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The addition of nutrients to foods

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Several nutrients have been added to food and drink products around the world as public health measures and as effective ways of ensuring the nutritional quality of the food supply. Additions of some nutrients have also formed the basis of marketing strategies in product development (Richardson, 1993). The main criteria for selecting nutrients to add to foods are that they are shown to be safe, effective and beneficial to the nutritional status of the target population groups (Brady, 1996*a*,*b*). Long-term solutions to micronutrient deficiencies rest on the provision of adequate quantities of all micronutrients from a well-balanced diet. Food-based approaches around the world include: strategies to improve the availability of a variety of foods; food preservation methods to maximize nutrient retention; additions of nutrients to suitable food carriers. Nutrition education is also an important and parallel long-term strategy.

The aim of the present paper is to review the rationale, benefits and risks associated with the responsible addition of nutrients to foods. Safety and quality of foods are fundamental to any initiatives, as is the need to avoid inappropriate additions, which could undermine consumer credibility and mislead them about the role of enriched foods in a healthy, balanced diet. The addition of nutrients requires an understanding of local or national dietary patterns and of the nutritional status of the population or target groups. Major technical challenges are also involved in adding nutrients to foods, including identification of suitable dietary vehicles, the selection of appropriate compounds and the manufacturing technologies to be applied (Berry Ottaway, 1993). Nutrient additions to ordinary foods and the use of claims can also create difficulties because of the lack of common rules and approaches within the European Union and in other countries of the world. Current practices and legislation, which differ considerably in approach and degrees of restrictiveness, can also sometimes interrupt free trade.

Whereas additions of nutrients can undoubtedly improve nutritional status and the health of those segments of the population which are vulnerable and susceptible to deficiencies, there is also increasing awareness of the role of some foods, nutrients and non-nutrients, which can give positive nutritional and physiological benefits. Consumer interest in the link between diet and health is increasing and there are many opportunities for developing foods which could have positive effects on health (Young, 1996).

DEFINITIONS AND TERMINOLOGY

General agreement on terminology has been reached within *Codex Alimentarius* (Codex Alimentarius Commission, 1994), and further clarification has been suggested by the

Nordic Council of Ministers (Tema Nord, 1995). For the purposes of the present review, the term 'nutrient additions' refers to the addition of micronutrients, primarily vitamins and minerals. Amino acids and other substances with nutritional value such as fatty acids, fibres and macronutrients such as proteins, carbohydrates and fats could also be considered. 'Restoration' refers to the addition of nutrient(s) to a food to replace naturally-occurring nutrients which are unavoidably lost during the course of good manufacturing practice in the preparation and preservation of food, or during normal storage and handling procedures. The levels are restored to those which were present in the edible portion of the food before processing, storage or handling, e.g. Fe and B-vitamins to flours. 'Fortification' usually refers to the addition of one or more nutrients to a food, whether or not it is normally contained in the food, and where the level of nutrients present makes the food a 'richer' source. These enrichment practices are used for public health reasons to prevent or correct a demonstrated deficiency or risk of suboptimal intakes in a population or specific population groups (e.g. iodide to salt), and to produce quality products with enhanced nutritional value (e.g. breakfast cereals). 'Standardization' refers to the addition of nutrients in order to compensate for natural or seasonal variations in nutrient levels (e.g. vitamin C to juices). 'Substitution' refers to additions of nutrients to a substitute product to the levels in the food which they are designed to resemble or replace (e.g. margarine and fat substitutes). In practice it is often a combination of these different types of nutrient additions.

GENERAL PRINCIPLES FOR THE ADDITION OF NUTRIENTS TO FOODS

The addition of nutrients requires careful attention to food regulations, labelling, nutritional rationale, cost, the acceptability of the product to consumers and a careful assessment of technical and analytical limitations for compliance with label declarations (Richardson, 1990). The level of essential nutrients should not have any harmful effects on the consumers' nutritional status or health, excessive additions should be discouraged, and information on food labels should not over-emphasize or distort the role of a single food or

Table 1. *Ten general principles for the addition of nutrients to foods*
(Adapted from Codex Alimentarius Commission, 1994)

1.	The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet
2.	The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient
3.	The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use
4.	The essential nutrient should be biologically available from the food
5.	The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life
6.	Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner
7.	Addition of essential nutrients to foods should not be used to mislead or deceive the consumer as to the nutritional merit of the food
8.	The additional cost should be reasonable for the intended consumer
9.	Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available
10.	When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose

component in enhancing good health. The Codex Alimentarius Commission (1994) has adopted a number of basic principles, set out in Table 1, to achieve any one or a combination of the following: restoration, fortification, standardization and substitution, and for ensuring the appropriate nutrient additions to special purpose foods, such as those for special dietary use.

These principles apply to additions of nutrients to foods around the world as public health measures when foodstuffs are enriched compulsorily and also when proprietary foods are enriched voluntarily. If there are widespread deficiencies or likelihood of deficiencies, then the solution is usually compulsory enrichment at local, regional or national levels, as appropriate. Increased attention is also being given to the addition of nutrients to food aid commodities, particularly for foods targeted for emergency and refugee feeding. The levels of specific nutrients must be appropriate for the given situation, bearing in mind the cumulative amounts from other sources in the diet. More detailed discussion of the criteria for additions of nutrients can be found in Tema Nord (1995), Food and Agriculture Organization (FAO)/World Health Organization (WHO; 1996) and Codex Alimentarius Commission (1994).

