



Brussels, 15 December 2014
(OR. en)

16625/14

DENLEG 189
AGRI 777
SAN 475

"I/A" ITEM NOTE

From: General Secretariat of the Council

To: Permanent Representatives Committee (Part 1)/Council

No. Cion doc.: 15716/14 DENLEG 174 AGRI 716 SAN 438
15793/14 DENLEG 175 AGRI 719 SAN 443

Subject: COMMISSION REGULATION (EU) No .../.. of XXX amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6S)-5-methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements

COMMISSION REGULATION (EU) No .../.. of XXX amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Ephedra species and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

- *Decisions not to oppose adoption*

1. In accordance to Article 4(5) of Directive 2002/46/EC of the European Parliament and of the Council¹, "*Modifications to the lists referred to in paragraph 1, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 13(4) in order to remove a vitamin or a mineral from the list referred to in paragraph 1 of this Article.*".

¹ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

In accordance to Article 8(2) of Regulation (EC) No 1925/2006 of the European Parliament and of the Council², "*On its own initiative or on the basis of information provided by Member States, the Commission may take a decision designed to amend non-essential elements of this Regulation, following in each case an assessment of available information by the Authority, in accordance with the regulatory procedure with scrutiny referred to in Article 14(3), to include, if necessary, the substance or ingredient in Annex III.*"

The European Parliament and the Council may oppose to the adoption of such measures within the time-limit of 3 months.

2. The regulatory procedure with scrutiny is regulated by Article 5a of the Council Decision 1999/468/EC³, which effects are maintained for the purposes of existing basic acts making reference thereto, in accordance to Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council⁴.
3. In accordance with Article 5a(2) of Council Decision 1999/468/EC⁵, the Commission submitted the above drafting regulations to the Standing Committee on on Plants, Animals, Food and Feed on 17 October 2014, which voted by qualified majority in favour of both draft Regulations⁶.
4. Consequently, the Commission submitted the above draft Regulation to the Council on 18 November 2014 (doc. 15716/14) and 19 November 2014 (doc. 15793/14), in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.

² Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods OJ L 102, 12.4.2012, p. 2).

³ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

⁴ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13?).

⁵ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23), as amended by Decision 2006/512/EC (JO L 200, 22.7.2006, p. 11).

⁶ 267 votes in favour, 29 votes against and 56 abstentions concerning doc 15793/14 and 323 votes in favour and 29 votes against concerning doc. 15716/14.

5. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose the Commission's adoption of the draft Commission Regulation on the grounds that the draft measures presented by the Commission:
 - exceed the implementing powers provided for in the basic instrument, or
 - are not compatible with the aim or the content of the basic instrument, or
 - do not respect the principles of subsidiarity or proportionality.
6. The delegations were asked on 21 November 2014 to indicate until 5 December 2014 their possible opposition to the draft Regulation. The delegations did not raise any of the above-mentioned grounds for opposition.
7. The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as an "A" item of its agenda, that it is not opposed to the draft Regulations in subject. Unless the European Parliament opposes the Regulations within 3 months from their submission, the Commission may adopt them in accordance with the procedure under Article 5a(3)(d) of Council Decision 1999/468/EC.
