

Monitoring and Evaluating Food Fortification Programs: General Overview

Technical Consultation July 7, 2006



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International Micronutrient Malnutrition Prevention and Control Program (IMMPaCt)/
Centers for Disease Control and Prevention (CDC)
Pan American Health Organization/World Health Organization
U.S. Agency for International Development (USAID)
A2Z: The USAID Micronutrient and Child Blindness Project

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1. Introduction and Background

Food fortification, one of the most cost-effective interventions to control vitamin and mineral malnutrition, has been introduced in both industrialized and developing nations. Fortification aims to increase the intake of specific micronutrients (vitamins and minerals) found to be lacking or insufficient in the diet or whose additional intake may have health benefits, by making available and accessible food vehicles that contain additional amounts of those micronutrients. A critical component of these programs, as with any public health intervention, is to provide ongoing information on the progress of implementation and to measure the health impact among intended beneficiaries. Such data collection, analysis, and reporting systems are often collectively referred to as program monitoring and evaluation (M&E). However, common terminology and indicators used in M&E of food fortification programs have been lacking. To address this shortcoming, an interagency consultation was held in Washington, D.C., on July 7, 2006, with the broad participation of major public health agencies engaged in supporting national food fortification efforts with the following objectives:

1. To reach consensus on the concepts and terminology of food fortification M&E from a public health perspective, and
2. To explore appropriate M&E indicators for different phases of food fortification programs, including measures of penetration, availability, and utilization of the fortified foods as well as coverage and consumption by the target groups and the impact on public health.

Consensus on terminology is particularly important in the preparation of guidelines for designing appropriate M&E activities as well as for ensuring that indicators for M&E of food fortification programs are standardized among countries and among agencies and groups responsible for extending related support and technical assistance to national food fortification programs.

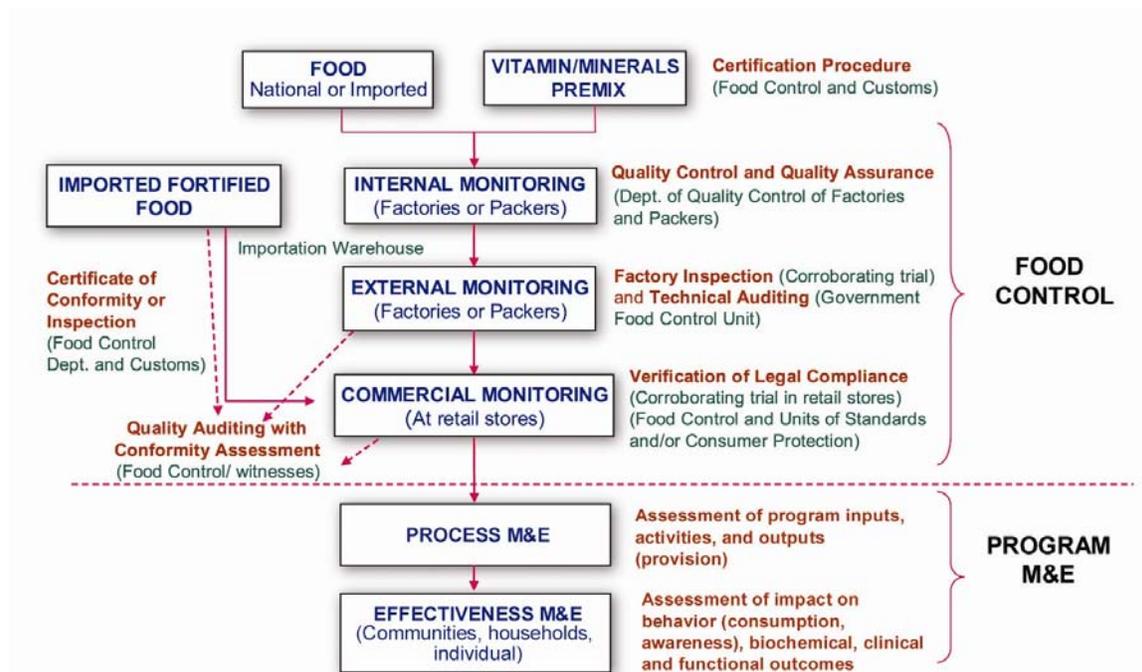
Standardizing M&E indicators across programs will allow for better comparison of results and sharing of knowledge.

