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## The impact of voluntary food fortification on micronutrient intakes and status in European countries: a review

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This review aims to assess the efficacy and safety of voluntary fortification as an option to address the occurrence of inadequate micronutrient intakes in population subgroups in Europe. Although legislation is harmonised across the European Union, fortification practices and patterns of consumption of fortified foods vary considerably between countries. While the proportion of children consuming fortified foods is greater than adults, the proportion of dietary energy obtained from fortified foods is generally low (<10% in Ireland, where fortified foods are widely consumed). There are a few systematic studies on the overall nutritional impact of voluntary fortification, but there are several studies on the impact of fortified ready-to-eat breakfast cereals. The available evidence indicates that voluntary fortification can reduce the risk of sub-optimal intakes of a range of micronutrients at a population level and can also improve status for selected micronutrients (e.g. folate, vitamin D and riboflavin) in children and adults. Although concerns have been raised regarding the potential of food fortification to lead to unacceptably high micronutrient intakes, particularly for those consuming higher amounts of fortified foods, data from national surveys on total micronutrient intakes (including fortified foods) in Europe show that small proportions of the population, particularly children, may exceed the upper intake level (UL) for some micronutrients. The risk of adverse effects occurring in these individuals exceeding the UL by modest amounts is low. In conclusion, voluntary fortification practices have been shown to improve intake and status of key micronutrients in European Union population groups and do not contribute appreciably to risk of adverse effects.

### Fortification: Micronutrients: Vitamins: Minerals: Micronutrient adequacy

It has been well established that micronutrients play a pivotal role in achieving and maintaining optimum health across all life stages. Data from a number of national dietary surveys across Europe suggest a significant prevalence of inadequate intake and suboptimal status of some micronutrients in population subgroups, such as children, adolescents, young women and older adults<sup>(1–10)</sup>. A recent paper by Mensink *et al.*<sup>(11)</sup> evaluated the prevalence of low micronutrient intakes in adults and children using recent nationally representative dietary survey data from eight European countries. Reanalysis of raw data was conducted to obtain uniformity with respect to age-groups and method of assessing adequacy. A significant proportion of individuals had intakes below the estimated average requirement and

lower reference nutrient intake for vitamin D, iron, vitamin A, iodine, magnesium and selenium in a number of population groups<sup>(11)</sup>.

In Ireland, recent data on micronutrient intake and status from the Irish Universities Nutrition Alliance national nutrition surveys<sup>(10,12–16)</sup> have indicated that inadequate micronutrient intakes occur in some population groups, particularly for iron, calcium, folate, vitamin A and vitamin D. The latest findings from the National Diet and Nutrition Survey (2008–2011)<sup>(3)</sup> in the UK showed that dietary intakes of vitamin A, vitamin D, riboflavin, magnesium and selenium were inadequate and suboptimal status was observed for iron and vitamin D, and to a lesser extent for riboflavin in many subgroups of the UK population.

**Abbreviations:** MDI, mean daily intake; NANS, National Adult Nutrition Survey; NSIFCS, North/South Ireland Food Consumption Survey; RTEBC, ready-to-eat breakfast cereal; RTEC, ready-to-eat cereal; UL, upper intake level.

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In light of these findings, it is important to consider methods for increasing the micronutrient intakes and nutritional status of population groups at risk of inadequate intakes. Improved nutrition education, nutritional supplement use and food fortification represent three options that have been put forward<sup>(17)</sup>. Nutritional supplement use has been effective in addressing inadequate micronutrient intake at an individual level<sup>(18)</sup>; however, uptake of use at the population level tends to be low<sup>(19)</sup>. For example, folic acid supplement use in women of child-bearing age is generally low despite nutrition education programmes<sup>(16)</sup>. Thus, relying on nutritional supplement use has limitations as a public health strategy to increase micronutrient intakes at a population level. The voluntary addition of vitamins and minerals to appropriate foods represents one approach that has been shown to be an effective food-based strategy to increase micronutrient intakes and reduce inadequacy at a population level<sup>(20)</sup>.

