BfR Concept for the Fortification of Food with Vitamin D

BfR Concept of 2 November 2016

Vitamin D regulates calcium and phosphate metabolism and promotes bone hardening. It influences muscle strength and is involved in metabolic processes in the body. A long-term undersupply of vitamin D can have an adverse effect on bone health. In addition, a prolonged oversupply can also lead to undesirable effects such as the formation of kidney stones and kidney calcification. In humans, vitamin D is mainly formed in the skin under the influence of sunlight; the intake via food accounts for only a relatively small proportion of the total supply. The risk of oversupply only exists with very high oral intake of vitamin D, e.g. via high-dose food supplements. Vitamin D formed in the skin does not lead to undesirable health effects. It can be stored by the body and retrieved when needed.

With sufficient exposure to sunlight, in particular the body's own production in the skin contributes to the vitamin D supply. The German Federal Institute for Risk Assessment (BfR) therefore recommends spending sufficient time outdoors, involving sports and other physical activities as well as appropriate sun exposure of the skin, although sunburn should be avoided at all costs. It is also recommended to eat oily sea fish, which naturally contains a lot of vitamin D, once or twice a week. However, not everyone achieves sufficient vitamin D levels through their body's own production. Especially in the winter months an additional intake of vitamin D may, therefore, be useful for certain groups of people. Those who would like to supplement vitamin D can use food supplements with up to 20 micrograms (µg) of vitamin D (equivalent to 800 IU) per day. With this amount the daily requirement is covered, while adverse health effects are not to be expected. Taking higher doses, especially very high amounts, should only be done under medical supervision and taking the individual vitamin D status into account.

Data on the supply status of the population in Germany show that the majority of the population is not at risk of vitamin D deficiency (25-hydroxyvitamin-D_3 (25-OH-D_3) < 30 nanomoles per litre (nmol/L)). However, about 26% of children and 34% of adults have serum levels below a 25-hydroxyvitamin-D_3 concentration of 40 nmol/L, which is used as an indicator of the estimated average requirement, and are therefore at risk for vitamin D undersupply.
The fortification of foods with vitamin D has been permitted in principle in the EU since 2006. In Germany, however, marketing requires an exemption or general disposition. So far, maximum amounts for the addition of vitamin D to foods have not been set by law in the EU and Germany.

From the BfR's point of view, a general fortification of foods with vitamin D is not recommended. Therefore, the BfR has developed a vitamin D fortification concept, in which it proposes maximum amounts for the addition of vitamin D to certain food groups. Ideally, a possible fortification of foods with vitamin D should be conceptualised in such a way that the total intake of vitamin D through the diet does not exceed the tolerable upper intake levels (UL) for vitamin D in all age groups and at the same time makes a meaningful contribution to the supply of the population.

In order to determine suitable fortification amounts, the BfR has carried out model calculations with different fortification scenarios. It recommends scientific monitoring of an application of the vitamin D fortification concept in order to be able to quickly identify the actual extent of the fortification, its associated increase in vitamin D intake and possible undesireable effects, as well as to be able to react to them, if necessary.

The accompanying main Opinion **"Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods"** is available here: https://www.bfr.bund.de/cm/349/updated-recommended-maximum-levels-for-the-addition-of-vitamins-and-minerals-to-food-supplements-and-conventional-foods.pdf

The **proposed maximum levels for the addition of vitamin D to foods including food supplements** can be found here: https://www.bfr.bund.de/cm/349/proposed-maximum-levels-for-the-addition-of-vitamin-d-to-foods-including-food-supplements.pdf

1 Basics and target parameters of the Concept

The fortification modalities on which the BfR Concept is based are presented below:

1.1 There are prerequisites for fortifying foods with Vitamin D according to Regulation (EC) No 1925/2006.

Rationale

According to Regulation (EC) No 1925/2006 Art. 3 para. 2, vitamin D may be added to foods in order to take into account, in particular:

a) a deficiency of vitamin D in the population or in specific population groups that can be demonstrated by clinical and sub-clinical evidence of deficiency or indicated by estimated low levels of intake; or
b) the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins and minerals due to changes in dietary habits; or
c) evolving generally acceptable scientific knowledge on the role of the vitamin in nutrition and consequent effects on health.

Vitamin D serum levels

The vitamin D status can best be determined by the serum concentration of 25-hydroxyvitamin-D_3 (25-OH-D_3), as this reflects both oral intake and endogenous synthesis. With regular outdoor exposure, endogenous synthesis in the skin is the main contributor to vitamin D supply (80-90%), while oral intake makes only a small contribution (10-20%) (Holick, 2007; Linseisen et al., 2011). According to the former US *Institute of Medicine* (IOM), a 25-OH-D_3 serum concentration of 40 nmol/L corresponds to the estimated average requirement (EAR) for vitamin D. Thus, if the median 25-OH-D_3 serum concentration in a population is 40 nmol/L, half of this population is at increased risk of suboptimal supply or even deficiency, while the other half is at low risk. A 25-OH-D_3 serum level ≥50 nmol/l indicates an adequate supply in terms of bone health for almost all individuals in a population, as values above 50 nmol/l do not lead to any further improvement in bone mineralisation.

To assess the vitamin D status of a population, *cut-off values* were defined. According to them, an increased risk of deficiency is seen at a serum concentration below 30 nmol/L. Serum concentrations between 30 and 50 nmol/L are seen as an increased risk for suboptimal supply and serum levels from 125 nmol/l upwards are seen as an increased risk for the occurrence of adverse health effects[1] (see Table 1) (Aloia, 2011; IOM, 2011, EFSA, 2016). In

[1] At this point, the BfR points out that the assessment of what constitutes "an increased risk of suboptimal supply, deficiency or adverse effects" is not equivalent to the actual occurrence of these conditions in individuals. For

the long term, however, increased all-cause mortality (Melamed et al., 2008; Sempos et al., 2013; Durup et al., 2012) as well as increased cardiovascular mortality (Durup et al., 2015) have been observed at 25-OH-D_3 serum concentrations of 75-80 nmol/L and above in large population studies. The extent to which a causal relationship exists between the two parameters cannot be concluded from this type of study.

