Vitamin Supplement

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Evaluation of the Dutch general exemption level for voluntary fortification with folic acid

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Abstract

Introduction: Fortification with folic acid was prohibited in the Netherlands. Since 2007, a general exemption is given to fortify with folic acid up until a maximum level of 100 μg/100 kcal. This maximum level was based on a calculation model and data of adults only. The model requires parameters on intake (diet, supplements, energy) and on the proportion of energy that may be fortified. This study aimed to evaluate the model parameters considering the changing fortification market. In addition, the risk of young children exceeding the UL for folic acid was studied.

Methods: Folic acid fortified foods present on the Dutch market were identified in product databases and by a supermarket inventory. Together with data of the Dutch National Consumption Survey-Young Children (2005/2006) these inventory results were used to re-estimate the model parameters. Habitual folic acid intake of young children was estimated and compared to the UL for several realistic fortification scenarios.

Results: Folic acid fortified foods were identified in seven different food groups. In up to 10% of the population, the proportion of energy intake of folic acid fortified foods exceeded 10% – the original model parameter. The folic acid intake from food supplements was about 100 μg/day, which is lower than the intake assumed as the original model parameter (300 μg). In the scenarios representing the current market situation, a small proportion (<5%) of the children exceeded the UL.

Conclusion: The maximum fortification level of 100 μg/100 kcal is sufficiently protective for children in the current market situation. In the precautionary model to estimate the maximum fortification levels, subjects with high intakes of folic acid from food and supplements, and high energy intakes are protected from too high folic acid intakes. Combinations of high intakes are low in this population. The maximum levels should be monitored and revised with increasing fortification and supplementation practices.

Keywords: *folic acid*; *voluntary fortification*; *maximum safe fortification levels*; *evaluation*; *Dutch fortification policy*

Fortification of foods with micronutrients should be safe for the whole population; hence, unacceptable high intakes from all sources (i.e. basic foods, fortified foods, and food supplements) should be prevented. Due to a small range between the recommended daily intakes and tolerable upper intake levels (ULs) in combination with a lack of proof of nutritional need, fortification (other than substitution or restoration) with vitamin A, vitamin D, folic acid, selenium, copper, and zinc is prohibited in the Netherlands (1). In 2004, the European Court of Justice decided that this prohibition of fortification contradicted the fundamental principle of 'free movement of goods' in the Treaty Establishing the European Community (2). Food fortification with these micronutrients may only be prohibited if there is harm to public health. This resulted in a more flexible handling of requests of exemption from the Dutch Commodity Act in order to fortify (3).

In 2007, a general exemption was granted for food fortification with folic acid or vitamin D up until a certain maximum fortification level (4). For folic acid, the maximum allowed fortification level is 100 μg per 100 kcal. In the case of light-food products (low-energy products), the same fortification level is approved as for their energy dense counterparts. In the Netherlands, a model was used to calculate the maximum safe fortification levels (MSFL)

from which the risk manager derived the maximum allowed fortification level (AFL) (5). Several input parameters are required for this model: micronutrient intake of diet and food supplements, energy intake, and the proportion of the energy intake that can and will be fortified. The intake parameters were estimated based on data of the Dutch National Food Consumption Surveys. However, intake data of food supplements were scarce and assumptions had to be made. In addition, the proportion of energy that can and will be fortified was a best educated guess based on knowledge of the Dutch dietary pattern and expected fortification practices. In deriving the AFL of folic acid from the MSFL, data on children were not taken into account because the risk-manager considered that exceeding the UL for children (extrapolated from adults based on masking of vitamin B12-deficiency) is a low risk (5).

To warrant safety of the Dutch population, the general exemption has to be evaluated regularly. The AFL might need revision when changes in the model input parameters occur, for instance due to changing dietary pattern or changes in supply of fortified foods. The aim of the present study was to evaluate the Dutch general exemption level for voluntary folic acid fortification 2 years after it came into force. For the evaluation, an inventory of the current market situation of folic acid fortified foods was made. The model parameters and MSFLs were re-estimated and evaluated using data of the Dutch Food Consumption Survey-Young Children 2005/2006 (DNFCS-children) (6) and the results of the market inventory. This article concludes with considerations whether the currently legal maximum allowed fortification level seems to warrant safe intakes in Dutch young children.

