



A large number of food supplement manufacturers have written about the implementation of Regulation (EC) No. 1924/2006¹ on nutrition and health claims made on foods (hereinafter "the Regulation") and the potential economic impact of this on their businesses. The letters express concern about the approach of the European Food Safety Authority (EFSA) to its assessment of health claims under Article 13.1 of the Regulation.

The aims of the Regulation are to protect consumers from misleading nutrition and health claims - ensuring that claims are truthful, clear, reliable and useful for the consumer when making healthier food choices, to provide a clear and level playing field for economic operators and to ensure the free circulation of foods bearing claims.

The fundamental principle underpinning the Regulation is that health claims shall be based on and substantiated by science. This principle was never questioned when agreed by the legislators. EFSA has the responsibility for advising the Commission as to the extent of the scientific substantiation of health claims and the Regulation requires EFSA to apply a scientific assessment of the highest standard. It is not for the Commission to stipulate how the independent scientists at EFSA should assess the science to substantiate health claims.

The claims under scrutiny are about the relationship that exists between a food category, a food or one of its constituents and health in humans. To facilitate submission of scientific data, EFSA has produced guidance to applicants and other guidance documents on its approach to assessment of claims for certain health effects. These are publicly available and can be accessed from the following link to the EFSA website: <http://www.efsa.europa.eu/en/topics/topic/nutrition.htm>. The Commission is satisfied that EFSA's assessments are consistent with the requirements set out in the Regulation.

The Commission announced on 27 September 2010 the restructuring of the approach to establish the list of permitted Article 13 health claims. The list of permitted claims will therefore be established in two steps. First, the list of permitted health claims for all food categories, foods or constituents of food other than so-called "botanicals" will be adopted in a single step. Subsequently, the claims regarding the botanicals will be considered. In addition, the Commission has agreed with stakeholders and Member States that some claims would benefit from a further assessment process. This would allow for submission of further evidence to EFSA for claims for which either the micro-organisms they relate to were not sufficiently characterised or where the data to substantiate them were insufficient to establish a cause and effect relationship between the foods and the claimed effects. The modalities of the process are currently under discussion, but remain within the current legislative procedures. No additional adjustment to the process is foreseen.

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. 9–25.

It is suggested that third country suppliers will be able to avoid the controls in the Regulation. It should be noted that EU food law requires all foods placed on the EU market, regardless of its source, to be safe and compliant with the relevant legislation. This will therefore ensure that imported foods must comply with the same controls as EU foods, including the legislation on claims. National controlling authorities are responsible for ensuring the enforcement of EU legislation on their territory.

Better informed consumers can make better choices, particularly when spending a part of a limited income on foodstuffs which can demand a premium due to the claimed health benefits. Consumer choice based on information backed by science will positively shape the market in favour of healthier food products. A positive impact on public health could be expected. Food business operators will have to adjust to the changes that better informed consumers will demand and do so under the protection of consumers provided for by the Regulation. This will help ensure fair competition and encourage research and innovation based on sound science. In the short term, the Regulation makes available transition measures to give operators time to adapt for necessary changes on the labelling, presentation or advertising of foods, as unsubstantiated claims become unavailable for use.

To conclude, the test of an acceptable health claim is whether it can be substantiated by science. Claims that cannot, should not be made. The interests of the industry as a whole would not be served by the relaxation of this fundamental principle, as no one wishes to see commercial practices based on misleading the consumer and making any choice a false one.