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## Evaluation of the Dutch legislation on food fortification with folic acid and vitamin D; focus on young children

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# Contents

<b>Samenvatting</b>		<b>6</b>
<b>Summary</b>		<b>8</b>
<b>Abbreviations</b>		<b>9</b>
<b>1</b>	<b>Introduction</b>	<b>10</b>
<b>2</b>	<b>Methods</b>	<b>14</b>
2.1	Evaluation of the legislation on the food level	14
2.1.1	<i>Inventory of folic acid and vitamin D fortified products</i>	14
2.1.2	<i>Evaluation of the fortification level in the identified products</i>	14
2.2	Evaluation of the legislation on the intake level	15
2.3	Evaluation of the model assumptions	16
<b>3</b>	<b>Results</b>	<b>20</b>
3.1	Inventory and evaluation of food products	20
3.1.1	<i>Folic acid fortified products</i>	20
3.1.2	<i>Vitamin D fortified products</i>	20
3.1.3	<i>Amounts of folic acid in fortified products</i>	21
3.1.4	<i>Amounts of vitamin D in fortified products</i>	23
3.2	Evaluation of intake: exceeding the tolerable upper intake level	23
3.2.1	<i>Folic acid</i>	23
3.2.2	<i>Vitamin D</i>	25
3.3	Evaluation of model assumptions: comparing old and new values	29
3.3.1	<i>Habitual energy intake</i>	29
3.3.2	<i>Folic acid-specific values and recalculation</i>	29
3.3.2.1	<i>Model parameters for folic acid</i>	29
3.3.2.2	<i>Recalculation of the maximum fortification level for folic acid</i>	30
3.3.3	<i>Vitamin D-specific values and recalculation</i>	30
3.3.3.1	<i>Model parameters for vitamin D</i>	30
3.3.3.2	<i>Recalculation of the maximum fortification level for vitamin D</i>	31
<b>4</b>	<b>Discussion</b>	<b>32</b>
4.1	Product inventory	32
4.2	Food consumption and composition data	32
4.3	Food supplements	33
4.4	Maximum fortification levels	34
4.5	The tolerable upper intake level	35
4.6	EU legislation	35

<b>5</b>	<b>Recommendations</b>	<b>37</b>
<b>6</b>	<b>Conclusions</b>	<b>38</b>
<b>7</b>	<b>Acknowledgements</b>	<b>39</b>
<b>8</b>	<b>References</b>	<b>40</b>
<b>Annex A</b>		<b>42</b>

## Samenvatting

Door een uitspraak van het Europese Hof is de Nederlandse wetgeving ten aanzien van verrijking van levensmiddelen met microvoedingsstoffen herzien. In 2007 is een algemene ontheffing afgegeven voor verrijking van levensmiddelen met foliumzuur en vitamine D tot een maximum niveau van respectievelijk 100 µg/100 kcal and 4.5 µg/100 kcal. Deze maximale niveaus zijn berekend met behulp van een rekenmodel dat is aangepast aan de Nederlandse situatie.

De verandering in wetgeving kan hebben geleid tot een toename van op de Nederlandse markt verkrijgbare foliumzuur- of vitamine D-verrijkte levensmiddelen. Bovendien kan de inneming van foliumzuur en vitamine D zijn toegenomen. Vooral jonge kinderen lopen het risico op een voedingsstofinneming boven de maximaal aanvaardbare bovengrens van inneming (UL). In deze studie hebben we geëvalueerd welke foliumzuur- of vitamine D verrijkte levensmiddelen er op de Nederlandse markt zijn en of het gehalte foliumzuur of vitamine D voldoet aan de maxima die gesteld zijn in de algemene vrijstellingsregeling. De levensmiddelen zijn geïdentificeerd in voedingsmiddelendatabases en een supermarktinventarisatie. Daarnaast is de inneming van foliumzuur en vitamine D bepaald voor verschillende verrijkingsscenario's met behulp van consumptiegegevens van de voedselconsumptiepeiling onder jonge kinderen (2-6 jaar) en is het percentage kinderen met een inneming boven de UL geschat. Verder zijn de verschillende input parameters van het rekenmodel geëvalueerd op basis van nieuwe gegevens over de inneming.

Het aantal foliumzuur- of vitamine D-verrijkte levensmiddelen op de Nederlandse markt is toegenomen. Echter het aantal productgroepen waarin deze levensmiddelen zich bevinden is nog relatief gering. Op één product na, voldoen alle verrijkte producten aan de wetgeving. In de huidige situatie heeft een klein deel (< 5%) van de kinderen een foliumzuurinneming boven de UL. Met de huidige inneming van foliumzuur uit voedingssupplementen en als de markt van vrijwillig verrijkte producten toeneemt lopen vooral jonge kinderen (2-3 jaar) risico op te hoge foliumzuurinneming. De huidige en mogelijke toekomstige vitamine D inneming bleef onder de UL. Het maximale verrijkingsniveau voor foliumzuur en vitamine D zijn in de huidige situatie hoog genoeg voor jonge kinderen. Verschillende model input parameters (bv. inneming uit voedingssupplementen en de fractie van de energie-inneming die verrijkt zou kunnen worden) zouden geüpdate moeten worden op basis van nieuw beschikbare gegevens. Herberekening van de maximale verrijkingsniveaus geeft waarden die overeenkomen met de huidige waarden. Indien de markt van vrijwillig verrijkte levensmiddelen toeneemt zullen de maximale verrijkingsniveaus herzien moeten worden. Het regelmatig monitoren van de Nederlandse markt aan verrijkte levensmiddelen en inneming uit de voeding wordt daarom aanbevolen.



## Summary

Due to a decision of the European Court, the Dutch policy on fortification of foods changed in 2007. A general exemption is given for fortification with folic acid and vitamin D, up till a maximum level of 100 µg/100 kcal and 4.5 µg/100 kcal, respectively. This maximum level was estimated using a calculation model for the Dutch situation.

The change in legislation may have led to an increase in folic acid and vitamin D fortified foods and their intakes. Young children may especially be at risk for intakes exceeding the tolerable upper limit (UL). Therefore, we evaluated the folic acid and vitamin D fortified foods available on the Dutch market, we evaluated the intakes of folic acid and vitamin D of young children, and we evaluated the input parameters and assumptions of the calculation model.

We identified folic acid or vitamin D fortified products using product databases and a supermarket inventory and compared their fortification levels with current legislation. We developed fortification scenarios using the results of the inventory and consumption data from the Dutch National Food Consumption Survey (DNFCS) on children aged 2-6 years. These intakes were compared with the UL. We recalculated the different model parameters using the results from the inventory and intake information and compared with the old parameters.

New fortified food products have entered the market, all but one comply with current legislation. Currently a small proportion (< 5%) of the children exceeds the UL for folic acid. With increasing availability of fortified food products and current intakes from food supplements, especially young children (2-3 yr) will be at risk on too high folic acid intakes. The current and estimated future vitamin D intake do not exceed the UL. The maximum fortification levels are accurate for young children (2-6 yr) in the current situation. Several input parameters (e.g. food supplement intake, fraction of energy intake that may and will be fortified) should be updated based on newly available data. However, the recalculated maximum fortification levels remain similar. With increased voluntary fortification the maximum fortification levels need to be revised. Regular monitoring of the Dutch market and dietary intakes is therefore recommended.

## **Abbreviations**

DNFCS	Dutch National Food Consumption Survey
UL	tolerable upper intake level

# 1 Introduction

The main reason why foods are fortified with micronutrients is to prevent deficiencies or to provide additional health effects. Such fortification should be safe for the whole population; unacceptably large intakes (i.e. above the tolerable upper intake level (UL)) of the micronutrient, from all sources, should be prevented. Fortification (other than restoration and substitution) with vitamin A, vitamin D, folic acid, selenium, copper, and zinc is prohibited in the Netherlands [1]. However, in 2007 a general exemption [2] on this prohibition on fortification with folic acid and vitamin D was set, due to a decision of the European Court of Justice of the European Community [3] (**Table 1.1**). This general exemption is in force until the maximum levels for food fortification (EC 1925/2006) and supplementation (2002/46/EC) are set in new EU legislation. In addition, several other legislations concerning addition of folic acid or vitamin D are in force for specific food products (**Table 1.1**).

