Question for written answer E-003084/2014
to the Commission
Rule 117
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Subject: Authorisation of nutrition and health claims provided for by the EFSA: what cost to SMEs?

Regulation (EC) No 1924/2006 states that all nutrition and health claims must be scientifically substantiated and can appear on labels only with the prior authorisation of the European Commission.

Regulation (EC) No 353/2008, in establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006, lays down extremely rigorous scientific criteria. In particular, the assessment of applications for the authorisation of health claims, conducted by the EFSA (European Food Safety Authority), requires the use of clinical trials on healthy individuals, in double blind against a placebo, whose results, published in prestigious scientific journals, are subject to peer review before publication.

The use of these studies and the preparation of a scientific dossier for authorisation imply costs in excess of EUR 500 000.

This high cost in effect implies elitist implementation of the regulation and the effective exclusion of SMEs which, faced with such costs, are no longer investing in research and innovation.

Consumers are also prejudiced because of the impact on their ability to make informed choices in accordance with their physiological characteristics and dietary requirements.

In view of all this, can the Commission answer the following questions:

1. Has it considered the possibility of providing financial help for SMEs in the food industry that wish to prepare an application dossier for authorisation of a health claim for a particular food product?

2. Does it, as part of the planned revision of Regulation (EC) No 1924/2006, intend to reduce the requirements concerning the preparation of an application dossier for authorisation of a health claim?

3. Is it intending to guarantee SMEs access to the use of a health claim for a food product?