Methods

Inventory of folic acid fortified foods

Folic acid fortified foods available on the Dutch market in early 2009 (February–April) were searched for. In the Netherlands, there is no complete central registration of fortified foods available on or introduced to the consumer market. Therefore, the inventory on folic acid fortified foods started by screening three food databases: (1) the Dutch Food Composition Database (NEVO) (7) extended with additional food product data for recent and ongoing Dutch National Food Consumption Surveys, (2) Innova database (commercial food database) (www.innovadatabase.com), and (3) Compendium dietary products and food supplements (www.dieetconsult.nl). Unfortunately, the databases were incomplete, in particular, foods recently launched, foods recently reformulated, and home brand products were missing. To complete the inventory as much as possible, a supplementary supermarket inventory was conducted (March–April 2009). This supermarket inventory was limited to the food groups containing folic acid fortified foods identified in the database search. Eight supermarket chains with the highest Dutch market shares (www.distrifood.nl) were visited, as well as two supermarkets with relatively high contribution of foods in the DNFCS-children and two supermarkets with a low market share.

Of all folic acid fortified foods, data were collected on product name, brand name, folic acid content, and energy content. Missing data were completed by searching for information on manufacturer websites or contact with manufacturers. All data were collected based on information provided on the label or by manufacturers; no chemical food analyses were conducted. The folic acid content of the fortified foods was compared with the currently permitted maximum levels of the 2007 general exemption (4).

Evaluation of model parameters

All model input parameters were re-estimated using data of DNFCS-children (6) and the results of the inventory for folic acid fortified foods available in the Netherlands. The model input parameters are: the 95th percentile (P_{95}) of habitual energy intake (EI_{95}), the P_{95} of the habitual folic acid intake from the background diet (CI_{95}), the P_{95} of folic acid intake from food supplements, and the proportion of the energy intake that can and will be fortified (PFFn). All analyses were performed with SAS 9.2 (SAS Institute Inc., Cary, NC, USA) unless otherwise stated.

P_{95} of habitual energy intake (EI_{95})

Data of DNFCS-children 2005/2006 among 1,279 children aged 2–6 years old (6) were used. Consumption data were collected by means of two food records on independent days (8–13 days in between). The food records were filled in pre-structured diaries by the care taker of the children. To calculate energy intake, data on food consumption was linked with data on food composition (7). Habitual energy intake was estimated by correcting the intake data for within-person variation using the ISU-method (IML-SIDE) (8). In order to make the sample representative to the Dutch population of young children, data were weighted for socio-demographic factors and season.

P_{95} of habitual folic acid intake from background diet (CI_{95})

The UL of folic acid is based on the intake of synthetic folic acid only and not on the intake of natural folate (9). As we were interested in safety and made comparisons with the UL, only the intake of synthetic folic acid should be taken into account. Since synthetic folic acid is only consumed via food supplements or fortified foods, the intake of the background diet (i.e. excluding fortification) is zero.

P_{95} of folic acid intake from food supplements (SI)

The intake of folic acid from food supplements was calculated using data from DNFCS-children (6), briefly

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described above. In the two food diaries, the use of food supplements on that day was also recorded. To calculate folic acid intake from food supplements, data on supplement intake was linked with data on food supplement composition (10). Mean intake over two observed days was calculated and P_{95} was derived. Due to the infrequent use of food supplements and lack of FFQ data, no habitual intake could be estimated.

Proportion of energy intake that can and will be fortified (PFFn)

At the time the DNFCS-children (2005/2006) was conducted, the general exemption for folic acid fortification was not in force. Based on results of the product inventory, four scenarios of food fortification were defined. The scenarios were applied to the consumption data of DNFCS-children and the proportion of the energy intake of folic acid fortified foods was calculated on each observed day by dividing the amount of energy consumed from all folic acid fortified foods by the total amount of energy consumed. This proportion was corrected for within-person variation using ISU-method (IML-SIDE and C-SIDE) (8) and weighted for socio-economic factors and seasons.

