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CARMEN Policy Observatory



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**CARMEN Policy Observatory for Noncommunicable Diseases:**

**Case Study, Costa Rica —**

***Formulation of the Folic Acid Wheat Flour Fortification Policy***

San José, Costa Rica, 2006

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**Case Study, Costa Rica:  
Formulation of the Folic Acid Wheat Flour  
Fortification Policy**

**Final Report**

**Costa Rica, 2006**

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# Table of Contents

I. Introduction.....	1
II. Background .....	2
1. Costa Rica’s Political and Administrative Characteristics.....	2
2. Health and Demographic Indicators.....	3
3. The CARMEN/CINDI Initiative .....	3
4. CARMEN NCD Policy Observatory .....	4
III. Framework.....	5
IV. Objectives.....	10
General Purpose.....	10
Specific Objectives .....	10
V. Methodology.....	10
Sources of Information.....	11
Document Review and Analysis .....	12
In-Depth Interview .....	12
Selection of Key Informants .....	14
Data Analysis .....	15
VI. Analysis of Results.....	16
1. Context of Policy Formulation.....	16
1.1. Economic Model and Food Security .....	16
1.2. State Reform, Health Sector Reform .....	18
1.3. The Country’s Economic Status in 1996.....	19
1.4. Health Status in 1996 .....	20
1.5. Evolution of the Population’s Nutritional Status .....	20
2. Identification of the Problem, and Placing it in the Agenda .....	22
3. Proposed Solution.....	24
3.1. Food Fortification Experience in the Country .....	24
3.2. Influence of International Forums .....	26
4. Policy Negotiation Process.....	27
4.1. First Stage: Establishing a Base of Scientific Evidence and Strategic Alliances.....	28
4.2. Second Stage: Building a Technical-Political Alliance .....	31
4.3. Third Stage: Meeting with the Mill Owners .....	37
5. Policy Design and Implementation.....	44
5.1. Adjusting Criteria for Standardization .....	44
5.2. Drafting the Decree .....	47
VII. Conclusions .....	50
VIII. Lessons Learned .....	56
IX. Bibliographic References.....	57
X. Annexes .....	60
Annex 1: Guideline for Documentary Review and Analysis, and In-Depth Interview .....	60
Annex 2: Letter for Key Informants .....	63
Annex 3: Informed Consent Form.....	65
Annex 4: Intentions, Capacities, Needs, Alliances and Conflicts of the Different Actors When the Policy Was Formulated .....	66

# I. Introduction

Noncommunicable diseases have become one of the main public health problems in many countries; in Costa Rica they are the main cause of general mortality. A series of initiatives aimed at preventing them has therefore been undertaken; one of them is the creation of the CARMEN Network, which Costa Rica joined in the year 2000.

CARMEN (the Set of Actions for the Multifactorial Reduction of Noncommunicable Diseases) is a comprehensive approach to noncommunicable chronic diseases (NCD) that has been established in many countries, and which has served as the basis for formulating effective policy and actions to prevent and control these types of diseases in Latin America and the Caribbean.

During the year 2003, the CARMEN Network—whose purpose is to promote a joint agenda for integrated NCD prevention through greater technical cooperation among the countries of the Americas—promoted creation of the CARMEN NCD Policy Observatory, with support from the WHO Collaborating Center on NCD Policy in Canada, to promote a culture of formulating policies based on evidence.

As one of the countries in the CARMEN Network, Costa Rica committed itself to creating the NCD Policy Observatory, jointly with Canada and Brazil, based on case studies focused on the formulation and approval of public policy in the area of nutrition, making it possible to analyze and compare these processes in the three countries. In Costa Rica, it was decided to carry out a retrospective analysis of the experience of formulating, negotiating and approving the folic acid wheat flour fortification policy, which contributes to the reduction of congenital malformations. This policy was used as the basic context for the development of this inter-country project.

This document discusses results of the research carried out on this case study to generate evidence for health policy formulation. The case study deals with an already-approved policy that showed its impact on reducing the prevalence of deficient blood folate levels among women, and the incidence of neural tube defects. The study discusses the context in which the policy was generated, provides details about the elements of the process that promoted or hindered its approval, the sectors that participated, and their negotiations and interests, as well as the State's successes and errors during this process.

This document provides fundamental information which serves to highlight the relevance of establishing the NCD Policy Observatory in Costa Rica to promote the analysis and evaluation of public health policy. By doing so, the country has subjected its public policy formulation and approval to systematic regulations that provide scientific, timely and updated information to effectively and efficiently face health problems.

## II. Background

### 1. Costa Rica's Political and Administrative Characteristics

Costa Rica is located in Central America, with an area of 51.100 km<sup>2</sup>; it is bordered to the North by Nicaragua, to the Southwest by Panamá, to the East by the Caribbean Sea, and to the West by the Pacific Ocean. For political and administrative purposes, the national territory is divided into 7 provinces and 81 cantons; however, for planning purposes, it is divided into 6 regions: Central, Central Pacific, Chorotega, Brunca, North Huetar and Atlantic Huetar.

It is a democratic country whose judicial, economic and social institutions are based on the Political Constitution of the Republic created in 1949, which also included abolition of the army starting in the same year (MH, 2002).

Power is exercised by three different and independent branches: Legislative, Executive and Judicial. Legislative power is exercised by the Legislative Assembly. As indicated by its name, the Executive Power is the State's executing agency and is exercised by the President of the Republic and its Ministers as representatives of the people. Judicial Power is exercised by the Supreme Court of Justice and legally-established courts. Representatives of the first two branches are elected by popular vote every four years.

The Health Sector includes the Ministry of Health, the Costa Rican Social Security System (CCSS), the Costa Rican Water and Sewage Institute (A y A), the National Insurance Institute (INS), Universities and Municipalities.

The Ministry of Health is the governing body of the country's health sector; its power was strengthened starting in 1994 as a result of a structural adjustment that entailed a reorganization of the Health Sector. Since that year, the Ministry of Health has directed and guided the political process for the social production of health, with assistance from other civil and political organizations, working to identify health problems and design and execute interventions.

On the other hand, the CCSS is in charge of direct comprehensive attention to individuals through actions that promote health, prevention, healing and rehabilitation.

## 2. Health and Demographic Indicators

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In 2004, the total population of Costa Rica was 4,248,508, out of which 50.8% were men and 49.2% were women. Most of the population was concentrated in urban areas (71.3%). Population growth for that year was 2.8% (INEC 2005).

According to the population census carried out in 2000, the structure of the Costa Rican population showed a trend towards aging: there was a reduction in population under 15 years of age with respect to the year 1950, and an increase in the population 56 years and older. The 2004 dependency ratio was 60/100 people.( INEC, 2001).

On the other hand, life expectancy at birth of the Costa Rican population has been increasing, from 76.0 years in 1996 to 77.4 years in 2000, and 78.4 years in 2004. For 2005, the figures were 81.0 and 76.2 years for women and men, respectively (MH 2005).

Infant mortality rate is low and decreasing, being 9.2/1000 births in 2004; the overall mortality rate has remained stable at low levels (3.7/1000 persons).

Regarding overall mortality, diseases of the circulatory system (10.5/10 000 people in 2003) has have been the leading cause of mortality for more than 10 years, followed by tumors (8.2/10 000 people), which is to be expected given that an increased life expectancy at birth also increases people's exposure to risk factors of chronic diseases, such as inadequate diets, sedentary lifestyles, smoking and stress, among others (MH, 2005).

## 3. The CARMEN/CINDI Initiative

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A series of actions aimed at the prevention of noncommunicable diseases (NCD) have been undertaken: in Europe through the Countrywide Integrated Noncommunicable Diseases Intervention (CINDI) program, and in Latin American and Caribbean countries, through the CARMEN initiative.

Both programs promote implementation of the Health for All Strategy in a practical way, providing participating countries with an

*“... approach or framework for activities to prevent and control risk factors that are common to a number of NCDs, such as smoking, high blood pressure, high blood cholesterol and excessive alcohol consumption as well as addressing social and environmental determinants”. (PAHO, 1997)*

The CARMEN initiative is based on the principle of inter-sectoral, multidisciplinary community action, involving all sectors that are responsible for creating socio-economic, physical and cultural contexts that promote health and provide opportunities for choosing a healthy lifestyle.

The purpose of this initiative is to improve health by reducing morbidity and mortality rates through actions focused on prevention and health promotion, thus reducing common NCD risk factors such as an inadequate nutrition, alcohol abuse, physical inactivity, and psychosocial stress (Morice, 1998).

In Costa Rica, the National Executive Committee is in charge of this Program, with participation by the Ministry of Health (coordinator), the Ministry of Public Education, the Costa Rican Institute on Nutrition and Health Research and Teaching (INCIENSA), the Alcoholism and Pharmacodependency Institute (IAFA), the Costa Rican Social Security System (CCSS), the Central America and Panama Nutrition Institute (INCAP)-PAHO, and the PAHO representative in Costa Rica. Its actions are intended to establish an organizational and functional structure that – through a multisectoral approach and strategic alliances – will set forth national policy and guidelines of the initiative in the country. Likewise, it will develop a

*“...comprehensive, interinstitutional and multidisciplinary work, that act individually and collectively on conditioning factors of noncommunicable diseases” (MH, 2000).*

In 1998 the Project was included in the Guidelines on Health Policy for the 1998 - 2002 governmental period, and by the end of 1999 the initiative was implemented in the Central Canton of the Province of Cartago, producing important actions and achievements (MH, 1999).

#### **4. CARMEN NCD Policy Observatory**

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The countries of the Americas face common challenges regarding regulations in NCD prevention policies, since there are at the present critically important knowledge gaps about the effectiveness of certain policies, and a lack of pertinent information for decision-makers and representatives of the region’s organizations (PAHO et al., 2005).

Based on those challenges, and on the need to acquire expertise in systematic policy analysis and evaluation, and to provide support to those in charge of formulating effective and comprehensive NCD prevention policy, in November 2003, during the CARMEN Network meeting carried out in Brazil, the PAHO Member States requested that Canada, through its WHO Collaborating Center on NCD Policy, carry out a fundamental effort to establish a NCD Policy Observatory in the Americas.

The Observatory's **goals** are:

- ➔ To support the formulation of effective and comprehensive NCD prevention policy through systematic analysis of the processes involved in the formulation, adoption, and execution of such policies, and relating this analysis to an evaluation of programs and interventions established through these policies.
- ➔ To strengthen multisectoral collaboration in adopting complementary policies that will maximize NCD prevention.
- ➔ To give NCD prevention a more prominent place in policy-makers' agendas.

Implementation of the Observatory using the case of folic acid food fortification is compatible with national objectives, such as those established in the 2004 - 2008 National Food and Nutrition Plan (MH et al., 2004), whose Policy No. 3 is "*Malnutrition Prevention and Comprehensive and Intersectoral Control on a Timely Basis, with Quality and a Gender Focus*": strategies 3.3, 3.4, 3.5. The Observatory is also compatible with the 2005 - 2010 National Agenda on Research and Technological Development in Health Care (MH, MICIT, UCR, 2004)—specifically, with the *Health Care Policy and Systems area (strategic action No. 5)*, and with the *Food and Nutrition area (strategic actions No. 5 and 6)*. Likewise, it defines a new focus for NCD efforts and provides a platform for further investigations, for joint actions in creating national public health policy and decision-making, as well as among health agencies, institutions or other international organizations.

### III. Framework

The framework for this research was that proposed by the CARMEN Noncommunicable Diseases Policy Observatory (Clotey, 2005), based on a policy cycle made up of four consecutive stages - policy formulation, followed by implementation, evaluation and feedback. For the purposes of this research, emphasis was given to the initial stage of the cycle, i.e., formulation of policy that guides the actions to be developed, which has three phases:

- Defining the agenda: including problem identification and the place of the problem in the agenda.
- Defining the problem: including description of the problem, starting from its causes and possible solutions.
- Decision-making: when policy-makers decide to adopt a policy to face the problem.

There are also three different moments that can be defined in this first stage of the cycle, corresponding to the way in which the policy was created, how it was negotiated to make it feasible, and how it was approved.

The Observatory's proposal also includes discussion of six basic concepts that interact among themselves and contribute particular characteristics to each process in the formulation of public policy. These are context, ideas, policy interests and conflicts, institutions and governmental agencies.

**Context is related to people's living conditions and resources owned by individuals and collectives (in the public and private spheres) to confront their health needs and problems. The dynamics that establish the direction of the determining factors of health and disease—to either improve or impair health—are evident in the context.**

The social response to health-related problems and needs may be translated into policies, programs and services whose creation, and definition of their relevance and reach, must take into consideration contextual elements. Therefore, the political, social and economic circumstances that prevail at the moment when policies are created will define the current elements that will favor or hinder the process, as well as the relevant social forces acting at that moment.

The actors who participate in policy generation, as well as the general population, have their own values and criteria according to their ideological orientation. These ideas represent beliefs and values of different groups and individuals, and reflect different positions with respect to an issue or problem, thus defining policy orientation. Likewise, existing investigations on policy issues provide information not only about the issues being investigated, but also about their implicit approach and values.

Thus, if ideas are shared and accepted by, and relevant to, important groups, they are the seeds for formulating public policy.

In the same way, particular interests play an important role in policy formulation. When a series of interests converge and interact in different groups or on a specific issue, they become policy networks.

Interests are present in both the public sphere and the private sphere. Groups and individuals with definite interests become interest groups, and they interact in both the formal and the informal structure.

These groups have different resources and ways of interacting among themselves:

*“Interest groups are constantly trying to present their point of view about a problem that affects them to the person in charge of formulating the corresponding policy. Some of these groups are well-organized and have considerable resources. Frequently, this capacity enables them to be taken into account in policy formulation processes, before*

*other groups with lesser resources. Up to a certain point, governments depend on interest groups with significant resources to help them make decisions regarding specific problems" (OPS, 2005).*

When a government decides to place an issue on its agenda for discussion and perhaps policy formulation, it does so it through its institutions:

*"These are the formal structures and processes through which those in charge of formulating policy make decisions about public policy issues. Formal structures include the government's executive, legislative and judicial branches; formal rules created through legislation, regulations and judicial decisions, and formal structures (divisions, organizations) and processes are created by the various government branches " (PAHO, 2005).*

Depending on the government's organization, institutions may or may not establish links with each other in such a way that the various sectors can establish their policies, and then perhaps establish a comprehensive approach to a specific health-related need or problem, either dealing directly with the problem or need itself, or orienting the approach towards its determining factors.

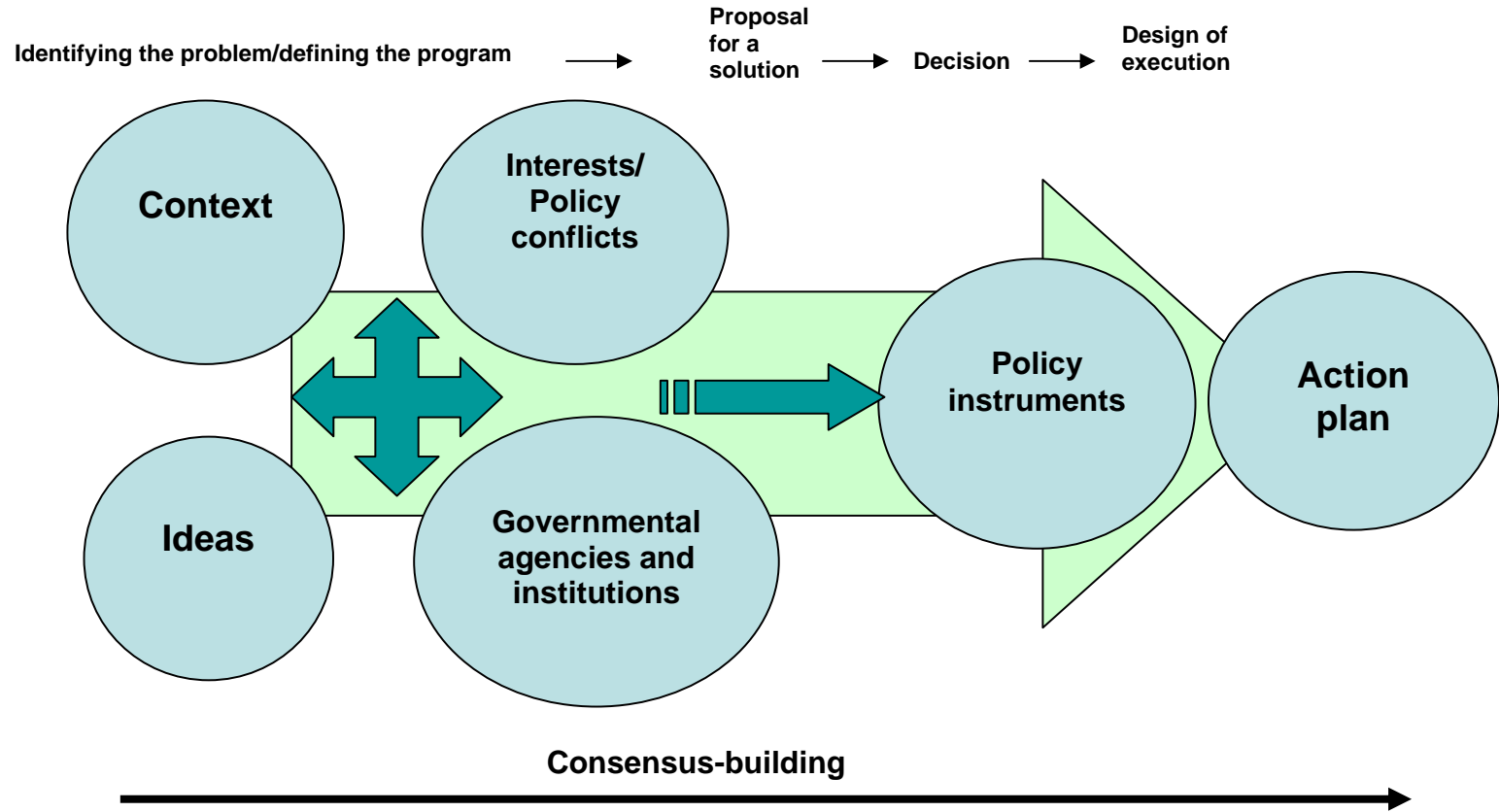
Likewise, governments use a series of political instruments that are a combination of resources to approach policy-related issues, consisting of inputs and outputs of government activities, such as legislation or regulations at a national or international level. These instruments may or may not be coercive in nature.

Effectiveness of these instruments is related to the context in which they are applied, as well as to the prevailing environment at the moment when they are formulated and applied.

For a policy to work, there must be an operating plan, i.e., the interaction of policies of the different government sectors, which makes it possible to obtain a health result—specifically reducing the load of major diseases or conditions in the population—because they have an effect on their determining factors.

Observing the interaction of this set of elements assists a systematic analysis to define which of them facilitate and which of them hinder formulation and execution of the policy under analysis. At the same time, it contributes in a certain way to build consensus that will make it possible to arrive at the final phase of policy formulation. This is shown in Chart 1, which synthesizes all these elements.

**Chart 1: Analytical Framework – Policy Formulation Phase**



Source: WHO Collaborating Center on NCD Policy, Canada Public Health Organization and PAHO. *Methodology Report Project*. March 18, 2005.

It may be said that policy formulation arises as a response by the State to fulfill the needs of the population and regulate its interactions. Political decisions have to be made by the State; however, they are made with participation from individuals and groups that are immersed in a complex social system, which includes, among other things, individual and collective expressions of national identity, ethnos, culture, ways to acquire goods and services, differentiated economic structures, public election mechanisms, organization of groups (Ayala, 1997).

For this reason, policy formulation includes a series of elements involved in the complexity of social relationships, and unequal distribution of resources and power, making it necessary to use different mechanisms to formulate and negotiate them.

As previously indicated, when policy is being generated there are interactions of various groups and individuals, and a series of ideas and interests arise that will also determine alliances and conflicts. These constitute the social actors, defined as:

*“individual or collective subjects that, acting in their own interests, hold the capacity to meaningfully intervene in the situation, or have power that enables them to play a determining role in the policy development process” (Purcallas, 1979, Pg. 231).*

During the process of policy analysis it is necessary to try to understand participating actors in the light of the formulation, negotiation and approval of said policy. Purcallas, 1979, proposes that the following characteristics of social actors must be considered:

- a. **Intentions:** including ideology, idealistic projects, concrete plans, tendencies and reactions to past situations, and values. This information helps to understand the value each actor is willing to give to policy formulation.
- b. **Capacities:** the political power of each one of the actors, the resources they have, their creativity, the way in which they act, and how they work. This provides information about the behavior and resources controlled by each actor, which give them a certain political weight when formulating policy.
- c. **Needs:** the actors' requirements for their plans, their demands and most obvious dissatisfactions. This information helps to understand the interest each actor may have in the creation of a certain policy.
- d. **Alliances and conflicts:** agreements or disagreements with other actors, leadership capacity and capacity to mobilize other actors toward their interests. This information makes it possible to understand the possibilities for building the required consensus for policy formulation.

The objectives of the investigation discussed in this document are to identify social actors and analyze how those characteristics discussed above combined to facilitate or hinder formulation of the folic acid wheat flour fortification policy.

## IV. Objectives

### General Purpose

To analyze the process of formulation, negotiation and approval of the folic acid wheat flour fortification policy in Costa Rica, to obtain evidence for formulation of health policy.

### Specific Objectives

- ➔ Identification of the process of formulation, negotiation and approval of the folic acid wheat flour fortification policy.
- ➔ Exploration of the main conditions and factors that affect formulation and approval of the folic acid wheat flour fortification policy.
- ➔ Statement of the lessons learned during the interinstitutional and inter- sectoral design, implementation and approach to the formulation and approval of the folic acid wheat flour fortification policy.

## V. Methodology

This investigation was carried out according to the qualitative research methodology proposed by the NCD Policy Observatory, based on case studies. Case studies are defined as:

*“descriptions and intensive analyses of a single unit or specific system, such as an individual, a program, an event or group, an intervention or the community” (PAHO, 2005).*

As previously indicated, the case of Costa Rica deals with the formulation and approval of the folic acid wheat flour fortification policy. A qualitative research methodology was used to make a more in-depth and comprehensive analysis of the nature, circumstances, context and characteristics of this case.

A team of nine investigators carried out the research. They were employees from the Ministry of Health, the CCSS, and INCIENSA. They were previously trained in qualitative research methodology, and were accompanied by an expert on qualitative research during the different phases of the research process.

## **Sources of Information**

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Sources of information included documents about the subject, and key informants. These sources were chosen in such a way that contrastable data could be obtained about the diversity of perspectives involved. The methods used were document review and analysis, along with in-depth interviews with key informants.

## Document Review and Analysis

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Technical documents, government plans, official reports, correspondence from the relevant period, newspaper and magazine articles, and official decrees were analyzed, as well as information from other sources such as journal articles. The documents were selected according to the criteria of experts on the subject, and are enlisted in the bibliography.

A guide for the review and analysis of documents was prepared, and key concepts established in the framework for in-depth interviews (Annex 1). This helped the researchers to classify the information gathered.

## In-Depth Interview

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In-depth interview was defined as follows:

*“...a face-to-face encounter between researchers and informants seeking to understand the informants’ perspective regarding their life, experiences or situations as they express them with their own words” (Taylor and Bordan, 1998).*

As a qualitative method, an in-depth interview is not intended to have a restricted direction established by the researcher, or to be structured or standardized—it is basically open. It is also based on the premise that investigators themselves are the research tool, rather than a protocol or interview form. It is based on an interview guide that guides the encounter, but does not determine its outcome.

In-depth interviews were carried out to learn about the different perspectives of actors participating in the process of formulation and approval of the folic acid wheat flour fortification policy, making it possible to retrieve the internal dynamics of a complex process involved in the formulation of public policy in a specific case.

To achieve this goal, an interview guide was created with open questions (Annex 1), making it possible to get deeper into the subject guided by basic concepts of the framework:

- Context
- Ideas
- Interests and power
- Institutions
- Policy tools
- Policy action plans

The review of documents and interviews with key informants permitted cross-checking of information, making it possible to ensure the investigation's internal validity.

Interviewers received training to carry out the interviews, as well as to play an observer's role. Each interview was carried out by two investigators: one conducting the interview, and the other one as an observer, taking notes of relevant elements in a research diary, and providing support to the interviewer whenever required.

Interviews were recorded with previous consent from interviewees, and then transcribed by a person that had been trained to perform that task. Transcriptions were then reviewed by interviewers and handed back to interviewees, so that they could check them, correct them or add whatever they deemed pertinent (member control). Final versions of the interviews were then analyzed. Each interview was assigned an alphanumeric code to ensure informant anonymity.

Before the interview was conducted, all key informants received information about the nature of their participation in the study, were asked to consent to participation, and to sign a document indicating that they understood and accepted the terms in the corresponding document (Annex 2). They were assured of anonymity - that any report of the results would be generic and not attributed to any particular person, organization, project or institution.

## Selection of Key Informants

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Interviewees or key informants were selected according to their knowledge, experience and work on the subject of the folic acid wheat flour fortification policy in the country. Even though the “snowball” sampling method was initially considered, selection was made based on criteria from the technical team that conducted the process of formulation of the folic acid wheat flour fortification policy, using responses to the following questions:

1. Who are the experts in wheat flour fortification?
2. Who are the people with most expertise with wheat flour fortification policy?
3. Who were the persons who participated at that moment in the process of formulation, negotiation and approval of this policy?

Twenty-two persons were selected, out of which 20 agreed to be interviewed:

- Two officials from the Ministry of Health (political level).
- Six technicians from the Ministry of Health (2 medical doctors, 4 nutritionists) that participated in the policy formulation process, or belonged to the Ministry of Health’s Nutrition Division at the time of policy formulation.
- A technologist from INCIENSA who participated in development of the Nutrition National Survey and in the policy formulation process.
- An attorney who represented the Ministry of Health processing legal instruments such as decrees, regulations, and other policy instruments, and participated in the process of formulation and approval of the folic acid wheat flour fortification decree.
- A representative from the Ministry of Economic Affairs, who participated in negotiations with the industrial sector and in preparing the decree.
- Two representatives from INCAP who had an active role in the policy formulation process.
- A representative from UNICEF who provided advice to the Ministry of Health technical team at that moment.
- Two technicians who worked in the Pharmaceutical Company A and participated in the policy negotiation process with the industrial sector.
- Three persons who held managerial positions in mill industries when the policy was formulated, negotiated and approved.
- A manager from the food industries association who participated in policy negotiation and approval.

The research team coordinator made the first contact with interviewees over the telephone. During this first contact they were provided with information on the case study, at which time their consent was requested and an appointment for the interview

was programmed. Most people were interviewed only once, but two of them were interviewed two or three times each.

## Data Analysis

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Research diaries used by investigators during the interviews, and study of documents made it possible to create memoranda in which researchers took notes of their impressions, interpretations and questions that arose during the interview process. Therefore, data were analyzed throughout the investigation process, and not just after data had been collected.

In addition, the research team performed a content analysis of the documents and interviews through an open-ended codification process. Data were closely examined, breaking them into parts through microanalysis to find the meanings contained in the words used by interviewees, and information found in the documents. A systematic inductive consideration of the subjects and data tendencies was used to classify ideas and concepts into categories according to their primary characteristics.

Then an axial codification process was used that made it possible to establish relationships among categories and sub-categories pertaining to the questions of when?, where?, how?, and with what consequences?

The meanings drawn from the data were then interpreted within the context in which the policy formulation process took place. Structural and process elements were identified (Strauss and Corbin, 2002). The term “structure” refers to the conditional context in which policy formulation took place, while the term “process” is defined as the sequence of actions and interactions that occurred during policy formulation over time. This made it possible to understand the way in which analysis categories were defined through the policy formulation development process. In this way, it was possible to detect conditions and factors that facilitated or hindered this process.

As indicated by these authors:

*“... the structure or conditions define the scenario, i.e., create the circumstances under which problems, issues, facts or events related to a given phenomenon arise or occur. The process denotes the action/interaction - through time - of the people, organizations and communities, regarding certain problems and issues. Combining structure and processes enables analysts to perceive some of the complexity that is an important part of life (...) I you study only the **structure**, then you learn **why**, but not **how** certain events occur. If you study only the **process**, then you understand how people act and interact, but not why. To come to understand the dynamics and evolving nature of events, one must study both the structure and the process”.* (Strauss and Corbin, 2002, pg. 139)

The results produced by following the logic indicated above, showing how the context articulated (structural conditions) with the process of interaction among the various social actors to achieve the policy formulation, are presented below.

## VI. Analysis of Results

### 1. Context of Policy Formulation

To understand the process of formulation, negotiation and approval of the folic acid wheat flour fortification policy, it is necessary to analyze the scenario and circumstances that made it possible. The phenomenon is placed in context, i.e., a structure of conditions that framed the actions and interactions of different social actors, providing this policy formulation process with particular characteristics. This process of formulation, negotiation and approval of the folic acid wheat flour fortification policy occurred in 1997, and putting it into context implies relating it to the country's situation at that moment.

#### 1.1. Economic Model and Food Security<sup>8</sup>

The 1980s and beginning of the 1990s were characterized in Costa Rica by complex transformations in the economic, social and political spheres. There was a transition from an economy regulated by the State to a free-trade open economy. With regard to food security, during the decade of the 1970s and beginning of the 1980s national food policy was based on food availability through local provision of staple products. As a result, domestic policy was oriented toward regulation of prices by the State, subsidy of domestic products, and import and export tariffs and licenses to achieve food self-provision in a timely and stable manner from an inward-looking development model sustained through protectionist measures. (Costa Rican Government, 1997).

At the beginning of the 1980s, the country underwent an economic crisis that resulted in an important deterioration of macroeconomic indicators. The inadequacy of the Import Substitution Model (ISM) used in the country since the end of the 1950s became evident. After this crisis there was a stabilization period during which measures were taken to reduce fiscal and commercial imbalances, and to control inflation. Government expenditure was reduced, and the cost of living rose due to rises in public services and taxes, and salary austerity policies.

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<sup>8</sup> Food security is "is the condition in which all people enjoy access to the food they need in a timely and permanent basis, in the proper amount and quality, for their adequate consumption and biological use" (INCAP/OPS, quoted by the Costa Rican Government, 1997).

To stabilize the balance of payments, the dollar exchange rate was adjusted, and exports were encouraged, replacing the Import Substitution Model with the Export Promotion Model (EPM). This was followed by a structural reform process that extended from the second half of the 1980s through the beginning of the 1990s. This reform was motivated not only by the exhaustion of the ISM, but also by pressure from international financing organizations, especially the International Monetary Fund (IMF) and the World Bank (WB), which demanded greater external opening and increased participation of the private sector (Villasuso, 1998).

At the end of the 1980s and during the 1990s, changes were even more oriented towards an outward-facing development model. The opening of commerce that started in 1985 with the structural adjustment programs (PAE I and PAE II) and Costa Rica's accession to the GATT in 1990, the passing of the Competition and Effective Defense of Consumers Law in 1994, and reorganization of the State during the 1990s, reflect a substantial change that had an effect on the State's intervention mechanisms in the national market of staple products.

The structural transformation was reflected in different dimensions. From the economic perspective, the starting premise was that international commerce must be the motor of development, which required national competitiveness in external markets under the rules of free trade. This implied elimination of distortions caused by State intervention in the markets, which had an impact on imposed protectionist barriers that previously permitted restriction of imports in order to protect domestic production. At the same time, economic blocs arose, seeking to strengthen regional commercial actors, grouped around negotiation processes and agreements inside the blocs where the nature, volumes and direction of trade flows were established.

Competitiveness thus emerged as a new value that entailed necessary adjustments in the public and private sectors. The State had to assume a facilitating role in production, the market and the agro-industrial sector, abandoning its interventionist role. National and international policies became subject to global economic trends.

In the case of the flour industry, which is of interest in the present case, Costa Rica imported wheat flour from the United States until the end of the 1960s. When the import substitution model was developed, the first national wheat processing industry appeared in 1967 (Mill 1) governed by the Industrial Development Law. This mill was a monopoly for more than a decade, and wheat supply was concentrated and regulated by the State through the National Production Council (CNP). With the liberalization of the national economy, the second mill (Mill 2) appeared in 1979, and for the first time the wheat flour production monopoly in the country was broken. The CNP lost control of wheat imports and import barriers, and price control barriers on wheat and bread disappeared.

As described by an interviewee, by 1997

*“The country had undergone an opening process, and liberalization of old barriers to free trade. In the case of wheat mills, a privatization process of imported wheat to the country had occurred (...) Price control for wheat flour and breads and their by-products had been abolished. It was a process in which there was a great deal of competition between the mills, because the large mill (Mill 1), that had had the monopoly here was competing for the first time against a small mill (Mill 2)” (INF19).*

## 1.2. State Reform, Health Sector Reform

The economic crisis of the 1980s and macroeconomic stabilization policies that began at that time also challenged the sustainability of the Costa Rican Social State, raising concerns about the effectiveness and efficiency of public expenditure in health care. From that time on, State reorganization processes started to directly involve most of the country's welfare and social assistance institutions.

