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# **Developing a National Food Fortification Program in the Dominican Republic**

By:

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**CASE STUDY #3-5 OF THE PROGRAM:  
“FOOD POLICY FOR DEVELOPING COUNTRIES: THE ROLE OF  
GOVERNMENT IN THE GLOBAL FOOD SYSTEM”  
2008**

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## Executive Summary

Micronutrient deficiencies, particularly iron and vitamin A deficiencies, are considered a major public health problem in the Dominican Republic. In 2003, to respond to this problem and to take advantage of the opportunity to receive financial support from a global funding donor, the Dominican Republic developed a proposal to implement a national wheat flour and sugar fortification program to improve the micronutrient status of its population. This case study explores the country's experience in developing the national food fortification program, offering an analysis of policy issues, stakeholders, and policy options.

Food fortification has led to rapid improvements in the micronutrient status of large proportions of a population at very low cost and is generally considered highly cost-effective compared with other public health interventions. The decision to implement a food fortification program is complex, however, involving critical analysis of the evidence of need; of the types and amounts of the micronutrients to be delivered within the constraints of safety, technology, and cost; of the quality and adequacy of the fortified foods; and of trade-offs with other intervention strategies.

A food fortification program as a public health intervention requires continuous multisectoral collaboration. Specifically, it calls for collaboration by three key sectors: the public sector or government, the private sector or food producers, and the civil society or consumers. Within the collaborative process, there is some natural tension between the public sector emphasis on consumer rights, equity, and health context and the private sector focus on consumer demand, commercial viability, and revenue. A balancing of public and private perspectives is thus necessary.

A food fortification program must also be developed in the country-specific context, with clear designation of roles and responsibilities at the various levels of the program. Food fortification is just one of many possible public health measures, and the relative importance of other strategies must be weighed under local conditions and the specific mix of local needs.

Your assignment is to consider any possible unintended consequences of the proposed national food fortification program, recommend alternative(s) to mandatory mass fortification, and identify the pros and cons of such alternative(s).

## Background

### The Basics of Food Fortification

Food fortification is the intentional addition of one or more micronutrients (vitamins and minerals) to processed foods to increase people's intake of the micronutrients and provide a health benefit. The impact of food fortification on public health depends on various factors, including the fortification level, the bioavailability of the added fortificants (or the extent to which a nutrient is taken up and used by the body), and the amount of the food consumed.

The Codex Alimentarius *General Principles for the Addition of Essential Nutrients to Foods* (FAO/WHO 1987) defines "fortification" 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." Furthermore, the first condition for fulfillment by any fortification program is that "there should be demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, data indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits" (FAO/WHO 1987, 3).

In addition to fulfilling a "demonstrated need," food fortification is often more broadly defined to include other plausible public health benefits from increased micronutrient intake, based on emerging scientific knowledge and public health circumstances. Still, the decision to implement a fortification program is usually taken in response to the nutrient deficiencies that are most common in the

population and have the most adverse health and functional consequences.

In many situations, food fortification has led to rapid improvements in the micronutrient status of a population at very low cost, particularly through the use of existing technology and local distribution networks. Thus, food fortification is generally considered a highly cost-effective public health intervention, provided that the fortified food is consumed in adequate amounts by a large proportion of the target population. In many industrial countries, food fortification has been used for the successful control of deficiencies of vitamins A and D, thiamin, riboflavin, niacin, iodine, and iron (Allen et al. 2006). Salt iodization started in the early 1920s in the United States and Switzerland and is now common practice in most countries around the world (Marine and Kimball 1920; Burgi et al. 1990). For decades, the United States has been fortifying milk with vitamin D, and many countries have been fortifying their cereal products with thiamin, riboflavin, and niacin. Food fortification is also becoming increasingly feasible in developing countries. Vitamin A fortification of sugar in Central America reduced the prevalence of vitamin A deficiency in that region (Mora et al. 2000).

Advantages to food fortification include the following (adapted from Allen et al. 2006):

- Fortified foods that are consumed on a regular and frequent basis will maintain body stores of nutrients more efficiently and more effectively than intermittent supplements and can lower the risk of the multiple deficiencies that can result from seasonal deficits in the food supply or a poor-quality diet.
- Fortified staple foods will likely contain levels of micronutrients that approximate the supply from a good regular diet.
- Fortification of widely distributed and widely consumed foods has the potential to improve the nutritional status of a large proportion of the general population.
- Fortification of common staple foods does not require changes in existing food patterns nor individual compliance.

