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Fortification strategies to meet micronutrient needs: successes and failures

Ian Darnton-Hill[1]* and Ritu Nalubola[2]
[1]*World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland*
[2]*US Food and Drug Administration, Washington, DC, USA*

Food fortification is likely to have played an important role in the current nutritional health and well-being of populations in industrialized countries. Starting in the early part of the 20th century, fortification was used to target specific health conditions: goitre with iodized salt; rickets with vitamin D-fortified milk; beriberi, pellagra and anaemia with B-vitamins and Fe-enriched cereals; more recently, in the USA, risk of pregnancy affected by neural-tube defects with folic acid-fortified cereals. A relative lack of appropriate centrally-processed food vehicles, less-developed commercial markets and relatively low consumer awareness and demand, means it has taken about another 50 years for fortification to be seen as a viable option for the less-developed countries. The present paper reviews selected fortification initiatives in developing countries to identify different factors that contributed to their successful implementation, as well as the challenges that continually threaten the future of these programmes. Ultimately, the long-term sustainability of fortification programmes is ensured when consumers are willing and able to bear the additional cost of fortified foods. There has been an enormous increase in fortification programmes over the last couple of decades in developing countries. Considerable progress has been made in reducing vitamin A and I deficiencies, although less so with Fe, even as Zn and folic acid deficiencies are emerging as important public health problems. Food fortification based on sound principles and supported by clear policies and regulations can play an increasingly large role in this progress towards prevention and control of micronutrient malnutrition.

Micronutrient malnutrition: Fortification: Vitamin A: Iron-deficiency anaemia: Iodine-deficiency disorders

Fortification of foods with micronutrients is a technologically, programmatically and economically-effective method of increasing micronutrient intakes in populations (Nestel, 1993; Lotfi *et al.* 1996; Darnton-Hill, 1998). Food fortification is likely to have played an important role in current nutritional health and well-being of populations in industrialized countries. Starting in the 20th century, fortification was used to target specific health conditions: goitre with iodized salt; rickets with vitamin D-fortified milk; beriberi, pellagra and anaemia with B-vitamins and Fe-enriched cereals; more recently, in the USA, risk of pregnancy affected by neural-tube defects with folic acid-fortified cereals.

Fortification is defined by the *Codex Alimentarius* as 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 nutrients in the population or specific population groups (Food and Agriculture Organization, 1996). The fortification vehicle can be either a staple food, or a more-processed commercially-available food, and many have been tried. The requirements for a potential food vehicle for fortification are well established (Table 1; Food and Agriculture Organization, 1996).

There is now extensive literature on food-fortification programmes, especially recently in the non-industrialized world (Nestel, 1993; Lotfi *et al.* 1996; Micronutrient Initiative, 1997; Darnton-Hill, 1998). Fortification of foods is one intervention for the prevention and control of micronutrient malnutrition, along with other food-based approaches and supplementation, the mix of interventions depending on the local situation, experience, commitment and resources, and infrastructure. Fortification has the advantage of requiring relatively less change in consumer behaviours and food habits than the other interventions, although this approach does not mean that nutrition

Abbreviation: NHANES, National Health and Nutrition Examination Survey.
***Corresponding author:** Ian Darnton-Hill, present address 111 East 14th Street, #190, New York, NY 10003, USA, fax +41 22 791 4186, email darntonhilli@who.int

Table 1. Requirements for a food vehicle for fortification (Food and Agriculture Organization, 1996)

Commonly consumed by the target population
Constant consumption pattern with a low risk of excess consumption
Good stability during storage
Relatively low cost
Centrally processed with minimal stratification of the fortificant
No interactions between the fortificant and the carrier food
Contained in most meals, with the availability unrelated to socio-economic status
Linked to energy intake

education and social marketing can be ignored. Without convincing consumers and policy makers of the need and benefits of fortification, its sustainability will always be at risk.

A relative lack of appropriate centrally-processed food vehicles, less-developed commercial markets and relatively low consumer awareness and demand has meant that another 50 years passed before fortification was seen as a viable option for the less-developed and industrializing countries. The minimisation of many of these earlier constraints and the increasingly global market, has led to a great deal of current interest in the use of fortification as one approach to the prevention and control of micronutrient malnutrition. The present paper will (1) outline the various strategies available for fortification of foods in the prevention and control of micronutrient malnutrition, (2) review currently successful programmes in developing countries and the elements of success, some past illustrative failed programmes and identified constraints, monitoring and evaluation and (3) finally, identify some innovations in the field, followed by conclusions.

