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DENLEG 48
AGRI 168
SAN 92

"I/A" ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

No. Cion doc.: 7326/15 DENLEG 40 AGRI 140 SAN 76 + ADD1
7390/15 DENLEG 41 AGRI 147 SAN 80 + ADD1

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
COMMISSION REGULATION (EU) No .../.. of XXX refusing to authorise certain health claims made on foods and referring to the reduction of disease risk
- *Decisions not to oppose adoption*

1. In accordance with Article 18(5) of Regulation (EC) No 1924/2006¹, a decision on the application to authorise health claims referred to in Article 13(5) containing a request for the protection of propriety data on which the European Food Safety Authority issued an opinion not supporting inclusion of the claim in the Community list shall be taken in accordance with the regulatory procedure with scrutiny.
2. In accordance with Article 17(3) of Regulation (EC) No 1924/2006, a decision on the modification or authorisation of an Article 14(1)(a) health claim referring to a reduction of a disease risk shall be made in accordance with the regulatory procedure with scrutiny.

¹ 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 (OJ L 404, 30.12.2006, p. 9).

3. According to the second subparagraph of Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council², the effects of Article 5a of Council Decision 1999/468/EC³ are maintained for the purposes of existing basic acts making reference thereto.
4. Before adopting the draft Regulations referred to in the subject and in accordance with Article 5a(2) of Council Decision 1999/468/EC, the Commission consulted the Standing Committee on Plants, Animals, Food and Feed on 10 February 2015. The Committee voted by unanimity in favour of both draft Regulations mentioned in the subject of this note.
5. Consequently, the Commission submitted the above draft Regulations to the Council on 17 and 19 March 2015 respectively, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.
6. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose within 3 months the Commission's adoption of the draft Regulations 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.
7. The delegations were asked on 23 March 2015 to indicate until 31 March 2015 their possible opposition to the draft Regulations. The delegations did not raise any of the above-mentioned grounds for opposition.

² 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).

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).

8. **The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as "A" item of its agenda, that it is not opposed to the draft Regulations referred to in documents 7326/15 + ADD1 and 7390/15 + ADD1.** Unless the European Parliament opposes the draft 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.
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