- The delivery system for fortified foods usually already exists, generally through the private sector.
- In many cases it is technologically feasible to fortify foods with several micronutrients simultaneously.
- One or more micronutrients can usually be added without adding much to the total cost of the food at the point of manufacture.
- With the appropriate food system and technology in place, fortification is often more cost-effective than other public health strategies (Horton 1999; World Bank 1994).

This strategy also has limitations, however (adapted from Allen et al. 2006):

- The fortified food(s) might not be consumed by all groups within the general population. Infants and young children consume relatively small amounts of food and are therefore less likely to be able to obtain their recommended intakes of all micronutrients from fortified food staples or condiments. It is also likely that in many locations (such as remote areas), fortified foods will not supply adequate amounts of some micronutrients among population groups with high micronutrient requirements because the fortified foods will not reach these locations.
- The most undernourished population groups often live on the margins of the market economy, produce their own food, or acquire their food locally. For these populations, it may be difficult to find an appropriate food vehicle to fortify.
- Poor population groups often have multiple micronutrient deficiencies resulting from inadequate intakes in the overall diet. Although fortification with multiple micronutrients is possible, these people are unlikely to obtain the recommended intakes of all the micronutrients from fortified foods.

- Technological issues related to fortifying different foods still exist, specifically concerning the levels of added nutrients, stability of the fortificants, nutrient interaction, characteristics of physical properties, and acceptability by consumers, including cooking properties and taste.
- The nature of the food vehicle, the fortificant, or both may limit the amount of fortificant that can be added. Although it is generally possible to add a mixture of vitamins and minerals to relatively inert and dry foods such as cereals, interactions between fortificants can occur, adversely affecting the sensory qualities of the food or the stability of the nutrients and complicating the estimation of how much of each nutrient should be added.
- Everyone in the population is potentially exposed to increased levels of micronutrients in the fortified foods, regardless of whether or not they will benefit from fortification.
- Although food fortification is often more cost-effective than other public health strategies, the costs associated with the fortification process can still limit the implementation and effectiveness of fortification programs. These costs include capital investments, trials to determine micronutrient levels and effects on physical qualities and taste, analysis of the purchasing power of beneficiaries, recurrent costs involved in generating and maintaining product demand, and the cost of an effective monitoring and evaluation system to ensure that fortification is effective and safe.

Considering both the advantages and limitations, it is clear that food fortification is an effective solution to a nutritional problem, but it cannot be expected to solve all micronutrient problems. Furthermore, other options must be considered when access to commercially or centrally processed food is limited owing to geography, poverty, or cultural preferences.

### Types of Food Fortification

Food fortification programs are not all created equal. There are at least three types, classified by how they are aimed at the expected beneficiaries and regulated. According to Allen et al. (2006), the types include (1) fortification of foods that are widely consumed by the general population (mass or universal fortification), (2) fortification of foods designed for specific population groups (targeted fortification), and (3) voluntarily fortified foods available on the market (market- or industry-driven or open market fortification).

Mass fortification of foods such as cereals, condiments, and milk is usually instigated, mandated, and regulated by the government. Mass fortification is often implemented when the majority of the population has an unacceptable public health risk of being or becoming deficient in specific micronutrients. It might also be implemented when fortification offers an expected health benefit, as in the case of mandatory flour fortification with folic acid to reduce the risk of birth defects in Canada, the United States, and many Latin American countries.

Targeted fortification includes complementary foods for young children, foods for school feeding programs, and rations for emergency feeding and displaced persons. These foods may provide a large proportion of the daily micronutrient requirements for specific target groups.

Market-driven fortification occurs when a food manufacturer voluntarily makes a business decision to add one or more micronutrients to processed foods. Because these foods are intended for wide consumption, some regulation is still necessary to ensure that consumption of these foods will not result in an excessive intake of micronutrients and pose a health risk. The importance of market-driven fortification is likely to grow with increasing urbanization and the availability of greater varieties of processed foods.

### Global Funds and Food Fortification

Early 2000 opened the era of global funds and alliances, particularly with the support of the world's single largest philanthropist, Bill Gates. The Bill and Melinda Gates Foundation mobilized new resources for global health by promoting innovative financing mechanisms and product development and making focused investments in problems



with proven solutions that might be attacked with money and technology.

