European Journal of Clinical Nutrition (2013) **67,** 592–597
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ORIGINAL ARTICLE

Voluntary food fortification in the United States: potential for excessive intakes

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BACKGROUND: Historically, the voluntary addition of micronutrients to foods in the United States has been regarded as an important means to lessen problems of nutrient inadequacy. With expanding voluntary food fortification and widespread supplement use, it is important to understand how voluntary food fortification has an impact on the likelihood of excessive usual intakes. Our objective was to investigate whether individuals in the United States with greater frequency of exposure to micronutrients from voluntarily fortified foods (vFF) are more likely to have usual intakes approaching or exceeding the respective tolerable upper intake levels (UL).
SUBJECTS/METHODS: The National Cancer Institute method was applied to data from the 2007–2008 National Health and Nutrition Examination Survey (NHANES) to estimate the joint distribution of usual intake from both vFF and non-vFF sources for 12 nutrients and determine the probability of consuming these nutrients from vFF on a given day. For each nutrient, we estimated the distribution of usual intake from all food sources by quintile of probability of consuming vFF and compared the distributions with ULs.
RESULTS: An increased probability of consuming zinc, retinol, folic acid, selenium and copper from vFF was associated with a greater risk of intakes above the UL among children. Among adults, increased probability of consuming calcium and iron from vFF was associated with a greater risk of intakes above the UL among some age/sex groups.
CONCLUSION: The high nutrient exposures associated with vFF consumption in some population subgroups suggest a need for more careful weighing of the risks and benefits of uncontrolled food fortification.

European Journal of Clinical Nutrition (2013) **67,** 592–597; doi:10.1038/ejcn.2013.51; published online 6 March 2013

Keywords: voluntary food fortification; NHANES; tolerable upper intake level

INTRODUCTION

In the United States, fortification of any non-standardized food with a vitamin or mineral is permitted at the discretion of the manufacturer.[1] Voluntary nutrient additions are guided by a policy statement recommending that fortification be linked to evidence of nutrient insufficiency in the population, and that nutrients added be bioavailable, safe and stable.[2] With few exceptions, minimum and maximum permitted levels of addition are not defined.[3]

Fortified foods contribute substantially to total nutrient intakes in the United States and thus mitigate risks of nutrient inadequacy in the population.[4,5] However, the continued expansion of voluntary fortification[6] and evidence of micronutrient intakes above tolerable upper intake levels (UL) among children[4,5,7] raise questions about the potential of food fortification to lead to excessive intakes.[8,9] Examinations of the effect of fortification on the upper tails of usual-intake distributions have to date been limited to single nutrients[10–13] and specific population subgroups,[10] or they have failed to differentiate the effects of voluntary fortification practices from mandatory programs designed to address specific public health problems.[4] Our objective was to determine whether individuals with greater frequency of exposure to nutrients from voluntarily fortified foods (vFF) are more likely to have usual intakes (from all food sources) approaching or exceeding the UL for those nutrients, considering a broad spectrum of nutrients and age/sex groups.

SUBJECTS AND METHODS

Dataset and analytic sample

We analyzed data from the What We Eat in America (WWEIA) component of the 2007–2008 NHANES, which contains dietary intake data from a nationally representative sample of the civilian non-institutionalized United States population. The automated multiple pass method was used to collect up to two 24-h dietary recalls, the first in person and the second via telephone 3–10 days later. Nutrient composition data was derived from the Food and Nutrient Database for Dietary Studies (FNDDS), version 4.1.

The 2007–2008 WWEIA included 9762 individuals. We excluded those providing incomplete or unreliable 24-h dietary recall data, pregnant and breastfeeding women, children who consumed breast milk, children <1years and participants with zero energy intake from food. Our analytic sample is 14 728 recalls on a sample of 8709 individuals.