In the *first scenario* the food composition (i.e. folic acid level) of all foods currently fortified that were consumed during DNFCS-children was replaced with the current (2009) folic acid level. Foods currently fortified but not consumed in DNFCS-children were not taken into account. Foods fortified during DNFCS-children and not anymore were regarded as not fortified. Current fortification levels were used for foods fortified during DNFCS-children and currently fortified with a different level.

The *second scenario* is an expansion of the first scenario. Foods consumed in DNFCS-children belonging to the same food group and brand as the fortified foods found in the inventory were considered to be fortified. The highest currently legal fortification level found within the same food group and brand was applied.

The *third scenario* is a further expansion of the first and second scenario. In this scenario foods also belonging to the same food group and of other brands consumed in DNFCS-children were considered to be fortified. Again, the highest currently legal fortification level found in the same food group and brand was applied. One exception was made: bread, which is a staple food in the Netherlands, was not taken into account except the specific brand currently applying fortification, as this will have very high influence on the total intake.

The most expanded scenario is the *fourth scenario* in which not only foods belonging to the same food group (all brands) but also foods belonging to similar food groups (Table 1) (all brands) were assumed to be fortified. Similar to the above, the highest currently legal fortification level found in the same food group and brand was applied.

Evaluation of the maximum safe fortification level (MSFL)

The MSFL is calculated as follows: $MSFL = (UL - [CI_{95} + SI])/([EI_{95} \times PFFn]/100)$. Using the re-estimated model input parameters (see above) the MSFL was also re-estimated. The re-estimated MSFL was compared with the 2007 MSFL.

Folic acid intake of young children and exceeding the UL

In order to get insight in the risk of potentially too high folic acid intakes due to voluntary fortification for each scenario and for the reference situation (i.e. DNFCS-children), the habitual folic acid intake was estimated and compared to the UL for children as set by EFSA (9) using the cut-point method (11).

Results

Inventory of folic acid fortified foods

In the product inventory, 139 folic acid fortified foods of 43 different brands were found. These foods were divided into seven food groups: bread, cereal products, dairy products, drinks, fats and oils, pastry and cookies, and soy products (Table 1). The level of folic acid declared on the label varied from 15 to 500 μg per 100 g (or ml); this

Table 1. Overview of folic acid fortified foods on the Dutch market (first half of 2009), number of foods (number of brands) within different food groups, and specification of type of foods that are fortified

Food group	No folic acid fortified foods (no brands)	Type of food	Scenario 4: included similar food groups
Bread	4 (2)	Bread, cracottes	Cream crackers, knackerbröt
Cereal products	62 (15)	Breakfast cereals (cornflakes, muesli), baby porridge	Cruesli
Dairy products	6 (2)	Yoghurt drink, instant chocolate /fruit-milk drink	Dairy-fruit drink
Drinks	20 (8)	Fruit soft drink, fruit drink, sports drink, sweetened water	Fruit drink (>2 fruits), fruit lemonade
Fats and oils	19 (8)	Margarine (low fat)	Regular margarine
Pastry and cookies	26 (7)	Cereal bars, cereal snacks, nutritional biscuits	
Soy products	2 (1)	Drink	

was equivalent of 3 to 267 μg per 100 kcal. Correction of the declared folic acid amount for natural folate content showed a small decrease in folic acid content to 1 to 235 μg per 100 kcal. Most foods with a higher folic acid content than the legal maximum amount of 100 μg per 100 kcal could be considered as light food products ($N = 22$). The folic acid contents of those foods were at or below the legal maximum amount for their energy-dense counterparts. The remaining food ($N = 1$) with a too high folic acid level belonged to the food group 'drinks.'

Evaluation of model parameters

In Table 2 both the original input parameters of the model as used to set the MSFL on which the current AFL is based (5) and the input parameters based on the recent DNFCS-children and the inventory are presented (i.e. re-estimation). It should be noted that differences are not only due to, for instance, time trends or different consumption patterns, but also due to differences in survey methodologies and different age categories (1–3 years for the original intake parameters, 2–3 years for the re-estimated parameters).