Table 1: 25-OH-D_3 serum concentration and supply status* in the population

Supply status	25-OH-D_3 serum concentration		Possible health effects
	nmol/L	ng/ml	
Increased risk of deficiency	< 30	< 12	Increased risk of rickets in children and osteomalacia in adults
Increased risk of suboptimal supply	30 - < 50	12 - < 20	Increased risk of inadequate bone health
Adequate supply	≥ 50	≥ 20	Adequate for bone health
Increased risk of oversupply	> 125	> 50	Increased risk of adverse health effects

* Modified according to IOM (Aloia, 2011; IOM, 2011)

After standardisation of the 25-OH-D_3 values from the national health surveys of the Robert Koch Institute (RKI) – the KiGGS study (German Health Interview and Examination Survey for Children and Adolescents) and the DEGS study (German Health Interview and Examination Survey for Adults) – that were included within the ODIN project (Cashman et al., 2016), mean 25-OH-D_3 serum concentrations in adults were 49.5 nmol/L (women 49.7 nmol/L; men 49.3 nmol/L) and 53.5 nmol/L in children (girls 53.2 nmol/L; boys 53.7 nmol/L).

The median of the standardised 25-OH-D_3 serum levels for all adults was 47.7 nmol/L and 52.9 nmol/L for all children, while the 95th percentile was 84.0 nmol/L for adults and 82.9 nmol/L for children (Cashman et al., 2016).

In adults across all age groups, a proportion of about 15% (9.8-19%) and among children (with the exception of infants), a proportion of about 12.5% (4.9-18.9%) was found with a 25-OH-D_3 serum level below 30 nmol/L (Table 2 a-d, pre-announcement data from the RKI for the Nutrition Report 2016). Serum levels below 40 nmol/L, which are used as an indicator of the estimated average requirement, were found in about 26% of children and 34% of adults, who were thus at risk of suboptimal supply with vitamin D or deficiency. Serum concentrations of 75 nmol/L and above were found in 9.1% of adults and 16.2% of children (Cashman et al., 2016).

example, individuals whose individual nutrient requirements are lower than the average requirement are adequately supplied with vitamin D even if 25-OH-D_3 serum levels are below the EAR. Therefore, knowledge of a selective 25-OH-D_3 serum value is not sufficient for the determination of an actually existing vitamin D deficiency in individuals, especially since the **individual vitamin D requirement** is usually not known.

Table 2a: Vitamin D status of girls (1 to 17 years) in Germany* after standardisation of the method in the ODIN project

25-OH-D_3 cut-off values	Age in years				
	1–2	3–6	7–10	11–13	14–17
	Proportion in %				
<30 nmol/L	5.7	9.1	12.2	18.9	13.9
30-<50 nmol/L	19.7	31.8	36.7	41.4	32.0
≥50 nmol/L	74.6	59.1	51.1	39.6	54.2

Table 2b: Vitamin D status of boys (1 to 17 years) in Germany* after standardisation of the method in the ODIN project

25-OH-D_3 cut-off values	Age in years				
	1–2	3–6	7–10	11–13	14–17
	Proportion in %				
<30 nmol/L	4.9	11.5	10.9	11.0	18.3
30-<50 nmol/L	15.5	31.5	31.6	39.2	36.8
≥50 nmol/L	79.6	57	57.5	49.8	44.9

Table 2c: Vitamin D status of adult women in Germany* after standardisation of the method in the ODIN project

25-OH-D_3 cut-off values	Age in years					
	18–29	30–39	40–49	50–59	60–69	70–79
	Proportion in %					
<30 nmol/L	14.4	18.7	14.8	14.9	9.8	15.9
30-<50 nmol/L	34.6	33.0	39.3	42.2	48.5	51.1
≥50 nmol/L	51.0	48.3	45.9	42.9	41.7	33.0

Table 2d: Vitamin D status of adult men in Germany* after standardisation of the method in the ODIN project

25-OH-D_3 cut-off values	Age in years					
	18–29	30–39	40–49	50–59	60–69	70–79
	Proportion in %					
<30 nmol/L	16.2	19.0	19.4	13.3	9.9	14.9
30-<50 nmol/L	39.7	42.7	36.0	44.9	38.1	43.6
≥50 nmol/L	44.1	38.4	44.6	41.8	52.1	41.5

* KiGGS and DEGS data (pre-announcement data from the RKI for the Nutrition Report 2016)

Dietary Vitamin D intake

Based on the intake values for children from the DONALD (*DOrtmund Nutritional and Anthropometric Longitudinally Designed)* study (Kersting and Bergmann, 2008) and the nationally representative EsKiMo study (**nutrition study as KiGGS module)** (Mensink et al., 2007) as well as on the intake values for adults from the NVS (National Nutrition Survey) II (MRI, 2008), the intake of vitamin D via food was found to be low, at around 2 to 4 µg per day (Table 3), which is due to the naturally low content of vitamin D in food.

Table 3: Average vitamin D intake from the diet*

	DONALD	**EsKiMo**				**NVS II**	
Age groups and sex	1-12 yrs. (m/f)	6-11 yrs.		12-17 yrs.		14-80 yrs.	
		M	f	m	f	m	f
Vitamin D intake in µg/day	1.9	1.9	1.7	2.7	2.0	3.8	2.9

* Data from the DONALD study (Kersting and Bergmann, 2008), EsKiMo study (Mensink et al., 2007) and NVS II (MRI, 2008)

Conclusions

Serum levels show that under current conditions about 33 to 52% of adults and 40 to 80% of children are adequately supplied with vitamin D (25-OH-D_3 ≥ 50 nmol/L), with 9.1% of adults and 16.2% of children, however, reaching high serum levels, that have been associated with increased mortality in the long-term in large population studies.

On the other hand, approximately 15% of adults and 12.5% of children (excluding infants) are at increased risk of vitamin D deficiency, while approximately 40% of adults and approximately 33% of children are at increased risk of suboptimal supply.

Overall, it can be concluded that the distribution of 25-OH-D_3 serum levels reflects a supply in the population that is comparable to the intake distributions for other micronutrients. However, the vitamin D status in Germany can still be improved without disproportionately increasing the risks for adverse effects caused by excessive intakes. Thus, prerequisites for fortification of foods with Vitamin D according to Regulation (EC) No 1925/2006 are given. Besides the intake of food supplements, a targeted fortification of foods can contribute to the supply of the population with vitamin D.