REGULATORY ASPECTS

Principles and practices vary considerably and a survey (Tema Nord, 1995) showed a number of approaches: general permission, where nutrient addition is regulated by legislation which specifies the foods and/or nutrients permitted. Levels of permitted nutrients might also be specified; individual authorization, where nutrient addition is not permitted unless permission is specifically applied for from the authorities; notification, where nutrient addition is permitted but notification is required; free nutrient addition, i.e. there are no authorization procedures or restrictions governing nutrient additions to foods, or no legislation. Table 2 summarizes the approaches and underlying legislation on additions of nutrients to ordinary foods in the seventeen countries surveyed. For example, in the UK, a liberal approach has been successfully and safely adopted for almost 50 years, and additions of nutrients are not restricted in terms of types of food, nutrients or nutrient levels provided there is compliance with section 7 of the Food Safety Act 1990 (Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996) and they are not injurious to health. Typically, if a general claim is made for 'a useful source' or 'with added', then the daily intake (described as the quantity of food that can reasonably be expected to be consumed in 1 d) must contain at least one-sixth of the recommended daily amount (RDA) of two or more of the scheduled micronutrients. For a food to be claimed generally as a 'rich' or 'excellent' source of vitamins and minerals, then the typical daily amount consumed must contain at least half the RDA of two or more of the scheduled micronutrients (Food Labelling Regulations 1996; Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996). For specific claims for named vitamins and minerals, these conditions must be complied with in respect of every micronutrient named. The percentage of the RDA in a quantified serving and the number of servings must also be declared on the pack. According to the Nutrition Labelling Directive 90/496/EEC (EEC, 1990), vitamins and minerals can only be declared when they are present in significant amounts, and must be declared when a claim has been made. As a rule, a significant amount means 15 % of the RDA that is supplied by 100 g or 100 ml of a food, or per package of a food if the package contains only a single portion. In contrast to the UK, the additions of nutrients are strictly controlled in Denmark, Finland, Norway and Sweden,

Table 2. *Principles underlying legislation on addition of vitamins and minerals to ordinary foods in the surveyed countries* (Tema Nord, 1995)

Country	Legislation on nutrient addition	Legislation based on:				Positive list with nutrients specified	Remarks
		General permission	Individual authorization	Notification	Free		
Austria	No (except salt)				X	No	Nutrient addition is free as long as no health hazards exist and labelling does not mislead or decieve
Belgium	Yes	X		X		Yes	Nutrient addition allowed for all foods but notification is needed. Minimum and maximum final levels of nutrients in foods are defined
Denmark	Yes	X*	X			Yes	*For flours, oatcakes, cereals, juices
Finland	Yes	X*	X			No	*For margarines
Germany	Yes	X				Yes	Addition of named vitamins permitted without limitations. For vitamins A and D maximum levels given
Greece	Yes	X*	X			No	*For margarines, fat emulsions, salt
Iceland	Yes	X*		X		No	*For margarines
Italy	No		X			No	Nutrient addition allowed to ordinary foods only if approved by Ministry of Health
Luxembourg	No				X	No	Nutrient levels should not be high enough to exceed RDI
The Netherlands	Yes					No	Nutrient addition prohibited except compulsory additions to margarines and breadsalt and optional addition to salt
Norway	Yes	X*	X			No	*For margarines, butter, oils, salt and goat whey cheese
Sweden	Yes	X*	X			Yes	*For fat reduced milk, oils, salt, flours, pasta
Switzerland	Yes (for vitamins)	X				No	Addition on named vitamins allowed to all foods, maximum limits set
UK	Yes				X	No	Addition not restricted, provided not injurious to health
Australia	Yes	X				Yes	Foods, allowed nutrients and their levels specified
Canada	Yes	X				No	Foods, allowed nutrients and their levels specified
USA	Yes	X				No	Food standards specify what nutrients may be added. Nutrients must be added to substitute food

RDI, recommended daily intake.

whereas Belgium adopts a middle approach whereby additions of vitamins and minerals are allowed for all foods, but notification is needed.

EXAMPLES OF ADDITIONS OF NUTRIENTS TO FOODS

Four categories of foodstuffs can be identified: (a) foods for special dietary uses, (b) foods having lost nutrients during manufacture, (c) foods resembling a common food (substitute products), (d) staple foods representing ideal vehicles for nutrients (du Bois, 1987).

Foods for special dietary uses

The EU directive on Foods for Particular Nutritional Uses 89/398/EEC (EEC, 1989; PARNUTS) sets out the general principles governing the composition and marketing of foods for PARticular NUTritional useS, or dietetic foods as they are more commonly known. The Directive covers foodstuffs for which the composition and preparation is specifically designed to 'meet the particular nutritional requirements of the persons for whom they are mainly intended'. They must have a special composition or manufacturing process and be clearly distinguishable from everyday foodstuffs for normal consumption. Although the Directive requires the development of specific Directives for nine categories of dietetic foods, only three of these have been adopted. These are the Directives on Infant Formulae and Follow-on Formulae 91/321/EEC (EEC, 1991); the Directive on Processed Cereal-based Foods and Baby Foods for Infants and Young Children 96/5/EC (EEC, 1995); and the Directive on Foods Intended for Use in Energy-Restricted Diets for Weight Reduction 96/8/EC (EEC, 1996). This latter Directive comes fully into force on 1 April 1999 and requires that single meal substitutes contain 30 % of the daily requirements for the vitamins and minerals listed in the annex to the Directive. The remaining product categories are still being debated by Member States and to date, the draft proposals are still to be developed. Although the issues go beyond the scope of the present paper, another requirement in Directive 89/398/EEC (EEC, 1989) is the adoption of a positive list of nutrient sources permitted for use in PARNUTS products. Lists are now included as Annexe III to Directive 91/321/EEC (EEC, 1991) and as Annexe IV to Directive 96/5/EC (EEC, 1995). The establishment of advisory lists of nutrients and nutrient compounds was also recommended by Codex Alimentarius Commission (1994) and FAO (1996), taking into account new scientific and technological developments and data on safety, bioavailability, stability and other relevant information.