Voluntarily fortified foods are not tracked in the FNDDS, so voluntary fortification was inferred from indications of nutrient addition under conditions not captured by mandatory fortification programs (for example, enrichment of flour). After excluding foods with a standard of identity for enrichment or fortification, we systematically searched the FNDDS food descriptions for terms indicating nutrient addition (for example, added, vitamin or mineral, plus), including the variable ‘added vitamin B12’ (Figure 1). Vitamin B12, folate and vitamin E are the only nutrients in the

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Contributors: JS and VT designed the research; KD adapted the NCI method macros to perform the statistical analysis; JS conducted research and performed statistical analysis; KD and SK provided critical input on the analysis and interpretation; JS had primary responsibility for writing the paper. All authors read and approved the final manuscript.
Received 17 July 2012; revised 29 January 2013; accepted 3 February 2013; published online 6 March 2013

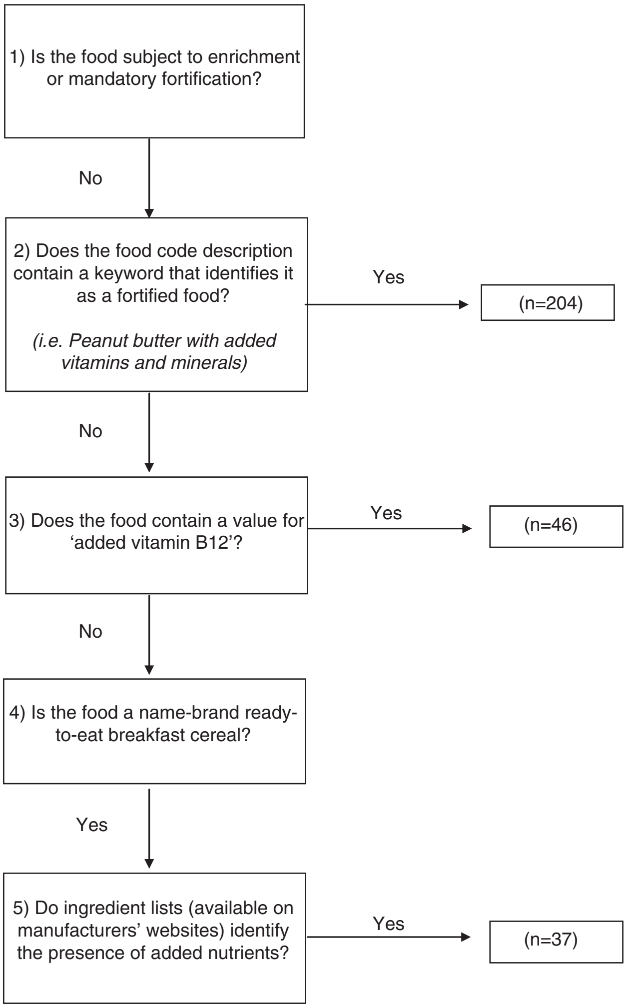

Figure 1. Identification of vFF in the FNDDS 4.1.

FNDDS 4.1 for which added and naturally occurring sources are differentiated, but the latter two additions cannot be assumed to be voluntary as they are mandated in some foods and vitamin E is often used as a preservative.

As breakfast cereals are widely fortified, cereals not identified as fortified through our search criteria were cross-checked against ingredient lists on the manufacturers' websites, resulting in the identification of an additional 37 voluntarily fortified products.

We considered all but three nutrients with ULs, including zinc, iron, calcium, folic acid, retinol, vitamin C, D, B6, E, phosphorous, copper, selenium and choline. Niacin was not included because the UL applies only to added sources, and these could not be reliably differentiated from natural sources. Magnesium was not examined because the UL applies only to intakes from supplements. Sodium was not examined because most Americans exceed the UL for this nutrient; it is being targeted for removal from foods, not addition.[14]

Statistical methods

Our analytic approach takes into account the fact that, for a given nutrient, most individuals consume some amount from non-vFF sources every day, whereas intake from vFF sources is episodic in nature. Drawing upon the National Cancer Institute method established for estimating usual intake distributions for dietary components consumed nearly every day by nearly all persons,[15] we employ an extension that allows bivariate modeling of an episodically consumed dietary component and a non-episodically consumed dietary component.[16–19] This extended model is required because only 2 days of intake data may not capture consumption of vFF, even among individuals who sometimes consume vFF. Usual intake of a nutrient from vFF is the probability of consuming any of the nutrients from vFF on a given day multiplied by the usual amount of the nutrient from vFF on days when vFF containing the nutrient are consumed. Distributions reflect nutrient intake from both naturally occurring and added sources, because the FNDDS does not readily permit differentiation of nutrient content by source.

