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# Summary

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Ministers of the Dutch government asked the Health Council to address a number of questions regarding foods and dietary supplements with health claims. The questions raised related to the health benefits achievable by the use of such products, their safety, the differentiation between different types of claims, and the evidential basis for these claims. A Health Council Committee has addressed these questions.

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## Health benefits

Diet influences health; it is possible to obtain health benefits by consuming certain foods and dietary supplements. Vitamins and minerals, for example, prevent deficiency diseases. Energy intake influences the risk of obesity, and therefore has an effect on the risk of cardiovascular disease and diabetes mellitus. Dietary fats and fibres influence the risk of cardiovascular disease, and the use of folic acid by pregnant women reduces the likelihood of foetal neural tube defects. Under the present circumstances, the greatest public health benefits are likely to be achieved through the consumption of new or established products that utilise these already demonstrated effects of diet on health. Optimisation of the national diet depends at the very least on consumers having correct information. Producers, the Netherlands Nutrition Centre and the government, as well as dietitians and doctors all have a role to play in this regard.

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## **Safety**

Products with health claims are frequently enriched with “classic” nutrients. Enrichment is useful insofar as it results in more people consuming the recommended daily intake of a nutrient. Increasing intake to a level in excess of the recommended daily intake is generally pointless, and is therefore not a valid case for enrichment. Consumption should not exceed the safe upper limit of intake. The risk of such excess consumption is greatest where several products enriched with the same substance are used concurrently, and especially where supplements are concerned. By reference to the findings of the Food Consumption Surveys, it is possible to estimate whether and, if so, to what extent the enrichment of a given product is liable to lead to overdosing. The intention is that food is safe. Actual practice, however, shows that many foods, including some widely consumed products, can have undesirable effects. These effects may nevertheless be deemed acceptable if offset by significant positive effects. Market monitoring is desirable in order to highlight these sorts of issues.

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## **Differentiation of claims**

The law in the Netherlands allows foods and dietary supplements to be accompanied by “health claims”, defined as claims relating to the “promotion and maintenance of health”. Medical claims are those involving the “prevention, treatment and cure of disease”. These claims may be made only for medicines and are forbidden for foods and for dietary supplements. However, the Committee believes that there is no scientific or practical distinction between the “prevention of disease” and the “promotion and maintenance of health”. Hence, the boundary between medical claims and health claims is not clear. The same applies to the boundary between foods and medicines. Both may be capable of beneficially influencing disease risk factors, causing reduction of disease risks. And any intervention aimed at reducing a disease risk (to or towards zero risk) is at the same time aimed at disease prevention.

The ministers asked whether a claim regarding the reduction of a risk factor may legally be interpreted as a (lawful) health claim, rather than an (unlawful) medical claim. However, as indicated above, the Committee does not see a difference between health claims and prevention-related medical claims. A claim that a product influences a particular factor can give the impression that use of the product reduces the likelihood of developing a certain disease. If this impression is correct, it is better to explicitly state that effect. If this impression is not correct, the claim is irrelevant and therefore misleading. Only explicit, specific and evidence-based claims regarding the prevention, and possibly the treatment, of diseases or conditions are of any value to public health.

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The prohibition of claims regarding risk reduction is an obstacle to ensuring that consumers are fully and correctly informed.

Nutrient content claims are statements such as “rich in ...” or “low in ...”. Such claims can also easily give the impression that use of the product is healthy and reduces the risk of developing certain diseases. It is better that this impression be made explicit, that the diseases in question are specified, and that evidence is provided. Here as well the principle should rule that if a claim cannot be made explicit or supported by evidence, then it is irrelevant and therefore misleading.

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### **Evidential basis**

No general and precise guidelines can be provided for the assessment of claims. A group of experts should be given the task of reviewing all the research data relevant to a claim, taking account of the methodological quality of the studies, their duration and nature, and the consistency of the findings. A claim must always be supported by research involving human subjects and generally accepted scientific criteria must be followed. Along with being statistically significant, a claimed effect must be of sufficient practical significance. Because new scientific developments can invalidate a claim, it is important that claims be periodically re-assessed.

Health effects from foods or dietary supplements do not normally occur in everyone. Their occurrence depends partly on factors such as lifestyle, including the consumption of other substances, sex and other genetic factors. The reporting of a claim that does not specify the target group is incomplete and therefore misleading.

In the assessment of claims, account should be taken of any adverse effects that a product may have. It would improve the clarity of the system for the business community, the government and consumers if the same agency were responsible for assessing both the safety and health effects of foods and dietary supplements.