Chapter 2

Methodology

An analytical framework for the country investment plans

The moral imperative to address the overwhelming and needless human tragedy caused by micronutrient malnutrition is clear. However, the successful implementation of food fortification to reduce micronutrient malnutrition rests with a more pragmatic imperative: attracting the necessary investment in public and private capacity by making a clear and compelling business and investment case. The Country Investment Plans are an attempt to do this. The CIPs are specific, concrete, and quantified. Each of the CIPs includes the following elements.

- a public health situation analysis that includes prevalences of micronutrient malnutrition and their consequences as well as a review of existing policies, programs, and strategies, and their strengths and weaknesses;
- proposed fortified food vehicles selected on the basis of industrial feasibility, commercial potential, projected consumption by the poor, and access and affordability to low-income consumers;
- a defined production-sector strategy outlining implementation needs, capital investments, and recurring costs;
- an elaboration of government commitments and responsibilities as well as capacity needs, including projected budgets for regulatory, food control, and nutrition monitoring and surveillance functions;
- best estimates for coverage and protection of low-income and at-risk consumers based on consumption, stability, and industry coverage;
- projections for the reduction in national prevalence of VAD and IDA, and estimated impacts of the addition of folic acid; and
- a financial summary reviewing benefits and costs on annual and 10-year bases.

The CIPs represent a needed first effort to systematically quantify the inputs and outputs of food fortification programs. They include benefit-cost ratios and internal rates of return for each proposed food vehicle. The analysis undertaken to arrive at these figures is inchoate and complex and crosses many disciplines. While detailed documentation is included in Annexes C, D, and E, a summary explanation of the methodology used is provided in this chapter.

Need for a New Framework for Analysis

Micronutrient malnutrition has received significant attention not only because of the harsh human toll, but also because of the high economic costs to society and the low costs of vitamins and minerals. A robust body of literature focuses on the financial burden imposed by widespread micronutrient deficiencies—including increased morbidity and mortality, decreased cognitive development, higher health care utilization, and depressed productivity. However, few models have projected the concrete costs of the inputs needed to implement fortification, and fewer still have realistically estimated the potential benefits. For the CIPs, an analytical framework to estimate benefits and costs was developed. This involved gathering evidence, defining critical gaps, and ultimately making educated assumptions based on the best available information. This framework is proposed as a practical and immediate tool to identify public health and development priorities, make policy decisions, and take reasonable business risks.

Determining the Costs of Micronutrient Malnutrition

In the CIPs, the national costs of micronutrient malnutrition were determined using an adapted version of PROFILES,[12] a widely used tool for analysis and advocacy related to nutrition interventions. This was augmented by a subsequent analysis by the developers of this model.[13] PROFILES is based on assumptions established from the analysis of a large number of scientific studies, and reflects the scientific consensus on the devastating human, social, and economic consequences of micronutrient malnutrition. Some of the consequences are as follows:

- The relative risk of mortality among children from 6- to 60-months old with VAD is 1.75. The economic cost of deaths arising from VAD is then measured by the foregone wages earned.[14]
- Children from 6- to 60-months old with VAD suffer higher rates of morbidity. Their relative risk of clinic attendance is 1.19 and hospitalization is 1.84. The increased economic burden is based on national rates of utilization and costs for clinic and hospital visits.
- As a consequence of anemia, cognitive development is impaired. Intelligence measures in children generally drop by 7–8 IQ points (i.e., 0.5 standard deviation)—a change associated with a 4% loss of future earnings power. Losses are projected at the average national hourly wage.
- Anemic adults engaged in heavy manual labor are 12% less productive than adults without anemia. For blue-collar workers the deficit is 1%. The impact for workers in less physically demanding labor is not measured.

