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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	27 October 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	D045163/01
Subject:	COMMISSION REGULATION (EU) …/… of XXX refusing to authorise a health claim made on foods and referring to the reduction of disease risk

Delegations will find attached document D045163/01.

Encl.: D045163/01

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10221/2016
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D045163/01
[…](2016) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[1], and in particular Article 17(3) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof, and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Anxiofit Ltd. and ExtractumPharma Co Ltd, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Anxiofit-1 and reduction of subthreshold and mild anxiety (Question No EFSA-Q-2015-00006[2]). The claim proposed by the applicant was worded as follows: “Anxiofit-1 has been shown to

[1] OJ L 404, 30.12.2006, p. 9.
[2] EFSA Journal 2016;14(1):4365.

ameliorate subthreshold and mild anxiety. Subthreshold and mild anxiety are risk factors in the development of anxiety disorders and depression".

(6) On 8 January 2016, the Commission and the Member States received the scientific opinion from the Authority, which concluded that, on the basis of the data presented, the scientific evidence is insufficient to establish a cause and effect relationship between the consumption of Anxiofit-1 and reduction of subthreshold and mild anxiety. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) The measure provided for in this Regulation is in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER