Health Enhancing Foods

Country Case Studies of China and India

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Abbreviations and Acronyms

CFTRI Central Food Technological Research Institute
CGIAR Consultative Group on International Agricultural Research
CHFA Chinese Health Food Association
CIF cost-insurance-freight
CITIC China International Trust and Investment Industrial Bank
CSIR Council for Scientific and Industrial Research
FCI Food Corporation of India
FDA Food and Drug Administration
FOB freight-on-board
FOSHU Food for Specific Health Use
FSS Food Safety and Standards
GAP Good Agricultural Practices
GDS Global Development Solutions, LLC
GM genetically modified
GMP Good Manufacturing Practices
HACCP Hazard Analysis and Critical Control Points
HFR Health Food Regulations
ICDS Integrated Child Development Services
ISO International Standards Organization
IVCA Integrated Value Chain Analysis
MOH Ministry of Health
PASSCLAIM Process for the Assessment of Scientific Support for Claims on Foods
PDS Public Distribution System
PFA The Prevention of Food Adulteration Act
PRFA Provisional Rules on Food Advertising
PSFDA Provincial State Food and Drug Administration
R&D research and development
SARS Severe Acute Respiratory Syndrome
SFDA  State Food and Drug Administration
TCM   Traditional Chinese Medicine
UNICEF United Nations Children’s Fund
USDA  United States Department of Agriculture
VCU   Value for Cultivation and Use

**Units of Measure and Currencies**

<table>
<thead>
<tr>
<th>Unit</th>
<th>Description</th>
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<tr>
<td>g</td>
<td>gram</td>
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<tr>
<td>ha</td>
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<td>ml</td>
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<td>MT</td>
<td>metric ton</td>
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<tr>
<td>RMB</td>
<td>Chinese renminbi</td>
</tr>
<tr>
<td>Rs</td>
<td>Indian rupee</td>
</tr>
<tr>
<td>US$</td>
<td>U.S. dollars</td>
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The Definition of Functional Foods Used in This Report

As noted in this report, there are many definitions used for functional foods around the world. Some definitions are very narrow, while some are quite broad to encompass most food. This report uses the following definition:

*A functional food is one that, in addition to providing basic nutrition, has additional attributes that have a direct positive effect on health and well-being.*
Executive Summary

Background

The relationship between food and health has long been known to exist. Today, the fundamental concept of food is changing from one that involves the maintenance of life to one that uses food to improve health and contribute to a better quality of life. As a result, there is great interest in this connection by public health officials, consumers, and the food sector industry. These foods, once referred to as “health foods,” are now described as “functional foods,” and the food industry is reflecting this change in its production and marketing of functional foods.

Public health officials’ increased interest in functional foods is in response to the increasing incidence of obesity and its wider health impacts and to the connections between food and this disease. Governments and many consumers recognize that eating foods that are good for health are part of a healthy lifestyle and that eating habits will have an impact on obesity and also may affect chronic disease and the health problems of the elderly. As life expectancy throughout the world is increasing, including in developing countries, governments have to deal with the health problems of an aging population. At the same time, some countries are still dealing with high levels of malnutrition.

The way that people in different parts of the world view functional foods varies, particularly when considering the view from the Eastern hemisphere versus that from the Western hemisphere. For centuries, those living in the East have believed that particular foods have therapeutic properties and are beneficial to health. In the West, foods linked closely to health have been referred to as “health foods” and have remained on the periphery of the food sector.

This view of food is closely tied into the concept of food as medicine and medicine as food. In many Asian cultures, the line between food and medicine has not been as clearly marked as it has been in European or American cultures. For centuries, foods have commonly been used along with medicines to treat ailments or prevent illnesses. With economic growth in Asia and an expanding middle class, there is more interest in preventive health care, including the use of supplements and food believed to have a health component, while also embracing some of the so-called Western concepts of food and medicine.

Functional foods have been known for centuries. The modern concept of “functional foods” dates from 1987 when the Government of Japan introduced legislation known as Food for Specific Health Use (FOSHU), which regulated health claims for food. The FOSHU regulations have become a guide for other...
countries as they grapple with the need to provide some sort of regulatory framework for functional foods.

In many countries, food items have been sold claiming health benefits but often failing to deliver them. Although these false claims may have turned the public away from such products, they have resulted in some governments taking action to define and regulate these foods. Many governments, however, still have not taken action.

China, the Philippines, and the United States currently allow health-enhancing claims for foods to be made, but these claims must first be substantiated. Other countries such as India are in the process of establishing such rules, while the European Union in 2001 established the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM).

Between 1998 and 2003, growth in the local, regional, and global functional food and beverage markets increased by nearly 60 percent, and this figure is set to rise by an additional 40 percent during the period from 2004 to 2008. (Benkouider 2003). Accordingly, this growth provides opportunities for manufacturers.

**Functional Foods in China**

The Chinese Health Food Regulations define functional foods (known as “health foods”) as “food indicated to have specific health functions, which is suitable for the consumption by specific groups of people and has the effect of regulating human body functions, but is not used for the purpose of treating disease.” The Chinese have traditionally considered the health effect of food consumed on a daily basis as Traditional Chinese Medicine (TCM), which is based on food that has some health-enhancing functions, either from plants or animals, and has been a staple of their society for centuries. The term “medicinal food” first appeared frequently in the literature of the East Han dynasty in approximately 100 B.C. and the term “food therapy” began being used about the same time.

Currently, TCM food is now part of regulation rather than literature as a result of developments in the functional foods market in the 1980s. Problems connected to unscrupulous manufacturers and poor hygienic production practices led to problems that depressed the functional foods sector. These problems ended in the mid-1990s when new laws and regulations gave consumers a sense of confidence that these foods were safe and would provide the specific health benefits they claimed. Perhaps the most important outcome of the problems of the 1980s was government and industry agreement that sound evidence of efficacy must be obtained and publicized to substantiate health claims. By the end of June 2005, more than 7,200 kinds of functional food products for the market had been approved.

The regulatory framework introduced the principle that a functional food had to meet at least 1 of the 27 specific health claims allowed by the government. China’s functional foods market has faced numerous constraints over its short life span as a regulated industry. Although the government has taken action through regulations and enforcement of newly established laws, there are still
difficulties in the marketplace, particularly for domestic producers. Some of these constraints are as follows:

Widespread availability of fake or copied products,

- Public distrust as a result of false advertising claims,
- Lack of research and development (R&D) in functional foods by domestic companies and institutes,
- Strong international and domestic competition, and
- Management that is not internationally competitive combined with poor manufacturing practices in many small and medium-size companies.

Notwithstanding these constraints, there has been considerable growth in the market and trends that indicate continued growth. In the late 1980s, there were fewer than 100 enterprises, while today there are 4,000 producers selling more than 7,000 approved products. The functional foods market is approximately US$6 billion and this is expected to double by 2010 (Sun 2006). Factors influencing the strong industry growth rate include the following:

- China’s large population;
- Improved income levels that enable greater consumer spending at a rate never-before witnessed in China;
- Increased access to global trends (travel and media) provide the opportunities, particularly those in metropolitan areas, to fulfill desires to be trendy and functional foods fall into this category;
- Increased awareness and concern about health issues driven by Severe Acute Respiratory Syndrome (SARS) and the Avian Flu (Hoggard 2005); and
- Functional foods are seen as a means to alleviate some of the problems caused by an increasingly unbalanced diet (NutraIngredients.com 2003).

Functional Foods in India

India’s history in functional foods, on the other hand, is one that is full of traditional and regionally ethnic foods. Cooking contains condiments, herbs, spices, whole foods, fruits, and vegetables, many of which are unique to Indian cuisine. In India, food containing healthy properties, beyond its nutritional value, has been documented throughout the ages, and many foods and medicinal plants have been used to treat common illnesses. New research shows that many of these foods, in fact, do have preventative properties.

As in China, India’s new interest in functional foods also resulted in producers mislabeling and overstating the efficacy of their products. The Government of India is now paying special attention to the regulatory aspects of functional foods because the current laws are outdated. Parliament is considering the Food Safety and Standards (FSS) Bill. This bill will completely overhaul the laws governing the food industry, as its aim is to modernize the food law. Currently, the food industry is governed by The Prevention of Food Adulteration Act (PFA), passed in 1954, and amended 11 times since then. However, even with these amendments, the PFA fails to provide the regulations needed to make the food industry competitive in the global marketplace.
The difference between the PFA and the FSS is that the former is a preventive or defensive legislation intended to stop food manufacturers, traders, and sellers from adulterating food with cheap or dangerous additives, while the FSS is an attempt to provide a modern food law to enable a competitive food processing industry to develop.

Under the PFA, creating new and healthy food alternatives is virtually forbidden, even if there is a great demand in the market. The PFA defines what food and additives are permitted and which ones are not allowed. The Act mandates definitions or recipes for various food preparations, and any deviation from the prescribed recipe is not permitted unless prior approval is received from the Central Committee for Food Standards, which is chaired by the director general of Health Services. Obtaining approval can take months and even years, depending on a number of factors including the complexity of the product and how competitive the market is for a particular food type.

Such definitions preclude most innovation in the industry and are factors in preventing much of the Indian food industry from becoming more competitive in global markets. The PFA makes it difficult for the development of the functional foods sector, which is characterized by its change in efforts to meet consumer preferences resulting from new research and technology.

The market environment for functional foods is relatively advanced although there are constraints, such as the following:

- Low income of a vast majority of the population,
- Existence of unscrupulous manufacturers,
- Lack of testing infrastructure to validate claims made by manufacturers,
- Lack of physical infrastructure,
- Lack of a regulatory framework for functional foods, and
- Some resistance to the introduction of genetically modified (GM) foods.

The trends in India are not unlike those observed in China. The history of India’s functional foods dates back centuries and the increasing interests in functional foods have provided new opportunities for these foods. With its strong tradition of healthful eating, India ranks among the top 10 nations in buying functional foods (Watson 2006) and India’s food industry is generating US$6.8 billion in annual revenues, with that number expected to double in the next five years (Ismail 2006). Additionally, India’s predominantly young population of 516 million between the ages of 20 and 55 is expected to increase to 800 million within the next 40 years. If India’s economy continues to grow at a reasonable rate, it can be expected that the size of the middle class will also increase and their disposable income and their interest in maintaining or establishing a healthy diet will result in increased functional food consumption.

The functional foods sector in India is strong and growing with aims of becoming a major force in the international health foods market. With a strong interest in developing the functional foods sector for the domestic and international foods market, the government is working to modernize intellectual property laws and is increasing investment in R&D in this sector.
At the present time, there is unanimity of purpose concerning development of the food sector and the resultant cooperation exists among major Indian food companies, key government ministers, the various government departments responsible for the food industry, and state food research organizations.

**Integrated Value Chain Analysis**

Global Development Solutions, LLC (GDS) employed its proprietary Integrated Value Chain Analysis (IVCA) methodology to make a “snapshot” of the value structure of a functional food. Soybean was selected because it is produced in large quantities in both China and India, is regarded as perhaps the “perfect” functional food by many, and is the basis for many products.