In the health care area, the Health Sector Reform Project was approved and its execution begun in 1994, with support from international organizations such as the Interamerican Development Bank and the World Bank. For Costa Rica, the reform entailed extensive institutional transformations intended to generate greater efficiency; among them, the segregation of institutional functions for provision of public health services, and administration carried out by the State. This implied a reorganization of institutions; for instance, some functions and resources – such as those related to health promotion and disease prevention – that had been assumed by the Ministry of Health were transferred to the CCSS, while the Ministry of Health was assigned the exclusive role of Governing the Health Sector<sup>9</sup>

Güendel (1997) summarized this situation as follows:

*“The Health Sector Reform Project has lead the discussion toward reform instruments, and proposes a target image of the public health system based on three aspects: 1. Development of a comprehensive health care model combining quality ambulatory and in-hospital medical attention, preventive actions, and community participation in health care. 2. Strengthening the State's governing and regulatory role through the formulation of coherent policies that would articulate the national health system. 3. A resource allocation model that separates financing of services production to rationalize the management approach”. (Güendel, 1997, pg. 114).*

However, one of the weaknesses of this approach observed at that time by the author is the lack of a strong financial patrimony for the Ministry of Health, which raised doubts

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<sup>9</sup> According to Miranda (1997, Pgs. 161 - 62) The Ministry of Health's administrative role is understood as “the capacity of making all technical and social health system entities that are responsible for providing services, able to produce them in coordination, under quality and cost standards, as integrated and executing parties of health policies dictated by the administering Ministry and approved by the National Health Council”.

about its political capacity to assume strong leadership and to be able to exert the required pressure necessary to govern the sector.

### 1.3. The Country's Economic Status in 1996

Placing ourselves at the time when the policy under study was created, we see that the Third Report on the State of the Nation of 1996 (Proyecto Estado de la Nación, 1997) – which falls into that time period – states that the economic recession and transition towards a more open and less regulated economy, had exclusionary effects on some parts of the population, especially affecting women and rural areas, tending to widen structural equity gaps within the country. The report stated that the national financial base did not have sustainable conditions for the reduction of poverty.

It also stated that 1996 was one of the worst years for the country's economy since the 1980-82 crisis. Overall and per capita production decreased in real terms for the first time in 15 years, and there was visible deterioration in the labor sphere (increase in open unemployment, as well as in visible and hidden underemployment, and the rate of underemployment of the work force reached almost 14%).

Loss of dynamism in the economy leads to increased poverty, and the report mentions decreases in the purchasing power in the middle and low income groups of the population. Poverty, which had been slightly decreasing over the previous years, began to increase between 1994 and 1996. The poor from the countryside and families that lived in extreme poverty showed more difficulties than the rest of the population in overcoming these circumstances. Noticeable equality gaps were seen between urban and rural populations, and between the central region and the rest of the country. The worst living conditions within the country were in cantons near the coasts or borders, and in those regions that were more dependant on agricultural production for the internal market, especially in the case of producers of basic grains such as corn and beans. In addition, there were strong consequences of natural disasters such as hurricane Cesar, which brought about losses of millions, once again affecting the poorest people of the country and causing new pressures on the government to pay for damages.

According to data provided by the General Direction of Statistics and Censuses (DGEC), in 1995 households that lived in a situation of poverty represented 20.4% of the country's total population; this figure rose to 21.6% in 1996. According to data from the 1996 Multipurpose Household Survey, the income of 141.477 families was under the minimum required to purchase the Basic Food Basket (BFB)<sup>10</sup>, signifying that 13.551

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<sup>10</sup> The BFB is defined as "The group of foods expressed in sufficient amounts to satisfy, at a minimum, the basic caloric needs (energy), of an average household of a population of reference" (INCAP/PAHO, 1992, quoted by the Government, 1997)

families had been added to the poorest groups in the country (DGEC, 1996, quoted by the Government, 1997).

On the other hand, a restrictive monetary and fiscal policy reduced public sector investment. Private investment stagnated, and imports increased moderately, while growth rates of exports were reduced far below the average of previous years. This happened in an economy that was increasingly open to international markets.

#### **1.4. Health Status<sup>11</sup> in 1996**

By 1996, life expectancy at birth was estimated at 76.3 years: 79.2 years for women, and 74.5 years for men. The overall mortality rate reported that year was 4.2 per 1000 people, and infant mortality rate was 11.8 per 1000 born alive. This last rate was part of a systematically decreasing pattern since 1986, when the rate was 17.8 per 1000 live births. The four main causes of infant mortality between 1991 and 1997 were:

1. Diseases during the perinatal period
2. Congenital malformations
3. Respiratory system and cardiovascular diseases
4. Infectious and parasitic diseases

Within the 1990–1997 period, the behavior of mortality for the first five groups of causes had been similar: mortality caused by circulatory system diseases occupied first place, with a rate of 11.1 per 1000 people, and second place was occupied by tumors, with a rate of 7.8 per 1000 persons.

#### **1.5. Evolution of the Population's Nutritional Status**

Before 1996, four national surveys had been carried out (in 1966, 1975, 1979, and 1982) that allowed observation of the evolution of the population's nutritional status, in particular maternal and infant nutrition. In 1966, the nutritional profile of the Costa Rican population was very similar to that of third world countries. These problems included caloric-protein malnutrition, hypovitaminosis A, endemic goiter, and ferropenic anemia. In 1966 the population younger than six years of age showed 57.4% malnutrition, and 13.7% had moderate or severe malnutrition. This situation started to improve through the promotion of health policies such as strengthening the Nutrition National Program, promotion of the primary health care strategy, and social welfare programs aimed at social groups with limited economical resources; an improvement in the population's level of living also contributed to the change. By 1982 a considerable reduction in the percentage of malnutrition among school children had been achieved (30.9%).

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Ministry of Health, 2000.

Five height censuses had also been performed with first-grade students between 1979 and 1989, and comparative data showed that the percentage of girls and boys with height retardation had decreased from 20.4% in 1979 to 9.3% in 1989 (Ministry of Health, 1995).

Malnutrition decreased, while overweight became an increasing problem in children and adults, particularly among women, marking a change in the population's nutritional profile that became more similar to that of developed countries. (MIDEPLAN, *Panorama Nacional*, 1996, quoted by the Government, 1997)

The different surveys show that people had deficiencies of several micronutrients, principally iron, iodine, vitamin A, and fluorine. Anemia of nutritional origin was identified as having been a problem since 1966, primarily caused by iron deficiency, and to a lesser degree by folic acid deficiency. Measures adopted to reduce this problem included daily supplementation of iron for gestating women and for boys and girls under one year of age, as well as wheat flour fortification with iron and other vitamins.

Prevalence of endemic goiter due to iodine deficiency was 18% in 1969; thanks to salt iodization it went down to 3.5% in 1979. Retinol (Vitamin A) deficiency was also detected as a public health problem in 1966, affecting 32.5% of preschool boys and girls with low and deficient serum retinol values. By 1979, the prevalence of this condition went down to 2.3%, and in 1981 it decreased to 1.8%, thanks to the enrichment of sugar with Vitamin A that started in 1974, and the distribution of whole milk to 30% of preschool children. However, this measure was discontinued in 1980, which brought back vitamin A deficiencies in the population. At the same time, the problem of dental cavities caused by lack of fluorine was faced with salt fluoridation beginning in 1983, which produced favorable results.

On the other hand, since the 1994-1998 administration, there had been concerns about the anemia suffered by people in the country, and a special concern for reducing the level of poverty.

The National Health Policy of the 1994–1998 period established for the Social area focused on:

*"Assisting those that were more economically and socially vulnerable in the population, particularly children, adolescents, the elderly, native Americans and the disabled, seeking to ensure real equality of opportunity "* (Ministry of Health, 1995, pg. 38).

During this administration, three fundamental policy instruments were developed which placed nutritional problems on the agenda. They were:

- A Declaration to create and execute an Agro-alimentary and Nutritional Plan, signed by the Costa Rican Government on the World Food Day, October 1994.
- A National Anti-Poverty Plan, November 1994.
- A National Health Plan, placing priority on attention to anemia.

Following these guidelines and the country's health needs, the Ministry of Health established actions for taking care of nutritional problems and ferropenic anemia as a health priority, as shown in the following documents:

- ➔ A 1995 Ministry of Health Annual Report: stating that "*Promoting nutritional food security and preventive nutrition*"<sup>12</sup> was a strategic action within the National Health Policy 1994–1998, because it had been determined that 35% of children and pregnant mothers covered in the study of growth and development had anemia caused by iron deficiency.
- ➔ The comparative study on the nutritional status of preschool children covered by the Primary Health Care Program in Costa Rica between 1994 and 1995 showed an increase in moderate malnutrition from 2.01% to 2.65%, and in mild malnutrition from 16.1% to 19.6%, with a slight nutritional deterioration among those younger than 6 years of age who were covered by the Primary Health Care Program (Ministry of Health, 1997, pg. 3).
- ➔ The results of the 1996 National Nutrition Survey were an important input to policies orientation, plans and programs related to the food and nutrition field, making it possible to identify nutritional problems, as discussed previously.

All of this helped to create the conditions to place the specific anemia problem on the health agenda. Later, the problem of congenital malformations would be addressed as part of health problems related to folic acid deficiency.

## **2. Identification of the Problem, and Placing it in the Agenda**

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Faced with this situation, it became evident that it was urgently necessary to carry out a fifth national nutrition survey that would indicate the evolution of nutritional problems in the country, with up-to-date information.

The survey's results showed a decrease in moderate and severe malnutrition between 1982 and 1996, which went from 6.3% to 5.1%. Mild malnutrition went from 24.6% to 17.3% during the same period. Preschool children showed a decrease in moderate and

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<sup>12</sup> Idem, Pg. 41

severe height retardation, going from 7.6% in 1982, to 6.1% in 1996. Mild retardation went down from 21.7% to 15.3%.

Caloric-protein malnutrition is not now considered to be a public health problem; however, this is not the case with micronutrients, and micronutrient deficiencies are known as “hidden hunger” (because in general, the symptoms of such deficiencies are not visible at first glance).

The 1996 survey showed that iodine and fluorine deficiencies were no longer nutritional problems in the population—the country had reached the goals set for the year 2000. On the other hand, a high deficiency in micronutrients was found, such as vitamin A deficiency, which again became a health problem. It also showed that nutritional anemia continued to be a moderate public health problem with a 27.9% prevalence among gestating women, 26.0% among preschool children, and 18.9% among women in fertile age. The main cause was iron deficiency<sup>13</sup> (44.6% of gestating women and 24.2% of preschool children had their reserves depleted), followed by folate deficiency, whose prevalence of deficiency among women of child-bearing age was 24.7% and 11.4% among preschool children.

Iron deficiency problems persisted, with a constantly high prevalence of ferropenic anemia since 1966. This problem has been greater in rural areas, where prevalence reaches 32.7%, as opposed to 16.6% in urban areas, without regard to sex (Ministry of Health, 1997<sup>a</sup>).

Folate deficiency is not only associated with anemia. Folic acid is an essential nutrient for the development of children’s neural tubes during the embryonic phase. However, survey results show that this deficiencies in this micronutrient were exclusively related to anemia.

This shows that extensive sectors of the population are consuming deficient diets, both in quality and quantity, and, as stated by one of the informants, alimentary patterns are increasingly poorer, monotonous and deficient in micronutrients:

*“...the diet of Costa Ricans is becoming increasingly monotonous. There is not as much variety as there used to be, when things were a little better, and everybody could eat ‘gallo pinto’<sup>14</sup> (...) Foods of animal origin are consumed with less frequency every day, and are more expensive; even vegetables and grains are consumed with less frequency every day.*

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<sup>13</sup> Iron is an essential component in the formation of red blood cells, whose main function is to carry oxygen throughout the body. Among nutritional anemias, the most important ones are the result of dietary deficiencies of iron and folic acid. Worldwide, they are an important public health problem, due to their magnitude and relevance to countries’ economic and social development. Anemia is defined as a reduction of hemoglobin levels in the blood; it varies with age and sex, and the most vulnerable groups are pregnant women, children younger than 6 years of age, and women of child-bearing age (15 to 44 years old), because they require greater levels of iron and other micronutrients. For instance, women of child-bearing age lose an amount of blood every month with their period. (Press release, Vice-Minister of Health, 5/27/1997).

<sup>14</sup> Traditional food made by mixing rice and beans.

*It therefore becomes necessary to add micronutrients, so that the population can have access to them” (INF01).*

In the findings of the 1996 survey, the technicians in charge stated that:

*“Therefore, the recommendation is to review, adjust, and strengthen – in the short term – strategies to reduce prevalence of nutritional anemia, and hypovitaminosis A, and to increase coverage and optimization of existing micronutrient programs” (Ministry of Health, 1996, pg. 6).*

### **3. Proposed Solution**

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The response or solution to folic acid deficiency was framed within the strategies developed some decades ago by the Ministry of Health’s Nutrition Division. Food fortification was a well-known and proved measure, as will be shown below.

#### **3.1. Food Fortification Experience in the Country**

The idea of food fortification, as a public health measure, was not new in the country. Salt fortification had been considered since the 1940s as an urgent measure to reduce thyroid pathology detected through clinical studies. During that time, endemic goiter had already been identified as a public health problem. The experience developed in other first-world countries on this issue was then taken as a basis for a similar initiative in Costa Rica. At the same time, regional investigations carried out by INCAP and the Ministries of Health of the Central American countries and Panama during the decade of the 1950s indicated that anemia represented a generalized nutritional problem in the region. In Costa Rica, this resulted in the first decree passed in 1958 for fortification of wheat flour with iron, calcium, thiamine, niacin and riboflavin.

However, results of these first initiatives did not have the expected impact because it was not possible to ensure the desired fortification and required coverage. It was necessary to meet a series of conditions in order to unite political will, institutional capacity, development of industrial technology, social sensibility and social commitment to make fortification policies effective.

The 1966 National Nutrition Survey made it possible to measure low levels of several nutrients, making fortification activities more systematic. However, the pioneer salt iodization policy was not feasible until 1972, reducing goiter incidence to the point where it was no longer a public health problem. Social and health policies, and cooperative development of salt businesses contributed to this reduction. In addition, sugar fortification with vitamin A was decreed in 1974. As stated by one of the

interviewees, “[Costa Rica] was the first country in the world where sugar was fortified with vitamin A” (INF13). At the same time, a water fluoridation program was developed to reduce incidence of dental cavities in the population. However, this measure was interrupted in 1980 due to lack of financial resources and coverage problems in rural zones.

The foundations that would permit adoption of food fortification from a comprehensive and preventive public health perspective were laid out during the decade of the 1970s. This was done in response to a particular concern regarding insufficiencies and inequities in the population, which were expressed in health problems. Primary preventive health care programs were established and universalization of health services was promoted, thus increasing the population’s access to health care. Rural and urban-marginal zones received special attention, and food distribution and nutritional assistance programs were launched. The context favored inclusion of micronutrient deficiencies within universal social policies, seeking to improve the population’s life and health conditions.

Food fortification was introduced in nutritional programs as a working area. A food fortification program with three sub-programs was included in the 1974–1980 National Food and Nutrition Plan:

- a. Salt iodization for human consumption, to reduce endemic goiter.
- b. Sugar fortification with vitamin A to reduce hypovitaminosis A in vulnerable groups.
- c. Wheat flour enrichment with ferrous salt to reduce prevalence of iron deficiency anemia.

The choice of the food that would be used as a vehicle to carry micronutrients was based on national consumption studies. Foods chosen had to be safe and practical in terms of their fortification, of universality of use, low cost, and safety for the population.

The State’s role and protectionist legislation during that decade played an important role in organizing the national industrial sector, and in providing credits for its strengthening and technological development which permitted improvements in production and regulation of the quality of the food produced. This favored food fortification policies, and made them feasible, as shown in the salt iodization experience<sup>15</sup>.

Important economic, social and political changes took place during the decade of the 1980s. However, fortification policies did not decline. Instead, they found a new scenario where industrial development and quality of products acquired an important value in the face of free market competition. Importantly, at the beginning of the 1980s, when water fluoridation was interrupted, the National Congress of Odontologists

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<sup>15</sup> Castro, C. 1997

recommended salt fluoridation. This program started in 1987 with support from the Kellogg Foundation, which contributed to the introduction of new technological procedures to fortify salt with iodine and fluorine.

During that decade, more systematic controls were established and technological development made possible more effective fortification methods; also, clearer and more stringent regulations were established regarding physical-chemical food quality and fortification procedures. The State played a role in regulating food imports with respect to established fortification standards.

During the 1990s new legislation was created as a response to economic liberalization processes, leading to the elimination of licenses, recommendations and permits that the State had required for imports<sup>16</sup>, as well as requirements and regulations for economic activities<sup>17</sup>. However, this did not necessarily weaken food fortification policies, since they became valid and justified issues that the State regulated.

World forums and the compromises assumed by governments in them became a new driving force for the food fortification strategy during the 1990s, as can be seen below.