Fortification as a means of addressing micronutrient malnutrition

Over 2000 million of the world's population, or more than one in three individuals throughout the world, are at risk of Fe, vitamin A or I deficiency (World Health Organization, 1995; Micronutrient Initiative, 1997). Zn, folic acid and other micronutrients are also increasingly being recognized as public health problems in many disadvantaged populations. The public health importance of micronutrient malnutrition in the developing world was recognized and acknowledged globally in December 1992, at the FAO/WHO International Conference on Nutrition, where representatives of 159 countries agreed to eliminate the I-deficiency disorders and vitamin A as public health problems by the end of the century and to substantially reduce Fe-deficiency anaemia by one-third of the 1990 levels. In 1990 the World Summit for Children, sponsored by UNICEF, had established broader goals for the health and well-being of children (UNICEF, 1990), and the nutrition goals, including those for micronutrients, agreed to at this forum were echoed at the International Conference on Nutrition. It is likely that these goals will be re-affirmed and extended at a UN Special Session on Children to be held in May 2002. The proposed goals are to 'achieve sustainable elimination of iodine deficiency disorders by 2005 and vitamin A deficiency disorders by 2010, reduce by one third the prevalence of anaemia, including iron deficiency, by 2010, and accelerate progress towards reduction of other micronutrient deficiencies, through food fortification and supplementation.' It is notable that this time, one decade after the 1992 International Conference on Nutrition declaration, fortification is specifically mentioned as an intervention strategy.

The World Bank (1993) has identified micronutrient interventions in general, and food fortification in particular, as amongst the most cost-effective of all health interventions and as a major factor in the control of the micronutrient deficiencies in the industrialized world. In the past fortification efforts have been less effective, both in terms of start-up and sustainability, in developing countries compared with the more industrialized world. However, in the last few years the experience in many countries of Latin America, especially with vitamin A in sugar (Mora *et al.* 2000) and with Fe and B-vitamins in cereals indicates the potential for considerable expansion of fortification as an approach to address micronutrient malnutrition in the developing world (Murphy, 1996). Indeed, fortification of appropriate food vehicles is being used as a public health intervention in many developing countries, as will be discussed.

Successes in developing countries

Food-fortification programmes that have been successfully implemented in developing countries have been reviewed previously (Nestel, 1993; Lotfi *et al.* 1996; Darnton-Hill, 1998) and, therefore, are only summarized here. Table 2 presents foods that are fortified under mandatory fortification regulations in selected developing countries. The most common food-fortification practice has been salt iodization, which has been in existence for over 70 years (Bürgi, 1998). Its success has been largely through its relative simplicity and low cost, but also the more recent international endorsement and advocacy and its coalition of partners. In 1994 UNICEF and WHO recommended universal salt iodization as the prime approach to correcting I deficiency in the many countries where it is a public health problem. In 1992 at the 7th World Salt Symposium in Kyoto, Japan introduced the global elimination goal in a special session presented by International Council for the Control of the Iodine Deficiency Disorders Board members. Following the introduction of this goal, in 1993 Kiwanis International, the worldwide service organization, became an important contributor. Finally, at the 8th Session of the World Salt Symposium at The Hague in 2000, the salt industry publicly accepted their specific role and responsibility for delivering the fortified product and the service necessary in achieving and sustaining this goal (International Council for the Control of the Iodine Deficiency Disorders, 2000*a*). Today, almost 126 countries in the developing world have salt-iodization programmes in place (Mason *et al.* 2001).

During the 1970s sugar fortification with vitamin A was first implemented in Guatemala, followed by other Central American countries, including Costa Rica, Honduras and El Salvador. Although the programmes have been suspended at

Table 2. Mandatory food fortification programmes in developing countries (from Nutriview, 2000)

Country	Food vehicle(s)	Nutrient
Bolivia	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
Brazil	Dried skimmed milk for complementary food programmes	Vitamins A and D
Chile	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Pasta	Thiamine, riboflavin, niacin, Fe
	Margarine	Vitamins A and D
Colombia	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Margarine	Vitamins A and D
Costa Rica	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Sugar	Vitamin A
Dominican Republic	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
Ecuador	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Margarine	Vitamins A and D
El Salvador	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Margarine, sugar	Vitamin A
Guatemala	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe, Ca
	Pasta	Thiamine, riboflavin, niacin, Fe
	Skimmed milk	Vitamins A and D
	Margarine, sugar	Vitamin A
Honduras	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Milk, margarine	Vitamins A and D
	Sugar	Vitamin A
Mexico	Sterilized low-fat milk, pasteurized low-fat milk, evaporated whole and low-fat milk, margarine/spreads	Vitamins A and D
Nicaragua	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Sugar	Vitamin A
Panama	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
	Sugar	Vitamin A
Paraguay	Wheat flour	Thiamine, riboflavin, niacin, folic acid, Fe
Peru	Wheat flour	Fe
	Margarine	Vitamins A and D
Venezuela	Wheat flour	Thiamine, riboflavin, niacin, Fe
	Precooked maize flour	Thiamine, riboflavin, niacin, vitamin A, Fe
	Dried milk powder	Vitamins A and D
Nigeria	Enriched flour	Thiamine, riboflavin, niacin, Fe, Ca
South Africa	Enriched maize meal	Riboflavin, niacin
	Margarine	Vitamins A and D
Zambia	Sugar	Vitamin A
India	Vanaspati, margarine	Vitamin A
Indonesia	Wheat flour	Thiamine, riboflavin, Fe, Zn
	Margarine	Vitamins A and D
Malaysia	Evaporated milk, condensed milk, filled milk	Vitamin A
	Table margarine	Vitamins A and D
Pakistan	Oil products (ghee, butter oil)	Vitamin A
Philippines	Filled milk	Vitamins A and D
	Margarine	Vitamins A and D, thiamine
Thailand	Sweetened condensed milk	Vitamin A
Turkey	Table margarine	Vitamins A and D