The general exemption for fortification with folic acid and vitamin D is given for fortification up till a maximum level; for folic acid this is 100 µg / 100 kcal and for vitamin D 4.5 µg / 100 kcal [2]. These maximum fortification levels were defined using a calculation model for the Dutch situation [4]. With this calculation model the ‘free space’ between the UL and intake from both background diet (i.e. without voluntary fortification practices, but including ongoing mandatory or otherwise via national policy regulated (e.g. covenants) fortification practices) and food supplements. The remaining ‘free space’ is divided over the proportion of the energy intake that may and will be fortified, resulting in a maximum fortification level per 100 kcal food. The calculation model requires several input parameters that are based on actual data or best educated assumptions (**Box 1**). With changes in e.g. dietary patterns or when more or new data will be become available the input parameters of the model might change and as a consequence this might have influence on the maximum fortification levels.

The risk manager decided that light foods (at least 30% less energy than energy dense counterpart) may be fortified up till the same maximum level as their energy-dense counterparts [2]. With respect to the general exemption for folic acid, the risk-manager focussed on the results of the calculation model of adults only [4]. The UL for adults is based on the risk of masking vitamin B<sub>12</sub> deficiency. The UL for children is extrapolated from the UL for adults. The risk-manager assumed this extrapolation to be conservative, because the risk of masking B<sub>12</sub> deficiency is thought to be low in children. Other issues, are also relevant in the ongoing debate about the UL for folic acid, such as the recent data on colon cancer risk [5,6]. However, these data are currently not yet taken into account in the UL.

The change in legislation may have led to an increase in foods voluntarily fortified with folic acid or vitamin D available on the Dutch market and as a consequence the intake of these micronutrients might have increased. In this study, we evaluated three aspects that are important to the ultimate aim of guarding a fortification practice that is safe for the whole population.

- 1) An inventory of the folic acid and vitamin D fortified foods available on the Dutch market in first half of 2009 was made. The amounts of folic acid or vitamin D in these foods were compared with the currently legal maximum fortification levels.
- 2) The habitual folic acid and vitamin D intakes of Dutch young children were estimated for several scenarios of food fortification, using the results of the product inventory and the data of the Dutch National Food Consumption Survey among young children (2005-2006). The proportion of Dutch young children with intakes above the UL were determined for these scenarios.
- 3) We evaluated whether the current market situation meets the model assumptions and input parameters of the calculation model used to define the maximum fortification levels. This is important, because changes in the model parameters might have an effect on the maximum fortification levels. Depending on the changes in the parameters, the currently legal maximum fortification levels might be correct, too low (assumptions were too conservative) or too high (assumptions were too liberal).

This report describes the evaluation of new legislation with respect to the fortification of foods with folic acid and vitamin D. In chapter 2, the methods behind our evaluation are described. Chapter 3 presents its results. In chapter 4, we discuss our methods and results, in light of the question whether the current and possible future market situation of fortification may result in a folic acid or vitamin D intake that is too high, from a public health perspective. We end with our conclusions (chapter 5) and recommendations (chapter 6).

**Table 1.1: Overview of current legislation concerning addition of folic acid and vitamin D to foods\***

Product	Exceptions	Directive/Date Source	Title (English/Dutch)	Level of fortification allowed	
Foods and drinks		Staatsblad 1999, 428 {#5015}	'Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen'	Folic acid	prohibited (article 5)
	Substitution products	Staatsblad 1999, 428 {#5015}	'Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen'	Vitamin D	prohibited (article 5)
	Spreadable fats	Staatsblad 1999, 428 {#5015}	Warenwetbesluit Toevoeging micro-voedingsstoffen aan levensmiddelen'	Vitamin D	Max natural level of product to be substituted (article 5 & 6.2)
		EC 2991/94 Pb EG L 316	Council Regulation (EC) No 2991/94 of 5 December 1994 laying down standards for spreadable fats'		Max 7.5 µg/100 grams (article 5a)
		GZB/VVB/2037714 (Staatscourant 25 January 2000, nr 17)	Convenant vitamining van smeerbare vetproducten'		
Foods and drinks		VGP/VV 2742234{#1138}{#1139}	'Warenwetregeling vrijstelling toevoeging foliumzuur en vitamine D aan levensmiddelen'	Folic acid	Max 100 µg/100 kcal (article 2.1.a)
				Vitamin D	Max 4,5 µg/100 kcal (article 2.1.b)
	'Light' food products	VGP/VV 2742234{#1138}{#1139}	'Warenwetregeling vrijstelling toevoeging foliumzuur en vitamine D aan levensmiddelen'	Folic acid and vitamin D	Adjust to level of energy dense counterparts (article 2.2)
Processed cereal-based food and baby foods for infants (-12 mo) and young children (1-3 yr)		2006/125/EC{#1138}{#1139}, article 1.2.a	'Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children'	Folic acid	Max 50 µg/100 kcal (annex 1, 6.2)
				Vitamin D	Max 3 µg/100 kcal (annex 1, 7)

\*with relevance to this report

**Box 1: Calculation model, model parameters and assumptions used to estimate the maximum fortification levels [4]**

	<b>risk-assessment</b>		<b>risk-management</b>
	$MSFL = UL - (CI_{95} + SI) / ((EI_{95} / 100) * PFF_n)$	evaluation →	AFL
MSFL	Maximum safe fortification level per 100 kcal		
AFL	Allowed fortification level per 100 kcal (folic acid 100 µg / 100 kcal; vitamin D 4.5 µg / 100 kcal)		
UL	Tolerable upper intake level [7]		
CI <sub>95</sub>	Current intake at the 95 <sup>th</sup> percentile of habitual micronutrient intake distribution of non-fortified foods (background diet), per age group; based on data of DNFCS-3 (1997-1998) [8]		
SI	Realistic high intake scenario from food supplements, crude assumptions based on [9,10]		
EI <sub>95</sub>	Intake at 95 <sup>th</sup> percentile of habitual energy intake distribution, per age group, based on data of DNFCS-3 (1997-1998) [8]		
PFF <sub>n</sub>	Proportion of the total energy intake that comes from fortified foods; 10% assumed		

## 2 Methods

### 2.1 Evaluation of the legislation on the food level

Foods fortified with folic acid or vitamin D and available on the Dutch market were identified and their fortification levels were compared with the current legislation.

#### 2.1.1 *Inventory of folic acid and vitamin D fortified products*

In the Netherlands there is no central registration of fortified foods available on or introduced to the market. We used three databases to start the inventory on folic acid and vitamin D fortified foods: Dutch Food Composition Database (including additional food product data collected for recent and ongoing Dutch Food Consumption Surveys) [11], Innova database (commercial food product database) ([www.innovadatabase.com](http://www.innovadatabase.com)), and Compendium dietary products and food supplements ([www.dieetconsult.nl](http://www.dieetconsult.nl)). In all three databases we searched (February-April 2009) for foods containing folic acid or vitamin D as an ingredient on the declaration. Unfortunately, all databases are incomplete, especially foods recently launched, foods recently reformulated, and home brands are missing. Therefore a supermarket inventory was conducted (March-April 2009) to complete the product evaluation as far as possible. This supermarket inventory was limited to the food groups identified in the database search, as we expected that the most important food groups were represented in the three databases. The eight supermarket chains with highest market share (2008) were visited (i.e. Albert Heijn, C1000, Aldi, Super de Boer, Plus, Jumbo, Dirk van den Broek, Lidl) ([www.distrifood.nl](http://www.distrifood.nl)), as well as two supermarkets with relative high contribution of foods in the Dutch Consumption Survey among young children (i.e. Coop, Spar) and two supermarkets with a low market share (2%) (i.e. Deen, Dekamarkt). Although the addition of vitamin D to spreadable fats and baking fats has an independent legislation [12,13], these food products were also taken into account in the inventory to be able to update the vitamin D levels. For all folic acid or vitamin D fortified foods, data were collected on product name, brand name, folic acid or vitamin D content, and energy content. Missing data were completed by searching for information on manufacturer websites or by contact with manufacturers. All data were collected on the basis of information provided on the label or by manufacturers; no chemical food analyses were conducted.

#### 2.1.2 *Evaluation of the fortification level in the identified products*

All folic acid or vitamin D fortified foods found in the inventory were evaluated on amount of folic acid or vitamin D per 100 kcal and compared to the legal amounts (100 µg/100 kcal for folic acid; 4.5 µg/100kcal for vitamin D). For each food the declared amount of folic acid or vitamin D 100 g (or ml)

was divided by the amount of energy (kcal) per 100 g (or ml) times 100. The declared micronutrient amounts on the label are the total micronutrient content in the food product, not only the proportion added. As the legislation applies to the added part of micronutrients, the natural content of folate and vitamin D was estimated based on similar food products in the Dutch food composition database [11]. Using these corrected amounts, representing the added micronutrient content, the folic acid or vitamin D level per 100 kcal were calculated again and compared to the legal maxima.

