



Beneficial physiological effects and risk factors - *Introduction* -

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- According to Regulation 1924/2006

Definitions and contents of claims

§ 2 **Nutrition claim:** a food has particular **beneficial** nutritional properties

Health claim: a relationship between a food.....and **health**

§ 13 Claims may refer to a) *a role in growth, development and functions of the body; or b) psychological and behavioural functions; or c) slimming, weight control, reduction in the sense of hunger, increase in the sense of satiety or reduction of energy from the diet*

§ 14 Claims have to be applied for and authorised.

Conditions of use for health claims

§ 5 *“The use of ...claims shall only be permitted if...the presence, absence or reduced content ...of a nutrient or other substance...has been shown to have a **beneficial nutritional or physiological effect**, as established by generally accepted scientific evidence“* – relates also to quantity, availability

§ 10 *“Reference to..non-specific benefits....for overall good health or ..well-being may only be made if accompanied by a specific health claim..“*

Claimed effect beneficial?

- is the claimed effect a beneficial physiological effect?
 - specific requirement of Reg 1924/2006
 - case by case judgment by NDA Panel
 - may depend on context of the claim (e.g. target group, whether other conditions are fulfilled)

Example § 13(1)

Linoleic acid and „*brain development and maturation of neurosensorial functions*“.

Interpretation by Panel:“..neurological development and function. According to the Terms of Reference health claims referring to children’s development and health are outside the scope of the § 13(1) health claims“.

- The Panel considers that **maintenance of normal neurological function is a beneficial physiological effect**

Beneficial physiological effect

Example § 14 (children's development and health)

Iron is *“necessary for the cognitive development of children”*

- The Panel considers that **normal cognitive development is beneficial to children's health**

Beneficial physiological effect

- **Example § 13(5)**

Food X “*contributes to the management of vasomotor symptoms, particularly hot flushes in peri- and postmenopausal women/ to the reduction of the number of hot flushes*“

The Panel assumes that the claimed effect relates to the reduction in the number of episodes of hot flushes. Hot flushes are episodes of intense heat and sweating with increased heart rate followed by a cold , clammy sensation. The hormonal changes of menopause appear to cause the symptoms. The symptoms of hot flushes cause considerable discomfort to those who are affected.

- The Panel considers that the **reduction in the frequency of episodes of hot flushes is beneficial to the health of peri- and postmenopausal women**

- According to Regulation 1924/2006

Definition

§ 2, 4 *“Reduction of disease risk claim means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease“*

§ 14 *“...reduction of disease risk claims....may be made where they have been authorised....the labelling.....shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect“.*

- According to...the Standing Committee dd 14.12.2007
„When the claim mentions a disease risk factor generally recognised by scientific evidence, it should be considered as an § 14 claim only when a reduction of this risk factor is stated...“

- Physiological factor associated with the risk of a disease that may serve as a predictor of development of that disease
- relationship of the risk factor to the development of the disease biologically plausible
 - Some well-established risk factors, e.g. elevated LDL-cholesterol and heart disease
 - Otherwise, case by case judgment by NDA Panel

Multiple risk factors for a disease

Example: CHD

Non modifiable risk factors

- Increasing age
- Male sex
- Heredity

Modifiable risk factors

- Smoking
- High blood cholesterol
- High blood pressure
- Physical inactivity
- Obesity and overweight
- Diabetes mellitus

Other contributing factors

- Stress
- Too much alcohol

(according to the American Heart Association)

Example

Claimed effect: Food X “*prevents adhesion of bacteria (mostly E. coli) to the cell surface, a risk factor for urinary tract infections.*”

Proposed wording: “*eliminates the adhesion of harmful bacteria to the bladder wall. The adhesion of harmful bacteria to the bladder wall is the main risk factor in the development of urinary tract infections*”.

- **Accepted health relationship by EFSA:**

“Reducing the risk of urinary tract infection by inhibiting the adhesion of certain bacteria in the urinary tract is beneficial to human health”.