Micronutrient malnutrition is recognized as the world's most prevalent nutritional disorder, and fortification of common foods offers an effective, inexpensive, and sustainable solution. Thus the Global Alliance for Improved Nutrition (GAIN) was created to support countries in implementing and strengthening food fortification and other effective nutrition strategies. GAIN was launched at the UN General Assembly Special Session on Children in New York in May 2002, with an initial establishment grant provided by the Gates Foundation and supplementary funding from the U.S. and Canadian development agencies and other partners. GAIN disbursed grant funds to developing countries, stimulating governments and markets, and built momentum to reduce the prevalence of micronutrient deficiencies through national or large-scale programs to fortify staple foods and condiments widely accessible to low income and at-risk populations—in other words, mass fortification programs.

With this opportunity for large funding support, countries like the Dominican Republic were poised to take the next step toward implementing their national food fortification programs. In mid-2003 the Dominican Republic submitted a grant proposal detailing its plans to implement a national wheat flour and sugar fortification program, which GAIN approved for funding in 2004–2005.

### Rationale for Food Fortification in the Dominican Republic

Micronutrient deficiencies are considered a major public health problem in the Dominican Republic, despite the lack of recent data on the prevalence of specific micronutrient deficiencies. In 1993, 35 percent of pregnant women and 20 percent of nonpregnant women, as well as 27 percent of all children under five years of age, were anemic, mainly owing to iron deficiency anemia (CENISMI 1995). Vitamin A deficiency was found to be a problem in 6 percent of children under five years, and 23 percent had low levels of serum retinol, a sign of risk for vitamin A deficiency (CENISMI 1995). In 2002, 34 percent of school-age children were iodine deficient (CENISMI 2003). According to the National Surveys of Household Income and Expenditure, the lack of variation in the content of

the family food basket suggests that major changes or improvements in micronutrient intake through the diet are unlikely (Banco Central 1998).

As in many other Latin American countries, the Dominican Republic has prior experience in food fortification. A universal salt iodization program was started in 1996, and voluntary fortification of wheat flour with iron and some B vitamins began in the early 1990s based on the initiative of several flour mills. In 2003, of the six main flour mills active in the country, four were still reported to be fortifying voluntarily, without any governmental regulation. It was estimated that 77 percent of the wheat flour in the country was fortified at varying levels (SESPAS 2003).

The mills that were fortifying their flour voluntarily began to demand that fortification be required for all wheat flour for domestic consumption. Because wheat flour is a low-cost staple food with very little marginal profit, the mills wanted a level playing field in the market. The national government also wanted to move toward mandatory fortification to assure that all wheat flour is fortified with the same types and levels of fortificants and is available to most of the general population. Wheat flour was also considered a good food vehicle for mandatory fortification, given its high consumption level relative to other foods in the country. Derivatives of wheat flour, including bread, were second, after rice, in household expenditures on grains. Daily average consumption per capita of wheat flour was about 82 grams (g), and there was very little variation in its consumption throughout the year (Banco Central 1998). Also, 100 percent of the wheat flour consumed in the country is produced domestically; wheat flour is not imported.

To address the problem of vitamin A deficiency, the national government also wanted to initiate mandatory fortification of sugar with vitamin A. An appraisal of the technical and economic viability of introducing sugar fortification with vitamin A was conducted in 2001, and preliminary tests were carried out (INCAP/PAHO 2002). According to the 1996 National Sugar Consumption Survey, sugar consumption per capita was 48.2 g/day in urban areas and 52.6 g/day in rural areas. Preschool children consume 26.0 g/day/person of sugar. Raw brown sugar was consumed by 67 percent of the population in rural areas and 20 percent in urban areas, whereas refined sugar was

consumed by 73 percent of the population in urban areas and 27 percent in rural areas (IDAN 1996). The government wanted to fortify all brown and refined sugars with vitamin A to assure maximum coverage of the target population in both rural and urban areas.

## **Policy Issues**

### How Much Evidence Is Enough?

The decision to implement a food fortification program requires documented evidence that the micronutrient content of the diet is insufficient or that the added nutrients will produce a health benefit. In some cases an inadequate intake of micronutrients is not the only risk factor for micronutrient deficiency. Other factors may also play a major role—for example, infections and parasites can explain a high proportion of anemia in a population. In these situations, it is important to determine the costs and benefits of fortification compared with or in conjunction with other interventions.

