

Response of the Ministry of Health, Welfare and Sport (The Netherlands) on the Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.

The Dutch Ministry of Health, Welfare and Sport welcomes the opportunity to comment on the discussion paper and has consulted with stakeholders in The Netherlands on the issues raised. I have pleasure in presenting the responses given by the Ministry to your questions.

The response of the Netherlands Ministry of Health, Welfare and Sport is based on three principles;

- The Netherlands policy concerning nutrition and health is based on dietary guidelines that for the general population should foresee in the required nutrients. The use of fortified foods and food supplements can have a role in maintaining health, but this will mostly be supplementary and directed towards specific target groups, specific foodstuff and even specific micronutrients. In case of the necessity for supplementary use of fortified foods and/or food supplements the Netherlands competent authority choose to have a specific and active policy regarding the target group, foodstuff or nutrient in question. When there is no need for a specific policy, fortified food and food supplements should at least be safe.
- The Netherlands Ministry of Health, Welfare and Sport are in favour of a coherent approach of the different EU-directives to ensure the effective functioning of the internal market and to provide a high level of consumer protection. We want to avoid increasing administrative burden through new regulations.
- Within the EU directives there should be the possibility to ensure the national public health through specific national policy i.e. specific national legislation. For example when dealing with the addition of vitamins and minerals to foodstuffs the national policies on compulsory fortification (substitution and/or restoration) should be taken into account, as they might differ between the member states, for example in the case with the fortification of margarine with vitamin A and D in the Netherlands.

General Observation

- As an observation on paragraph 13 on page 7 of the discussion paper, the word 'latter' in the third sentence seems to imply you are just talking about minerals whereas it appears to be the aim of the rest of the text that the level of intake of both vitamins and minerals should be taken into account.
- We are not aware of any evidence to support the statement that changes in culinary and social habits have led to low intakes for some vitamins and minerals, paragraph 14 on page 7.
- In addition to that, in the same paragraph it states that recommendations concerning vitamins and minerals are today set on the basis of avoiding deficiencies, i.e. stopping anything bad happening. However recent recommendations have been based on the maintenance of health, i.e. making good things happen.

Questions 1-3

The questions 1 till 3 can be summarised as follows;

- If there is no scientific evidence to establish a safe upper level of intake for vitamins and minerals, should there be a maximum set to the levels of these vitamins or minerals in foods?
- If the risk of adverse effects, even at high levels, of the intake of vitamins and minerals is low or non-existent, should there be a maximum set to the levels of these vitamins and minerals in foods?
- If a maximum level for vitamins and minerals in foods is set, should these be different for food supplements and fortified foods.

It is the Netherlands point of view that at this moment there are three options concerning the setting of a maximum level for vitamins and/or minerals;

- there is enough scientific evidence to define a safe upper limit of intake and thereby set a maximum level,
- the existing evidence indicates that even at high doses of administration for some vitamins or minerals the toxicity is extremely low or non-existing and thus a maximum level can not be set
- there is a lack of sufficient scientific data and hence it is not possible to set a maximum level.

If it is not possible to set a maximum level the following preconditions are important to consider;

- The use of a substance must be safe and not harmful to public health.
- The maximum level must be based on scientific evidence with a preference for toxicological evidence, otherwise exposure data or highest observed intakes as explored by FAO/WHO might be useful, or the guidance levels as set by the FSA.
- There should be a social necessity (either for the industry or for the benefit of consumer information) to set a maximum level. An example of the call for a 'standard' concerning the setting of a maximum by industry is a Code of Practice for food supplements, which includes a list of maximum levels for the use of vitamins and minerals in food supplements. This code of practise is now no longer used because of the discrepancy on what is the uppermost maximum between the EU and the USA.

To aid in the setting of a maximum for vitamins and minerals in foodstuff and to overcome existing discrepancy it is possible to use a model.

This model should be applicable to all age groups including all sensitive groups, such as children and elderly. Furthermore the model should take into account the exposure of the population to fortified foods and food supplements.

In the Netherlands the National Institute for Public Health and the Environment (RIVM) has built up experience with the model developed by the Danish Institute of Food and Veterinary Research. They have adapted the Danish model for the Dutch situation and used it to set a maximum level for foods fortified with vitamin D and folic acid. For a further explanation of the contents and use of the RIVM-model we would like to refer to the enclosed abstract of an article (annex 1).

Questions 4 - 6

Questions 4 to 6 summarise the request for information on intakes of vitamins and minerals, if such existing data should only refer to the intake in some of the Member states and if it is necessary to take different population groups into account when setting maximum levels of vitamins and minerals?

It is the opinion of the Netherlands Ministry of Health, Welfare and Sport that the Netherlands can contribute in collecting data on food consumption. The data which have been gathered in the Dutch Food Consumption Survey by the Netherlands National Institute for Public Health and the Environment (RIVM) can provide information on the usual intake of foods in the Netherlands including the use of fortified foods. The RIVM, in cooperation with the Netherlands Consumers' Association, has gathered some marginal information on the use of food supplements. For more information on the data collected, methods used, etc we would like to refer to annex 2.

