
Minister's letter

On 18 October 2001, the Minister of Health, Welfare & Sport, acting partly on behalf of the Minister of Agriculture, Nature Management & Fisheries, wrote to the Health Council asking for recommendations (letter reference GZB/VVB 2218011). The text of the minister's letter is reproduced below.

I hereby request the Council's attention to the following.

In recent years, public interest in diet and the significance of diet in relation to health has grown considerably. Partly as a result of scientific advances, the business community is now able to respond to this interest by marketing foods that contain ingredients that are specifically intended to promote health. The ingredients in question are (for the most part) not traditional nutrients and, in terms of effect, occupy a position somewhere between foods and medicines.

The significance of such products for public health is presently difficult to determine, but some optimism regarding the impact of such products seems justified. It is nevertheless important that such products are introduced with care, partly in order to avoid undesirable distortions of eating patterns. The emergence of these products therefore raises a number of pertinent questions, on which the Minister of Agriculture, Nature Management and Fisheries and I would like your recommendations.

The questions concerned are as follows:

- 1 The significance of health-promoting ingredients

- a Can such ingredients provide health benefits for the consumer and, if so, under what conditions?
- b Can the Council draw up a list of substances likely to be marketed as health-promoting and indicate which of these substances promise to make a genuine contribution to consumer health?
- c What steps can be taken to ensure that the relevant ingredients reach their intended target groups and that the groups in question actually benefit?

Notes:

It is clear that consumer attitudes to health and the significance of diet in relation to health have changed significantly in recent decades. Consumers are more individual in their habits and make other choices than those made in the middle of the last century. The government's food policy therefore currently uses a differentiated approach to encourage consumers to eat sensibly. Against this background, it remains our belief that the availability of a varied selection of foods is important in relation to healthy eating and thus in relation to public health. Nevertheless, it is appropriate to consider whether health-promoting ingredients can also play a role and should therefore be addressed by food policy, and – if so – under what conditions. Important issues in this context include what information consumers require in order to understand the nature of such products and arrive at reasoned decisions, and how such information should be provided.

2 Safety issues

- a Are any special safety measures justified and, if so, what measures?
- b To what extent is there a danger of overdosing and how can overdosing be prevented, where necessary?
- c How can any possible undesirable effects of a product be identified once the product has been introduced to the market?

Notes:

The use of health-promoting ingredients must of course be conditional upon their safety. They should not endanger the health of the target group (undesirable effects), or of other groups or individuals. The existing legislation, and particularly the EU regulation on novel foods and novel food ingredients, provides the necessary guarantees concerning safe use. The Health Council may consider that additional safety measures are necessary or desirable, such as the introduction of a system for detecting undesirable effects (a post-marketing surveillance system). There has also been debate as to whether the use of a given approved health-promoting ingredient should be allowed in different products, since this could lead to a danger of overdosing. It is not our wish that the Council comments in this context on the safety issues associated with dossiers covered by the EU regulation on novel foods and novel food ingredients. Nevertheless, the experience acquired in the meantime through the assessment of novel foods is relevant for the assessment of safety issues concerning health-promoting ingredients.

3 Categorisation of permissible health claims

- a Are there grounds for stricter differentiation than we presently have between medical claims and health claims, and, if so, what form should this differentiation take?
- b Can a claim regarding the demonstrable diminution of a risk factor for having an illness or condition be considered to be a health claim?

Notes:

Section 19 of the Commodities Act prohibits medical claims. The Act's definition of a medical claim refers to "the prevention, treatment or cure of disease in humans". The explanatory notes to Section 19 of the act describe a health claim as a claim regarding "the promotion or maintenance of the health of the user". Thus, there is a subtle difference between the two types of claim as defined in the act, but in practice this distinction between a medical claim and a health claim is likely to be lost on many consumers. A review of the distinction between types of claim is therefore in order.

4 Evidential basis for health claims and the supervision of their use

- a Is it important that the government pays special attention to claims made regarding the efficacy of health-promoting ingredients and, if so, what approach should the government take?
- b Can the Health Council indicate the minimum requirements that should be made regarding the evidential basis for such health claims?
- c Should equally strict requirements be made in connection with all types of claim, or should the requirements be differentiated?

Notes:

It has so far been left largely up to producers to ensure that claims made regarding the efficacy of foods are accurate. The National Commodity Inspectorate makes only retrospective assessments as to whether claims are misleading. However, since health-promoting ingredients form a special category of products (whose specific purpose is to influence health and regarding which claims are made by their producers concerning their effectiveness for this purpose), it may be considered desirable to focus greater attention on this issue. One of the issues that would need to be decided is whether the efficacy and effectiveness of an ingredient should be demonstrated at the population level, at the individual level or at both levels. The way in which the efficacy of such an ingredient is demonstrated is also relevant in relation to the nature of the producer's claim. Another pertinent question is how such claims should be supported and whether equally strict requirements regarding evidential basis should be created for all types of claim.

In view of the wish to contribute to ongoing policy discussions at the national and European levels, and in view of the wide-ranging nature of the recommendation requested, I will be grateful if you will report back to me in stages.

The Minister of Health, Welfare and Sport,
Signed Dr E Borst-Eilers