If the actual fortification levels of the food products appeared to exceed the maximum fortification levels, we considered if they meet the definition of so-called 'light' products. Light products are defined as foods containing  $\leq 30\%$  less energy than energy dense counterparts. There is no clear definition on required similarity between the counterparts. Advice on whether or not a food could be stated as 'light' was obtained from the Dutch Food and Consumer Product Safety Authority (VWA). For the foods defined as 'light' the folic acid or vitamin D content per 100 kcal was also calculated using the energy content of energy dense counterparts and compared to the legal maximum fortification level.

## 2.2 Evaluation of the legislation on the intake level

In this study we used data of the Dutch National Food Consumption Survey among young children (DNFCS-kids) [14]. In brief, this survey was conducted in 2005-2006 among 1279 children aged 2-6 years old. Data were collected by means of a written general questionnaire and two food records on independent days (8-13 days in between). The food records were filled in by the care taker of the children; in pre-structured diaries all foods and drinks and food supplements consumed on that day were recorded. In addition, data of an extended version of the Dutch food composition database (NEVO) [11] and the Dutch supplement database (NES)[15] were used. For a small fraction of the foods, no vitamin values are available in the Dutch food composition database. For these products, values were set at zero.

The general exemption for folic acid and vitamin D was not in force during the data collection of DNFCS-kids. Therefore, four different scenarios of fortification strategies were defined based on the results of the inventory (see below). These scenarios represent a realistic situation in 2009 up to a potential future, more worst-case, situation based on the current market situation (**Table 2.1**). The situation in 2005-2006 was taken as a reference. The **first scenario** is a representation of the situation in 2009. In the DNFCS-kids data all foods currently fortified with folic acid or vitamin D (and consumed in DNFCS-kids) were identified based on brand name and product name. The micronutrient (folic acid or vitamin D) content of these foods was replaced by the levels that were applied in 2009. Foods fortified during DNFCS-kids and not fortified in 2009 were regarded as not fortified. For foods

fortified during DNFCs-kids and currently fortified with a different level, the micronutrient content was replaced by the content in 2009. Foods not consumed during DNFCs-kids were not taken into account in this scenario.

The **second scenario**, 'all brands', represents the situation where the current fortified foods are expanded with currently not fortified foods of the *same food groups and same brands*. For the foods currently not fortified, the highest fortification level of the same brand and food group was assigned, taking into account the legal maximum.

In the 'all food group' scenario (**scenario 3**), not only foods currently not fortified in same food group and with same brand, but also foods in the *same food group of other brands* are assumed to be fortified. For the currently not fortified foods, the highest fortification level in the same brand or product group was allocated, taking into account the legal maximum. For folic acid one exemption was made, bread (see below) was not taken into account in scenario 3 only in scenario 4, as this was considered as staple food.

In **scenario 4** ('similar food groups'), not only foods in the same food group, but also foods in similar food groups are assumed to be fortified. For the currently not fortified foods, the highest level in the same brand, the same or a similar food group was assigned, taking into account the legal maximum.

In **all scenarios** we assumed folic acid and vitamin D intake from food supplements to be the same as in the reference situation. Eventual reformulations since 2005-2006 were not taken into account. For vitamin D the current market situation of addition of vitamin D to spreadable fats and baking fats was applied in scenario 1 through 4 without changes.

Based on the consumption data of DNFCs-kids and the defined fortification scenarios the habitual folic acid and vitamin D intake was calculated for four age-gender groups (i.e. boys 2-3 yr, girls 2-3 yr, boys 4-6 yr, girls 4-6 yr). Data was corrected for within-person variation using ISU-method (IML-SIDE and C-SIDE) [16] and weighted for socio-demographic factors and season. The proportion of the children with intakes above the UL was also estimated using the cut-point method. The age-specific ULs set by the Scientific Committee on Food and the Scientific Panel on Dietetic Products, Nutrition and Allergies were used [7]

## 2.3 Evaluation of the model assumptions

In the model used to calculate the maximum fortification levels, input was needed for the following parameters (Box 1) [4]:

- the 95<sup>th</sup> percentile of habitual energy intake
- the 95<sup>th</sup> percentile of habitual folic acid or vitamin D intake

- folic acid or vitamin D intake from food supplements
- the fraction of the habitual energy intake that may and will be fortified.

For children, these parameters on habitual energy, folic acid, and vitamin D intake are based on outdated food consumption data of the DNFCS-3 (1997-1998) [8]. Assumptions were made on the intake from food supplements based on scarce data [9,17]. The fraction of the total energy intake that may and will be fortified was rather arbitrary chosen and mainly based on the fact that a traditional Dutch dinner in general consists of fresh products like meat, vegetables and potatoes.

The different model parameters were recalculated using data of the DNFCS-kids and for the different fortification scenarios that were defined based on results of the inventory. A comparison is made between the old and recalculated parameters, and the maximum fortification levels of folic acid and vitamin D are recalculated for children aged 2-3 yr and 4-6 yr old. For each fortification scenario the proportion of the habitual energy intake originating from folic acid or vitamin D fortified foods was calculated and the proportion of the children with a fraction larger than the assumed proportion was estimated.

**Table 2.1.** Description of the fortification scenarios

	Reference	Scenario 1	Scenario 2	Scenario 3	Scenario 4
	'reference'	'situation 2009'	'all brand'	'all food groups'	'similar food groups'
<b>General explanation</b>	As consumed during data collection of DNFCs-kids 2005-2006	Foods consumed in DNFCs-kids are replaced with current levels of fortified folic acid/vitamin D. These include new fortified foods, new fortification levels, foods that are not fortified anymore. Foods currently fortified but not consumed cannot be used.	Foods currently fortified and similar foods in same food group of same brands are assumed to be fortified. Fortification level as currently present or highest of brand.	Foods currently fortified and foods of all brands in same food group are assumed to be fortified. Fortification level as currently present or highest in food group.	Foods currently fortified and foods of all brands in same food group and in similar food groups are assumed to be fortified. Fortification level as currently present or highest in food group.
<b>Explanation by product group: folic acid</b>					
<b>Drinks</b>	Fruit soft drink/lemonade (n=1)	Fruit soft drink/lemonade	Fruit soft drink/lemonade	Fruit soft drink/lemonade Sports drink Flavoured water	Fruit drink (> 2 fruits) Fruit lemonade Fruit soft drink/lemonade Sports drink Flavoured water
<b>Bread</b>	No fortification	Bread Cracottes	Cracottes Bread only the identified fortified food product	Cracottes Bread only the identified fortified food product	Cracottes Cream cracker Knackerbröt Bread
<b>Pastry and cookies</b>	Cereal bar (n=1)	Cereal bars	Cereal bars of same brand Nutritional biscuits	Cereal bars Muesli bar Nutritional biscuits	Cereal bars Muesli bar Nutritional biscuit
<b>Cereal products</b>	Breakfast cereals (cornflakes; n=20)	Breakfast cereals (cornflakes) Baby porridge	Breakfast cereals (cornflakes) Baby porridge	Breakfast cereals (cornflakes, muesli) Baby porridge	Breakfast cereals (cornflakes, muesli, cruesli) Baby porridge
<b>Dairy products</b>	Instant chocolate drink (n=1)	Instant chocolate drink	Instant chocolate/fruit drink	Yoghurt drink Instant chocolate/fruit drink	Dairy-fruit drink Yoghurt drink Instant chocolate/fruit drink
<b>Soy products</b>	No fortification	No fortification (fortified products not consumed)	Soy-milk	Soy-milk	Soy milk
<b>Fats and oils</b>	Low-fat margarine (n=2)	Low-fat margarine	Low-fat margarines	Low-fat margarines	Low-fat and regular margarine

**Table 2.1 continued**

<b>Explanation by product group: Vitamin D</b>					
<b>Drinks</b>	No fortification	No fortification (fortified product not consumed)	Fruit drink	Fruit drinks Fruit juices	Fruits drinks Multi fruit juices Fruit lemonades
<b>Cereal products</b>	No fortification	Baby porridge	Baby porridge	Porridge Muesli Breakfast cereals (cornflakes)	Porridge Muesli Crueli Breakfast cereals (cornflakes)
<b>Dairy products</b>	No fortification	Fruit-flavoured yoghurt Children's dessert (cottage cheese)	Fruit-flavoured yoghurt Children's dessert (yoghurt or cottage cheese)	Fruit flavoured cottage cheese Children's desserts (yoghurt or cottage cheese) Fruit flavoured yoghurts	Yoghurt Cottage cheese Children's desserts (yoghurt or cottage cheese)
<b>Soy products</b>	Soy milk (substitution)	Soy milk	Soy milk	Soy milk	Soy milk