The bivariate modeling approach permits estimation of the distribution of the usual amount from the combination of non-vFF and vFF sources, conditional upon the probability of consuming the nutrient from vFF on a given day (that is, the frequency of exposure) and adjustments for nuisance effects, including recall collection method (in person or by telephone) and day of the recall (weekend or weekday). After fitting the bivariate model, a Monte Carlo procedure was used to simulate a representative sample from the estimated joint distribution of the three components of usual intake (usual intake from non-vFF, probability of consuming from vFF on a given day and usual amount from vFF on consumption days). The Monte Carlo sample was stratified by quintile of probability of consuming the nutrient from vFF, and distributions of usual intake from all food sources were estimated among each of the five subsamples. The proportion exceeding the UL was estimated from each resulting distribution. For nutrients and age/sex groups with any evidence of excessive intakes, we also examined the 90th percentile of usual intake within each quintile as a ratio of the UL, to gauge the proximity of the upper tails of the distributions to the UL. In the presentation of results, reference to 'quintiles' indicates the probability of consuming the nutrient from vFF. No results are presented for vitamin E because the UL applies only to added sources and consumption was too low to estimate usual intakes.

We examined the relationship between vitamin and mineral supplement use and vFF consumption by estimating the association between probability of consuming energy from vFF (as a crude proxy for total vFF consumed) and supplement use.

Balanced repeated replication was used to calculate standard errors that take into account correlation among individuals sampled within the same cluster. Survey weights were applied to adjust for differential sampling of individuals. Given the complexity of the bivariate model, the SAS procedure NLMIXED (version 9.2 (2008), SAS Institute, Cary, NC, USA) was used to fit the model using an iterative algorithm. For 3% of data combinations, the algorithm failed to converge on a unique solution. We chose to suppress the results in these cases, rather than attempt to further adjust the model specification and/or covariate choices until we could obtain convergence. For most nutrient/life-stage combinations, the estimation was quite stable for both the point estimate run and the repeated runs used for balanced repeated replication s.e. estimation.

RESULTS

Almost half of the population consumed vFF on either recall day, most commonly reporting breakfast cereals or beverages (Supplementary Table 1). Within the lowest quintile, the mean probability of consuming vFF ranged from close to zero for most nutrients among adolescents and adults, to 36% for calcium and phosphorus among quintiles of children 4–8y (data not shown).

Among children aged 1–3 years, prevalences of usual intakes above the UL were observed across all quintiles for selenium, retinol, copper and zinc, with prevalences $>50\%$ for zinc (Table 1, Figure 2, Supplementary Figure 1). The prevalence of intakes of these nutrients above the UL rose with the increasing probability of consuming vFF (that is, across quintiles), but differences between quintiles were not statistically significant at $P<0.05$. Prevalences of usual intakes exceeding the UL were also observed among the upper quintiles for folic acid and the upper tails of the distributions of usual vitamin C and calcium intake among 1–3-year olds in the fifth quintile were in close proximity to the UL (vitamin C: $0.6\%>\text{UL}$, s.e. $=0.8$; calcium $0.3\%>\text{UL}$, s.e. $=0.3$). Intakes above the UL were less likely among 4–8-year olds, but prevalences of intakes exceeding the UL were observed for zinc, retinol and folic acid, particularly among the upper quintiles (Table 1). Among children aged 1–3 and 4–8 years, prevalences above the UL were negligible for iron, choline, phosphorous, vitamin D and B6 (data not shown).