various times since their inception due to political and other constraints, all three countries currently operate successful sugar-fortification programmes because of active collaboration between the public and private sectors. The programmes are estimated to reach about 95 % of households in El Salvador and Guatemala, and more than 80 % of households in Honduras (Mora *et al.* 2000). The success of these programmes provided the impetus for sugar fortification to be explored as an effective intervention strategy in other developing countries. Fortification of sugar with vitamin A was initiated in 1998 in Zambia and is ongoing despite economic constraints, including the falling international price of sugar and the continuous infiltration of cheaper unfortified sugar from bordering countries. Currently, other African and Asian countries are also exploring the feasibility of sugar fortification with vitamin A (Micronutrient Initiative/UNICEF/International Sugar Organization/USAID/Swaziland Sugar Association, 1999).

Other food vehicles, besides sugar, fortified with vitamin A include fats and oils, tea, cereals, flour, monosodium glutamate and instant noodles, as well as milk or milk powder, whole wheat, rice, salt, soyabean oil and infant formulas (Nestel, 1993; Lotfi *et al.* 1996). At least one common brand of margarine is currently fortified with vitamin A in the Philippines, along with fourteen other foods commercially available, and efficacy has been demonstrated for margarine (Solon *et al.* 1996), although it is unclear if the at-risk rural poor are being reached. Similarly, the feasibility and efficacy of vitamin A added to wheat flour fortified with Fe and B-vitamins has been tested in a small-scale trial in the Philippines (Solon *et al.* 2000). Although the implementation aspects and the effectiveness of such a fortification programme still need to be clarified, over half the flour millers have agreed to fortify, and legislation has recently been enacted. Malaysia has done much work with retaining the β-carotene content of refined red palm oil (Ong, 1994), and the use of red palm oil as a vitamin A fortificant added to other edible oils is being explored in Asia (Solomons, 1998) and in West Africa. Additionally, noodles (or the accompanying sauce or spices sachet) are increasingly being used as vehicles for vitamin A fortification in South East Asia (Nutriview, 2000). Twenty-nine developing countries are now actively fortifying, or are in advanced development stage, a range of foods with vitamin A (Mason *et al.* 2001).

Fortification of cereal products with Fe and B-vitamins has been in practice for a number of years throughout the developing world (Johnson, 2000). Fortification with multiple micronutrients is increasingly being used as micronutrient deficiencies tend to manifest concurrently in at-risk populations. Several Latin American countries have extensive experience fortifying maize flour and maize meal with Fe, thiamin, riboflavin and niacin, and more recently with folic acid and vitamin A. Wheat-flour fortification is now policy in most countries in Central and South America (Darnton-Hill *et al.* 1999). Cereal flour or meal fortification with B-vitamins, Fe, and sometimes vitamin A, is going ahead in several Middle East countries (A Verster, personal communication), and is being explored in many more throughout Asia and Africa (Nutriview, 2001). Fe-fortification programmes have faced several daunting challenges, technological as well as programmatic. Achieving a balance between the bioavailability of the Fe fortificant, its cost and its stability in foods has been a major challenge in delivering Fe through foods to at-risk populations. Another challenge has been the lack of a clear demonstration of benefit of national Fe-fortification programmes to at-risk population groups, including children. The multi-factorial causative factors of anaemia, including non-dietary factors such as helminth infestations, further adds to the challenge of demonstrating a benefit of Fe fortification of foods. Nevertheless, thirty countries throughout the developing world now have a range of commodities (mainly wheat flour but also maize flour, milk, rice and weaning foods) that have fortification programmes with Fe actively in place, although to a greater or lesser extent (Mason *et al.* 2001).

