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Risk analysis applied to food fortification

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Abstract

Objective: To describe how a risk analysis can be applied to food fortification, with emphasis on voluntary fortification and intake levels that might exceed usual dietary levels.
Design: Use of the risk analysis model as a frame to classify nutrients according to the risk of exceeding upper safe intake levels. Furthermore, to apply the model when discussing possible consequences of liberal fortification practices on eating behaviour and disease patterns.
Setting: The discussion on food fortification presently going on internationally.
Results: Micronutrients can be classified according to their safety margin, i.e. the size of the interval between the recommended intake and the upper safe level of intake. We suggest that nutrients with a small safety margin, i.e. for which the upper safe level is less than five times the recommended intake, be placed in a category A and should be handled with care (retinol, vitamin D, niacin, folate and all minerals). Category B comprises nutrients with an intermediate safety margin (vitamins E, B_6, B_{12} and C), while nutrients that according to present knowledge are harmless even at 100 times the recommendation (vitamin K, thiamin, riboflavin, pantothenic acid and biotin) are categorised as C.
Discussion: The risk analysis model is a useful tool when assessing the risk of both too low and excess intakes of single micronutrients, but can also be applied to analyse the consequences of fortification practices on eating behaviour and disease patterns. Liberal fortification regulations may, for example, distort the conception of what is healthy food, and drive consumption towards a more unhealthy diet, contributing to the plague of overweight and concomitant increased risk of degenerative diseases.
Conclusion: The impact of fortification practices on the total eating pattern of a population should become an integrated part of the discussions and regulations connected to the issue.

Keywords
Fortification
Food
Risk analysis
Discussion paper

A lively discussion about food fortification is presently taking place internationally. Different countries, also within the European Union (EU), have different fortification regulations, a situation that by many is considered to be a barrier to trade, and against EU free-trade philosophy. Basically, two different attitudes to the question are apparent. The first is a 'selective' attitude, based on Codex Alimentarius principles, claiming that fortification should not take place unless there is a documented need[1], and the second is a 'non-selective' attitude, claiming that as long as there are no documented adverse health effects, fortification regulations should be liberal[2,3]. The selective attitude comprises the historical approach, where fortification of certain staple foods has been used as a means to alleviate deficiency diseases in the general population; e.g. iodine in salt to alleviate goitre and vitamin D added to margarine or milk to alleviate rickets. The selective approach has also been targeted, i.e. only meant for specific population groups, like iron added to infant formula or flour to combat iron deficiency and anaemia. Recently, cereals fortified with folic acid were introduced in the USA to reduce the prevalence of neural tube defects, and the result is already measurable[4,5]. Both general fortification and targeted fortification have been carefully regulated by the health and food authorities of the various countries and, by and large, have been a blessing to consumers through their eradication of serious nutrient deficiency diseases.

The 'non-selective' approach comprises all voluntary fortification by the food industry; that is to say, the motivation is to increase the nutrient content of foods irrespective of there being a documented need for it or not. All of the Nordic countries have in general been very restrictive towards voluntary fortification, considering it unnecessary and potentially harmful. Many other countries,

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like the USA, Britain, Switzerland and Belgium, have been more liberal, allowing foods to be fortified voluntarily as long as harmful concentrations and effects were avoided.

Harmonising EU regulations implies making these two basically different attitudes towards voluntary food fortification merge. In a joint effort to meet the coming discussions, the Working Group on Diet and Nutrition under The Nordic Council of Ministers initiated work with a discussion paper on the issue, which recently was published as a report[6]. The present debate paper is based on, and is a continuation of, the Nordic report. The most common arguments for and against voluntary, i.e. liberal, fortification practices are presented and discussed, using a risk analysis model as a frame. This frame is also used when discussing the possible impact of voluntary fortification on the total eating behaviour of people. The paper does not discuss issues connected to two other aspects of the addition of micronutrients to foods: restoration and standardisation (Table 1).

What is a risk analysis?