Small prevalences ($<6\%$) of intakes above the UL were observed for calcium, iron, zinc and folic acid among some adult

Table 1. Proportion of usual nutrient intakes that exceeds the tolerable upper intake level (UL) for each quintile of probability of consuming nutrients from voluntarily fortified food, among children aged ⩽8 years[a]

Quintile	*Selenium*		*Folic acid*		*Retinol*		*Copper*		*Zinc*	
	1–3 years	4–8 years	1–3 years	4–8 years	1–3 years	4–8 years	1–3 years	4–8 years	1–3 years	4–8 years
	%>UL (s.e.)									
Q1	4.5 (2.0)	0.2 (0.1)	0.0 (0.0)	0.0 (0.0)	15.7 (3.6)	0.0 (0.0)	10.9 (3.0)	0.0 (0.0)	52.9 (9.7)	4.9 (2.3)
Q2	5.5 (1.6)	0.1 (0.1)	0.1 (0.1)	0.0 (0.0)	15.1 (3.3)	0.0 (0.0)	10.3 (2.2)	0.0 (0.0)	57.2 (7.2)	7.2 (2.0)
Q3	6.5 (1.7)	0.2 (0.1)	0.5 (0.4)	0.0 (0.1)	17.4 (3.8)	0.1 (0.1)	11.0 (2.2)	0.0 (0.0)	61.1 (6.5)	11.1 (1.9)
Q4	8.5 (3.0)	0.2 (0.2)	2.8 (1.5)	0.4 (0.5)	23.3 (5.6)	0.5 (0.3)	13.0 (2.7)	0.0 (0.0)	65.0 (6.1)	17.5 (4.1)
Q5	9.3 (4.8)	0.1 (0.3)	7.4 (4.2)	5.2 (3.9)	30.2 (11.4)	3.6 (1.9)	19.4 (4.4)	0.0 (0.0)	67.5 (7.7)	35.9 (14.0)

Abbreviation: UL, tolerable upper intake levels. [a]ULs for 1–3 and 4–8 years, respectively are: selenium (µg/day) 90, 150; folic acid (µg/day) 300, 400; retinol (µg/day) 600, 900; copper (µg/day) 1000, 3000; zinc (mg/day) 7, 12.

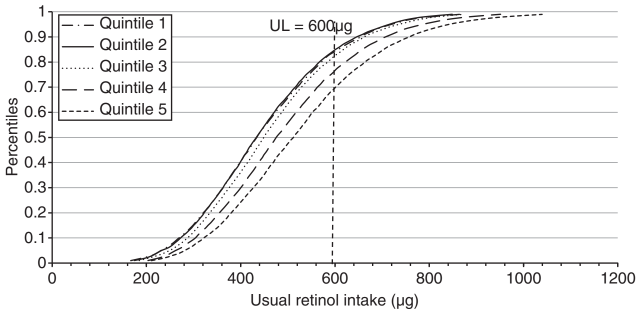

Figure 2. Cumulative distribution function of usual retinol intake among children aged 1–3 years, by quintile of probability of consuming retinol from vFF.

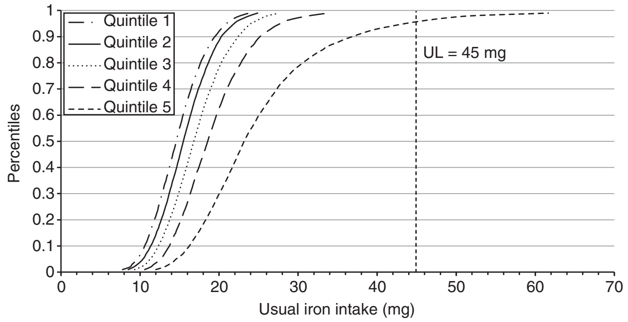

Figure 3. Cumulative distribution function of usual iron intake among men aged 19–30 years, by quintile of probability of consuming iron from vFF.

and adolescent age/sex groups, primarily in the fifth quintile (Figure 3, Supplementary Figure 2). For iron, there was a significant difference in the prevalence of intakes above the UL across quintiles among men aged 19–30 years; 4.3% of usual intakes in the highest quintile fell above the UL (Figure 3). Among those older than 8 years, prevalences of intakes above the UL were negligible for selenium, copper, retinol, choline, phosphorous, vitamin D, C and B6 (data not shown).