Foods having lost nutrients during normal manufacture, storage and handling

In the UK, there are requirements for the compulsory addition of certain micronutrients to bread and flour (Bread and Flour Regulations 1995; Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996). It is compulsory to fortify extracted flours with Fe (16·5 mg/kg), Ca (940–1560 mg/kg), thiamin (2·4 mg/kg) and niacin (16 mg/kg). The additions of vitamins A and D to skimmed-milk powder, of vitamin D to evaporated milk, vitamin C in the preparation of instant potato and vitamin C to some juices and nectars are examples of voluntary vitamin restoration in the UK. A comprehensive review of the mandatory and voluntary additions of nutrients to wheat flour and margarine worldwide is in a report of an FAO (1996) Technical Review. Although some losses of nutrients are inevitable, particularly losses of the more labile nutrients in any wet process, many

manufacturers endeavour to conserve nutrients with attention to good quality assurance and manufacturing practices.

Foods resembling a common food

The principle of substitution underlies the regulations in many countries for adding vitamins A and D to margarine (e.g. Germany, Austria, Greece, Iceland, The Netherlands, Norway, Sweden, Australia, Canada, USA). In the UK, the compulsory addition began at the start of World War II as part of a major public health measure to prevent rickets. By law, margarine must be enriched to contain 800–1000 μg retinol (vitamin A) and 7·05–8·82 μg vitamin D per 100 g (Spreadable Fats Regulations 1995; Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996), to make it comparable with butter.

In 1991, the Committee on Medical Aspects of Food Policy (COMA) published a report of the Working Group (Department of Health, 1991*b*) which advised on the need in the UK for continued mandatory fortification of margarine with vitamins A and D and whether this requirement should be extended to all fat spreads other than butter. Food manufacturers had begun to develop a range of low-fat and reduced-fat spreads in response to consumer demand. These types of products are not subject to specific legislation and they were taking a growing proportion of the total yellow-fats market. Fortification of these products is not mandatory, but the Working Group (Department of Health, 1991*b*) recommended that the manufacturers should be encouraged to continue and extend the practice of voluntary fortification of these products with vitamins A and D to the levels currently required for margarine.

The fat substitute 'olestra' which was granted approval for limited use in the USA in 1996 must be fortified with vitamins A, D, E and K. Olestra is a unique food component which can be used as a non-digestible substitute for fat. It is a sucrose polyester and because of its chemical composition, olestra passes undigested through the body and adds no fat or energy to the diet. On 24 January 1996, after a long review of the safety data and concerns about olestra's nutritional effects, the Food and Drug Administration (FDA; 1996) approved its use as a direct human food additive in a limited range of snack foods such as flavoured and unflavoured crisps, snack products and crackers. These uses include frying, because it is the only fat substitute that can withstand high temperatures (Giese, 1996). One of the concerns about the use of olestra is that the fat-soluble vitamins dissolve readily in the fat substitute as it moves through the digestive tract and the nutrients are carried out of the body before they can be absorbed from the intestine (Blackburn, 1996). Hence, the FDA (1996) decided that olestra must be fortified with all four vitamins to compensate for the amounts that are not absorbed. The FDA (1996) also required the label of the food containing olestra to bear the following statement, which reflects the nutritional concerns: 'This product contains olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E and K have been added'. The Proctor and Gamble Company (Cincinnati, OH, USA), the manufacturer which developed this novel fat-based substitute (marketed as Olean®), and the FDA are continuing to monitor and evaluate the safe use of olestra (G. Allgood, personal communication).

In the UK, COMA (Department of Health and Social Security, 1980) laid down the general principle that 'any substance promoted as a replacement or an alternative to a natural food should be nutritionally equivalent in all but unimportant aspects of the natural food which it would simulate.' Thus, COMA (Department of Health and Social Security, 1980) gave their recommendations and specifications for the nutritional quality and use of

textured-vegetable-protein foods which simulate meat. Codex Alimentarius Commission (1994) has also stated that nutritional equivalence means being of a similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, and that are present in a serving or portion or 420 kJ of a food at a level of 5 % or more of the RDA of the nutrient(s), are present in the substitute or partially-substituted food (extender) in comparable amounts.

Staple foods

Foods which are to be used to supply nutrients must be likely to be widely consumed in quantities that will make a significant contribution to the diet of the target population. Hence, one of the solutions is to add nutrients to staple foods such as wheat, rice, maize, bread, pasta, sugar, vegetable oils, liquid- and powdered-milk products and breakfast cereals as well as dietary components such as table salt, tea, monosodium glutamate (MSG) etc.

A good example is the fortification of several foods with vitamin A. Vitamin A deficiency causes the deaths of approximately 500 000 children annually in developing countries and xerophthalmia is the most widespread nutritional disorder that results in blindness in man (Underwood, 1994). In most developing countries there is no legislation and the practice of adding vitamin A is voluntary, requiring concerted action with partners such as grant and aid agency groups, technical agencies, the food industry and consumer groups. Vitamin A fortification of several foods for developing countries, including wheat, rice, table salt, sugar and MSG, has been worked on with various degrees of success (Bauernfiend & Arroyave, 1986; Murphy *et al.* 1992). However, there are a number of technical and logistical problems associated with the development of suitable forticants and carrier foods (Murphy, 1995).