Risk is defined as the probability of a negative health event. Risk analysis has been developed as a method to evaluate existing knowledge and subsequently take measures so that risk of disease or adverse health effects can be reduced or prevented. The method is used widely in fields connected to environmental medicine and food safety. The method ensures that the description of the hazard and the risk is scientifically based, that risk-reducing strategies are conducted on a professional basis and that uncertainty in the premises is clearly described. It is a method to describe uncertainty in a systematic way, and the roles of scientists, risk managers and other stakeholders are separated and clear. An analysis has three components: risk assessment, risk management and risk communication[7]. Table 2 summarises the main steps in risk assessment[8].

Risk assessment applied to fortification

In classical risk assessments one deals with potentially toxic compounds, either hazards connected to environmental pollution, pesticides, food additives and micro-organisms or compounds originating from natural sources, and with no beneficial effects on health. In many cases the database is insufficient for doing a quantitative risk assessment describing the risk to humans at different exposure levels, and safety assessments based on animal and human data are performed ending up in acceptable or tolerable levels of intake. Uncertainties owing to the lack of data for humans and extrapolation from animal data are accounted for by uncertainty factors in the derivation of acceptable or tolerable intake levels, to ensure that this intake is below the dose threshold of effect for the population. This is not problematic when there is no need for the compound or the exposure can be easily reduced. Nutrients are different. We need a certain amount of them almost daily to survive. The health risk is connected to both too low and too high intakes. Thus a risk assessment of micronutrients comprises finding an acceptable range of intake for each vitamin and mineral. Nutritionists are familiar with handling the risks connected to low intakes of micronutrients, and uncertainties due to deficiencies in the database are taken into account in the evaluations to ensure a sufficient intake in the population. Preoccupation with toxic intake ranges is a rather new exercise in the field of nutrition. Normally, it is virtually impossible to reach toxic levels when eating a normal, balanced diet without fortified foods or supplements. Intakes causing adverse health effects and even plain toxicity through a normal diet have been observed only for vitamins A and D, iodine and selenium, but such cases have been rare[9,10].

Can food fortification cause risk of adverse health effects?

There is a risk of adverse health effects when a sufficient number of foods are fortified with a specific nutrient. For example, cereal products fortified with folic acid have a potential of masking vitamin B_{12} deficiency in elderly people[11,12]. There has also been a worry about negative health effects of increased iron and vitamin D intakes in infants consuming fortified formula[13,14]. A recent paper illustrates how easily upper safe intake levels for calcium may be exceeded in today's Finland[15]. Uncontrolled or accidental high intakes of vitamins through fortified products have occurred several times during the last 50 years, e.g. with vitamin D in England in the 1960s and in the USA in the 1980s[16,17]. In acknowledgement of the risk of excess intake levels of micronutrients, both the Nordic

Table 1 Definitions of the Codex Alimentarius[1]

Fortification or enrichment	The addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more essential nutrients in the population group
Restoration	The addition to a food of essential nutrient(s) that are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the level(s) of the nutrient(s) present in the edible portion of the food before processing, storage and handling
Standardisation	The addition of essential nutrients to a food in order to compensate for natural variations in nutrient level

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Table 2 The elements needed to perform a risk assessment of food fortification

Stages in a risk assessment*	Application to the question of fortification	Suppositions or data needed to perform the risk assessment
1. *Hazard identification* (the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods)	Risk of too high intake of micronutrients, risk of adverse effects Risk of too low intake of micronutrients, risk of deficiency	Agreement on which micronutrients are essential Lower safe intake levels Upper safe intake levels (based on what we know about adverse effects/toxicity) Recommendations and optimal intakes
2. *Exposure assessment* (the qualitative and/or quantitative evaluation of the likely intake of biological, chemical or physical agents via food as well as exposures from other sources if relevant)	What do we know about the distribution of the present intake, both median and 95th percentile?	Food intake data Micronutrient content of food items Biomarkers of intake and status
3. *Hazard characterisation* (the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical or physical agents that may be present in food. For biological or physical agents, a dose–response assessment should be performed if data are obtainable)	The hazard is different for the different micronutrients Describe dose–response for symptoms of deficiency and adverse effects	Dose–response data for deficiency and adverse effects Groups susceptible to deficiency or toxicity Classification of the micronutrients
4. *Risk characterisation* (the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on steps 1–3)	Integrate data on intake in the population, and identify groups exceeding the upper safe intake level and groups at risk of intake below recommendations	Problems: Information gaps (lack of good data in many of the fields needed to do the risk analysis) A broader perspective needed

* As suggested by Codex Alimentarius Commission, 1997[8].

countries and the US Food and Nutrition Board have published Upper Safe Intake Levels for micronutrients in recent years[18–20]. The EU is working on the issue in its Scientific Committee on Food, and upper levels for a number of vitamins and minerals have been developed and are being published continuously[21]. An unacknowledged EU report including upper safe levels was published in 1993[22].