### Definition of voluntary fortification

Voluntary fortification refers to the addition of vitamins or minerals to foods at the discretion of the manufacturer for a number of purposes: restoration, ensuring nutritional equivalence of substitute foods and enhancing the nutritive value of a food. Restoration refers to the replacement of nutrients that may be lost during manufacturing and processing of foods and during normal storage and handling, to the levels that were present prior to the manufacturing procedures. Foods that are produced for use as a partial or complete replacement of a food item may be fortified to ensure that the substitute food is of a similar nutritive value in terms of the quantity and bioavailability of the micronutrients. Foods may also be fortified to enhance their nutritive value, irrespective of whether the nutrient was originally present in the food<sup>(21)</sup>.

### Legislation

Prior to 2006, the national regulations that governed the voluntary fortification of foods intended for general consumption in Europe varied widely. Countries such as Ireland and the UK permitted liberal voluntary fortification practices in which the addition of nutrients to foods was not restricted in terms of the types of food, nutrients or amounts that were added, provided it was not injurious to health and labelling did not mislead the consumer<sup>(22)</sup>. Voluntary fortification in these countries was governed by the general regulations of food safety<sup>(23)</sup>. Nordic countries such as Norway, Denmark, Finland and Sweden have traditionally been restrictive in their policies on voluntary fortification, viewing it as unnecessary and potentially harmful, requiring a documented public health need to justify fortification<sup>(24)</sup>. Permission was required for voluntary fortification in countries such as Denmark and Italy, while tight controls on fortification with specific nutrients

(fat-soluble vitamins and some minerals) existed in Germany, the Netherlands and Finland to a lesser extent<sup>(23)</sup>. These variations in policy were seen as a barrier to trade by the Food and Agriculture Organization<sup>(25)</sup> and against the European Union free-trade philosophy<sup>(21)</sup>.

In 2006, the adoption of Regulation 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and certain other substances to foods<sup>(21)</sup> resulted in a wide-ranging debate on the benefits and possible risks of voluntary fortification. This regulation set out to harmonise the legislation pertaining to the addition of micronutrients to food and to provide for free movement of goods within the European Union. This regulation also outlined a list of all substances that are permitted for fortification<sup>(26)</sup>, in order to take into account: (1) deficiency of one or more nutrients in a population or sub-population group that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; (2) potential for improving the nutritional status of a population and/or correct possible deficiencies in dietary intake due to changing dietary habits; and (3) evolving generally acceptable scientific knowledge on the role of micronutrients in nutrition and their consequent effects on health.

### Fortification practices and consumption in Europe

Although regulation of voluntary food fortification is harmonised across the European Union, there are differences in fortification practices between countries. Some countries also have separate national policies on voluntary fortification, e.g. fortification of fluid milk products and margarines with vitamin D in Finland<sup>(27)</sup>. In response to very low intakes and poor status of vitamin D in the Finnish population, the Finnish Ministry of Trade and Industry launched a decree on optimal fortification of foods in 2003, encouraging the addition of vitamin D to fluid milk products (0.5 µg/100 ml) and margarines and butter (10 µg/100 g)<sup>(27)</sup>.

In Ireland, national food consumption data of adults<sup>(20)</sup> show that ready-to-eat breakfast cereals (RTEBC), cereal bars, fat spreads, breads and juices and juice drinks are the main food groups that contribute to energy intake from fortified foods. In Irish adults aged 18–64 years, the proportion of participants consuming fortified foods increased from 67% in the North/South Ireland Food Consumption Survey (NSIFCS; 1997–1999)<sup>(20)</sup> to 82% in the National Adult Nutrition Survey (NANS; 2008–2010)<sup>(28)</sup> and the number of fortified foods recorded as consumed increased from 54 to 150. The proportion of energy from fortified foods also increased from 4% in the NSIFCS to 9% in the NANS<sup>(28)</sup>. RTEBC are the most commonly consumed fortified foods by Irish adults and their contribution to energy intake has generally remained constant across the two surveys. The increase in energy from all fortified foods was partially attributable to fortification of some brands of bread with folic acid, primarily white breads. There is evidence to suggest that this practice of

fortifying bread with folic acid in Ireland has declined significantly since the time of NANS data collection. The fortification of fat spreads with folic acid, vitamin B<sub>6</sub> and vitamin B<sub>12</sub> has also contributed to the increase in energy from fortified foods. The increase in the number of fortified foods in other food groups such as powdered beverages, isotonic and energy drinks and powdered soups and sauces has had a very minor effect on increasing energy intake from fortified foods.