Another good example of the fortification of a suitable dietary vehicle is the iodization of table salt for the general population. Table salt has been used successfully and, in general, safely for over 70 years in programmes around the world to prevent I deficiency disorders (IDD). Hetzel *et al.* (1987) and Hetzel (1989) drew attention to the fact that visible goitre was only one of a series of consequences of inadequate I intake. He demonstrated that insufficient I during early fetal development resulted in inadequate development of the baby's brain, because insufficient I-containing thyroid hormones were available. It is now realized that I deficiency may actually contribute to the process of underdevelopment, by limiting the development and learning capacity of children. 'Cretinism' is a term that embraces the most severe forms of damaged persons and it is related to the severity and duration of I deficiency, particularly in the children of mothers who themselves are I deficient and frequently goitrous (Stanbury, 1996).

Edible table salt has been the favoured carrier for I owing to its widespread use, effectiveness, simple technology involved and low cost. Iodized table salt can be used in the home and in a wide variety of commercially-prepared foods. Iodization of table salt began in Switzerland in 1922, and today most countries have either mandatory controls or voluntary programmes to eliminate this public health problem of IDD (FAO, 1996). The levels of fortification that have been used range from 30 to 200 mg/kg and the Codex Alimentarius Commission (1994) standards for food-grade table salt permits the use of the Na and K salts of iodides and iodates. The iodide compounds are cheaper, more soluble and have a higher I content (so that less is needed to achieve the same level of iodization than the corresponding iodates). Major considerations need to be made in the choice of the two

compounds. Iodates are generally more stable under high moisture, high ambient temperature, sunlight, aeration and the presence of impurities compared with the iodide compounds. The use of iodized table salt in commercially-prepared foods, however, needs to be harmonized in Europe to remove barriers to trade. Simple goitre is probably the easiest of all human diseases to prevent if there is action and good cooperation between governments, table-salt producers and refiners and international agencies (Alnwick, 1995). Today, it is United Nations policy that all table salt programmed for food and distribution to beneficiaries has to be I-fortified and of 109 countries where IDD is a problem, most have already passed laws which require all table salt to be iodized and many more countries are following suit to meet the UNICEF challenge to eliminate this public health problem by the year 2000. I-fortification programmes should be continued and extended vigorously so that instances of newly-susceptible persons and especially developmentally-damaged children become very rare (Stanbury, 1996).

HEALTH AND SAFETY ASPECTS

There is a substantial need for objective, scientific evaluations of the safety of micronutrients and for the determination of agreed safe intakes that provide acceptable margins of safety from any adverse effects. Several assessments have been undertaken recently: four government-commissioned reviews (Ministry of Agriculture, Fisheries and Food, 1991; Netherlands Food and Nutrition Council, 1993; Australian National Food Authority, 1994; University of Toronto, 1996); also two comprehensive industry-sponsored reviews by Shrimpton (1995, 1996). These sources of information, together with the COMA (Department of Health, 1991*a*) report on dietary reference values and 'the guidance on high intakes', provided the basic data for developing risk categories for individual micronutrients shown in Table 3. The data show the RDA, where these have been set by the European Commission (Directive 90/496/EEC; EEC, 1990), typical UK daily intakes (Office of Population Censuses and Surveys, 1990; Shrimpton, 1995), summaries of adverse effects and best estimates of upper, safe, daily intakes. The US Food and Nutrition Board, Institute of Medicine (1994) defined the upper safe level as the level of intake of a nutrient or a food component that appears to be safe for most healthy people and beyond which there is concern that some people will experience symptoms of toxicity over time. Most substances will cause harmful effects at some level of intake and any assessments in the levels of micronutrient additions, or the food categories to which nutrients may be added, need to be based on demonstrated risk using scientific risk assessment methods.

The traditional approach to estimating safe levels of vitamins and minerals for enrichment purposes and for nutritional supplements on free sale has tended to be based on an arbitrary multiple of the RDA. However, recent developments in nutrition science have drawn attention to the shortcomings of a single RDA and pointed to the need for the development of an 'upper safe level' reference point for both short-term and long-term consumption (for references see Table 3). Since additions of nutrients to foods are usually based on delivering a predetermined proportion of the RDA, any review of current recommendations would affect enrichment practices. Similarly, the current principle in some countries of restricting nutrient addition to foods primarily on the basis of 'correcting demonstrated nutrient deficiency' as judged by classical nutrition methods is no longer appropriate. It cannot be emphasized enough that the inadequacies of the scientific basis for RDA for 'optimal health' and the difficulties in assessing safe levels of nutrient additions to the food supply underlie the current restrictions on the levels of micronutrient additions, the food categories to which nutrients may be added and the inconsistencies in practice and

legislation between different countries and trading partners. For the UK food industry to be innovative and competitive, there are increasing economic advantages that can be achieved through regulatory efficiencies and harmonization. Shrimpton (1995) proposed that 'any micronutrient may be consumed in an amount that is less than that for which an adverse effect has been confirmed either in peer-reviewed scientific literature or in responsibly monitored practice'. There is a need for caution, and in such dynamic areas of research and dietary experience and practice, the subject area should be kept under review at regular intervals.

Table 3 attempts to categorize the risk for individual micronutrients. Category 1 low-risk nutrients are those with few or no adverse effects, and they include thiamin (vitamin B_1), riboflavin (vitamin B_2), vitamin B_{12}, pantothenic acid, biotin, niacin (amide), β-carotene and vitamin E (α-tocopherol). Category 2 low-risk nutrients have known adverse effects but a wide safety margin, such as vitamin C, pyridoxine (vitamin B_6), folic acid, Ca, Mg, I and K. Category 3 lists known risk nutrients where nutrients are known to have adverse effects at higher levels with a relatively narrow safety margin, such as vitamin A, vitamin D, Se, Fe, Zn, Cu and P. Category 4 refers to nutrients having uncertain risks, with no known dietary-related adverse effects and little safety data.