### 3.2. Influence of International Forums

During the International Conferences on Nutrition carried out in Rome in 1992 and 1996, ensuring adequate and safe food<sup>18</sup> became again a concern, and there was a commitment of participating countries to:

*"... make all efforts to eliminate before the coming millennium the following problems: famine and famine-related deaths; starvation and widespread chronic hunger; under-nutrition, especially among children, women and the aged; other important micronutrient deficiencies, including iron, iodine, vitamin A; diet-related communicable and non-communicable diseases"*<sup>19</sup>.

During the Sixth Conference of Wives of Heads of State and Governments of the Americas carried out in La Paz in 1996, which focused on the "Rights of Women and Children within the Framework of Sustainable Human Development"<sup>20</sup>, a commitment was made to foster and support implementation of the regional project for the reduction of malnutrition caused by micronutrient deficiencies in the hemisphere, in the light of

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<sup>16</sup> Law # 7473 Execution of the Agreements of the Uruguay Round of Multilateral Trade Negotiations, 1994. Quoted by Castro, 1997.

<sup>17</sup> Law # 7472 Promotion of Competition and Effective Advocacy of Consumers, 1995. Quoted by Castro, 1997.

<sup>18</sup> World Food Summit (November 13-17, 1996)

<sup>19</sup> International Conference on Nutrition. A confirmation of the FAO commitment to improve nutrition. 1992

<sup>20</sup> Declaration of Peace. Sixth Conference of Wives of Heads of States and Governments of the Americas, Bolivia. 1996

the documented high rates of anemia and their severe consequences for children and women.

In brief, there were a series of international and national commitments:

- The World Summit for Children. New York, 1990
- Conference on Micronutrient Malnutrition, Montreal, 1991
- Central American Summit on Human Development, Children and Youth. Tegucigalpa, 1991.
- International Conference on Nutrition. Rome, 1992
- XLIII and XLIV Meetings of the INCAP Council, COMISCA. San José, 1993
- XX Resolution on the Initiative of Food and Nutritional Safety in the XIV Summit of Presidents. Guatemala, 1993.
- World Food Summit. Rome, 1996.

International conferences contribute guidelines and establish commitments of countries to strengthen nutritional policies. Even though in Costa Rica since the 1970s the intention has been to formulate nutritional policy through an inter-sectoral approach<sup>21</sup>, world conferences provide them with greater support. In the International Conference on Nutrition that took place in Rome in December, 1992, Costa Rica made a commitment to intensify—in the short- and medium term –studies aimed at determining the magnitude and characteristics of micronutrient-related problems to facilitate design of future actions. This was accomplished with the 1996 National Nutrition Survey.

The international conferences mentioned stimulated a special interest in Costa Rica to establish an inter-sectoral plan with measurable objectives that were followed up on and evaluated. For this reason, during the 1990s efforts were made in Costa Rica to strengthen and organize inter-sectoral or inter-institutional actions aimed at ensuring the country's food and nutritional security.

#### **4. Policy Negotiation Process**

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The formulation and negotiation process of the folic acid wheat flour fortification policy followed a logical path in which each stage generated conditions for the following ones. As indicated by several interviewees, it was an easy process. This document intends to present the sequence of the process and the way in which consensus was built to arrive at the approval of the decree.

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<sup>21</sup> This is shown by the creation of the SEPAN (the Food and Nutrition National Political Secretariat), as an organization assigned to the Office of the Ministry of Health, which was established by law in 1973 (Ministry of Health Organic Law); among its functions are the formulation of national food policy and coordination of actions in the food and nutrition area.

Cause-and-effect logic is inappropriate in this situation, since it is too simple to explain as complex a process as this one. The intention in this section is rather to define the multiple factors that operated in combination to create the conditions that favored or hindered the process. In particular, it was interesting to focus on those actions and interactions among social actors that were characteristic of the process, and which provided it with dynamism, generating new conditions. For this reason, the intention is to review the process from the perspective and words of the different actors involved.

#### **4.1. First Stage: Establishing a Base of Scientific Evidence and Strategic Alliances**

The 1996 National Nutrition Survey made it possible to obtain an updated diagnosis of nutritional problems, and information about their magnitude and tendencies through time. Nutrition surveillance efforts developed by the Ministry of Health Nutrition Division over decades served as the basis for choosing the policies. At that time the Nutritional Surveillance technical team, consisting of a medical doctor and two nutritionists, became the leading group during the initial and later stages.

However, it is important to emphasize that there was a 14-year gap during which no nutrition national survey had been carried out, which indicates that in previous administrations, nutritional surveillance had not received enough support to develop the required level of national surveillance. As pointed out by one of the interviewees:

*“...it is incredible, because [surveys] are not even very expensive, because there was money for other things, it is necessary to sensitize politicians so they budget money for these extremely important things in public health”. “... a national nutrition survey is carried out precisely to find out how policies and programs can be redirected in order to improve the deficiencies found” (INF15).*

It is therefore important to understand how conditions changed, thus leading to the effective development of the survey in 1996.

According to correspondence between the Ministry of Health’s Nutritional Surveillance Division and other offices and institutions, the National Commission for the Nutrition Survey was coordinated by this Division, and had support from the General Director of the Ministry of Public Health, and INCIENSA’s participation. Political support from health authorities was evidenced by the amount of resources allotted, which in previous administrations had not been provided because financing of other surveys had always come totally from external aid. It took all of 1995 to obtain resources and establish the logistics necessary to carry out the survey in 1996.

This survey involved a high level of coordination among the different institutions and entities inside and outside the Ministry of Health<sup>22</sup>. At an international level, technical assistance from INCAP was fundamental; PAHO and the European Union also provided financial aid. In addition, Pharmaceutical Company A provided reagents for laboratory analyses required during the survey.

The organization and development of the National Nutrition Survey turned out to be a good experience for the development of technical skills, and new alliances resulted from these efforts. It is worth emphasizing several points about the alliance with INCIENSA.

*“...INCIENSA has its own goals and priorities, which in this area coincide precisely with those of the Ministry, and it has a laboratory that fulfills all the needs of the Ministry; I think that it has been a joint effort for what they most need (...) (INF12). People in charge at the Ministry think in the same way (...), on the day that a single child presents a folic acid or vitamin A deficiency, or any type of deficiency, I think that we must continue working on that (...) this has been like a guiding light that has pulled the two of us to work for a common objective (INF 12).*

These words summarize the vision and mission shared by both institutions. Although not explicitly stated, they correspond to a human rights approach, particularly the right to health for all members of a society. As stated by one of the informants *“within a framework of rights, institutional capacity acquires an important role” (INF16).*

During the development of the survey, INCIENSA undertook sample analyses, and together with staff from the Ministry of Health, they received training from INCAP<sup>23</sup>. This aided the installed capacity of the country’s public institutions.

*“Previously, INCAP used to get paid for carrying out the nutrition surveys. We (the Ministry of Health and INCIENSA) decided that we had to do it here; from that moment on we thought about the country, the population. INCIENSA had very valuable people (...) obviously with the collaboration of people from INCAP that trained us, they were always with us” (INF12).*

In addition, there was a special need to plan actions based on evidence about the country’s health requirements in the 1994–1998 administration. The aims of this planning were to reach the goal of Health for All by the year 2000, respond to the Five-Year Plan for Food and Nutritional Security, and respond to the Government Plan,

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<sup>22</sup> According to correspondence between 1995-97 from the Ministry of Health, several institutions participated in the survey process: the General Direction of Health, the Nutrition Division, the Nutritional Surveillance Division, the Direction of Health Laboratories, Medical Services, and the Department of Odontology. Divisions that provided support to INCIENSA included the Scientific Direction, the Technological Nutritional Unit, and the Food Analysis Laboratory. From the General Direction of Statistics and Censuses, the General Direction, the Cartography Department, the Division of Statistical Design and Analysis, and the Sampling Design Section.

<sup>23</sup> Divisions from INCAP that participated in the process were: the General Direction, the country’s Technical Cooperation Agency, the Food Unit of the Science and Technology Area, and experts in statistical design.

which identified as a priority the need to prevent and eradicate “*nutritional anemia and other diseases caused by deficiencies that substantially affect the potential capacity of human development*”<sup>24</sup>. It was therefore considered essential to have available updated, accurate and timely information to guide policies, plans and programs related to the field of food and nutrition.

On the one hand, the Ministry of Health’s technical team in charge of nutritional surveillance was able to establish a strong alliance with the new health authorities, becoming their advisors on nutritional issues and providing technical support to policies proposed by the new government. On the other hand, health authorities provided the support necessary to enable technical processes. The nutritional surveillance team was thus able to position its concerns and efforts within the range of health priorities established by the new government.

The following factors favored these developments:

- ➔ The new authorities were very interested in aiming efforts at primary health care.
- ➔ They started from a public health vision, with a demonstrated commitment to public health development in the country. The Ministry had played a critical role in a previous government in strengthening primary health care. The Vice-Minister had also developed a cooperative model of attention at a local level including health promotion, prevention and attention actions that would become a model when reorganizing health services in the country with creation of the EBAS (Basic Health Attention Teams).
- ➔ There was dynamism and teamwork in the Direction of General Health, and the Minister and Vice minister supported these efforts.
- ➔ The Government Plan created interest in developing a Plan Against Poverty in the social area, and in the health area it had a proposal to face the problems posed by anemia in the country, concerning which there was already some information available from partial investigations.

From this first stage, important alliances were established that would later assist in the policy formulation process. The development of the 1996 National Nutrition Survey thus allowed the creation of a solid platform to support policy, and at the same time, became a staging area for the creation of strategic alliances that would support the policy formulation and negotiation process.

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<sup>24</sup> National Survey on Micronutrients, 1996

## 4.2. Second Stage: Building a Technical-Political Alliance

As previously indicated, the experience of developing the National Nutrition Survey was the beginning of a close collaborative relationship between the Nutritional Surveillance technical team and higher authorities from the Ministry of Health. The General Director of Health made it possible for the technical team to approach the Vice minister, who was in charge of health interventions, and who was also the right hand of the Minister, who trusted her and gave her a fundamental advisory role. In words of the Vic minister: *"[she was] brilliant, efficient and effective, ... I respected her greatly"* (INF04).

But having updated information was not enough for health authorities. A decision had to be made to improve the population's nutritional status. From the technical perspective, the National Nutrition Survey had shown that public health measures adopted to reduce nutritional anemia had not produced observable results in the last decade, making it necessary to promote more adequate measures.

Health authorities entrusted the task of defining the most appropriate intervention strategies to the technical team, as a result of the confidence they had in this team. As the highest authority at that moment indicated *"... I believe that they are good people, well trained"* (INF04). The Vice minister also had great confidence in the technical group, which promoted good technical and political coordination:

*"The technical team always had direct access to the authorities, which facilitated their access to information, decision-making, and transfer of resources"* (INF05).

For the technical team, political support made a great difference in their work:

*"When there is political interest, nothing is delayed, because if they were not sufficiently interested, they would not hinder the work, but neither would they help speed the process"* (INF01).

Authorities thus entrusted the technical team to search for information and analyze alternatives, and to review experiences in other countries.

In turn, INCAP assistance was one of the most important results of strategic alliances in this process. According to correspondence from that period, INCAP established recommendations for folate analyses in the national survey on micronutrients. However, even though investigations carried out by INCAP during the last twenty years indicated that ferropenic anemia in the region was so widespread as to consider them a public health problem, emphasis was given to iron deficiency, and to a lesser degree, to folic acid deficiency. On the other hand, there had been progress in the development of the technological aspects of fortification of food that was universally consumed. Experience indicated that the most appropriate food to fortify was wheat flour.

Support from INCAP became critical in assisting the technical team in the investigation of this problem, and in seeking solutions such as advocacy efforts that had to be carried out with politicians. The INCAP provided knowledge accumulated in other countries, and at the same time deployed its capacity to convince politicians, based on agreements made in the Institution's Consultative Council and Directive Council (in which the General Director of Health and the Ministry of Health participated), where Central American governments made a commitment to fortify food with iron, folic acid and vitamin A. Health authorities had to meet the mandate that they themselves had approved.

When trying to technically justify the measures to be taken, investigative reviews revealed the existence of congenital malformation in association with folic acid deficiency in gestating women.

As indicated before, when the 1996 National Nutrition Survey was carried out, attention was focused on anemia. However, the technical team, with support from INCAP, carried out a literature review which showed that congenital malformations were associated with folic acid deficiency<sup>25</sup>. There had also been successful experiences in other countries that helped strengthen the national proposal.

As one of the interviewees said:

*"...approaching the issue of ferropenic anemia and the alternative of fortification of some foods to fight it, the opportunity to do something about congenital malformations associated to lack of folic acid arose, which was then included in the work plan" (INF 05).*

The interviewee then added:

*"...the concern about folic acid was part of a wider issue: food fortification to prevent anemia. Malformations were not one of the twelve priority points, but indeed, flour fortification was seen as an opportunity to contribute to the reduction of that problem" (INF05).*

The scope of the policy selected and its limitations were also clear:

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<sup>25</sup> Neural tube defects include a whole range of congenital malformations and are produced when the neural tube does not close during the incipient phases of embryonic development. These neural tube defects have been associated with folic acid deficiency since 1930, when Dr. Lucy Wills pointed for the first time at folate as an anemia healing factor, in cases when there is an insufficiency of folate in pregnant women. In addition, in 1964, Hibbard published a scientific document in which he reported a link between certain congenital malformations (not of the neural tube) and folate deficiency. In 1980, Laurence published a clinical essay that showed a 60% reduction in the risk of recurrent neural tube defects in women who took folic acid. In 1991, the CDC published a review of evidence on the prevention of recurrence of pregnancies affected by neural tube defects, and recommended administration of 0.4 mg of folic acid to women who had had a baby or a fetus with some neural tube defect (PAHO/WHO, year not indicated).

*“Taking care of malformations in a comprehensive manner requires more complex interventions. Food fortification and enrichment are broader measures, with less actors involved, and they are less expensive” (INF05).*

Once the deficiencies and population at risk were identified, three types of measures were defined to solve iron and folic acid deficiencies:

- ➔ **Supplementation:** this measure is focused on the population at risk and implies consumption of the missing micronutrient in pills. *“The problem is to have to remind people to take the pill, or they will forget” (INF01).*
- ➔ **Improving the general diet:** this measure implies education and diffusion of healthy diets in the population. However, it requires *“nutritional education, greater availability and people’s access to the foods that are a source of those nutrients and have long-term effects” (INF11).* Foods containing the required micronutrients are not always accessible for the at-risk population, just as nutrient use is another factor that must be considered.
- ➔ **Food fortification:** this measure has an advantage because it uses *“food of universal consumption, of wide coverage, which does not require changes in the population’s eating habits” (INF11)* and *“its effects are seen quickly; its results may be seen in the very short term, at low cost, and populations recover successfully” (INF12).*

The selection of the foods to fortify will depend on the population’s existing eating habits, to avoid changes in food purchase, preparation or consumption habits, so that *“people will not notice any changes, the flavor will not change, and the food’s organoleptic properties (color, smell, flavor) will not change” (INF08).*

Another interviewee stated: *“fortification acts in the following way: first it solves severe cases of anemia, and then it starts to reduce the overall level of deficiencies, up to a point at which this level remains stable and will not go down further, because the causes are not any longer due to folic acid deficiencies, but to other factors” (INF12).*

To make the decision as to whether to *“fortify or supplement, first, there have to be studies on the state of the problem in the population, who, and why. Once you have the basic information, then the decision is made on whether to fortify or supplement. Fortifying is easier because the population is already consuming the food; then, the only thing you need to know is how many grams they consume, to define the dosage” (INF12).*

Out of the three measures, wheat flour fortification with iron and folic acid was chosen based on several technical and political reasons:

### Technical Reasons

- ➔ Bread is one of the foods of mass consumption in the country.
- ➔ Wheat flour is easy to fortify and micronutrients remain as stable as possible until their final consumption.
- ➔ Folic acid is *“a multipurpose micronutrient for megaloblastic anemia and for the prevention of neural tube congenital malformations”* (INF 01).

### Political Reasons

- ☑ Existence of Decree No. 18 of July 28, 1958 which mandated wheat flour fortification with thiamin, riboflavin, niacin, iron and calcium.
- ☑ Negotiation implied agreements with only two mills as external actors.
- ☑ The proposal was feasible, since there were no problems regarding required inputs.

With reference to this last point, the technical team also sought the advice of a pharmaceutical company to obtain information about prices for a premix that would contain the vitamins, its availability, and possible economies of scale and discounts for volume purchasing. This information was critical for the analysis of the proposal's feasibility. It was known that inputs were not a problem, and all this information was to form part of the proposal presented to the mills.