Public health actions are often taken based on the best available information, but what should be the minimum amount of information required? The decision to launch a fortification program, for instance, should not be made without at least collecting food intake data, supported by other information on nutritional status, wherever possible. This information is important for justifying the program, making an informed judgment about the types and amounts of nutrients to be added, and selecting suitable food vehicles for fortification. Apart from the technical aspects of the fortification process, consideration needs to be given to whether or not food fortification is an appropriate and acceptable intervention among the expected beneficiaries. One of the key features of mass fortification of food staples is that it does not introduce a “new” product or require any behavior change on the part of the consumer. Thus, in the initial development phase national authorities and industry often make the decision to implement this strategy with little input from consumers.

In the Dominican Republic, the decision to implement the nationwide program to fortify wheat flour and sugar was made by actors at the national level through the National Fortification Alliance (see “Stakeholders”), mainly based on the available

food intake data. Food intake data provided more recent information on the nutritional situation of the country than did the available biochemical data on the status of the main micronutrients of interest (iron and vitamin A), which dated from 1993. The low consumption of animal-source foods and other foods rich in iron and vitamin A, combined with the older data on the prevalence of iron and vitamin A deficiencies in different population groups, was used to justify the intervention. Faced with little recent evidence on micronutrient status, national actors highlighted the need for strong monitoring and evaluation for the national fortification program.

### How Much of a Good Thing?

In mass fortification, the food vehicles are likely consumed by most of the population, but average consumption levels (for example, intake levels per capita) usually reflect how much is consumed by an average adult. Male adults are likely to consume much more than the average amounts, and young children and hard-to-reach population groups often consume much less. Given this wide range of variation in consumption levels within a population, determining the level of fortification requires providing enough nutrients to produce a health benefit without posing risk of excessive intakes. But this is not all. Not all of the synthetic forms of fortificant nutrients are absorbed equally by the body or to the same extent as naturally occurring nutrients. Thus, the bioavailability of the fortificant nutrient also needs to be considered.

In practice, particularly in the case of mass fortification of food staples, the levels of micronutrients that can be added are also limited by safety, technological, and cost constraints (Allen et al. 2006). Given that intakes of the food vehicle will range from low to very high, assessing safety constraints involves simulating the feasible upper levels of fortification and the upper food intake levels in the population to avoid possible excessive intakes. Technological constraints include changes in the sensory properties or organoleptic qualities of the food vehicle or of other foods in which the food vehicle is used as an ingredient. The technological limit is defined as the highest level of addition possible without causing adverse organoleptic changes in the food vehicle. Cost constraints must also be carefully considered in mass fortification, in contrast to targeted and

market-driven fortification, where the original price of the food product is usually high enough to “mask” the cost of fortification from consumers. Under free trade economies, the most important condition for the sustainability of food fortification programs is a low proportional increase in price due to fortification.

In developing the proposed fortification program in the Dominican Republic, authorities used average consumption data to calculate the effect on intake of adding a range of nutrient levels to the foods. As they selected the final fortificant types and levels, they considered the technological constraints identified in previously conducted studies and experiences in other countries and the recommendations of the scientific community regarding health benefits and safety. Because the program’s target groups were primarily women of reproductive age (10–49 years) and children less than five years of age, authorities estimated what percentages of the recommended nutrient intake (RNI) these groups would achieve by consuming the fortified foods. Women were assumed to consume foods at about the average consumption levels, but children were expected to consume half those amounts. Based on these assumptions, it was estimated that fortified wheat flour would provide 4 percent of the RNI of iron for women and 10 percent for children, and 52 percent of the RNI of folic acid for women and 68 percent for children. Fortified sugar was estimated to provide 60 percent of the RNI of vitamin A for women and 39 percent for children (SESPAS 2003).

It was proposed that the increase in the consumer price of the fortified foods be kept as low as possible by arranging for the relevant public and private sector actors to cofinance the investments in equipment, installation, supplies, training, marketing activities, and other costs of fortification and production. The increase in the cost of wheat flour to the consumer due to fortification with multiple micronutrients was estimated to be 0.5 percent, or about a 0.12 percent increase over the cost of the previously fortified wheat flour. The cost of sugar fortification was estimated at US\$9.36 per metric ton, and the increase in the cost of sugar to the consumer due to vitamin A fortification was estimated to be 2.3 percent (SESPAS 2003). When the proposal was developed, members of the National Fortification Alliance found both of these price increments acceptable.

