



FoodDrinkEurope proposes guiding principles on the setting of EU harmonised maximum amounts of vitamins and minerals in fortified foods

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IN BRIEF

Voluntary food fortification is an effective public health strategy to improve the nutritional status of the population and to address micronutrient deficiencies.

In this paper, FoodDrinkEurope provides its key recommendations on the setting of EU maximum amounts for the addition of vitamins and minerals to foods.

KEY MESSAGES

- **Micronutrient deficiency remains a public health problem within the EU. Food consumption surveys across Europe show that food fortification can improve the nutritional status of the population.**
- **Fortified foods and drinks have been safely consumed in Europe for several decades.**
- **The setting of maximum amounts for vitamins and minerals should be based on sound science and robust evidence from comprehensive food consumption data.**
- **Any limitation and/or restriction should be proportionate and based on scientific evidence.**
- **The maximum amounts of vitamins and minerals should be set only for micronutrients whose excessive intake is associated with a known risk, according to the level of risk identified.**
- **The addition of vitamins and minerals to foodstuffs remains relatively limited to some food categories.**
- **The capacity of the European food and drink industry to deliver high quality and safety standards, to support consumer health and to promote growth through innovation, should be preserved.**

1. Fortification is recognised by health authorities as a tool for improving the nutritional status of the population

Micronutrient deficiency is a public health problem within the EU. In its 2022 Scientific Opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods ¹, the European Food Safety Authority (EFSA) identified several micronutrients for which there is a risk of inadequate intake amongst the European population.

Inadequate intake of potassium has been observed among most of the European adult population, while inadequate intake of iodine particularly affects some European countries and sub-groups of European populations. Women of childbearing age, pregnant women, and children are generally considered at higher risk of inadequate iron intake, while vitamin D deficiency is evident throughout the European population at prevalence rates that are concerning and that require action from a public health perspective. Intake of calcium is also inadequate among adolescents ^{2,3}.

Regulation (EC) No. 1925/2006 on the addition of vitamins, minerals and certain other substances to foods and several national regulatory frameworks across the EU acknowledges that fortified foods make an appreciable contribution to the intake of micronutrients which are consumed below recommended levels ⁴. As stated in the recitals of Regulation (EC) 1925/2006, surveys show that dietary requirements for minerals and vitamins are often not met through the average diet. Therefore, foods to which vitamins and minerals are added can increase the intake of adequate micronutrient levels in all population groups.

Food consumption surveys across Europe show that food fortification can improve the dietary intake of critical micronutrients ⁵. Recent studies confirmed the positive effect of national food fortification and supplementation policies on vitamin D status in Finland ⁶. In Ireland and the Netherlands, voluntary food fortification had a positive impact on the diet of the adult population ^{7, 22}. In 2018, the European Society for Paediatric Gastroenterology Hepatology and Nutrition Committee confirmed that consumption of young child formula by children aged 1 to 3 years old increases the intake of vitamin D, iron and n-3 polyunsaturated fatty acids. It is clear, therefore, that these fortified products can be part of the strategy to improve the nutritional status of this population group together with a healthy and varied diet, and the use of food supplements ^{8, 9, 10, 11, 12, 13, 14}. Recent publications further illustrate the positive contribution of breakfast cereals to the intake of vitamin D, folic acid, B vitamins and iron ^{15, 16, 17, 18, 19} and the positive impact of fortified margarine ²⁰ to the micronutrient intake in different Member States.

2. Fortified foods and drinks have been safely consumed in Europe for decades

Fortified foods and drinks have a long history of safe use around the globe. In 1987, FAO Codex Alimentarius adopted the first Guidelines on the “General principles for the addition of essential nutrients to foods”²¹, which serve as the global basis for the rationale and safe addition of micronutrients to food. In the EU, fortified products, such as breakfast cereals, chocolate powder or milk, have been marketed since the 1970s. In 2006, the EU adopted a harmonised regulatory framework to ensure the safety of fortified foods, Regulation (EC) No. 1925/2006.

The long history of use of fortified foods and drinks goes hand-in-hand with the safe consumption of these products. An analysis in Ireland, an EU country with a history of liberal fortification practices, shows that consumers with a high micronutrients intake (at the P95) did not exceed or even approach the Tolerable Upper Intake Levels (ULs), with or without the inclusion of added nutrients from voluntary fortification⁷. The tolerable upper intake level is the highest intake that is unlikely to pose a risk of adverse health effects for the human population. A recent study in the Dutch population reported results similar to the study carried out in Ireland²². See further examples in Annex 1 of this document.