The factors contributing to the success of established food-fortification programmes both in the industrialized and developing countries have been previously addressed (Nestel, 1993; Darnton-Hill, 1998; Asian Development Bank/Micronutrient Initiative/International Life Sciences Institute, 2000; Bishai & Nalubola, 2002). However, relatively little is known about the impact of fortification programmes, primarily due to the limited number of good assessments that have been conducted or documented. Nevertheless, there are some data available which highlight the potential effectiveness of a properly-implemented fortification programme. A recent evaluation of the possible health impact of niacin fortification of flour and bread in the USA showed that food fortification played an important role in the decline of pellagra-attributed mortality in the 1930s and 1940s, and finally, in the elimination of pellagra in the USA (Park *et al.* 2000). Anaemia and vitamin A deficiency ceased to be public health problems in Newfoundland, Canada only after the fortification of margarine and flour in 1945 (Micronutrient Initiative, 1997). Folic acid fortification of cereal products was authorized in the USA in 1996 as a public health measure to decrease the risk of pregnancy affected by neural-tube defects. Since the programme began neural-tube birth defects have decreased by 19 %, and fortification, educational outreach and increased consumer awareness have been noted to contribute to this decrease (Caudill *et al.* 2001; Center for Disease Control, 2001; Honein *et al.* 2001).

National programmes of sugar fortification with vitamin A in Central American countries have been evaluated for their effects on vitamin A deficiency in at-risk population groups. National surveys conducted between 1995 and 1998 in Guatemala, Honduras and El Salvador have shown clear reductions in the prevalence of vitamin A deficiency among preschool-age children (Mora *et al.* 2000). The primary source of dietary vitamin A in these countries has been found to be fortified sugar, with a coverage of > 80 % of the households in these countries. When fortification was halted in the 1980s for various political reasons in Guatemala, vitamin A deficiency prevalence was found to have increased (Arroyave *et al.* 1979; Mora *et al.* 2000; Dary, 2001).

The effectiveness of Fe-fortification programmes in combating anaemia has been less clear. In 1994 Sweden ceased fortifying its bread because of a lack of perceived benefit in a replete society, although this action is currently being re-evaluated. In Venezuela fortification of wheat and maize flours with Fe, B-vitamins and vitamin A was initiated in 1993, and a preliminary survey carried out among a small group (*n* 307) of children in 1994 showed that the prevalence of Fe deficiency and anaemia had decreased significantly ($P < 0.05$) (Layrisse *et al.* 1996). The mean average increase in Fe intake of 6 mg/d that was observed is similar to that found in other interventions in Latin America, South Africa and Thailand (Beard, 1996). A large-scale effectiveness trial of wheat-flour fortification with two different Fe fortificants, electrolytic Fe and hydrogen-reduced Fe, has been completed recently in Sri Lanka, and results from this trial are awaited (P Nestel, personal communication).

A single micronutrient addition to an appropriate food vehicle is increasingly the less common approach in food-fortification programmes. As Huffman *et al.* (1998) have shown, women in developing countries are often consuming diets of poor bioavailability and limited micronutrient content, leading to concurrent deficiencies of Fe, vitamin A, Zn, folic acid and vitamins B_6 and B_{12}, and occasionally other vitamins and minerals. Such deficiencies have important consequences for women's own health, pregnancy outcomes and their breast-fed children's health and nutritional status (Huffman *et al.* 1998). UNICEF has recently recommended that a combined vitamin–mineral supplement for pregnant women, similar in composition to those freely available in the more industrialized world is an option that needs to be considered for developing countries (UNICEF/World Health Organization/United Nations University, 1999).

Fortifying foods with multiple micronutrients is another avenue to deliver micronutrients, complementing supplements. This approach is important, as supplementation may not reach non-pregnant women, female adolescents and young children, who are not usually being directly targeted by supplementation programmes, but who might be reached by appropriately fortified foods. One example is the VitaLeite programme in the State of Sao Paulo in Brazil, where the distribution of free milk fortified with vitamins A and D and Fe is targeted to over 700 000 poor families. A small survey (*n* 269, children aged 6 months–2 years) in Angatuba found anaemia prevalence dropped from 62·3 % to 26·4 % in 1 year (Ferrer, 2001). In Asia, at least, investment per head in fortifying staples and complementary foods for older infants is one-tenth that of supplementation programmes (Mason *et al.* 1999). Fortification of complementary foods has been shown not only to improve the status of the young child, but where the community is involved, to empower the women in these communities. Another important delivery mechanism using fortification is the internationally-recognized imperative of fortifying all food used in humanitarian aid, although this provision is tragically occasionally still not made.

Elements of successful fortification in industrializing countries

From the experiences of successful fortification programmes, facilitating factors have been briefly summarized (Darnton-Hill, 1998) as the following:

political will and support, which must be maintained from the development stage;
understanding of the problem by having adequate data on the magnitude of the nutritional problem being addressed;
adequate data on food-consumption patterns;
support of industry, with early involvement of local industry and the private sector;
adequate technical expertise, proper testing under a range of real field conditions, and adequate training in fortification technology, quality assurance and control;
a multi-sectoral approach in establishing a programme, including key governmental organizations, the scientific community, consumers, marketing specialists and other relevant interested parties early in the process;
adequate application of legislation and regulations, including resources for effective enforcement;
facilitative rather than punitive regulations, i.e. guidelines should not be so restrictive as to impede the provision of high-quality fortified foods nor hinder communication on fortification between relevant parties;
human resource training at the industry and marketing levels and of public health and food-safety personnel;
appropriate fortification levels evaluated and adjusted according to the bioavailability of the nutrient in the diets of the target population;
good bioavailability of the compound and no constraints on procurement of the micronutrients, e.g. financial support for initial batch of fortificant;
intensive and appropriate investment in the information, education and communication about the problem and the fortification approach to raise consumer awareness and ensure consumer acceptability, and also to ensure that there are no cultural or other objections against fortified foods;
minimal cost increase to the consumer, to the extent feasible;
relevant nutritional information available through adequate labelling to help ensure consumer involvement, commitment and understanding of the advantages of fortifying foods.