The various committees working on the establishment of upper safe limits do not necessarily arrive at the same figures, as summarised in Table 3. Risk of adverse health effects of high doses may also deviate depending on the chemical form of the micronutrient, e.g. the difference in toxicity of nicotinic acid and nicotinamide, or retinol and carotenoids. Examples of adverse effects, based on present-day knowledge, are described in Table 4. As with micronutrient deficiencies, individual variation is wide, and depends on factors like individual biochemical make-up, bioavailability, etc. Micronutrients are 'tricky' because they interact. For example, zinc in doses up to 500 mg day^{-1} (50 times the recommendations) is tolerated by most people, without measurable clinical effects. However, at daily zinc intakes of 50 mg, one can already measure negative effects on iron and copper metabolism, which, in the context of setting upper levels, is considered an adverse effect[25–28]. The most important interaction potentials of each micronutrient have been included in Table 4. More important, though, is that our knowledge in many cases is too limited to describe the distribution curve for the most sensitive adverse effects, first and foremost because there are few human studies. In many cases we have to rely on extrapolations from animal studies.

Exposure assessment (dietary intake)

To be able to evaluate the need for fortification or food supplements (vitamin and/or mineral concentrates), and estimate eventual negative health outcomes of excessive intakes, intake data for nutrients among population groups are necessary. To get a true estimate of intake, they should include nutrients provided not only by food and drink, but also by food supplements (vitamin and mineral concentrates) and medications. The challenges are formidable, though, especially in countries with liberal fortification practices, because a good estimate of nutrient intake necessitates an updated database on the nutrient content of all brands of a food on the market, and a dietary survey method that will allow for brands to be reported. Recent EU directives on food additives mandate all member states to monitor their usage and consumption[29–31]. In the wake of this demand, simulation models have been developed to estimate food additive intake[32,33]. Similar methods have been developed for assessing the prevalence of nutrient inadequacy[34], and may prove useful when we want to estimate the true intake of micronutrients, including the contribution from fortified foods.

A way to get around the challenges with dietary surveys is to use biological markers of nutrient intake. Unfortunately, few such have been found to date[35].

Hazard characterisation

There are quite extensive variations between vitamins and minerals regarding the range between the recommended level of intake and the intake level that gives rise to adverse/toxic effects. For some components this range can be quite small, e.g. ≤5-fold, whereas for others the range may be more than 100-fold. For vitamins with a narrow range and hence a greater risk of excessive consumption and adverse health effects, it is necessary to be more cautious from both scientific and regulatory points of view. However, larger ranges do not necessarily imply harmlessness, but simply that the amount of data is limited. Caution may be warranted also for such micronutrients.

In an attempt to approach this problem, we have, on the basis of easily available information from nutrition textbooks and recommended intakes[18,23,24], roughly divided the vitamins and minerals into three categories (Table 4).

- *Category A:* Nutrients where the range between recommendations (or actual intakes) and the upper safe intake level is very narrow (≤5-fold) and great caution should be employed, for instance, in regulatory contexts (vitamins A and D, nicotinic acid, folate and all minerals).
- *Category B:* Upper safe intake level is 5–100 times above recommendations. Considerations should be taken regarding side-effects or interactions with other components in the diet (vitamins B_6, B_{12}, C and E).
- *Category C:* Upper safe intake range is virtually impossible to set, as no adverse or toxic effects have been observed even at >100 times the recommendations (vitamin K, thiamin, riboflavin, pantathenic acid and biotin) and interactive effects have hitherto not been observed.

