COMMISSION IMPLEMENTING DECISION

of 24 January 2013

adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council

(Text with EEA relevance)

(2013/63/EU)

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 10(4) thereof,

Whereas:

(1) Article 10(4) of Regulation (EC) No 1924/2006 provides for a possibility to adopt guidelines for the implementation of that Article on specific conditions for health claims.

(2) Both national control authorities and food business operators have raised questions about the implementation of paragraphs 2 and 3 of Article 10 of Regulation (EC) No 1924/2006. In order to ensure consistency in the application of those provisions and to facilitate the work of the control authorities and ensure greater clarity and certainty for economic operators, it is appropriate to issue guidelines.

(3) The guidelines set out in the Annex to this Decision should be taken into account by the national control authorities and food business operators. Interested parties, in particular food business operators and consumer groups, have been consulted on 12 October 2012.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health [2].

HAS ADOPTED THIS DECISION:

Article 1

The guidelines for the implementation of Article 10 of Regulation (EC) No 1924/2006 are set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 24 January 2013.

For the Commission

The President

José Manuel BARROSO

[1] OJ L 404, 30.12.2006, p. 9.

[2] http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/index_en.htm

ANNEX

Guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006

Introduction

The following guidelines are addressed to the national control authorities and food business operators as regards the implementation of Article 10 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods ('the Regulation'). A health claim is any voluntary commercial message or representation in any form such as words, statements, pictures, logos, etc. which states, suggests or implies that a relationship exists between the food that is the subject of the claim and health.

Article 10 lays down specific conditions for the permitted use of authorised health claims. It should be observed together with the general principles and requirements for all claims (e.g. Article 3 of the Regulation and provisions of Directive 2000/13/EC of the European Parliament and of the Council [1] and Council Directive 84/450/EEC [2] that operators using health claims must also respect), with the conditions for the use of nutrition and health claims set in Article 4 and with the general conditions for all claims provided in Article 5 as well as with the specific conditions of use foreseen in the list of permitted health claims. For example, in the case of '*reduction of disease risk*' health claims referred to in point (a) of Article 14(1), additional information is required in Article 14(2). It is important to note that even authorised health claims may not be used unless their use fully complies with all the requirements of the Regulation. Accordingly, even where a claim is authorised and included in the lists of permitted health claims, national authorities should take action if its use does not comply with all the requirements of the Regulation.

It would be easier to achieve compliance with the provisions of the Regulation and in particular Article 10, if the food business operator is able to demonstrate due diligence and steps taken to comply with each part of the Regulation.

1. **Prohibition of unauthorised health claims and of health claims the use of which does not comply with the Regulation – Article 10(1)**

Article 10(1) provides that all health claims are prohibited unless: a) authorised by the Commission and b) their use complies with the provisions of the Regulation. Health claims must have been authorised under the appropriate procedure provided in the Regulation and been inserted in one of the lists of permitted health claims referred to in Article 13(3) and Article 14(1). Health claims which are not authorised (not inserted in one of the lists of permitted health claims) and health claims which have been authorised (inserted in one of the lists of permitted health claims) but their use does not comply with the rules set out in the Regulation are prohibited.

2. **Mandatory information accompanying authorised health claims – Article 10(2)**

2.1. *Distinction of three cases for the implementation of Article 10(2)*

In order to comply with the Regulation, Article 10(2) requires two, or where appropriate, four pieces of mandatory information to be provided to the consumer when using a health claim. The information laid down in points (a) to (d) of Article 10(2) must be given in the labelling of the food, or in its presentation and advertising if no such labelling exists. This provision should be understood in the light of the objective of the legislator to ensure a high level of consumer protection by providing accurate and truthful information to help consumers make an informed choice.

'*Labelling*', is defined in point (a) of Article 1(3) of Directive 2000/13/EC and point (j) of Article 2(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council [3]. That definition states that '"*labelling*" *means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food*". In the Union law there is a definition of 'advertising' [4], but no definition of 'presentation', which should therefore be understood in the light of the explanation provided for in point (a) of Article 2(3) of Directive 2000/13/EC and point (b) of Article 7(4) of Regulation (EU) No 1169/2011.

[1] OJ L 109, 6.5.2000, p. 29.
[2] OJ L 250, 19.9.1984, p. 17.
[3] OJ L 304, 22.11.2011, p. 18.
[4] Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising states: 'advertising' means the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations (OJ L 376, 27.12.2006, p. 21).

A health claim can be made on the 'labelling' which can mean more than just the label, since it encompasses all the information to the consumer about the food which it accompanies or refers to. The distinction between 'labelling' and 'advertising' is that 'labelling' is concerned with the delivery of the food to the final consumer, while 'advertising' is about the promotion of the supply of food by the food business operator.

(a) In order to comply with Article 10(2), it is necessary to include the mandatory information in the labelling of the food for which the health claim is made.