### How to Assure Quality and Adequacy?

A well-established and active monitoring and evaluation system is at the core of a food fortification program yet is the single most important programmatic component that is often neglected or poorly functioning. Without effective monitoring and evaluation, the fortification program runs the risk of producing poor-quality products that are inadequate to meet its nutritional goals. A fortification program’s monitoring system should ensure that the fortified product is available and accessible to consumers in sufficient amounts and with the desired quality, and evaluation should provide evidence that the program is reaching its nutritional goals.

In the Dominican Republic, several regulatory instruments within the existing regulatory framework, as well as internal (by food producers) and external (by government sector) monitoring and evaluation, were proposed. A regulatory framework for wheat flour fortification already exists through the General Health Law and the General Regulation for Risk Control in Food and Beverages (2001) under the State Secretary of Public Health and Social Assistance (SESPAS) and the General Bureau of Quality Standards and Systems (DIGENOR) under the Secretary of Industry and Trade. DIGENOR and the General Environmental Health Directorate (DIGESA) plan to establish fortification standards for wheat flour and sugar, including characteristics of fortified foods and minimum conditions for packaging and storage. Given that the national fortification program is proposed to be universal and mandatory in the country, the establishment of a fortification law is also in progress.

The mechanisms for external monitoring or regulatory enforcement include inspections and quality auditing. DIGESA inspectors plan to visit the flour mills and sugar plants regularly to confirm adequate execution of quality control activities at the plant and distribution level. Results of the inspection will be reported to the respective mill or plant and the Department of Nutrition of SESPAS, and the frequency or intensity of inspections will be adjusted as appropriate. DIGESA inspectors also plan to monitor the fortified foods at the retail level and at border control and customs with similar flow of reporting, including recommendations for corrective measures if necessary, to food producers or distributors and SESPAS. Also, it is



proposed that DIGESA with the Department of Nutrition of SESPAS prepare a brief report (like an industry report card) on the results of random product testing at the plant and retail levels. These reports would be disseminated to every sector involved in the program—government, food industries, other institutions, and the general public.

More important than the enforcement process, however, is the industries' routine internal quality control activities during production, which will assure the quality of the fortified foods at the moments when it really matters. The flour mills, sugar plants, and food distributors plan to undertake day-to-day quality control and assurance and comply with established standards and norms, and the regulatory enforcement is expected to act as a periodic accountability mechanism.

In addition to quality control and assurance during production, packaging, storage, and distribution, another issue of interest is the labeling of nutrient content and health claims. Research and experience have shown that consumers often respond to health claims more than to simple nutrient claims, and a food fortification program could be enhanced by manufacturers' and distributors' making truthful relevant claims. If consumers understand the health advantages of consuming foods that contain particular components, they may be more likely to select foods containing those substances. Given that the proposed national fortification program requires universal and mandatory flour and sugar fortification, which places some constraints on commercial considerations such as product differentiation and competitive pricing, the program does not explicitly address this issue.

In terms of monitoring and evaluation of impact, several activities are proposed, including a baseline survey, a hospital-based registry for neural tube defects (to assess the impact of fortification with folic acid), a post-fortification survey, and final evaluation. The program will be monitored and evaluated for biological impact, program coverage, and achievement of expected programmatic results.

### Trade-offs with Other Interventions?

Because national budgets for food and nutrition programming are limited, it is important to consider the trade-offs between implementing food

fortification and implementing, continuing, or strengthening other interventions. How much additional financial, institutional, and human resources are required for implementing a food fortification program? How will this step affect resources and focus on other intervention strategies, if any?

Mass food fortification offers advantages, such as cost-effectiveness, lack of behavior change in diet patterns, and involvement of other sectors, particularly the private sector, compared with other interventions aimed at improving the nutrient intake of a large segment of the population. But sustaining food fortification also imposes costs related to collaboration, regulation, monitoring and evaluation, communication, and education. And to the extent that implementing and sustaining the food fortification program requires resources, it must be determined whether the program is contributing to existing resources, maximizing under- or unutilized resources, or extracting resources from one area to another.