The original PROFILES analysis included no component to measure the impact of folic acid deficiency (FAD). For this project, a preliminary approach was developed based on reports of the United States' Centers for Disease Control and the Canadian Public Health Service[15] and an analysis by Tice, et al., published in *The Journal of the American Medical Association*.[16] This preliminary model, which has not been tested outside the CIP project, is based on the US experience, in which an added daily intake of approximately 100 micrograms folic acid has provided the following benefits:

- Neural tube defects (NTDs) are reduced by up to 30%. When national data was too sparse, a rate of 4 NTD births per 10,000 was applied.[17] Relative risk of death was taken from country data; where such data were not available, NTD children are presumed to die. Their lives are measured by 30 years of discounted earnings at the average wage.
- CHD events are reduced by up to 13% for men and 8% for women, with comparable reductions in CHD mortality. The costs of treating these are modeled using national health care utilization and cost data.
- A reduction in CHD events in turn results in a corresponding and proportionate reduction in the number of deaths attributable to CHD. While deaths averted were calculated, the model assumes that CHD events occur after an individual's primary earning years. Therefore, no economic consequences were calculated.

These practical assumptions provide the framework for calculating national economic benefits emerging from reduced rates of VAD, IDA, and FAD. The results are based on a number of specific relational variables in the five countries, including prevalence rates among risk groups, demographic data, health care

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12 Ross, J. and V. Aguayo, *PROFILES Guidelines: Calculating the Effects of Malnutrition on Economic Productivity, Health, and Survival* (Washington, DC: The Academy for Educational Development, 2000). Modified for this project by Bing Alano, Jack Fiedler, and Jack Bagriansky, The Keystone Center advisors.

13 Horton, S. and J. Ross, "The economics of iron deficiency," *Food Policy* 28 (2003): pp. 51–75.

14 This is estimated by the discounted earnings (at the average wage) up to age 50. The use of shortened productive years is to take into account that not all survive up to retirement age. The estimate also takes into account the employment rate.

15 Honein, M.A., L.J. Paulozzi, T.J. Mathews, J.D. Erickson, and L.Y. Wong, "Impact of folic acid fortification of the US food supply on the occurrence of neural tube defects," *JAMA* 285 (2001): 2981–6. Also: Ray, J.G., C. Meier, M.J. Vermeulen, S. Boss, P.R. Wyatt, and D.E. Cole, "Association of neural tube defects and folic acid food fortification in Canada," *Lancet* 360 (2002): 2047–8.

16 Tice, J. et al., "Cost-effectiveness of vitamin therapy to lower plasma homocysteine levels for the prevention of coronary heart disease: Effect of grain fortification and beyond," *JAMA* (2001).

17 Personal communication with Dr. Godfrey Oakley, US Center for Disease Control and Prevention and Rollins School of Public Health at Emory University, based on his global research and field work in the PRC.

costs and utilization rates, as well as a range of wage and labor statistics and other economic data. For example, the global assumption for the impact of anemia prevalence on productivity is qualified by the national situation, including the number of women in the labor force, the proportion in heavy manual and blue-collar labor, and the average annual wage. In this model, anemia in a full-time mother or an office worker presents no cost to society.

Each CIP proposes specific food vehicles to be fortified at specific levels and estimates the total number of metric tons (MT) fortified of each. Between 48% and 95% of the project costs are composed simply of the cost of the vitamins and minerals or the micronutrient mix that is actually added to the food vehicle.

However, successful implementation depends on a series of significant investments in key public- and private-sector capabilities. These capabilities include the following.

- advocacy, capacity building, and empowerment of government agencies through legislation and regulations to establish a positive market environment;
- plant improvements, equipment purchases, and ongoing quality control and other recurring operational costs (A common basis for this analysis emerged from the Regional Workshop on Flour and Cooking Oil Fortification.);
- food regulatory and inspection activities (For this item, budgets are based on the estimated number of production sites and sampling frequency to establish operational, analytical, and management costs. In some cases, the CIPs propose capital investment in building public laboratories. In other cases, the analysis is outsourced to the private sector.);
- nutrition monitoring and biological evaluation (In many cases, these costs are based on consensus methodologies developed at the Regional Workshop on Trade, Regulation, Surveillance, and Quality Assurance of Fortified Food Products); and
- social marketing (National leadership advocacy and public communication were seen as essential to establishing a foundation of consumer support and awareness.).

