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Questions and Answers on the list of permitted Health Claims on food products

Why has the EU tackled the issue of "health claims" on food products?

Consumers are looking for added value when purchasing food. They attach great importance to health and are becoming increasingly aware of its relationship with their diet and the food they eat. Health claims can therefore be an important source of information, and became a vital marketing tool used by food business operators to attract consumer attention and influence choice. Concern that health claims could be less than informative or be misleading, by accident or by design, has given voice to calls for clear rules on authorisation and tighter controls.

The so-called **claims Regulation from 2006** ensures a high level of protection for consumers while in parallel ensures legal clarity and fair competition for food business operators. Claims must not mislead consumers; they must be, accurate, truthful, understandable and substantiated by science. Implementation of this Regulation requires the adoption of a list of permitted health claims, based on an assessment by the European Food Safety Authority (EFSA) of the science substantiating the claimed effect, and compliance with the other general and specific requirements of the Regulation. This list of permitted health claims is today adopted by the Commission after **scrutiny by the European Parliament and the Council** and will be **published** in the Official Journal.

Why is this particular list so important?

This list represents the outcome of the work undertaken by the Commission and EFSA on health claims submitted by Member States on behalf of their food industry and consumers. It deals with claims about the function of the body, based on generally accepted scientific evidence and is one generic list.

This is different to individual applications for function claims based on new science and proprietary data, and claims about the reduction of disease risk and the development and health of children. Claims as a result of these individual applications have been undergoing a separate process of authorisation since the claims Regulation entered into force and are already listed in the Union Register.

Why has the implementation taken from mid-2006 until mid-2012?

44,000 health claims had been submitted by Member States by January 2008. It required a consolidation of this large number of claims to over 4,600 entries in a list for assessment by EFSA and consideration by the Commission and Member States as risk managers.

What was the role of the European Parliament and Council in the process of adopting the permitted list?

After the Member States expressed their positive opinion in the Standing Committee on 5 December last year, the measure to adopt the permitted list of health claims has been at the European Parliament and the Council for their scrutiny of the Commission's decision, as the rules require. A resolution to veto the measure was rejected in the European Parliament in March and no opposition was raised in Council. The list of permitted health claims therefore has the support of all the European institutions.

The list has 222 health claims – what happened to the other claims from the consolidated list?

The health claims now included on the permitted list represent some 500 entries from the consolidated list Member States have submitted. . The process of authorisation is also completed for another 1600 entries from the consolidated list, but these entries could not be authorised. The remainder of the claims (about 2200, mainly so-called "botanical substances") are still awaiting completion of the authorisation process.

What is the status of the claims not in the permitted list?

Claims not authorised for inclusion in the permitted list will be inserted into the "Union Register" of nutrition and health claims making it clear why they are not authorised. Six months after the entry into force of the Regulation setting the list of permitted claims, they will be considered as **non-compliant with the claims Regulation** and subject to the prohibition laid down in that Regulation. The rules will be directly applicable to all food business operators in the EU and it will be the responsibility of the national authorities to enforce them.

There are also a number of claims that are **on hold** pending a final decision. These may continue being used under the conditions pertaining before adoption of the list of permitted health claims. This means they may remain on the market under the responsibility of the food business operator provided they comply with the claims Regulation and existing national provisions applicable to them.

Where can I find clear information on the status of all the claims?

Now that the measure has been adopted, it will be published in the Official Journal. The **Union Register** has been updated with all the claims for which the authorisation process is completed – both the list of permitted health claims and those not authorised. The Union Register is available on the website of DG Health and Consumers where you will also be able to find the status of all the claims originally submitted to the process.

How are permitted health claims to be used?

Anyone will be able to use permitted health claims on the list, provided the conditions of use and other requirements of the Regulation are met. Conditions of use make sure that the claimed effect is achieved.

Must claims on the list be used exactly as written?

The measure adopting the list of permitted health claims **allows some flexibility** in the use of the wording of a claim to take into account linguistic or cultural differences, provided that the wording used has the same meaning as that of a permitted health claim on the list. The key here is that claims should not be presented that they become misleading.

Where can operators find guidance on how to comply with the legislation?

National competent authorities are responsible for enforcing the legislation and can provide food business operators with useful advice on how to comply with it.

Are all claims in the list of non authorised claims not true?

This is not necessarily the case. A scientific assessment was the first requirement, followed by a test of compliance with the other requirements in the claims Regulation. In its assessments EFSA looked at three consecutive elements:

- whether the subject of the claimed effect (food, substance) can be defined sufficiently for a scientific assessment
- whether the claimed effect is indeed beneficial for health
- whether the studies considered as pertinent by EFSA could allow establishing of a cause and effect relationship between the food and the claimed effect

An unfavourable EFSA opinion could be linked to any of these elements. Some claims with a positive EFSA assessment were judged not to meet the other requirements of the claims Regulation. Claims that are not authorised are included in the Union Register with clear reasons as to why they are not authorised.

What claims are on hold?

In September 2010 the Commission decided not to continue with the assessment of health claims for plant and herbal substances, the **so-called "botanical" substances**. Certain herbal substances can be present in the composition of both Traditional Herbal Medicinal Products (THMPs) and in foods. Different treatment can be given and different requirements apply to the same herbal substance, if it is included in a food product or a medicinal product. This could create discrimination on the market of herbal products and potential confusion for consumers. Since the Commission and Member States need more time to decide how to address this issue, it was decided to put these claims on hold.

Also, some **claims for micro-organisms** were considered insufficiently characterised as a result of a lack of understanding of the methodology of characterisation; and some claims were submitted with compelling but **insufficient** evidence for EFSA to reach a conclusion. In these special cases a further assessment was allowed, which is ongoing. EFSA will give its further assessment on these claims by the end of the year.

A number of other claims are on hold because the Commission and Member States could not come to a decision without further consideration of certain elements, such as conditions of use and target population.

See also:

IP/12/479