



Council of the
European Union

019817/EU XXVI. GP
Eingelangt am 02/05/18

Brussels, 2 May 2018
(OR. en)

8547/18
ADD 1

DENLEG 34
SAN 130
AGRI 208

COVER NOTE

From:	European Commission
date of receipt:	30 April 2018
To:	General Secretariat of the Council

No. Cion doc.:	D055983/01 - ANNEX
Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... refusing to authorise a health claim on foods and referring to the reduction of disease risk

Delegations will find attached document D055983/01 - ANNEX.

Encl.: D055983/01 - ANNEX



Brussels, **XXX**
SANTE/11491/2017 ANNEX
(POOL/E1/2017/11491/11491-EN
ANNEX.doc) D055983/01
[...] (2018) **XXX** draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../...

refusing to authorise a health claim on foods and referring to the reduction of disease risk

ANNEX

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.	Condensyl®	The combination of opuntia fruit dry extract standardised in quercetin and betalain, N-acetyl cysteine, zinc, vitamin B3, E, B6, B2, B9 and B12 in Condensyl® decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility.	Q-2016-00665
Article 14(1)(a) health claim referring to a reduction of a disease risk.	Sugar-free hard confectionery with at least 90% erythritol	Sugar-free hard confectionery sweetened with at least 90% Zerose® erythritol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries.	Q-2017-00002
Article 14(1)(a) health claim referring to a reduction of a disease risk.	<i>Lactobacillus fermentum</i> CECT 5716	<i>Lactobacillus fermentum</i> CECT 5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis.	Q-2016-00318