See Table 7, at the beginning of Chapter 3, for a summary of the 10-year costs of the food fortification projects proposed in the CIPs.

Projecting the Benefits of Fortification

While the cost side of the equation may entail the fortification of 100% of a particular food, the benefit is determined by the amount of fortified food consumed by at-risk populations. A mix of national consumption surveys and industry data, along with the USDA Foreign Agricultural Service's information and the FAO's Food Balance Sheets, was used to project the potential consumption of fortified foods, with an emphasis on consumption by low-income populations. To determine the projections for added micronutrient intake, the estimated consumption of fortified food was essentially multiplied by the level of fortification and other relevant factors (e.g., vitamin stability, and products from small producers and the informal production sector, which are not considered "fortifiable"). Thus, the analysis arrived at milligrams or micrograms of each micronutrient that would be added to the daily intake of foods consumed by low-income and at-risk groups. However, the benefits of fortification are not measured by added micronutrients but by real reductions in the prevalence of micronutrient deficiencies and the subsequent functional benefits in health and performance.

Prevalence reduction thus drives the benefit calculations. In the case of fish and soy sauce fortification proposed respectively by the Viet Nam and PRC CIPs, the projections for prevalence reduction were based on the results of large-scale effectiveness trials. In the other CIPs, however, the uncharted leap from estimates of added micronutrient intake to projections for reductions in prevalence was based on a methodology developed for this project. This methodology, which is described in Annex C, is based on a review of the best available evidence.[18]

- Projected reductions in VAD are based on studies documenting consumption, added micronutrient delivery, and changes in

[18] For a full elaboration of the proposed approaches to projecting prevalence reduction, please see Annex C.

prevalence after national sugar fortification in Guatemala and large-scale MSG fortification market trials in Indonesia.

- Reductions in NTDs and CHD are based on changes measured in the US and Canadian populations after national flour fortification increased the average per capita intake of folic acid by 100 micrograms per day.[19]
- Since data from iron fortification programs are limited, the projected reductions in iron deficiency anemia prevalence are based on a published meta-analysis reviewing the impact of 35 supplementation trials in Africa, Asia, and Latin America.[20]

The CIPs project reductions in the national prevalence of IDA or VAD for each of the 14 proposed fortification projects. The projected reductions range from 1% to more than 30%. Table 6 outlines the expected 10-year benefits of these improved national prevalences. The same assumptions and calculations used to estimate the prefortification costs of micronutrient deficiency are used to measure the remaining postfortification losses. As illustrated in Table 6, this results in specific projections for benefits, or costs to society averted. Having calculated specific benefits and costs, annual and 10-year benefit-cost ratios and internal rates of return can be specified.[22]

Special Note on Complementary Foods

Improving the physical and mental growth of children under age 2 in developing Asia is a great challenge to public health programs and to private sector applications of food science and technology for young children, including the processed food industry. The enormous problems of stunting and multiple micronutrient deficiencies in very early childhood are

TABLE 6: Projected Ten-Year Benefits of Projects Proposed in the CIPs
(in thousands of deaths averted and US Dollars)

Project Vehicle	Micronutrient	Deaths Averted	Health Care Costs Saved ($ '000)	Productivity Saved/ Gained ($ '000)
Indonesia				
Wheat Flour	Iron and Folic Acid	111	924	103,210
Oil	Vitamin A	44	555,802[21]	110,575
Pakistan				
Wheat Flour	Iron	38	9,603	328,259
Oil	Vitamin A	42	18,234	120,026
PRC				
Soy Sauce	Iron	0.5		2,250,056
Wheat Flour	Iron and Folic Acid	32	5,195	538,151
Thailand				
Wheat Flour	Iron and Folic Acid	5	384	13,019
Fish Sauce	Iron	0.014		160,725
Viet Nam				
Fish Sauce	Iron	0.8		257,825
Wheat Flour	Iron and Folic Acid	8	2,216	34,889
Total		**281.3**	**592,358**	**3,916,735**

19 Tice, J. et al., "Cost-effectiveness of vitamin therapy to lower plasma homocysteine levels for the prevention of coronary heart disease: Effect of grain fortification and beyond," *JAMA* (2001).