The P_{95} of habitual energy intake is about 50–110 kcal lower in DNFCS-children (2005/2006) then in the previously used data of DNFCS-3 (1997/1998).

In DNFCS-children, data on food supplement use was available for each recorded day. About 20% of the children used folic acid containing food supplements on at least one of the record days. The P_{95} of the folic acid intake distribution from food supplements was 100 μg per day (2-day mean). This is one-third of the best educated estimation used as original input parameter for the MSFL in 2007 (5). For users of folic acid containing food supplements, the 95th percentile of the intake distribution was 300 μg/day (2-day mean) and intakes up to 800 μg per day were recorded in DNFCS-children. Our results show that although intakes of 300 μg folic acid per day or higher are realistic among users of food supplements for the 95th percentile of the intake distribution of the whole population, this is an over-estimation. For this input parameter, 100 μg per day or when taking into account some uncertainty among this value 150 μg per day is more realistic.

The third input parameter is the estimation of the proportion of the energy intake that can and will be fortified (PFFn). The original PFFn was estimated at 10% (best educated guess). For each of the four scenarios of folic acid fortification, the population distribution of this proportion was calculated (Fig. 1A and 1B). In the scenarios most representative for the current situation (1 and 2), up to 10% of the children aged 2–3 years and up to 5% of the children 4–6 years had a habitual proportion of the energy intake coming from folic acid fortified foods that was higher than 10%. In the scenarios realistic for the current Dutch situation, a higher PFFn of

Table 2. Comparison of the model parameters required to calculate the maximum safe fortification level[a] of folic acid for Dutch young children (5): 2007 versus 2009

	Year	Age category (year)		UL (μg/day)	CI_{95} (μg/day)	SI_{95} (μg/day)	EI_{95} (kcal/day)	$MSFL_{(PFFn = 0.15)}$ (μg/100 kcal)	$MSFL_{(PFFn = 0.10)}$ (μg/100 kcal)	AFL (μg/100 kcal)
Original model	2007 (5)	1–3		200	0	300	1890	<0	<0	100
	2007 (5)	4–6		300	0	300	1995	0	0	100
Re-estimation	2009	2–3	Low supplement	200	0	100	1779	56	37	
		2–3	High supplement	200	0	150	1779	28	19	
	2009	4–6	Low supplement	300	0	100	1941	103	69	
		4–6	High supplement	300	0	150	1941	77	52	

[a]MSFL = (UL–CI_{95}–SI_{95})/([EI_{95} × PFFn]/100).
UL = tolerable upper intake level; CI_{95} = 95th percentile of habitual intake of background diet; SI_{95} = 95th percentile of intake of food supplements; EI_{95} = 95th percentile of habitual energy intake; MSFL = maximum safe fortification level; PFFn = proportion of energy intake that may and will be fortified; AFL = allowed fortification level according to Dutch legislation (5).

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15% was exceeded by up to 3% of the young children (Fig. 1A and 1B). In the more extreme scenarios (3 and 4), illustrating an ongoing trend of folic acid fortification in similar food groups, the percentage of the children with more than 10% of the energy intake coming from folic acid fortified foods increased to 53 to 100% (Fig. 1A and 1B). Our results show that a PFFn of 10% seems an underestimation, especially when taking into account the potential ongoing increase in folic acid fortified foods entering the Dutch market, a proportion of 15% seems more realistic.

Evaluation of calculated maximum safe fortification levels

The maximum safe fortification levels were re-estimated using both 100 and 150 μg per day as folic acid intake from food supplements and a PFFn of both 10 and 15% (Table 2). For children 2–3 years old, the newly calculated maximum safe fortification levels ranged from 19 to 56 μg/100 kcal and for children 4–6 years old from 52 to 103 μg/100 kcal, depending on the assumed model parameters for intake of food supplements and PFFn (Table 2). The re-calculated MSFLs are higher than those originally calculated (i.e. ≤0 μg/100 kcal). The current AFL for folic acid of 100 μg/100 kcal is higher than the re-estimated maximum levels for children aged 2–3 years old. In the most liberal situation (i.e. PFFn = 15% and intake from food supplements = 100 μg folic acid/d) the re-estimated maximum level for children aged 4–6 years old is similar to the current AFL.