## 3 Results

### 3.1 Inventory and evaluation of food products

#### 3.1.1 *Folic acid fortified products*

139 folic acid fortified foods in 7 food groups were found in the inventory (**Table 3.1**). These foods were from 43 different brands. In the supermarket inventory, 54 folic acid fortified foods were found that were not found in the database inventory, mainly home brands but also new variants of fortified foods. 24 foods found in the database inventory were not or not anymore available in the supermarket. Largest amount of folic acid fortified foods (n=62) is in the food group 'cereal products'; all fortified foods in this group are breakfast cereals. The food group 'pastry and cookies' is second with 26 fortified foods; these foods are mainly cereal bars. The food groups 'drinks' and 'fats and oils' have 20 and 19 fortified foods, respectively. Compared to the *consumed* folic acid fortified foods during DNFCS-kids (2005-2006) the number of food groups containing folic acid fortified foods hardly changed. In the current situation there is one additional food group with folic acid fortified foods: soy products. On the other hand, the number of folic acid fortified foods in each food group did expand. It should be noted however, that the number of fortified foods in DNFCS-kids is not based on the actual number of fortified foods on the market 2005-2006, but on the consumed foods. One dairy product fortified with folic acid in 2005-2006 is currently not fortified anymore.

#### 3.1.2 *Vitamin D fortified products*

Our inventory identified four product groups containing 24 vitamin D fortified products in 2009 (**Table 3.2**): 'drinks' (1), 'cereal products' (9), 'dairy products' (13) and 'soy products' (1). Most vitamin D fortified foods were found in the database inventory or on manufacturer websites, only one product was additionally found in the supermarket inventory. Five foods (3 brands) found in the database inventory were not available (anymore) in the supermarket. Compared to the *consumed* vitamin D fortified foods during DNFCS-kids (2005-2006) the number of food groups containing vitamin D fortified foods increased from 1 to 4, the number of vitamin D fortified foods increased from 1 to 24 (excluding 'fats and oils'). However, it should be noted that the number of fortified foods in DNFCS-kids is not based on the market situation in 2005-2006, but on the consumed foods.

**Table 3.1 Inventory of folic acid fortified foods on the Dutch market in 2009 per food group and folic acid fortified foods consumed in DNFCs-kids (2005-2006)**

Food groups	# folic acid fortified foods (# brands) – 2009	Type of product - on market 2009	# folic acid fortified foods <u>consumed</u> in DNFCs-kids – 2005-2006 (# brands)	Type of product - consumed in DNFCs-kids
<i>Drinks</i>	20 (8)	Fruit soft drink Fruit drink Sports drink Sweetened water	1 (1)	Fruit soft drink
<i>Bread</i>	4 (2)	Bread cracottes	1 (1)	White bread
<i>Pastry and cookies</i>	26 (7)	Cereal bars Cereal snacks Nutritional biscuits	1 (1)	Cereal bar
<i>Cereal products</i>	62 (15)	Breakfast cereals (cornflakes) Baby porridge	20 (7)	Breakfast cereals (cornflakes)
<i>Dairy products</i>	6 (2)	Yoghurt drink Instant chocolate/fruit drink	3 (1)	Instant chocolate/fruit drink
<i>Soy products</i>	2 (1)	drink	0	
<i>Fats &amp; oils</i>	19 (8)	(low-fat) margarine	2 (2)	Low-fat margarine

### 3.1.3 Amounts of folic acid in fortified products

The amounts of folic acid available from the database inventory often deviated from the levels declared on the label. The level of folic acid declared on the label varied from 15-500 µg per 100g. Five products (bread and ‘pastry cookie’) did not have the level of folic acid declared on the label, and levels were provided by the manufacturers. The level of folic acid per 100 kcal, taking the levels declared on the label as being added synthetic folic acid, ranged from 3 – 267 µg/100 kcal. Thirty products had folic acid levels above the maximum of 100 µg per 100 kcal. Correction of the levels of folic acid declared on the label for estimates of natural folate present resulted in a range of 1 – 235 µg added folic acid per 100 kcal. After this correction 22 food products were left with folic acid levels above 100 µg per 100 kcal. There is an exception for ‘light’ food products (i.e. foods containing 30%

less energy than counterparts); these food products may contain similar folic acid levels as their energy dense counterparts. In the food group ‘fats and oils’ only low-fat margarines are fortified with folic acid, 9 have levels above 100 µg per 100 kcal. Low-fat margarines can be seen as light versions of margarine (containing 80% fat; about 720 kcal/100 g). In that case, the levels of folic acid fortification are below the legal maximum. The remaining food products with folic acid levels above the legal maximum belong to the food group ‘drinks’. Four of these drinks could be regarded as light-products with an easy to define energy-dense counterpart (i.e. exactly same food product) and contain folic acid levels below the legal maximum.

Ten other drinks, which cannot be regarded as light-products with an easy to define energy-dense counterpart (i.e. exactly the same food product was not available), contain folic acid levels of 155-235 µg per 100 kcal. A common energy dense soft drink (NEVO code 400) which has an energy content of 38 kcal/100 ml. Considering this energy content, six of the ten ‘drinks’ have folic acid levels below the legal maximum, three ‘drinks’ have folic acid levels just above the maximum level (105 µg / 100 kcal), one remains with too high folic acid levels.

Cereal products specifically for young children may contain at maximum 50 µg folic acid per 100 kcal ready-to-consume product (EC directive 96/5/EC), all cereal products for young children found in our inventory did have folic acid levels below this maximum (data not shown).

In summary, most of the folic acid fortified foods did contain folic acid levels at or below the legal maximum level of 100 µg per 100 kcal. Only one of the folic acid fortified foods contain folic acid levels way above the legal maximum level.

**Table 3.2 Inventory of vitamin D fortified foods on the Dutch market in 2009 per food group and vitamin D fortified foods consumed in DNFCS-kids (2005-2006)**

<b>Food groups</b>	<b># vitamin D fortified foods (# brands) 2009</b>	<b>Type of product on market 2009</b>	<b># vitamin D fortified foods consumed in DNFCS-kids 2005-2006</b>	<b>Type of product consumed in DNFCS-kids</b>
<i>Drinks</i>	1 (1)	Fruit drink	0	
<i>Cereal products*</i>	9 (1)	Porridge and special breakfast cereals	0	
<i>Dairy products</i>	13 (1)	Fruit flavoured cottage cheese and children’s desserts	0	
<i>Soy products*</i>	1 (1)	Milk substitute	1 (1)	Soy milk (substitution)

\*subject to exceptions to the general exemption law (see table 1)

### 3.1.4 Amounts of vitamin D in fortified products

The vitamin D level declared on the label varied from 0.1 to 16.5 µg per 100 grams or 100 ml. It is not clear what proportion of this amount is added to fortify the food product. The level of vitamin D ranged from 0.2 to 5.8 µg per 100 kcal. For two drinks containing vitamin D as an ingredient this could be regarded as restoration or substitution rather than fortification.

Four products had a vitamin D level above the legal maximum level of 4.5 µg per 100 kcal. One of these products (a drink) could be regarded as light product, and after correction for energy content, the legal maximum level was not exceeded anymore. It should be noted that this vitamin D fortified drink that was found in the supermarket in the first half of 2009 could not be detected on the website of the manufacturer or elsewhere in second half 2009. This product may be taken off the market. The other three food products with vitamin D levels (i.e. 4.8 µg per 100 kcal) above the legal maximum are breakfast cereals specifically for young children (aged 6, 8, or 12 months). The EU commission directive 2006/125/EG gives another legislation concerning 'simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids' aimed at young children with a maximum fortification level of 3 µg vitamin D per 100 kcal ready-to-consume product. This means that the amount vitamin D should be 3 µg/100 kcal or less in the porridge using the recipe on the label. In general, 20 grams of cereals will be combined with 200 ml follow-on formula, which results in about 3 µg per 100 kcal.

In summary, all vitamin D fortified foods available on the Dutch market have vitamin D levels at or below the legal maximum level of 4.5 µg per 100kcal.