A series of presentations that provided a basis for discussions included general principles of public health program M&E (Ame Stormer), an overview of the World Health Organization (WHO) Food

Fortification Guidelines with a focus on monitoring (Marie Ruel), the Global Alliance for Improved Nutrition (GAIN) Performance Measurement Framework (Barbara MacDonald), and the Centers for Disease Control and Prevention (CDC) approach to monitoring (Tom Chapel). The presentations are included as an annex to this report.

From the outset, it was important to consider distinct aspects of food fortification programs with direct relevance to M&E, and, for this purpose, the model recently recommended by WHO was proposed (Figure 1).¹

Figure 1. Framework for Monitoring and Evaluating Food Fortification Programs. (Adapted from WHO, 2006).



In this framework, there are two primary components of food fortification programs: (1) the supply and control of adequately fortified foods (nationally produced and/or imported), and (2) population

¹ World Health Organization and Food and Agriculture Organization of the United Nations. Guidelines on Food Fortification with Micronutrients. Eds: Allen L, De Benoist B, Dary O, Hurrell R. Geneva: World Health Organization, 2006.

access and utilization of fortified foods. The first component is concerned with the product, or the fortified food being supplied, and the second component relates to dissemination and acceptance of the product, its consumption, and its impact among the population. These two components require distinct approaches to M&E, with the former subject to *food control activities (regulatory monitoring)*, which are the responsibility of food industries and food control authorities, while tracking access to and the impact of consumption of fortified foods are the focus of *public health M&E* from an epidemiologic perspective. The public health M&E encompass data collection activities conducted at the population (community, household, and individual) level. This distinction is particularly significant when considering the roles and responsibilities of different agencies and groups involved with M&E of food fortification programs.

While all the M&E activities presented in **Figure 1** are integral to a successful fortification program, regulatory monitoring is the business of food technologists and food control authorities. For this purpose, the food industry and food control agencies have established terminology and standardized protocols, such as the Codex Alimentarius,^{2,3,4} International Standards Organization, Hazard Analysis and Critical Control Point, and others. In general, regulatory monitoring has legal implications and typically consists of four steps: certification of the premix, internal monitoring (quality control and quality assurance) in factories, external monitoring (inspection and auditing) in factories and importation sites, and commercial monitoring (verification of compliance) at distribution centers and retail stores.

In the past, in some national fortification interventions, such as universal salt iodization, program managers took on the responsibility of both regulatory and public health monitoring, and the line between the M&E activities of these two distinct components of fortification programs has been blurred. However, this approach has been increasingly abandoned, and the two different components of monitoring food fortification programs are allocated to those groups (and sectors)

² Food and Agriculture Organization. General Requirements (Food Hygiene). Codex Alimentarius (Supplement to Volume 1B). Rome: Food and Agriculture Organization, 1997

(<http://www.fao.org/docrep/w6419e/w6419e00.htm>).

³ Codex Alimentarius. General Principles for the Addition of Essential Nutrients to Foods

(http://www.codexalimentarius.net/download/standards/299/CXG_009e.pdf).

⁴ Codex Alimentarius. Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems. (http://www.codexalimentarius.net/download/standards/354/CXG_026e.pdf).

best equipped to handle them. This technical consultation focused on the epidemiologic aspects of the M&E of food fortification programs that relate to tracking and assessing access, utilization and consumption of fortified foods by the population, and the health and nutritional impact of the intervention.

The meeting aimed to develop consensus among public nutrition specialists on terminology, either mandatory or voluntary, that could be applied to food fortification programs.

2. Definitions of M & E

The consultation proposed adopting the following definitions of M&E and recommended using them for the design, implementation, and assessment of food fortification programs.

Monitoring is the frequent and continuous collection, analysis, and interpretation of data and use of the resulting information on program inputs, implemented activities, outputs, and outcomes to assess how the program is performing according to predefined criteria. One main objective of food fortification program monitoring is to identify problems such as inadequate availability and access of adequately fortified food by the target population and insufficient awareness, utilization, and consumption of the food by the target population so that corrective actions may be taken to improve program performance. In this way, monitoring has the purpose of revealing what is happening in programs or how it is happening; programs should be monitored often enough to identify problems and address them in a timely fashion as well as to identify those parts of the program that appear to be operating successfully. Furthermore, food fortification program monitoring includes tracking the trends in primary outcomes that are expected to lead to effectiveness in the nutritional/health status of the population.

