## Fortified foods. Criteria for vitamin supplementation in Spain

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#### **Abstract**

Objective: To review and analyse criteria for vitamin supplementation and fortification in Spain.

Design: Systematic review of scientific literature and simulation analysis of food fortification.

*Methods*: A simulation analysis using a fortified beverage was performed in a random sample of 2855 children aged 2 to 24 years in Spain.

Results: High-risk groups for vitamin supplementation and fortification in Spain are highlighted, and target vitamins considered have been: folic acid, vitamin A, vitamin E, vitamin D and vitamin  $B_{12}$  (particularly in the elderly). A beverage fortified with vitamins C, A,  $B_1$  and  $B_6$  may contribute to improving the intake of all of these vitamins with the exception of vitamin A, since the Recommended Nutrient Intake is already covered with current consumption.

*Conclusions:* A detailed knowledge of nutritional status helps to ensure the rationale and follow up of nutrient supplementation and fortification.

Keywords
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Several studies have associated the utilisation of supplements and fortified foods with specific health advantages. Concretely, these include a decreased risk of offspring with congenital malformations<sup>1</sup>, reduced incidence of cardiovascular diseases<sup>2</sup>, cancer<sup>3</sup>, ocular degenerative processes<sup>4,5</sup>, infections and neurological deterioration (such as Alzheimer's, Parkinson's, tardive dyskinesia)<sup>6,7</sup>. However, its principal use is to assist in meeting reference intakes specific for different individuals, in the case that these persons are not able to do so through regular food intake<sup>8,9</sup>.

It is widely accepted that adequate nutrition is essential for achieving optimal health and a satisfactory functional capacity. The theoretical benefit of meeting recommended intakes is the delaying of the onset of chronic diseases and enhancing the quality of life (with concomitant increases in functional capacity and productive longevity, and reduced healthcare costs)<sup>9</sup>.

For these reasons, improving the nutritional status of the population becomes a priority focus at the collective as well as the individual level<sup>10</sup>.

†All authors are members of the GRAN Group, a Steering Committee for research and advice on vitamins and applied nutrition in Spain.

### Fortified foods or supplements?

Nutrient supplementation and fortification are commonly employed for the following purposes:

- to enhance the daily intake within a population of vitamins and minerals so as to meet Recommended Nutrient Intakes (RNIs) when intakes from unfortified foods do not reach the recommended levels; and
- to provide levels of vitamins, minerals and trace elements greater than the current RNIs in the case of a demonstrated protective benefit against disease in healthy individuals or against the progression of a pre-existing disease in affected persons<sup>11</sup>.

The advantages and disadvantages of nutrient supplementation versus fortification have already been mentioned. On one hand, the advantages of supplementation are greater specificity in the intervention and better dose adjustment, while those of fortification include universality of the intervention and greater compliance. Conversely, the disadvantages of supplementation are incurred user cost, low compliance, increased risk of toxicity and self-prescription. Drawbacks of fortification include that the dose is a function of food quantity consumed, low specificity and varying standards legislated for each country<sup>12</sup>.

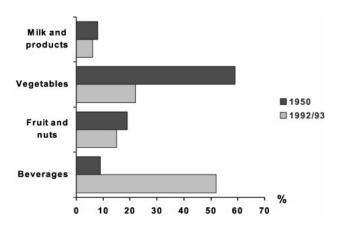
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To maximise a programme's effectiveness, the perceptions and attitudes of the population towards nutrition education and supplementation should be analysed. Supplementation is often seen as an additional health risk due to possible problems with toxicity associated with certain vitamins and minerals. As such, it is important to keep in mind the potential health risk that an excessive intake of a nutrient could represent 13,14. However, in practice, this risk is greater with supplements than with enriched foods. The risk of toxicity is minimal and almost non-existent when a level equal to or less than the RNI is applied as criterion for fortification or supplementation. For the majority of nutrients, the upper limit of safe intake exceeds 10 times the recommended value 13.