## 3.2 Evaluation of intake: exceeding the tolerable upper intake level

### 3.2.1 Folic acid

During DNFCs-kids (2005-2006) 16-24% of the young children (grouped as boys 2-3 years, girls 2-3 years, boys 4-6 years and girls 4-6 years) consumed folic acid fortified foods (data not shown). Of these, 36-44% children used folic acid fortified foods and or folic acid containing food supplements. At the 95<sup>th</sup> percentile the habitual folic acid intake ranged from 14-27 µg per day for the different age-gender groups (**Table 3.3**). For the consumers of folic acid fortified foods the 95<sup>th</sup> percentile of intake was somewhat higher and ranged from 29-60 µg per day (**Annex A**). Including the use of food supplements, the habitual folic acid intake at the 95<sup>th</sup> percentile increased to 105-122 µg per day (**Table 3.3**) and 157-233 µg per day and for consumers only (**Annex A**). In general there are no large differences in intake between the four age-gender categories.

In the **first scenario**, representing the situation in 2009, the percentage of the young children consuming folic acid fortified foods increased to 37-49% and to 57-66% for the combination of fortified foods and food supplements (data not shown). The 95<sup>th</sup> percentile of habitual folic acid intake from food only increased little to 30-55 µg per day, see table 3.3 (when looking at consumers only, this is 40-72 µg/day; **annex A**). When also taking into account the folic acid intake from food supplements, the habitual intake increased to 117-132 µg per day (for consumers only this is 145-184 µg/day). Increasing the number of fortified foods in **scenario 2-4** resulted in a proportion of the young children consuming folic acid fortified foods of about 90% in scenario 2 'all brand' to 100% in scenario 3 and 4 (data not shown). In the second scenario, 'all brand', the 95<sup>th</sup> percentile of habitual folic acid intake from foods ranged from 88-106 µg/day (when including food supplements this is 150-198 µg/day). In the 'all food groups' scenario (scenario 3) the habitual intake from foods increased to 176-204 µg/day at the 95<sup>th</sup> percentile (when including food supplements this is 245-260 µg/day). The habitual folic acid intake from foods further increased to 221-254 µg/day at the 95<sup>th</sup> percentile in the fourth scenario, 'similar food groups', (when including food supplements this is 289-316 µg/day).

The folic acid intake from *food supplements only* at the 95<sup>th</sup> percentile was 100 µg/day for girls 2-3 years old, 200 µg/day for boys 2-3 years old, and 100 µg/day for children 4-6 years old. These results represent the mean intake over 2 days (as it was not possible to estimate habitual folic acid intake from food supplements only) and therefore are somewhat overestimated.

During DNFCs-kids (2005-2006) the habitual *food* folic acid intake of young children (2-6 yr) did not exceed the UL (**Figure 3.1**). Also in scenario 1, '2009', and scenario 2, 'all brand', the UL was not exceeded. In the 'all food groups' scenario (scenario 3) 3-4% of the children aged 2-3 years exceeded the UL (i.e. 200 µg/d), in the group with older children (4-6 yr) there was no exceeding of the UL (i.e. 300 µg/d). In the scenario with the highest amount of fortified foods (scenario 4) the UL was exceeded by about 10% of the children aged 2-3 years and by about 1% of the children aged 4-6 years. When the use of folic acid containing *food supplements* was taken into account, a proportion of the Dutch young children exceeded the UL in all scenarios including the reference situation of DNFCs-kids (2005-2006). In the reference situation, up to 2% of the children in the different age-gender groups exceeds the UL. In scenario 1 and 2, this proportion increased up to 5%. In the third scenario, 'all food groups', 10-12% of the children aged 2-3 years and about 1-3% of the children aged 4-6 years had habitual total folic acid intakes above the UL. In scenario 4, 'similar food groups', these proportions increased to about 20% and about 5%, respectively.

In summary, children 4-6 years old are not at risk of too high folic acid intakes in the current situation (scenario 1 and 2 are most realistic). For the children 2-3 years old, the habitual folic acid intake from *foods* only does not exceed the UL in the current situation. However, the folic acid intake from food

supplements is high in this age group compared to the age-specific UL. The combined intake from food and food supplements results in up to 5% of the young children exceeding the UL in the scenarios for the current situation.

### 3.2.2 Vitamin D

During DNFCs-kids vitamin D fortified foods were not available on the Dutch market except for spreadable fats, baking products etc. The 95<sup>th</sup> percentile of habitual food vitamin D intake ranged from 3.0-3.7 µg/day for the different age-gender groups (**Table 3.4**), which is very similar. When including the use of food supplements, the habitual intake was higher and ranged from 4.9-10.0 µg/day. The vitamin D intake from food and food supplements was higher for the youngest children (2-3 yr) compared to the children aged 4-6 years. Parents in the Netherlands are advised to give their children a daily food supplement of vitamin D in addition to a healthy diet until they are 4 years old. In 2005-2006, the advised amount was 5 µg vitamin D. Recently this advice was revised and the amount was increased to 10 µg/day [18].

In the **first scenario** representing the situation in 2009 the 95<sup>th</sup> percentile of habitual vitamin D intake from food only increased a little to 3.3-4.1 µg per day (**Table 3.4**). The main increase was observed for the children aged 2-3 years old. When also taking into account the vitamin D intake from food supplements, the habitual intake increased to 5.2-10.6 µg per day. Increasing the number of fortified foods in **scenario 2**, 'all brand', resulted in very similar intake compared to scenario 1: 3.4-4.3 µg/day from food only and 5.2-10.6 µg/day from both food and food supplements. In the 'all food groups' scenario (**scenario 3**) the habitual intake from foods increased more to 5.2-6.3 µg/day at the 95<sup>th</sup> percentile (including food supplements: 7.0-12.8 µg/day). The habitual vitamin D intake from foods further increased to 6.0-7.3 µg/day at the 95<sup>th</sup> percentile in the **fourth scenario**, 'similar food groups', (including food supplements: 7.7-13.6 µg/day).

The vitamin D intake from *food supplements only* at the 95<sup>th</sup> percentile was 9 µg/day for children 2-3 years old and 3.1 µg/day for children 4-6 years old. These results represent the mean intake over 2 days (as it was not possible to estimate habitual vitamin D intake from food supplements only), and therefore are somewhat overestimated.

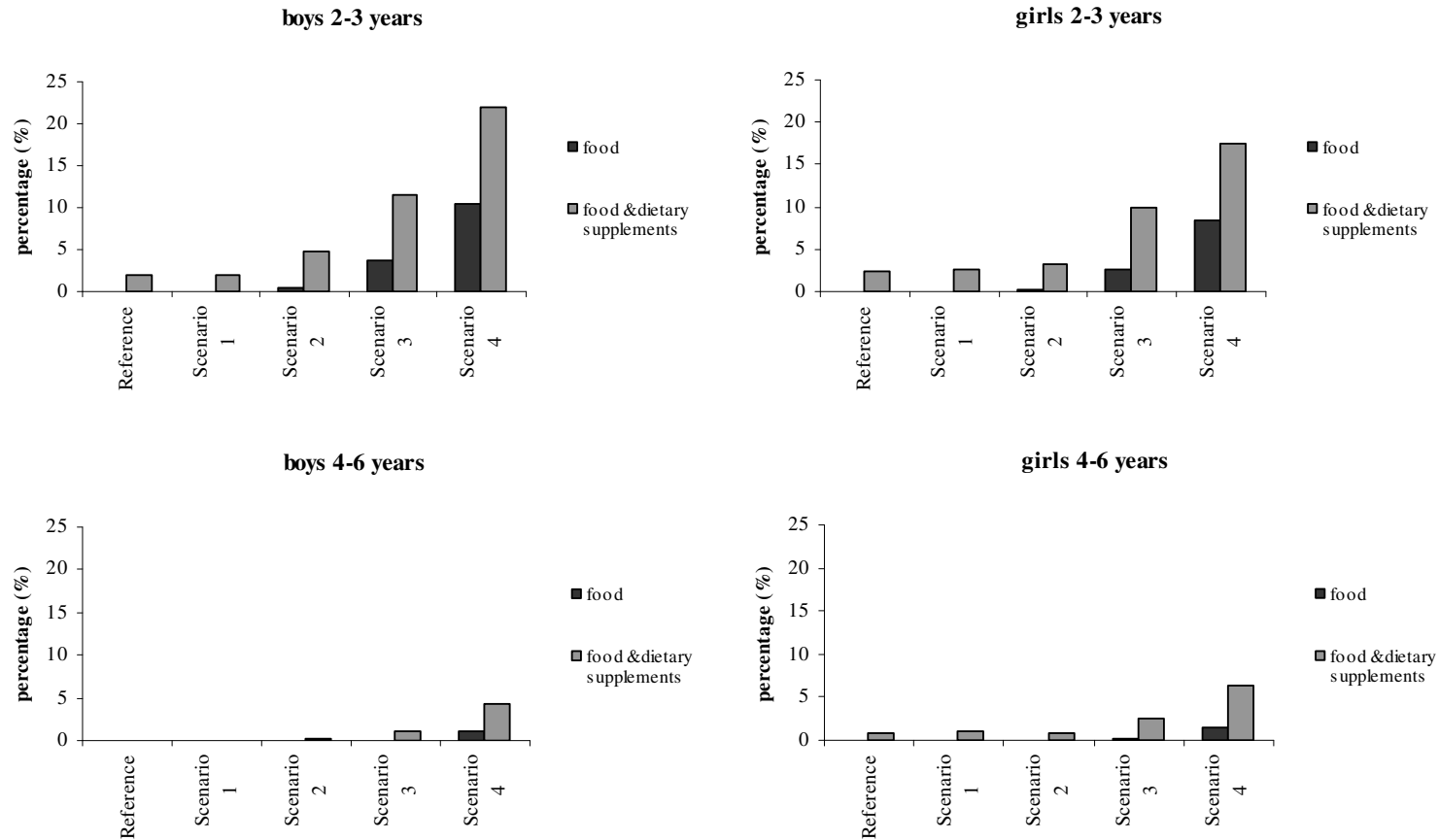
For vitamin D the EFSA and the Health Council of the Netherlands have set different ULs. The UL set by the Health Council of the Netherlands is 50 µg/day [19], the UL set by EFSA is 25 µg/day [7] for children aged 2-6 years old. Comparison of the habitual vitamin D intake with the UL set by EFSA, the lowest value, showed that neither in the reference situation nor in one of the scenarios the habitual intake exceeded the UL.