In this case, and using the IVCA methodology (as discussed in detail later in this report), soy was used as a proxy for the entire functional foods sector. Although results for different products within a product cluster will often vary, experience suggests that the policy, legal, and market distortions facing a product cluster and the impact these distortions have on the competitiveness of players along the supply chain vary only marginally. Therefore, the final value chain analysis will look similar for major products across the spectrum of product clusters. Figure 1a shows side-by-side comparisons of the IVCA analysis of the value chains for soy farming in India and China and the results of the IVCA analysis for soy milk in India.

As the analysis shows, soy farming in both China and India can be cost-competitive depending on the region involved in the analysis. However, when the results are compared with global best practice, both countries could improve their competitiveness. For example, labor costs required to produce a metric ton of soy are much higher in India and China than in the United States. China’s total labor input cost per metric ton of soy is 378 percent higher for soybean production than in the United States, even though the wage rate in the United States is a striking 462 percent higher than China’s wage rate. If the levels of efficiency in China can be improved, and if there is only a marginal improvement in labor productivity, all else being equal, China’s soybeans could become as competitive as those in the United States.

For India, an important finding of the soybean farming analysis is that seed costs are high at 74 percent of the cost of planting, versus only 46 percent for China, whereas the cost of seed accounts for only 50 percent in the United States. There are several reasons for the apparently high seed costs in India. First, the Indian Government has imposed high tariffs on the import of soybeans and related products. The tariffs are supposedly to protect soybean farmers, most of whom are smallholders who have limited financial resources to adopt techniques associated with modern farming, such as irrigation. Second, there is weak support for institutions that do R&D of seed varieties in India and for those institutions that produce seeds for the farming community.

While many other soybean-producing countries provide some level of support to their farmers and producers, India’s level of tariffs is extraordinarily high. In most cases, the tariffs are higher on processed goods than on raw materials, thereby supporting higher margins for domestic producers. This high cost of
seed increases the cost of the final soybean to the producer of soy-based products like soy milk.

In analyzing soy milk production in India, the field team observed that, given the very small-scale production and the very low utilization of plant capacity, unit cost would not be competitive with other countries or other milk products until a number of issues were resolved. These issues included lowering the cost of financing (see cost of financing for cooking and pressing or filtering) and investigating the high costs of fuel and packing materials. Improvements in these areas would reduce unit costs.
Market Drivers
In recent years, the food sector and consumers have begun to look at food as providing basic nutrition and additional health benefits. The market for functional foods is being driven largely by four key components:

- A growing consumer understanding of the benefits of functional foods, including an increased understanding of links among diet, health, and disease;
- Advances in food technology and nutrition;
- An increasingly aging population and the concerns about rising health care costs by the elderly and by governments, especially in developed countries; and
- Increased awareness in the agro-food sector and the research community about the potential for functional foods to improve citizens’ health and to help agricultural growers diversify their production into high-value products for niche markets (a process in many countries that is supported by government-based marketing and investment initiatives).

Opportunities for Growth and Development of Soy-Related Products
The need to establish health benefit credentials for functional food products is a relevant issue for the growth and development of the functional foods market. In the United States, for example, the Food and Drug Administration (FDA) establishes the labeling rules for any health claim, which must be supported by the weight of the credible scientific evidence available. In contrast to many other functional foods, soy protein has an established record of health benefits and is one of the few components in food that is recognized as having such benefits by the scientific community and such regulators as the FDA.

As soy protein is a component with established health benefits, India’s and China’s initial emphasis on soy-related products is an appropriate strategy for developing their functional foods sector. Moreover, in India, for example, major functional food processors believe that

> health awareness in India is phenomenal and the soy market is expected to grow at a rate of 200 percent per annum. Also, about 50 to 60 percent of the Indian population is lactose intolerant and a large number of the population is vegetarian to whom soy milk can provide the alternative for a high-protein, low-calorie nutritional supplement (Rekha 2004).

Similar statements could be made about China, where soy-based products such as tofu are staples of the diet and the expectations are for high future growth in such products.

Expanding the domestic market for all soy protein food supplements is a key avenue for growth in the functional foods sector. Notwithstanding its potential, soy milk plants in India operate at very low levels of utilization. For example, the installed capacity of one large producer that was interviewed for this report is around 20 million liters per year but only 5 percent of its capacity is used. This unused capacity suggests that diversification in the soy milk
category through introduction of multiple flavors, for example, as well as introducing other related products such as soy milk powder could improve the growth prospects of the soy milk market in India.

**Conclusion**

The global functional foods sector has experienced considerable growth in recent years as a result of food and nutrition research, consumer and public policy interests in links between food and well-being and health, and food companies seeking new markets. Most of these same interests exist in China and India.

As the market for functional foods expands and develops, and as the market promises to continue growing, multinational companies and government regulators are increasingly involved its development. The global market is large at US$63 billion and is expected to grow to as much as US$67 billion by 2010 and even larger as the actively retired elderly in developed countries live longer (Hoggard n.d.). The current global growth rate for functional foods is approximately 14 percent (Hoggard n.d.) and this is expected to continue through at least 2010, after which the market will see some maturity and rates of growth may decline accordingly. It is expected that the size of the functional foods market will account for an estimated 5 percent of total food expenditures in the developed world by 2010 (Hoggard n.d.). Credible scientific evidence that demonstrates safety and efficacy of the claims made for functional foods is critical in guaranteeing future markets and consumer confidence.

With large populations and an increasing middle class, with consumer spending on food high in both countries, with middle-class household incomes increasing, and with a growing recognition that functional foods are critical for a healthy diet, both the markets in China and India provide the basis for growth in this functional foods sector and growth prospects are expected to be very good.
1. Introduction

Background

“Let food be thy medicine and medicine be thy food.” These words spoken by Hippocrates, the father of modern medicine, two-and-a-half thousand years ago are as relevant today as then. The relationship between food and health has long been known to exist, and today the fundamental concept of food is changing from one involving the maintenance of life to one maintaining and promoting better health and quality of life by preventing chronic diseases. The increasing interest in public health provides investment opportunities in such foods in many countries, including in India and China.

People in various parts of the world view have different views on the nature of functional foods. For centuries, those living in Asian countries have believed that particular foods are beneficial to health and offer therapeutic properties. These beliefs are based on centuries of tradition and, until recently, rarely have any of them been supported by documented scientific research. In western developed countries, functional foods (also known as health foods) have been a small segment of the food sector. In all countries, food items have been sold promising but failing to delivery better health. This has had the effect of turning the public away from such claims and products. It has also resulted in governments taking action to regulate these foods.

Objectives of This Study

While many developing countries could potentially benefit from investing in functional foods, relatively little is known about the current status of production and market development in most of these countries. Therefore, there is a need to assess the functional foods sector and its growth potential because such information is needed to make investment decisions. The information is also needed to support the design and implementation of development and research projects aimed at improving the value added features of agricultural and food processing activities.

The main objective of this functional foods sector study is to provide a comprehensive review of the sector in developing countries and an assessment of its investment potential in two countries—India and China. There are two components of this report. The first component is a desk review of literature and internet search on functional foods in developing countries and contacts with resource personnel in development organizations and businesses operating in the functional foods market in developing and emerging economies. The second component of the report comprises the country case studies of China and India.

Limitations of This Report

The report provides a comprehensive study of the functional foods sector in India and China and assesses the sector’s investment potential in both
countries. Methodologies included literature reviews, Internet searches, interviews, and the proprietary Integrated Value Chain Analysis (IVCA). The Japan Development Institute licensed and used the proprietary IVCA methodology and software development created by Global Development Solutions, LLC (GDS) of Virginia, United States, to undertake this analysis. The objective of using the IVCA was to take a “snapshot” of a value structure that was representative of a particular health-enhancing functional foods product or industry. The IVCA was used as a method to help identify areas in which opportunities exist for investment, either by the public sector in improved laws, regulations, and infrastructure or by the private sector. It was not used to examine all of the problems of the soy industry in either country.

Because the health benefits of soy, a functional food, are known, it was chosen as a proxy for the entire functional foods sector. Although the results for different products within a product cluster will often vary, experience suggests that the policy, legal, and market distortions facing a product cluster—and the impact these distortions have on the competitiveness of players along the supply chain—vary only marginally. Therefore, the final value chain analysis and the results of the analysis will look very similar for many other products across the spectrum of a product cluster. The scope of this study did not provide for completion of any more IVCAs, although two or three additional IVCAs along the spectrum of the functional foods sector would likely have proven beneficial had time and resources been available.

Case Studies: India and China

In 1996, a 70-year-old Chinese worker in Hunan Province, with a long history of chronic health problems, bought several bottles of a potion touted as a virtual panacea for all ills. After consuming the potion, the man died, resulting in a backlash against the company and the industry. This backlash is still felt in China today. As a result, a number of regulations on the health food and functional food industries were established. Perhaps the most important outcome of this tragic event was the agreement of government and industry on the need to substantiate and publicize the health claims of products.

Stories like this one have focused and continue to focus the attention of regulators and public health officials in China and India on functional foods. For many, in both countries, high levels of malnutrition are still the main food problem, while for a small but increasing minority obesity is a problem. With life expectancy increasing throughout the world, including in developing countries, the cost of health care for an aging population is of concern to the elderly and to governments. And, as the evidence about the relationship between diet and chronic disease risk becomes stronger, preventing disease through diet and a healthy lifestyle increases in importance to individual consumers and governments. This relationship has the food industry thinking about the development, processing, and marketing of functional foods. With this background, this paper addresses the functional foods sectors in India and China and assesses the investment potential in the sector in each country.
2. The “Modern” Beginning of Functional Foods

The Japanese Experience

In Asian cultures, the distinction between food and medicine has never been as clearly defined as it is in Europe and North America. For centuries, foods have been commonly used with medicines to treat ailments or prevent illnesses. As Asian countries have become wealthier with growing urban middle classes, people have become interested in preventive health care, involving the use of supplements and food believed to have a “health” component.

Japan has been the leading country in defining functional foods since 1987. The modern concept dates to that time when Japan introduced legislation regulating health claims for food, known as Food for Specific Health Use (FOSHU). These foods are defined as derivatives of natural substances (not a capsule, pill, or powder) that can be eaten as part of a daily diet and that regulate a specific function of the body when consumed.

FOSHU foods are classified into five categories:

- Foods that enhance the body’s immune system by boosting defense mechanisms;
- Foods that help prevent or control disease such as diabetes or heart disease;
- Foods that aid recovery from disease such as lowering high cholesterol levels;
- Foods that regulate body rhythms by aiding digestion or enhancing absorption of vitamins and minerals; and
- Foods that help to suppress aging (Asian Food Information Centre 2004).

Very few countries have defined a health-enhancing food. China, the Philippines, and the United States currently allow claims to be made for a food provided these claims are substantiated. India is in the process of establishing such rules. In 2001, the European Union created the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM), which is seen by many in Europe as an initiative leading to the creation of global standards for defining functional foods. PASSCLAIM has the following principal objectives:

- to evaluate existing schemes that assess scientific substantiation,
- to produce a generic tool for assessing the scientific support for health claims for foods, and
- to establish criteria for markers that can be used to explore the links between diet and health (European Journal of Nutrition 2005).
The Rise in Interest of Functional Food and Drink

The increased global interest in functional foods is occurring at a time when a number of factors are prompting people to reconsider their eating habits; requiring governments to examine food policy and regulation; and driving companies to look for new markets.

These critical factors include the following:

- The decline for many in personal health, caused by unhealthy foods, lack of exercise, and stressful lifestyles;

Table 1 provides an outline of various foods that have been approved by FOSHU, their related health claims, and functional factors that led to approval.