1.2 The fortification concept is based on the dietary reference value for vitamin D intake of the German Nutrition Society (DGE) of 20 µg vitamin D per day (without taking endogenous synthesis into account). To assess an intake of vitamin D at which undesirable health effects are not to be expected, the tolerable upper intake level (UL) derived by the European Food Safety Authority (EFSA) in 2012 for children (1 to 10 years) of 50 µg of vitamin D per day is used.

Rationale

The estimated value for an adequate vitamin D intake of 20 µg per day for adults and children over one year of age, updated by the DGE in 2012, indicates how an adequate 25-OH-D_3 serum level of 50 nmol/L can be achieved by oral intake of vitamin D alone, i.e. without taking endogenous synthesis into account (D-A-CH, 2012). The derivation of the estimated value by the DGE is based on the results of a study by Cashman et al. (2008). According to this study, in the Irish population during the winter months a vitamin D intake (as a supplement) of 10 µg per day or 20 µg per day achieved a 25-OH-D_3 concentration over 50 nmol/L in about 50% and 90 to 95% of the population, respectively. Thus, it can be concluded that the D-A-CH societies have taken into account groups of people who are particularly at risk of vitamin D deficiency, e.g. in the absence of UVB exposure, when deriving the estimated value for an appropriate vitamin D intake.

EFSA has defined 15 µg per day as Adequate Intake for adults and children from the age of one year, whereby, compared to the DGE estimate, this value takes into account a low level of endogenous synthesis through the skin (EFSA, 2016).

In 2012, EFSA updated the UL for vitamin D (EFSA, 2012) and used hypercalcaemia as an indicator of adverse health effects from vitamin D oversupply. Based on intervention studies, a UL of 100 µg per day was derived for adults including pregnant and breastfeeding women. For children under the age of ten years no vitamin D intervention studies using higher doses were available and for children 10-17 years old, only studies with weekly bolus doses were available. Nevertheless, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded that children and adolescents are likely to tolerate high doses of oral vitamin D equally well as adults due to increased bone formation and rapid bone growth. EFSA therefore also set a UL of 100 µg per day for 11- to 17-year-old children and adolescents. For children aged 1 to 10 years, a UL of 50 µg per day was derived, taking into account their smaller body size (EFSA, 2012).

The endpoint hypercalcaemia essentially characterises acute vitamin D intoxication. In large national cohort studies, however, increased all-cause mortality was found both with 25-OH-D_3 serum concentrations below 30 nmol/L and with increasing serum levels from 75-80 nmol/L (Melamed et al., 2008; Sempos et al., 2013; Durup et al., 2012). Overall, these studies show a U-shaped or inverted J-shaped correlation between vitamin D status and mortality. One of the studies was conducted using the US national cohort NHANES III (*Third National Health and Nutrition Examination Survey*; 1988-1994, 13,331 subjects ≥ 20 years) and mortality data from 1991-2000 (Melamed et al., 2008) and was repeated after six years. In this second follow-up, 15 years after the start of the study, the inverse J-shaped correlation between vitamin D status and all-cause mortality was even more evident and was thus confirmed (Sempos et al., 2013). The Copenhagen Vitamin D Study (CopD Study), in which data from 247,574 people were evaluated, also showed an inverse J-shaped correlation between vitamin D status and all-cause mortality (Durup et al., 2012) and in addition also to cardiovascular mortality (Durup et al., 2015). The mortality minimum in all these studies was between 40 and 80 nmol/L 25-OH-D_3 in serum.

Although epidemiological studies, which also include cohort studies, generally cannot establish a cause-effect relationship, the comparability of results from several large population studies suggests that the observed association is real. Furthermore, high-quality intervention studies (overview in Challoumas et al., 2015) and systematic reviews show that positive health effects of an additional vitamin D intake in the range of 20 µg/day are primarily limited to people with insufficient vitamin D status (Bjelakovic et al., 2014), while high 25-OH-D_3 serum levels are associated with less favourable values for subclinical parameters of cardiovascular health (Kamycheva et al., 2013).

The serum levels determined in KiGGS and DEGS correspond to a situation in which around 80-90% of the vitamin D supply was achieved through exposure to sunlight and only 10-20% through dietary intake, since so far in Germany (as of 2015) there are very few foods on the market to which vitamin D is added, and food supplements predominantly contain 5 µg vitamin D per daily dose. In recent years, however, it has become apparent that vitamin D monopreparations with 20 µg (corresponding to 800 IU) or 25 µg (1000 IU) vitamin D or more per daily dose are increasingly available on the market as food supplements.

In the BfR Concept for fortifying foods with vitamin D, a dietary intake reference value of 20 µg vitamin D per day (without taking endogenous synthesis into account) and a UL for children of 50 µg vitamin D per day are therefore used as orientation values. In this way, an improvement of the supply status for people with an increased risk of insufficient vitamin D supply can be achieved without disproportionally increasing the proportion of the population who have 25-OH-D_3 serum levels that have been associated with an increased all-cause and cardiovascular mortality.

1.3 As a target value for vitamin D intake of the population after fortification of foods with vitamin D, a mean total dietary intake of around 10 µg per day is aimed for.

Rationale

Reference values for nutrient intake are not individual intake recommendations, but correspond to the estimated average requirement (EAR) of the population, plus 2 standard deviations (Bechthold, 2009; IOM, 2006). As such, they represent a value found at the upper end of the distribution of individual values for physiological requirements in the population. Accordingly, the intake of nutrients in populations often follows a distribution in which the 95th or 97.5th consumption percentiles are between 2 and 3 times the mean value.

This results in the following strategy for the fortification concept: fortification of foods with vitamin D should take place in such a way that the population achieves an average daily intake of around 10 µg of vitamin D. Taking into account the expected intake distribution, vitamin D intakes at the level of the dietary reference value of 20 µg per day would thus be achieved in the high consumption percentiles (e.g. in the 95th percentile). A higher mean vitamin D intake would lead to correspondingly higher intakes in the high consumption percentiles and thus to an increased risk of exceeding the UL.

Conclusions

The average intake of about 10 µg vitamin D per day in the general population targeted by the fortification concept roughly corresponds to the estimated average requirement (EAR) of the population.