We are aware that there are more countries within the EU who have validated data on food consumption at their disposal, for example England, France, Belgium, Germany and the Scandinavian countries.

However the Netherlands competent Authority strongly suggests and encourages the European Commission initiatives to develop a European monitoring of the food consumption in Europe, particularly since this includes those countries that haven't been able to develop their own national food consumption monitoring.

The monitoring of food consumption to acquire data on the use and intake of fortified foods and food supplements might be prioritised by selecting those vitamins and minerals with a small range and critical attribution to nutrition.

Generally it might be possible to use existing food consumption data from a part of Europe to set maximum amounts for the whole of Europe. In this case it is also necessary to take into account these micronutrients that have the smallest range of safety and/or have the biggest possibility for a deficiency.

Although the population group of children until the age of three is not a part of the Food supplement regulation or the new regulation on fortified foods the Dutch Ministry does suggest taking different population groups into account when setting maximum levels and would favour at least a separate category for children (age 3 and up) and maybe elderly.

Question 7

Should PRI's and/or RDA's be taken into account when setting maximum levels for vitamins and minerals?

The Netherlands Ministry of Health, Welfare and Sport are of the opinion that when setting a maximum level the safety of foodstuffs is the first priority. When it is not possible to set a maximum using toxicological evidence then Population Reference Intakes (PRI's) or Recommended Daily Allowances (RDA) should be taken into account. Furthermore the PRI's and RDA's can be used in the eventual separation of fortified foods and food supplements.

Question 8

Should the minimum amount of a vitamin or mineral in a fortified food be in accordance with the EU-directive on claims and/or labelling?

Setting a minimum amount for fortified foods in agreement with the EU-directive on nutrition labelling will have benefits. This will mean a significant amount of a vitamin or mineral will be required to be present in a fortified food. The Netherlands competent authority agrees with the definition of a 'significant amount' as given in the EU-directive on nutrition labelling for solid foodstuff, which is 15 % of the recommended allowance per 100 gram. We would propose to make a difference for fluid foodstuff and have the significant amount here set for 7,5 % per 100 ml.

Question 9

Should the minimum amount of a vitamin or mineral in a food supplement be in accordance with the EU-directive on claims and/or labelling?

The Netherlands government agrees that a significant amount of a vitamin or mineral has to be present in a food supplement. It remains to be seen if this can be the 15% of the recommended allowance in 100 gram, as presently stated in the EU-directive on nutrition labelling. As a singular supplement most of the times does not weigh more than a few grams.

Annex 1. RIVM - Abstract

Safe addition of vitamins and minerals to foods: setting maximum levels for fortification in the Netherlands

Janneke Kloosterman, Heidi P. Fransen, Joyce de Stoppelaar , Cathy Rompelberg, Hans Verhagen

National Institute of Public Health and the Environment (RIVM), Bilthoven, the Netherlands

Ministry of Health, Welfare, and Sport, The Hague, the Netherlands.

Corresponding author to whom also requests for reprints should be addressed:

Cathy Rompelberg

National Institute of Public Health and the Environment (RIVM)

PO Box 1

3720 BA BILTHOVEN

The Netherlands

Tel: +31 30 2742387

Fax: +31 30 274 4466

E-mail: Cathy.Rompelberg@RIVM.nl

Column title: Setting maximum safe levels for fortification

Summary

BACKGROUND: Foods are enriched with micronutrients for several reasons, such as the prevention of deficiencies and to provide additional health effects. This addition should be safe, so that unacceptable high intakes, above the upper level (UL), are prevented. Because of a small range between the recommended daily intakes and the UL, fortification with vitamin A, vitamin D, (synthetic) folic acid, selenium, copper, and zinc is prohibited in the Netherlands. In 2004 the European Court of Justice decided that this prohibition is against the free movement of goods in Europe (article 30 of the Treaty). This decision instigated a change in the Dutch policy, leading to a more flexible handling of requests for exemption of this prohibition to fortify. Therefore, a policy granting a general exemption in the Dutch Commodity Act was proposed. **AIM OF STUDY:** To develop a risk-assessment model to estimate the maximum safe level of addition of micronutrients, which is practical applicable to the Dutch situation, and to set maximum safe levels of fortification after evaluation of the risk-assessment by a risk-manager. **METHODS:** A risk-assessment model to estimate maximum safe levels per 100 kcal of a product, was developed based on existing models by Flynn *et al.* and Rasmussen *et al.* European ULs, in combination with national consumption data were used to estimate maximum safe levels for addition of folic acid, vitamin A, and vitamin D for all ages. The following model parameters were used: the 95th percentile the energy intake in the population (groups), a realistic worst-case scenario for the intake of dietary supplements and the assumption that 15% of the energy intake will consist of fortified foods in the future. The resulting maximum safe levels were considered by the risk-manager and discussed extensively with stakeholders and other experts. **RESULTS:** For folic acid, vitamin A, and vitamin D maximum safe levels (acceptable levels of addition, ALA) were calculated in the risk-assessment model. For folic acid children up to six years old were the most sensitive group with an ALA of 0 µg/100kcal. Among adults the age group of 18-30 yrs (men) was the most sensitive group with an ALA of 67 g/100 kcal. After extensive discussions with stakeholders and other experts, and taking into consideration the fact that it is a temporary measure pending the establishment of harmonized maximum levels of fortification in the EU, the maximum safe levels were re-calculated at the request of the risk-manager. To this end, a less conservative scenario for food supplement intake was used and it was assumed that 10% of the energy intake will consist of fortified foods in the future. Because the UL for children is extrapolated from the UL of adults, and the risk of negative health effects by exceeding this UL is thought to be low by the risk manager, for folic acid the ALA was