The Netherlands Food and Nutrition Council (1993) evaluated the potential negative consequences of adding nutrients to foods, and the report concluded that, with the exceptions of vitamins A, D and folic acid, there are no indications that the addition of vitamins to foods needs to be restricted on public health grounds. For trace elements, only Se and possibly Cu and Zn were identified as potential risks. In the case of minerals with relatively high RDA, such as Ca, P and Mg, in practice there is little risk of excessive intake through the consumption of individual foods to which these minerals have been added, since the addition of large quantities of these minerals would have a marked effect on the organoleptic properties of the food. Again, a cautious approach is needed should a situation develop where a large number of foods are consumed to which small amounts of these minerals are added. Among all the trace elements, Se must be regarded as carrying the highest risk (Clydesdale, 1991) because of the narrow margin of safety.

There have been relatively few reports of hypervitaminosis or other harmful effects of excessive intakes of essential nutrients resulting from the consumption of foods to which they have been added (Tema Nord, 1995). In 1953–5, a clinical survey in the UK found 204 cases of hypercalcaemia in infants resultant from the excessive ingestion of vitamin D-fortified foods. This observation led to the cessation of the vitamin D fortification of milk and highlights the need for thorough risk assessments. There is a possibility that the frequent consumption of foodstuffs with added nutrients set out in category 3 (Table 3), could lead to a high cumulative intake of some of the specific nutrients, thereby increasing the risks of acute or chronic intoxication and an imbalance in nutrient supply. However, in practice the use of enriched foods has rarely led to excessive intakes of essential micronutrients.

TECHNOLOGICAL ASPECTS OF MICRONUTRIENT ADDITIONS TO FOODS

Industrially processed and prepared foods are making important contributions to our dietary intakes and the nutrient content of foods is increasingly regarded as being a mark of quality. The levels of micronutrients can vary considerably in the raw materials as a result of genetic differences, cultivation conditions, stage of maturity, and pre- and post-harvest treatments. Developments in process technology and food preparation techniques in the kitchen can have either positive or negative effects on the levels of micronutrients in foods. Heat treatments (e.g. frying, roasting, blanching, boiling, pasteurizing, sterilizing and high-

Table 3. *Categories of risk for individual micronutrients*

Nutrient	Unit daily usage	EU labelling RDA*	Typical daily intake from diet†	Maximum total safe daily intake‡	Guidance on high or toxic level§	Adverse effects in human subjects
Category 1: Low risk and no known adverse effects						
Thiamin	mg	1·4	1·8	50	500–3000 (ne)‖	No known effects
Riboflavin	mg	1·6	2·0	200	ne	No known effects
Vitamin B_{12}	μg	1	7·0	3000	ne	No known effects
Pantothenic acid	mg	6	6·0	1000	ne	No known effects
Biotin	μg	15·0	39	2500	ne	No known effects
Nicotinamide	mg	18	40	500	3000	No known effects
β-Carotene	mg	–	1·9	25	ne	Reversible yellowing of subcutaneous fat and skin discoloration
Vitamin E (α-TE)	mg	10	10	800	3200 (ne)‖	No known effects
Category 2: Low risk and acceptable safety margin						
Vitamin C	mg	60	75	1000	2000 (ne)‖	Gastrointestinal distress and diarrhoea at 10–15 g/d; reported pro-oxidant effects, excessive Fe absorption
Vitamin B_6	mg	2	2·5	100–200¶	500–7000	Sensory neuropathy of extremities
Folic acid	μg	200	300	1000	ne	Masking of vitamin B_{12} deficiency and pernicious anaemia; interferes with effectiveness of anticonvulsant drugs, neurotoxic in epilepsy patients at high oral intakes
Ca	mg	800	900	1500–2500	ne	Hypercalcaemia; urinary stone formation (in predisposed persons); inhibition of absorption of other essential nutrients e.g. Fe, Zn, Mn
Mg	mg	300	310	700	3000–5000	Diarrhoea; neurological disorders
I	μg	150	225	1000	5000	Rare cases of hypersensitivity
K	mg	–	3200	ne	17600 (ne)‖	Hyperkalaemia in sensitive individuals

Table 3. (*Continued*)

Nutrient	Unit daily usage	EU labelling RDA*	Typical daily intake from diet†	Maximum total safe daily intake‡	Guidance on high or toxic level§	Adverse effects in human subjects
Category 3: Known risk and narrow safety margin						
Vitamin A (RE)	μg	800	1200	3000–3300	6500 (9000)‖	Teratogenic; liver damage
Vitamin D	μg	5	3·5	20	50 (1500)‖	Hypercalcaemia; kidney damage
Se	μg	–	63	200	750 (900)‖	Neurological disorders; hair loss; paralysis; nail and skin disorders
Fe	mg	14	13	60–75	100	Relates to hereditary disorders of Fe uptake and storage; high chronic Fe and alcohol intakes leads to liver disease; formulation of free radicals
Zn	mg	15	11	30	75–300	Cu deficiency induction
Cu	mg	–	1·5	9	ne	Toxicity from diet rare; acute, massive dose causes epigastric pain, nausea, vomiting and severe diarrhoea
P	mg	800	1400	1500–3000	4500 (ne)‖	Hypercalcaemia
Category 4: Uncertain risk and little safety data						
Vitamin K	μg	–	80	ne	ne	Haemolytic anaemia
Cr	μg	–	–	1000	ne	None from dietary sources
Mn	mg	–	4·6	20	ne	May interfere with Fe absorption
Mo	μg	–	128	300	1000–1500	Elevated plasma uric acid level at intakes of 10–15 mg/d for prolonged periods

ne, not established; RDA, recommended daily allowance; α-TE, α-tocopherol equivalent; RE, retinol equivalent.

