

Marlous Stal-Hilders of Nederlandsch Octrooibureau wonders whether the new European Regulation will help or hinder food manufacturers and scientists

## EU tries to stimulate healthy eating

**O**n July 1 2007 the European Regulation 1924/2006/EC on Nutrition and Health claims on foods became effective. One of the aims of the Regulation is to stimulate a healthy eating pattern among the inhabitants of Europe. Functional foods such as chocolate bars containing fibre and bread containing omega are selling well, which indicates that many Europeans are aware of obesity.

Products containing nutrition and/or health claims are often bought by the consumer at random without obtaining information about the composition of the product. This makes nutrition and/or health claims into an ideal marketing instrument.

Considering the common reaction of consumers, the European Committee holds the opinion that consumers should be protected and should not be misled by tempting nutrition and health claims. At the same time the Committee wishes to stimulate nutrition and innovation in this field.

It is obvious that the investments that must be made in order to develop functional foods have to be recovered, and the use of nutrition or health claims in marketing is one of the obvious means of doing so. The Regulation wishes to respond to this need by abolishing the differences between the national laws and making the internal market function and consequently creating equal competitive conditions.

The question is whether these effects will be obtained by the entry into force of this Regulation. How interesting will it still be for companies to invest in nutrition and/or health claims? In order to answer this question, it is first necessary to study the Regulation and its pitfalls.

### The Regulation

It is necessary to review the definitions of the Regulation. First of all it is important to establish the Regulation's definition of the word "claim". The definition in the Regulation is: "Any message or representation which is not mandatory under Community or national legislation including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics." Not only do written health claims belong to this Regulation but also figurative elements, such as a beating heart.

Next the Regulation distinguishes between nutrition and health claims. A nutrition claim gives the impression or implies that a food possesses certain curative food qualities that are due to the energetic value rendered by the product (either in decreased or in increased degree), or to the nutrients or other substances that it contains (either in decreased or in increased degree). Think, for instance, of the slogans "Full of building materials" or "enriched with good fats Omega 3 and 6". A health claim gives the impression or implies that there is a relation between a food category, a food article or a part of it, and health. An example is: "Helps to keep the hearth and the vessels healthy".

### Marlous Stal-Hilders



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Functional foods are selling well, which indicates that many Europeans are aware of obesity

Whether a nutrition or a health claim is in question, the claims should observe the following principles. Claims may not be misleading or ambiguous. They may not give rise to doubt about the safety of other foods. They may not encourage excessive consumption. They may not suggest that a balanced and varied diet would not be sufficient. They may not give rise to fear. Claims may only be made if the presence or the absence of a certain substance has a real and positive effect. The quantity of the substance that is present must produce the effect that has been claimed. The average quantity that the consumer eats of this product will have to be

remainder of the nutritional value of the product could be unhealthy.

### Unanswered questions

With respect to trade marks that support a claim, it is important to know if the claim will appear on the generic lists. If this is the case trade mark proprietors may maintain the trade mark. However, if this is not the case, trade mark proprietors will have to decide how long they will be able to maintain the trade mark, on the basis of the transitional measures. This creates an uncertain situation for food manufacturers. It is also important that device marks are taken into consideration, for they may also fall within the scope of the Regulation.

What should be done with future trade marks? Manufacturers and their advisers should now pay additional attention to the introduction of new

## Will manufacturers still put their energy into innovation?

taken into account. This implies that the substance should be present in the product in a form that can be absorbed by the human body. The claim must be understandable to the average consumer. Last, but not least, all claims must have a scientific basis.

Apart from these principles the Regulation also contains specific requirements or principles regarding nutrition and health claims. Nutrition claims are only allowed if they appear on the list of claims that has been added to this Regulation. This list contains claims with an addition of the maximum and minimum values of substances that products are allowed to contain.

Thus a claim that a food is a source of protein may only be made when 12% of the energy value of the food is provided by protein. The list may be extended at the request of the individual member states.