<table>
<thead>
<tr>
<th>Health Claim</th>
<th>Functional Factors</th>
<th>Number of Products Approved</th>
<th>Types of Products in the Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foods that improve gastrointestinal conditions</td>
<td>Prebiotics Oligosaccharides Raffinose Lactulose Arabinose Probiotics Lactobacillus Bifidobacterium Dietary fibers</td>
<td>336</td>
<td>Soft drink, yogurt, biscuit, cookie, table sugar, tables candy, pudding, cereal, soybean curd, vinegar, chocolate, powdered soup, fermented milk, miso soup</td>
</tr>
<tr>
<td>Foods for people with high serum cholesterol</td>
<td>Soya protein and peptide Alginate Chitosan Sitosterol ester</td>
<td>26</td>
<td>Soft drink, meat ball sausage, soy milk, soup, biscuit, margarine</td>
</tr>
<tr>
<td>Foods for people with high blood pressure</td>
<td>Peptides</td>
<td>42</td>
<td>Soft drink, soup, lactic acid bacterium drink, soybean</td>
</tr>
<tr>
<td>Foods for people with high serum triacylglycerol</td>
<td>Diacylglycerol and Sitosterol</td>
<td>9</td>
<td>Cooking oil</td>
</tr>
<tr>
<td>Food related to mineral absorption and transport</td>
<td>Casein, Calcium citrate, Isoflavone</td>
<td>17</td>
<td>Soft drink, fermented soybean (Natto), jelly</td>
</tr>
<tr>
<td>Noncarcinogenic foods</td>
<td>Manitol, Polyphenols, Palatinose, Xylitol</td>
<td>6</td>
<td>Chocolate, chewing gum</td>
</tr>
<tr>
<td>Foods for people Concerned about their blood sugar level</td>
<td>Wheat albumin, Globin digest, Polyphenols</td>
<td>4</td>
<td>Candy, soup, soft drinks</td>
</tr>
</tbody>
</table>

Source: Asian Food Information Centre 2004.
A food market characterized by large numbers of players, increasingly intense competition, and smaller profit margins;

- The availability of information on nutrition and on the link between diet and health from health professionals and the media; and

- Developments in the area of nutrition research.

The local, regional, and global functional food and beverage markets offer exceptional growth prospects for manufacturers. Between 1998 and 2003, global sales increased by nearly 60 percent; this figure is expected to increase by another 40 percent from the period 2004 to 2008 (Benkouider 2003).

**Types of Functional Foods**
There are numerous categories and types of functional foods. Common to all is the reported increase in nutritional benefits with the claim to promote improved physical and mental health for the consumer. Common functional foods found in supermarkets are as follows:

- Products in which the amount of a component or ingredient that is naturally present is increased or reduced. Examples include breakfast cereals with added bran or dairy products with reduced fat.

- Products into which components or ingredients are introduced that are not normally present to any significant extent. Examples include fruit juice with added fiber, bread with added folic acid, and spreads containing fish oils or olive oil.

- Fermented dairy products such as certain yogurts in which bacteria used to bring about the milk fermentation are specially selected for their functional benefits. Examples include yogurts with bacteria such as *Lactobacillus casein*, *Lactobacillus acidophilus*, or *Bifidobacteria*.

- Sports drinks in which the ingredients have been specially formulated to provide a balanced replacement for fluids lost during exercise or to provide energy.

- Products, such as certain cereals, in which the carbohydrates are only slowly released in the body so that they supply energy over a prolonged period (Institute of Food Research 2006).

Annex 1 lists the categories of functional components, foods in which these components are found, and the potential benefits associated with each component.
3. Country Case Study: China

The Functional Foods Sector in China

As noted previously, the definition of functional foods varies around the world. The Chinese definition is not as broad as the one used in this report. The Chinese Health Food Regulations (HFR) define functional foods (known as “health foods”) as “[f]ood indicated to have specific health functions, which is suitable for the consumption by specific groups of people and has the effect of regulating human body functions, but is not used for the purpose of treating disease.” For the purposes of this report, the term “functional foods” equates to the Chinese use of the term “health foods.”

Awareness of Functional Food

In China, the belief that food and medicines are from the same origin has a long-established history, and people traditionally considered the health effect of food consumed on a daily basis. In Traditional Chinese Medicine (TCM), food that has some health-enhancing functions, either from plants or animals, has been a staple belief in Chinese society. The term “medicinal food” first appeared frequently in the literature of the East Han dynasty (in approximately 100 B.C.) with the term “food therapy” being used about the same time.

TCM has a great influence on the attitude of the Chinese toward health promotion. Many ancient TCM books record prescriptions using foods and herbs for many ailments. Many are widely used in present-day China. TCM is a part of a culture of health promotion with medical cuisine, some special approaches to cooking and eating, many choices of food prescriptions, and so on. Functional foods in TCM are believed to have a wide range of applications and functions. Table 2 lists some of the major uses, ingredients, and products.

Market Evolution of Functional Food

With traditional awareness of food functions and increasing knowledge of vitamins, the market has evolved from TCM to more functional food or nutraceuticals in the form of capsules, tablets, or syrups that are designed to help with blood sugar, blood pressure, blood lipids, weight loss, the immune system, and detoxification. The evolution and trends of the modern functional foods market are described in box 1.

In the 1980s, as the functional foods market began to develop, a number of producers entered the market. Some of these producers were unscrupulous, while others did not follow proper hygienic production practices. This led to a number of problems that depressed the functional foods industry and this depression only ended with new laws and regulations enacted in the mid-1990. Box 2 details a major event of one company that had a significant impact on the government and industry.
### Table 2. Functional Foods for Specific Purposes in China

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Food Ingredients</th>
<th>Medicinal Ingredients</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of aging</td>
<td>Chinese yam, lotus seed, honey, tremella, pork skin, beef, wood ear, quail meat, quail egg, lotus root, hawthorn, lily bulb, green tea, konjac, celery, pear, coriander</td>
<td>Ginseng, cordyceps, poria, wolfberry, pilose antler, deer tail, antler glue, gastrodia tuber, chrysanthemum, orange peel, acanthopanax bark, donkey-hide gelatin, solomon seal rhizome</td>
<td>Porial pancake, mashed yam, tremella soup, pork skin jelly, beef extract jelly, tremella, quail egg, konjac tofu, stewed pig feet with chestnut</td>
</tr>
<tr>
<td>Cosmetological purposes</td>
<td>Chinese yam, sesame seed, honey, sea cucumber, turtle, mutton, milk, cheny, lichee, pine nut, Qix seed, bean sprouts, Chinese toon</td>
<td>Lotus flower, wolfberry astragalus, solomon seal rhizome, fingered citron, <em>Artemisia apiacea</em></td>
<td>Stewed sea cucumber with bamboo shoots, fried green cabbage with dried shrimp, bamboo shoots with fingered citron, turtle soup with <em>Artemisia apiacea</em>, mixed tofu with Chinese toon, fried bean sprouts with portulaca</td>
</tr>
<tr>
<td>Controlling body weight</td>
<td>Watermelon, Chinese date, water caltrop, lotus root, lotus seed, oats, mung bean sprouts, watermelon cucumber, onion, turnip, hot pepper, old hen meat, mutton, liquor</td>
<td>Ginseng, astragalus root, poria skin, winter melon skin, com stigma, lotus leaf, bark of Chinese cassia tree, nutmeg</td>
<td>Stewed chicken, meat slices with ginseng, astragalus, winter melon, fried mutton with hot pepper and onion, fried bean sprouts with lotus leaf, lotus seed, lotus root</td>
</tr>
<tr>
<td>Treating hypertension</td>
<td>Celery, sponge gourd, tomato, wood ear, hawthorn, green tea</td>
<td>Mulberry leaf, wolfberry, chrysanthemum flower, prunella spike, dogbane leaf, solomon seal rhizome, fingered citron, com stigma, gastrodia tuber, selfueal</td>
<td>Beverages made of chrysanthemum flower, hawthorn, cassia seed, celery and Chinese date soup, hawthorn, wood ear, prunella soup, fish head soup with gastrodia tuber, fermented bitter melon with wolfberry and tomato</td>
</tr>
<tr>
<td>Treating diabetes</td>
<td>Bitter melon, pumpkin, Chinese yam, west lake greens, spinach, black plum, mulberry fruit, green tea, gluten, wood ear, quail egg, duck egg, beef</td>
<td>Dried rehmannia root, ophiopogon root, wolfberry, solomon seal rhizome, rhizome of wind weed</td>
<td>Stewed gluten with wolfberry, steamed crucian carp with green tea, steamed silver carp with solomon seal rhizome, duck egg boiled with green tea, fried spinach with egg white</td>
</tr>
</tbody>
</table>


1984–88

- Modern functional food appeared in shops during 1980s; some pharmaceutical enterprises produced special products that were not medicines, but they declared that these “foods” provided specific functions to improve health and remedy certain maladies.

1989–96

- From 1989–96 more than 3,000 so-called functional food products appeared in the market.
- The government decided that new laws and regulations for functional food were needed.

1996–present

- The Food Hygiene Law and Health Food Regulations were enacted.
- Functional foods entered a new era.

By the end of June 2005, more than 7,200 kinds of functional food products had been approved to enter the market, including 6,694 domestically produced goods and 537 foreign ones.

Source: China State Food and Drug Administration.

Box 2.  China: A Difficult Start to the Modern Health Food Boom.

From Humble Beginnings

From an initial investment of 300,000 yuan, a “secret” biological formulation, decades of sales experience and 30 years of political education, Wu and his son began producing and marketing the San Zhu Oral Health Potion in 1994. Within three years, sales went from RMB 1 billion to RMB 8 billion.

Wu pledged his commitment to Chinese society by announcing his company’s plan to become the nation’s biggest taxpayer, to be among the world’s top 100 firms, and to increase the average life expectancy of all Chinese citizens by 10 years within 20 years; all of this by simply drinking his health potion regularly.

The Effect of Testimonials

Having had experience from the marketing of health potions in the newly opened consumer market of China, The San Zhu Company chose to publicize its product through the use of expert testimonials. The company provided gifts to medical schools, hospitals, and medical research centers in return for their testimonial and public approval of San Zhu Health Potion.

Nationalistic Propaganda

The older Wu was a faithful party member of 30 years. Using various slogans like “Revitalize the Nationalistic Industry”, and “Strive to Be the No. 1 Taxpayer”, San Zhu gained rapid recognition even into the most remote rural communities of China. To reinforce his message, hundreds of thousands of advertisements were put up throughout the country, including on the walls of rural public toilets. He also initiated tens of thousands of free health clinics throughout the country with medical personnel from state hospitals visiting each week. His sales team grew to 150,000.

Unsubstantiated Claims

The company claimed to have conducted large scale research and development work in life sciences at its research center. It also received hundreds of Certificates of Recognition and awards for its products in return for its sponsorship of various research and government agencies.

The Secret Formula

The older Wu himself was regarded as the formulator of the original Health Potion. However, Wu evaded questions as to the nature, rationale,
or history of his “secret potion” leading some to speculate that the potion may not be all that it was claimed to be.