In contrast, *evaluation* is the systematic and objective assessment of a program. The aim is to determine the relevance and fulfillment of objectives, quality of performance, outcome

achievements, cost-effectiveness, and sustainability.⁵ Evaluation is most concerned with providing evidence for policy makers and program managers to make decisions about continuing, modifying, expanding, or interrupting a program. In this context, evaluation helps to answer why or why not certain things are happening in a program. Typically, program evaluation is done periodically and elaborates on the information on program implementation and impact generated through the ongoing monitoring system; it is often targeted to problems identified through the monitoring process.

The above definitions were integral in guiding discussions.

3. Types of M & E

M&E can play a complementary role at each stage in the implementation of food fortification strategies. Monitoring can be done at all stages, but evaluation should be done only when guided by monitoring data or stakeholders' interests. In fact, stakeholders may lead us to evaluate any part of the program and not just the outcomes. The data and information about the status of different program elements, including inputs, activities, outputs, and outcomes should be analyzed and used by program managers and stakeholders to improve, strengthen, and sustain food fortification.

The consultation identified the key stages in the evolution of a food fortification program where different types of data/information-gathering activities, including program M&E assessment activities, provide information to guide program planning, implementation, and continuation/sustainability. These stages and some important questions to be answered at each stage of a fortification program are illustrated in **Table 1**.

⁵ Kuzek JZ, Rist RC. Ten Steps to a Results-Based Monitoring and Evaluation System, A Handbook for Development Practitioners. Washington, D.C.: World Bank, 2004
(<http://www.preval.org/documentos/00804.pdf>).

Table 1. Monitoring and Evaluation Framework

Assessment, Monitoring, and Evaluation in the Evolution of Food Fortification Programs			
Program Planning	Program Monitoring		Program Evaluation
Formative research Concept and design	Program process/performance Monitoring program inputs, activities, and outputs	Program effectiveness Tracking and assessing trends in primary outcomes (e.g., intake)	What aspects of the program worked or did not work (and why?); what aspects should be strengthened, continued, or discontinued? Assessing outcomes, including secondary (e.g., biochemical indicators) and tertiary (e.g., functional indicators) Cost-effectiveness, including sustainability
Questions Answered by Different Stages of Food Fortification Program Monitoring and Evaluation			
Is the intervention needed and can it be implemented given the local situation and capacity? How can the food industry be best engaged to widely market quality fortified foods? Which group most needs the nutritional benefits of the intervention? Will a substantial proportion of the target population access and regularly consume the fortified foods?	To what extent are planned activities accomplished? How widespread is the market penetration of the fortified food(s) and what percent of the population accesses the product(s) regularly? What is the quality and micronutrient content of the foods at the consumer table?	Is there an increased intake of the micronutrients that are expected to be associated with changes in nutrition and health? What is the awareness of the consumer about the consumption of fortified foods?	Are program activities and outputs causing the increases in primary outcomes? [Are our efforts leading to increased consumer awareness?] Are changes in nutritional and health status the result of increased consumption generated by our program? Is the level of cooperation and information sharing between the food industry and the public sector sufficient to sustain the efforts? If not, how can it be improved? To what extent should government/public sector resources be reallocated?

It was appreciated that all stakeholders should be engaged and involved with selecting indicators and targets for each stage of implementation of food fortification, from planning and design to M&E components. The different stages in implementing food fortification efforts are elaborated below:

- **Program planning:** Appraisal of the conditions and feasibility for introducing a food fortification program; determining objectives, purposes, and goals; formulating expected outputs and outcomes; selecting indicators; planning the interventions; and preparing implementation tools and manuals (answering the question, “What are we planning to do?”).
- **Program monitoring:** Entails two components:
 1. Ongoing collection of data and information to help assess the processes of program implementation—that is, inputs and activities carried out and products and services (outputs) generated by the program according to pre-established