1.4 Vitamin D fortification is not focused on one food, but is spread across a manageable range of carrier foods, excluding unsuitable foods.

Rationale

Since about 12.5% of children (excluding infants) and about 15% of adults have 25-OH-D_3 serum concentrations below 30 nmol/L, the concept envisages fortifying foods that are consumed by large parts of the population in quantities that are as consistent as possible. This excludes the fortification of "peak foods" (foods with strongly fluctuating consumption quantities at high peak consumption). According to the BfR, foods should be excluded from vitamin D fortification if they are subject to strong individual or seasonal fluctuations, if they are mainly consumed as luxury foods, if their consumption should not be increased due to their high energy density and simultaneously unfavourable nutrient profile, or if they are only consumed in small amounts. However, already approved food products fortified with vitamin D should be integrated into the concept.

Unprocessed foods are in principle excluded from fortification by Regulation (EC) No 1925/2006. However, it must be taken into account that in certain unprocessed foods the vitamin D content can be increased by UVB irradiation. Foods subjected to such a process require approval as a novel food.

Conclusions

Foods that have the following characteristics are excluded as carrier foods for vitamin D fortification:

- foods whose consumption is subject to strong individual and seasonal fluctuations (e.g. juices, soft drinks, water, fruit teas);
- foods that are mainly consumed as luxury foods (e.g. coffee and sweets);
- foods whose consumption should not be increased due to their nutrient profile (e.g. sweets, cakes and biscuits);
- foods that are only consumed in very small quantities or that are primarily used as ingredients (e.g. spices, seasoning sauces of all kinds, salt and flour); and
- foods that are usually stored for a long time (e.g. jams and pasta);
- unprocessed foods, which are in principle excluded from fortification by Regulation (EC) No 1925/2006;
- processed meat and sausage products that, according to the recommendations of the DGE, should only be consumed in moderate quantities and are not consumed at all by people who follow a vegetarian or vegan diet.

Taking these restrictions into account and based on the consumption habits of the German population, products from the following food categories are considered suitable carrier foods:

- bread and baked goods (except pastry goods);
- breakfast cereals;
- milk and dairy products including cheese and spreadable fats; and
- cooking oils (including liquid vegetable fat preparations and vegetable creams), as these have already been approved (Table 4).

The BfR Committee for Nutrition, Dietetic Products, Novel Foods and Allergies (EDNA) also endorsed this selection (see minutes of the 7th meeting (in German): https://mobil.bfr.bund.de/cm/343/7-sitzung-der-bfr-kommission-fuer-ernaehrung-diaetetische-produkte-neuartige-lebensmittel-und-allergien.pdf).

1.5 Maximum amounts are set for the addition of vitamin D to foods.

Rationale

In order to meet the requirements mentioned in 1.3 and 1.4, the maximum amounts for fortification per 100 g or 100 ml of a food were chosen in such a way that the intake of vitamin D from all sources in the 95th percentile reaches the DGE intake reference value of 20 µg per day (without taking endogenous synthesis into account) and that in the entire population the UL for children aged one to ten years of 50 µg per day is not exceeded.

2 Concept development

Applying the above key points, the BfR considered provisional maximum levels for vitamin D fortification for the selected carrier foods, on the basis of which various intake scenarios for vitamin D were calculated.

As described in Section 1.4, bread and baked goods (except pastry goods) as well as breakfast cereals, milk and dairy products including cheese, but also spreadable fats and cooking oils, including liquid vegetable fat preparations and vegetable creams (Table 4), are considered suitable for vitamin D fortification, as they are consumed by large parts of the population in relatively constant amounts or are already permitted (spreadable fats and cooking oils).

The following foods, for which vitamin D fortification is legally permitted in Germany, were taken into account in the exposure estimates for the Concept: In Germany, fortification of margarine and mixed fats with vitamin D at a level of 2.5 µg/100 g is generally permitted. In addition, the Federal Office of Consumer Protection and Food Safety (BVL) has granted exemptions (§ 68 LFGB) or issued general dispositions (§ 54 LFGB) for the fortification of cream cheese preparations (1.25 µg/100 g), breakfast cereals (1.7 µg/100 g), cooking oils (2.0 µg/100 g), liquid vegetable fat preparations (2.3 µg/100 g), vegetable creams (4.0–7.8 µg/100 g) and margarines/spreadable fats (7.5 µg /100 g).

Furthermore, UV-irradiated yeast for use in bread and baked goods for up to a maximum of 5 µg vitamin D per 100 g product, UV-irradiated milk (0.1-3.2 µg/100 g), UV-irradiated bread (0.75-3 µg/100 g) and UV-irradiated mushrooms with increased vitamin D content (10 µg/100 g) were approved/applied for via the novel foods authorisation procedure.

In order to identify suitable fortification levels for the selected carrier foods, the vitamin D concentrations of fortified foods already on the market were considered (Table 4, column 2).

For foods belonging to the above-mentioned categories but not already available on the market in a fortified form, fortification amounts were determined following Hirvonen et al. (2007) such that a typical product of the respective food category contains between 1 and 1.5 µg vitamin D per 100 kcal. The resulting fortification amounts were then converted to 100 g of a product and applied to all products in the corresponding food category. This procedure resulted in the following possible fortification amounts:

- milk and dairy products (including cheese): maximum of 1.5 µg per 100 g;
- bread and baked goods (except pastry goods) and breakfast cereals: maximum of 5 µg per 100 g;
- spreadable fats and cooking oils, including liquid vegetable fat preparations; and
- vegetable creams: maximum of 7.5 µg per 100 g (Table 4, column 3).