Tables 2 and 3 provide the 90th percentile of usual intake in each quintile for nutrients with any evidence of intakes above the UL as a ratio of the UL among age/sex groups older than 8 years, indicating the proximity of the upper tails of these distributions to the UL. The ratio of the 90th percentile of usual nutrient intake to the UL exceeded 75% in the fifth quintile among adult men for calcium and iron (Table 2), among boys and girls aged 9–13 years for folic acid and among boys aged 9–13 years for zinc (Table 3). In other words, 10% of the fifth quintile for these groups was within 25% of the UL. For calcium, iron, zinc and folic acid, the ratio of the 90th percentile of usual intake to the UL increased systematically with increasing quintile for most adolescent and adult age/sex groups, and in most cases, the differences between each of the first four quintiles and the highest one were significantly different ($P<0.05$).

Our evaluation of usual nutrient intakes was based on intakes from food alone, but 37% of respondents consumed vitamin or mineral supplements on either recall. Consumption on either day ranged from 12% among 14–18-year old boys to 71% among women aged 71+ years. Supplement consumption was associated with an increased probability of energy consumption from vFF among girls aged 9–13 years, women aged 31–50 and 71+ years, and among men aged 31–50, 51–70 and 71+ years ($P<0.05$) (Supplementary Table 2).

DISCUSSION

This study is the first to examine the potential for high nutrient intakes from vFF in the United States, while taking into account differing levels of exposure within the population. We found that vFF were widely consumed. For many nutrients, we estimated substantial prevalences of usual intakes above the UL, particularly among young children. Most of our comparisons of prevalences of intakes exceeding the UL across quintiles of vFF exposure were not significant at $P<0.05$, which may owe to the high variability in the estimated upper tails of the distribution. However, the overall direction of our results indicates higher prevalences among children with higher exposure to vFF. This supports earlier concerns about the potential of fortification to contribute to excessive nutrient intakes among young children.[8,9] Although the proportion of usual intakes above the UL rarely exceeded 4% among older children, adolescents and adults, in many cases the 90th percentile of usual nutrient intake was in close proximity to the UL, implying that a small increment in usual intake could shift an individual beyond this level. Further, in many cases, the ratio of the 90th percentile of intake to the UL was significantly higher among the highest quintile, suggesting an increased risk of intakes approaching the UL with increased exposure to vFF.

In interpreting our results, it is important to note that intakes approximating the ULs cannot be assumed to indicate risk of adverse effects. By design, these values have been set at levels with a high probability of being tolerated biologically.[20] The risk associated with usual intakes above ULs is not defined,[21] in part because of a lack of dose-response data and the unknown shape of the risk probability function associated with high nutrient intakes.[22] Nonetheless, charting the upper tail of the distribution of usual nutrient intake, including intakes both approaching and

Table 2. Values at the 90th percentile of the usual nutrient intake distributions as a ratio of the UL[a], by quintile of probability of consuming each nutrient from voluntarily fortified foods