Programmes and problems

An innovative approach to vitamin A deficiency in Bangladesh was tried in the late 1980s, whereby a shellac containing vitamin A was to be sprayed on wheat coming in as aid wheat from the USA. As wheat was much the less-preferred staple, this cereal had the added advantage of being indirectly targetted to the very poor, those in the vulnerable-group feeding programme of the UN World Food Programme. Although it was new technology, it was very extensively developed and tested and was technically feasible (Darnton-Hill, 1989). After a great deal of effort it finally became untenable and politically unacceptable; partly, it appeared that there was concern about a foreign power being involved in the food system, rumours about the fortificant and it was also probably insensitively handled (Darnton-Hill, 1989). Atta (ground wheat flour) may be fortified now through a partnership of UN World Food Programme, USAID and the Government of Bangladesh, and the millers. A similar process occurred with vitamin A in monosodium glutamate in Indonesia; again a combination of technology and politics led to this programme being stopped by the government after extensive laboratory work, efficacy trials and a successful effectiveness trial (Muhilal *et al.* 1988). Although the microencapsulated vitamin A remained white in rigorous laboratory testing, when hanging in the sun in small cellophane packets outside the small rural sarisari shops there was enough discolouration to concern the producer who sold monosodium glutamate as the whitest of white products, and who had anyway been excluded from the early planning (R Tjiong, unpublished results). There was also some concern from professional medical associations and the government about possible toxicity of monosodium glutamate, although it is not classified as such by *Codex Alimentarius*.

The fortification of sugar with vitamin A in the Philippines did not go ahead when the world market price plummeted just a few months after the launch in February 1997; the sugar company was sent into financial crisis and then had to withdraw (FS Solon, personal communication), but sugar fortification is now being tried again. In Zambia, while certainly not a failure, results are still awaited due to problems with private sector commitment, price of fortificant and the considerable duty to be paid on the fortificant, which the government has said it will lift, but has not yet done so.

With the iodization of salt in the Philippines, a monopoly was given to a single producer as an incentive, but it was not then produced as anticipated. Special provisions given to one firm to encourage start-up action can distort incentives for other companies, as happened in this case, when the concession of an extended monopoly effectively inhibited competitors from also fortifying salt. The national parliament of India recently repealed legislation that mandated universal iodization of salt, thus turning a success story into a potential failure. This action hinged on arguments of personal rights of access to non-iodized salt, and underlines the importance of consumer education and political will. It seems the Indian states may enact their own legislation. However, as was the case with the cantons of Switzerland (Bürgi, 1998), some states will be considerably more pro-active about enacting legislation than others. With all fortification programmes there is concern about the leakage of non-fortified (and hence usually cheaper) foods across borders, e.g. leakage of non-iodized salt across borders in Africa. Some apparent success stories, such as the iodization of salt in Eritrea and its export to neighbouring countries, collapsed under the pressure of the conflict with Ethiopia. Another such reverse occurred in Sierra Leone, where iodized salt coverage declined from 75 % to 8 % in 1999 due to the civil war (International Council for the Control of the Iodine Deficiency Disorders, 2000*b*).

Similarly, in the USSR, where severe I-deficiency disorders had been eliminated by effective control measures as early as the 1940s and 1960s, government programmes were discontinued in 1970. After the dissolution of the USSR in 1991, I-deficiency disorders again became a common problem in nearly all the newly-independent states (Gerasimov & Delange, 1998). Dary (2001) sees such reversals as a continuing tension between the needs of 'free trade' and 'public health', and that legislative tools may be insufficient without reliable enforcement mechanisms and consumer awareness.