**Table 3.3** Habitual folic acid intake from food or food and food supplements for Dutch children (2-6 yr)\*

Age category	Source	Reference			Scenario 1			Scenario 2			Scenario 3			Scenario 4		
		P50	P75	P95	P50	P75	P95	P50	P75	P95	P50	P75	P95	P50	P75	P95
boys 2-3 yr	food	0	0	14	0	7	30	26	51	106	75	112	186	111	155	235
	food & supplements	0	28	122	8	36	117	40	82	198	92	145	259	132	190	304
girls 2-3 yr	food	0	0	27	0	14	55	24	48	101	78	112	176	113	152	221
	food & supplements†	0	22	110	5	37	129	32	68	165	89	137	246	125	176	289
boys 4-6 yr	food	0	0	23	0	17	52	32	55	98	100	140	204	141	187	254
	food & supplements	0	33	105	11	44	119	45	79	150	117	166	245	159	212	293
girls 4-6 yr	food	0	0	25	0	11	43	31	54	88	92	128	193	135	177	249
	food & supplements	0	30	107	6	42	132	44	78	167	108	159	260	150	205	316

\* UL for children 2-3 yr old is 200 µg/day, for children 4-6 yr old 300 µg/day[7]

† reference results CSIDE type 1 error rate A-D test = 0.01 (default = 0.15)



**Figure 3.1** Percentage of Dutch children (2-6 yr) with habitual folic acid intake from food or food and food supplements above the UL for different scenarios of folic acid fortification.

**Table 3.4** Habitual vitamin D intake from food and food supplements for Dutch children (2-6 yr)\*

Age category	Source	Reference			Scenario 1			Scenario 2			Scenario 3			Scenario 4		
		<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>
boys 2-3 yr	food	1.8	2.2	3.0	2.1	2.7	4.1	2.1	2.9	4.3	3.1	4.2	6.2	3.7	4.8	6.9
	food & supplements	3.9	6.2	8.7	4.3	6.6	9.4	4.4	6.7	9.6	5.5	7.8	11.3	6.1	8.3	12.0
girls 2-3 yr	food	1.7	2.2	3.3	2.0	2.7	4.1	2.1	2.8	4.2	3.0	4.1	6.3	3.6	4.9	7.3
	food & supplements	4.4	6.7	10.0	4.7	7.0	10.6	4.8	7.1	10.6	5.7	8.2	12.8	6.3	8.8	13.6
boys 4-6 yr	food	2.1	2.6	3.7	2.2	2.9	4.0	2.3	2.9	4.0	3.3	4.3	6.1	4.0	5.1	6.9
	food & supplements	2.6	3.7	6.2	2.8	3.9	6.5	2.8	3.9	6.5	3.9	5.4	8.2	4.6	6.2	9.1
girls 4-6 yr	food	1.9	2.3	3.0	2.0	2.5	3.3	2.0	2.5	3.4	3.0	3.8	5.2	3.6	4.5	6.0
	food & supplements	2.3	3.1	4.9	2.4	3.3	5.2	2.4	3.3	5.2	3.4	4.6	7.0	4.1	5.4	7.7

\* UL for children is set at 50 µg/day by Dutch Health Council [19] and at 25 µg/day by EFSA[7]

### 3.3 Evaluation of model assumptions: comparing old and new values

#### 3.3.1 *Habitual energy intake*

The 95<sup>th</sup> percentile of habitual energy intake calculated from DNFCS-kids was for children 2-3 years old 1725 kcal/day for girls and 1814 kcal/day for boys and for children 4-6 years old 1891 kcal/day for girls and 1977 kcal/day for boys. This is in the same order of magnitude as the 95<sup>th</sup> percentile of habitual energy intake used in the calculation model (based on data from DNFCS-3 (1997-1998)); for children 1-3 years old 1890 kcal/day and for children 4-6 years old 1995 kcal/day (girls and boys together). The differences can partly be explained by the difference in age group and by difference in methodology collecting the data among the surveys.

#### 3.3.2 *Folic acid-specific values and recalculation*

##### 3.3.2.1 *Model parameters for folic acid*

In the UL only synthetic folic acid is taken into account and not dietary folate, therefore dietary folate is not taken into account in the calculation model. Synthetic folic acid is naturally not present in the diet.

Based on DNFCS-kids, the 95<sup>th</sup> percentile of folic acid intake from food supplements is 106-135 µg per day (205-264 µg per day for food supplement users only) (**Table 3.2**). In the calculation model this intake was estimated at 300 µg per day, based on research from 2002 among toddlers [9] and levels of folic acid in food supplements specific for children available on the Dutch market [17]. This seems an overestimation. Taking into account some margin because of the relatively small number of users of food supplements, an amount of 150 µg seems a more realistic value.

It was assumed that up to 10% of the total energy intake would be consumed as folic acid fortified foods. In the reference situation (DNFCS-kids (2005-2006)), although folic acid fortification was not legal, several folic acid fortified foods were on the market. < 1% of the children had a proportion of the energy intake above 10%. In scenario 1 '2009' this increased to 0.8-5%, in scenario 2 'all brand' to 4-10%, in scenario 3 'all food groups' to 49-57%, and in scenario 4 'similar food groups' to almost 100%. These results show that a fraction of 10% of the energy intake that will be consumed as folic acid fortified foods is currently occurring among young children (scenario 1 and 2 are most realistic for the current situation). With an increasing market more children will exceed this fraction of 10% and reconsideration of this fraction will be advised. Taking a fraction of 15%, that was originally applied in the calculation model, resulted in somewhat smaller percentage of the children exceeding this fraction:

reference  $\leq 1\%$ , scenario 1 '2009'  $\leq 2\%$ , scenario 2 'all brand' 0.7-4%, scenario 3 'all food groups' 23-30%, and scenario 4 'similar food groups' 97-98%. In conclusion, the fraction of 10% seems somewhat conservative for the current situation; a fraction of 15% seems a better estimate for the current situation as most children have currently intakes below this fraction.

### 3.3.2.2 *Recalculation of the maximum fortification level for folic acid*

Recalculation of the maximum fortification levels using the above described data results in a maximum fortification level of 28  $\mu\text{g}$  per 100 kcal for children 2-3 yr and about 76  $\mu\text{g}$  per 100 kcal for children 4-6 yr (intake from food supplements 150  $\mu\text{g}$ , fraction 10%). Taking a fraction of 15%, the maximum fortification level becomes lower to about 20  $\mu\text{g}$  per 100 kcal for children 2-3 yr and about 50  $\mu\text{g}$  per 100 kcal for children 4-6 yr. In both situations the recalculated maximum fortification level is higher than the level estimated earlier [4], however still below the currently legal maximum level of 100  $\mu\text{g}$  per 100 kcal, which is based on data of adults only.

### 3.3.3 *Vitamin D-specific values and recalculation*

#### 3.3.3.1 *Model parameters for vitamin D*

Based on DNFCS-kids, the 95<sup>th</sup> percentile of habitual vitamin D intake from background diet (including vitamin D added to spreadable fats and baking fats) ranged from 3.0 to 3.7  $\mu\text{g}$  per day. This is lower than the 95<sup>th</sup> percentile of habitual vitamin D intake used in the calculation model: 4.8  $\mu\text{g}/\text{day}$  for children 1-3 yr and 4.4  $\mu\text{g}$  per day for children 4-10 yr. Similar as for habitual energy intake, the differences can partly be explained by the difference in age group and by difference in methodology collecting the data among the surveys.