Several points convinced the highest Ministry of Health's authority to accept fortification of wheat flour with folic acid as a pertinent measure for the country:

- ➔ The belief that *“in the face of proven facts that we could bring about health benefits, we had to take the corresponding actions”* (INF04).
- ➔ In 15 years it had not been possible to reduce prevalence of anemia or iron and folic acid deficiencies in the diet of Costa Ricans.
- ➔ The measure did not entail creation of a new decree, but only modifying the existing one, changing the dosage of iron and other complex B vitamins that had already been defined in the previous decree, as well as adding folic acid.
- ➔ The existence of investigations and experiences in other countries that showed successful results in the reduction in the incidence of spina bifida and neural tube defects. *“I was convinced that we had to do it”* (INF04).
- ➔ The wheat flour fortification policy would be an opportunity for health authorities to show the effective exercise of power by the Ministry of Health.

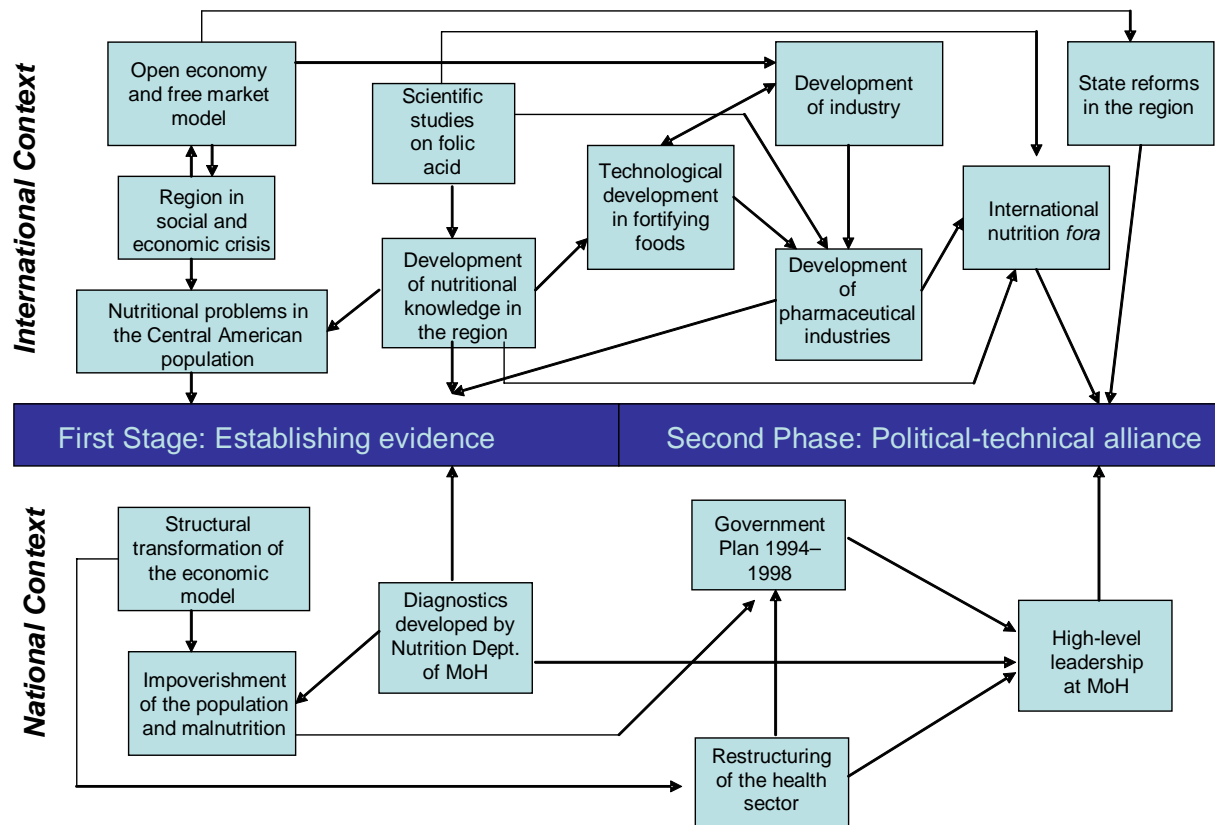
National pride also played an important role in this process, as was emphasized by several key informants:

*“...I feel very proud when Costa Rica is mentioned regarding these issues, mostly in forums, because in other countries politics hinders processes a lot; there are many barriers. In Costa Rica this never happens in the political area, in political decision making, I have never seen or heard that anybody has been opposed to flour fortification, or fortification of any other food”* (INF12).

As a result of the factors discussed above, health authorities decided to revoke Decree No. 18, and substitute a new decree that would include the technical measures required to achieve a true impact on the population's nutritional status. This type of political instrument was always used for all food fortification measures, supported by the Health General Law.

Chart 2 synthesizes the network of conditions and factors that favored the formulation of this policy.

**Chart 2: Network of Conditions and Factors that Facilitated Policy Formulation**



### 4.3. Third Stage: Meeting with the Mill Owners

The analysis of the actors made it clear to the technical and political team that the two mills were the key actors that needed to be convinced. Bread makers, with whom the Ministry of Health had had confrontations because of a measure to eliminate potassium bromide<sup>26</sup>, were not considered. It was decided that the main external actors were the mills, and negotiations with them were sought.

For the health authorities, the issue was not to discuss with millers the possibility of modifying the wheat flour fortification formula, but rather to obtain their support for the decision that had already been made by the Ministry of Health. However, they were aware that a demanding attitude would not contribute to a good environment for making the policy effective. As one of the health authorities stated:

*“... we were not expecting that the millers would accept or reject the decree, since the decision had already been made. We met with them to seek their support, because otherwise, a very expensive control system would have had to be established; you cannot have police at the mills controlling compliance with the measures ” (INF05).*

This meant that the objective was to convince millers of the importance of the measure, and to reach a sustainable alliance with them. Several strategies were prepared for the meeting with the millers:

- ➔ Approaching the proposal from a technical point of view, offering updated information about the population’s nutritional and health problems, why they existed, and possible solutions, as well as information about fortification experiences in the country and abroad.
- ➔ Taking advantage of the alliance with salt businesses: *“... the fact that salt was already being fortified with iodine and fluorine helped us a lot (...) when we called meetings with the millers, we also invited the salt businessmen, because they spoke in favor of fortification, and they also had a public health approach, not an eminently commercial one” (INF01).*
- ➔ Related to the previous point, the technical team had received advice from UNICEF regarding human rights and social responsibility approaches, as a result of which it was decided to approach the proposal with a “social investment” vision (INF11).

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<sup>26</sup> Additive used by bread makers to make the bread rise when it is baked, but the Ministry of Health claimed that it was a carcinogen.

- ➔ Taking advantage of assistance from INCIENSA's Bromatology Laboratory. Pharmaceutical Company A assisted in the process from its first stages, when they presented the millers with the technical details of adding nutrients to food. The MEIC (Ministry of Economy, Industry and Trade) also joined the negotiations with businessmen.
- ➔ Study of premix alternatives and costs, as well as a study about wheat flour prices in the marketplace.

Referring to this last point, health authorities were worried about the cost of fortification. For them, it was necessary to arrive at the meeting with the millers with a strong bargaining card so that they could negotiate that fortification costs were not passed along to consumers through a price increase.

*"...we went completely prepared to convince millers to pay for the costs, instead of the consumers (...) Due to the country's economic status, it was not feasible to say that the price of bread was going to be increased, in spite of the benefit of fortification" (INF05).*

To accomplish this, they studied costs and international wheat price fluctuations, which showed a reduction in wheat prices that had not been passed along to consumers. From the perspective of politicians, the strategic conditions already existed to convince millers about this policy. It was a moment in which there were arguments to counter the logic of trade in which the goal is to earn more and lose less. However, it was not necessary to play that card, since the millers were in agreement from the beginning.

*"we went to the meeting prepared for a very hard negotiation, but at the end it turned out to be easy and speedy, and we obtained full collaboration from the two mills (...) The Minister of Health participated in the activity, which gave the process more strength" (INF05).*

Comparing this negotiation to similar negotiations with other industrialists for food fortification, the highest health authority considered that the negotiation with the millers:

*"...was the simplest process (...) the one with most acceptance from the beginning. I don't remember having any problem, not even minimal opposition " (INF04).*

For a better understanding of this favorable reception from millers, it is necessary to put their situation in the context of the moment of negotiation, specifying the conditions that existed to facilitate the positive attitude of the millers in the face of the proposal from the Ministry of Health.

As previously indicated, Mill 1 was a wheat flour production monopoly until 1979, when Mill 2 was established. This second mill was small throughout the 1980s, but during the 1990s it started to grow. In the words of one of the interviewees:

*“... in 1990, Mill 2 had 12% of the flour market in the country; by 1996, 1997, it probably had about 30% of the market. It grew a great deal, so competition for improving quality, innovation, improving the product, and enrichment, played an important role in brand differentiation, and the qualities of different brands of flour” (INF19).*

By this time, the ISO 9000 standard had become important for ensuring product quality. This brought about research oriented towards maintaining products at competitive levels. Research about folic acid and flour fortification were not unfamiliar to industrialists. Since the 1980s, millers’ international meetings had been taking place to discuss the issue of flour fortification. Vitamin-producing firms gave speeches about them. Governments promoted fortification, and private businesses discussed the issue in sectoral forums. Central American countries were in agreement in this respect, and it was important to act as a bloc within international trade.

At the same time, “trade partners” of the mills, particularly pasta producers, needed to have their products accepted in the United States market, and in order to do so they had to adjust to USDA vitamin enrichment regulations in that country. In that sense, in 1997 Mill 2 was busy trying to upgrade fortification requirements so that they would be equivalent to those of the external market, to respond to pressures from the pasta industry.

*“...at that moment we were trying to help several of our large users of flour by-products export their products to the United States. In that sense, by trying to standardize enrichment requirements with those of the USA, we became pretty much updated regarding those regulations in other countries that were more aware of the effect of folic acid as an inhibiting agent of genetic malformations. For that reason the project was acceptable to... really, both mills, ours in particular and the other one, which were established in the country” (INF19).*

From the perspective of Mill 2, there was a vacuum with regard to State regulations. *“The vitamin complex that had been added to flour was not under any national regulation” (INF 19)*, so that the standards to be applied had to be taken from abroad. Also, specific needs of flour by-products producers were not included in the 1958 decree, because it was specific to wheat flour, and semolina—which is the raw material for pasta products—was not included. Mill 2 was *“voluntarily migrating to American standards” (INF 19)*.

Another important factor was the technological development that had taken place in the industrial sector at an international level to adequately measure micronutrient dosage. The country’s laboratories were not equipped to verify adequate micronutrient dosage. From the point of view of Mill 2, the Ministry of Health was not perceived as a

*“controlling agent”* to confirm compliance with the standard. This business therefore undertook chemical experimentation with potassium iodine to determine the concentration of iron ions in flour, thus allowing the national industry to avoid having to send samples abroad for analysis. As a result, businesses invested in technology (purchase of volumetric and gravimetric dosimeters) and contracted specialists in food technology. This development made possible a positive linkage with the Government’s initiative.

However, it is worth pointing out that the image Mill 2 had of the Government was different from that of Mill 1, due to the particular background of each business. The flour fortification regulation had existed since Mill 1 was established, and the Ministry of Health’s laboratories were in charge of approving premix imports. The first general manager of Mill 1 was a specialist in chemistry and had always had an interest in food fortification, and a close relationship with the Government, particularly with the Ministry of Health. As for Mill 2, since it was established within a framework of commercial market opening, the Government was seen as an obstacle that imposed *“obsolete controls”*, and *“did not facilitate development of the market as it should have, imposing barriers to free commerce”*. There was no perception of support from Ministries; the MEIC (Ministry of Economy, Industry and Commerce) was the most active participant, but it had a price-control role, instead of *“truly promoting development”*. It was felt that the State’s interest was *“to maintain a police-like control over a staple foodstuff and was wrongly conceived”*. In brief, the perception that Mill 2 had about the Government was that it was *“discouraging”* (INF19).

From this perspective, flour fortification was assumed to be an effort that had to be undertaken by the industry, and standards were established based on that point of view.

*“... since there were not any regulations, then for practical effects, dosage was always present, but without regulation, or standardization; it was more symbolic than real. Because of this, and as an initiative by the mills and a real exporting effort made in combination by different private entities, a regulated flour fortification process became stronger, and then even the formulations were changed, vitamin complexes were sought to protect vitamins such as “coatings” that would support drying at very high temperatures, and then a truly intense competition process between the two mills started, where consumers are direct beneficiaries ”* (INF19).

The union of businesspersons, the technical team and politicians from the Ministry of Health took place within this scenario. Convincing industrialists of the worth of the Government proposal was based on several elements:

- The strategy of the Ministry of Health technical team was convincing because it presented the country's nutritional status, implications regarding health problems in population groups with less resources and pregnant women, and the benefits and impact of flour fortification in a well-founded way<sup>27</sup>. As one of the industrialists said: *"The Ministry set forth the need and raised awareness about the problem "* (INF17).
- Costs were low and benefits were great: *"cost was practically insignificant, (...) that is why I was so relaxed in all the meetings"*. (INF 18); *"it was something good to do at a very low cost (...) it was a winning proposal"* (INF19).<sup>28</sup>
- The 1958 decree existed, even though it was considered to be obsolete. Both businesses were already fortifying flour, the new proposal only entailed changes in dosage and adding folic acid to the formula; they only had to adjust the equipment and make a change in the premix formula.
- The private companies had already started an organized exporting effort in the face of intense competition. Both mills, in spite of being each other's competition, were operating under the same conditions. They had to maintain the strategic association with exporting partners that was required for acceptance of their products abroad.
- Fortification was in agreement with product quality improvement requirements, which would bring about greater competitiveness and better acceptance in the international market. Adding folic acid to flour was a way to differentiate the product in the market. It allowed industrialists to promote their products as innovative and as promoters of health and social well-being .
- Previous experiences with fortification of food and other mass consumption products had proven to be successful. The experience of salt makers was relevant; they came to the negotiation as allies of the technical team, showing the positive impact of salt ionization and fluoridation on population's health. They also indicated that iodized and fluoridated salt was very attractive in the external market.
- Experiences in other countries with wheat flour fortification had proven to have an impact.

As one of the industrialists said:

*"I believe it was a good culture medium without obstacles of any kind for the process, and things moved along"* (INF19).

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<sup>27</sup> Several informants were surprised and happy about the ease with which mills accepted the measure, and noted how the industry became an ally in favor of public health: *"they were convinced that there are diseases they can help prevent"* (INF12).

<sup>28</sup> *"Regarding costs, the impact of fortification is less than 0,5% in the price of flour for consumers, which was considered to be relatively low cost and high impact"*.