Table 4: Vitamin D addition in already authorised/applied for products and possible maximum levels for the selected carrier foods

Categories of suitable carrier foods • **Fortified food groups on the market**	**Vitamin D levels in products already approved/applied for** *(according to §§ 68 and 54 LFGB; or based on Novel Food Regulation)*	**Possible maximum quantities for selected carrier food categories**
	µg per 100 g	
Milk and dairy products, including cheese		1.5
• Cream cheese preparation (for children)	1.25	
Bread and cereal products (except pastry goods)		5.0
• Breakfast cereals	1.7	
• UV-irradiated yeast for use in bread and baked goods	5.0	
Spreadable fats and cooking oils		7.5
• Cooking oils	2.0	
• Liquid vegetable fat preparation	2.3	
• Vegetable cream	4.0-7.8	
• Margarine/spreadable fat	7.5	

2.1 Verification of the suitability of the selected carrier foods and the proposed maximum amounts for vitamin D fortification on the basis of model calculations

Model calculations were used to check whether fortification of the selected carrier foods with the proposed maximum amounts of vitamin D is suitable for achieving the previously defined target parameters (average daily intake of 10 µg; in the 95th percentile intake of 20 µg and no exceedance of the UL for children of 50 µg/day). The model calculations were based on the German Nutrient Data Base (German: *Bundeslebensmittelschlüssel* (BLS)) version 3.01 (MRI, 2010) and the consumption studies NVS II (14 to 80 years) (MRI, 2008) and EsKiMo (12 to 17 years) (Mensink et al., 2007). In addition to the basic levels of vitamin D in the individual foods, fortification amounts for the individual products within the selected food categories were entered into the BLS. The BLS modified in this way was linked to the food consumption quantities recorded in the NVS II and EsKiMo (based on the data from diet history interviews). For younger children in the EsKiMo study (six to eleven years), a conservative estimate was made, based on the consumption of carrier foods observed in these age groups (see Section 2.2.3).

In the model calculations, a vitamin D content of 1.5 µg/100 g was assumed for all milk and dairy products, a vitamin D content of 5.0 µg/100 g for all bread and cereal products (except pastry goods) and a vitamin D content of 7.5 µg/100 g for all spreadable fats and oils as well as vegetable creams listed in the BLS. This means that a 100% fortification of all carrier foods was simulated, which would lead to a maximum possible vitamin D intake. This approach was chosen so that health risks would not be expected even if all or a great many manufacturers were to practice vitamin D fortification of the carrier foods.

The vitamin D fortified foods currently on the market were included in the calculations, thus upon application of the vitamin D fortification concept (*VitD fort. concept*), no additional vitamin D intake would be expected from the previously approved cream cheese preparations, breakfast cereals, cooking oils, liquid vegetable fat preparations, vegetable creams, margarines/spreadable fats and UV-irradiated yeast for use in bread and baked goods.

In the case of UV-irradiated milk, the vitamin D levels are above the maximum amount specified so far, and mushrooms were not intended as carrier foods in the concept. In order to also consider UV-irradiated milk as well as UV-irradiated mushrooms, the following two additional scenarios were created:
VitD fort. concept + UV milk, and *VitD fort. concept + UV milk + UV mushrooms.*

So far, the novel food authorisation for UV-irradiated milk only applies to unprocessed milk, i.e. not to processed food products such as cheese. According to the approval decision, a vitamin D content of 0.5 to 3.2 µg per 100 g is specified for novel food whole milk and a vitamin D content of 0.1 to 1.5 µg per 100 g for semi-skimmed milk. For the calculation of the *VitD fort. concept + UV milk* scenario, a vitamin D content of 2.7 µg per 100 g for all unprocessed dairy products was entered into the modified BLS - in addition to the values changed for the *VitD fort. concept*.

To calculate the *VitD fort. concept + UV milk + UV mushroom* scenario, further additional vitamin D exposures from UV-irradiated mushrooms with an assumed vitamin D content of 10 µg per 100 g were entered into the BLS (according to the present novel food application, this is the specified maximum amount in UV-irradiated mushrooms).

2.2 Results

2.2.1 Dietary vitamin D intake based on the respective model calculations

The daily dietary vitamin D intake of the NVS II and EsKiMo study populations resulting from the individual scenarios is shown in Table 5 and in Figures 1 and 2. Of the EsKiMo population, the subgroup of 12- to 13-year-old children was selectively considered (the 13-year-olds were included due to the sample size), since children over 14 years old are already recorded within the NVS II. The data show that, as expected, vitamin D intake through normal diet is low (median for 12 to 13-year-olds 1.8 µg per day and for NVS II participants 3.2 µg per day).

Based on the fortification concept (*VitD fort. concept*), the median maximum possible daily vitamin D intake is 16.8 µg for the NVS II population and 18.0 µg for the 12- to 13-year-old children. Thus, fortification of the carrier foods would increase the median vitamin D intake by about 5-fold for the NVS II participants and by about 10-fold for the 12- to 13-year-olds. Thereby, men and boys would have a higher intake of vitamin D than women and girls (Figures 1 and 2). In the 95th percentiles, daily vitamin D intake would be up to 36.8 µg per day in the NVS II population and up to 37.8 µg per day in the 12- to 13-year-old children (Table 5).

The calculated vitamin D intakes are above the target values defined under 1.3: 10 µg per day for the average dietary intake of the population and 20 µg per day in the 95th percentile.

However, it can be assumed that in reality vitamin D will not be added to all products of a food category and that not all carrier foods will be consumed in fortified form by each individual. The actual daily intakes would therefore probably be lower. Assuming that 50% of carrier foods within a category are fortified, the intake would be approximately in the range of the stated target values.

Furthermore, it can be assumed that food supplements containing vitamin D will additionally be consumed, most of which contain around 20 µg of vitamin D per daily dose.

Table 5: Vitamin D intake from normal diet (base) and based on the three different fortification scenarios assuming a 100% fortification rate of the relevant food categories

	Basic intake (Base)	VitD fort. concept*	VitD fort. concept +UV milk**	VitD fort. concept +UV milk +UV mushrooms***
NVS II (14 - 80 year olds) N = 15371				
Supply percentile	**µg/day**			
5	0.90	7.53	7.81	7.93
50	3.19	16.78	17.59	17.77
95	11.10	33.20	36.46	36.75
EsKiMo (only 12- to 13-year-old children) N = 416				
Supply percentile	**µg/day**			
5	0.70	8.84	10.07	10.14
50	1.81	17.96	20.48	20.65
95	4.89	31.46	37.67	37.76

The scenario is based on a vitamin D fortification rate of 100%

* of all foods of a category present in the BLS that are suitable as carrier foods.

** of all carrier foods present in the BLS plus consideration of the vitamin D input from UV-irradiated milk approved/applied for in the novel food procedure.

*** of all carrier foods present in the BLS plus consideration of the vitamin D input from UV-irradiated milk and UV-irradiated mushrooms approved/applied for in the novel food authorisation procedure.