#### Food fortification: the case of beverages

Vitamin and mineral enrichment of a wide variety of foods has contributed to improving nutrient intake and nutritional status. Perhaps the most illustrative example is seen in the case of ready-to-eat breakfast cereals (RTEC). Numerous advantages in the health of a population that consumes a complete breakfast have been attributed to the inclusion of RTEC as a part of this meal<sup>15</sup>. The analysis of RTEC consumption supports this point. A French study has described the association between having a complete, balanced breakfast and including RTEC<sup>16</sup>. In a country such as the United Kingdom, which has a long tradition of consuming these products, RTEC intake has contributed considerably towards improving the intake of specific nutrients in the last 50 years<sup>17</sup>. Fortified beverages (FBs) have also positively contributed to vitamin C consumption in several countries, such as Great Britain. For example, in the UK, the main sources of vitamin C in 1950 primarily came from vegetables (59%) and fruit and nuts (19%), whereas beverages provided only 9% of the 40 mg day<sup>-1</sup> consumed. In 1992–93, the mean intake of vitamin C was 48 mg day<sup>-1</sup> in which beverages contributed 52% and constituted the main source of dietary vitamin C, followed by vegetables (22%) and fruit and nuts (15%)  $(Fig. 1)^{17}$ .

To analyse the nutritional impact of FBs in Spanish schoolchildren, a simulation analysis was conducted using the enKid study. The methodology of The enKid Study has been described elsewhere 18. It was comprised of a random sample of 3534 individuals aged from 2 to 24 years in Spain, and the main dietary tool included two 24-hour recalls. Nutritional data were adjusted for intraindividual variability 19, and underreporters were excluded 20. A total of 2855 people were included in the simulation analysis. An FB with a standard composition for 100 ml of 120  $\mu$ g retinol equivalents of vitamin A, 210  $\mu$ g of thiamine, 300  $\mu$ g of vitamin B<sub>6</sub> and 30 mg of vitamin C was used. Three scenarios were established: the current situation, a situation in which 25% of the beverages were fortified in accordance with the formula,



**Fig. 1** Percentage contribution of major food groups to vitamin C intake of children aged 4 years in national British studies in 1950 (n = 4599) and 1992/93 (n = 493) (source: Prynne et al.<sup>17</sup>)

and a third situation in which half of the beverages were fortified. Results are presented in Table 1. Mean vitamin A and C intakes increased with the level of fortification (yet not those of thiamine and  $B_6$ ) but the impact on meeting RNIs was reliable only for vitamin C (the percentage of the population with intake below 2/3 RNI decreased from 63% to 48%) and to a lesser extent for  $B_1$  and  $B_6$ . The results of these analyses suggest a mild effect of FB on vitamin intake in Spanish schoolchildren and adolescents, and emphasises the rare risk of toxicity with these kinds of fortified food at a population level.

Without a doubt one can see the clear example of how an enriched or functional food can contribute to improving the health status of a population that consumes it, and thus is of great interest to nutrition and public health experts. This could be especially relevant for folate, given the risk of unplanned pregnancies in females of this age range, and its role in the reduction of neural tube defects, and also for other nutrients such as iron, calcium, vitamin D or thiamine.

# Criteria of supplementation and fortification in Spain

The preferred source of information for the population at large is the community of health professionals. Therefore the role of doctors, pharmacists, nurses and dietitians in nutrition education is essential, and should be emphasised. Effective contact between professionals and the public should be maximised to transmit dietary and nutritional messages that are considered high-priority<sup>21</sup>. In the case of supplements – which, in certain European countries, are mainly bought in pharmacies (80% in Spain or Italy, versus less than 60% in Great Britain for example)<sup>22</sup> – pharmacists can play a decisive role in the appropriate use of supplements by the general public. Schools also constitute a fundamental base for nutrition education during childhood. Solid political support is

**Table 1** Intakes of vitamin A, thiamine, and vitamins  $B_6$  and C in Spanish children and adolescents before (CS – current situation) and after a simulated beverage fortification (BF) (n = 2855)