From the perspective of technicians:

*“... it was self-evident” (INF11).*

Information from the interviews indicated that arguments in favor of public health had an impact on businesspeople. In the case of Mill 1, there was an identification with the need to improve health in an important group of the population:

*“In that sense, the business was willing to do it (...) Support was never denied because it was a social well-being issue” (INF17); “all of us were in agreement (...) there was willingness from the businesses” (INF17).*

Something that is worth mentioning is the way in which businesspersons reacted in a way that is characteristic of the national industry, that sets it apart from that in other countries. This has to do with a certain pride about Costa Rica compared to the situation in other nations, which facilitates identification with values that are related to public health advocacy in the country. It may be said that the experience of salt makers was a pioneer effort, and they had advanced in something that would later be known as “social responsibility”. These are the words of a businessperson with respect to this theme:

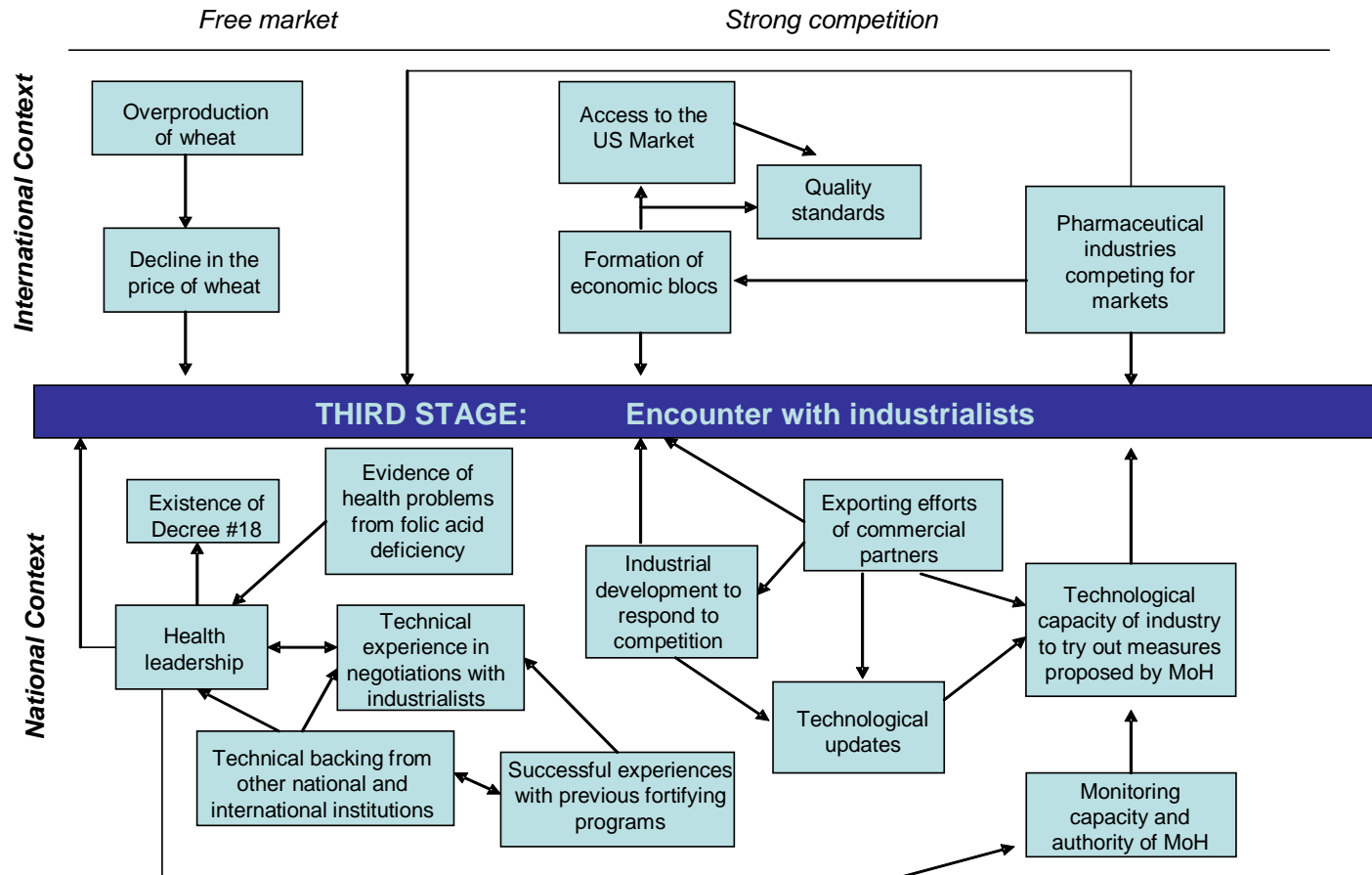
*“... it is one of the characteristics that Costa Ricans have had for a long time, we are used to concerns of a social nature, and it is also very natural, the truth is that in many countries it is not like that, unfortunately” (INF 18).*

This perception is also confirmed by another person that collaborated in the technical part of the process:

*“...an industry that is highly identified with health problems (...) and delighted when it is actually convinced of the reason of the effort (...) I do not mean to say that it is perfect here, but there is a lot of good will” (INF12).*

Chart 3 synthesizes the network of conditions and factors that favored negotiation of this policy.

Chart 3: Network of Conditions and Factors that Facilitated Policy Negotiation



## 5. Policy Design and Implementation

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### 5.1. Adjusting Criteria for Standardization

Once fortification had been agreed upon, the following tasks were technical and technological in nature. In the words of one of the actors:

*“That was a period of investigation and conversation, of dialogue to see if it was possible” (INF15).*

It was a period to solve a series of concerns that arose regarding the process of fortification itself: possible organoleptic changes in flour or in food products made with flour, iron and folic acid stability at high temperatures, homogeneity of the mix, differential dosages for semolina and for flour. The mills convinced themselves of the need to add adequate dosages of micronutrients to the flour. According to INF19 there was a *“process of private industry awareness”* – of trying to guarantee that products were safe for consumers’ health without mandate from the state.

During the policy negotiation phase, general managers or financial officers from both companies and health authorities were present. In this other phase, the Health Ministry’s technical team monitored the process, with advice from INCAP, INCIENSA (regarding technology), and the MEIC, but the quality and production management departments of the companies played a relevant role in this task, as well as Pharmaceutical Company A, which provided the pre-mix. With regard to this point, one of the key informants from the Ministry of Health pointed out that:

*“As public institutions, we did not have all the resources to establish various points; for instance, they wanted us to show that formulation did not change flour’s organoleptic properties, but we did not have the resources to do that. That was a weakness of the institution as such, but at the same time it became a strength because they (industries) participated more and took over more of the process. Because they did have the resources, they did the tests, and realized that there weren’t any problems.” (INF 11).*

Pharmaceutical Company A provided support by supplying the samples to adjust the pre-mix formula to the requirements set by the Ministry of Health. They showed that *“the government’s proposal was technically feasible” (INF 21)*, and gave information about equipment costs:

*“... we were called on to help with the application of technology, and we also helped with some other information and analytical methodology, provided samples of the product and participated in the eventual sale of this product to the mills, when we became competitive in the market” (INF21).*

Even though fortification costs were not considered to be high, the new measure entailed performing market tests to verify whether the product would be affected or not. Mill 2 offered its laboratories to perform the tests and Pharmaceutical Company A provided premix so that industrialists could test dosages and observe the results in final products. Different tests were carried out until the desired vitamin complex was achieved.

Pharmaceutical Company A was not the only participant in this process. Pharmaceutical Company B was called at the beginning of the process, but did not continue throughout the process. The Ministry of Health had worked with company A on other occasions and they were always willing to attend meetings with industrialists, contribute the first samples, and work closely with the Ministry of Health and local industries to obtain the desired product.

Pharmaceutical Company A provided a series of controls for the formula, as well as tests under realistic conditions regarding folic acid stability through chemical analyses of the quantity of micronutrients in the final product which would be reaching the target population, and of the plant quality necessary to guarantee premix uniformity.

Many of the technical questions and issues were related to industry concerns about food products derived from flour, such as loss of micronutrients during processing of products such as pasta, which require high temperatures during their production. Wheat semolina is used in pasta production, requiring special micronutrient dosages, so they would not be lost during the drying process.

To guarantee micronutrient stability it was necessary to add coatings to some vitamins so that high temperatures would not vaporize them. The pharmaceutical industry had developed the necessary technology to overcome that problem.

Even though the millers were key actors selected by the Ministry of Health to achieve its fortification objective, it was the mills that adopted the interests of food producers. This improved the proposal and the impact of the fortification policy, allowing adjustments that permitted flour-derived products to actually be fortified. Tests to prove resistance to heat in bread and cookies manufacturing plants were also performed.

*“... indirectly, we transferred fortification to other businesses (...), I can assure you that nobody escapes the benefits of fortification” (INF18).*

The Food Industries Association joined this process, and some exporters participated actively in the tests. Micro-dosages were added in the laboratories of Mill 2, where they also verified that an adequate dosage was present in finished products, and then each of the actors received samples so they could confirm compliance with the standard for finished products.

Unlike the mills, the Costa Rican Chamber of Food Industries showed at the beginning some opposition to the government proposal. In this case, the image and previous experiences they had had with the government and its institutions—in particular the group's Board of Directors—were relevant. There was an atmosphere of disbelief and deprecation of the work done by the Ministry of Health, and claims that the Ministry had failed to comply with their responsibilities, resulting in a weakened market—for instance, the bureaucratization of new product registration, the absence of regulations against unfair competition, and lack of labeling control on imported products, including information about expiration dates. They saw no signs of the State protecting consumers and domestic producers, and doubted the State's ability to carry out its regulatory functions. This gave rise to the impression that the government did not understand the industry's reality, and that its proposals and actions always hindered competitiveness in the sector. The Chamber was, at that time, aiming its efforts at helping food producers to produce more, and more profitably, and did not see the wheat flour fortification proposal as an advantage for businesses. *"Giving attention to Dr. X's request was outside of the strategic plan"* (INF20).

The following words summarize the first impressions of this group:

*"Look, here they're going to impose something on us that businesses have to comply with, where the State doesn't give us anything, where costs will increase, where we don't know what effects it will have" (...): "Why don't you fortify water?, that's a public service" (...): "There's no reason to force a particular group or specific sector to increase its costs, so the first impression was not positive"* (INF20).

In this atmosphere of distrust, they wondered whether there might exist some other hidden interests, such as Pharmaceutical Company A wanting to promote the sales of its products. This position started to change as the technical team presented world-wide evidence and experiences. *"Now all those efforts started to be more effective"* (INF20).

Once convinced, this group wanted to obtain some advantages for its members, such as regulation of imports of unfortified cookies. *"We wanted to see if we could use the excuse of fortification to impose a commercial barrier"* (INF20). The Ministry did not accept this; regulations were to be imposed only on wheat flour imports. Finally the group yielded and accepted the measure:

*"...we saw that a great deal of the ideas being considered were perhaps influenced by our innate mischievousness, that maybe we could take advantage of fortification from a financial and commercial perspective; it didn't work out that way, and we started to yield on that point and finally arrived at the conviction that fortification was important, that this was the final result. The clouds of the day went away"* (INF20).

For the Ministry of Health it was critical that wheat flour fortification fit within the framework of public health policy. Therefore, during negotiations, it could not let the

issue of fortification be used to promote increased consumption of fortified food, because that would have brought about new health problems for the population.

The monitoring role assumed by the Ministry of Health's technical team was appreciated by businesspeople, and turned out to be a good experience for the technicians:

*"... we never felt that our orientation, at least the one Dr. X gave to the process, was hostile and burdensome, on the contrary, a joint effort was agreed upon to seek a reduction in neural tube defects (...) The relationship between the Ministry of Health and private-sector businesses was handled very well, there were no disputes or confrontations; instead they tried to find a feasible, realistic solution that was objectively necessary in order to obtain the desired result (...) there was no police work, there was great faith that everybody was contributing their part to the effort "* (INF 19).

According to Dr. X:

*"We had to review bibliographies (...) On several occasions the manager of Mill 2 sent us questions via e-mail, and we answered them; it was a very rich dialogue from the technical perspective". "...the Ministry has never had a verbal or written debate with the industrial sector; instead, in the case of fortification, there have always been very technical notices, wisdom has prevailed in this regard"* (INF01).

It may be said that the type of relationship the technical team established with the industry marked a different experience for the latter with governmental agencies, breaking down defensive attitudes—even from the technical team—against bureaucratizing the process. This is why it was mentioned many times that the process was very smooth.

*"It was confidence that allowed the project to flow quickly"* (INF19).

## **5.2. Drafting the Decree**

According to the industrialists, there was a great deal of transparency in the process, and information was constantly available: *"we were all well informed"* (INF18). The different actors had access to decree drafts to review them, and made commitments to comply with it. In this way, when the regulation was put into effect, industrialists were already prepared to implement it.

*"...unexpected things happened here (...) I always thought that the policy of the government and the Ministry of Health was good (...), problems got solved within a reasonable time frame and with acceptable costs (...) I was very happy with that (...) I think all of this was very well done, with a procedure to provide information, training for those in charge; and agreement among all of us"* (INF18).

As pointed out by an international advisor who participated:

*“Everything was harmonious... When the decree was created, industrialists were already applying the fortification measure (...) when things are done correctly and logically, things are self-evident” (INF15).*

From the point of view of the Ministry of Health’s Direction of Juridical Affairs

*“the historical record was very transparent, there was no evidence of pressure from any actor, nor opposition” (INF10).*

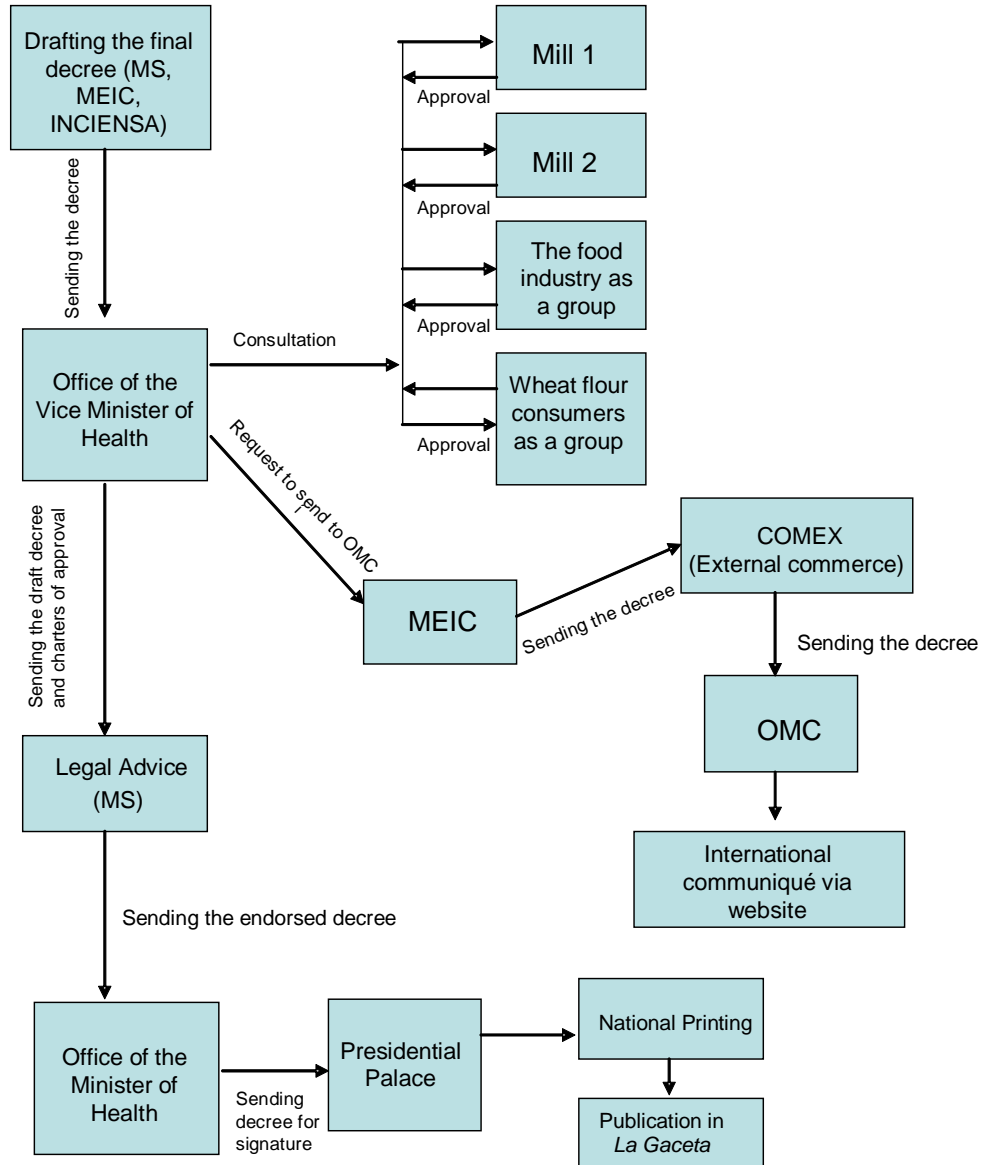
In looking back, the Minister of Health at that time observed that:

*“...to make the train run, the first thing to do is to get it started, and to get it started you have to have fuel, so we all made up the team, and since I could make the decision by myself as the head of the group, I made it, and we pushed for the corresponding decree” (INF04).*

The Minister of Health had credibility and support from the President of the Republic. The President was greatly identified with the public health cause, attended all activities in the sector, and frequently offered his opinions.

One of the members of the Ministry of Health’s technical team drew up the decree, with support from the MEIC representative to review its organization and the specification of procedures to expedite its implementation. Existing decrees from Guatemala were used as examples, because wheat flour fortification had already been implemented there. In addition, participation by a technician in food fortification workshops in Central America had provided some insight on how to draw up the decree. The process followed to draft the decree is presented in Chart 4.

Chart 4: Approving the Policy



Executive Decree N° 26371-S revoked Decree N° 18 and established Regulations for enrichment of wheat flour of alimentary quality. These Regulations mandated enriching wheat flour with iron and folic acid, and its reconstitution with thiamin, riboflavin, and niacin. The difference with respect to Decree N° 18 consists in an increase in the dosage of those micronutrients, elimination of calcium, and introduction of folic acid, as observed in Table 1.

**Table 1: Enrichment Levels Pursuant to the Decree**

Nutrients	Decree N° 18 (1958)		Decree N° 26371-S (1997)	
	<i>Minimum</i> (mg/kg)	<i>Maxim.</i> (mg/kg)	Wheat flour (mg/kg)	Wheat semolina (mg/kg)
Thiamin			6.0	6.0
Riboflavin	4.4	5.5	4.0	4.0
Niacin	2.6	3.3	55.0	55.0
Iron (elemental)	35.2	44.0	60.0	30.0 (minim)
Calcium (ion)	28.7	36,4	-	-
Folic acid	1.100.0	1.377.8	1.5	1.5

This decree applies for wheat flour and semolina for domestic consumption, either from local or foreign origin. The decree entailed updating the industrial equipment, specifically in Mill 1 which had to acquire new dosimeters that would comply with regulations.