Constraining factors in non-sustained programmes

A recent review of food-fortification practices, which started as public health intervention programmes early in the 20th century in the USA, concluded that the primary factor contributing to the long-term sustainability of food fortification is consumer awareness of the nutrient deficiency and consumer demand for and perceived benefits of the fortified food (Bishai & Nalubola, 2002). It has become apparent that constraining factors in non-sustained programmes in developing countries are the lack of consumer demand due to a non-recognition of any likely benefits to come from consuming fortified foods, as well as the lack of public sector policy makers' recognition of the nutrient deficiencies as a public health problem. That fortification requires minimal consumer involvement and little-to-no change in dietary habits is often stated as an advantage of food fortification over other interventions. In the past this approach has been construed to mean that there is therefore no need to educate the public of the need and role of food fortification, and the result was less emphasis on consumer education in national fortification programmes. The importance of advocacy at the political level, as well as raising consumer awareness regarding the magnitude and effects of the nutrient deficiency, and the role of fortification as a complementary approach to other interventions, need to be recognized as prerequisites for success (Micronutrient Initiative, 1997). A recent example of this approach was the previously mentioned revoking of universal iodization of salt in India, but examples could be quoted from European countries with long histories of iodization, such as Switzerland, where the programme continues to need constant monitoring and adjustment, in particular in response to importation of food prepared with non-iodized salt (Bürgi, 1998).

The socio-economic constraints faced by consumers when fortified foods are being promoted, and the likely benefits of food fortification, are now being increasingly recognized as critical factors in gaining public and private sector commitment to, and eventually the success of, a fortification programme, and these factors need to be addressed early. Ignoring these factors has been shown to contribute to the failure of programmes. Nevertheless, even with the best social marketing, price can remain a constraint. In very poor households there is very little price elasticity, and even a minimal increase can discourage the buying of fortified foods. In a study in South Kalimantan and South Sulawesi in Indonesia it was found that while instant noodles were consumed in nearly all households in both areas, consumption of fortified noodles was related to socio-economic status and was lowest among farmers and share croppers, who might well be some of those most at risk (Melse-Boonstra *et al.* 2000).

These and other constraints can be summarized as the following:

technical constraints: installation and maintenance of fortification machinery; stability of fortificants under the suboptimal distribution and storage conditions traditionally found in developing countries; the development of new cost-effective fortificants;

socio-economic constraints: the targeted groups are often those with least purchasing power; price of initial batch of fortificant and capital costs; the demand on foreign exchange;

infrastructural constraints: poor distribution systems due to poor infrastructure; lack of access to commercially-processed food limited by geography, poverty or cultural preferences; limited experience of intersectoral coordination; frequent changes of government;

political constraints: political support may be lacking due to perceived priority of other health and nutrition interventions; lack of awareness of magnitude of problem and benefits of addressing it; lack of facilitating legislation and of equal opportunities for all potential fortifying companies;

other implementation constraints: often there is a lack of a clearly appropriate food vehicle that addresses all the desirable qualities of Table 1; weak quality assurance systems at the private sector level; ineffective enforcement of any existing fortification regulations at the public sector level; a lack of proper monitoring and evaluation of the programme and, therefore, limited intermediate corrective follow-up measures. Perhaps the greatest potential constraint is who bears the added cost, e.g. to the millers, the added cost is the sum of premix, equipment amortization, labour and quality control. To these factors must be added advocacy, social marketing, increased public awareness, monitoring and effectiveness of quality assurance, and someone must pay for all this additional cost, however small the actual amount (Micronutrient Initiative, 1997).

Monitoring and evaluation as a critical factor in the sustainability of fortification

As discussed earlier, the success of fortification programmes depends on several essential factors. One of the critical ones that is needed for long-term sustainability is discussed in detail here, not because it is more important than the others discussed earlier, but primarily because it is largely ignored in the implementation of fortification programmes. Monitoring and evaluation are critical aspects of a fortification programme, and a key constraint for countries with limited funds. The current trend is towards a public–private sector collaboration, with facilitative legislation and quality assurance by the fortifying company. It is recommended that any new legislation sets forth in the regulations the requirements and standards for food fortification, rather than amending the food laws in a piece-meal fashion to address fortification of a particular food vehicle with a particular nutrient (Nathan, 2000). This approach puts the onus on the commercial company itself to assure the quality of the fortified food. It is not clear, however, whether this system has necessarily been successful, even though it is frequently cited as a pre-requisite to sustained food fortification.

Monitoring includes measures taken by the private and public sectors to assure that the food is fortified at adequate levels and is properly labelled when it reaches the consumer. A good monitoring system needs specific mechanisms for prompt corrective actions to be taken by relevant parties when problems are identified. Evaluation includes: identifying patterns of consumer behaviour in terms of the purchase and consumption of the fortified food; determining intake of the nutrient of interest and the contribution of the fortified food to this intake (in the case of multiple micronutrient fortification, one nutrient may be chosen as an indicator); impact on the public health problem being addressed. As discussed earlier, few programmes have been properly evaluated and impact on public health determined, although some successful programmes have been shown to have had the intended health benefits. Despite economic constraints, evaluation should be given more emphasis in the design and implementation of fortification. It has been shown that demonstrating the public health benefits of fortification programmes is critical in long-term sustainability and in gaining the commitment of public and private sectors as well as consumer demand for the fortified food (Mora *et al.* 2000; Bishai & Nalubola, 2002). The Institute of Medicine of the US National Academy of Sciences also identified demonstrated feasibility, along with efficacy, appropriateness and political commitment, as essential for sustainability (Institute of Medicine, 1998). In this report the authors point out that sustainability has two components: process, the continuity of a successful intervention; outcomes, continuation of a substantial positive impact on the intended beneficiaries.