If liberal practices are advocated, it may be useful to have a classification like the above in mind. If no safety restrictions are applied, cases of nutrient overloading due to fortification may easily occur. It is necessary to respect the potential adverse effects of micronutrients in category A, and also be careful about the ones in category B. New information may eventually change our views on micronutrients in all categories, necessitating changing of categories.

Risk characterisation

As adverse health effects/toxicity from too high intakes of vitamins and minerals is normally only possible through the consumption of multiple fortified foods or food supplements, groups at risk of excess intake will be high consumers of fortified foods and supplements. A number of countries, e.g. Britain, Switzerland and Belgium, have

Table 3 Recommendations and upper safe intake levels of micronutrients, based on references 18–22

	Recommended daily intake			Upper safe intake level		
Nutrient	Nordic countries 1996, men aged 18+	EU SCF 1993, population reference intake for men aged 18+	US FNB Dietary Reference Intakes 1997–2001, men aged 19–30	Nordic countries 1996	EU SCF 2002 (EU SCF 1993)*	US FNB 1998, Tolerable Upper Intake Level
Retinol (μg)	900	700	900	7500	3000	3000
Vitamin D (μg)	5 above 61 years: 10	0–10	5	50	50	50
Vitamin E (α-TE)	10	0.4 per g PUFA, minimum 4	15		2000*	1000
Vitamin K (μg)			120			ND
Thiamin (mg)	1.4	1.1	1.2		Not sufficient data†	ND
Riboflavin (mg)	1.6	1.6	1.3		Not sufficient data†	ND
Niacin (mg)	18	18	16	500	Nicotinic acid: 10 Nicotinamide: 900	35
Pyridoxine, vitamin B_6 (mg)	1.5	1.5	1.3	50	25	100
Folate (μg)	300	200	400	1000	1000	1000
Vitamin B_{12} (μg)	2	1.4	2.4	100	Not sufficient data†	ND
Pantothenic acid (mg)		3–12	5		Not sufficient data†	ND
Biotin (μg)		15–100	30			ND
Vitamin C, ascorbic acid (mg)	60	45	90	1000	1000–10 000*	2000
Calcium (mg)	800	700	1000	2500	2500*	2500
Magnesium (mg)	350	150–500	400		250‡	350§
Phosphorus (mg)	600	550	700	5000		4000
Chromium (μg)			35			ND
Copper (mg)		1.1	0.9		10*	10
Fluoride (mg)			4			10
Iodine (μg)	150	130	150	1000	600	1100
Iron (mg)	10	9	8	60	30–100*	45
Manganese (mg)			2.3		Not sufficient data†	11
Molybdenum (μg)			45		600	2000
Selenium (μg)	50	55	55	300	300	400
Zinc (mg)	9	9.5	11	45	30*	40

EU – European Union; SCF – Scientific Committee on Food; FNB – Food and Nutrition Board; ND – not determined; α-TE – α-tocopherol equivalents; PUFA – polyunsaturated fatty acids.
* From Reports of the Scientific Committee on Food, 1993[22].
† Not enough data to establish a numerical upper level. Some advice is provided to the risk manager under risk characterisation.
‡ From supplements only.
§ As readily dissolvable Mg salts.

Table 4 Main symptoms of excessive intakes of micronutrients and their interaction potential, based on references 18–24. The right column is a suggested safety categorisation, based on how short the span is from recommended to upper safe intake level (A – handle with care, small safety margin; B – intermediate safety margin, interaction potential; C – harmless at 100 times the Recommended Daily Allowance)