				· · · · · ·				% Population with intakes			
	Mean	SD	Min	P5	P50	P95	Max	<1/3 RNI	<2/3 RNI	<rni< th=""><th>% RNI (mean)</th></rni<>	% RNI (mean)
Vitamin A (µ	g retinol e	equivalent	s)								_
CS "	492.8	116.4	20.2	333.4	486.6	663.9	2791.9	0.0	0.0	1.8	147.7
BF 25%	521.4	134.4	20.2	350.2	504.6	754.6	2791.9	0.0	0.0	1.2	152.8
BF 50%	550.0	175.0	20.2	351.4	513.1	877.5	2791.9	0.0	0.0	1.1	158.0
Thiamine (m	ıg)										
CS `	1.3	0.3	0.6	0.9	1.3	1.8	3.0	0.0	2.7	48.8	107.2
BF 25%	1.4	0.3	0.6	0.9	1.4	1.9	3.0	0.0	1.9	41.0	111.5
BF 50%	1.4	0.4	0.6	1.0	1.4	2.1	3.7	0.0	1.7	37.7	115.8
Vitamin B <sub>6</sub> (	mg)										
CS (	1.7	0.3	0.7	1.1	1.6	2.2	3.7	0.3	8.1	31.9	131.7
BF 25%	1.7	0.4	0.7	1.2	1.7	2.4	4.1	0.1	5.8	24.4	144.1
BF 50%	1.8	0.5	0.7	1.2	1.7	2.7	5.3	0.1	5.6	23.2	156.0
Vitamin C (n	ng)										
CS `	77.2	31.9	14.5	35.5	73.6	136.0	326.7	1.2	62.9	75.9	77.8
BF 25%	84.6	35.0	15.7	37.5	79.6	146.0	333.3	0.9	54.2	74.8	81.4
BF 50%	91.9	44.3	15.7	37.7	83.6	174.4	408.3	0.9	48.3	71.9	85.0

SD - standard deviation; P5, P50 and P95 - 5th, 50th and 95th percentile, respectively.

required as well in order to carry out school programmes that are effective and have continuity<sup>23</sup>. Governments should actively provide incentives for conducting nutrition education programmes in schools and in primary health care settings.

Identification of nutritionally at-risk groups and the orientation of fortified foods and programmes of supplementation towards these populations are necessary strategies to be coherent. In this sense, the Spanish Advisory Nutrition Group (www.grannutricion.org) has reviewed the criteria for vitamin supplementation and fortification in Spain, identifying high-risk population groups and nutrients<sup>24</sup>.

Community nutrition interventions should take place within the context of food availability and nutrition education should constitute their principal approach. They should also be in accordance with food guides and, whenever the circumstances are called for, with fortification of foods and eventually supplementation. Such interventions should be adequately planned and evaluated within the context of each country or region.

Criteria for supplementation and fortification in Spain can be summarised in the following points.

- At-risk groups include pregnant and post-menopausal women along with those of childbearing age, children (in periods of rapid growth and development), smokers, drinkers and the elderly (who suffer additional health and social problems).
- **2**. The benefits of supplementation can be categorised in the following applications:
  - 2.1. the administration of multivitamins, iron and folate during the preconceptual stage and the first trimester of pregnancy;
  - 2.2 starter and follow-up infant formulas, cereals and homogenised foods;

- 2.3 multivitamins and/or fortified foods for at-risk children and adolescents;
- 2.4 certain vitamins specific for the elderly population (vitamin E, folate, carotenes, vitamins D and  $B_{12}$ );
- 2.5 vitamin compounds or foods fortified with several nutrients for those with inadequate food intake, difficult food compliance or following a low-calorie diet;
- 2.6 vitamin B<sub>12</sub> for vegetarian populations;
- 2.7 for smokers and heavy drinkers who are resistant to discontinuing their habit;
- 2.8 for patients with digestive and renal pathologies, signs of malnutrition or undergoing major surgery; and
- 2.9 for patients with chronic conditions compromising nutritional status.

It is noteworthy that, according to the Spanish Advisory Nutrition Group (Grupo GRAN), it is preferable to have intakes above, rather than below, the RNIs. In addition, it is stated that the effects and bioavailability of vitamins in the form of supplements are superior to those naturally occurring in foods.

Attempts should be made to improve dietary habits by the 50% of the Spanish population who need them in order to approximate a healthier model within the context of the Mediterranean Diet. In the recently published White Book on vitamins in foods of the Spanish population, The eVe Study, the following factors were confirmed as being determinants for achieving an adequate nutrition profile: abstaining from smoking and drinking, moderate physical activity and high consumption of fruits, vegetables and legumes along with moderate intakes of meat, fish and dairy products<sup>25</sup>.

The choice of supplementation or fortification will

depend on characteristics of the population and approaches of the required nutrition intervention.

In conclusion, the authors would make manifest to health authorities and the scientific community the need to deepen our knowledge in the years to come on the role of vitamins in the health of the Spanish population. Priority should be given to establishing new criteria for food enrichment, fortification and supplementation that are based on epidemiological studies and other scientific evidence<sup>25</sup>.

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