More specific rules apply to health claims. First of all the following claims are excluded:

- Claims that insinuate that not eating the food could be detrimental to the health.
- Claims that refer to the degree of loss of weight.
- Claims that refer to the opinions of individual doctors.

Further, the label, advertisement or the presentation of the product should indicate:

- That a varied and balanced diet and a healthy lifestyle are important.
- The quantity of the food that should be consumed in order to obtain the effect that has been claimed.
- A list of people who should abstain from using the food.
- If applicable, a warning against excessive consumption.

Furthermore, the health claims are subdivided into three different categories – generic health claims, claims concerning a reduction of disease risk and children's claims. A system of permits is applicable for the last two claims. This means that the Committee will not draw up a generic list but that manufacturers will have to file individual requests for a permit. If a permit has been granted the same claim may also be used by third parties if they adhere to the conditions that have been indicated on the list with respect to the claim.

In addition, all foods that contain a claim should fall within the nutrient profiles. A nutrient profile describes the nutritional value of a product. This system has been chosen because of the demand that a product with a claim should be a healthy food. Without the profiles it might be possible to make a justified claim for a product, even when the

trade marks. Does the trade mark contain a visual or written claim? If so they should check whether the product meets the requirements that have been made with respect to the claim. The registration of trade marks that support a claim is possible. However, manufacturers might not want this. At any rate it would be advisable to incorporate a claim from the existing list since, if a request for a permit has to be filed, consent for the use of the trade mark is a long way off. However, this would be a valid reason for non-use of the trade mark, which would make the application for registration vulnerable to charges of non-use. Let us hope that granting a permit will not take five years or more.

The Regulation contains a stipulation that, when filing a request for the grant of a permit with respect to a reduction of a health risk and/or a children's claim, makes it possible to protect the research data submitted for a period of five years from the date of permission. This will make it easier to keep know-how secret.

What if the request for the grant of a permit is based on data covered by a patent? Will it be possible to keep the claim for the exclusive use by the manufacturer? This will depend on the interpretation of the nutritional claim. If the patent covers the interpretation, exclusivity has in my opinion been obtained. If, however, the wording can be attained in another way, a third party may also use the claim. If that is the case, manufacturers should consider whether they should proceed with the use of the claim or communicate the exclusivity in another way.

### Stagnating effect

An extensive set of rules exists. This does not favour uniformity. Will manufacturers still put their energy into innovation? The difference between nutrition and health claims cannot always be determined, let alone distinctions within the field of health claims. Another source of legal insecurity may arise because the Regulation has been determined on a national level. How will the responsible authorities carry out the observance and will differences occur between the member states?

Apart from the legal framework there is a set of transitional regulations. For manufacturers it is sometimes difficult to judge these transitional regulations or to apply them because essential information, such as the nutritional profiles and the list of claims, has not yet been determined. The deadlines mentioned in the Regulation will probably not be met because of

the number of applications and the limited capacity of the authorities. This creates uncertainty for the manufacturers that use a nutrition claim. They may have to adapt their packaging more than once.

This delay also has a stagnating effect on the development and innovation of new products, since it is questionable whether new developments will fall within the scope of the claims. If not, will a claim be granted? And how long will it take before the required consent is obtained? If the claim has not been obtained, it cannot be used, which could have a negative effect on the commercial value of the product. These are difficult circumstances for the companies involved. With respect to future products it will be difficult to plan scientific research. It will also be difficult to predict the return on investments – if a request for using a claim on an innovative product is successful anyone is

free (on certain conditions) to use the same claim. Lastly, procedures are public, so competitors will be informed. They will try to conquer the market by means of other market instruments.

The Regulation does not achieve the aims that it describes. It will have a stagnating rather than a stimulating effect on innovation. Perhaps the result will be that nutrition claims made in the future will be more informative for consumers. Let us hope so. For in that case the necessary investments have at any rate contributed to the achievement of one aim of the Regulation.

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