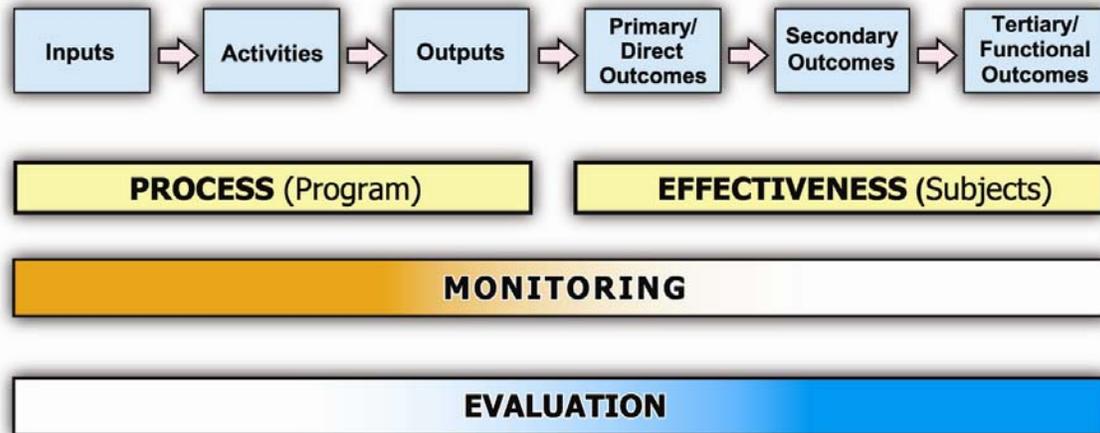
criteria—and review of performance quality (answering the question, “How is the program proceeding?”).

2. Appraisal of the quality, extension, and consequences of program outcomes on the target population by using and interpreting indicators with different degrees of dependence on the program outputs (answering the question, “Is the program having the expected effects on the population?”).
- **Program evaluation:** Estimation of the effectiveness of the program (to assess how successful it has been). In addition, evaluation may focus on efficiency in use of the resources to attain the program outputs and outcomes and critical analysis of the program results compared with alternative and complementary interventions and to identify ways to reduce costs and improve program sustainability.
 - In summary, program monitoring helps answer questions about what, how, and who, and the responses are useful to program managers to gauge the performance of the program and to implement corrective measures. Program evaluation, on the other hand, responds to why or why not interventions are having the intended results and effects (positive and negative). Evaluation is needed for policy makers to decide about maintaining, extending, modifying, or halting a program as well as to compare it with alternative interventions.

4. Elements of Program Monitoring and Evaluation: The Logic Model

Figure 2 lists the program elements that are subject to M&E of any health-related program, suggesting a clear division between program processes (inputs, activities, and outputs) and program effectiveness (outcomes that are assessed among target beneficiaries).

Figure 2. Macro Logic Model for M&E



- **Inputs** refer to the financial, human, and material resources used for a program.
- **Activities** are the specific actions taken or work performed through which inputs, such as funds, technical assistance and other types of resources are mobilized to produce specific outputs.
- **Outputs** include the products, capital goods and services that result from a project or intervention, which are relevant to the achievement of outcomes.
- **Outcomes** extend to anticipated or potentially unanticipated effects, or the impact of a program in the target population.

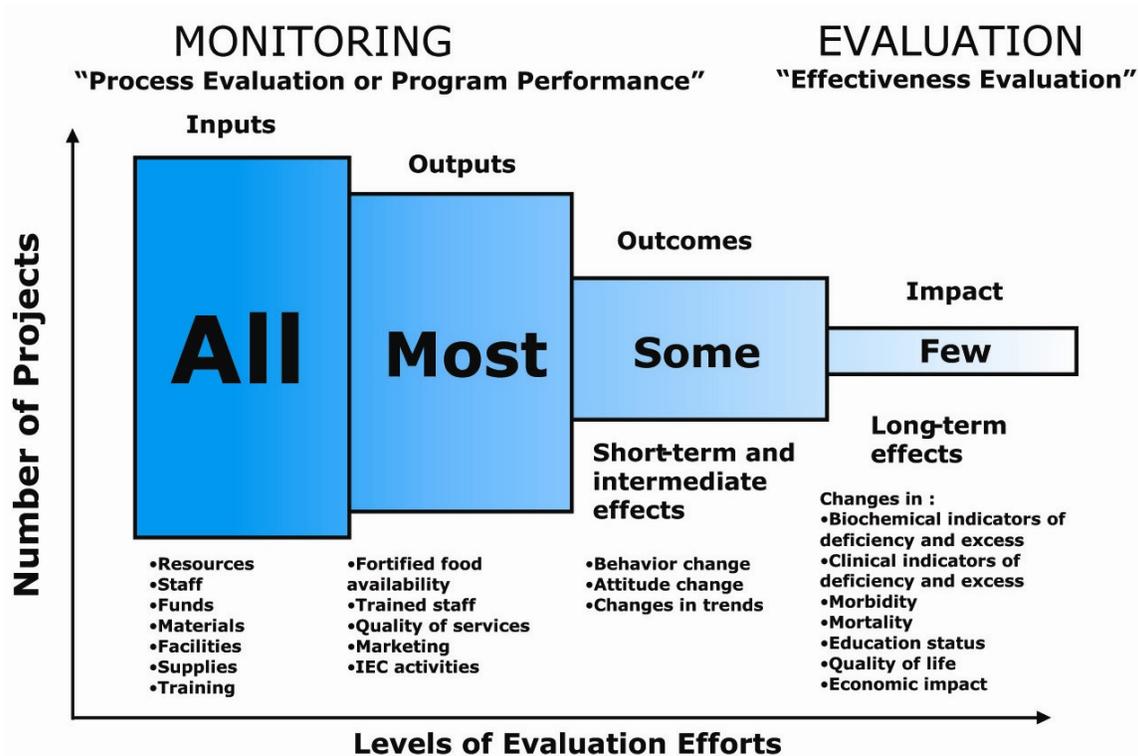
Three types of outcomes often used are **primary**, **secondary**, and **tertiary** outcomes, which also may be referred to as **short-term**, **intermediate-term**, and **long-term** outcomes.