**Eight Bottles, a Dead Man, and a Bankrupt Empire** Due to explosive growth in sales and personnel, the San Zhu Company was unable to assert effective control over its 150,000 person sales force. This resulted in many salesmen pitching the product as a cure all solution, in order to meet their strict sales quotas. This led to the banning of television advertising in Guangdong after an official investigation into the use of unapproved and unproven claims.

On June 3, 1996, a 70 year old worker in Hunan with a long history of chronic health problems bought eight bottles of San Zhu Health Potion. Using much of his life’s savings for the purchase, this man was hoping that the promises of better health were true and that his own health would soon improve. Instead, after consuming all eight bottles of the San Zhu Health Potion, he died. Although the company finally won a long legal battle with the family, by the time the appeals process had run its course, 200 of its subsidiary companies and branches had already closed due to a drastic drop in sales as a result of the bad publicity that this event aroused. This led to the inevitable filing of bankruptcy for the company.

**China’s Health Food Market and Health Food Product Life** At the time of this event, the Chinese health food industry was in the ascendency with growth of 20 percent to 50 percent a year. This one event caused a near collapse of the industry, one that was not reversed until nearly a decade later.

Source: “Awakening Dragon, Doing Business with China” October, 2001 and from interviews in Beijing and Shanghai in April 2006.

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**Functional Food Trends and Opportunities in the Chinese Market**

In the late 1980s, the functional food enterprises numbered fewer than 100. This sector is now valued at approximately $6 billion, with as many as 4,000 producers. The sector is expected to double to approximately $12.5 billion by 2010 (Sun 2006), although according to some sources, the market is nearly that size already (Peverelli 2003; NutraIngredients.com 2006). Several factors are influencing strong industry growth rates, namely the following:

- A large population
- Improving income levels, especially in urban areas that are providing more discretionary income to consumers
- Increased access to global trends (travel and media) allowing people, particularly in urban areas, to follow trends such as functional foods
- Increased awareness and concern over health issues driven by SARS and the Avian Flu (Hoggard 2005)
- Awareness that functional foods may alleviate some problems caused by an unbalanced diet (NutraIngredients 2006).

Given the concerns about unbalanced diet, functional foods can supply the necessary nutrients that are lacking in most Chinese diets. One example is the need for supplementary calcium in the Chinese diet, and this need represents a growing market opportunity because it is estimated that approximately
one-third of the population has less than the required daily calcium intake. The number of calcium supplements and ingredients is substantial, with the annual national market estimated at more than $500 million. The functional foods market has responded by producing high-calcium milks, noodles, biscuits, candy, and flour (fortified with other vitamins and minerals as well) (Starling 2003a). It is anticipated that the increased variety of calcium-fortified functional foods will take part of the market share from calcium supplements. Other supplements in high demand are iron, iodine (now obligatory in salt), and selenium (Peverelli 2003). Proper targeting of consumer segments combined with adequate investment in research and development (R&D) to meet the needs of these targeted segments will ensure continued industry growth.

In addition to the factors influencing the growth rate in the functional foods sector, the government is considering functional foods as part of its plan to tackle malnutrition in its underdeveloped, poverty-stricken regions (Jungbeck and Benkouider 2004). The Center for Public Nutrition and Development of China has, in recent years, proposed that essential consumables such as salt, flour, edible oils, baby foods, and soy be fortified. With the government’s interest in developing the industry, and as a result of the finalized regulations over health food registration, functional foods are even more acceptable to consumers. Part of a government public health drive is to provide new measures for examining and administering health food advertisements (Jungbeck and Benkouider 2004).

As the industry continues to develop, more opportunities will be realized through foreign joint ventures. For example, one of the world’s leading suppliers of natural food ingredients, Chr Hansen of Denmark, has formed a strategic alliance with Mengniu Dairy, China’s leading milk producer (with headquarters located at Hohhot, Inner Mongolia Autonomous Region), to promote probiotics and the concept of healthy bacteria in the market (NutraIngredients 2006).

As of early 2004, China’s formal regulator of the health food industry, the State Food and Drug Administration (SFDA), had certified a total of 5,000 functional food products for sale on the Chinese market (Hoggard 2005). Chinese people spend only about 0.07 percent of total annual personal expenses per capita on health foods and vitamins. Experts estimated that the average per capita consumption will triple between now and 2010. In recent years, the expenditures for health foods and vitamins by urban residents, especially intellectuals and white-collar workers who have higher incomes and rising living standards, grew by 15 to 30 percent (Sun 2006).

With a long history of using traditional herbal medicines, the Chinese have always had a tendency to consume functional foods. One early medicinal handbook states, “When the doctor has found the cause of a disease, he should first cure it with food and only if food does not cure, seek the help of medicine” (Peverelli 2003). The current rise in consumption of functional foods, therefore, is a continuing tradition. Chinese researchers are now using modern technology to discover and extract active ingredients from traditional sources to develop them into commercially viable ingredients. One example is the research with mushroom extracts. The functionality ascribed to these
extracted substances (in particular fungal polysaccharides) includes enhancing the immune system, inhibiting the growth of certain cancers, and slowing down the aging process. The popularity of polysaccharides is growing, and they have been used to fortify a variety of beverages (Peverelli 2003). Another example of research in converting traditional medicinal herbs into functional foods is the addition of fleece flower, which is believed to keep hair black, to teas and candies (Peverelli 2003).

Although R&D is conducted by the government in the functional foods industry, local companies have lagged behind. According to a recent report from the U.S. Department of Commerce, as a result of the lack of product variety, short product life cycles for certain approved brands, and a low level of investment in R&D, many Chinese manufacturers have gone bankrupt. Domestic functional food manufacturers have noted that their products have a short life cycle of three to five years before they are replaced. However, with little or no investment by manufacturers in researching ways to add value to their current line(s), they have not developed new products needed in the market. These facts coupled with their short-term view of the market mean that they have not focused on making quality products (Sun 2006).

Additionally, the Chinese Health Food Association (CHFA) attributes a recent slowdown in the health food industry to the relatively large number of small enterprises. Of the approximately 4,000 health food manufacturers, two-thirds are small to medium enterprises. Rather than investing in market research to determine what is actually demanded by the market, many manufacture products that are anticipated to gain swift government approval. This approach gets their product to market quickly, but as a result, two-thirds of current Chinese health foods have as their main function either relieving fatigue, enhancing the immune system, or lowering cholesterol (Sun 2006).

Given the state of domestic manufacturers, foreign producers account for 40 percent of all sales according to the CHFA. Imported products have been reportedly growing by 12 percent per year in the last five years (Sun 2006). Concerning imports, American-made products account for more than half of the total registered import products in China, followed by Japan, Canada, Korea, and Australia.

Since the opening up of the retail and distribution industries to foreign businesses in late 2004, China has experienced large amounts of capital investment into these two sectors. The retail channel is highly underdeveloped and currently going through an expansion and consolidation phase. Under these circumstances, new retail channels are opening with specialty stores and niche retailers are taking advantage of the new regulatory changes. China also offers other marketing channels in the form of home delivery, television shopping, Internet purchases, and multilevel marketing (Habiger 2005). In 2004, pharmacies, specialty health food stores, and supermarkets were the dominant channels used to promote health foods and dietary supplements. The future trend for the distribution of health food products is expected to include a mix of multilevel marketing, chain store sales, and hypermarket sales (Sun 2006).
The regulatory environment in China for functional foods—including all health foods, supplements, and medicinal herbs—has changed dramatically in recent years. The move is away from looking at functional foods in the tradition of TCM and instead viewing them more in the way that countries in the Western hemisphere consider and evaluate functional foods, namely by examining the science of the food and how it interacts with the body. These regulatory changes are driven by the following factors:

- China’s entry into the World Trade Organization,
- Quality problems evident in products for domestic and export markets, and
- The government’s view that the industry is a growth sector in the economy.

Some significant regulatory changes implemented include the following:

- Merging the SFDA and the Ministry of Health (MOH) and addressing public health and safety problems that have undermined social stability,
- Proclaiming new laws for the application of health and nutrition products (both domestic and imported) in July 2005,
- Decentralizing advertising and marketing approvals for the health and nutrition industry in early 2005,
- Changing the labeling law on product claims by imported and domestic products in October 2005, and
- Legalizing multilevel marketing in September 2005—foreign firms such as Amway (United Kingdom), Nu Skin (United States), and Herbalife (United States) have driven these regulatory changes.

Other changes resulting from this transformation of the regulatory environment include the following:

- An opening up of the retail and distribution industries to foreign investment (prior regulations barred foreign investors from wholly owning retail operations). This has provided large capital investments from both local and foreign entities to upgrade the underdeveloped retail channels; and
- Approval for retail development, but companies are finding it difficult to obtain approval for entering the distribution industry. A new franchising law allows for quick expansion in the retail sector (Sun 2006).

Regulatory considerations are addressed in greater detail later in this text and also in annex 2.

**Regulating Functional Foods**

In 1995, the MOH enacted the Food Hygiene Law to enhance food safety. This law was amended and updated in August 2005 when the SFDA issued Decree No. 19 titled the “China—Interim Administrative Measures for Health Food Registration” (annex 6 contains the text of Decree No. 19).

The legal definition of functional foods first appeared in the Food Hygiene Law of the Peoples Republic of China, October 30, 1995, Articles 22 and 23 (see box 3).
Additional HFR were approved by the MOH on March 15, 1996, which contain 7 sections and 35 articles. In October 2003, the MOH transferred the supervision and management responsibility of functional food to the SFDA, where they currently reside.

According to the regulatory framework for functional food enacted in 1996, the definition of functional food is as follows: “food indicated to have specific health functions, which is suitable for the consumption by specific groups of people and has the effect of regulating human body functions, but is not used for the purpose of treating diseases.”

According to the HFR, food products that claim to have certain health functions must meet the following requirements:

- It must be demonstrated through animal and/or human tests that the product exhibits definite and stable health functions.
- The product and its raw materials must meet the minimum hygienic requirements of food. They must not cause any acute, subacute, or chronic harm to the human body.
- The prescription of a functional food must have a scientific basis and the functional ingredients shall be clearly identified.
- The product should not be used for therapeutic proposes and this point must clearly be stated in the product’s instruction.
- After review and approval by the MOH, a product will be certified as a functional food and a special symbol and a functional food code number will be permitted on the label. (China State Food and Drug Administration, 2003)

To be considered a functional food the product must meet at least 1 of the 27 specific health claims allowed by the Chinese government. These claims fall under the regulatory purview of the SFDA. All other claims must first meet strict requirements as prescribed for safety and functional testing before they

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**Box 3. Food Hygiene Law of the Peoples Republic of China, October 30, 1995**

**Article 22**
With regard to the food claimed to have specific health functions, the product and its description material must be submitted to the administrative department of public health under the State Council for review and approval; and its hygiene standard and regulations for the control of its manufacturing and marketing shall be formulated by the administrative department of public health under the State Council.

**Article 23**
The food claimed to have specific health functions shall not be hazardous to human health; the content of the product description material shall be true, and the functions and ingredients of the product shall be identical with the information given in the product description material, and there shall be no deceiving information.

*Source: Translated from the Chinese version of the Food Hygiene Law of China, October 30, 1995.*
can be used to promote, position, or sell the product. The product must have a special health care function and be registered as a functional food if it fits within the government’s 27 preapproved functions (Hoggard n.d.; China State Food and Drug Administration). A detailed discussion regarding the 27 preapproved functions along with further regulations detailing requisite claims is provided in annex 2.