Nutrient	Possible adverse effects of high intakes	Interaction potential	Suggested category
Retinol	Liver toxicity; eye and skin disorders; loss of appetite; bone disorders; teratogenic effects	Antagonist to vitamin D	A
Vitamin D	Hypercalcaemia; hypercalciuria, anorexia, muscular weakness, joint pains	Antagonist to vitamin A	A
Vitamin E	200–800 mg TE day^{-1} well tolerated without adverse effects by adults (adverse effects in premature neonates). Doses >800 mg day^{-1} may decrease platelet adhesion	Large doses may interfere with the absorption of vitamins A, D and K. Intakes above 1200 mg TE day^{-1} can interfere with the metabolism of vitamin K, potentiating the effect of anticoagulation drugs	B
Vitamin K	No known toxicity of phylloquinone (natural vitamin K). Menadione, synthetic vitamin K, leads to haemolytic anaemia and liver toxicity in newborns		C
Thiamin	No known effects (reports of adverse reactions after parenteral administration)		C
Riboflavin	No known effects (apart from discoloration of the urine)	Has photosensitising properties that may accelerate oxidation of the amino acid tryptophan	C
Niacin	Flushing of skin, hyperuricaemia, hepatic and ocular abnormalities Possible hepatotoxicity	Nicotinic acid Nicotinamide	A B
Pyridoxine, vitamin B_6	Doses >500 mg day^{-1}: peripheral neuropathy; photosensitivity		B
Folate	Neurotoxic (in epilepsy patients); mental changes; sleep disturbances; gastrointestinal symptoms, nephrotoxic effects known in rats	Masking of vitamin B_{12} deficiency	A
Vitamin B_{12}	No known adverse effects in doses <100 μg day^{-1}		B
Pantothenic acid	No known adverse effects		C
Biotin	No adverse effects in trial with 200 mg day^{-1}		C
Vitamin C, ascorbic acid	Doses <500 mg: no adverse effects in healthy people. Doses >500 mg may increase urinary oxalate in patient groups. Doses >1000 mg: oxaluria; uricosuria in healthy people	Improves non-haem iron absorption (haematomachrosis). Adverse effect on copper absorption; increased metal toxicity	B
Calcium	Hypercalcaemia; urinary tract stones (in predisposed persons)	Interacts with magnesium absorption and transport	A
Magnesium	Diarrhoea; neurological disorders	Interacts with calcium absorption and transport	A*
Phosphorus	Hypocalcaemia; diarrhoea; metastatic calcification		A
Chromium	Low toxicity of Cr^{3+}. Cr^{6+} forms are carcinogenic	Competition with iron for transport proteins	A
Copper	Gastrointestinal toxicity, liver cirrhosis	Large doses inhibit zinc absorption	A
Iodine	Elevated TSH concentration; thyrotoxicosis	Iron and vitamin A deficiency; decreases plasma T_4 and T_3 concentrations	A
Iron	Gastrointestinal damage; liver necrosis; formation of free radicals. Coronary heart disease? Colon cancer?	Inhibits manganese, zinc, copper and possibly selenium absorption	A
Manganese	Neurotoxic effect	Interacts with iron and calcium absorption	A
Selenium	Neurological disorders; hair loss; nail and skin disorders; liver toxicity	Iodine, copper, iron	A
Zinc	Leucopaenia, neutropaenia, anaemia, impaired immune function and altered lipoprotein metabolism	Even moderate doses inhibit iron and copper absorption	A

TE – tocopherol equivalents; TSH – thyroid-stimulating hormone.
* Upper level is based on supplements, and not directly comparable to bound Mg in food.

years of experience with rather liberal fortification practices. Apparently, no signs of adverse health effects have been reported in recent years as having connection to fortification practices in these countries. However, as frank toxicity is not expected, negative health effects may be difficult to reveal, they may be subtle and indirect. Because our normal dietary survey methods are limited and considered a very inexact science, and the situation is not being made easier with fortified foods, the true impact of micronutrients from the diet, both fortified and non-fortified, will perhaps only be understood when adequate biomarkers for nutrient intake and status have been found. Meanwhile, the best tool we have is to compare thorough consumption data with the upper safe level of intake. Such an exercise has been done in the development of upper levels in the Nordic countries[18], by the EU[21] and by the National Academy of Science in the USA[19].