Although a program may choose to track outcomes at all three levels, it was recognized that, for secondary (intermediate-term) and tertiary (long-term) outcomes, the area of interest is usually attributing cause [usually through special (survey or operational research) designs]. This type of study typically falls within the domain of evaluation as we have described it.

Figure 3 illustrates the questions and different degrees of attention M&E places on the elements of food fortification programs. M&E can be applied as complementary processes at any part of the logic model, including distal outcomes. Where one focuses M&E depends on program maturity, expertise, and needs and desires of stakeholders. In general, we would expect program M&E to be more intense in early parts of the logic model and less often directed to intermediate- and long-term outcomes. However, programs in existence a long time or with a lot of expertise may productively study even long-term outcomes.

While it is important to carry out M&E for each of these program elements, the relative priority and allocation of resources to each element should depend on program maturity, program expertise, program resources, and the needs/desires of stakeholders. That is, initial emphasis of M&E efforts as programs are getting established should be on inputs and outputs, and once there is evidence of progress, then it may be reasonable to shift attention to outcome measurement.

Figure 3. Monitoring and Evaluation Pipeline



M&E should be simple and affordable, particularly in low-resource settings. This will be greatly facilitated by developing clear M&E plans with well-defined data sources, indicators, and protocols for data collection, analysis, and use.

Food fortification programs should be evaluated as needed, especially to determine why or why not the expected progress is achieved in any stage of implementation. The intensity of program monitoring or evaluation should reflect the objectives of the program, available resources, level of sophistication desired, and the need for different types of data and information. Given that resources are often the limiting factors, certain designs for program evaluation may be used to generate meaningful data and useful information.

5. Types of Program Evaluation

When planning a program evaluation exercise, it is important to consider the intensity of data collection and the rigor that is required. Habicht and collaborators⁶ identified three types of data collection designs and inferences for program evaluation, including *adequacy*, *plausibility* and *probability* assessments and statements which are distinguished by the purposes of data being collected and the availability of resources. The precision required to satisfy the needs of stakeholders to evaluate their program is another important factor to bear in mind when designing methods and data collection protocols. The classification of these three inferences is based on the premise that the choice depends on the type, extent, and sophistication/detail of data stakeholders required by to assess whether the program has been or is being effective, and if not, why not.

An *adequacy* inference is most appropriate if the objective is to assess whether a sufficient supply of fortified foods is accessible to the expected population or whether the prevalence of a particular micronutrient deficiency is at or below a predetermined level. Activities that will lead to adequacy evaluation of a program are the simplest (and least costly) type of data collection to carry out, primarily because they do not require randomization or use of a control group, yet they still demand scientific rigor.