* European Commission Nutrition Labelling Directive 90/496/EEC (EEC, 1990).

† Office of Population Censuses and Surveys (1990).

‡ Data from Shrimpton (1995, 1996), University of Toronto (1996), Hathcock (1996), Netherlands Food and Nutrition Council (1993).

§ Department of Health (1991).

‖ Toxic levels are shown in parentheses.

¶ At the Food Advisory Committee (FAC) meeting of 26 June 1997, members endorsed advice from the Committee on Toxicology that in view of nerve damage reported from prolonged high levels of B_6, intake from dietary supplements should not exceed 10 mg/d (FAC Press Release FAC 6/907, 4 July 1997). The subject of an upper safe level of Vitamin B_6 therefore requires further careful, scientific consideration.

temperature–short-time (HTST)), drying, chilling, freezing, fermentation, milling, irradiation etc. can all affect nutrient retention.

Although minerals and trace elements can be lost by leaching out with the water used in the manufacturing process or in milling procedures, by far the greatest potential is for loss of vitamins. The losses may be due to the length of the process, the temperature to which the product is exposed, the conditions such as presence or absence of air, water, acidity, nutrient–nutrient interactions, nutrient–food matrix interactions etc. Mechanical processes to which a product is subjected and any structural changes in the food influence nutrient retention. The treatment and preparation of foods in the home and in catering establishments can also dramatically influence nutritional value.

Because of the heterogeneity of the chemical structures of vitamins, their stabilities range from being relatively stable to very unstable. Berry Ottaway (1993) summarized the factors which can influence the rate of vitamin content, both endogenous and added as forticants (Table 4). In order to improve stability, vitamins are available in coated or encapsulated forms. Coating agents include gelatin, edible fats, starches, sugars and gums. In most cases where a number of vitamins are being added, a nutrient premix is prepared with the nutrients dispersed in a compatible base, and this technique has a number of advantages in terms of good manufacturing practice. There is greater accuracy with the level of addition, the premix is dispersed throughout the product and from the operational point of view, a premix can be used to manufacture a number of defined batches or days' production and analytical tests can be reduced by measuring 'tracer' nutrients to check each batch. When nutrients are required in microgram amounts per serving, great care has to be taken.

In the UK, *The Food Labelling Regulations, 1996* (Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996) permit nutrition claims for six minerals (Ca, P, Mg, Fe, Zn and I) and twelve vitamins (A, C, E, D, thiamin, riboflavin, niacin, folic acid, biotin, pantothenic acid, B_{12} and B_6). These regulations require the indication of *minimum* durability ('best before date') for most foods and the percentage of the RDA of every vitamin and mineral named in the claim, present in a quantified serving to be stated on the label. Hence, the food technologist must have a good understanding of the extent to which the food processes and distribution system could affect nutrient retention to establish a realistic shelf-life and to adjust the 'overages' of the less-stable vitamins above the level of the declared values to ensure that all the declared values are met over the period of the life of the product (Institute of Food Science and Technology, 1997). The risk of excessive intakes must take into account cases of additions of nutrients where the actual level being added and present at the beginning of the shelf-life is greater than the declared level because of the need for 'overages' (Tema Nord, 1995).

Table 4. *Factors influencing vitamin stability* (From Berry Ottaway, 1993)

1.	Temperature
2.	Moisture
3.	Oxygen
4.	Light
5.	pH
6.	Oxidizing and reducing agents
7.	Presence of metallic ions (e.g. Fe, Cu)
8.	Presence of other vitamins
9.	Other components of food such as SO_2
10.	Combination of the above

Additions of nutrients to foods are generally made in order to improve their nutritional value and there is no advantage at all for manufacturers to process products in such a way as to reduce nutritional value. Similarly, if nutrients are added, care is taken to ensure that as much as possible is utilized and retained. There are no indications that the increasing consumption of industrially-prepared foods has led to reductions in the supply of essential micronutrients among different groups of the population, nor is there any evidence that the possibility of adding nutrients has led the food industry to adopt process conditions which are less favourable for the retention of these nutrients in manufactured foods.

When foods have added nutrients then attention must also be paid to their bioavailability. Assessments of the degree of risk from nutrient excesses or deficiencies cannot be made without an evaluation of the bioavailability as well as the amounts of nutrients in foods and diets as a whole. In the case of Fe, significant progress has been made in understanding the wide variations in bioavailability as a result of the form of chemical Fe and the food and diet consumed. While meals with a large meat component are an excellent source of Fe, many cereal and vegetable foods contain large quantities of phytate, polyphenols and other constituents which bind Fe rendering it unavailable for absorption (British Nutrition Foundation, 1995). Some Fe salts added to foods are affected by the same inhibitory factors as the Fe already present in the food. The use of readily-bioavailable Fe compounds in food enrichment, however, presents the food industry and legislators with a major dilemma. Forms of Fe that are easily added to foods without causing adverse changes in colour, taste or stability are generally poorly absorbed, whereas the highly-bioavailable forms of Fe, such as $FeSO_4$, may affect the storage and organoleptic properties of the final product for the consumer (Richardson, 1983). Although considerable research has been devoted to identifying and modifying the factors governing the bioavailability of Fe, the addition of Fe to food can be both technically difficult and expensive.