Analysis of Irish food consumption data for school children (2003–2004), teenagers (2005–2006) and adults (2008–2010) has shown that fortified foods are consumed by a greater proportion of school children (98%) than teenagers (90%) and adults (82%). This age-related decline of fortified food consumption has also been shown in other countries<sup>(5,9,29)</sup>. In Irish teenagers<sup>(30)</sup> and school children<sup>(31)</sup>, RTEBC represent the main contributor to energy intake from fortified foods, followed by cereal bars and beverages.

In the UK, RTEBC, cereal bars, soft drinks (encompassing fruit juices and fruit juice drinks, squashes and sports drinks) and milks made up the largest proportion of fortified foods reported in a survey in 1999 by the Food Commission<sup>(32)</sup>.

Data from the Dutch National Food Consumption Survey (2007–2010)<sup>(9)</sup> of people aged 7–69 years indicate that the most frequently consumed fortified food products in the Netherlands are margarines, accounting for 28% of the fortified foods, dairy products (12%), carbonated and cordial beverages (11%) and fruit juices (9%). In Finland, the use of voluntarily fortified foods among adults was investigated by Hirvonen *et al.*<sup>(33)</sup> using data collected in the FINDIET Survey 2007. FINDIET 2007 used a 5-d barcode-based product diary in which a sub-sample of participants (50%) were asked to record all food items that were purchased for home consumption by any member of the household or by the participant for their outside-the-home food consumption. The authors found that 2.6% of all foods purchased (by mass) were voluntarily fortified and the most common were yoghurts (44%) followed by fruit drinks (36%).

A report by Wagner *et al.*<sup>(34)</sup> in 2005 collected details on the Austrian fortified food supply through a number of supermarket surveys and inspections over a period of 4 months. In total, 470 fortified foods were identified. Fortified baby foods were found to be the most common type of fortified food (29%), followed by beverages (21%), which were made up mainly of multivitamin or vitamin C-enriched products, energy drinks and isotonic sports drinks. Sweets (including biscuits, chocolates and marmalade) made up 17% of the fortified foods identified, whereas beverage powders (including instant teas, instant powders or chocolate powders) made up 11% of fortified foods.

The Dortmund Nutritional and Anthropometric Longitudinally Designed study in German children tracked the consumption of fortified foods, starting in 1985 with children and adolescents of different ages and followed them up to the age of 20 years (girls) and 23 years (boys). Sichert-Hellert *et al.*<sup>(35)</sup> reported that

energy intake from fortified foods increased from 6 to 9% between 1987 and 1996. Sichert-Hellert *et al.*<sup>(29)</sup> reported that from 1986 to 1996 the most commonly fortified food products recorded were beverages (30%), children's foods (22%), cereals (13%), fats/oils (10%) and sweets/biscuits (10%). Kersting *et al.*<sup>(36)</sup> also conducted a market survey to characterise the German fortified food supply in 1994 and reported a total of 288 fortified foods available for consumption, predominantly made up of beverages (44%), sweet foods (20%), breakfast cereals (18%) and dairy products (12%). In the same year of the Dortmund Nutritional and Anthropometric Longitudinally Designed study, participants consumed 158 fortified food products with the same food group proportions, indicating that the Dortmund Nutritional and Anthropometric Longitudinally Designed study participants consumed a typical part of the fortified food supply available in Germany.