⁶ Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. *Int. J. Epidemiol.* 1999;28:10-18

A *plausibility* inference seeks to demonstrate, with a given level of certainty, that changes in program performance or impact, such as reducing the prevalence of iron deficiency, are related to the fortification program. Many factors unrelated to food fortification can decrease the prevalence of iron deficiency, and thus the reduction can be wrongly attributed to the fortification program unless the evaluation takes these factors into consideration. It is important that data collection that leads to plausibility inferences control for potential confounding factors and biases through careful selection of an appropriate study design and statistical analysis techniques.

Finally, data collection activities that aim to achieve *probability* inferences provide the highest level of confidence that the food fortification program is responsible for the observed reduction in the prevalence of deficiency. Only probability methods can establish causality and they necessitate the use of randomized, controlled experiments, carried out in a double-blind manner when possible. Data collection activities that lead to probability inferences are complex and expensive to perform because they need a randomized sample and a control group. They may not be feasible in typical field conditions, either for practical or for ethical reasons.

The participants in the technical consultation agreed that monitoring activities, as described above, would provide sufficient programmatic information to allow for adequacy evaluation of food fortification programs. In some cases, effectiveness evaluation of the program may require additional rigor and require plausibility inferences. However, because food fortification programs are to be implemented on a broad scale after controlled, randomized trials demonstrate the efficacy of the intervention, the consensus of the consultation was that probability inferences are NOT required as part of typical effectiveness evaluations of national fortification programs.

6. Indicators of M & E

Finally, given the discussion on the framework for M&E, the consultation addressed the definition and selection of indicators for different aspects of food fortification programs. An indicator is defined by Kuzek and Rist as a “quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of the intervention”.⁵ Indicators are used for program

implementation and its results or consequences (i.e., processes and effectiveness, respectively). Thus, two groups of indicators can be identified in food fortification programs:

1. Process indicators are associated with the performance of inputs, activities, and outputs—for example, proof of commitment to carry out the programs, provision of products and services, and their coverage (or market penetration in business terms)—product quality and accessibility of it by the target population, and materials and actions aimed to raise awareness, educate, or transfer information. Indicators need to be developed for different program elements, as indicated in **Figure 2**.

2. Effectiveness indicators measure the diffusion and quality of outcomes in the target population, such as changes in behavior, consumption of foods and additional intake of micronutrients, and biochemical, physiological, and functional parameters.

This consultation did not elaborate further on indicators, and the discussion of this subject was postponed, particularly with respect to the choice of parameters and criteria to reflect the impact of fortification programs. Nevertheless, there was some debate on whether outcomes and impact represent the same dimension of programs. The consultation recognized the importance of distinguishing between the measurement of *micronutrient intake* and *micronutrient status* and that measuring individual dietary intake may be cumbersome and costly, as there are few (biological) indicators of intake for most micronutrients, except for iodine and folate. In addition, few indicators have been able to capture the risk of adverse effects due to excessive intakes, which has been recognized as an important parameter to monitor fortification programs. It is important to consider the level of nutrient intake in the population and the expected increase that may result from fortification inputs when selecting appropriate outcome measures.

An additional consideration is the importance of estimating the contribution of fortified foods to the overall improvement in micronutrient status to estimate attribution of different interventions and control program strategies to reduce micronutrient deficiency. It was recognized that fortification may provide only a partial response to nutritional deficiencies and that it is important to be realistic when setting expectations about what fortification alone can achieve.

While this consultation raised several important questions about outcome measures, it was evident that there is a lack of consensus about the most appropriate biochemical indicators; in some cases, there is little evidence of whether certain biomarkers are responsive to the range of additional intake levels provided by fortified foods.

The WHO Guidelines of Food Fortification has proposed to measure results by estimating the additional intake of micronutrients by the target population in terms of the proportion of the population that moves from below to above the estimated average requirement values. Nevertheless, this approach is in the initial phases of being considered, and there is little programmatic experience with these tools and methodologies. The epidemiologic criteria to assess results using intake parameters are also lacking. More work is required in this area of outcome indicators.

Two documents were presented, although not discussed extensively at the meeting, that outline biochemical parameters as indicators for evaluation of micronutrient interventions and criteria used to interpret the epidemiologic significance of the biochemical parameters.

In summary, there was agreement that monitoring and evaluating program effectiveness is essential for sustaining successful food fortification efforts, and it is important to assess the outcomes of these programs by monitoring indicators that provide data on the increasing proportion of the population receiving additional nutrient intakes through the consumption of fortified foods as well as reduced prevalence of nutrient deficiency.

ANNEX: List of Participants

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