The scientific challenges connected to risk assessments of nutrients

Although modified versions of traditional risk and safety assessment models for chemicals are now being taken into use for the establishment of upper safe intake levels for vitamins and minerals, there is no international consensus on which methodology to use when determining these levels. There is also a long way to go before we have adequate data to use these models in an effective way in relation to micronutrients. Lack of data makes the use of uncertainty factors difficult, particularly when the margins to nutritional needs are small. In addition, there are few human studies, and the existing ones often consist of a limited number of persons studied over short time spans. In many cases they have been conducted for other purposes. Furthermore, as already mentioned, humans vary greatly metabolically, and bioavailability and interactions must be taken into account. Adverse health effects due to distorted ratios between micronutrients may be very difficult to reveal. Distorted ratios between micronutrients may influence the metabolism of normal body substances in ways not easily traceable to the real cause. Critical reviewing of available data to assess upper safe intake levels of micronutrients will reveal the lack of data in the assessment, and should be used as a guidance for directing future research.

As illustrated above, a risk assessment model is already in use when it comes to single nutrients. The risk assessment model has not, as far as we know, been used for assessing the consequences of liberal fortification practices. It is important to discuss the necessity of applying the model also when analysing the total impact of fortification on people's general eating behaviour.

Risk management of fortification

Risk management is normally the responsibility of the food authorities in a country, which in collaboration with e.g. health authorities suggest and implement food regulations. There are three main questions to be discussed in this context. If needs are not met by the habitual consumption of foods, what strategies are best to improve the situation? What measures are best to prevent the consumption of excess, unsafe levels? Will fortification influence dietary habits? There have in general been two principal approaches to answering these questions, which we name 'the selective approach', i.e. a general approach, and the 'non-selective approach', comprising voluntary fortification.

The selective approach: alleviate micronutrient deficiencies while maintaining food safety

This is the original approach, arising approximately 80 years ago with the identification of micronutrients and their deficiency diseases. In the selective approach, public health authorities make decisions and regulations, and supplementation programmes are considered a public health responsibility. Foods are selected for fortification largely by efficiency criteria, i.e. items with a mediocre 'health profile' may be chosen, such as salt and margarine. Selective, voluntary or compulsory, fortification of a selection of foods ingested by the vast majority of the population (i.e. flour or bread) will often be preferred. Ideally, the effects of the fortification (e.g. iodine status of targeted population groups, selenium through selenium enrichment of fertilisers) are assessed, and regulations may be modified according to the outcome. (In reality, such assessments are often given low priority.) Safety limits for each nutrient are set conservatively, so that harmful intake levels are unlikely to occur. Fortification is considered a part of a total nutrition and health policy.

The selective approach is rather well defined, both with respect to what it tries to encompass and what it does not. Little room for choices has been left for industry. This has made it possible to put the approach on a sound, scientific basis, but it has also, occasionally, led to criticism. The selective approach is in accordance with Codex Alimentarius general principles and has formed the basis for regulations in the Nordic countries (and several others).

The non-selective approach: no unnecessary constraints on fortification

The basic concept of the non-selective approach is that as long as there are no health risks, there should be as little food regulation as possible. Regulations may function as trade obstacles and limit the operational freedom of the food industry. The basic philosophy is that industry and the market will adjust themselves in fortification matters, and provide healthy products for the consumer. Regulations that place restrictions on fortification will reduce the total offerings of foods containing appreciable amounts of micronutrients. However, dietary deficiencies are a public health problem in several European countries, and new deficiencies may develop with changing lifestyles

and eating habits. For instance, the consumption of snack and 'fast food' products is increasing, and the more sedentary life now enjoyed by most people may result in a reduced food intake, and consequently in an inadequate vitamin and mineral supply. With more liberal practices, there is higher risk that deficiencies may not be adequately met at the same time as harmful intake levels may occur. Therefore, safety considerations should play a more important role in this approach. Liberal fortification with nutrients belonging to category A should preferably be avoided.

Other considerations

There is little knowledge about the impact of fortification on dietary eating patterns. Does fortification contribute to driving food consumption in a more unhealthy direction? In the EU discussions on food fortification strategies, we believe that the question of fortification having the potential to influence the dietary habits of a population should also be considered carefully.

The United Kingdom is one of several countries having practised more or less free fortification for years. As in many other countries, the sales of convenience foods and foods rich in fat, starch and sugar have skyrocketed in the last decades, and combined with sedentary lifestyles there has been a concomitant increase in average weight for all population groups[36,37]. A report from the UK states that of 260 foods which declared fortification on their labels, almost three-quarters were high in fat, sugar or salt[38]. This has strengthened the concern that fortification is being used as a marketing tactic to promote a range of processed foods, many of which we should be eating less of, rather than more, and undermining the meaning of nutritious foods and healthy diets.