based on the most sensitive adult group. This resulted in an upgrading of the ALA to 100 µg/100kcal for folic acid. For vitamin D the ALA was 3.0 µg/100kcal (children 4-10 years), which was elevated to 4.5 µg/100kcal by the risk manager, for the same reasons as described for folic acid, and the fact that only one request for exemption had been received so far suggesting that the number of products fortified with vitamin D will be limited in the near future. For vitamin A, children up to 10 years old, adult men, and post-menopausal women were the most sensitive groups (0µg/100kcal). Because this is a large part of the population, the UL was already reached by intake of background diet only, and considering the serious harmful effects of vitamin A, no general exemption was set by the risk manager. *CONCLUSIONS:* This is the first paper describing the practical combination of a risk-assessment model and evaluation by a risk manager to set safe maximal levels for fortification of foods with vitamins. In the Netherlands, this resulted in general exemptions for folic acid and vitamin D and values will be published in the Dutch Commodity Act. Monitoring is recommended to evaluate the model parameters and ALA periodically and make adjustments when required.

Keywords: vitamins, minerals, micronutrients, fortification, food, tolerable upper intake level

Annex 2. Dutch National Food Consumption Survey

Collection of periodic data on food consumption and nutrition status of the Dutch population and of specific groups within the population has been carried out since 1987 under the authority of the Netherlands Ministry of Health, Welfare and Sport.

Since 2003, the Dutch National Food Consumption Surveys (DNFCS) has been carried out by RIVM and TNO using a new method for food and nutrition surveys. A new method for data collection was needed because of changing policy needs, socio-demographic developments, trends in food habits as well as developments in research methods.

Methods

Total population

The food consumption survey is designed for continuous collection of basic data on the Dutch population of people from seven years of age. The participants are selected from a consumer panel. The food consumption survey method comprises two 24-hour dietary recalls on two non-consecutive days. General information is obtained about the participants from a written questionnaire which they are asked to complete. The 24-hour dietary recalls are analysed by purpose-designed computer software.

Specific groups

Additional food consumption surveys are needed for specific groups such as young children, immigrants, pregnant and lactating women, and institutionalised elderly people. The selection of participants and/or the food consumption method employed with these groups requires modification to the approach used in the collection of basic data. In 2003, a survey of young adults (19 to 20 years) was carried out and in the period 2005-2006, young children between 2 and 6 years were surveyed.

Specific products

Data needs also to be collected about the consumption of important products that are only eaten by relatively few people. Data collection via the internet from tens of thousands of people is, for example, necessary to gain insight into the consumption of specific health enhancing products, food supplements, fish, organic meat, herbs, baby food or products that are specifically eaten by immigrants.

Nutritional status/ food behaviour

When the above food consumption surveys indicate problems or issues in nutrition, a follow-up study may be undertaken, for example, on the nutritional status or determinants of food behaviour.

DNFCS-1 (1987-1988); DNFCS-2 (1992); DNFCS-3 (1997-1998)

At five-year intervals, three population wide food consumption surveys were carried out with approximately 6000 people. These surveys were based on family food diaries. This method was discontinued in 2003 with the consequence that the results of the first three food consumption surveys are not comparable with the later surveys

DNFCS-2003: Food consumption survey of young adults

The DNFCS-2003 aimed to obtain data about the food consumption by men and women between the ages of 19 and 30 years. These data should give insight into the extent to which the nutrition of this population group meets the targets/objectives set in nutrition policy. Specifically, this concerns the consumption of fruit and vegetables, total fat intake, saturated fatty acids, trans fatty acids and energy. The DNFCS-2003 showed that a new design was needed for the Dutch food consumption survey in order to focus on healthy nutrition and food safety.

FCS-2005/2006: food consumption survey of young children

The DNFCs-2005/2006 aims to obtain data on the food consumption of children (boys and girls) between the ages of two and six years. Attention was given to the average intake of energy, total fat, saturated fatty acids, trans fatty acids, fruits and vegetables. In addition, attention focused on the percentage of children consuming the recommendations amounts of nutrients, and fruits and vegetables. Another point of attention is exposure to certain substances related to food safety.

Correspondence address DNFCs-team:

National Institute for Public Health and the Environment
Centre for Nutrition and Health

PO Box 1

3720 BA Bilthoven

the Netherlands

Tel: +31 30 27443318

Fax: +31 30 2744466

E-mail: VCP@rivm.nl