

## **New EU Regulation on Nutrition and Health Claims final effective as per December 14, 2012.**

Until December 14, 2012 companies have time to adjust labelling and marketing material towards the new EU Regulation. This includes packaging, advertising and web-sites. After December 14, 2012 companies can only use Nutrition and Health claims that are aligned to the new regulation.

During 2013 national food authorities will have a thorough control to ensure that the new regulation has been implemented by all relevant companies.

The new EU Regulation is not only towards Direct Selling Companies, but towards all companies within nutrition, health and food in general.

### **History:**

The European legislation has never allowed health claims on food (including food supplements), but early this century the EU Commission suggested an equal and consistent regulation for all the member states. As you might know a regulation must be nationally implemented as is, i.e. it is the identical legislation all through the EU. Regulation No 1924/2006 (Reg 1924) passed the European Parliament and the Council December 20, 2006, to apply July 1, 2007. One of the main objects for the Regulation was to list allowed nutrition and health claims on food. If not on the list, then the claim is not allowed. As the list was not ready to be included in Reg 1924 its implementation did not make much difference and impact when in force.

To create the list all member states were to collect and submit claims to be included. Totally 44000 requests were submitted. In May 2012 Regulation 432/2012 (Reg 432) was published with the list of permitted health claims made on foods, totally 222. The regulations are published in the Official Journal of the European Union, - accessible via [eur-lex.europa.eu](http://eur-lex.europa.eu).

### **How this impact member companies:**

All member companies must ensure that they fulfill the regulations timely and accurately. If you need any further advise in regards to implement the new regulations, the DSA recommend you to contact a consultant specialized in these matters.

Just as important is to ensure that all the member companies distributors are not only aware but also follows the new regulation.

**Regulation 1924 have already been implemented in July 1, 2007 – please check that you are aligned with the EU-Regulation 1924. Some of the most important points are listed as follows:**

Art. 1.2 :

“This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labeling, presentation or advertising of foods to be delivered as such to the final consumer. “

Art. 2.1.4:

“Nutrition claim means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy (caloric value) it provides, provides at reduced or increased rate, or does not provide and/or the nutrients or other substances it contains, contains in reduced or increased proportions or does not contain”.

Art. 2.1.5:

“Health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health”.

Art. 3 :

“The use of nutrition and health claims shall not give rise to doubt about the safety and/or the nutritional adequacy of other foods.”

Clarification 25:

“ In the light of Directive 96/8/EC on foods intended for use in energy restricted diets for weight reduction which prohibits, in the labeling, presentation and advertising of products covered by the that Directive, any reference to the rate or amount of weight loss, which may result from their use, it is considered appropriate to extend this restriction to all foods.”

Art. 10.3 :

“Reference to general, non-specific benefits of the nutrient or food for overall good health or health related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.”

Art. 11:

Exceptions from Art. 12:

National associations of medical, nutrition or dietetic professionals and health related charities.

Art. 12 a-c :

“The following health claims shall not be allowed: (a) claims which suggest that health could be affected by not consuming the food, (b) claims which make reference to the rate or amount of weight loss, (c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.”

**The new EU-Regulation 432 from May 2012 and effective from December 14, 2012 includes 222 approved health and nutrition claims (see annex). The list of these can be viewed in 432. The new regulation is on top of the Regulation 1924. Please ensure that you have implemented the new regulation before December 14, 2012.**

Clarification 1 :

“ Health claims made on foods are prohibited unless they are authorised by the Commission in accordance with the Regulation and included in a list of permitted claims.”

Clarification 10 :

“The Commission has identified a number of claims submitted for evaluation, referring to effects of plant or herbal substances, for which the Authority has yet to complete a scientific evaluation.”

Clarification 13 :

“ The Regulation should apply six months after the date of its entry into force... .”

Art. 1 :

“The list of health claims which may be made on foods,....., is set out in the Annex to this Regulation”.

Annex:

37 pages with the “Nutrient, substance, food or food category” listed in alphabetical order. The claim listed should be used with identical wording. There is also noted “Conditions of use of the claim”.

**Examples on could be said or not said:**

- 1) The 13.1 refers to “claims that are general (generic) functional health claims”.
- 2) An example of a health claim considered to be medical is “enhances/improves/ strengthens/etc the immune system”
- 3) Examples regarding claims:
  - a) Polyphenols in olive oil and 7 vitamins and minerals (vit. B2, C and E, plus copper, manganese, selenium and zinc) are approved for the antioxidant claim “ contributes to the protection of cells from oxidative stress”. On a product with this claim it is allowed to state “Contains antioxidants”.
  - b) Vitamin A, B6, B12, C and D, plus copper, iron, selenium, and zinc are approved for the claim “contributes to the normal function of the immune system”.
  - c) An approved EPA/DHA claim is “ EPA and DHA contribute to the normal function of the heart”.
  - d) A nutrition claim such as “ High content of flavonoids” must on the label specify the flavonoids contained and in what amounts. The company must be able to show that the general conditions of Reg 1024/art. 5 are fulfilled.
  - e) The only approved probiotic bacteria strain claim concerns the live yoghurt cultures. However, around 60 denied probiotic claims are being revalued, the so called “further assessment” procedure.
  - f) The non-authorized claims can be found in the Commissions database under Register/non-authorized, with the information why the claim has been denied.
- 4) Examples of situations with different ways of communicating:
  - a) The Regulations do not apply to non-commercial communication, but if advertising/promotion of a product is on the same page, then all the communication is considered commercial.
  - b) All companies in a supply/retail chain are responsible for their advertising/promotion material /website information even if it is the same as and received from the original supplier.
  - c) The Regulations also apply to verbal information/claims.

It is very important that you as a member company of the DSA read, understand and implement both the two EU-Regulations.