In the Dominican Republic, other ongoing interventions for reducing micronutrient deficiencies include vitamin A supplementation for young children and postpartum women, salt iodization, iron supplementation for pregnant women who attend prenatal consultations, and water fluoridation. These programs and related national policies are included in the National Food and Nutrition Plan, an integral part of the government's social policy, which seeks to fight poverty and achieve nutritional and sanitary well-being for the Dominican population. Each of these programs is currently being implemented, and the government determined that the resources required for these programs will be maintained and not altered. Although the proposed food fortification program was planned not to divert resources from the ongoing programs, some existing financial, material, and human resources will likely be designated to support or complement the fortification program.

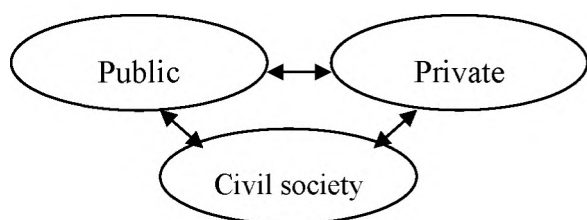
### **Stakeholders**

Operating a food fortification program as a public health intervention requires continuous multi-sectoral collaboration. Within the collaborative process, there is some natural tension between the public sector emphasis on consumer rights, equity,



and health context and the private sector focus on consumer demand, commercial viability, and revenue. Balancing public and private perspectives involves opening communication channels and negotiating various issues. At the implementation level, food fortification essentially calls for the collaboration of three key sectors—the public sector or government, the private sector or food producers, and the civil society or consumers (Figure 1).

**Figure 1: Three Sectors That Collaborate in Food Fortification**



Recognizing the importance of multisectoral collaboration, GAIN mandated the creation of a National Fortification Alliance (NFA) as part of the country proposal development process. The Dominican Republic already had the National Commission of Micronutrients, created by the Department of Nutrition of SESPAS in April 2002. This commission (hereafter referred to as the NFA) was a formal multisectoral coordination body that worked on issues related to micronutrient deficiencies, and when the country proposal was being developed, it also acted as the NFA required by GAIN. The NFA consisted of other departments of SESPAS, the state secretary of agriculture, the state secretary of industry and commerce, the state secretary of education and culture, the food industries, public and private laboratories, research institutes, civil society organizations, nongovernmental organizations (NGOs), and international cooperation agencies. In the NFA, members officially represented the interests of their organization, and participation included stakeholders involved in the technical implementation of fortification, as well as those offering credible channels to key audiences, institutions, and decision makers. The NFA served as an official alliance that could achieve commitment, gain consensus, and coordinate the contributions of various sectors. The

perspectives and roles of specific key stakeholders are discussed here.

### The National Government

Inasmuch as food fortification is a public health intervention, the national government, consisting of entities responsible for health and nutrition, food safety, trade and finance, and industry regulation, among other areas, plays several important roles. In the case of mandatory fortification of food staples, there is an even stronger need for active government involvement to ensure that the program is meeting its objectives and for regular open communication with the public regarding the program and its progress. Government roles include establishing the regulatory framework, implementing monitoring and evaluation, and providing education and communication to the public.

With SESPAS as the secretariat and the institutional head for the food fortification program in the country, the NFA included strong representation from the national government, particularly the relevant ministries—Agriculture, Industry and Commerce, and Education and Culture. To fulfill its objectives and address the components of the National Food and Nutrition Plan mentioned in the previous section, the NFA consisted of the following functional and administrative units: an Advisory Sub-Commission and separate Sub-Commissions for Iron; Vitamin A; Iodine and Fluorine; Quality Control and Monitoring; Information, Education, and Training; and Healthy Life. The roles of each government entity were further specified according to their involvement within the sub-commissions.

### Food Producers (Wheat Flour and Sugar)

The feasibility of food fortification and the specific type of fortification program are largely dependent on the food industries—their number, capacity, geographical distribution, organization, and commitment to carry out fortification and sustain internal control of the fortification process. In developing countries, mandatory fortification is more likely when the relevant industry is large and organized. In most cases, it is preferable to have central processing of the food vehicles and the support of the food industry. If the food industry consists of many small, widely dispersed producers, mandatory fortification may be difficult to achieve unless these small units have some forms of

collective arrangement, such as an established industry association.

