

ANNEX

Guidelines for the implementation of specific conditions for health claims

1. Introduction: Health claims are prohibited unless they are authorised

1.1 Introduction

The following guidelines are addressed to food business operators and the national control authorities in respect of the implementation of Article 10 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (hereinafter the Regulation). A health claim is any voluntary 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 subject of the claim and health.

Article 10 of the Regulation lays down specific conditions for the permitted use of authorised health claims. It should be read together with the general principles and requirements for all claims (Article 3 of the Regulation, which cross-refers to other general food law that operators using health claims must respect), with the conditions for the use of nutrition and health claims set in Article 4 of the Regulation and with the general conditions for all claims (Article 5 of the Regulation). It should not be forgotten that even authorised health claims may not be used unless their use fully complies with all the requirements of the Regulation, and with specific conditions of use foreseen in the list of permitted health claims. Health claims must also meet other relevant requirements of the Regulation as appropriate; for example, in the case of '*reduction of disease risk*' health claims referred to in Article 14(1)(a) of the Regulation, additional information is required by Article 14(2) of that Regulation. Finally, health claims may not be used on foods which fail to respect the conditions set in Article 4 of the Regulation (as appropriate).

Compliance with Article 10, as with all of the Regulation, would be easier to achieve if the food business operator is able to demonstrate due diligence and steps taken to comply with each of its constituent parts. Even where a claim is authorised and included in the lists of permitted health claims, national authorities may take action if its use does not comply with the specific conditions laid down in Article 10(2) of the Regulation, as well as the other requirements of the Regulation.

1.2 Article 10(1) Prohibition of unauthorised health claims

Article 10(1) of the Regulation sets the principle that all health claims are prohibited unless they are authorised by the Commission. Health claims must have been authorised under the appropriate procedure foreseen in the Regulation, been inserted in the lists of permitted health claims foreseen in Articles 13(3) and 14(1) of the Regulation and their use must comply with the Regulation. Health claims which are not authorised and therefore are not in the lists of permitted health claims shall be prohibited (unless the specific conditions foreseen in Article 10(3) of the Regulation applies).

2. Mandatory information accompanying authorised health claims

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

Article 10(2) of the Regulation requires that two, or where appropriate, four pieces of mandatory information must be given to the consumer when using a health claim, or use of the claim will be considered as non-compliant with the Regulation. This information laid down in Article 10(2)(a) to (d) of the Regulation must be given in the labelling of the food, or in the presentation and advertising if no such labelling exists.

This provision should be understood in the light of the objective of the legislators to ensure a high level of consumer protection, satisfied here by the provision of accurate and truthful information to help consumers make an informed choice, and in relation to the definition of 'labelling'.

'Labelling', is defined in Article 1(3)(a) of Directive 2000/13/EC² and Article 2(2)(j) of Regulation (EU) No 1169/2011³. This 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'. There is a separate definition of '*advertising*'⁴ and no definition of '*presentation*', which must therefore be understood as anything which is not labelling, nor advertising.

A health claim can be made on the '*labelling*' and the '*labelling*' can mean more than the label, encompassing all the information to the consumer about the food - on, accompanying or referring to the food. The distinction with '*advertising*' can be understood in 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) For compliance with Article 10(2) of the Regulation, therefore, it is considered necessary to include the mandatory information in the labelling of the food for which the health claim is made.
- b) Where there is no '*labelling*', the mandatory information shall be given in the '*advertising*' and '*presentation*' of the food bearing the health claim. For example, if using a health claim in generic advertising for a food (e.g. olive oil, dairy, meat, etc), but which does not link to a specific product which would have '*labelling*', then the mandatory information must also be given.

Considering the Regulation (EU) No 1169/2011 on the provision of food information, the principle is that the consumer should always have the mandatory information when making a decision about purchase of the food. Special mention must therefore be made of Article 14 of Regulation (EU) No 1169/2011 referring to distance selling. This requires

² Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws on the Member States relating to labelling, presentation and advertising of foodstuffs OJ L 109 6.5.2000, p. 29-56

³ Regulation (EC) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provisions of food information [...] OJ L 304 22.11.2011 p. 18-63.

⁴ Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, OJ L 376 27.12.2006 p. 21-27 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.

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that mandatory information shall be available to the consumer before purchase, and where this is by distance selling, access to the 'labelling' is restricted, so 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 on the internet, a catalogue, leaflet, letter, etc.

- c) An exemption exists for non-prepacked foodstuffs and foodstuffs packed at the point of sale at the request of the purchaser or pre-packed with a view of immediate sale, by virtue of Article 1(2) of the Regulation. This exemption means that for these products the mandatory information listed in Article 10(2)(a) and (b) is not required. But if appropriate, the information foreseen under Articles 10(2)(c) and (d) is always required.

2.2. The four pieces of mandatory information

- 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 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 (see recital 18 of the Regulation) in order to achieve healthy outcomes and that consumption of the food bearing the health claim (and 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"*

This provision relates to the information that a food business operator should give based on the composition of the food, to ensure it can deliver the claimed effect. How that food is consumed is important and communicating this to the consumer may also be a requirement of the specific conditions of use set for health claims by the Commission when those are authorised and listed in the Union Register⁵. However, this provision is to ensure that for all health claims the consumer is fully informed of how much of a food is required and how this should be eaten over the day. For example, information should be given whether the claimed effect is likely to be achieved in one "consumption opportunity" or several over the course of the day (see recital 15 of the Regulation). When giving this information to the consumer there must also be compliance with Article 3(c) of the Regulation. If this is not possible, the health claim should not be made.

⁵ The Union Register is requirement under Article 20 of Regulation (EC) No 1924/2006. It is to be found on the official website of the European Commission, DG Health and Consumers <http://ec.europa.eu/nuhclaims/>

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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 legislation specific to categories of foods may indicate the need for additional labelling requirements. All such requirements are cumulative and operators should respect all the relevant legislation 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 injurious to health and utilise such statements on their own recognisance.

3. Health claims making reference to general, non-specific health benefits

The use of health claims making reference to general, non-specific benefits of the food for overall good health or health-related well-being may be said to be useful to consumers, summarising health benefits into easy, top-line statements. Article 10(1) makes their use possible without prior authorisation, subject to specific conditions. Given that such general and vague statements could be easily misunderstood and misinterpreted, possibly allowing consumers to imagine better health benefits than actually exist or not understand the claimed benefit, it is required to use a specific health claim from the lists of permitted health claims (to be found in the Union Register) if such claims making reference to general, non-specific health benefits are used.

The specific claims from the lists of permitted health claims should bear some relevance to the general claim. As the claim becomes more top-line, e.g. "for good health", more claims could be eligible to accompany it but attention should be paid to the fact that Article 10 of the Regulation is about context of use of health claims and context is also a factor for Article 10(3). Therefore, to avoid misleading consumers, food business operators have the responsibility to demonstrate the link between the general and specific accompanying health claim.

Some claims submitted for authorisation, were judged during their scientific assessment, to be too general or non-specific for evaluation. These claims could not be authorised and can therefore be found in the list of non-authorised claims of the Union Register of nutrition and health claims⁶. This does not exclude that these claims could benefit from the provisions laid down in Article 10(3) of the Regulation 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.

⁶ <http://ec.europa.eu/nuhclaims/>