Age/sex	*Calcium*					*Iron*				
	Q1	*Q2*	*Q3*	*Q4*	*Q5*	*Q1*	*Q2*	*Q3*	*Q4*	*Q5*
	90th percentile/UL (s.e.)									
Males (years)										
9–13	0.43 (0.06)	0.47 (0.04)	0.49 (0.03)*	0.52 (0.03)*	0.63 (0.06)	0.44 (0.06)*	0.46 (0.04)*	0.50 (0.04)*	0.55 (0.04)*	0.68 (0.05)
14–18	0.54 (0.07)	0.57 (0.04)	0.58 (0.05)	0.59 (0.06)	0.59 (0.09)	0.40 (0.04)	0.42 (0.03)	0.45 (0.02)	0.49 (0.03)	0.56 (0.06)
19–30	0.53 (0.06)*	0.60 (0.04)*	0.67 (0.05)*	0.75 (0.05)*	0.91 (0.07)	0.43 (0.04)*	0.46 (0.03)*	0.49 (0.03)*	0.57 (0.04)*	0.80 (0.08)
31–50	0.50 (0.05)*	0.56 (0.04)*	0.60 (0.04)*	0.66 (0.04)*	0.77 (0.07)	0.43 (0.02)*	0.46 (0.02)*	0.50 (0.03)*	0.58 (0.04)*	0.79 (0.09)
51–70	0.61 (0.04)*	0.66 (0.04)*	0.71 (0.03)*	0.77 (0.04)*	0.86 (0.05)	0.44 (0.02)*	0.44 (0.02)*	0.48 (0.03)*	0.57 (0.03)*	0.78 (0.05)
71 +	0.48 (0.05)*	0.53 (0.04)*	0.58 (0.03)*	0.64 (0.04)*	0.75 (0.04)	0.35 (0.03)*	0.37 (0.02)*	0.44 (0.03)*	0.55 (0.03)*	0.73 (0.05)
Females (years)										
9–13	0.29 (0.04)*	0.34 (0.04)*	0.37 (0.04)*	0.42 (0.05)	0.47 (0.06)	0.33 (0.02)*	0.38 (0.02)*	0.42 (0.02)	0.46 (0.02)	0.51 (0.04)
14–18	0.34 (0.05)*	0.39 (0.03)*	0.43 (0.03)	0.46 (0.03)	0.52 (0.04)	0.35 (0.04)*	0.38 (0.04)*	0.42 (0.04)	0.49 (0.05)	0.58 (0.07)
19–30	0.47 (0.06)	0.47 (0.04)	0.50 (0.04)	0.51 (0.03)	0.53 (0.06)	0.34 (0.04)	0.35 (0.02)*	0.37 (0.01)	0.40 (0.02)	0.46 (0.05)
31–50	0.41 (0.03)*	0.44 (0.02)*	0.47 (0.02)*	0.51 (0.02)*	0.65 (0.04)	0.36 (0.02)*	0.36 (0.01)*	0.39 (0.02)*	0.44 (0.02)*	0.59 (0.04)
51–70	0.51 (0.03)*	0.55 (0.03)*	0.58 (0.03)*	0.62 (0.03)*	0.72 (0.03)	0.31 (0.02)*	0.33 (0.01)*	0.38 (0.02)*	0.46 (0.02)*	0.57 (0.05)
71 +	0.41 (0.02)*	0.45 (0.02)*	0.51 (0.02)*	0.56 (0.02)*	0.67 (0.03)	0.26 (0.01)*	0.30 (0.01)*	0.35 (0.01)*	0.44 (0.02)*	0.53 (0.04)

Abbreviation: UL, tolerable upper intake levels. *indicates that the value is significantly different from quintile 5 (Q5) at $P<0.05$. [a]The values at the 90th percentile of the usual nutrient intake distributions as a ratio of the UL indicate the proximity of the upper tails of the distributions of usual intake to the UL. For example, a value of 0.75 for a given quintile indicates that 10% of the quintile was within 25% of the UL.

Table 3. Values at the 90th percentile of the usual nutrient intake distributions as a ratio of the UL[a], by quintile of probability of consuming each nutrient from voluntarily fortified foods