## VII. Conclusions

Formulation, negotiation and approval of the folic acid wheat flour fortification policy was made possible thanks to the conjunction of various favorable conditions and the contributions of several actors. It is notable how a small group of technicians was able to establish alliances and mobilize actors to achieve their goal. They took advantage of favorable circumstances to create an atmosphere of confidence, participation and consensus. They achieved this with scientific support, evidence of success in other countries, and successful Costa Rican experiences. This small technical team was based on a foundation built through decades by the Ministry of Health, which provided credibility for its actions, and allowed it to successfully lead the process. Annex 4 summarizes the intentions, capacities, needs, and alliances and conflicts among the different social actors that worked together to formulate this policy.

Chart 5 presents the degree of involvement of the different actors in the policy formulation process. The chart is organized in concentric circles: at the center are the actors who were most involved in the process, and those who participated to a lesser degree are at the periphery. The actors that participated actively to achieve a positive result in the policy formulation are in the green circles. Those in colorless circles participated informally in the policy process, but not in its formulation. And the actor in the red circle was initially opposed to the process, although later on it was convinced to favor the initiative. The size of the circles also indicates the degree of importance of the actors during negotiations.

When asked about who was responsible for achieving this policy, one of the health authorities said:

*“This [policy] was possible through team work (...) If I have to attribute its achievement to anybody, I would said that the Ministry was the one, a governing Ministry that exercised leadership in both the technical and the political areas. Those decisions would not have been possible without the great technical support from those employees who were responsible for nutritional surveillance, with all the work regarding information collection, research and analysis. It really is a success for the Ministry (...) it was mostly a public health measure” (INF05).*

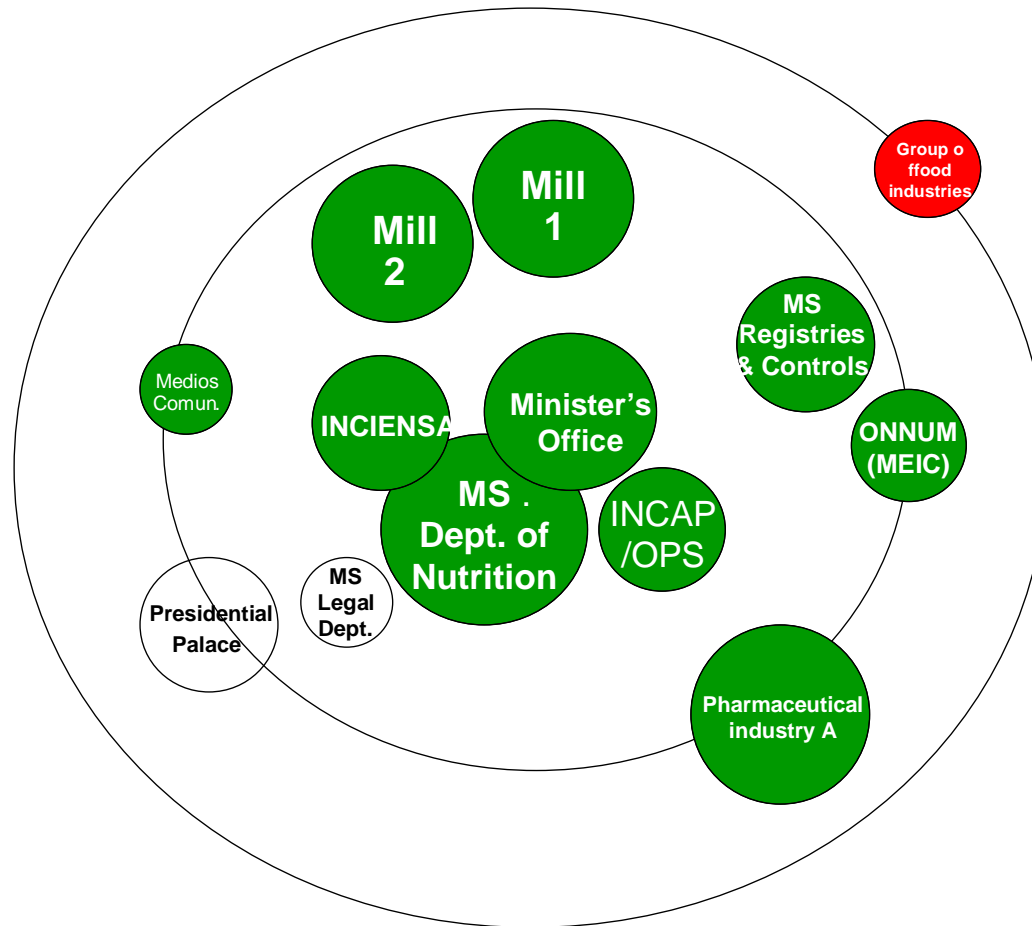
According to another informant from the public sector:

*“... I say that they (the technical team) were the head and behind them, [was] all the machinery that gave them support” (INF13).*

From the industrialists point of view:

*“coordination from the Ministry of Health made it possible to arrive at agreements between us and our competition (...) There was adequate coordination with the industrial sector” (INF17).*

Chart 5: Actors' Participation in Formulating the Policy



Although Mill 1 had been historically involved in flour fortification, its attitude had been one of observance of the mandated regulations; now, for the first time, it participated in drawing up the policy: *“that was the first time that the business got close to a health policy process”* (INF17).

A new policy-making style was created, in which the technical team was capable of creating the conditions for a different type of interaction between the public and private sectors. It was no longer possible to draw burdening policies or regulate commerce, as had been the case in past decades when the point of origin for policies was the State. Thus, processes to generate commitment and convince all the stakeholders became indispensable for joint creation of a policy.

In this regard, the technical team leading the process was anticipating what would later be known as *“social responsibility”*, when businesspeople changed their idea of responsibility from one based only on payment of taxes, and instead undertook a greater commitment to society and got actively involved in designing and implementing policies.

It is obvious that public health measures such as food fortification would have been impossible without food production industrialization and industrial technological development. That is why fortification required commitment from the business sector, as well as its willingness to provide continued follow-up on compliance with regulations.

According to an international advisor, the technical team gained a level of expertise that was highly valued in the field:

*“... not everybody knows the art of negotiation, and here (fortification) there is a lot of negotiation”* (INF15).

The technical team was also capable of adopting and putting into practice the notion of *“advocacy”*.

*“...I remember that they (the technical team) started to adopt some very interesting concepts such as the issue of advocacy, for instance. Advocacy is very practical, and it makes sense if you have a clear strategic vision of what it is you want to do; then “advocacy” means to raise awareness in a group of people, such as businesspeople, who have economic power, it means to sensitize certain sectors of the State, who are at the end the ones that draw up the decree”* (INF16).

Another critical element that helped direct advocacy efforts was a human rights approach, in which the right to health is pivotal in health actions; this was complemented by social responsibility, and both of these elements would translate into institutional and social practices that were realized in this fortification experience.

However, it is important to emphasize that the beneficiaries of this policy were notable for their absence during its formulation, negotiation and approval stages. There was no consultation with communities or specific groups that might have represented the population. They were only informed once the decree had been written, in a press conference held on May 27, 1997. The Social Welfare Principle prevailed, and the Ministry of Health made the decision without any consultation with the population, because it was considered that the measure was not going to cause any damage, and that people trusted the Ministry of Health to make such decisions for them. This can be clearly seen in the words of health authorities:

*“... because the Ministry of Health said so, because it is going to do a great deal of good, because we enjoy almost implicit approval for all these measures we take”(INF04).*

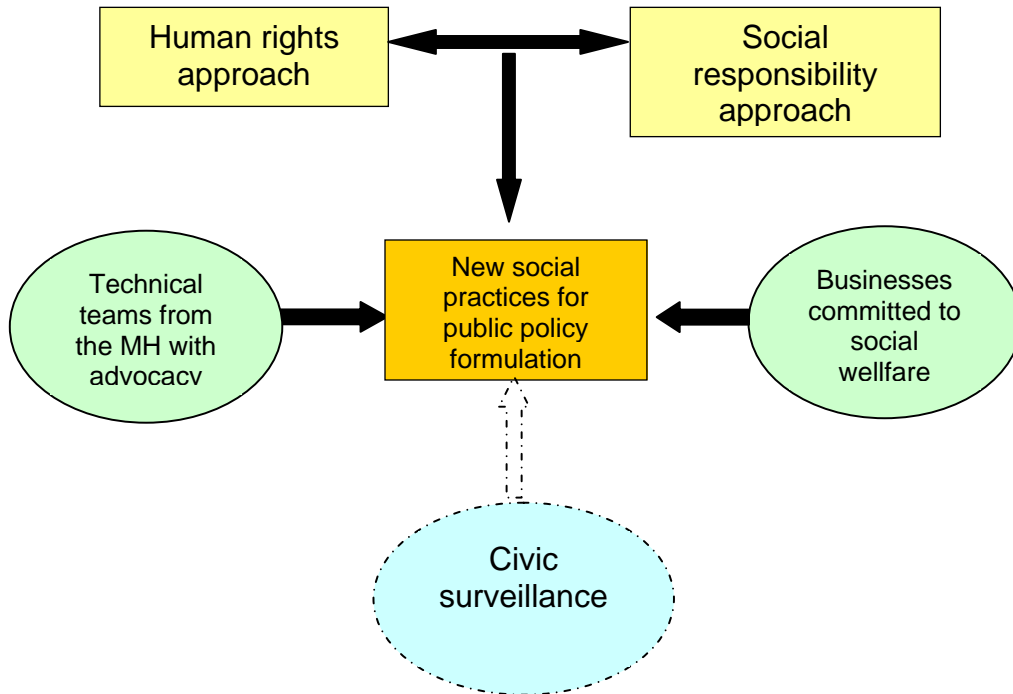
According to health authorities, it all started with a “*proved benefit*” without any negative consequences, and what was considered important was informing the population, instead of convincing them. It also had its basis in a vision of managerial efficiency: “*feasibility in this type of interventions entails searching for key actors to avoid wasting time*”.

However, a wider conception of the human rights approach was not involved in this decision, one in which a process for demanding rights is enabled and safeguarded by the State. That is why it was so important to create the necessary conditions for true citizen surveillance in the population – it would operate as political oversight that could become an ally for the government in technical follow-up and surveillance of the fortification process. As pointed out by INF 16, “*this gives rise to a social network*”. The socio-political conditions of the country also play an important part: “*we have a highly developed social State(...) we have a highly state-oriented vision*” (INF16).

These features may be positive. However, as long as the Costa Rican State continues to respect free market demands, and the trend to minimize the role of the State continues, there is a high risk that the population may not be protected, and it does not have the experience or organizational capacity to defend the rights it has delegated to the Social State over many years.

Chart 6 shows how the articulation of the human rights approach may be linked to the social responsibility approach, to create new practices in public policy formulation.

**Chart 6:  
Linking Approaches with New Practices for  
Public Policy Formulation**



Beyond question, international cooperation organizations contributed to make this process possible. In particular, INCAP provided information, knowledge and technical support, and technical and political training in the country and the region. Expertise was also obtained through technical capacity building promoted by INCAP, with a regional vision oriented towards making up technical teams, holding sessions for exchange of experiences and providing advice. INCAP also helped create a committed and responsible decision-making entity that was assumed by the highest health authorities from each country.

It is worth including the words of an interviewee from an international organization:

*“...I think cooperation organizations that replace governmental institutions are causing damage to Nation States; they are not building institutional capacity. I believe contributions have to be made in the areas of political advocacy, conceptual feedback, and connection networks, but it also has to be very clear that those who develop initiatives are*

*governmental or social institutions. Cooperation organizations are entities that make possible building institutional capacity, either in the legal, programmatic or even advocacy fields ” (INF16).*

Furthermore, international meetings promoted by international organizations—with participation of governments and private businesses—offered the opportunity to exchange experiences, thus stimulating technology development and reciprocal learning.

Again, according to an employee from an international organization:

*“Each one of the countries shares its experiences, technological development, learned lessons and also its problems or obstacles, letting other nations learn from them, thus contributing to standardize health policy in the region, helping build international standards, and allowing flows of knowledge and information” (INF16).*

From this particular experience in policy formulation, negotiation and approval, we may contribute valuable information about lessons learned to the NCD Policy Observatory in our country and the rest of the region.

## VIII. Lessons Learned

- ➔ Although initiatives to create food fortification policy arise to reduce the incidence or prevalence of health problems, as health measures they should not be interrupted when the problems for which they were implemented disappear. Experience shows that health problems may reappear when public health measures are interrupted. This is a lesson learned related to epidemiological surveillance, which makes it necessary to consider policy sustainability through time.
- ➔ As shown in the case analyzed, having evidence on a health problem is an essential requirement for policy formulation. This provides the opportunity to convince different actors that must get involved in the process, giving them support and enabling them to measure policy benefits and impact through time.
- ➔ Related to the previous point, lack of investment in epidemiological studies, when studies are considered as a luxury and not as a priority, is a weakness. Permanent allotment of resources is vital for epidemiological investigations that will generate updated information to be used as input for decision-makers in the health area.

- The role of Health Administration is strengthened with initiatives such as that discussed in this document, because they make it possible for the Administration to demonstrate its ability to call on different institutions and organize actions, thus optimizing results to the benefit of public health.
- Alliances between technicians and politicians prove to be fundamental in public policy formulation. Technicians contribute their knowledge of reality and their experience, while politicians enable organization of different social actors, supporting technical recommendations.
- Alliances between the public and private sectors prove to have a great potential in solving health problems. For this reason, the public sector must seek to obtain commitment and involvement from private businesses in social welfare initiatives
- Formulation of successful public policy depends on authentic teamwork. Policy formulation processes should not be carried out by a single institution, but require cooperation and participation of different institutions.
- Dividing the responsibilities involved in the execution of a policy among many social actors—both public and private—has proven to yield better results than assigning the task to a single actor, because the power of the opposition is greater when policy responsibilities are concentrated in a few actors.
- Clarity regarding what each actor has to do facilitates policy formulation processes. At the same time, transparency regarding the intentions of a policy helps overcome doubts and distrust in the face of new policy proposals.
- Technical discourse backed by scientific evidence and assertive communication provides a policy with unity and an image of value with which to engage the private sector.

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## X. Annexes

### Annex 1: Guideline for Documentary Review and Analysis, and In-Depth Interview

Fundamental concept	Key aspects	Key questions
1. Context	<ul style="list-style-type: none"> <li>• Social, political and economic status in Costa Rica when the policy was formulated</li> <li>• Influence of the national and international contexts when the policy was formulated</li> <li>• Specific target population benefited by the policy</li> </ul>	<ol style="list-style-type: none"> <li>1. What was happening at a national and international level in the social, political and economic spheres that may have had an effect on the formulation of the folic acid wheat flour fortification policy?</li> <li>2. What were the health priorities at the moment when the folic acid wheat flour fortification initiative emerged?</li> <li>3. Which factors promoted placing the folic acid wheat flour fortification issue on the agenda?</li> <li>4. Which population was the folic acid wheat flour fortification measure intended to benefit?</li> </ol>
2. Ideas	<ul style="list-style-type: none"> <li>• Information management in determining the folate deficiency problem in the population and in defining policy.</li> <li>• Existing information, who presented it and to whom it was presented</li> </ul>	<ol style="list-style-type: none"> <li>5. What information and/or experience existed already in the country regarding food fortification, before the proposal to fortify wheat flour with folic acid arose?</li> <li>6. Who had knowledge about food fortification with folic acid? What information did they have?</li> <li>7. What were the sources of information that made it possible to visualize the nutritional problem of folate deficiency as a public health problem?</li> <li>8. Were there different ideas, values, and strategies regarding the way in which these nutritional problems were faced? Which were they and who defended them?</li> <li>9. Which informative strategy was used for policy formulation? Who promoted it, and how was it promoted among health authorities and other participating sectors?</li> </ol>