Several relevant regulatory topics related to functional foods are as follows:

**Manufacturing of Functional Foods**

At present, the manufacture, marketing, examination, and approval of functional food are supervised and managed by the SFDA. No functional food product can be manufactured, marketed, or imported unless it first obtains an approved code number issued by the SFDA.

Furthermore, targeting TCMs (herbs and similar ingredients), the government has addressed the quality issues directly by mandating compliance with Good Manufacturing Practices (GMP) and Good Agricultural Practices (GAP). By April 2004, all manufacturers of traditional medicines had to comply with GMP as established by the SFDA in 1998. Farms producing raw ingredients for TCM have until 2007 to meet GAP. As a result, quality has begun to improve and, reportedly, the supply of raw materials is now more stable than before the change, thus decreasing price fluctuations previously experienced (Starling 2003a).

**Descriptions and Labels of Functional Foods**

Descriptions of functional food products must be examined and approved by the SFDA. In addition to fulfilling the requirements for general food products, such descriptions must also state the health maintenance effects of the functional food products, the suitable target users, the methods of consumption, the recommended amount to consume, the functional components, the names of all ingredients, the code number, and a special functional food label issued by the SFDA. The supervision of labels and descriptions focuses on whether the relevant product circulars contain false and exaggerated advertising elements regarding the product’s functions, whether the indicated contents are complete, and whether such contents are in line with the requirements established during the product evaluation and approval procedure.

**Advertisements**

For the regulation of advertisements, there is no preapproval system for functional food advertisements. The Provisional Rules on Food Advertising (PRFA) stipulate the following:

- the contents of functional food advertisements must be in line with those of the descriptions of the product on the label as approved by the administrative department of public health under the State Council;
- the advertisements may not arbitrarily extend beyond the approved scope, and the code number of the approved functional food must also be promulgated;
Health Enhancing Foods

Applications for Certification of a Functional Food for Domestic Goods

Figure 1 provides a graphical presentation of the application process for certifying a functional food for a domestically produced good. See annex 2 for more details.

Applications for Certification of a Functional Food for Imported Goods

Figure 2 provides a graphical presentation of the application process for certifying a functional food for an imported product. Further details are provided in annex 2.

Functional Food Constraints in the Chinese Market

The functional foods market in China has faced numerous constraints over its short life span. The government has taken action to overcome many of these constraints:

- functional comparisons may not be drawn between functional food products and other health care instruments or pharmaceutical products; and
- the promotion of the functional food may not reference feudal and superstitious elements. (Food Hygiene Law of PRC 1996)

* Those claims that need supplementary support materials require an extra 30 days for inspection. The 30 days will be counted from the date of last submission.

Source: Interviews conducted by Japan Development Institute and Global Development Solutions, LLC, in May 2006.
constraints through regulations as indicated in the “Functional Food Trends and Opportunities in the Chinese Market” section of this report. Even with these steps to deal with these constraints, there are still difficulties in the marketplace, particularly for domestic producers. Constraints include the following:

The widespread distribution of fake or copied products. According to a September 2005 article, the then-latest report from the MOH concluded that more than 90 percent of the medical products in China are either fake or copies. In the functional foods industry, on average, copies are only about 70 percent as effective as the genuine product. Such developments have given Chinese-manufactured products a very bad reputation within China and Hong Kong (China) (Hoggard 2005).

There are adverse health effects caused by these faked or copied products, because there is a lower potency, and people who take the faked product may encounter difficulties when taking the same dosage of the genuine product,
whose potency is much higher. The consequences may be serious and, in extreme cases, can result in death.

The growth of the domestic functional foods industry will depend on winning back consumer confidence. This will be particularly acute in Shanghai, where, from 1997 to 1999, more than 86 percent of the functional food products were found to be adulterated with fillers and contained reduced active ingredients (Hoggard 2005).

**Public distrust from false advertising claims affects domestic competitors.** Years of false claims by functional food manufacturers have resulted in consumers turning away from many local manufacturers. Even as the government has cracked down on false advertising, the damage caused by these unethical practices remains. Although foreign producers have not been affected as greatly, the lack of public trust has been harmful to their market efforts, requiring them to work harder to gain consumer confidence.

**Lack of R&D by domestic companies.** As already discussed, most domestic competitors are small to medium enterprises that do not have the R&D capital—or are not willing to invest in R&D—to effectively supply the market with new and innovative products. These smaller firms are not able to compete with the larger companies that are better equipped to internally fund the R&D necessary to produce new product lines and replace obsolete products. In addition, these small and medium enterprises are not able to attract foreign partners in the way that the larger, more established firms are able to, such as the large Chinese dairy company, Mengniu.4

**Most small and medium-size manufacturers are not demand driven.** Related to the lack of R&D, suppliers produce what they feel will give them the fastest return. There is little research regarding actual market demand, resulting in overcrowded markets for some products and opportunities for other products going undetected.

**Strong international and domestic competition.** The attractiveness of the domestic market has resulted in an increased number of businesses that are interested in the market. Depending on which statistics are cited, domestic competitors in the functional foods industry number anywhere from “more than 3,000” (Sun 2006) to “some 4,000” (Peverelli 2003). But despite the rapid market growth, the industry is witnessing bankruptcies among domestic manufacturers because of a lack of a variety of products, short product life cycles for certain approved brands, and the low level of investment in R&D. Furthermore, data show that foreign functional food products occupy more than 40 percent of market share. It is estimated that sales of foreign products have grown 12 percent per year over the last five years and the prospect for their continued growth and expansion is positive. Foreign companies compete on the basis of strong management, financial resources, investment in R&D, and marketing techniques. Additionally, many consumers believe that foreign products are of higher quality than domestic products; thus, they are more willing to try and pay high prices for foreign products (Sun 2006).
Poor management combined with poor manufacturing practices. Growth of the domestic industry has been limited by poor management; the use of older, inefficient equipment; and the lack of willingness to buy newer raw materials for use as ingredients for the production of higher-quality functional foods. These factors affect customer confidence in the credibility of certain local brands, which has declined (Sun 2006). Poor quality control and management will make it difficult for the long-term survival of many of the smaller domestic companies. Only 1.45 percent of all manufacturers have a total investments of more than RMB100 million and there are only five publicly listed companies (Sun 2006).

Government regulations will do much to improve the market, although infractions are numerous. On October 25, 2005, several government agencies jointly conducted a review and noted that 897 companies were suspended for failing to employ GMP for functional foods. Additionally, 3,364 cases of false advertising were reported (Sun 2006). While progress is being made, continued infractions make it difficult for the domestic industry to gain consumer confidence.
4. Country Case Study: India

The Functional Foods Sector in India

India’s traditional and regional foods have been documented throughout the ages as containing healthy properties, beyond just their nutritional value. Such historically functional foods include herbal extracts, fortified foods, spices, pulses (lentils), and vegetables and fruits.

The proven special health properties of functional foods have treated common ailments for centuries. New research is showing that many of these foods have preventive properties as well. The Central Food Technological Research Institute (CFTRI) in Mysore is documenting this history as well as newer trends in functional foods through its Knowledge Digital Library (Central Food Technological Research Institute 2005). This effort will support a better understanding of the functional attributes of these foods while protecting the intellectual property rights of those who develop new types of foods through R&D.

Functional foods R&D in India is rapidly expanding and includes, among other products, nutraceuticals, prebiotics and probiotics, and newer additives, which are known to prevent certain diseases or other maladies. New research shows that many of the traditional Indian foods have characteristics of functional foods and underscores the fact that the Indians have been consuming functional foods for centuries.

With this new recognition of functional foods comes new opportunities for producers to mislabel and overstate the efficacy of their products, requiring that special attention be paid to the regulatory aspects, particularly as the laws on functional foods require updating.

Functional Food Trends

As in China, India’s health foods history dates back centuries. The developments over the last few decades now recognize the value of traditional medicines and naturally health-enhancing foods. With its strong tradition of healthful eating, India ranks among the top 10 nations in buying functional foods (Watson 2006). India’s food industry is generating $6.8 billion in annual revenue, and this is expected to nearly double in the next five years (Ismail 2006).

The government is working to help India become a major force in the international functional foods market by updating its intellectual property laws and increasing investment in R&D infrastructure (Ismail 2006). There is unanimity among major companies, and in government, where both ministers and the substantial state research organizations are behind the idea of India becoming a major force in the international health foods market.
Agricultural and Rural Development

(Shrimpton 2004). In addition, there is little resistance from consumers to buy functional foods.

In 1950, the Indian government established CFTRI, which has grown to be one of the world’s largest food research institutes and one that is actively involved in teaching (Shrimpton 2004). Furthermore, according to sources interviewed, of the more than 200 research institutes and laboratories in India, 25 percent are involved in food research. With such substantial scientific support, the Indian food industry has the possibility to become a significant player in the international market supplying high-quality functional foods.

According to Dr. S. R. Rao at the Council for Scientific and Industrial Research (CSIR), New Delhi, the thrust of publicly funded research in functional foods has been on developing fortified foods, because this research reflects the government’s concern with malnutrition. According to Dr. Rajesh Kapur, director of the Department of Biotechnology, approximately 60 percent of children below 14 years of age are malnourished (Kapur 2006). Thus, the government has launched the national nutrition mission with the objective of providing ready-to-eat precooked food at a low cost and midday meals to students at government schools.

Dr. S. R. Rao noted that basically there are three countrywide government-sponsored distribution channels for general nutrition-enhancing functional foods, namely the following:

- Public Distribution System (PDS): A system of government-licensed shops where grains, sugar, and kerosene oil are subsidized and priced according to each family’s monthly entitlement.
- Midday Meal Scheme: A government-funded program under which precooked meals are provided to children at government schools throughout the country (the national nutrition mission referred to above).
- Integrated Child Development Services (ICDS) Scheme: A program conceived in 1975 aimed at improving the nutritional and health status of vulnerable groups (for example, preschool children, pregnant women, and nursing mothers) by providing a package of services including supplementary nutrition, preschool education, immunization, health checkups, referral services, and nutrition and health education.

On consumer behavior, Dr. Kapur said that there is very little awareness of functional foods among general consumers even though these foods have always been part of the Indian diet. This opinion is supported by research analysts whose report states that awareness of the term “fortified foods” among Indian consumers is low, but there is a high awareness of certain brands, especially in the case of iodized salt. According to the report, although many people may be eating fortified foods without being aware of it, approximately 30 percent of people in India’s cities regularly consume fortified foods. India has been quite progressive in its fortification programs as an early adopter, and often initiator, of many processes.

The government is expected to continue to actively press for the development of the functional foods industry. According to a representative of the Ministry
of Food Processing Industries, the ministry’s mandate is to develop and promote the food processing sector, including functional foods, throughout the country. It conducts seminars, workshops, and training programs and has a financing scheme that provides grants-in-aid to the food processing companies that want their manufacturing or processing units certified for international safety standards, such as Hazard Analysis and Critical Control Points (HACCP) and the International Organization of Standardization (ISO).

In a speech at Foodworld India 2005, Mr. D. P. Singh, secretary, Ministry of Food Processing Industries, introduced “Vision 2015,” which aims to triple the size of the food sector in 10 years time by increasing the level of processing of perishable goods from 6 percent to 20 percent, value added products from 20 percent to 35 percent, and share in global trade from 1.6 percent to 3 percent. Such efforts would require making processed foods affordable domestically and competitive globally; this effort would include functional foods. An investment of approximately US$25.5 billion is envisioned in the next 10 years.