20 Beaton, G. and G. McCabe, *Efficacy of Intermittent Iron Supplementation in the Control of Iron Deficiency Anemia in Developing Countries* (Ottawa: Micronutrient Initiative, 1999).

21 High returns relative to other countries are due to the highest reported VAD prevalence in children in the region (over 50%) as well as the structure and costs of health care utilization. This figure remains under review.

22 These 10-year projections take into account the time lag between the consumption of fortified foods and functional benefits. For example, it is assumed that added iron received via fortification will not impact anemia prevalence until 12 months after regular consumption of fortified foods begin.

not being adequately addressed within the economic means and parenting skills of poor Asian families, and Asian governments are not generally assisting the development of a complementary foods industry. Where complementary foods are available, they are of the "boutique" variety intended for, and priced within the means of, the middle and upper classes. Thus, experience with complementary foods for the poor is very limited in Asia. Moreover, the elimination of physical and mental deficits in very young Asian children also involves a strong shift in public health systems, which currently focus on micronutrient supplement programs rather than integrated growth scenarios. Several successful interventions, listed below, provide the necessary and sufficient conditions for poor children to grow normally and protect their health and learning potential.

- promoting exclusive breastfeeding for at least 6 months according to the Code[23];
- public education (formal and informal media) and health promoters with responsibility for community outreach which conduct home visits working with primary caregivers to optimize infant feeding practices and domestic hygiene that will reduce diarrhea prevalence and growth faltering in very young children;
- integrated breastfeeding and semisolid complementary foods introduced at 6 months and monitored by community programs that chart the growth and development milestones[24] of children; and
- introduction of food-based programs for young child feeding, including home-based and industrially processed complementary foods, with strengthened social marketing, regulatory and quality-assurance systems at national and subnational levels of government. Affordability and food safety/quality should be the instruments of effective demand and consumer choice.

It is obvious that the contribution of processed complementary foods must be considered in this context, and in any case should not be regarded as the "magic bullet" that will reverse physical and mental growth faltering in young Asian children. But the potential role of multiple micronutrient-fortified complementary foods should not be underestimated either, because studies on the economic losses from stunting and micronutrient deficiencies have demonstrated the high "shadow price" of the nutritional status quo and the weak impact of public health programs; because scientific reviews[25] have shown significant shortfalls in macro- and micronutrients that young children need; and because the velocity of growth in the first 12, 18, and 24 months of life is so rapid that responsive feeding must be elastic. This is precisely where the "scaling up" of affordable processed complementary foods could make a big difference in the future learning and earning potential of children.

For all these reasons, it is premature to develop a rigorous economic benefits analysis for industrially processed complementary foods, but their inclusion in this study, and the production frontier of the Asian food industry, is warranted.

Conservative Approaches

To prevent overly optimistic projections in the CIPs, the assumptions used are generally based on conservative interpretations of the evidence. Therefore, the projected benefits are intended to provide a floor rather than a ceiling. For example:

- The CIPs attach no dollar value to an adult life saved. Reduced maternal mortality and deaths from CHD are not quantified.
- In the CIPs, productivity loss attributed to anemia for heavy manual labor and blue-collar labor is among the lower estimates found in the literature. While the CIP model used a 1% figure for productivity loss among anemic blue-collar

[23] The International Code of Marketing of Breast-Milk Substitutes, described in the context of international agreements on appropriate infant feeding practices in Clark, D. and R. Shrimpton, "Complementary feeding, the Code and the Codex," *Food and Nutrition Bulletin 21* 1 (2000): pp. 25–29.

[24] Psychomotor, psychosocial, and cognitive.