Moreover, when considering the overall range of food products that people consume in their daily diets, only a small proportion of the daily intake of micronutrients comes from fortified foods and drinks. The impact of voluntary food fortification on micronutrient intakes and status in European countries has been recently reviewed²³. Whereas the proportion of children consuming fortified foods is greater than it is with adults, the proportion of dietary energy obtained from fortified foods is low both in children and adults (<10% in Ireland, where fortified foods are widely consumed). The risk of sub-optimal intakes of a range of micronutrients at a population level can be reduced and the status for selected micronutrients in children and adults can be improved through voluntary fortification. Data from national surveys on total micronutrient intakes (including fortified foods) in Europe show that only a small proportion of the population may exceed the ULs for some micronutrients. However, the risk of adverse effects occurring in these individuals exceeding the UL by modest amounts is low.

In general, only a small part of the food consumed daily is fortified because unprocessed foods cannot be fortified. In a 2021 study by Euromonitor, only 3.6% of pre-packaged foods, by value, were fortified²⁷. This share was 3.5% in 2015 and is expected to remain stable over the period 2021-2025. See more details about the Euromonitor survey in Annex 2 of this document.

3. Sound science and robust evidence from food consumption data should underpin the setting of maximum amounts for vitamins and minerals

The regulatory framework governing the maximum amounts of vitamins and minerals that can be added to foods should ensure that fortification is appropriately regulated in order to ensure the safety of all consumers. Any such regulation should ensure that food

fortification can continue to deliver the maximum benefit to target groups, while leaving appropriate freedom to the consumer to choose from a varied portfolio of products. In this regard:

- FoodDrinkEurope supports the conditions laid down in article 6 of Regulation (EC) No. 1925/2006 on the addition of vitamins, minerals and certain other substances to foods.
- Maximum levels should be derived from food consumption data and based on sound scientific evidence. With regard to Member States' legislation, the European Court of Justice stated in the *Noria* and the *Queisser* rulings that the setting of maximum amounts in food supplements should be "*based not on general or hypothetical considerations, but on relevant scientific data*"²⁴ and that "*the assessment of the risk cannot be based on purely hypothetical considerations*"²⁵.
- Fortified foods are consumed by the general population. Accordingly, only the most recent and reliable adults' food consumption data should be used to derive maximum amounts. These should subsequently be checked against consumption data for children to ensure that they do not reach levels at which there is risk of excessive intake.
- Micronutrient intake from other sources (conventional foods and food supplements) should also be considered and thoroughly assessed. In this regard, dietary intake data should distinguish between conventional foods, fortified foods, and food supplements.
- The most appropriate reference value for determining the safety of micronutrient intakes in population subgroups is the Tolerable Upper Intake Level (UL). ULs set by EFSA or - where EFSA's ULs are not available - ULs set by other national or international expert committees should be considered.
- The general principles laid down in the EFSA Guidance on human health risk-benefit assessment of foods (from 2010)²⁶ should be applied to set maximum levels. These principles ensure a balanced assessment of the benefits for those populations groups whose micronutrient intake is below the nutrient reference values (NRVs) and the risks of exceeding the UL for other population groups.
- Models under discussion for the setting of maximum levels propose calculating per 100 kcal, which is widely accepted by national authorities and academia. For the setting of maximum amounts in foods, it is critical that the calculated amounts per 100 kcal are converted to weight-based values, such as 100g/100ml, based on the mean energy densities of solid foods and energy-containing beverages. Where maximum levels are set per 100 kcal, the case of low/no-calorie products as well as products consumed in small quantities, should be treated as their regular counterparts. For example, skimmed and semi-skimmed milk should be fortified at the same level as full fat milk; low-fat margarine should be fortified at the same level of full-fat margarine; a zero-calorie beverage should be fortified at the same level of a regular beverage. For products consumed in small quantities, including products that are used to season dishes (like salt, seasonings, condiments), the portion size should be the reference.

4. Where no safety concerns have been identified for a vitamin or mineral no maximum levels should be set

FoodDrinkEurope supports the widely accepted approach based on the categorisation of risks in three categories.

- Group 1: micronutrients for which no risks have been identified and therefore no maximum levels should be set.
- Group 2: low risk of adverse effect and use of a calculation to derive the maximum level per 100 kcal and to convert it to 100 ml/g, as appropriate.
- Group 3: micronutrients for which the difference between the UL and the reference intake is small and the calculation used for group 2 leads to values which are not applicable. Therefore, a case-by-case analysis is needed, taking into account the contribution of individual products to the overall diet of the population or of sub-groups. The principles set in the 2010 EFSA guidance on human health risk-benefit assessment ²⁶ should be followed.