### Impact of food fortification on micronutrient intakes and status

There are few nationally representative studies that examine the impact of food fortification on micronutrient intakes and status within Europe. Comprehensive data on the impact of food fortification on micronutrient intake are available for Ireland. In a paper by Hannon *et al.*<sup>(20)</sup>, the impact of food fortification was quantified using data from the NSIFCS (1997–1999) of adults aged 18–64 years. In consumers of fortified foods (67%), the authors reported that relative to the percentage contribution of fortified foods to energy (men: 4%; women: 5%), fortified foods contributed a greater percentage to the mean daily intake (MDI) for iron (men: 16%; women: 19%), total folate (men: 18%; women: 21%), thiamin (men: 14%; women: 16%), riboflavin (men: 16%; women: 18%), vitamin B<sub>6</sub> (men: 12%; women: 15%), vitamin D (men: 5%; women: 11%), vitamin B<sub>12</sub> (men: 5%; women: 7%) and total niacin (men: 10%; women: 12%). This study also suggests that voluntary food fortification had a significant impact on reducing the proportion of the population with suboptimal intakes for many micronutrients, particularly iron (women: 49 to 31%), folic acid (women: 12 to 3%) and riboflavin (men: 16 to 7%; women: 26 to 12%). A more recent analysis of food fortification in Ireland from the NANS (2008–2010)<sup>(28)</sup> has shown that relative to energy intake (9%), fortified foods made a substantially greater contribution to intakes of a number of micronutrients, such as folate (27%), vitamin B<sub>6</sub> (22%), iron (21%), vitamin D (21%) and riboflavin (19%)<sup>(28)</sup>.

Data collected in the National Children's Food Survey (2003–2004) of Irish children aged 5–12 years showed that relative to the contribution of fortified foods to MDI of energy (9%), fortified foods made a substantial contribution in particular to MDI of iron (33%), folate (30%), vitamin B<sub>6</sub> and thiamin (28%), riboflavin (26%), niacin (21%), vitamin D and pantothenic acid (15%)<sup>(37)</sup>. The authors also report that voluntary fortification of food significantly improved adequacy of intake of



riboflavin, vitamin B<sub>6</sub>, folate and iron in children. Similarly in Irish teenagers (13–17 years), relative to their contribution to MDI of energy (7%), fortified foods made a significant contribution to intakes of a number of micronutrients, such as folate (25%), iron (23%), thiamin, riboflavin and vitamin B<sub>6</sub> (21% respectively), niacin (14%) and vitamin D (13%)<sup>(38)</sup>.

In the Netherlands, voluntary fortification was found to contribute significantly to intakes of B vitamins and vitamin C in Dutch people aged 7–69 years<sup>(9)</sup>. This may be reflective of the types of foods that are most commonly fortified in the Netherlands, for example, margarines, dairy products and juices. The added nutrient component of fortified foods accounted for 17% of total vitamin B<sub>6</sub> intake, 10% of total riboflavin intake, 9% of total folate and total vitamin C intake and 8% to total intake of thiamin.

In Germany, the Dortmund Nutritional and Anthropometric Longitudinally Designed study reported on the contribution of fortified foods to nutrient intakes of children aged 2–14 years, over a 10-year period (1987–1996)<sup>(35)</sup>. Over time, the consumption of fortified foods was found to increase as indicated by the observed increase in percentage energy from fortified foods (6–9%) and as expected, the contribution of fortified foods to total intakes of vitamins and minerals was also found to increase significantly over time. Sichert-Hellert *et al.*<sup>(35)</sup> assessed the efficacy of food fortification in raising micronutrient intakes (as % of the German reference intake values). The authors reported that food fortification was effective in raising low intakes of vitamin E and folate from 50% of reference intake values to 80% (folate) and 100% (vitamin E) of reference values. Food fortification increased already sufficient intakes of vitamins A, C, thiamin, riboflavin, niacin and vitamin B<sub>6</sub>.