It turns out that an additional consumption of UV-irradiated milk or UV-irradiated milk and UV-irradiated mushrooms would only slightly further increase the vitamin D intake already achieved by the *VitD fort. concept*. This can be explained by the fact that, according to the consumption studies, mushrooms are only consumed in small quantities and the UV-treated milk was only considered as unprocessed milk based on the information in the novel food application documents. For children who have a higher milk consumption compared to adults, UV-irradiated milk therefore has a slightly stronger effect on vitamin D intake. Overall, however, the additional vitamin D intake from these two novel food products is only slightly further elevated compared to the vitamin D intake from the *VitD fort. concept*.

However, should applications be made for the extension of use of UV-irradiated milk in processed foods or other novel foods with increased vitamin D content, the respective impact on vitamin D intake would have to be reviewed again. In any case, the application of the vitamin D fortification concept should be accompanied by “post-marketing monitoring” (a corresponding monitoring of the market) in order to check the effect on the vitamin D intakes and the vitamin D supply of the population and, if necessary, to be able to react to changes in consumption habits, the scientific data situation or the market.

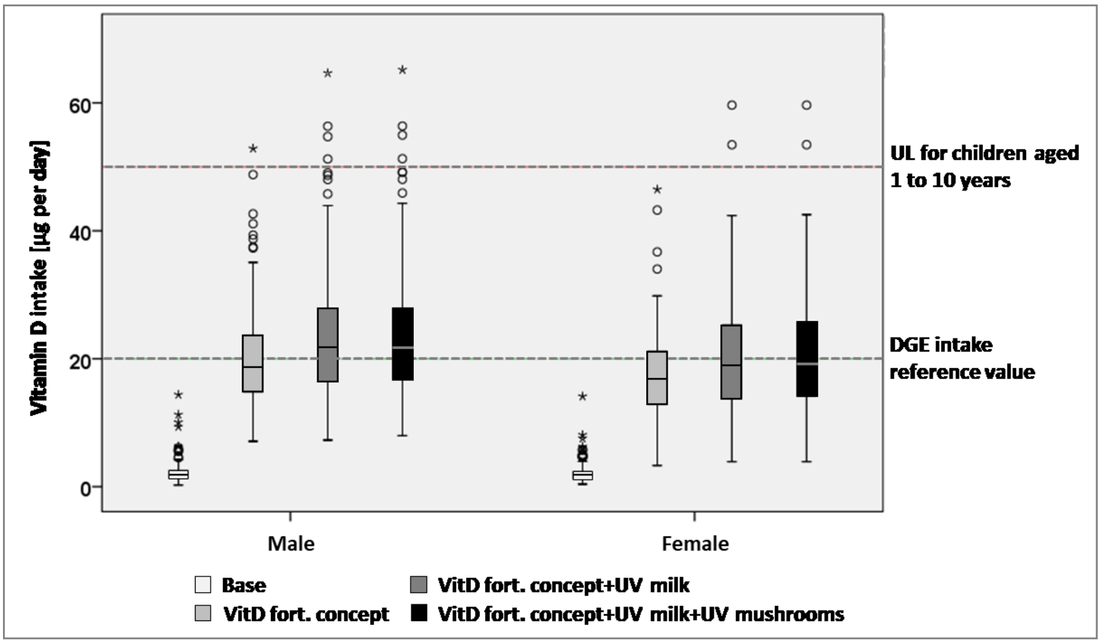

Figure 1: Vitamin D intake of 12- to 13-year-old children* from normal diet (base) as well as based on the three different fortification scenarios with a 100% fortification [a]
* based on EsKiMo data (Mensink et al., 2007)

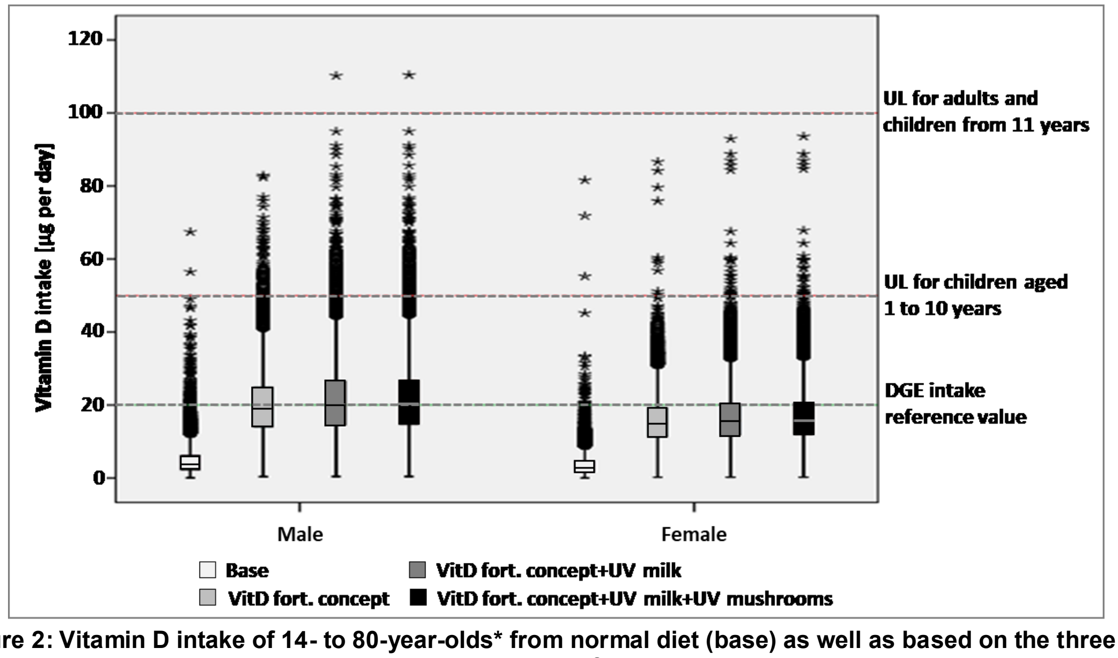

Figure 2: Vitamin D intake of 14- to 80-year-olds* from normal diet (base) as well as based on the three different fortification scenarios with a 100% fortification [a].
* based on NVS II data (MRI, 2008)
[a] Each scenario is based on a 100% vitamin D fortification of all carrier foods present in the BLS or all carrier foods present in the BLS and novel foods which have been approved/applied for.
o outliers[2]
✱ extreme values[3]

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[2] Outliers are values whose distance from the 25[th] percentile downwards or from the 75[th] percentile upwards is between 1.5 times and 3 times the box height. The box height reflects the distance between the 25[th] and 75[th] percentile.
[3] The distance of extreme values from the 25[th] or 75[th] percentile is more than 3 times the box height.