In this model the 95<sup>th</sup> percentile of vitamin D intake from food supplements was estimated to be 10  $\mu\text{g}$ , based on research from 2002 among toddlers [9] and levels of vitamin D in food supplements specific for children available on the Dutch market [17] an amount of 10  $\mu\text{g}$  seems indeed a realistic value for children 2-3 years old. For the older children (4-6 yr) a lower estimate of about 5  $\mu\text{g}$  might be more realistic.

It was assumed that up to 10% of the total energy intake would be consumed as vitamin D fortified foods (excluding spreadable fats and baking fats). In the reference situation (DNFCS-kids (2005-2006)), vitamin D fortification was not legal and also not applied. In scenario 1 '2009'  $< 1\%$  of the children had a proportion of the energy intake from vitamin D fortified foods above the fraction of 10%. In scenario 2 'all brand' this increased to almost 2%, in scenario 3 'all food groups' to 3-10% and in scenario 4 'similar food groups' to 8-23%. For the current situation (scenario 1 and 2 are most

realistic) a fraction of 10% seems adequate, however when the market will increase a little higher fraction should be considered. Taking a fraction of 15%, in scenario 4 'similar food groups' < 5% of the children had a proportion of the energy intake from vitamin D fortified foods above 15%. The proportion of the children exceeding the fraction is higher for the youngest age group, this might be due to the fortification of breakfast cereals specific for these young children, and although these products have their own legislation, they were taken into account in these calculations.

### *3.3.3.2 Recalculation of the maximum fortification level for vitamin D*

Recalculation of the maximum fortification level 6.4-7.0 µg per 100 kcal is calculated with the model for children 2-3 years old, and 8.6 µg/100kcal for children 4-6 yr old. Both values are higher than the currently legal maximum level of 4.5 µg per 100 kcal. It should be noted that the age groups used for this recalculation are different from the age groups used in the model setting the maximum levels, new consumption data of children aged 7-10 years old are not available yet. These results indicate that the maximum level of 4.5 µg per 100 kcal [4] seems conservative, however the proportion of energy intake from vitamin D fortified foods (excluding spreadable fats and baking fats) of 10% might be rather low with increasing market. Taking a proportion of energy intake from vitamin D fortified foods of 15%, instead of 10%, the recalculated maximum level is 4.3-4.6 µg/100 kcal for children 2-3 years old and 5.7 µg/100 kcal for children 4-6 years old. The result is a similar maximum fortification level.

## **4 Discussion**

### **4.1 Product inventory**

The results of our inventory show that the market of folic acid and vitamin D fortified foods increased since the new legislation [2]. Unfortunately, an up-to-date database of fortified foods, including the fortification levels, on the Dutch market is not available. Lack of these data makes it difficult to evaluate the legislation on the exemption of fortification with folic acid and vitamin D. In the current evaluation study, several incomplete databases were searched for folic acid and vitamin D fortified foods. In these databases mainly the recently launched fortified foods and home brands were missing. To fill this gap, an additional supermarket inventory was conducted. Such a supermarket inventory is very time-consuming and labour-intensive. Therefore we limited our supermarket inventory mainly to the supermarkets with the highest market shares and we visited only one store per supermarket chain. In addition, we restricted the supermarket inventory to the product groups in which folic acid or vitamin D fortified foods were identified in the database search. These limitations may have resulted in an incomplete overview of folic acid and vitamin D fortified foods on the Dutch market. Although we might have missed some food groups or specific foods, as we have searched in three independent databases and did visit the main supermarkets, we do think that we have identified the main food groups containing folic acid or vitamin D fortified foods.

Based on our experience we would recommend having an up-to-date database on fortified foods and food supplements available on the Dutch market. The food database is currently under development by the National Institute of Public Health and the Environment (RIVM) and the Nutrition Centre. It will be filled with product information from the manufacturers and might be a helpful instrument for monitoring.

### **4.2 Food consumption and composition data**

In this evaluation study we used data of the Dutch National Food Consumption Survey among young children. These data were collected in 2005-2006 in the period before the change of the legislation on fortification with folic acid and vitamin D [2]. It was therefore not possible to directly evaluate the model assumptions and proportion of children exceeding the UL. We therefore had to define several scenarios of potential situations of fortification. The results of the inventory were the basis of the definition of the scenarios. Although none of the scenarios will exactly represent the current market situation, the first and second scenarios are thought to be most close to this situation. The third and

fourth scenario present the situation of a continuing increase in folic acid or vitamin D fortified foods in similar type of foods as currently fortified. These scenarios did not take into account the situation in which the type of food products fortified will change. With data of new DNFCs, e.g. DNFCs-basic that is currently conducted, it will be possible to evaluate this legislation more directly.

The estimated proportion of children exceeding the UL as well as the habitual intakes are based on a sample of young children from the Dutch population. This sample is considered representative (if weighted) for the Dutch population of young children (excluding children of non-Dutch speaking parents/caretakers) on age, gender, education level of household head, region of residence, population density and season. However, this is no guarantee that the study population is representative for e.g. lifestyle factors.

The food composition database had a small number of NEVO-codes with missing data for vitamin D or folate levels. We assumed these values to be zero. This might have resulted in a small underestimation of total vitamin D intake and an overestimation of the fraction added as folic acid. However, the data were complete for the most important sources of these micronutrients, indicating that the respective underestimation and overestimation is low. We believe that the current calculations do give a good picture of the intake and the potential risk of exceeding the UL. We did not chemically analyse foods to obtain the folic acid or vitamin D levels, but used data declared on the label or provided by manufacturers. In general, no information on possible overages was available. When overages are applied in fortification, depending on the decline of the micronutrient over time, the declared amounts will be an underestimation of the true amounts.

The amount of micronutrients presented on the label is the total amount in the food. The level of micronutrient naturally present and the level added with fortification can not be distinguished. Especially for folic acid this was difficult as the legislation [2] is based on folic acid only. Based on manufacturers information we assumed that the amount declared on the label is the sum of natural folate and added folic acid without correction for differences in bioavailability. We estimated the level of folate from the folate levels presented in NEVO for similar foods. This assumption might cause an over- or underestimation of the added folic acid; however the order of magnitude will be correct. It is recommended that when the amount of folate is declared on the label, it is also stated how much of this total folate consists of folic acid. Especially as the UL is also only based on folic acid.

### 4.3 Food supplements

In this evaluation study we did take into account the micronutrient intake from food supplements. We used the food supplement composition data of 2005-2006 and did not check whether this composition changed in 2009.

For folic acid the intake from food supplements was above the UL in part of the young children (2-3 yr). It is not known if this is due to the intake of multiple food supplements and/or to the use of dietary supplements containing folic acid levels not suitable for children of this age. For 2010 it is planned to study the micronutrient intake from food supplements in more detail.

Based on DNFCS-kids we estimated the vitamin D intake from food supplements. In 2005-2006 it was recommended for children up to 4 years old to daily use a food supplement containing 5 µg vitamin D. Recently the Health Council of the Netherlands revised this recommendation and increased the amount to 10 µg vitamin D per day. The vitamin D intake from dietary supplements might therefore be an underestimation of the actual situation. When the vitamin D intake will be higher the maximum fortification level will decrease.

#### 4.4 Maximum fortification levels

For the comparison the actual fortification levels and the set maximum fortification levels the exemption for light food products had to be taken into account. In the current legislation the description of the demands of similarity between a light-food product and the energy dense counterpart are vague. On what level is similarity required? Is a general soft drink a counterpart of a sports drink or water-like drink or is more similarity needed? If we make the comparison using very strict guidelines for similarity (exact same food), ten foods in the product group 'drinks' had folic acid levels above the legal maximum level. However, applying less strict guidelines for similarity (i.e. general product group) only one of these drinks remained to have folic acid levels way above the legal maximum (three drinks had folic acid levels slightly above the maximum level). This shows that the proportion of foods with too high fortification levels depends on the applied guidelines for similarity in the comparison of light food products with energy dense counterparts.

The currently legal maximum fortification levels for folic acid and vitamin D are calculated with a calculation model using several assumptions and input data based on DNFCS-3 (1997-1998) [8]. Using the data of DNFCS-kids and the results of the inventory, we evaluated these assumptions. DNFCS-kids and DNFCS-3 are conducted with different methodology and therefore differences in outcome are not only caused by differences in dietary pattern over years.