Surveillance systems set up to observe trends in the prevalence of the public health problem over time help evaluate the impact of the fortification as well as other intervention programmes. For example, in Australia and the USA it seemed that I levels may have needed to be reduced, largely because individuals are getting I from other sources, e.g. in bread, and when iodophors are used to clean cow's udders. Urinary I was measured in the National Health and Nutrition Examination Survey (NHANES) I (1970–4), and found to be higher than desirable, which prompted bans on some iodophors and adoption of alternatives for I in dairy operations. However, the median concentration decreased more than 50 % between 1971–4 and 1988–94 (NHANES III). These findings, although not indicative of I deficiency in the overall US population, were considered to define a trend that needed monitoring (Hollowell *et al.* 1998). On the other hand, in European countries, at times, I levels have decreased even when fortification has been in place for many years; for example, Germany, after the adoption of the 'principles of voluntary action' following reunification (Meng & Schindler, 1998), and in Switzerland, where to correct for falling levels of urinary I it was decided to raise the salt I to 20–30 mg/kg in 1998 (Bürgi, 1998). Europe has had fortification for over 70 years now, and still has not achieved true sustainability, as evidenced in the rising rates of I-deficiency disorders in the Eastern Block countries (Gerasimov & Delange, 1998), and as in the examples of Germany and Switzerland.

Monitoring and evaluation is also helpful to address concerns of safety of food fortification. For example, concern has been expressed in the case of vitamin A fortification, especially when several foods are fortified. An intake of 3 mg/d has been set as the level safe for adults, including pregnant women. Excessive amounts of vitamin A are known to have teratogenic effects in pregnant women, especially during the first few weeks of pregnancy. In developing countries, where levels of fortification are poorly monitored, the introduction of several commercial foods each fortified with up to 100 % of the recommended daily intake for vitamin A might lead to potentially unacceptable levels of vitamin A intake in pregnant women. However, it should be noted that at the levels of fortification currently practised around the world, enormously high and practically impossible amounts of an individual food or a combination of fortified foods would have to be consumed on a daily or regular basis to reach this toxicity threshold for human subjects. Thus, vitamin A toxicity from fortified foods is highly unlikely. Indeed, even in developed countries where many foods may be fortified with vitamin A, there have been no reports of vitamin A toxicity attributed to the intake of fortified foods (Nalubola, 2000). A case study of vitamin fortification in the USA shows that, although many foods are fortified with vitamin A in the USA and, according to NHANES III, about 40 % of the US population regularly consumes dietary supplements, there have been no reports to date of vitamin A toxicity through fortified foods in the USA (Nalubola, 2000).

Nevertheless, theoretical concerns continue to be of relevance when a programme is being started. Sometimes these are real concerns, which is where monitoring is essential. In Zimbabwe, and later in the People's Republic of Congo, there were several reports of salt fortification with I in communities with chronic I deficiency leading to potentially fatal cases of Jodbasedow or I-induced hyperthyroidism disease (Delange, 1998; International Council for the Control of the Iodine Deficiency Diseases, 2000*b*). These cases were found to be due to poor or absent monitoring, and sudden introduction of overly-fortified salt coming in from surrounding countries (Todd *et al.* 1995). A more theoretical possibility is Fe overload, especially in Caucasian men suffering from a tendency to haemochromatosis. With the exception of massive amounts of Fe in locally-brewed beer in south and east Africa, this potential overload does not appear to be a real concern in developing countries where Fe deficiency is widespread (Harvey *et al.* 2000).

Given the presumed success of fortification in the industrialized countries, coupled with the greater demonstrated need in developing countries, fortification should be actively pursued in the developing world. It has been shown in Europe that adults and children who include fortified foods in their diets have higher micronutrient intake and status compared with those who do not (McNulty, 1999; Serra-Majem, 2001). There is also evidence that fortification may be particularly important in contributing to the micronutrient status in those with low nutrient intakes generally (McNulty, 1999). It remains for this possibility to be confirmed in the developing world. The most pressing factor to be actively addressed is the development of adequate monitoring mechanisms that must be in place.