The report concluded that UK consumers would benefit from a more restrictive regulatory approach. Fortification is to a large extent being used to polish the image of foods with low nutritional value.

Risk communication of fortification

Participants in risk communication are the risk assessors, risk managers, politicians and other decision-makers, professionals (both inside and outside the health sector), the food industry, the media, and anyone being interested in the matter. The first step is to get the scientific advice across to the risk managers, whose task is to translate this into management actions, while taking into account inputs from industry and society. Politicians have to consider pressure from their voters, even if conceptions held by the lay public may be unreasonable when seen from a professional point of view. Journalists will estimate information about a risk from a news point of view. Information involving an increase in risk will be more interesting to publish than information about reduced risk. Professional disagreement may in itself be of public interest.

Although it is our impression that the debate connected to food fortification so far has been one between professionals mainly, it is easy to anticipate that once the Scientific Committee on Food of the EU commission has come up with its final recommendations, and these have been translated into management decisions including regulations, depending on the interest group affected – the food industry and the public – a wider, public debate may arise. A major challenge in this respect will be how to explain to the public the impact of healthy eating. When a chocolate bar may contain 10 times more vitamin C than an orange, people may easily be confused about the nutritional quality of foods, a major concern in the Codex Alimentarius principles.

Future perspectives and recommendations

The obligation of food authorities is to ensure food safety. We have argued that a risk analysis has to go beyond the evaluation of single nutrients, and include the impact of food fortification on eating and disease patterns, and this is a public health responsibility. This includes ensuring that the population has adequate intakes of both nutrients and beneficial non-nutrients. Health statistics should be evaluated against knowledge about the impact of diet (and other input factors), and regulations can be assessed as a tool to improve the health condition of the population. This approach has been very clearly pointed out in articles by Gussow and Akabas[39], Mertz[40] and Backstrand[41], all expressing deep concerns about the situation in the USA. The main goal would be to use food regulations to influence the total eating behaviour of a population in a healthy direction. In this approach, people's concept of healthy foods is an important target. Liberal fortification practices have the potential of distorting those views.

Globalisation and urbanisation are influencing dietary habits and patterns all over the world. The transition implies on the one hand that the diet is becoming more varied and thus possibly nutritionally better. On the other hand, there has been a substantial increase in the consumption of foods rich in fats and sugar, with a concomitant increase in overweight, obesity, cardiovascular diseases and diabetes. The most rapid increase in chronic diseases in Westernised countries today is seen in immigrant subgroups, where the prevalence of type II diabetes, for example, is increasing much more rapidly than in the host population[42].

One should have this broad perspective in mind when discussing issues connected to fortification of foods. Europe has become a consumer society where the individual has a large degree of freedom when choosing foods. This requires knowledge and awareness when purchasing and preparing foods. Education and information are among our most important, political tools.

If the ultimate aim of health policies is to reduce the incidence of degenerative diseases caused by overweight and nutritionally unbalanced diets, a risk analysis of food fortification should also include an evaluation of whether fortification practices may drive consumption towards an unhealthy diet, i.e. a diet with many high-sugar, high-fat foods. Analysis of fortification practices shows that the majority of foods being fortified belong to such food groups[38]. Liberal fortification regulations distort people's concept of nutritious foods and may stimulate increased consumption of food groups we encourage a reduced intake of. As long as the majority of fortified foods in reality are ones we want a reduced intake of, it seems meaningless to limit a risk analysis to looking at one and only one nutrient at a time. The impact of fortification practices on the total eating pattern of a population should become an integrated part of the discussions and regulations connected to the issue.

Changing people's eating habits is laborious and costly, and has a better chance of success in co-operation with the food industry. The food industry should be challenged to sort out the most appropriate ways to preserve, store and prepare food products to maximise delivery of a broad range of food components, rather than focusing on highly adulterated foods by adding a couple of single nutrients or functional foods that are perceived as a quick fix by the public.

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