Age/sex	*Folic acid*					*Zinc*				
	Q1	*Q2*	*Q3*	*Q4*	*Q5*	*Q1*	*Q2*	*Q3*	*Q4*	*Q5*
	90th percentile/UL (s.e.)									
Males (years)										
9–13	0.30 (0.04)*	0.34 (0.04)*	0.42 (0.05)*	0.55 (0.05)*	0.93 (0.08)	0.64 (0.07)	0.64 (0.05)	0.67 (0.04)	0.71 (0.05)	0.86 (0.09)
14–18	0.33 (0.03)*	0.37 (0.02)	0.42 (0.03)	0.48 (0.04)	0.57 (0.09)	0.45 (0.05)	0.50 (0.04)	0.53 (0.04)	0.57 (0.05)	0.60 (0.08)
19–30	0.25 (0.04)	0.26 (0.03)	0.30 (0.04)	0.36 (0.06)	0.53 (0.14)	0.45 (0.04)	0.47 (0.02)	0.50 (0.03)	0.55 (0.05)	0.68 (0.10)
31–50	0.24 (0.02)*	0.24 (0.01)*	0.26 (0.01)*	0.32 (0.02)*	0.56 (0.05)	0.44 (0.04)*	0.46 (0.03)*	0.50 (0.03)*	0.54 (0.03)*	0.64 (0.04)
51–70	0.21 (0.02)*	0.21 (0.01)*	0.23 (0.01)*	0.31 (0.01)*	0.43 (0.03)	0.48 (0.04)	0.47 (0.03)*	0.49 (0.03)	0.51 (0.03)	0.57 (0.04)
71 +	0.13 (0.01)*	0.14 (0.01)*	0.19 (0.02)*	0.30 (0.03)*	0.51 (0.05)	0.34 (0.04)*	0.34 (0.03)*	0.37 (0.03)*	0.43 (0.04)*	0.58 (0.05)
Females (years)										
9–13	0.28 (0.03)*	0.37 (0.05)*	0.47 (0.05)*	0.59 (0.06)	0.79 (0.13)	0.42 (0.04)*	0.48 (0.05)*	0.53 (0.05)	0.58 (0.06)	0.65 (0.07)
14–18	—	—	—	—	—	0.32 (0.03)	0.33 (0.03)	0.35 (0.02)	0.38 (0.03)	0.43 (0.05)
19–30	0.18 (0.03)	0.18 (0.02)	0.20 (0.02)	0.23 (0.03)	0.32 (0.07)	0.31 (0.04)	0.31 (0.02)	0.31 (0.02)	0.32 (0.02)	0.35 (0.05)
31–50	0.19 (0.02)*	0.19 (0.01)*	0.20 (0.01)*	0.26 (0.02)*	0.44 (0.05)	0.32 (0.02)*	0.32 (0.01)*	0.34 (0.01)*	0.37 ((0.01)*	0.47 (0.04)
51–70	0.15 (0.02)*	0.16 (0.01)*	0.19 (0.01)*	0.28 (0.02)*	0.49 (0.05)	0.28 (0.01)*	0.30 (0.01)*	0.32 (0.01)*	0.36 (0.02)*	0.42 (0.03)
71 +	0.14 (0.01)*	0.15 (0.01)*	0.20 (0.02)*	0.31 (0.03)*	0.50 (0.06)	0.24 (0.01)*	0.27 (0.01)*	0.30 (0.02)*	0.35 (0.02)	0.41 (0.04)

Abbreviation: UL, tolerable upper intake levels *indicates that the value is significantly different from quintile 5 (Q5) at $P<0.05$. '—' indicates that the model failed to converge. [a]The values at the 90th percentile of the usual nutrient intake distributions as a ratio of the UL indicate the proximity of the upper tails of the distributions of usual intake to the UL. For example, a value of 0.75 for a given quintile indicates that 10% of the quintile was within 25% of the UL.

exceeding the UL, remains important given the expanding and uncontrolled nature of nutrient additions.

