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New EU Guidance on Health Claims

By Sebastián Romero Melchor & Vanessa Edwards

Two recent developments of importance for the interpretation of the new list of permitted health claims in the Nutrition and Health Claims Regulation (Regulation 1924/2006 on nutrition and health claims made on foods, "the Regulation") have just been adopted. The first one, on which only certain Member States have agreed, deals with how the so-called “flexibility” principle in the wording of health claims should be applied. The second one, on which all Member States have agreed and which entered into force today, sheds light on the scope of application of Article 10 of the Regulation (specific conditions for health claims).

General Principles on Flexibility of Wording for Health Claims

Recital 9 in the preamble to the Regulation envisages that, where the wording of a claim has the same meaning for consumers as that of a permitted health claim because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, that claim should be subject to the same conditions of use indicated for the permitted health claims.

In December 2012, 17 Member States' experts agreed on a series of general principles on flexibility of wording for health claims ("General Principles"). The Member States are Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden and United Kingdom.

The General Principles set out the main rules to be respected when authorised health claims are used but the wording is not exactly as authorised. Helpful examples of acceptable and unacceptable variations are given. The Principles are summarised below:

- The adapted wording must have the same meaning for the consumer as the authorised wording. In particular, it must not be stronger, or a medicinal claim, or misleading;
- The word "*normal*" in authorised health claims in the English version of the Regulation should not be replaced or removed (e.g. “*Beta-glucans contribute to the maintenance of normal blood cholesterol levels*”) ;
- The claim must not state or imply that there is a link between the claimed effect and anything other than the nutrient, substance, food or food category which is directly responsible (e.g. “*Product X contributes to the maintenance of normal blood levels*”);
- Although mandatory statements on food supplements are exempt from the Claims Regulation, that Regulation may apply if the context and overall presentation of a claim go beyond a simple mention of the nutrient or substance (e.g. “*Food supplement with gut-protecting probiotic bacteria*”);
- Where reference is made to general, non-specific benefits of a nutrient or food or for overall good health or health-related well-being, it must be accompanied by a specific, authorised health claim. This applies also where the general claim is a trade mark, brand name or fancy name; and
- Extreme care should be exercised if using sentences or words from an EFSA opinion to adapt the wording of an authorised health claim, since this may change the meaning of the claim.

New EU Guidance on Health Claims

Guidelines for the Implementation of Specific Conditions for Health Claims

The Commission recently adopted guidelines for the implementation of specific conditions for health claims ("Guidelines"). These Guidelines are to be taken into account by the national control authorities and food business operators.

The Guidelines are summarised below:

1. Health claims which are not authorised and health claims which have been authorised but whose use does not comply with the Regulation are prohibited;
2. Article 10(2) of the Regulation requires that authorised health claims include certain mandatory information in the labelling or in the presentation and advertising if there is no labelling.
3. The guidelines clarify as follows:
    - An example of a situation where there is no labelling (so that the information would need to be included in the presentation or advertising) would be where a health claim is used in generic advertising for a food, e.g. olive oil;
    - In cases of distance selling (e.g. internet orders), access to labelling is restricted and the information must be included in the presentation and advertising of the food;
    - Article 1(2) of the Regulation provides that the mandatory information listed in Article 10(2)(a) (a statement indicating the importance of a varied and balanced diet and healthy lifestyle) and (b) (the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect) does not have to be provided in the case of non-prepackaged 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. In contrast, the Guidelines state that the information required under Article 10(2)(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) is always required;
    - Further guidance is given regarding the information listed in Article 10(2). In particular, the Guidelines note that Food Business Operators (FBOs) should assume their responsibilities under general food law and comply with the fundamental and overriding requirement to market food which is safe and not harmful to health.
4. Article 10(3) of the Regulation permits reference to general, non-specific benefits for overall good health or health-related well-being provided that a specific, authorised health claim is also provided.
    - The Guidelines state that the accompanying specific health claim should be made next to or following the general statement and should bear some relevance to the general reference;
    - Moreover FBOs have the responsibility to demonstrate the link between the general reference and the accompanying health claim;
    - Finally, the Guidelines clarify that a general or non-specific claim that is on the list of non-authorised claims may still be lawfully used in accordance with Article 10(3) provided that they are accompanied by a specific, authorised claim.

The General Principles and the Guidelines provide timely and useful guidance for the interpretation of the list of permitted health claims. Whilst the documents are “soft law” instruments and do not have legal value, they represent a safe harbour for companies willing to

adjust to the interpretation of the national authorities. However, a different interpretation may still be lawful.

Authors:

Sebastián Romero Melchor
sebastian.romeromelchor@klgates.com
+32.(0)2.336.1906

Vanessa Edwards
vanessa.edwards@klgates.com
+44.(0)20.7360.8293