In addition to the substantial government support, the functional foods industry is thriving in the private sector. According to the Frost and Sullivan marketing study, the large food manufacturers understand their consumers in both the mass market and the value added market. With many people suffering from deficiencies of iron, iodine, and vitamin A, the consumer can buy many fortified foods, such as wheat flour, iodized salt, calcium, and vitamin-enriched jams and soft drinks. To address vitamin A deficiency, which is prevalent in much of rural India, food companies have introduced specific products at affordable prices. For the middle-class consumer, companies have launched such products as low-sodium salt, which is beneficial to patients with high blood pressure (NutraIngredients.com 2006).

Although China is seen as the major competitor, Indian research technology in areas like fermentation processes, plant extraction, and chemical synthesis are more developed than their Chinese counterparts, and they still benefit from the labor cost savings that make outsourcing to India so attractive (Ismail 2006). Some people among those involved with functional foods development believe that Ayurvedic medicine and philosophy, based on knowledge accumulated over 4,000 years, offers India several advantages. It is also recognized that for these products to be successfully exported, however, the herbs that form their basis must be standardized, or at least their potency must be measurable. Traditionally, this is not in accordance with Ayurvedic philosophy, which recognizes the benefits of variation between growing conditions and individuals. Currently, there is no regulation concerning Ayurvedic-based products (Shrimpton 2004).

Recognizing the favorable government support combined with the research-friendly environment and available qualified human resources, European and U.S. multinational firms are already located in India, including Herbalife, DuPont, GlaxoSmith Kline, Akzo Nobel Chemicals, Hindustan Lever, Heinz, Novartis, and Roche. There are also a growing number of Indian companies that are working internationally, such as the Associated Capsules Group (which is ranked number three in the world for capsules), Solae (an alliance
between DuPont and Bunge), Avesthagen, RSA Vitamins, Zytex, and MM Activ. These companies export products ranging from raw materials to completely formulated supplements as well as enzyme preparations and immunological and diagnostic products (Shrimpton 2004).

Robust industry growth is expected to continue in the functional foods industry with productivity expected to grow 68 percent in the five years from 2005 to 2010. Solely based on this productivity growth, the size of the nutrition industry will nearly double to $13.5 billion by 2010 (Ismail 2006). Additionally, India’s population is large and predominantly young. With 516 million people between the ages of 20 and 55 today, this number is expected to increase to 800 million within the next 40 years. As the younger generation moves toward middle age, especially among the urban middle class who have increased disposable income, the need to maintain or establish a healthy diet will increase functional food consumption.

Food Laws in India

The food industry is currently governed by The Prevention of Food Adulteration Act (PFA), Amended 2005 (11th Amendment). The Act was originally drafted and passed by the Indian Parliament in 1954. The government is currently debating an overhaul of this law with the intent of modernizing India’s food laws. The PFA is administered by the MOH and is still the current law. The proposed law, currently called the Food Safety and Standards (FSS) Bill, when passed by Parliament, will come under the jurisdiction of the Ministry of Food Processing Industry.

The PFA is a preventive or defensive legislation intended to stop food manufacturers, traders, and sellers from adulterating food with cheap or dangerous additives. The FSS legislation is an attempt to provide India with a modern food law so that a world-class food processing industry can develop. The opening paragraph of the PFA reads as follows:

An Act to make provision for prevention of adulteration of the food (1954).

In contrast to the PFA, the first paragraph of the FSS reads as follows:

A BILL to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto (2005).

However, there is no timetable for final passage of the pending legislation and there is debate as to whether the FSS should replace or just be an addendum to the PFA. Therefore, the PFA remains the law for all food currently grown, processed, and marketed.

The significance of the opening line of the PFA Act reflects both the context and the era in which it was passed into law. In 1954, India was a food-deficient country and there were shortages of most foods, particularly grains, pulses (lentils), and milk. There were recurring instances of adulteration of primary
Health Enhancing Foods

foods by traders and shopkeepers that increased food availability. The Act was passed to deal with this problem.

The Act’s objective was and is to protect the nation against impure, unsafe, and fraudulently labeled foods and has been amended 11 times. The standards and regulations established over time apply equally to domestic and imported products and cover various aspects of food formulation, food processing, and distribution, such as food standards, food color, preservatives, pesticide residues, packaging and labeling, and regulation of sales. The law is enforced by the director general of Health Services, Ministry of Health and Family Welfare. The PFA focuses primarily on the establishment of regulatory standards for primary food products, which constitute the bulk of the Indian diet.

The PFA is punitive or reactive in nature rather than proactive. It seeks to protect the food chain by mandating what can and cannot go into food. The Act does not take into account technological changes in the food processing sector nor changes in diet and in eating behavior. There is no mention of functional foods anywhere in the Act. PFA regulations sometimes appear to be drafted in a manner that establishes minimum product quality specifications, such as prescribing recipes for how food products should be manufactured (see box 4).

The environment in which the PFA operates has changed dramatically since its passage in 1954. India is not a food-deficient country as the universal availability of cereal-based carbohydrates has been almost achieved. There is a well-functioning market intervention system in the form of the Food Corporation of India (FCI) and the PDS. Many farmers and producers, no longer satisfied with incomes from grain-based agriculture, want to produce value added products for a growing Indian market. By its very nature, the PFA prevents a modern, globally competitive food system from developing in India; hence the need for the FSS.

Creating New Kinds of Food

Given the stringent nature of the PFA, creating new and healthy food alternatives is a current challenge. The Act defines which food and additives are permitted and which ones are not allowed, and it tries to establish standards of quality (“sweet and wholesome” refers to wheat). The Act mandates definitions (recipes) for various food preparations, and any deviation from the prescribed recipe is not permitted, unless prior approval is received from the Central Committee for Food Standards. The same mandates apply to preservatives, additives, colorants, irradiation of food, sequestering and buffering agents, antioxidants, and emulsifying, stabilizing, and anticaking agents. The list of what is not allowed in food runs into dozens of pages in the Act.

Box 4 presents how the Act prescribes the provisions for wheat and biscuits. Any deviations from what is established here would make the product adulterated. For wheat, the law does not take into account the fact that different kinds of wheat have been developed over the years or such technological changes as genetically modified (GM) foods.
The Act defines each item that goes into processed food. A food substance with characteristics that do not meet the Act’s definitions, and that are then used in a processed food, would mean that the processed food would be considered an adulterated item and would be illegal to sell.

Although such definitions remove doubt and ambiguity about what is and is not acceptable, it also precludes any innovation in the industry and prevents the Indian food industry from becoming competitive. It also hinders wholesale development of a thriving functional foods sector in which the characteristics and recipes can change at a rapid pace to keep up with technology and consumer preferences.

**Licensing**

Although the PFA is a Federal law, the licensing authorities are the state governments and their designated city- or district-level governments or other

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**Box 4. India: PFA’s Prescription for Wheat and Bread**

**Wheat**

Wheat shall be the dried mature grains of Triticum aestivum Linn. Or Triticum vulgare vill. Triticum durum Desf, Triticum sphaerococcum perc. Triticum dicoccum schubl, Triticum Compactum Host. It shall be sweet, clean and wholesome. It shall also conform to the following standards, namely:

(i) Moisture content: Not more than 14 per cent by weight (obtained by heating the pulverized grains at 130 °C – 133 °C for two hours).

(ii) Foreign matter: Not more than 1 per cent by weight of (extraneous matter) of which not more than 0.25 per cent by weight shall be mineral matter and not more than 0.10 per cent by weight shall be impurities of animal origin.

(iii) Other edible grains – Not more than 6 per cent by weight.

(iv) Damaged grains – Not more than 6.0 per cent by weight including karnal bunt affected grains and ergot affected grains. The limit of karnal bunt affected grains, ergot affected grains shall not exceed 3.0 per cent and 0.05 per cent by weight, respectively.

(v) Weevilled grains – Not more than 10 per cent by count.

**Biscuits**

Biscuits including wafer biscuits shall be made from maida, vanaspati or refined edible oil or table butter or deshi butter or margarine or ghee or their mixture containing any one or more of the following ingredients, namely: edible common salt; butter, milk powder; cereals and their products; cheese, cocoa; coffee extract, edible desiccated coconut; dextrose; fruits and fruit products; dry fruit and nuts; egg; edible vegetable products; ginger; gluten; groundnut flour, milk and milk products; honey; liquid glucose; malt products; edible oilseeds, flour and meals; spices and condiments; edible starches such as potato starch and edible flour; sugar and sugar products; invert sugar; jaggery, protein concentrates, vinegar and other nutrients, and vitamins: provided that it may contain food additives specified in these rules and in Appendix C: provided further that it may contain artificial sweetener as provided in rule 47 under label declaration as provided in sub-rules (ZZZ) (1) (A) and (ZZZ) (1) (B) of rule 42.

local government authority. Under the Indian constitution, health is a state (provincial) subject, so every state government has its own PFA rules to implement the law in its respective state, which adds to the complexity and the difficulties of developing the functional foods industry (see box 5).

### Functional Food Constraints and Opportunities in the Indian Market

The market environment for functional foods in India, while cooperative and relatively advanced, faces the following constraints and opportunities:

**Low income of vast majority of the population.** For the domestic market to reach its full potential, income levels for the vast majority of the population will have to rise. Although disposable income has increased over the years and is expected to continue to do so (see the section “Functional Food Trends”), it is still very low and likely to remain so for many years.

Various creative solutions by private industry have been used to overcome the problem of people having a very small daily disposable income. Some
manufacturers are packaging their goods in single-use packages because this reduces the cash outlay and may result in more frequent purchases. For example, there are a number of supplements sold in the form of single-serve herbal tonics, but they are priced between $0.15 and $0.25 per serving. Even with this approach, single-serving prices generally are still out of the reach of the poorer consumers for use on a daily basis (Ismail 2006).

Another marketing strategy is to sell products in less-processed forms, thereby reducing the cost of the product. For example, in situations in which even the single serving is too expensive for low-income consumers, companies sell the supplements in powdered forms, which is not the normal means of sale. With India’s exceptionally large population, a reduced price does not necessarily mean reduced company returns; instead it could mean significantly more volume by targeting a much larger base (Ismail 2006).

Existence of unscrupulous manufacturers. Although the problem is not as damaging as in China, there are unscrupulous manufacturers that are producing pirated functional food products and making false claims about their products. Such activities affect the reputation of the industry and can be especially damaging to companies in the export market. Pirate products are less effective than the genuine product and can cause serious harm and may even lead to fatalities. Producers of supplements and Ayurvedic medicines are particularly vulnerable. At present, GMP in the functional foods industry are voluntary (Starling 2004).

Lack of testing infrastructure to validate manufacturers’ claims. There are limited laboratories to validate the functional or therapeutic claims of functional foods. Many of the current laboratories require additional investment in equipment and infrastructure to meet both the needs and the required testing standards. According to Ms. Rekha Sinha, executive director, International Life Sciences Institute, the World Bank has sanctioned a loan of US$44 million to US$55 million to strengthen the food testing infrastructure needed to validate and certify the packaged foods (Sinha 2006).