Similarly, attempting to add nutrients such as Ca and Mg also presents potential problems with colour, flavour, texture and quality control. Table 5 illustrates the sensorial impact of some sources of Ca and Mg. For any added nutrient, the technological problems increase as a higher proportion of the RDA is included per serving, or as the serving size

Table 5. *Sensorial evaluation of calcium and magnesium salts*

Source	Ca or Mg content (g/kg)	Flavour or taste
Calcium salts		
Lactate	135	Neutral
Ascorbate	103	Medicinal
Phosphate	170–380	Sandy, bland
Citrate	240	Tart, clean
Gluconate	93	Bland
Chloride	360	Salty, bitter
Carbonate	400	Soapy, lemony
Magnesium salts		
Lactate	100	Neutral
Citrate	100	taste, bland
Gluconate	55	Neutral
Carbonate	280	Soapy
Oxide	600	Sandy

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decreases. Close attention, therefore, must be paid to nutrient additions in terms of shelf-life stability and sensory acceptability.

NUTRITION AND DISEASE PREVENTION

Folic acid and prevention of neural-tube defects (NTD)

There is now compelling evidence that the majority of NTD can be prevented by an adequate intake of periconceptional folate (Selhub & Rosenburg, 1996). This relationship between a vitamin and reduction of risk of disease is the culmination of over 25 years of research and has highlighted a number of challenges for nutrition science policy. These challenges include the ways in which folate intake can be increased, the risks and benefits of food fortification and the opportunity to make health claims on labels of foods and dietary supplements.

NTD develop very early in pregnancy (18–30 d after conception) and, hence, folate nutritional status is important at the periconceptional period before a woman knows she is pregnant. Practically, good nutrition must be maintained throughout the child-bearing period. Folate intake can be increased in three complementary ways: by taking a folic acid supplement; by eating folate-rich foods; by eating foods fortified with folate. Human subjects obtain most of their folate from fruits and vegetables and typical intakes are 0·15–0·2 mg/d. Folate intake needs to be increased about threefold to reach the level of 0·4 mg/d, the amount of folate known to be effective against NTD, and which does not mask the diagnosis of pernicious anaemia and/or vitamin B_{12} deficiency.

Many countries have now issued public health advice, recommending a combination of dietary and supplemental means to increase periconceptional folate intake, and many have recommended fortification of food with folic acid. In the USA, the Centers for Disease Control and Prevention (1992) concluded that the development and implementation of a fortification programme for the addition of folic acid to the food supply could be effective in increasing the folate intake of women of child-bearing age. Because the FDA has a mandate to set fortification levels that are safe for all population groups, and the fact that the effects of long-term high intakes of folic acid are not well-known, the FDA ruling has been designed to keep folic acid intake under 1 mg/d. Hence, fortification will be mandatory from 1 January 1998 (Federal Register, 1996), and folic acid must be added to flours, breads, maize meals, rice, noodles, macaroni and other grain products at a level of 1400 μg/kg. These foods were chosen for folate fortification because they are staple foods and they have a long history of being successful vehicles for improving nutrition by reducing the risk of classic nutrient deficiency diseases. In the UK, efforts are being made to improve further the knowledge about folate and NTD prevention (Health Education Authority, 1996) and an increasing number of breads and cereals are being fortified with folic acid. For example, the level of folic acid added to breakfast cereals is between 50 and 100 μg folic acid per serving and a number of soft-grain breads contain 105 μg per serving. These additions, but not the levels, are governed by the Food Labelling Regulations 1996 (Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996).

Currently there is discussion on whether to make fortification mandatory and the UK food industry has stated that, if the medical view is that addition of folic acid to flour would be a safe and effective means of reducing the incidence of NTD, a statutory approach should be followed (Food and Drink Federation, 1996). The scientific issues and the risks and benefits of folic acid fortification to prevent NTD have been reviewed by Daly *et al.* (1995), Wald & Bower (1995) and Bower & Stanley (1996). Interestingly, the synthetic

form of the vitamin folic acid used in fortification practices and supplements is more stable and more bioavailable than folate from natural foods (Cuskelly *et al.* 1996).

In the UK, food law prohibits claims that a food has the ability to prevent, treat, or cure disease. However, it is possible to draw attention to the beneficial role of nutrients within a food either on the packaging or in advertising and other promotional activities. These means of communication are effective ways of raising public awareness and supporting other programmes aimed at increasing population folate intake. In the USA, an Editorial (1996) on folic acid fortification describes the FDA proposal to authorize a health claim about the relationship between folate and the risk of NTD on food labels. In the final rules on folic acid fortification, effective from 1 January 1998, manufacturers will be allowed to make claims on labels that fortified products contain folic acid and that an adequate intake of the nutrient may reduce the risk of NTD. It should be noted that unenriched cereal-grain products without folic acid added will continue to be available to consumers who do not wish to use them. In conclusion, the additions of folic acid to foods will continue to attract interest from academia, government, consumer and industry sectors with respect to the application of scientific knowledge and the issues of voluntary *v.* mandatory fortification, bioavailability, level of addition, risks and benefits, health claims and freedom of choice.

Recent research has also shown that an elevated plasma homocysteine concentration is an independent risk factor for cardiovascular disease and stroke (Scott & Weir, 1996), that such elevations are widespread in the normal population and that dietary folic acid at levels found in existing fortified products, such as breakfast cereals, have a homocysteine-lowering effect (Ward *et al.* 1996). Hence, the benefits of folic acid used in fortified foods to achieve optimal folate status may well have implications for reducing risk of both NTD and cardiovascular disease.