Fundamental concept	Key aspects	Key questions
3. Interests and strategic conflicts	<ul style="list-style-type: none"> <li>• Individuals, groups, organizations and institutions that participated in policy formulation.</li> <li>• Promoting or hindering factors for policy formulation and approval</li> <li>• Contributions from those groups</li> <li>• Groups that lead policy formulation and approval.</li> <li>• Process of interaction among different institutions or organizations during policy formulation and approval</li> </ul>	<ol style="list-style-type: none"> <li>10. What persons, institutions or organizations were identified as key actors for the folic acid wheat flour fortification policy's formulation and approval?</li> <li>11. Who lead this policy's formulation and approval processes?</li> <li>12. Which were the aspects that promoted or hindered this policy's formulation and approval?</li> <li>13. Which interests and conflicts existed during this policy's formulation and approval?</li> </ol>
4. Institutions	<ul style="list-style-type: none"> <li>• Experience of institutions or organizations in setting priorities regarding health requirements in the target population</li> <li>• Strategies of institutions or organizations in setting priorities regarding health requirements in the target population</li> <li>• Mechanisms for participation of institutions or organizations in policy formulation and approval</li> <li>• Formal process and decision-making structure within institutions or organizations</li> </ul>	<ol style="list-style-type: none"> <li>14. What experience did participating institutions and organizations have regarding food fortification with micronutrients?</li> <li>15. What institutional mechanisms facilitated or hindered the folic acid wheat flour fortification policy formulation and approval?</li> <li>16. To what degree did the mission of each participating institution or organization facilitate or hinder formulation and approval of the folic acid wheat flour fortification policy?</li> <li>17. What are the formal processes and structures in decision-making regarding public policy inside participating institutions and organizations?</li> <li>18. What strategies were used by those who led the process to access formal decision-making structures at institutional and organizational levels, and to influence the approval of that policy?</li> </ol>

Fundamental concept	Key aspects	Key questions
5. Policy instruments	<ul style="list-style-type: none"> <li>• Political options considered</li> <li>• Policy chosen and criteria used to select it</li> <li>• Existing policy and legislation when the policy was formulated</li> <li>• Policy resources available when the policy was formulated</li> </ul>	<ol style="list-style-type: none"> <li>19. What were the options available to formulate a policy that would meet folate deficiency in the population?</li> <li>20. Why was folic acid wheat flour fortification chosen as the best alternative to face this nutritional problem?</li> <li>21. What legal instruments did the Ministry of Health have to formulate and approve a folic acid wheat flour fortification policy?</li> <li>22. What other resources did institutions and organizations use to formulate and approve this policy?</li> </ol>
6. Policy Action Plan	<ul style="list-style-type: none"> <li>• Existence of an Action Plan</li> <li>• Stages of the Action Plan</li> <li>• Actors who participated in preparing the Action Plan</li> <li>• Promoting and hindering elements of the Action Plan</li> </ul>	<ol style="list-style-type: none"> <li>23. Is there an Action Plan for folic acid wheat flour fortification?</li> <li>24. What stages were identified in the formulation of the Action Plan?</li> <li>25. Who is involved in preparing that Action Plan?</li> <li>26. Which institutions and organizations are involved in that Action Plan, and which are the responsibilities assigned to each sector?</li> <li>27. Which elements promoted or hindered the Action Plan formulation process?</li> <li>28. To what extent does this Action Plan satisfy the goals set at the beginning of the policy formulation process?</li> </ol>

## Annex 2: Letter for Key Informants

---

DATE: \_\_\_\_\_

**TITLE OF THE STUDY:**

**Case Study, Costa Rica:** Formulation of the Folic Acid Wheat Flour Fortification Policy

Dear (a) \_\_\_\_\_ (key informant):

As part of the inter-county Project, the Pan American Health Organization, the Ministry of Health, the CCSS (the Costa Rican Social Security System) and INCIENSA (the Costa Rican Institute on Nutrition and Health Research and Training), request your consent to participate in a study intended to analyze and compare Public Policy formulation and approval process in three countries: Canada, Brazil and Costa Rica.

The case study in Costa Rica is based on the analysis of the **“Folic Acid wheat flour fortification policy formulation”** and its purpose is to analyze the formulation, negotiation and approval of the folic acid wheat flour fortification policy to generate scientific evidence for formulation of public health policy.

People who participated in the study were chosen through extensive research carried out on the issue of wheat flour fortification which helped identify *“key informants”* based on their active participation in, knowledge and experience of, and work with the folic acid wheat flour fortification policy in the country. Your assistance in reconstructing the process are therefore truly important for this study.

If you agree to collaborate, we ask for some of your time for an interview to get your perspective as a participating actor on the policy formulation and approval processes.

The interview will last approximately 90 minutes, at a time and place to be agreed upon. Due to the nature of the study, there might have to be more than one meeting in order to achieve the objective of the interview. Interviews will be carried out by two trained researchers: one who will conduct the interview, and the other one who will take notes. With your prior consent, interviews will be audio-cassette recorded, since this strategy allows investigators to make the most of your contribution, but if you do not want some of your statements audio recorded, you may say so to the interviewers. The interviews will later be transcribed by trained staff. Once these transcriptions are made, you will be asked to review them and make sure that the document reflects your input, and you may make corrections or add pertinent information.

All information you provide, as well as your personal data, are confidential. Once the conversation is transcribed and reviewed by you, contents of audio tapes will be deleted and the sources of transcriptions will not be identified with your name, but rather with a code.

Results of the analysis from the interviews will be compared to those from other studies carried out in Brazil and Canada, and may be disseminated and published in scientific reports or documents at the national and international levels.

Participating in this study does not entail any cost to you; likewise, no particular potential risks or benefits to you from your participation in this study have been identified. However, it is clear that your input is highly valuable for public health development in the country.

Your participation is voluntary and you have the right to not participate or withdraw from the study at the moment you wish. Likewise, you will have access to the investigation's final results.

If you wish to obtain more information about the study, please contact the study's coordinator in the telephone numbers given below.

Thank you very much for your collaboration,

Sincerely,

Project Coordinator

M.Sc. Melany Ascencio

Unidad de Estudios Estratégicos

Dirección de Investigación y Desarrollo Tecnológico en Salud

Ministerio de Salud

Tel. 257 31 18

[didt-uee@netsalud.sa.cr](mailto:didt-uee@netsalud.sa.cr)

## Annex 3: Informed Consent Form

---

DATE: \_\_\_\_\_

**STUDY TITLE:**

**Case Study, Costa Rica:** International Study for Establishing a Health Policy Observatory

I, \_\_\_\_\_, have read and understood the explanations given in the above letter concerning the study of Health Policy carried out by PAHO, the Ministry of Health, the CCSS, and INCIENSA. This study is intended to analyze and compare formulation and approval of Health Policy processes in three countries: Canada, Brazil and Costa Rica. The case study – Costa Rica, is based on the analysis of the **“Process of formulation, negotiation and approval of the folic acid wheat flour fortification policy”**.

I understand that I will participate in an interview of approximately 90 minutes, which will be recorded and transcribed. In addition, if I wish, I may have a copy of the issues to be discussed during the interview beforehand. I also understand that after the interview I will be asked to review the information transcribed so that I can verify it and make corrections or additions. I also understand that the information I provide is confidential and that its analysis will be compared to that from similar studies carried out in Brazil and Canada. I also understand that the results of this study will be disseminated and published at national and international levels.

I understand that there are not any known risks or benefits that may arise due to my participation in this study, which participation does not involve any financial cost to me. I likewise understand that I may decide not to participate the study or withdraw from it at any moment I wish.

I have read and understood the informative letter and this consent form. I also understand that I may contact the study coordinator at the telephone numbers included here if I wish to obtain more information regarding the development of this study.

Yes, I agree to participate in this study as a key informant.

_____	_____	_____
INFORMANT'S NAME	ID NUMBER	SIGNATURE

_____	_____	_____
WITNESS' NAME	ID NUMBER	SIGNATURE

<u>M.Sc. Melany Ascencio</u>	_____	_____
NAME OF COORDINATOR	ID NUMBER	SIGNATURE

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*Notes:* You will receive the original document that you have signed and a copy will be kept by the study coordinators. You may consult the document produced by this investigation if you wish to do so.

## Annex 4: Intentions, Capacities, Needs, Alliances and Conflicts of the Different Actors When the Policy Was Formulated

Actors	Intentions	Capacities	Needs	Alliances and conflicts
<p><b>Authorities from the Ministry of Health</b></p>	<p>Health authorities from the new government accepted the challenge to strengthen primary health care, thus promoting health and preventive programs.</p> <p>The Government Plan (1994-1998) to guide health efforts identified the fight against iron deficiency anemia as a priority.</p>	<ul style="list-style-type: none"> <li>• In charge of Health Administration</li> <li>• Power to convoke the various sectors</li> <li>• Power to decide on health priorities and interventions</li> <li>• Power to allot budget to health activities</li> </ul>	<p>Regaining "credibility" in the Ministry of Health. " <i>The Ministry was under a cloud</i>"; " <i>Administration had to be implemented, the Ministry had to play the role it was supposed to play</i>" (INF04)</p>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Presidency of the Republic</li> <li>• Technical team from the Nutrition Division</li> <li>• -INCAP</li> <li>• Wheat mills</li> </ul> <p><b>Conflicts</b></p> <p>Negotiations with bread makers to eliminate potassium bromide from flour had generated resistance and opposition. They paralleled the negotiation for folic acid wheat flour fortification.</p>

Actors	Intentions	Capacities	Needs	Alliances and conflicts
Ministry of Health's Nutrition Division	Ensuring good nutritional status in the population, through investigations that provided evidence on the nutrition status of Costa Ricans, and monitoring actions aimed at improving the population's nutritional status.	<ul style="list-style-type: none"> <li>• Technical Team for Nutritional Surveillance at the Ministry of Health, capable of leading food fortification policy formulation, negotiation and approval</li> <li>• Knowledge about nutrition</li> <li>• Experience in nutritional research</li> <li>• Experience in negotiations with businesses</li> </ul>	<ul style="list-style-type: none"> <li>• Getting political, technical and financial support to carry out the National Nutrition Survey and develop the best possible interventions to confront health problems related to the population's nutritional status.</li> <li>• Obtaining political support from private businesses to meet health problems made evident through the Survey</li> <li>• Having technical and technological criteria to ensure that the fortification process was in compliance with requirements</li> </ul>	<b>Alliances</b> <ul style="list-style-type: none"> <li>• -Health authorities</li> <li>• -INCIENSA</li> <li>• -INCAP</li> <li>• -Pharmaceutical Company A</li> <li>• -Flour industries</li> </ul>
The Costa Rican Institute on Nutrition and Health Research and Teaching (INCIENSA)	Providing support to the Ministry of Health for epidemiological and nutritional surveillance, and control of fortified food.	<ul style="list-style-type: none"> <li>• Laboratory for food analysis since 1989. The References and Micronutrients National Center has been working with food fortification since 1997.</li> </ul>	<ul style="list-style-type: none"> <li>• Training of human resources</li> <li>• Financing inputs for laboratory analysis required in the Nutrition Survey</li> </ul>	<b>Alliances</b> <ul style="list-style-type: none"> <li>• Close relationship with MH Nutritional Surveillance Department</li> <li>• INCAP</li> </ul>
Ministry of Economy, Industry and Trade (MEIC)	Regulating national and imported products through national standards	<ul style="list-style-type: none"> <li>• Legal framework to control the national industry</li> <li>• Extensive knowledge of and experience in regulation issues.</li> </ul>	<ul style="list-style-type: none"> <li>• Having updated criteria to regulate domestic and imported products</li> </ul>	<b>Alliance</b> <ul style="list-style-type: none"> <li>• -Ministry of Health</li> </ul>

Actors	Intentions	Capacities	Needs	Alliances and conflicts
<p>The Central America and Panama Nutrition Institute (INCAP)</p>	<p>Providing <i>knowledge and knowledge management (INF14)</i>; seeks to develop nutritional science, promote its application and strengthen the capacity of member countries to solve their own food and nutrition problems.</p>	<ul style="list-style-type: none"> <li>• Experience in conducting and developing nutrition research in the region</li> <li>• Technical knowledge for identifying nutritional deficiency, at-risk population, and measures to take care of nutritional deficiency.</li> <li>• Capacity to create technical teams with experts in nutrition in the region.</li> <li>• Experience in formulation of public policy.</li> <li>• Technical and financial resources to accompany nutritional surveillance processes in countries of the region.</li> <li>• Science and technology division with experts in biochemical analyses.</li> <li>• Consultative Council made up of the General Directors of Health in the region, and a Board of Directors made up by the Ministers of Health of the region.</li> </ul>	<ul style="list-style-type: none"> <li>• Complying with food fortification agreements in Central America.</li> <li>• Having evidence and experience in fortification in some country in the region, so it may be used as an example to try to implement such action in the rest of the region's countries.</li> </ul>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Technical groups in Central America</li> <li>• Health authorities</li> </ul>

Actors	Intentions	Capacities	Needs	Alliances and conflicts
<p><b>Mill 1</b></p>	<p>Producing wheat flour of good quality at national level and gaining the confidence of consumers in the national products (<i>"with the same or better quality as flour from the United States"</i> INF18). From its inception, it has been identified with fortification policy and commitment to social welfare: <i>"a solidary and comprehensive sense that guides it"</i> (INF17). <i>"Highly sensitive from the social perspective (...) a business that is concerned with the population's health"</i> (INF18)</p>	<ul style="list-style-type: none"> <li>• Extensive experience in wheat production and in fortification of wheat flour with vitamin complexes.</li> <li>• Training in wheat fortification in other countries.</li> </ul>	<ul style="list-style-type: none"> <li>• Greater regulation of flour imports to the country. Fighting unfair competition.</li> <li>• Increasing product quality to respond better to international competition. <i>"Market opening entails stronger competition, thus the quality of flour is an important competitive factor"</i>(INF18)</li> </ul>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Close relationship with the government since its inception (Ministry of Health, CNP, MEIC).</li> <li>• Chamber of Industries</li> <li>• International Association of wheat producers..</li> <li>• Food Industries Association.</li> </ul>
<p><b>Mill 2</b></p>	<p>Becoming more competitive and attractive to commercial partners, to be able to access more markets at the international level.</p>	<ul style="list-style-type: none"> <li>• Laboratory.</li> <li>• Experience in producing wheat flour.</li> <li>• Technical and technological resources for flour fortification with vitamin complexes.</li> <li>• Knowledge about issues regarding flour fortification, having participated in international millers' congresses and assemblies which presented information about the importance of fortification.</li> </ul>	<ul style="list-style-type: none"> <li>• Meeting requirements of its commercial partners.</li> <li>• Flour produced must conform to USDA regulations, so that its pasta producing commercial partner could export to the United States market.</li> <li>• Defining the adequate dosage of the vitamin complex in flour and wheat semolina.</li> <li>• Offering a product of greater quality to meet consumers' needs.</li> </ul>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Commercial partners</li> <li>• Food Industries Association</li> <li>• Chamber of Industries</li> <li>• Technical team</li> </ul>

Actors	Intentions	Capacities	Needs	Alliances and conflicts
<p><b>Pasta manufacturers</b></p>	<p>Producing pastas of competitive quality for the international market.</p> <p>Exporting fortified pastas to the United States under USDA regulations.</p>	<ul style="list-style-type: none"> <li>• Financial resources to produce and export pastas.</li> <li>• Important commercial partners of the mills.</li> </ul>	<ul style="list-style-type: none"> <li>• Extending its commercial borders, exporting to the United States.</li> <li>• Having wheat semolina to produce pastas that meet quality standards set by the United States</li> <li>• Preventing micronutrients added to wheat flour from producing organoleptic changes in the product, or wasting the products when they are subjected to high temperatures to produce pasta.</li> </ul>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Mills</li> </ul>
<p><b>Pharmaceutical Company A</b></p>	<p>Manufacturing vitamins and other nutrients.</p>	<ul style="list-style-type: none"> <li>• A vitamins division where vitamins' biologic and metabolic activity was analyzed.</li> <li>• Information about scientific research on folic acid use to reduce incidence of neural tube defects.</li> <li>• Information about fortification efforts around the world.</li> <li>• Distribution of scientific items in Governments and Industries.</li> <li>• Financial and technical resources to provide the mills with premix and support dosage and mix regulation process.</li> </ul>	<ul style="list-style-type: none"> <li>• Selling premix to national mills, as well as to those in the region.</li> </ul>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Health Ministry Nutritional Surveillance Division</li> <li>• Mill 1</li> </ul>

Actors	Intentions	Capacities	Needs	Alliances and conflicts
<p><b>Food Industries Association</b></p>	<p>Defending the interests of national businesses dedicated to production of both raw material and food. Its concern was to improve competitiveness in the food industry. Public policy such as food fortification <i>“was not among its priorities” (INF20)</i></p>	<ul style="list-style-type: none"> <li>• Representation of the industrial food sector.</li> <li>• Knowledge about its clients’ needs in the market, as well as of those of small producers.</li> </ul>	<ul style="list-style-type: none"> <li>• Having a competitive advantage over imported products.</li> <li>• Making businesses more productive.</li> <li>• Being different from the Chamber of Industries</li> <li>• Government policy to support the sector</li> </ul>	<p><b>Alliances</b></p> <ul style="list-style-type: none"> <li>• Members</li> </ul> <p><b>Conflicts</b></p> <ul style="list-style-type: none"> <li>• Conflicts of interests between flour producers and food industries that used flour to make their products within the association.</li> <li>• The government and its institutions were not connected to the industry reality. There were problems with bureaucracy and requirements of the Ministry of Health regarding food registration and control.</li> </ul>