Council of the
European Union

**Brussels, 29 July 2014**
**(OR. en)**

**12282/14**

**DENLEG 137**
**AGRI 519**
**SAN 303**

**COVER NOTE**

| | |
|---|---|
| From: | European Commission |
| date of receipt: | 23 July 2014 |
| To: | General Secretariat of the Council |
| No. Cion doc.: | D034097/02 |
| Subject: | COMMISSION REGULATION (EU) No …/.. of XXX 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 D034097/02.

Encl.: D034097/02

EUROPEAN
COMMISSION

Brussels, XXX
SANCO/10371/2014 Rev. 2
(POOL/E4/2014/10371/10371R2-EN.doc) D034097/02
[…](2014) XXX draft

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

**of XXX**

**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**

(Text with EEA relevance)

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

**of XXX**

**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**

(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 18(5) 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', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is 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 Italsur s.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage and protection of blood lipids from oxidative damage **(Question No EFSA-Q-2013-00574)**[2]. The

[1] OJ L 404, 30.12.2006, p. 9.
[2] The EFSA Journal 2013;11(10):3413.

claim proposed by the applicant was worded as follows: “contributes to the protection of blood lipids from oxidative damage”.

(6) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Italsur s.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and protection of blood lipids from oxidative damage **(Question No EFSA-Q-2013-00575)**[3]. The claim proposed by the applicant was worded as follows: “contributes to the protection of blood lipids from oxidative damage”.

(8) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Italsur s.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage and maintenance of normal blood LDL-cholesterol concentration **(Question No EFSA-Q-2013-00576)**[4]. The claim proposed by the applicant was worded as follows: “maintains normal blood cholesterol concentration”.

(10) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from Italsur s.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of red spinach, green spinach, red

[3] The EFSA Journal 2013;11(10):3414.
[4] The EFSA Journal 2013;11(10):3415.

chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and maintenance of normal blood LDL-cholesterol concentration **(Question No EFSA-Q-2013-00579)**[5]. The claim proposed by the applicant was worded as follows: “maintain normal blood cholesterol concentrations”.

(12) On 30 October 2013, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of red spinach, green spinach, red chicory, green chicory, green leaf chard, red leaf chard, red Swiss chard, golden Swiss chard and white Swiss chard and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from Omikron Italia S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of diosmin, troxerutin and hesperidin and maintenance of normal venous-capillary permeability **(Question No EFSA-Q-2013-00353)**[6]**.** The claim proposed by the applicant was worded as follows: "the flavonoid mixture containing 300 mg of diosmin, 300 mg of troxerutin and 100 mg of hesperidin is a useful co adjuvant in maintaining physiological venous-capillary permeability".

(14) On 13 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of diosmin, troxerutin and hesperidin and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) Following an application from Omikron Italia S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of diosmin, troxerutin and hesperidin and maintenance of normal venous tone **(Question No EFSA-Q-2013-00354)**[7]**.** The claim proposed by the applicant was worded as follows: "the flavonoid mixture containing 300 mg of diosmin, 300 mg of troxerutin and 100 mg of hesperidin is a useful co adjuvant in maintaining physiological venous tone".

(16) On 13 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of diosmin, troxerutin and hesperidin and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(17) Following an application from Italsur srl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a

---

5 The EFSA Journal 2013;11(10):3416.
6 The EFSA Journal 2014;12(1):3511.
7 The EFSA Journal 2014;12(1):3512.

health claim related to the effects of the barley soup "*Orzotto*" and protection of blood lipids from oxidative damage **(Question No EFSA-Q-2013-00578)**[8]. The claim proposed by the applicant was worded as follows: "contributes to the protection of blood lipids from oxidative damage".

(18) On 10 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of the barley soup "*Orzotto*" and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) 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*
*José Manuel BARROSO*

[8] The EFSA Journal 2014;12(1):3519.