The contribution of voluntary fortification to excessive micronutrient intakes among children has long been a question of interest.[8,10,12,13] Arsenault *et al.*[10] identified excessive zinc intakes among children in the 1990s and noted the substantial contribution of zinc-fortified foods to total intakes. Analyses of NHANES 2003–2006 have revealed significantly higher median usual folic acid intake among children and adults consuming breakfast cereals, but did not establish the specific contribution of breakfast cereals to excess intakes.[11–13] Intakes of zinc, retinol, folic acid, copper and selenium above the ULs among children aged 1–8 years were described in NHANES 2001–2002,[7] and vitamin A, folic acid and zinc intakes above the ULs attributable to mandatory and voluntary fortification were reported among children in NHANES 2003–06.[4] In pooling the results for children aged 2–18 years, this analysis masked the heightened vulnerability of young children revealed through our study. Some have argued that reports of children with intakes above the UL should be little cause for concern because the data on which the ULs for children are based are particularly limited, and there is little documentation of adverse effects.[23] However, given how far above the UL, the 90th percentile of young children's usual zinc intakes is, there is a need to exercise caution in the absence of a better understanding of the risks associated with intakes at this level. Our results also suggest that there may be reasons to monitor the effects of voluntary fortification on the nutrient intakes of older children and adults.

An important difference between our analytic methods and those applied by others to examine the risks associated with voluntary fortification in the United States[10–13] and elsewhere[24–27] is the recognition of variation in the likelihood of consuming nutrients from vFF within a population and within-/between-person variation in the intake of nutrients from these foods.

Prior studies have not assessed the risk in relation to individuals' propensity to consume vFF, but have rather estimated the contribution of vFF to total nutrient exposure based on observed intakes over a few days.[24,25] Characterizing people as high or low vFF consumers based on only a few days of intake may result in misclassification that masks the elevated risk associated with higher probability of vFF consumption.

Our results are sensitive to estimation errors in total nutrient exposure. Fortified foods were not consistently differentiated from unfortified versions in this survey, and the extent to which fortified food consumption was probed for during the data collection is unclear.[28] This estimation error, together with the likely underreporting of intakes for some individuals,[29,30] means that we have underestimated the upper tails of the usual intake distributions and the extent to which fortified food consumers have intakes above the ULs. In addition, estimating the upper tails of the distributions is challenging due to data scarcity, which may explain the significant effects observed only when we examined intakes approaching the UL (that is, the 90th percentile) and not when we examined prevalences exceeding the UL.

The FNDDS database in most cases does not differentiate between added and naturally occurring nutrients, and food code descriptions are often insufficient to identify fortificants. We therefore cannot directly attribute intakes above the UL to voluntary fortification. The observed intakes of retinol, folic acid and zinc in excess of the UL among children are likely, in part, a product of voluntary fortification as retinol and folic acid are not naturally occurring in breakfast cereals and beverages, and zinc is commonly added to breakfast cereals.[10] This inference is less readily drawn for our findings with respect to excessive copper and selenium intakes, as neither nutrient is commonly added to food.[31,32]

We did not consider supplement intakes in this analysis but supplement use has been shown to increase the risk of excess.[4,33] The observed positive associations between probability of consuming fortified foods and likelihood of supplement consumption among several groups suggest that the true risk of intakes above the UL among those with high exposure to vFF is even greater than our estimates suggest. Our findings highlight the increasing risk of nutrient intakes in excess of the UL with greater exposure to vFF, a risk that can only be compounded by dietary supplement use.

These results support the Institute of Medicine's recommendation that voluntary fortification not be employed without a public health rationale.[1] It could be argued that the risk of vFF consumption leading to intakes above the UL needs to be weighed against the benefits of reducing inadequate nutrient intakes in the population. However, it is important to recognize that decisions about nutrient additions in vFF rest with food manufacturers, not public health officials. Although some of the nutrients for which we observed intakes above the UL in conjunction with vFF consumption have a substantial prevalence of inadequacy (for example, calcium), others (for example, zinc) do not.[4] More research is needed to determine the health implications of usual intakes that approach or exceed the UL, but in the interim, it would seem prudent to consider restricting the addition of micronutrients to cases in which there are demonstrable health benefits. As voluntary food fortification continues to expand, more careful scrutiny and monitoring of this practice is needed.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

JE Sacco is supported by a Canadian Institutes of Health Research Doctoral Research Award.

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Supplementary Information accompanies this paper on European Journal of Clinical Nutrition website (http://www.nature.com/ejcn)