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Questions and Answers on the list of permitted Health Claims

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

Consumers are looking for added value when purchasing food. They attach great importance to health and are more 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. Concern that health claims could be less than informative or misleading, by accident or by design has given voice to calls for tighter controls.

A 2006 Regulation on nutrition and health claims made on foods makes these controls possible. This so-called **claims Regulation** ensures a high level of protection for consumers. It facilitates the choice of products for a varied and balanced diet which is a prerequisite for good health. 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. **Member States' endorsement of the list of permitted health claims** on 5 December marks a significant step in implementing the claims Regulation.

Why has the implementation taken from mid-2006 until late 2011?

44,000 health claims had been submitted from Member States. 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.

The list has 222 health claims – what happened to the other more than 4,000 claims from the consolidated list?

The health claims now included on the permitted list are representative of some 500 entries from the consolidated list for which the process of authorisation required is completed. The process of authorisation is also completed for another 2000 entries from the consolidated list. The remainder of the claims (some 2000) are still awaiting completion of the authorisation process.

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

For these claims we have two different procedures:

First, claims on hold will continue being used under the conditions pertaining before adoption of the list of permitted health claims. This means they may continue to be used 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.

Second, claims not included in the permitted list but for which the authorisation process is completed 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 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.

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

Once the measure adopting the list of permitted health claims has passed the scrutiny of the European Parliament and the Council, and is officially adopted, it will be published in the Official Journal. At the same time the **Union Register** will be 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 http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/index_en.htm where once the list is published 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 are met. Conditions of use make sure that the claimed effect is achieved.

Must claims on the list be used exactly as written – even if the language used is very scientific?

The permitted health claims may be required to be expressed differently due to linguistic or cultural differences. For this reason the measure adopting the list of permitted health claims **allows food business operators some flexibility**, provided that those adjusted claims have the same meaning for consumers as that of a permitted health claim on the list. The key here is that claims should not be presented such that they become misleading.

Are all claims that are not included in the list of permitted claims being rejected because they are 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 will be entered in the Union Register with reasons for rejection.

What claims does the list not represent, what's on hold?

In September 2010 the Commission decided that it was not possible to continue with the assessment of health claims for plant and herbal substances, the **so-called "botanical" substances**. EFSA was asked to discontinue its assessment on claims for botanicals and these, together with a number on botanicals already assessed, have been put on hold. Also consideration of some **claims for micro-organisms** was suspended. EFSA concluded that they were insufficiently characterised. Silimilarly for claims for which the evidence was insufficient for EFSA to reach a conclusion about the cause and effect relationship were put on hold. These claims are therefore also on hold pending a reassessment of the additional data where this has been submitted.

What is the status of the claims on botanical ingredients?

Certain herbal substances can be present in the composition of both Traditional Herbal Medicinal Products (THMPs) and in foods. It is therefore possible that, for the same substance, the therapeutic indication given by manufacturers of THMPs is similar (with the due distinctions, as medicinal claims are forbidden on foods) to a health claim made by food manufacturers.

Differences in legal requirements between health claims and THMPs could lead to a different treatment of the same substance, according to whether it is present in a food or in a medicine. This would create discriminations 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.

What will the Commission do on botanicals?

A reflection exercise is underway aimed at achieving a consistent and coherent treatment of botanicals in the future.