[25] Dewey, K. and K. Brown, "Update on technical issues concerning complementary feeding of young children in developing countries and implications for intervention programs," *Food and Nutrition Bulletin 24* 1 (2003):5–29; World Health Organization, *Complementary Feeding of Young Children in Developing Countries: A Review of Current Scientific Knowledge* (WHO/NUT/98.1) (Geneva: WHO, 1998); World Health Assembly, *Global Strategy for Infant and Young Child Feeding* (WHA55/2002/REC/1, Annex 2) (Geneva: WHA, 2002).

workers, a recent study in the *Asian Development Review* estimates a loss of 5%.[26] The same study estimates wage losses for heavy work at 17% while this model uses 12%. The less-conservative assumptions would have doubled the benefit-cost ratios for IDA interventions included in the CIPs.

- The estimated benefits of fortifying flour with iron are limited to populations with iron deficiency anemia. However, a number of studies indicate negative impacts on cognitive development and performance with iron deficiency, even without the onset of clinical symptoms of anemia. Iron deficiency anemia is used as a conservative standard because the functional impacts are more extensively documented and quantified and because few countries have data on the prevalence of iron deficiency as opposed to anemia. However, since it is generally thought that for every case of iron deficiency anemia there is another case of iron deficiency, this conservative standard may limit the projected benefits of iron fortification in the CIPs to half of the potential beneficiaries.
- For both anemia and VAD interventions, no benefits are attributed for the first year of fortified food consumption. Several supplementation trials have shown significant improvement in nutrition within shorter time frames. In the case of folic acid, the "time-lag" assumed for measurable impact is longer.
- The correction of anemia is complex and sets a much higher bar for impact than the correction of iron deficiency. For example, an evaluation of flour fortification in Venezuela shows little sustained impact on hemoglobin, the biochemical indicator of anemia, but a dramatic sustained drop on serum ferritin and other indicators of iron deficiency.
- Many negative impacts of micronutrient malnutrition suggested by the literature are not included in the analysis, either because consensus does not yet exist or because they were too complex to quantify within the context of the CIPs. These impacts include increased morbidity in anemic women and children, folic acid reducing the incidence of certain cancers, the impacts of VAD on pregnant women and other populations,[27] and the synergistic effects of adding multiple micronutrients to the diet that mutually promote absorption and bioavailability.
- The projections for prevalence reduction based on effectiveness trials were conservatively discounted. For example, while large-scale effectiveness trials in the PRC with iron-fortified soy sauce showed a reduction in anemia of more than 50%, the PRC CIP projects only 30%.

Error bands widen as assumptions are multiplied by assumptions. Therefore, the specific numbers and conclusions offered in the CIPs should be viewed accordingly. However, the analytical framework provided Country Teams with a transparent and systematic tool to scan for fortification opportunities, create and compare potential fortification scenarios, and make strategic choices. In several cases, proposed fortification strategies were discarded because they showed a low or negative benefit-cost ratio. This allowed for some informed strategic choices and a focus on scenarios suggesting greater impact. Based on this analytical framework, the five CIPs offer reasonable fortification strategies with defensible benefit-cost ratios that can be used in the larger public debate (outside the nutrition community). This systematic approach will assist policy makers and investors in setting priorities among competing investment and development opportunities.

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[26] Horton, S., "Opportunities for investment in nutrition in low-income Asia," *Asian Development Review 17*, 2 (1999): 246–273. See also Horton, S. and J. Ross, "The economics of iron deficiency," *Food Policy 28* (2003): pp. 51–75.

[27] The impact of enhanced vitamin A intake on pregnant women has been shown to reduce all-cause maternal mortality by more than 40%. West, K., J. Katz, S. Khatry, S. LeClerq, E. Pradhan, S. Shrestha, P. Connor, S. Dall, P. Christian, R. Pokharel, & A. Sommer, *Double Blind, Cluster Randomized Trial of Low-Dose Supplementation with Vitamin A or Beta Carotene on Mortality Related to Pregnancy in Nepal. British Medical Journal* (1999) 318:570–5.