COMMISSION REGULATION (EU) No 1161/2010
of 9 December 2010
refusing to authorise a health claim 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 food 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 appli-
cations 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 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 Laboratoire Vie et Santé
submitted on 29 December 2008 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 Catalgine®
bouffées de chaleur on reduction in the number of hot
flushes (Question No EFSA-Q-2009-00852) (2). The
claim proposed by the applicant was worded as follows: ‘Contributes to the reduction in the number
of hot flushes’.

(6) On 13 January 2010, 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 Catalgine® bouffées de
chaleur and the claimed effect. Accordingly, as the
claim does not comply with the requirements of Regu-
lation (EC) No 1924/2006, it should not be authorised.

(7) Health claims referred to in Article 13(1)(a) of Regulation
(EC) No 1924/2006 are subject to the transition
measures laid down in Article 28(5) of that Regulation
only if they comply with the conditions therein
mentioned, among which that they have to comply
with the Regulation. As for the claim subject to the
present Regulation, the Authority concluded that a
cause and effect relationship had not been established
between the consumption of the food and the claimed
effect and thus it does not comply with the Regulation
(EC) No 1924/2006, it could not benefit from the tran-
sition period foreseen in Article 28(5) of that Regulation.
A transition period of six months is provided for to
enable food business operators to adapt to the
requirements laid down in this Regulation.

(8) The measures provided for in this Regulation are in
accordance with the opinion of the Standing
Committee on the Food Chain and Animal Health and
neither the European Parliament nor the Council have
opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim set out 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.

However, it may continue to be used for six months after the
entry into force of this Regulation.

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, 9 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Rejected health claim

<table>
<thead>
<tr>
<th>Application – Relevant provisions of Regulation (EC) No 1924/2006</th>
<th>Nutrient, substance, food or food category</th>
<th>Claim</th>
<th>EFSA opinion reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data</td>
<td>Catalgine® bouffées de chaleur</td>
<td>Contributes to the reduction in the number of hot flushes</td>
<td>Q-2009-00852</td>
</tr>
</tbody>
</table>