The effect of voluntary fortification on the status of folate and related B vitamins in Northern Ireland was investigated by Hoey *et al.*<sup>(39)</sup> between 2003 and 2005 using a convenience sample of 662 adults (18–92 years). This study found that over three-quarters of participants consumed foods fortified with folic acid alone or in combination with other B vitamins more than once per week. The most commonly consumed folate and B vitamin fortified foods were RTEBC (63% consumers), followed by fat spreads (25% consumers). The authors found significant increases in dietary intakes of total folate, vitamin B<sub>12</sub>, vitamin B<sub>6</sub> and riboflavin with increasing consumption of fortified foods, which in turn were reflected in enhanced biomarker status of these vitamins. More specifically, Hoey *et al.*<sup>(39)</sup> found a significant graded increase in folic acid intake and red cell folate and serum folate status, with increasing level of fortified food consumption. Similar findings on folate status of the Irish adult population (18–90 years) from the NANS (2008–2010) were reported by Hopkins *et al.*<sup>(15)</sup> where folic acid consumers (from fortified foods) had significantly better folate status (red cell folate and serum folate) than non-consumers of folic acid.

Hoey *et al.*<sup>(39)</sup> examined red cell folate status separately in women of child-bearing age. The authors

found that the proportion of women with favourable red cell folate status with respect to preventing neural tube defects increased significantly with increasing fortified food intake. Participants in the top tertile of fortified food intake were found to have median folic acid intake of 208 µg/d. This value is comparable with the estimated increase of 190 µg/d folic acid as a result of mandatory fortification in the USA<sup>(40)</sup>. There is evidence to suggest that this level of intake is effective in improving folate status to prevent neural tube defects<sup>(41)</sup>. The findings of this study suggest that voluntary fortification may be effective in reducing neural tube defect risk in women who regularly consume fortified foods.

In Finland, Laaksi *et al.*<sup>(42)</sup> evaluated the impact of the vitamin D optimisation policy through the collection of serum samples from a total of 196 young Finnish male conscripts (18–28 years) in January 2003 (before the policy was implemented) and in January 2004, almost 1 year after national vitamin D fortification had started. The authors report that after fortification, the young men were ingesting on average 7 µg vitamin D daily from fluid milk products and margarine alone. The authors found that the mean serum 25-hydroxyvitamin D<sub>3</sub> concentrations during wintertime increased by 50% and the prevalence of vitamin D insufficiency (serum 25-hydroxyvitamin D<sub>3</sub> <40 nmol/l) decreased from 78% in January 2003 to 35% in January 2004. Vitamin D deficiency (serum 25-hydroxyvitamin D<sub>3</sub> <25 nmol/l) decreased from 19 to 5% since the implementation of the vitamin D fortification policy.

#### Impact of ready-to-eat breakfast cereals on micronutrient intakes and status

There are many studies on the beneficial impact of RTEBC on micronutrient intakes and status in a number of European countries<sup>(43–49)</sup>. Data from Ireland have consistently shown over time that RTEBC make a significant contribution to micronutrient intakes. Sommerville and O'Reagan<sup>(50)</sup>, using data from the Irish National Nutrition Survey<sup>(51)</sup> of people aged 8–80 years in 1990, found that breakfast cereal consumers had significantly higher intakes of B vitamins, calcium and iron than non-consumers. Galvin *et al.*<sup>(43)</sup> found that RTEBC consumption by Irish adults aged 18–64 years (60% of males and 63% of females) in the NSIFCS (1997–1999) contributed substantially to MDI of iron (18%), total folate (18%), riboflavin (17%), niacin (16%), thiamin (14%), vitamin B<sub>6</sub> (13%) and vitamin D (10%). Increased consumption of fortified RTEBC had a significant impact on improving adequacy of intake for a number of micronutrients, particularly calcium, copper, zinc, riboflavin and vitamin C in men and women and iron and total folate in women<sup>(43)</sup>.

Hannon and Flynn<sup>(52)</sup> reported that the majority of Irish schoolchildren in the National Children's Food Survey (2003–2004) were consumers of RTEBC (95% of boys and 91% of girls). The authors reported that RTEBC contributed significantly to intakes of iron (30%), folate (24%) and B vitamins (17–24%). Walsh

*et al.*<sup>(53)</sup> reported that 81% of Irish teenagers in the National Teens' Food Survey (2005–2006) were consumers of RTEBC and that RTEBC contributed significantly to intakes of B vitamins and iron (13–26%).