Current and potential folic acid intakes and exceeding of the UL

In the scenarios realistic for the current situation (i.e. 1 and 2) the habitual folic acid intake from *foods* of young

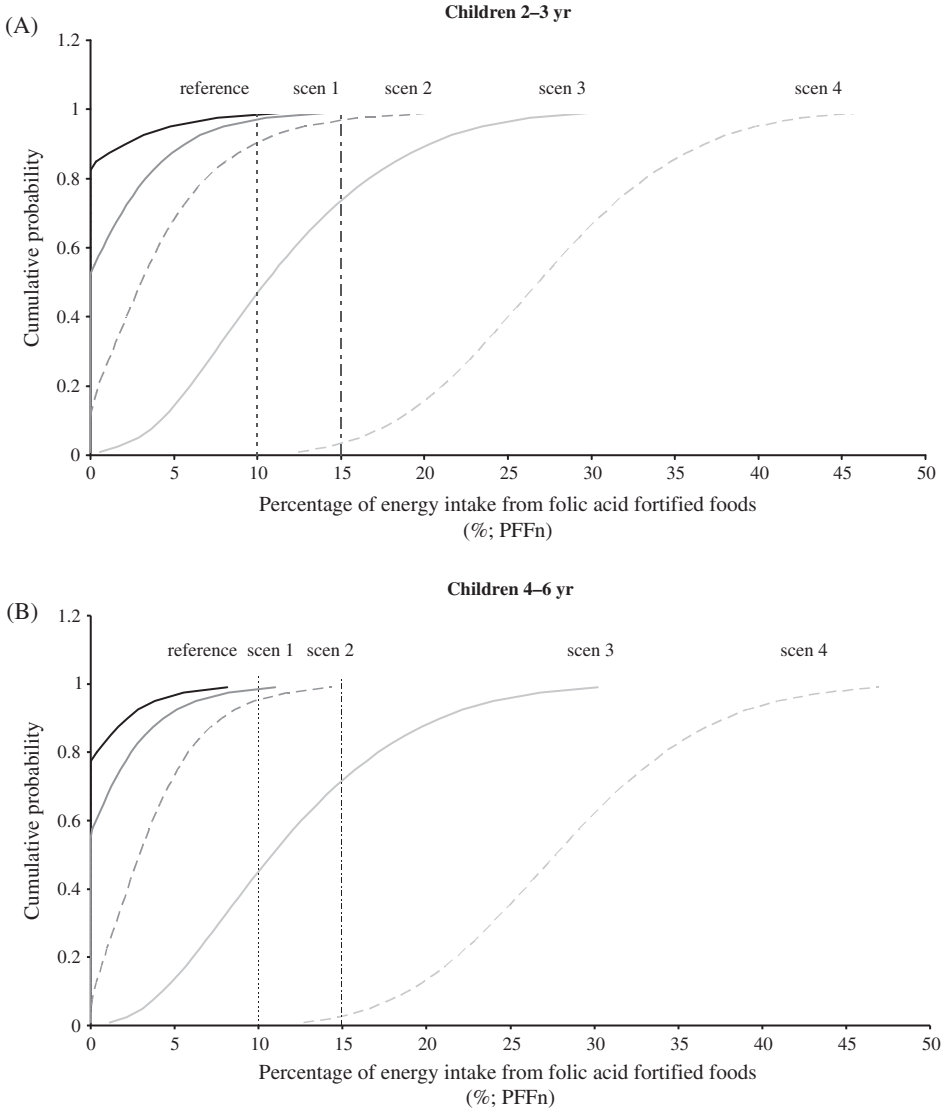

Fig. 1. Distribution of habitual proportion of the energy intake of folic acid fortified foods among Dutch young children (1A: 2–3 years and 1B: 4–6 years) for four different fortification scenarios.

children (2–6 years) did not exceed the UL (Table 3). In the more extreme fortification scenarios (i.e. 3 and 4), up to 10% of the children aged 2–3 years and up to 1% of the children aged 4–6 years did have habitual folic acid intakes of *foods* above the UL (Table 3). Considering the intake of both foods and food supplements, the proportion of children exceeding the UL increased in all scenarios. In general, the proportions exceeding the UL were higher in the age category 2–3 years than 4–6 years, due to the lower UL. In the scenarios representing the present situation (i.e. 1 and 2), up to 5% of the children had folic acid intakes above the UL. In the more extreme scenarios (i.e. 3 and 4), up to 20% had folic acid intakes above the UL (Table 3).