Innovations

While much of the fortification technology and implementation is transferable to developing countries, based on the relatively long experience in the industrialized countries, it may need new approaches or innovative thinking in order for the programmes to benefit the target population. This requirement for innovation is for all the reasons discussed earlier, but probably the overwhelming one is that the target populations are most often poor, relatively isolated and somewhat out of the global or even national market. Other facilitating groups may need to be involved, e.g. the non-governmental organizations that have been instrumental in testing the feasibility of hammer-mill stage fortification of maize in Africa. Maize meal fortification and hammer-mill technology is currently being tested for effectiveness in Zimbabwe. Families when they bring their maize to the hammer mill are offered a sachet of premix (vitamin A, B-vitamins, Fe and Zn) costing approximately $US 0·80 to add to 20 kg maize meal. Evaluated after 1 year, half of all maize in the operational research area was being fortified (although the local mixing process was seen as taking too long and a constraint; Lindsey & Kwaramba, 2001). Similar pilot schemes are also being undertaken in Malawi, Mozambique, Tanzania and Zambia. Quality assurance clearly becomes a challenging issue under these circumstances. Mobile self-contained mills for fortifying maize in refugee camps are also being tried. The UN World Food Programme is involved in Bangladesh and Afghanistan; in Afghanistan the World Food Programme is facilitating local fortification of its flour with vitamin A, thiamine, riboflavin, niacin, folic acid and Fe.

Exactly what is meant by fortification and what constitutes a fortified food has expanded. These definitions now include: a single micronutrient added to food, multiple micronutrients added to foods (e.g. triple fortification of salt); supplements (e.g. 'sprinkles') added to weaning foods and porridges; foods bioengineered to contain micronutrients that are not present in the traditional varieties; vastly improved fortification techniques, allowing for multiple, stable and acceptable fortification. 'Sprinkles' are microencapsulated micronutrients, including ferrous fumarate, which are available in a single-dose sachet, and can be sprinkled onto complementary and weaning foods, and other foods. In a randomized controlled trial in Ghana they were found to be as efficacious as Fe-containing drops in the treatment of anaemia (Zlotkin, 2001).

While multiple fortification has always been used in flour and breakfast cereals, many micronutrients are now being added to other commercially-processed foods, including confectionery foods in Indonesia (Sari *et al.* 2001), fortified drinks in Nicaragua, Peru, the Philippines and Tanzania (Micronutrient Initiative, 1997; Ash *et al.* 1999; Solon *et al.* 2001), and shortbread type biscuits in South Africa (van Stuijvenberg *et al.* 1997). An example of the technological innovations being explored is the double or triple fortification of salt with I, Fe and vitamin A, where the nutrients are microencapsulated to minimize cross-reactivity and improve stability. Preliminary studies to determine the feasibility of this technology are now underway in India and Indonesia, and may be expanded to Kenya and Nigeria (Micronutrient Initiative, 1997). The efficacy of fortifying fish sauce with 10 mg Fe as NaFeEDTA in 10 ml fish sauce has been demonstrated in Vietnam (Thuy *et al.* 2001) and trials of Fe fortification of soya sauce are well underway in China (Fidler *et al.* 2001).

Conclusions

There is a clearly identified need for interventions to combat micronutrient deficiencies worldwide. In the more affluent industrialized countries these have been, and continue to be, addressed by food fortification, as well as by overall economic growth and general improvements in health, sanitation and nutrition that have contributed to the prevention and control of these deficiencies. These same aspects must be addressed in any prevention and control programmes in non-industrialized countries. Fortification, supplementation, other food-based approaches and complementary public health measures are all necessary. This process can only be carried out by partnerships with government, industry and the consumer. There is a need to assess more widely the impact of interventions, not least for advocacy. Ultimately, the success, impact and sustainability of food fortification, like other interventions, rest with educating the consumer, developing consumer demand and demonstrating impact.

Successful fortification programmes have been identified as needing at least the following: strong political commitment and the ability to enforce regulations in a facilitative manner; early private sector involvement and willingness to comply with regulations; public sector backing including endorsement by professional medical organizations and financial support by donors; strong and active consumer education to raise consumer awareness and promote demand. Equally important is the necessity for a sound scientific basis in the design of any fortification intervention, including: documentation of the severity and effects of the deficiency in the relevant population groups; data on food consumption patterns, along with technological and market feasibility assessments; measures to monitor and evaluate the implementation of the intervention, followed by timely and effective corrective actions where needed. A minimal change in the cost of fortified food is ideal. Initially, absorption of the additional cost of fortification by the private sector or through government subsidies may be necessary. Ultimately, the long-term sustainability of fortification programmes is ensured when consumers are willing and able to bear the additional cost of fortified foods.

There has been an enormous increase in the number of fortification programmes in developing countries over the last couple of decades. With increasing urbanization this trend will continue. Considerable progress has been made in reducing vitamin A and I deficiencies, although less so with Fe, even as Zn and folic acid deficiencies are emerging as important public health problems. The recently-formed global forum on fortification, GAIN, is made up of multi-lateral organizations, bilateral agencies (Canada, USA) and the private sector, including the food industry and the Gates Foundation, suggesting a new level of identification of fortification as an important strategy in the less-industrialized world. Food fortification based on sound principles and supported by clear policies and regulations will play an increasingly large role in the progress towards prevention and control of micronutrient malnutrition.

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