In the UK, Gibson and Gunn<sup>(54)</sup> found that consumption of breakfast cereal by adults aged 19–64 years in the National Diet and Nutrition Survey (2000–2001) resulted in substantially higher micronutrient intakes (30–90%) than when a non-cereal breakfast was consumed. Given that the difference in energy intake between groups was relatively smaller, these findings indicate that there is a strong positive effect on nutrient density on breakfast cereal consumption days in particular. This increase in micronutrient intake and density may be largely attributable to the fortification element of breakfast cereals. McNulty *et al.*<sup>(55)</sup> have previously shown that fortification of breakfast cereals made a significant contribution to micronutrient intakes in British adults from the Diet and Nutrition Survey of British Adults (1986–1987) for each of the nutrients studied.

Gibson<sup>(44)</sup> found that British children aged 4–18 years in the National Diet and Nutrition Survey (1997), increasing consumption of breakfast cereals was positively associated with greater intakes of iron, folate, vitamin D, calcium, B vitamins and zinc, in addition to more favourable folate status, vitamin B<sub>12</sub> status and riboflavin status in boys and girls, and thiamin status and vitamin B<sub>6</sub> status in girls only. Gibson found a significant association between level of fortified RTEBC consumption and the reduced prevalence of inadequate intakes in girls of iron, riboflavin, calcium and potassium. However, there was no evidence of an association of breakfast cereal consumption and enhanced iron status or reduced prevalence of poor iron status. Gibson<sup>(47)</sup> also observed this disparity between iron intake and status in breakfast cereal consumers aged 1.5–4.5 years in the National Diet and Nutrition Survey (1992–1993). It has been suggested that reasons for the poor correlation of estimated dietary intake of iron with iron status may be due to the variability in iron absorption in different individuals based on their current iron stores, differing bioavailability due to the form of iron that is present in foods and the presence of iron absorption inhibitors or enhancers in the diet<sup>(56)</sup>. McNulty *et al.*<sup>(57)</sup> found that in Northern Irish school children (12–15 years old), the intakes of a number of micronutrients, such as folate, iron, calcium and B vitamins, increased significantly with increasing consumption of fortified breakfast cereals, as well as adequacy of micronutrient intake.

In Spain, the contribution of ready-to-eat cereals (RTEC) to micronutrient intakes was investigated in the enKid Study (1998–2000) of Spanish children, adolescents and young adults (2–24 years)<sup>(46)</sup>. Intakes of thiamin, riboflavin, vitamin B<sub>6</sub>, niacin, folate, calcium, iron and vitamin D increased significantly with increasing level of RTEC consumption and there was a significant association between the level of RTEC consumption and an improved likelihood of meeting daily nutrient requirements for calcium, iron, thiamin, riboflavin, niacin, vitamin B<sub>6</sub>, folate and vitamin D, some of which are not traditionally added to

RTEC. In an earlier study into fortified breakfast cereal consumption in Spanish schoolchildren, Ortega *et al.*<sup>(48)</sup> found that consumers of fortified breakfast cereals had significantly higher intakes of thiamin, vitamin B<sub>6</sub>, folate and carotene than non-consumers. In addition, a positive association of fortified breakfast cereal consumption with more favourable status of folate, retinol and riboflavin was found in Spanish school children.

Preziosi *et al.*<sup>(45)</sup> provided evidence for the positive impact of breakfast cereals on the nutrient intakes and status of French children, adolescents and adults. Intakes and dietary nutrient density of a range of micronutrients in children and adults was positively associated with consumption of RTEC. In children, higher dietary intakes of calcium, phosphorous, iron, thiamin and riboflavin were observed in consumers than non-consumers, whereas in adults consumers had higher intakes of calcium and phosphorous, thiamin and riboflavin, vitamins A and C and folic acid than non-consumers of RTEC. Children and adolescent consumers of RTEC had significantly higher serum riboflavin and β-carotene concentrations than non-consumers. The authors also report that adult consumers of RTEC had significantly higher status of thiamin and riboflavin and higher serum levels of folate and β-carotene than non-consumers.