Discussion

We presented an evaluation of the 2007 Dutch general exemption level for voluntary food fortification with folic acid of maximally 100 μg per 100 kcal focusing on young children. These maximum levels were estimated using a calculation model and several input parameters to which purpose several assumptions had to be made (5). Our study showed that the model assumptions made for the intake of folic acid from food supplements are over-estimated and that the prediction of the proportion of the energy intake of folic acid fortified foods is too liberal for an increasing market. Re-estimation of the maximum safe fortification level based on data of young children resulted in a higher maximum level compared to the results from 2007. However, the re-estimated maximum levels remain below the currently legal maximum of 100 μg per 100 kcal for children aged 2–3 years old. For the current Dutch situation, folic acid intake from foods only did not result in too high intakes among young children. However with combined intake from foods and food supplements, up to 5% of the young children did have habitual folic acid intake above the UL and this was mainly due to the intake of food supplements with dosages higher than the UL (data not shown). It is advised to better regulate the amounts of folic acid in food supplements for young children. Currently, EU legislation on this topic is under discussion (EC 1925/2006 and 2002/46/EC). Labeling that specific food supplements are not suitable due to high dosages will also be helpful. In our inventory one food product had a folic acid content higher than the legal maximum. Although this did not result in too high intakes immediately, it is recommended to enforce the maximum fortification level well. When more and more foods with higher folic acid levels than the maximum safe level will enter the food market, the risk of folic acid intakes above the UL will increase.

Several other models have been published calculating maximum safe fortification levels (12–15). However, to our knowledge, this is the first paper evaluating the model

Table 3. Habitual folic acid intake (μg/day; median and P_{95}) for four different folic acid fortification scenarios and percentage exceeding the UL, Dutch young children 2–6 years

Age (year)	Source	Reference			Scenario 1			Scenario 2			Scenario 3			Scenario 4		
		Median (μg/d)	P_{95} (μg/d)	% > UL	Median (μg/d)	P_{95} (μg/d)	% > UL	Median (μg/d)	P_{95} (μg/d)	% > UL	Median (μg/d)	P_{95} (μg/d)	% > UL	Median (μg/d)	P_{95} (μg/d)	% > UL
2–3	Food	0	20	0	0	43	0	25	105	0	77	180	3	111	229	10
	Food and supplements	0	117	2	6	119	2	36	184	4	91	253	11	129	297	20
4–6	Food	0	25	0	0	48	0	32	93	0	96	199	0	139	252	1
	Food and supplements	0	104	<1	8	119	<1	44	154	<1	113	254	2	154	306	6

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and assumptions a few years after the maximum safe fortification levels were adopted in national legislation. The Dutch calculation model is designed to estimate a maximum safe fortification level that will protect virtually the whole population from too high intakes (i.e. precautionary principle). To do this, high population intakes (95th percentile) of the micronutrient from food and food supplements, and high energy intake are combined. Only a small part of the population will have the combination of all high intakes and therefore be at risk of too high intake. On the other hand, there might also be a small part of the population with higher values for one or more of the model input parameters than applied. To some extent this will not result immediately in the risk of too high intakes. This is also what our study shows because even with a currently legal fortification level that is higher than the calculated maximum level for young children, a large part of the children have habitual folic acid intakes below their UL.

The current calculation models do not take into account correlations between, for instance, intake of a micronutrient from food supplements and from the diet or energy intake and micronutrient intake of each source. In case of strong correlations, they could be considered in modeling the maximum safe fortification level. In our study, correlations between folic acid intake of food supplements and energy intake were not found (data not shown). In the scenarios with more folic acid fortified foods (scenario 2–4), there was an increasing statistically significant positive correlation between the energy intake and folic acid intake of fortified foods (data not shown). This is logical as many food groups currently applying folic acid fortification are main energy suppliers (e.g. breakfast cereals, fats and oils).

