**
SANTE/12134/2015 ANNEX Rev. 1
(POOL/E4/12134/12134R1-EN
ANNEX.doc) D043609/02
[...](2016) **XXX** draft

ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) .../..

**refusing to authorise certain health claims made on foods, other than those referring to
the reduction of disease risk and to children's development and health**

ANNEX

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Caffeine	Caffeine helps to increase alertness* * For intakes of caffeine between 40 mg per serving and 75 mg per serving.	Q-2013-00399
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Clarinol® and Tonalin®	The consumption of Clarinol® or Tonalin® contributes to a reduction in body fat mass.	Q-2014-00580
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	SYNBIO®	SYNBIO® persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being”.	Q-2014-00567
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	FRUIT UP®	FRUIT UP® reduces post-prandial blood glucose responses compared to high-glycaemic carbohydrates.	Q-2014-00405
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of pomegranate pomace extract and greater galangal rhizome powder	A combination of standardised pomegranate pomace extract and greater galangal rhizome powder increases the number of motile spermatozoa in semen.	Q-2014-00566

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Bifidobacterium bifidum CNCM I-3426	<i>Bifidobacterium bifidum</i> CNCM I-3426 increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress.	Q-2014-00673
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Coffee C21 (coffee standardised by its content of caffeoylquinic acids, trigonelline and <i>N</i> -methylpyridinium)	Regular consumption of coffee C21 contributes to the maintenance of DNA integrity in cells of the body.	Q-2014-00624