#### Risk of excessive micronutrient intakes

The potential for voluntary food fortification to lead to unacceptably high intakes of micronutrients has been considered, particularly for those consuming large amounts of fortified foods. Although the European Union legislation provides for the setting of maximum safe levels of vitamins and minerals in fortified foods, this has not yet been implemented. Several models for estimating the safe levels of addition of micronutrients to foods have been proposed<sup>(58–60)</sup>. Some countries (Belgium, Denmark, the Netherlands and the UK) have placed restrictions on the level of folic acid that can be added to food and approval is required before a folic acid-fortified food can be marketed in Norway and Denmark<sup>(61)</sup>.

In general, total micronutrient intakes (including fortified foods and nutritional supplements) of high consumers (as defined by the 95th percentile of intake) in adults and children across Europe do not exceed the tolerable upper intake levels (UL) set by the European Food Safety Authority<sup>(23)</sup>. Flynn *et al.*<sup>(23)</sup> evaluated intakes of micronutrients derived from nine nationally representative surveys in Europe and found for most nutrients, adults and children generally consume considerably less than the UL. For some micronutrients (retinol, zinc, iodine, copper and magnesium) small proportions of the population, particularly children, exceeded the UL. However, the authors concluded that there is little risk of adverse effects occurring in the small proportion of individuals exceeding the UL by a modest amount given the use of adequate safety factors in establishing UL.

The impact of the added nutrient component of fortified foods has been investigated in a number of studies. In Ireland, Hannon *et al.*<sup>(20)</sup> reported that 95th percentile intakes of Irish adults from the NSIFCS (1997–1999) did not exceed or approach the UL for any micronutrient, with or without the added nutrient from fortification included in the estimate of intakes. While a small proportion of fortified food consumers (<2%) had intakes which exceeded the UL (for vitamin B<sub>6</sub>, folic acid, zinc and retinol), this was not driven by fortification, but rather by nutritional supplement use for folic acid, vitamin B<sub>6</sub> and zinc and from the base diet for retinol<sup>(20)</sup>. Preliminary analysis of more recent data from the NANS (2008–2010) in Ireland indicates that this situation has not changed.

Hannon<sup>(31)</sup> identified small proportions (<4%) of Irish children in the National Children's Food Survey (2003–2004) with total intakes of retinol, vitamin B<sub>6</sub>, folic acid, zinc and copper above the UL. Similarly in teenagers, Walsh<sup>(30)</sup> using data from the National Teens' Food Survey (2005–2006) identified small proportions (<4%) of Irish teenagers with total intakes of retinol, vitamin B<sub>6</sub>, folic acid and iodine above the UL. However, the voluntary fortification of foods did not contribute appreciably to increased risk of excessive intake for any of these nutrients.

In Finland, the introduction of the vitamin D optimisation policy resulted in a small increase in the proportion of young Finnish men with serum 25-hydroxyvitamin D<sub>3</sub> concentration higher than 100 nmol/l, from 0% before the policy was introduced to 5% after fortification; however no clinical signs of toxicity were observed at this concentration<sup>(42)</sup>.

### Conclusion

Although the proportion of children consuming fortified foods is greater than adults, the proportion of dietary energy obtained from fortified foods is generally low (<10% of energy intake for children, teenagers and adults in Ireland), where fortified foods are widely consumed. There are a few systematic studies on the overall nutritional impact of voluntary fortification but there are several studies on the impact of fortified RTEBC. The available evidence indicates that voluntary fortification can reduce the risk of sub-optimal intakes of range of micronutrients at a population level. There is also evidence that voluntary fortification can improve status for selected micronutrients (e.g. folate, vitamin D, riboflavin) in children and adults. Concerns have been raised regarding the potential of food fortification to lead to unacceptably high intakes of micronutrients, particularly for those consuming higher amounts of fortified foods. Data from national surveys on total intakes of micronutrients (including fortified foods) in Europe show that small proportions of the population, particularly children, may exceed the UL for some micronutrients. However, there is little risk of adverse effects occurring in the small proportion of individuals exceeding the UL by a modest amount. Current

fortification practices do not appear contribute appreciably to this risk.

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### Conflicts of Interest

None.

### Authorship

A. H. wrote the review, J. W. and A. F. provided expert advice in the drafting of the paper and were responsible for critically reviewing and approving the final version of the manuscript.

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