In the Dominican Republic, both the wheat flour and sugar industries consist mainly of medium- to large-scale plants with the infrastructural and human capacity to use technology for fortification and implement systems of quality control and assurance. The individual producers are also organized in national associations. Of the six existing wheat mills, four of the larger mills were already carrying out fortification voluntarily. These mills, however, wanted a mandatory flour fortification program to be put in place to assure a level playing field for costs in the domestic market. All the mills agreed to greater government regulation of fortified flour, provided that the national program provided support for start-up costs related to purchasing and installing the necessary equipment and training personnel for quality control. Sugar fortification, on the other hand, will be an entirely new intervention in the Dominican Republic. The national sugar institute that liaises between the state and the sugar producers was prepared to make the capital investment to install a central plant that would regularly mix all the sugar with the vitamin A premix, and the sugar producers agreed to cover all recurring operational and maintenance costs, provided that the national fortification program supported the sugar producers with necessary additional equipment and training for quality control personnel in all of the sugar-manufacturing facilities. Both the flour and sugar industries agreed to incorporate a system of quality-control and assurance for the fortification process and the fortified foods within their current good manufacturing practices.

### Consumers

Consumers are the beneficiaries who ultimately purchase or receive, consume, and maintain demand for fortified foods of good quality, particularly in the case of commercially sold fortified foods. In addition to creating and maintaining demand for high-quality fortified foods, consumers could play a role in monitoring and evaluating the food fortification programs. Where associations or organized groups of consumers exist, consumers have even greater collective power to act as “watchdogs” over the public health program by providing feedback and pressuring other entities to take timely action. For example, in Guatemala in

January 1998, the president and the cabinet voted to repeal the existing legislation for mandatory sugar fortification with vitamin A, owing to surging political and economic concerns. Social mobilization grew in response to the decision, and the general public organized in defense of the fortification legislation. Two weeks later, public pressure forced the reinstatement of mandatory sugar fortification (Solomons and Bulux 1998).

Representatives of three civil society groups are represented in the NFA: the Foundation of Consumer Rights (FUNDECON), the National Defense Front for Consumers (FRENADECO), and the Association of Housewife Committees (ACACDISMA). These groups promote education and consumer participation in extending consumer rights and in consumer-related social and economic research; disseminate information on fortified foods through consumer radio programs; and provide education and training to women, particularly in poor sectors. The involvement of these groups in the NFA is fairly new, and it is hoped that their participation will grow and other civil society groups will become more involved in the national fortification program as it is implemented.

### International Cooperation Agencies

International cooperation agencies working in developing countries play a number of roles in public health, such as providing funding or helping to secure funding, advocating specific policies and programs, and providing specific technical assistance or training. In the Dominican Republic, the United Nations agencies such as the Food and Agriculture Organization (FAO), the Pan American Health Organization/World Health Organization (PAHO/WHO), the United Nations Children’s Fund (UNICEF), and the World Food Programme (WFP) and the bilateral agencies such as U.S. Agency for International Development (USAID) and Japan International Cooperation Agency (JICA) worked actively and collaboratively in the process. These international agencies were an impetus for moving forward with the GAIN proposal for national food fortification. They reinforced the multisectoral national fortification alliance and its functions, coordinating a program development team to assemble evidence and synthesize a plan for the national program and providing technical and financial support to strengthen capacity in the specific components of the fortification process.

## Global Donors

Global donors such as GAIN provide a tremendous opportunity for countries to compete for grants, supplementing their own national investments, to implement and reinforce social programs. In 2002, GAIN provided funding for a single agenda—to support countries in implementing national or large-scale programs to fortify staple foods. A country's agenda must be in alignment with the donor's, and opportunely, the Dominican Republic's interest in implementing a national food fortification program matched GAIN's funding priority. The donor also often establishes a system of accountability and a "trustee" at the global, national, or local level to assure that funds are used according to the proposed plans. This layer of administrative and technical accountability could be seen as an added benefit or burden to country actors and programs. Given that the grant terms were still under negotiation at the time of this writing, it is still unclear how donor relations related to this program will play out in the Dominican Republic. With money, however, come expectations. What are the donor's expectations and its expected roles? What are the expectations of the different actors at the country level? And to what extent will the proposed national fortification program be driven by the country actors or by the actors' attempts to meet donor expectations?