2.2.2 Main sources of vitamin D from fortified foods

If one compares the contribution of the different food groups to vitamin D intake for the calculated scenarios, then, as expected, the selected carrier foods primarily contribute to vitamin D intake within the framework of the fortification concept. Bread and bread rolls make the largest contribution for both children and adults with over 40%. This is followed by milk/milk drinks with about 10% in the NVS II population and with more than 20% among the 12- to 13-year-old children. Due to the higher milk consumption of children, UV-irradiated milk also has a stronger effect on vitamin D intake here (over 30%). Yoghurt and dairy products contribute about 7% and 5%, respectively, and vegetable oils and margarines about 6% to vitamin D intake in both adults and children (Figure 3).

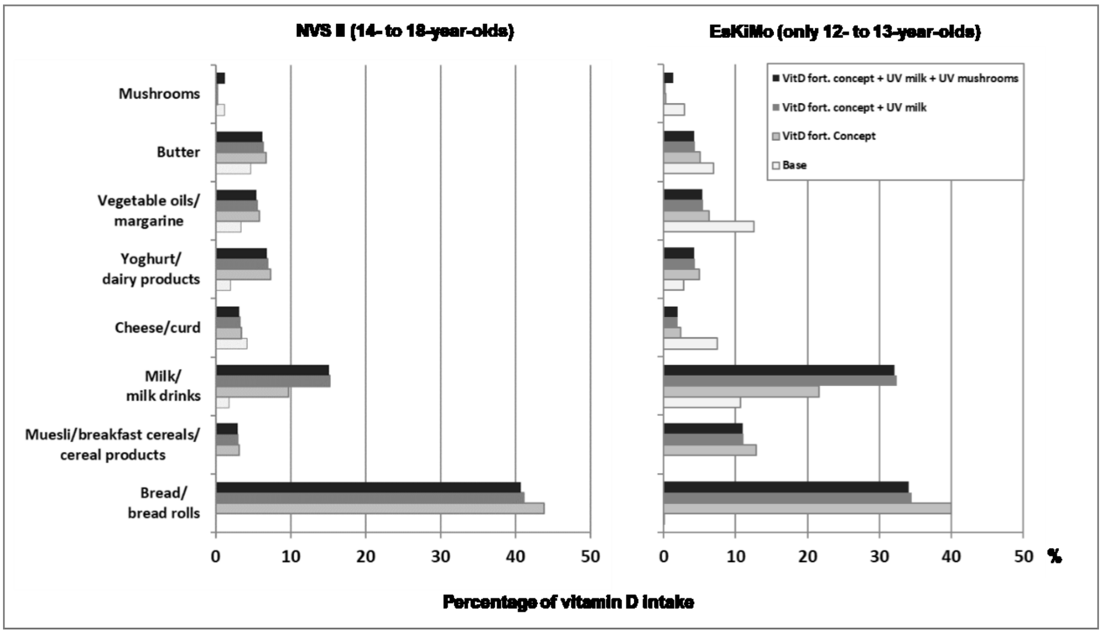

Figure 3: Main sources of vitamin D based on the different fortification scenarios with a 100% fortification[a]

[a] Each scenario is based on a vitamin D fortification of 100% of all carrier foods present in the BLS or all carrier foods present in the BLS and considered novel foods which have been approved/applied for. Basis: vitamin D intake from carrier foods and considered authorised/applied for novel foods without fortification.

2.2.3 Vitamin D intake in relation to the UL

2.2.3.1 Age groups from 12 years on

The scenario of a 100% fortification of all possible carrier foods was chosen in order to rule out health risks from the vitamin D fortification concept even in the event that actually all manufacturers practice vitamin D fortification of the carrier foods considered suitable and an additional vitamin D supply from novel foods (e.g. UV-irradiated milk and mushrooms) takes place.

Under the terms of the Concept, even in the 95th percentiles, neither adults nor 12- and 13-year-olds would significantly exceed the UL for 1- to 10-year-old children (50 µg per day) (Table 6; Figures 1 and 2; Table 1A in the Appendix). Overall, only 1.5% of 12- to 13-year-olds and 1.1% of the NVS II population have an intake above the UL under these conditions (Table 6).

It should be noted, however, that vitamin D-containing food supplements, which increasingly contain around 20 µg of vitamin D or more per daily dose, may be additionally consumed and were not considered in the model calculations carried out here.

Table 6: Number or percentage of people who would exceed the UL for vitamin D in the case of a 100% vitamin D fortification of carrier foods, including the possible additional vitamin D input from approved/applied for novel foods considered (VitD fort. concept + UV milk + UV mushrooms)

Study populations	Vitamin D intake above the UL			
	UL for children from one to ten years (50 µg/day)		UL for adults and children from 11 years (100 µg/day)	
	Number	Percent	Number	Percent
EsKiMo (12- to 13-year-olds only)	6 (of 416)	1.5 %	0 (of 416)	0 %
NVS II (14- to 80-year-olds only)	173 (of 15371)	1.1 %	2 (of 15371)	0.01 %

2.2.3.2 Age groups under 12 years

The model calculations were not carried out for children under the age of 12. Instead, a conservative estimation of the risk for too low or too high vitamin D intakes was carried out for this group:
For this purpose, the consumption amounts of the carrier foods in children aged between one and eleven years were compared with those in 12-year-olds (Tables 7 and 8). It was found that the carrier foods bread, cereals and fats were consumed in lower quantities by one to eleven year old children than by 12-year-olds. The consumption of dairy products is also slightly lower among younger children than among 12-year-olds. Only in one age group (four year-old girls) the amount consumed is slightly higher.