FUTURE DEVELOPMENTS

In 1911, when Casimir Funk enriched the language with the new word 'vitamine', a combination of the words 'vital amine', he would have scarcely believed how far the research would develop and the extent to which additions of nutrients to foods would benefit public health around the world. For a variety of reasons, however, many people still do not achieve the RDA for specific essential micronutrients. In the UK, changing lifestyles, decreasing energy intakes, the existence of vulnerable groups, such as women of child-bearing age, the increasing elderly population, slimmers etc., those who may not be able to afford the variety of foods necessary for a healthy-balanced diet and those who do not have the knowledge to make adequate food choices, are some of the socio-economic reasons why it is timely to re-evaluate the public health issues associated with the additions of nutrients to foods. Recent advances in nutrition science have provided increasing evidence that intakes of essential micronutrients not only prevent deficiency states but also have the potential to optimize physical and mental performance and reduce risk of chronic disease and disability.

Additions of nutrients to foods provide one of the safest ways of ensuring the nutritional status of populations and individuals, because the quantity of a food one has to eat to reach any potentially hazardous level of the few nutrients that are known to be toxic at high level limits the risk substantially. Generally, there are few significant safety concerns arising from foods with added nutrients. Intakes are generally well within safety limits and the risk of nutrient overdosing and imbalance is outweighed by the benefits to public health. The UK has a long tradition of adding essential nutrients to foods, and enrichment practices have been done safely and effectively for over 50 years. Enriched

foods, which are familiar and enjoyable, already contribute significantly to the UK diet (Brady, 1996*a,b*), and the food industry in many parts of the world has demonstrated that it has taken, and will continue to take, a responsible and sensible approach to both statutory and voluntary additions of nutrients to foods. Products with enhanced nutrient density have increased the chances that most people will meet the RDA and have virtually eradicated vitamin and mineral malnutrition. The industry is committed to giving active co-operation and support to achieve food security for all (FAO/WHO, 1992).

The recent scientific evidence for the roles of vitamins and minerals (e.g. antioxidant functions, hormone-like actions, optimization of the immune function and metabolic controls), indicate that the daily requirements go beyond the levels of intake for prevention of clinical disorders (Walter, 1995). There are increasing data which show that diets rich in antioxidant micronutrients are associated with lower risk of premature death from coronary vascular disease and cancer (Gey, 1995), and governments are being quick to recognize the economic significance of illness and disease prevention. These recent advances, demonstrating the potential disease-preventing role of certain nutrients at levels well above the RDA, raise a number of key issues, not least that the additions are safe. The present paper has shown that most nutrients are safe at levels used in food-enrichment practices, even at high intakes. With responsible fortification procedures, and addition levels usually as proportions of the RDA per serving, it is actually quite difficult, both for technological and sensory reasons, and as food intakes are limited, to exceed the upper safe levels. In those cases of nutrients where there are narrow safety margins, a careful risk and benefit analysis is required. Absence of significant risk is fundamental to the acceptance of any enrichment practice.

Although RDA are often criticised, they have a very important and established role. They provide governments with a set of criteria for a 'minimal' level of food provision and nutritional security. RDA are also the standards for additions of nutrients in food enrichment and the basis for nutrition labelling purposes. If one is to change RDA, it is essential to have substantial scientific agreement on broad and consistent evidence. At the present time, the evidence is not available and it is extremely difficult to define higher amounts of single nutrients for any disease prevention action (Walter, 1995). Whereas there is general accord on RDA, there needs to be a greater move towards harmonization on upper safe levels of daily dietary intakes over time. Progress in this area would help develop the new concepts of 'optimal' health, and stimulate further research on the relationships between higher micronutrient intakes and potential reduction of risk of certain diseases.

Harmonization of current practices and legislation has advantages and disadvantages, and several issues have been raised by the Commission of the European Communities (1991) and more recently by B. Mathioudakis (personal communication). Although mutual recognition by Member States is one option, the harmonization option is gaining support and, hence, there will need to be a thorough consideration of the purpose of the nutrient additions, the determinant principles for policy (mainly safety and nutritional need), as well as the implications for consumer understanding and dietary habits. Nutrient additions certainly need to be part of a broader strategy to include nutrition education and information. Although concerns have been expressed that consumers may be led to choose products on the basis of their added nutrient content rather than an overall nutrient profile, there is no evidence to support these concerns. There is, however, no doubt that more attention must be given to information and education about the importance of enriched foods and the role of individual nutrients in a healthy diet. Declarations on foodstuffs can help provide that information, consistent with the Food Labelling Regulations 1996

(Ministry of Agriculture, Fisheries and Food: Food Safety Directorate, 1996). Restrictions on the use of health claims will also need to be reviewed, e.g. statements such as 'folic acid reduces the risk of NTD'. If health claims are true, do not mislead and are based on sound, scientific evidence, they should be permitted on food packages (Richardson, 1996). Similarly, public health arguments for, and objections to, the restriction of additions of micronutrients to foods must be supported on the basis of objective scientific evaluations.

The addition of nutrients to foods requires a balanced, flexible and pragmatic approach, especially if the quantitative estimates of benefits outweigh any risk and hazard, taking into account all relevant scientific evidence. Inflexible application of absolute principles such as upper limits of intake based on arbitrary multiples of RDA and concepts based only on clinical deficiency states need to be re-evaluated in the light of new scientific research. The regulations and the moves towards the standardizing of food legislation throughout the European Union, for free trade and comparable food standards, are going to have to keep up with the science, particularly when consumers and governments are seeking ways to achieve health benefits and reduce risk and incidence of chronic disease. Responding to consumer demand is part of being in the food industry, and here there are opportunities to take a leadership role by developing new products which meet the needs and expectations of consumers. It is, however, timely to review policies, principles and practices, and it is anticipated that industry, governments, academic institutions, international agencies, scientific societies, trade associations and consumers will create the opportunities for dialogue and partnerships for sustainable improvements in the nutritional and health status of populations and individuals.

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