The habitual energy and vitamin D intake was somewhat lower in DNFCS-kids, however in the same order of magnitude as estimated from DNFCS-3.

The model assumption of the 95<sup>th</sup> percentile of folic acid intake from food supplements was overestimated. Based on the intakes observed in DNFCS-kids, lower levels seem more valid. For vitamin D, the intake from food supplements seem overestimated for children aged 4-6 years. However, due to the recent change in the recommendation of daily use of a food supplement containing higher

vitamin D levels, the vitamin D intake as estimated with data of DNFCs-kids might be an underestimation, especially for the young children (2-3 yr). In addition, the fraction of the energy intake that may and will be fortified was estimated at 10% in the calculation model [4]. Based on the results of our scenario calculations, this 10% seems rather conservative for folic acid and borderline accurate for vitamin D. This shows that it is difficult to make accurate assumptions on input data for the model if actual data is missing or poor. It is important to evaluate such input data regularly with the newest data available, to keep the maximum fortification levels indeed safe for virtual the whole population.

## 4.5 The tolerable upper intake level

The UL for folic acid for children is extrapolated from adults. For adults this UL is based on the masking of vitamin B<sub>12</sub>-deficiency. When medics are aware that not only the haematological picture has to be taken into consideration diagnosing vitamin B<sub>12</sub>-deficiency, but also the actual measurement of vitamin B<sub>12</sub> status this risk will diminish. Furthermore, vitamin B<sub>12</sub>-deficiency is mainly a problem of the elderly [7]. Other potential harmful effects, like the risk of exacerbation of existing cancer, might be more relevant in setting the UL [5,6,20,21]. However, it was not possible to set the UL for folic acid based on other end points [7]. As soon as it is possible to take these other end points into account, the UL for folic acid should be revised, especially for children.

For vitamin D there are two different ULs for children which are set based on the same scientific data. The Health Council of the Netherlands set an UL of 50 µg per day [19], the EFSA of 25 µg per day [7]. In our study we used the lowest UL as cut-off point in the calculations. With this low level we did not observe a risk of exceeding the UL. Although for our study the results did not change applying one or the other value, if the model calculating the maximum fortification level the UL set by the Health Council of the Netherlands was used [19]. Applying the UL set by EFSA, the maximum fortification level will be much lower (more than half). For these calculations it is important that ULs are set accurately. It is noted that for a similar population and based on same scientific data, the resulting UL values are not similar. However, the EU is more and more using the EFSA values.

## 4.6 EU legislation

Recently, within the EU two legislations concerning fortified foods (EC 1925/2006) and food supplements (2002/46/EC) became into force. These legislations regulate what micronutrients (and in what chemical form) may be applied in food supplementation or fortification (EC 1170/2009), as well as the minimum and maximum levels that may be applied. The actual maximum (and minimum) levels

are still under discussion. Models similar to our calculation model are proposed to calculate the maximum amounts of micronutrients that may be applied in food supplements or fortified foods. This evaluation shows that the used calculation model is accurate in setting a maximum fortification level given certain level of intake from dietary supplements. The calculation model is precautionary by the fact that the calculation is based on the combination of a high energy intake and high micronutrient intake from other sources than fortified foods. However, it is a risk manager's choice how safe such a calculation model should be: should it protect virtually the whole population or is some risk of too high intakes accepted?

In the EU-legislation both the maximum levels of food supplements and fortification have to be set. This is a different situation than in the Netherlands where maximum fortification levels were set given certain level of intake from food supplements. However our calculation model can be used to calculate maximum levels for food supplements given certain level of intake from fortification. Varying the given intake from food supplements or food fortification will result in a figure showing what maximum fortification level can be applied together with what maximum level in food supplements (the 'Gubbio principle'). The distribution of the level of micronutrient that may be applied in food supplements or in fortified foods cannot be defined scientifically and should be a policy (risk manager) decision. This distribution over fortified foods and food supplements should be decided by the risk manager *prior to* establishing maximum levels for fortification and the maximum amounts in supplements, in order to avoid potentially too high intakes from combined intake of fortified foods and food supplements. The maximum levels in food supplements and fortification should be valid for whole EU, country specific information on dietary intake and current fortification habits are needed. Furthermore, due to differences in recommended intakes and ULs between ages, such maximum levels should be set taking into account data of all ages.

## 5 Recommendations

Continuous monitoring of the fortification and supplementation market is recommended to follow the development of the market and the intakes in the Dutch population. Furthermore, due to changes in the market the model parameters may become outdated and the current maximum fortification level might become too liberal. To prevent too high intakes and potential harmful health effects, the maximum fortification levels should be revised with increased voluntary fortification and when mandatory fortification or policy regulated fortifications change. In addition, the distribution of the level of micronutrient that may be applied in food supplements or in fortified foods should be decided by the risk manager *prior to* establishing maximum levels for fortification and the maximum amount in food supplements.

As children have high folic acid intakes from food supplements, it is recommended to set age-specific maximum levels for folic acid, but also for other micronutrients. Information of the label information should be accurate whether or not a food supplement is suitable for a specific age. Within the EU-regulation (2002/46/EC) this should be taken into account.

To make evaluation of the exemption legislation less time-consuming and labour-intensive, but more important more complete, it is recommended to develop a database with all fortified foods and food supplements available on the Dutch market including details on fortification level. Such a database should be up-dated with the newest manufacturers' information regularly. The Food database of the National Institute for Public Health and the Environment and the Nutrition centre could be useful.

It is difficult to determine which foods may actual be seen as light food products and what is the energy dense counterpart. This is especially true for potential light food products with no existing energy dense counter part that is exactly the same except for energy content. It is recommended to make more clear how similar a potential light food product and its energy dense counterpart should be in order to fortify with the same fortification level.

It is advised to repeat the evaluation of this legislation on the general exemption to fortify with folic acid and vitamin D in several years. This new evaluation will provide insight whether the amount of fortified foods available on the Dutch market has changed and whether under this new circumstances the Dutch population might be at risk of too high intake levels and the input data of the calculation model and the set maximum fortification levels are still adequate.

## **6 Conclusions**

Based on the results of our inventory, the number of folic acid or vitamin D fortified foods available on the Dutch market increased after the introduction of the new legislation. However, the number of food groups with folic acid or vitamin D fortified foods is still limited. Almost all foods in the inventory had fortification levels below the legal maximum level. It is however difficult to determine what food products are light and compared to what energy dense counterpart.

Based on data from DNFCS-kids, folic acid intake from food supplements is high. Especially among children aged 2-3 years old, intake levels above the UL by food supplements only are observed.

Based on scenario calculations using DNFCS-kids and results from the inventory, currently there seems to be no risk regarding too high folic acid or vitamin D intakes in young children. Only a small proportion (<5%) of the Dutch children currently has folic acid intakes above the UL. When the observed trend of increased number of foods being fortified in similar food groups will continue, especially young children (2-3 yr) will have a risk of too high folic acid intakes; in that case a chance of harmful health effects can not be ruled out. Vitamin D intakes do not exceed the UL in any of the scenarios.

With current fortification practices, the by the calculation model calculate the maximum fortification levels are accurate for young children in the Netherlands. With changing fortification practices, but also changing dietary patterns, the model parameters need to be regularly evaluated and when needed updated.

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# Annex A

**Table A.1** Habitual folic acid intake from food or food and food supplements for Dutch children – consumers only

age category	source	Reference			Scenario 1			Scenario 2			Scenario 3			Scenario 4		
		<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>	<i>P50</i>	<i>P75</i>	<i>P95</i>
boys 2-3 yr	food	10	16	29	8	18	40	33	55	111	75	112	186	111	155	235
	food & supplements	34	69	189	24	55	149	44	86	203	92	145	259	132	190	304
girls 2-3 yr	food	17	32	60	15	34	72	28	51	104	78	112	176	113	152	221
	food & supplements†	38	64	233	28	57	179	34	71	169	89	137	246	125	176	289
boys 4-6 yr	food	13	21	38	18	33	69	34	57	99	100	140	204	141	187	254
	food & supplements	40	67	157	34	62	145	45	79	151	117	166	245	159	212	293
girls 4-6 yr	food	13	24	48	18	32	58	35	57	90	92	128	193	135	177	249
	food & supplements	36	62	168	36	67	184	47	80	169	108	159	260	150	205	316

\* UL for children 2-3 yr old is 200 µg/day, for children 4-6 yr old 300 µg/day[7]

† reference results CSIDE type 1 error rate A-D test = 0.01 (default = 0.15)