Lack of physical infrastructure. According to Ms. Sinha, the lack of physical infrastructure facilities in the food processing sector as a whole, such as cold chains and good roads that enable the timely supply of raw materials, are other bottlenecks.

Lack of flexible regulatory framework for functional foods. As discussed earlier, the food industry is governed by the PFA, a 50-year-old piece of legislation. According to those interviewed, several major bottlenecks are created by the current regulation:

- The Act has specific definitions for every food preparation permitted to be sold in the country and, as such, it does not provide flexibility to the food manufacturers to introduce new recipes without violating the law. To complicate matters, different laws govern GM foods, drugs, and pharmaceuticals. In all, there are about seven different laws governing the food sector.
• It is difficult for manufacturers to bring out new food preparations in a timely way. There is a process for approving recipes that are not included in the PFA (mainly functional foods and GM foods), but the appeals process is cumbersome and time-consuming, and may take up to two years for approval. In cases in which scientific evidence leads to a need to amend the standards, the producers can appeal to have the PFA rules amended. Under the PFA, the Central Committee for Food Standards is responsible for the final decision regarding PFA rules.

• Because many of these recipes are classified by their creators as proprietary foods, manufacturers are reluctant to share data with the authorities, fearing that this data might eventually be shared with competitors.

• The process of launching a new food product is cumbersome because the company has to go through a time-consuming application process.

Some resistance to GM foods. At the present time much opposition to GM foods has come from the educated elite who fear environmental damage, loss of biodiversity, and foreign control over India’s food supply. For example, Greenpeace campaigners dismissed the “protato,” a GM potato containing approximately 30 percent more protein, as an advertisement for biotechnology. “Years were spent in a lab trying to lever protein into potatoes, while cheap, protein-rich pulses grow abundantly all over India,” one opponent stated. “It makes you wonder what problem the scientists were trying to solve” (Vidal 2003).

Annex 3 documents India’s experience with Golden Rice and the HarvestPlus Initiative, providing background along with some dissenting opinions about why GM foods are counterproductive in alleviating malnutrition. Many people are relatively open-minded regarding GM foods, however, because science is still seen as a route to prosperity and a better quality of life (Ghosh 2003).

Many opportunities for growth in the functional foods sector relate to the need to curb malnutrition. As previously stated by Dr. Rajesh Kapur, 60 percent of children below 14 years of age are malnourished. His department’s mandate is to address this critical concern, and he cited the development of high-protein biscuits as an example of its work (Kapur 2006). The program is now in the commercial stage and the government plans to distribute the biscuits through the midday meal schemes run in government schools across the country.

Other opportunities include nutraceuticals, as Dr. Kapur stated that India has the potential to be the world’s leading producer and exporter of nutraceuticals. In the next five years, he estimated that the country could export nutraceuticals, including Ayurvedic and herbal products, worth US$1 billion.

Health issues provide further opportunities for increasing the functional foods market. Ms. Sinha claimed that child obesity is becoming a major health issue in large Indian cities, and this social problem presents a market opportunity if suitable functional foods can be developed to tackle it.
5. Integrated Value Chain Analysis: Methodology

For this report, a process called the channel mapping methodology was used to study the value chain of soybeans. This process traces a product flow through an entire channel from product conception to consumption. The process highlights the patterns of inputs, constraints, and competitive advantage that a producer has. It also traces the path of all value-adding and non-value-adding activities associated with the production of a good and approximates the costs involved at each stage.

The methodology provides opportunities to benchmark or compare one producer against another, as well as to benchmark production activities across regions and countries. Most of the data for the benchmarking stage are a result of IVCA of more than 120 specific product groups undertaken in more than 20 countries in Africa, Asia, and Europe. Similarly, this methodology is a tool for measuring and quantifying the cost of administrative distortions that hinder competitiveness of products and industries. Consequently, channel mapping can be used as an effective tool to identify discrete areas for policy reform and prospects for investment.

One of the principal ways in which the channel mapping methodology is applied is through the proprietary IVCA™, which provides a detailed breakdown of each stage of production, estimates the cost at each stage, and calculates the relative significance of these costs to the overall value of an end product.

Although more traditional methods of product and market analysis isolate operational costs along various stages of production, the IVCA is a much more comprehensive tool, particularly because it considers an entire spectrum of activities and inputs associated with a product. Although the IVCA is usually employed at a product level, output from the analysis provides useful indicative data on production and operational costs that are associated with a specific market.¹¹

Annex 4 provides a detailed description of the IVCA methodology.
6. Integrated Value Chain Analysis of Soy Farming and Soy Milk Processing in India and China

Product Profile: Why Soy?

Although it is unlikely that there will ever be any consensus on what really is the perfect food, a number of experts can make the case for the soybean. Soybeans are the most nutritious food among all the beans (some even call it the “king of beans”). A dry soybean contains 38 percent protein, which is twice the average of pork, triple that of an egg, and 12 times more than milk. It has an 18.4 percent fat content, which is basically unsaturated fatty acid.

For more than half a century, soybean has been the leading oil and protein crop in the world. It took several decades for the significance of soy to truly become widely understood. By the 1970s, the growth in global production and consumption of soy increased, rising from 94 million tons in 1979 to an estimated 220 million tons for 2005 to 2006. This growth was due to increased yields, increased areas for harvesting, and improved crop management in many major soybean-producing countries. The United States is the leading soybean producer, followed by Brazil, Argentina, China, and India (FAOSTAT 2006). See annex 5 for acreages and yields for India and China.

Soybean, rich in edible oil and protein, has now become one of the world’s most valuable agroproducts and, by some estimates, it is the most valuable crop in international trade. Around 60 percent of the protein food consumed in the world is provided by soybeans. Soy meal is the most valuable by-product from processing the soybean, ranging from 50 to 75 percent of its value (depending on relative prices of soybean oil and meal). According to the United States Department of Agriculture (USDA) soybean meal is the world’s most important protein feed, accounting for nearly 65 percent of world supplies (USDA n.d.).

Detailed research on the relationship between food and health has highlighted the health benefits of soybean to the human body, making this a popular topic in the international medical and food processing field. In a recent five-year period, three world symposia were held on the health effects of soybean and the developments in the field, thereby recognizing the global importance of soybeans as a health food.

Market Drivers

In recent years, the agribusiness food sector and consumers have begun to look at food not only for basic nutrition but also for health...
benefits. The market for functional foods is mainly driven by four key components:

- A growing consumer understanding of benefits of functional foods as well as their increased understanding of links between diet and disease;
- Advances in food technology and nutrition;
- Aging populations and their concerns about rising health care costs, especially in developed countries; and
- Increased awareness by the agro-food sector and the research community about the potential for functional foods to improve citizens’ health and connections with government-based marketing and investment initiatives, which provide an opportunity for producers to diversify into high-value products for niche markets.

**Robust Growth of Soy Milk Consumption in Asia-Pacific.** There are many products made from soy, but one of the fastest growing is soy milk (see figure 3 for a comparison of soy milk with several other competing beverage foods). Labeled by some as the healthiest beverage on earth, soy milk has benefited from its position as a healthy alternative to standard cow’s milk, with fewer calories (Redruello 2004; Thai Farmers Research Center 2006). In addition to its high protein, calcium, and vitamin content, manufacturers have increasingly stressed soy’s disease-prevention benefits. Soy milk also appeals to lactose-intolerant consumers, and this is particularly important to India where an estimated 50 percent of all consumers are lactose intolerant. Consequently, the market for soy milk has developed more quickly than the many dairy alternatives.

Soy milk is categorized as a dairy alternative, excluding goat milk. The global market for dairy alternatives in 2006 is projected to reach US$3.7 billion, with year-on-year growth of 20 percent. In the next five years, the dairy alternative market is expected to grow by 16 percent per year, on average. Globally, the

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**Figure 3. Global Market Sizes**

![Global Market Sizes](chart.png)

market turnover for soy milk accounts for some 85 to 90 percent of dairy alternatives, while the remainder are rice milk, oat milk, and almond milk, among others, all of which are less-popular dairy alternatives than soy milk. The Asia-Pacific region accounts for more than three-quarters of global volume sales of soy milk. Chinese consumers are estimated to have consumed more than 10 billion liters of soy milk in 2003, compared with a total consumption of 652 million liters just three years earlier. The major driving forces behind this robust growth are the growth in the economy, increasing average per capita income, and increased consumer consumption of healthier foods. In some Asia-Pacific countries such as Malaysia and Singapore, consumption of soy milk reached as high as 55 percent to 60 percent of their overall milk markets in 2003 and 2004.

*Soy Milk Growth Complemented by Emergence of New Functional Foods.* Aside from the Asia-Pacific region, North America is the only region with a double-digit share of global sales in 2003. Americans are estimated to have consumed 700 million liters of soy drinks in 2003, up from 200 million liters only three years earlier. An important characteristic of the American market that could be emulated by producers in India and China is that soy-related functional food sales are increasingly diversified, creating entirely new market segments, such as energy bars. This complements the growth of sales in soy milk and milk-related functional foods. Figure 4 shows the rise in the sale of

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**Figure 4** Soy Foods Sales Trends, United States, 1992–2003

Source: Soyfoods Association of North America.
soy-related foods from 1992 to 2003. This growth is particularly dramatic from 2001 onward.

In addition to the public’s growing awareness of soy-based products, manufacturer activity has been crucial in the development of the market. The unfamiliar taste has traditionally been the key factor inhibiting the expansion of soy milk to consumers beyond those with specific food allergies or lactose intolerance. The key to changing this negative consumer perception has been to make soy milk look more like standard cow’s milk by selling it refrigerated in half gallon containers similar to those used for cow’s milk.

**Threat to Soy Milk from GM Food Concerns.** Although soy milk has yet to achieve significant household penetration in regions other than Asia-Pacific and North America, sales have shown rapid progress in Western Europe. Likewise, the explosive growth predicted in Africa and the Middle East is not surprising given the current low levels of consumption, and in terms of volume, the market will remain small. In the long term, however, the continued expansion of the soy milk sector may be affected by consumer concerns about GM foods. Although soy milk positions itself in the market as a health food, it may be increasingly difficult to ensure that soy products are free from GM material. There is a risk of a consumer backlash against soy products, for example, as occurred in September 2003 in New Zealand over the inclusion of GM soy in infant soy milk formula. One solution, used by I-Mei Foods, Taiwan, China’s, leading soy milk producer, was to emphasize the use of non-GM soybeans to produce its milk. The success with which manufacturers can assure consumers of the provenance of a product claimed as “healthy” will be key to growth in the marketplace.
7. Integrated Value Chain Analysis of Soybean Farming in China

Background

China is the historical home of soybean. Some records of soybean cultivation in China date as far back as 6,000 years. During the Zhou Dynasty (11th century B.C.–256 B.C.) the soybean was a major crop in the Yellow River valley and became the main food source. By the time of the Ming Dynasty (1368–1644), soybeans were grown all over China. Chinese soybean entered the international market at the beginning of the 20th century and became one of three main export products in addition to tea and silk. By 1936, Chinese soybean production reached 11.3 million tons, which at this time accounts for 80 to 90 percent of the total global production.

The growth in Chinese soybean production also relates to the fact that soybeans are an important component of the diet of the East Asian population. Although, today, popular soybean-based foods have found markets around the world, soy foods were also known in earlier times when European travelers to China and Japan in the 16th and 17th centuries noted finding “a particular bean from which various foods could be made” (Tengäs and Nilsson 2002).

