

Nutrition and Health Claims

Introduction

Since the publication of the first labelling directive in 1979 the EU followed the project of limiting the use of certain claims for food. The final result is the Regulation(EC) Nr. 1924/2006 on nutrition and health claims. The regulation states as objectives

- insurance of a high level of protection for consumers by adequate not misleading labelling of products
- harmonization of national provisions to avoid unequal conditions of competition which could impede the free movement of goods.

The focus is on avoiding misleading labelling. As an anticipated conclusion one can say that there is a presumption that what is not in the list mentioned in the regulation is misleading.

The regulation applies to nutrition and health claims made in commercial communications in the labelling, presentation and advertising of food to be delivered as such to the final consumer. It applies also to food intended for supply to restaurants, hospitals, schools, canteens and similar ma caterers.

Definitions

As defined in the regulation a claim means any not legally mandatory message or representation including pictorial, graphic or symbolic representation in any form which states, suggests or implies that a food has particular characteristics.

Any claim which states or implies that a food has particular beneficial nutritional properties due to the energy value it provides or does not provide or due to the nutrients or other substances it contains or does not contain is a nutrition claim.

A (function) health claim is defined as any claim which states or implies that a relationship exists between a food category, a food or one of its constituents and health. If the claim goes so far as to state that there is a significant reduction of a risk factor in the development of a human disease than it is a reduction of disease risk factor claim. A specific function health claim is a claim which refers to the well-being or development of children.

General Conditions of Use

At first, products must comply with nutrition profiles which do not yet exist however. In general, the use of claims shall not

- be false, ambiguous or misleading
- give rise to doubt about the safety and or adequacy of other foods
- encourage or condone excess consumption of a food
- suggest that a balanced and varied diet cannot provide appropriate nutrients (Unilever Pro Activ: 2g sterols equates to the content of 8kg oranges o 42 kg tomatoes o 5 kg broccoli o 12 kg carrots pp. – Autorità garante della concorrenza)

The use shall only be permitted if

- the claimed beneficial effect is established by general accepted scientific evidence
- the substance is contained in a sufficient quantity to have the claimed effect
- the substance is in a form that it can be used by the body
- the average consumer can be expected to understand the claimed beneficial effect.

Specific Conditions of Use

- Nutrition claims can only be used if they are listed in the Annex the Regulation (positive list – quod non est in listas non est in mundo)
- Function, risk reduction health claims and claims referring to the well-being of children are prohibited unless they are authorized claims and are included in the lists of authorized claims – Art. 13,14
- Health claims relative to beverages containing more than 1,2% alcohol are not allowed at all, nutrition claims referring to low or reduced level of alc. Are permitted, however.
- Comparative nutrition claims can only be made between products of the same category which are not allowed to bear a claim

Conditions for General References

Such references to non-specific benefits of food for overall good health or health related well-being must be accompanied by a specific enlisted health claim.

Authorization of Art. 13 claims

A scientific assessment by the authority, i.e. EFSA, is required whether the claim is based on generally accepted scientific evidence. The commission shall then take a decision of including the claim in the list as provided in Art. 13.

Reduction of risk factor and children development claims – Art. 14

Primarily human (intervention) studies – published and non-published – including peer reviewed studies with regards to the health claim are required as well as any other scientific studies and available scientific data with relevance to the claim to substantiate the claim. A proposal for the wording of the claim and its condition for use are necessary, too.

Role and Importance of EFSA – European Food Safety Authority

EFSA – established pursuant to Reg. 178/2002 is the risk assessor of the EU. Its task is to produce scientific opinions to support the taking of effective risk management decisions by the competent bodies, the Commission, for example.

Case Law: Questions referred to the CoJ in preliminary proceedings

Case C- 544/ 10 regarding claims made for wine – „bekömmlich“ (digestible), „sante Säure“ (soft acidity) – German federal Administrative Court (Bundesverwaltungsgericht)

Questions:

- 1.: Does the reference to health require a beneficial effect aimed at a sustained improvement of physical condition or is a temporary effect sufficient)?
- 2.: Is it compatible with Arts. 15 and 16 of the Charta of Fundamental Rights for producer/marketer of wine to be prohibited from making a claim even if it is correct?

Case C- 51/11 regarding the claims „the beneficial and salubrious cordial from the Alps“ with a focus on „salubrious“ – German Federal Court (Bundesgerichtshof), which regards „benerficial“ as health claim.

Questions

- 1.:Does the concept of „health“ also cover general well-being?
- 2.:Is a claim intended to cover health related well-being where it refers to one of the functions mentioned in Art. 13 and Art. 14?

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EFLA Workshop Milano 2011

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- 3.: Is it consistent with principle of proportionality to prohibit a statement that beverage containing more than 1,2% alc. does not adversely affect the body or its functions?