(b) Where no 'labelling' exists, the mandatory information shall be given in the 'advertising' and 'presentation' of the food for which the health claim is made. For example, where a health claim is used in a generic advertising for a food (e.g. olive oil, dairy, meat, etc.) which does not link it to a specific product which would have 'labelling', then the mandatory information must also be given in the 'advertising' and 'presentation' of that food.

Article 12 of Regulation (EU) No 1169/2011 establishes a principle that the consumer should always have the mandatory information when making a decision about a purchase of a food. Special mention must be made as regards Article 14 of Regulation (EU) No 1169/2011 on distance selling. Mandatory information shall be available to the consumer before purchase and in the cases of distance selling where access to the 'labelling' is restricted, mandatory information must be included in the presentation and advertising of the food, in the material supporting the distance selling whether this is a website, a catalogue, a leaflet, a letter, etc.

(c) An exemption exists in Article 1(2) of the Regulation for non-prepacked foodstuffs put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packed with a view to an immediate sale. That exemption means that the mandatory information listed in points (a) and (b) of Article 10(2) is not required. On the contrary, where appropriate, the information required under points (c) and (d) of Article 10(2) is always required.

2.2. *Four pieces of mandatory information*

While allowing certain flexibility to food business operators as regards how to express mandatory information, the Regulation foresees that the following four pieces of information must be provided when a permitted health claim is used:

(a) '*A statement indicating the importance of a varied and balanced diet and a healthy lifestyle*'

The purpose of this provision is to help the consumer understand the specific beneficial effect of the food bearing the health claim. It underlines that consumers should be made aware that consumption of this particular food should be part of a varied and balanced diet and not eaten excessively or against good dietary practice (recital 18) in order to achieve healthy outcomes and that consumption of the food bearing the health claim in the context of a varied and balanced diet is only one aspect of a healthy lifestyle;

(b) *'The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect'*

The provision relates to the information that a food business operator should provide, based on the composition of the food, to ensure that the claimed effect can be delivered. The way the food is consumed is important and communicating that to the consumer may also be a requirement of the specific conditions of use set for health claims by the Commission when authorising and listing them in the Union Register ([1]). However, that provision must ensure that for all health claims the consumer is fully informed of how much of the food is required and how it should be consumed during the day. For example, information should be given whether the claimed effect is likely to be achieved by consuming the food just once or several times over the course of the day. In addition, that information must not encourage or condone excess consumption of a food as provided in point (c) of the second paragraph of Article 3. Where that is not possible, the health claim should not be made;

(c) *'Where appropriate, a statement addressed to persons who should avoid using the food'*; and

(d) '*An appropriate warning for products that are likely to present a health risk if consumed to excess*'.

Some claims may be authorised with restrictions on their use, or in the case of some substances other provisions specific to categories of foods may foresee additional labelling requirements. All such requirements are cumulative and operators should respect all the relevant provisions applying to foods and claims. However, food business operators should assume their responsibilities under general food law and comply with the fundamental requirement to market food which is safe and not harmful to health and utilise such statements on their own recognisance.

([1]) The Union Register is published on the official website of the European Commission, DG Health and Consumers http://ec.europa.eu/nuhclaims/

3. **Reference to general, non-specific health benefits – Article 10(3)**

Article 10(3) allows the use of easy, attractive statements which make reference to general, non-specific benefits of a food for overall good health or health-related well-being, without prior authorisation, subject to specific conditions. The use of such statements could be helpful to consumers as they would convey more consumer-friendly messages. However, they could be easily misunderstood and/or misinterpreted by consumers, possibly leading to imagine other/better health benefits of a food than those that actually exist. For this reason, when referring to general, non-specific health benefits, it is required to accompany such references by a specific health claim from the lists of permitted health claims in the Union Register. For the purposes of the Regulation, the specific authorised health claim accompanying the statement making reference to general non-specific health benefits, should be made 'next to' or 'following' such statement.

The specific claims from the lists of permitted health claims should bear some relevance to the general reference. As this reference becomes broader, e.g. 'for good health', more health claims from the permitted lists could be eligible to accompany it. Still, attention should be paid to the fact that Article 10 sets rules as regards the context in which health claims are used and given that Article 10 specifically refers to the rules of Chapters II and IV, those rules should also be taken into account if operators wish to comply with the requirement laid down in Article 10(3). Therefore, to avoid misleading consumers, food business operators have the responsibility to demonstrate the link between the reference to general, non-specific benefits of the food and the specific, accompanying, permitted health claim.

Some claims submitted for authorisation during their scientific assessment were judged to be too general or non-specific for evaluation. These claims could not be authorised and can therefore be found in the list of the non-authorised claims of the Union Register of nutrition and health claims. This does not exclude that those claims could benefit from the provisions laid down in Article 10(3) and can therefore be lawfully used when they are accompanied by a specific claim from the list of permitted health claims in accordance with that Article.