However, it can be assumed that younger children will, on average, take in less vitamin D per day via carrier foods than 12-year-olds in the context of the proposed fortification strategy. Thus, younger children would not exceed the UL for children (50 µg per day for one to ten-year-olds) in the 95th percentile, but still achieve an effective increase in their vitamin D intake. However, per kg body weight per day, the younger children would consume higher amounts of the carrier foods than the 12-year-olds and thus also consume more vitamin D per kg body weight.

Table 7: Consumption amounts (medians) of the carrier foods in one- to four-year-old children*

Age in years	Milk/dairy products	Bread/cereal/(flakes)	Fats/oils
	g per day (m/f)**		
1	271 / 186	65 / 55	11 / 10
2	271 / 244	72 / 74	15 / 14
3	238 / 224	81 / 75	18 / 16
4	279 / 268	98 / 98	19 / 19

* From the VELS study (Kersting et al., 2003)
** The values for boys (m) and girls (f) are listed individually; m/f

Table 8: Consumption amounts (medians) of the carrier foods in six- to 12-year-old children*

Age in years	Milk/dairy products	Cheese/ curd	Bread	Cereals	Fats/oils
	g per day (m/w)**				
6	316 / 245	15 / 12	80 / 94	13 / 7	10 / 9
7–9	260 / 215	18 / 19	99 / 89	13 / 9	12 / 9
10–11	244 / 220	17 / 17	105 / 99	9 / 8	11 / 10
12	329 / 252	19 / 28	131 / 127	14 / 14	27 / 21

* From the EsKiMo study (Mensink et al., 2007)
** The values for boys (m) and girls (f) are listed individually; m/f

3 Conclusion

From the BfR’s point of view, the fortification concept proposed here, which intends the addition of vitamin D to

- milk and dairy products (including cheese) at a maximum amount of 1.5 µg per 100 g;
- bread and baked goods (except pastry goods) and breakfast cereals at a maximum amount of 5 µg per 100 g;
- spreadable fats and cooking oils (including liquid vegetable fat preparations and vegetable creams) at a maximum amount of 7.5 µg per 100 g;

and which takes into account a number of already approved/marketed fortified products, is suitable to achieve a significant increase in vitamin D intake in the German population. At the same time, there is only a small risk that children from the age of one up to the age of ten will exceed the UL of 50 µg vitamin D per day derived for this age group[4]. The intake levels of adolescents and adults are also below the UL of 100 µg vitamin D per day.

The BfR recommends accompanying the fortification concept by appropriate monitoring of the market (“post-marketing monitoring”) in order to be able to quickly identify the actual extent of vitamin D fortification and any undesirable effects (e. g. expansion of the approved UV-irradiated novel foods). At the same time, from the point of view of the BfR, 25-OH-D_3 concentrations should be recorded regularly as part of the national health surveys of the RKI.

[4] A UL of 25 µg vitamin D per day was derived for zero- to one-year-old children (EFSA, 2012).

Further information on the subject of Vitamin D is available on the BfR website

https://www.bfr.bund.de/cm/349/selected-questions-and-answers-on-vitamin-d.40414212.pdf

Topic page on the assessment of vitamins and minerals in foods:
https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html

BfR “Opinions app”

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5 Appendix

Table 1A: Vitamin D intake from normal diet (base) as well as based on the three different fortification scenarios with a 100% fortification, depending on age [a]

Age in years	P5	P25	P50	P75	P95
	Vitamin D intake in µg per day				
Based on EsKiMo					
12	0.66	1.24	1.82	2.45	4.91
13–14	0.73	1.24	1.78	2.61	4.87
15–17	0.67	1.33	1.97	3.04	6.27
EsKiMo *VitD fort. Concept*					
12	8.56	14.05	17.70	22.46	31.40
13–14	8.36	13.54	18.40	22.79	33.58
15–17	8.76	14.18	18.85	25.39	39.85
EsKiMo *VitD fort. concept + UV-treated milk*					
12	9.40	15.52	19.97	26.73	35.52
13–14	9.40	15.03	21.45	27.00	40.09
15–17	9.27	16.06	21.07	28.94	46.97
EsKiMo *VitD fort. concept + UV-treated milk + UV-treated mushrooms*					
12	9.85	15.80	20.31	26.87	35.52
13–14	9.56	15.17	21.49	27.46	40.36
15–17	9.38	16.13	21.14	29.39	46.97
Based on NVS II					
14–18	0.62	1.38	2.04	3.00	5.51
19–24	0.77	1.50	2.30	3.65	7.19
25–34	0.89	1.76	2.85	4.61	9.25
35–50	0.98	2.02	3.32	5.35	10.68
51–64	1.04	2.37	3.94	6.56	12.87
65–80	0.97	2.11	3.79	6.48	13.23
NVS-II *VitD fort. Concept*					
14–18	7.08	11.96	16.68	22.52	33.57
19–24	6.85	11.14	15.30	20.71	36.05
25–34	7.12	12.05	15.99	21.59	33.52
35–50	7.38	12.24	16.83	22.19	33.73
51–64	8.16	13.03	17.59	22.36	33.51
65–80	8.39	12.90	17.07	21.90	30.98
NVS II *VitD fort. concept + UV-treated milk*					
14–18	7.38	13.04	18.46	25.03	37.97
19–24	7.05	11.79	16.43	22.57	42.72
25–34	7.24	12.59	17.14	23.42	37.42
35–50	7.61	12.79	17.48	23.48	36.60
51–64	8.52	13.43	18.06	23.53	36.33
65–80	8.63	13.40	17.95	23.25	33.37
NVS-II *VitD fort. concept + UV-treated milk + UV-treated mushrooms*					
14–18	7.55	13.15	18.54	25.30	38.01
19–24	7.19	11.94	16.65	22.70	42.72
25–34	7.42	12.82	17.35	23.48	37.67
35–50	7.76	12.95	17.65	23.70	37.03
51–64	8.59	13.58	18.28	23.77	36.53
65–80	8.84	13.45	18.06	23.33	33.37

For each scenario, the 5th percentile (P5), the 25th percentile (P25), the 50th percentile (P50), the 75th percentile (P75) and the 95th Percentile (P95) are shown in the columns from left to right.

[a] Each scenario is based on a 100% vitamin D fortification of all carrier foods present in the BLS and/or novel foods which have been approved/applied for.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States (‘Laender’) on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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