The original model made use of DNFCS-3 data conducted in 1997/1998 (5). The methodology of this survey is different from the DNFCS-children conducted in 2005/2006 and differences in habitual energy intake between the surveys can partly be explained by these methodological differences. It cannot be stated that the habitual energy intake among young children decreased from 1997/1998 to 2005/2006, but the values are in the same order of magnitude.

A limitation of our study is that the DNFCS-children was conducted in 2005/2006, just before the new legislation on voluntary folic acid fortification came into force. Our inventory showed that several new folic acid fortified food products entered the market since 2006. To estimate the situation for 2009 and later, four fortification scenarios were designed representing the currently realistic situation and potential future situations proposing an increase in fortification in similar foods. Although the inventory may have resulted in an incomplete overview of the folic acid fortified foods on the Dutch market, we do think that we have identified all main food groups containing folic acid fortified foods. The results for the various scenarios should be interpreted as indicative outcomes.

A second limitation is that the amounts of folic acid were not analytically analyzed, but taken from the label information. So potential overage could not be taken into account. Several studies show that overages in folic acid fortification are common (16, 17). This would imply that the figures used in our study are an underestimation of the true folic acid dosages in fortified foods. The folic acid information on the label is the total of folate and folic acid rather than folic acid only. Therefore, it is impossible to estimate the real amounts of folic acid from the label information only. To correct for the natural folate, data from the Dutch food composition database (NEVO) (7) was used to estimate the amounts of folic acid in the foods by subtracting the natural folate levels found in NEVO from the label information of the total of folate and folic acid. As there is only the UL for folic acid and it is needed to differ between both forms, we would therefore recommend labeling folate and folic acid separately.

Another limitation is that our study focused on young children and did not take into account other age categories. However, the UL for children is lower than for adults and therefore young children are the most vulnerable group regarding the risk of exceeding the UL. The UL for folic acid is under debate. For children, the UL is extrapolated from the UL for adults, which is based on masking the hematological picture of vitamin B12-deficiency, mainly a problem of the elderly (9). When physicians are aware that not only the hematological picture has to be taken into consideration diagnosing vitamin B12-deficiency but also the actual measurement of vitamin B12 status, this risk will diminish. Other potential health effects might be more relevant in setting the UL, but at present there is insufficient scientific data to set the UL for folic acid on other endpoints (18). As soon as it is possible to take other endpoints into account, the UL for folic acid should be revised, especially for children.

Within the EU legislation, it is regulated what micronutrients (and in what chemical form) may be applied in food fortification and supplements, as well as the minimum and maximum levels that may be applied (EC 1925/2006 and 2002/46/EC). However, the actual maximum and minimum levels are still under discussion. Our model (5) is accurate in setting a maximum level in foods protecting virtually the whole population given a certain intake of food supplements. By changing the 'given' intake of food supplements, the maximum safe level in fortified foods will change. It is important to realize that it is a risk manager's decision how to divide the free space between the P_{95} of intake from the background diet (excluding voluntary fortification or supplementation) and the UL between food supplements

and fortified foods (19). Models similar to our model (5) are also proposed to calculate the maximum amounts of micronutrients that may be applied in fortified foods and food supplements. Combining the maximum levels for fortification and food supplements calculated with different models should be done with caution, as there are differences in the proportions of the free space assigned to foods or food supplements (20). Further, 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 level of risk of too high intakes accepted?

This paper illustrates the importance of regular evaluation of maximum allowed fortification levels that are adopted in national policy. In setting the maximum safe fortification levels, modeling is needed based on input parameters with regard to food and food supplement consumption and predicted fortification practices. Fortification practices might develop differently than predicted. In addition, changes in dietary patterns might occur or better data might become available (like in our situation on intake of food supplements). Further, continued actual monitoring of the percentage of the population exceeding the UL is recommended.

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