This approach is also supported widely amongst stakeholders, regulators and the scientific community.

5. The proportionality principle should be one of the key elements underpinning the setting of maximum amounts of vitamins and minerals

FoodDrinkEurope supports a responsible use of micronutrient fortification practices. Any limitation and/or restriction should not only be justified by scientifically valid evidence but also be proportionate, in accordance with the principle of proportionality laid down in Article 5 of the Treaty on European Union (TEU), i.e. European Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

All relevant provisions of the Regulation (EC) No. 1925/2006, namely Article 3 on the requirements for the addition of vitamins and minerals and Article 6 on restrictions, including maximum levels, adhere to the proportionality principle: they set clear criteria for the addition of vitamins, minerals and other substances to foods, and for restricting such addition. Whereas fortification can be justified by either nutrient deficiencies in the population or the potential to improve the nutritional status of the population or to take into account evolving scientific knowledge, maximum levels can only be based on science-based safe levels and relevant intake data.

The European Court of Justice reiterated those principles in the *Noria* ²⁴ and *Queisser* ²⁵ rulings. The Court made it very clear that Articles 6 (Risk analysis) and 7 (Precautionary principle) of Regulation (EC) No. 178/2002 on the general food law are the basis and cornerstone of all EU Food Law. The provisions of Regulation (EC) No. 1925/2006 have laid down those basic principles (science-based and proportionality) into specific secondary legislation and must therefore be applied accordingly.

6. The addition of vitamins and minerals to foodstuffs remains relatively limited to some food categories

The share of fortified foods in total vitamin and mineral intake is often overestimated. A large part of our food cannot be fortified in any way by virtue that it remains in its raw form. Furthermore, the amount of micronutrients that can be added to foods is often limited by various technological limitations, organoleptic reasons, and economic constraints. A survey commissioned to Euromonitor confirmed that, even though fortification is relevant for many food categories, the overall market of fortified foods and beverages is a limited market within the pre-packaged food market²⁷. Furthermore, it is relatively stable, and it is not expected to increase in the near future. See Annex 2 for more information about the survey commissioned to Euromonitor and a survey commissioned to Mintel concerning new product launches.

Moreover, several consumers trends, such as the heightened consumer interest in home-cooking/food preparation and the increased consumption of organic products (which under the EU legal framework cannot be fortified) further contribute to limiting the growth of the fortified foods market.

7. The competitiveness of European companies needs to be preserved

According to Euromonitor, the market size value of fortified food and beverages in the EU in 2020 was €18 billion, thus representing 3.6% of the total market value of packaged foods and beverages, which is estimated at €506 billion. Food and beverage fortification, and related innovation in this market segment, play an important role in guaranteeing the food and drink industry's competitiveness. The capacity of the European food and drink industry to deliver high quality and safety standards, to protect consumer health, and to promote growth through innovation, should also be preserved.

Furthermore, it is important to consider the impact that any measure may have on companies, especially SMEs. The EU food and drink industry is comprised of almost 290,000 SMEs – making up 99% of the entire industry. SMEs are responsible for producing the vast range of food and drink products that satisfy the changing needs of consumers in the EU. These businesses employ 2.6 million people. Therefore, it is essential to ensure that SMEs are supported and remain at the heart of our economy. To this end, the adoption of legislation on maximum amounts of vitamins and minerals should consider any impact on the operations and profitability of SMEs and provide guidance and support to help them comply with new requirements.

By setting maximum levels that guarantee the safety of products and preserve the aims of food fortification - namely to overcome deficiencies in certain nutrients or population groups, improve the nutritional status of the population and allow for evolving scientific knowledge to be taken into account - the European legislator would help to safeguard the innovation capacity and the competitiveness of European manufacturers.

Annex 1: Role of fortified foods in vitamin D supply

Vitamin D intakes have been examined over a 10-year period by comparing two nationally representative dietary surveys in 1999 and 2009 implemented using the same methodology among 18- to 64-year-old Irish adults²⁸. The surveys differentiated the base diet, fortified foods, and supplements. Vitamin D intakes among Irish adults increased marginally (median: 2.9±3.2 to 3.5±3.7 mcg/day) over a decade and in the context of a voluntary fortification policy observed; however, intakes remain well below recommendations (Adults >18yo: 15mcg/day). In quantitative terms, the contribution of foods to vitamin D intakes did not vary between supplement users and nonusers or between fortified food consumers and base diet consumers. The authors indicated that there is potential to increase vitamin D intakes at the lower end of the distribution, without increasing the risk of exceeding the tolerable upper intake level.