## **Policy Options: To Fortify or Not to Fortify?**

### The Food Fortification Program in Context

As already discussed, there are different types of fortification programs and various types of evidence that must be considered before deciding whether to fortify a food item and how. In summary, the following factors should be considered to determine the food fortification program best suited to the country context:

- the public health need or risk of deficiency, as determined by the severity of the problem and its prevalence within a population group;

- the features of the proposed industry sector in terms of the number, capacity, and geographical distribution of producers, as well as the presence of any government support or control, and the prevailing commercial environment;
- the relevant population's level of knowledge about the importance of consuming fortified foods or their interest in consuming fortified foods, and the level of resources available to implement and sustain specific nutrition education programs;
- the political environment, particularly the acceptable level of government intervention and the value placed on informed consumer choice; and
- the food consumption pattern and the technical suitability of candidate foods as vehicles for fortification.

From an economic and political perspective, the feasibility of any food fortification program depends on its cost-effectiveness. Thus, a cost-benefit analysis framework should be set up to discuss any proposals for food fortification programs. For example, cost-effectiveness as measured by cost per case of nutritional deficiency averted or cost per disability-adjusted life-year (DALY) saved can help give fortification high priority as a preventive public health intervention. High benefit-cost ratios (comparing the economic benefits and costs of fortification) likewise can justify policies with regard to public sector investments.

Fortified products must be produced and distributed through normal market exchange channels controlled primarily by the private sector. This is an important bottleneck in implementing a fortification program that should continually be monitored, assessed, and supported. To promote continued private sector involvement, the government, international agencies, NGOs, and donors need to work together to create an environment (regulatory or incentive systems) that is conducive for the sector to produce and market fortified products.

Moreover, for adequate decision making, all of the available information—the extent of the nutritional problem, the implications of nutritional deficiencies for individual health and national social

development, analysis of alternative interventions, and the advantages and limitations of fortification—must be widely disseminated. The issues surrounding the nutritional problem and food fortification as a possible solution should be discussed openly from all perspectives by various actors.

### Defining Roles and Responsibilities

A critical next step is the optimal operationalization of the food fortification program, which involves clearly defining and executing the roles and responsibilities related to the following permanent and continuous components of the program:

- multisectoral national fortification alliance;
- food control, inspection, and enforcement;
- program monitoring and evaluation; and
- communication to and among various actors at different levels.

Assignment of these responsibilities should be continually revisited.

### Alternative Interventions

Given that the control of micronutrient deficiencies is an essential part of the overall effort to fight hunger and malnutrition, countries should adopt and support a comprehensive approach that addresses the causes of malnutrition and other often associated causes that relate to poverty and unsustainable livelihoods. Thus, to ensure the success and sustainability of fortification programs, especially in resource-poor countries, food fortification might be implemented alongside poverty reduction programs and various agricultural, health, education, and other social intervention programs that promote the consumption and utilization of adequate quantities of good-quality nutritious foods.

Alternative policies and programs also exist, such as dietary diversification, nutrition education, food safety and public health measures, and supplementation. Many of these different approaches should be regarded as complementary to food fortification, with their relative importance depending on local conditions. These options have their own advantages and limitations. For example, supplementation, which refers to the provision of large doses of micronutrients usually in the form

of pills, capsules, or syrups, is usually the fastest way to control deficiency in individuals or specified population groups. In some cases, however, multiple doses are required; micronutrients must be procured and purchased in a more expensive packaged form; an effective distribution system needs to be established; and consumer compliance is required. Increasing dietary diversity refers to the increased consumption of a variety of naturally occurring micronutrient-rich foods. This approach requires implementing programs to improve availability of, access to, and consumption of adequate quantities and varieties of micronutrient-rich foods, such as animal products and fruits and vegetables. Limitations of this strategy include the need for behavior change and for education about how foods provide the necessary micronutrients and other nutritive substances, and sometimes the lack of resources for poorer populations to provide and purchase higher-quality foods.

In addition to specific interventions to prevent and correct micronutrient malnutrition, more general public health measures are also often required because micronutrient malnutrition is associated with poor nutritional status in general and with infection. These public health measures include infection control (including immunization), malaria and parasite control, and improvement of water and sanitation. Food fortification is certainly one possible answer among a variety of responses, and in all cases, the relative importance of each of these strategies will depend upon local conditions and the specific mix of local needs.

### **Assignment**

Your assignment is to consider any possible unintended consequences of the proposed national food fortification program, recommend alternative(s) to mandatory mass food fortification, and identify the pros and cons of such alternative(s).

### **Additional Readings**

Allen, L., B. de Benoist, O. Dary, and R. Hurrell, eds. 2006. *Guidelines on food fortification with micronutrients*. Geneva: World Health Organization/Food and Agriculture Organization of the United Nations (WHO/FAO).



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