Further comparisons within the same surveys revealed that - although the supply of fortified foods increased between 1997-1999 and 2008-2010, resulting in a higher proportion of adults consuming fortified foods (from 67 to 82 %) and a greater contribution to mean daily energy intake (from 4.6 to 8.4 %) ⁷ - the increased consumption of fortified foods did not contribute to an increased risk of intakes exceeding the tolerable UL for any micronutrient.

The potential safety issue arising from vitamin D intakes and/or supplementation was also addressed based on collective data by Adebayo et al²⁹. High S-25(OH)D concentrations (>125 nmol/L) were rare - <10% when vitamin D supplements were administered, and <0.1% for fortified foods – in the RCTs and prospective cohort studies considered. No reported adverse effects in the RCTs (n = 3353, with vitamin D doses from 5–175 µg/day) were reported.

Annex 2: The EU market of fortified foods and beverages

Euromonitor reports that “the value share of fortified foods and food and beverages on total food and beverages in the EU reached a mere 3.6% in 2020, and this share is expected to remain relatively stable over 2021-25. The fortified food segment is, in fact, declining in the region’s biggest markets, Germany and France. This can be attributed to the increasing consumer shift from fortified foods products containing added functional ingredients, as they are perceived as artificial towards products with organic, naturally healthy and clean label positioning. The continuous decrease in the value share of fortified foods dairy on total fortified food and beverages in the EU during the entire review period can be attributed to its declining demand in the major markets - France, Spain, Italy and Germany. While in Spain, consumers avoid fortified dairy in favour of naturally healthy options like kefir, in France, consumers’ scepticism about the benefits of fortified dairy had a negative impact on its demand ²⁷.”

According to the Euromonitor report, the product categories most often fortified are dairy, beverages, cereals, and baked goods. Margarines and spreads are also often fortified. In addition, it should be noted that, in general, only some vitamins and minerals are added.

DSM commissioned in 2021 a survey to Mintel to better understand the dynamics of the market of fortified food and beverages³⁰. Mintel's Global New Products Data (GNPD) was used to count the number of fortified foods and beverages amongst the products launches between 2015 and 2020 in selected EU markets. The data confirm that the share of fortified food is low. Overall, less than 5% of all product launches (prepackaged food) were fortified. The survey found that fortification of most surveyed categories (juice drinks, breakfast cereals, margarine and other blends) is stable. Around 15% of new launches in these categories are fortified (with at least one vitamin or one mineral). Fortification of dairy carbonated soft drinks and bakery is below 7%. Sport drinks and energy drinks (which are combined in Mintel's categorisation) are the only categories showing a high fortification rate and an increased share of launches of products which are fortified (31% fortified in 2015 and 74% in 2020). However, sports and energy drinks represent only a small fraction of the total non-alcoholic beverages market – in 2020, representing only 3.1% of the total EU non-alcoholic beverage market³¹.

FoodDrinkEurope carried out a mapping exercise of current market practices on food fortification which covers 1400 fortified foods and beverages marketed in the EU³². The mapping identified the same categories identified by Euromonitor and Mintel's surveys and the confectionary category. Most of the fortified products are in the range of 15% to 30% Reference Intakes/100 g, 100 ml or serving, in line with the condition applying to nutrition claims under Regulation (EC) No. 1924/2006 with some differences seen between micronutrients (e.g. for vitamin D, E, B6, folates, niacin, calcium, iron and manganese, a larger number of products are containing between 30 and 100% RI per 100 g). Amongst the fortified foods studied, the fortification in minerals account between 2 and 20% of the products (with the exemption of iron, 49%, and calcium, 59%). The fortification in vitamins amongst fortified foods is higher and between 40 to 60% for water-soluble vitamins, 25% for vitamin A/beta-carotene and vitamin E and 49% for vitamin D.

About us

The EU food and drink manufacturing industry is made up of 289,000 businesses employing 4.5 million people. It generates €222 billion in value added every year and is the largest manufacturing industry in terms of jobs created. As an industry comprised of 99% SMEs our enterprises are intimately linked with their local communities. FoodDrinkEurope is the organisation of the European food and drink manufacturing sector, committed to achieving more sustainable food systems.

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