Today, China is the fourth largest producer of soybeans in the world, behind Argentina, Brazil, and the United States. Soybeans are farmed throughout China; the northeastern part of the country, primarily the Heilongjiang Province, produces the bulk of China’s soybeans.

Integrated Value Chain Analysis of Soybean Farming

An IVCA was undertaken of soybean farming in China. The cost of soybean production varies greatly from region to region, as evident in table 3. The fieldwork took place in Heilongjiang Province, which is the main soybean-producing and -exporting area, accounting for 10 percent and 33 percent of the country’s total, respectively.

<table>
<thead>
<tr>
<th>China</th>
<th>Northeast</th>
<th>North</th>
<th>East</th>
<th>Pastoral</th>
<th>South</th>
<th>West</th>
</tr>
</thead>
<tbody>
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<td>$221</td>
<td>$190</td>
<td>$187</td>
<td>$192</td>
<td>$316</td>
<td>$294</td>
<td>$337</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006; Midwest Agribusiness Trade Research and Information Center 2002.

Note: MT = metric ton.
China had about 9,500,000 hectares under soybean cultivation in 2003. The amount of acreage being harvested is likely not much different from 1999 to 2003, as the average increase in acreage growth has been only 0.6 percent. The three major varieties used in Heilongjiang are Sui Nong 14, Sui Nong 15, and Sui Nong 17, covering about 70 percent of the area. New seeds are being introduced every year and current varieties mature in the range of 115 to 120 days, depending on climatic conditions.

The IVCA objective is to provide a snapshot of a value structure representative of a particular health-enhancing functional product or industry—in this case, soybeans.

A value chain for soy farming can be divided into eight value-adding activities. This is graphically represented in figure 5. The total cost per metric ton of soybean produced in this example was RMB 1,528 (or US$190.26) with a yield rate of 1,750-1,950 kilogram per hectare. The eight value added components of soybean farming include the following:

- Land Preparation
- Planting
- Fertilizer
- Spraying
- Plant Maintenance
- Harvesting or Drying
- Shelling or Bagging
- Auction or Transport

Value Chain for Soybean Farming

Based on a preliminary analysis of the soybean value chain, the three highest value-adding stages of production were land preparation (21.2 percent), planting (18.6 percent), and fertilizing (16.8 percent) (see figure 5 and table 4).

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Figure 5  Value Chain for Soybean Farming in China

Source: Japan Development Institute and Global Development Solutions, LLC 2006.
Further analysis of the value chain suggests that, of the planting component, the cost of seeds (45.9 percent) and fuels (35.9 percent) are the highest cost items (see table 5 for the detailed breakdown of planting costs). Similarly, in the fertilizing component, chemicals constituted nearly 58 percent of the value added, while fuel added another 30 percent. These figures imply that the cost of agricultural inputs is high, which suggests that further investigation to determine whether access to and the use of agricultural inputs can be improved.

**Land Preparation**

For land preparation, land rent is the major cost item, with power and labor being minimal (see table 4). According to the farmers interviewed, land rent costs ranged from RMB 1,200 to RMB 2,700 per hectare. The farmers shared farm equipment and often worked on each other’s farms to help with the land preparation. In these cases, there were no equipment or depreciation costs to consider. This is noteworthy because, as the farms increase in size, farmers must either rent equipment or, in many cases, purchase equipment. This will add depreciation to the cost of farming and add equipment maintenance and financing costs. However, buying newer equipment should result in increased productivity.

**Planting**

The cost of planting represents about a fifth of the total costs to produce soybeans. Table 5 presents the breakdown of planting costs, which shows that seed is the highest component while fuel is a relatively close second. In China, the unit cost of seeds is relatively high when compared with other countries, particularly the United States. This relatively higher cost results from low yields, while the quantity used per hectare is higher (see details below). Furthermore, power or fuel costs are the highest total cost item of soybean production in all regions of China. However, the cost of power or fuel in northeastern China is rather close to that in the midwest region of the United States, making the region more competitive domestically and globally.

**Fertilizing and Spraying**

Table 6 provides a breakdown of fertilizing and spraying costs that account for nearly 30 percent of the value added of soybean farming. Fertilizers are widely...
used for soybean production around the world, including in China. Soybeans can fix atmospheric nitrogen in its root nodules, but this accounts for only about 50 percent of its nitrogen needs. Other common fertilizers used for soybean production by the farmer in Heilongjiang include ammonium phosphate, potassium sulfate, urea, and potash.

In the farms analyzed for this report, some of the farmers used pesticides regularly while others did not. One of the main complaints expressed in the interviews was that many farmers had received diluted and/or counterfeit fertilizers and sprays that were ineffective. This has led some to stop using chemicals altogether, which was detrimental to yield and quality.

In many parts of China, including Heilongjiang, soybean pests and diseases are serious problems that require focused attention. Soybean cyst (sporocyst), root-rot, and root-fly are an increasingly serious problem in Xinanming, for example, another large soybean-producing area in northern China. In the late 1990s, 88,000 kilometers of soybean farmland suffered these diseases, resulting in the loss of 32.9 million kilograms of soybean (Tengäs, and Nilsson 2002).

Because soybean pests and disease tend to get worse with time, integrated pest management measures need to be taken by the soybean farmer as a preventative. Such measures include the following:

- Sowing the land at the right time
- Rotating corps according to a proper schedule

Table 5  Breakdown of Planting Costs

<table>
<thead>
<tr>
<th>Cost Item</th>
<th>RMB/Y/MT</th>
<th>Percent of Planting Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seed</td>
<td>130.89</td>
<td>45.94</td>
</tr>
<tr>
<td>Power/fuel</td>
<td>102.24</td>
<td>35.92</td>
</tr>
<tr>
<td>Labor</td>
<td>51.49</td>
<td>18.14</td>
</tr>
<tr>
<td>TOTAL</td>
<td>284.62</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006.

Note: MT = metric ton.

Table 6  Breakdown of Fertilizing and Spraying Costs

<table>
<thead>
<tr>
<th>Cost Item</th>
<th>RMB/Y/MT</th>
<th>Percent of Fertilizer Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertilizer</td>
<td>147.70</td>
<td>57.46</td>
</tr>
<tr>
<td>Power/fuel</td>
<td>79.52</td>
<td>30.94</td>
</tr>
<tr>
<td>Labor</td>
<td>29.81</td>
<td>11.60</td>
</tr>
<tr>
<td>TOTAL</td>
<td>257.03</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006.

Note: MT = metric ton.
Applying the right kind of pesticides for the area and crop
Using proper techniques to plough the land
Applying proper amounts and timing of fertilizing

Weeds are a problem in China’s soybean-producing areas. Although farmers do use some herbicides to supplement hand weeding, improved weed control would contribute substantially to higher soybean yields. The field investigations also revealed a widespread imbalance of nutrients in fertilizers, indicating that finding a solution to this problem would increase soybean yields significantly and lower the cost of the labor required for manual weed control.

**Benchmarking Soybean Farming**

Table 7 provides a summary of IVCA for soybean production in China, India, and the United States. This analysis compares China’s northeast region with that of the central part of India (see the IVCA on Indian soybean farming later in this report) and the midwest region of the United States, which is the largest soybean-producing area in the United States (Iowa, Illinois, and Indiana are the three largest producing states). In this comparison, Chinese soybeans from the northeast region of the country are about 10 percent less costly to produce than those produced in the U.S. midwest, while Indian soybeans are a little over 2 percent costlier than those produced in the United States.

If national averages are compared, China has a cost disadvantage in soybean production, which is similar to its position with a number of other agricultural products, at least on a national scale (US$221/MT versus US$219/MT for the United States). Table 8 shows the regional disaggregated cost of soybean production broken down into the national average cost to produce in China, and then into the cost to produce soybeans in the various growing regions.

Table 9 divides the totals costs into various cost components. This information is then compared with the national cost to produce soybeans in the United States and regionally in the U.S. midwest.

**Fertilizers and Fuel**

In comparison with the United States, fertilizer and fuel are the two main contributors to China’s cost disadvantage in soybean production. The average fertilizer cost is 264 percent higher compared with that in the U.S. midwest, while total fuel cost is another large item contributing to higher cost in China (66 percent). In fact, fuel is the largest factor affecting China’s soybean cost in dollar terms ($44/MT higher). The power cost in the northeast region of China, however, is quite close to that in the U.S. midwest.

Fertilizer use per hectare in China on average is 32 percent lower than that in the U.S. midwest, as summarized in table 10. The difference in fertilizer utilization on a per metric ton basis is much smaller in soybean production than in corn production. The major factor contributing to higher fertilizer costs is the price. China’s northeast region (115.43 kg/ha) has almost the same amount of fertilizer use per hectare as the U.S. midwest (117.69 kg/ha).
Table 7  Benchmarking Soybean Farming—China, India, and the United States

<table>
<thead>
<tr>
<th>Land Preparation</th>
<th>Planting</th>
<th>Fertilizing</th>
<th>Spraying</th>
<th>Plant Maintenance</th>
<th>Harvesting/Drying</th>
<th>Shelling/Bagging</th>
<th>Auction/Transport</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Value Chain for Production of Soybeans ($/MT): China (US$/MT 190.26)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit Cost</td>
<td>40.40</td>
<td>35.44</td>
<td>32.01</td>
<td>24.77</td>
<td>15.14</td>
<td>29.72</td>
<td>7.07</td>
<td>5.71</td>
</tr>
<tr>
<td>% of total</td>
<td>21.2%</td>
<td>18.6%</td>
<td>16.8%</td>
<td>13.0%</td>
<td>8.0%</td>
<td>15.6%</td>
<td>3.7%</td>
<td>3.0%</td>
</tr>
<tr>
<td><strong>Value Chain for Production of Soybeans ($/MT): United States (US$/MT 209.15)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit Cost</td>
<td>73.64</td>
<td>34.36</td>
<td>17.61</td>
<td>17.61</td>
<td>11.16</td>
<td>28.28</td>
<td>11.78</td>
<td>14.72</td>
</tr>
<tr>
<td>% of total</td>
<td>35.2%</td>
<td>16.4%</td>
<td>8.4%</td>
<td>8.4%</td>
<td>5.3%</td>
<td>13.5%</td>
<td>5.6%</td>
<td>7.0%</td>
</tr>
<tr>
<td><strong>Value Chain for Production of Soybeans ($/MT): India (US$/MT 204.35)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit Cost</td>
<td>25.50</td>
<td>53.12</td>
<td>60.63</td>
<td>9.18</td>
<td>30.21</td>
<td>13.34</td>
<td>10.80</td>
<td>1.57</td>
</tr>
<tr>
<td>% of total</td>
<td>12.5%</td>
<td>26.0%</td>
<td>29.7%</td>
<td>4.5%</td>
<td>14.8%</td>
<td>6.5%</td>
<td>5.3%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006; Midwest Agribusiness Trade Research and Information Center 2002.
Table 8  Cost of Soybean Production—China and the United States (US$/MT)

<table>
<thead>
<tr>
<th></th>
<th>China</th>
<th>Northeast</th>
<th>North</th>
<th>East</th>
<th>Pastoral</th>
<th>South</th>
<th>West</th>
<th>U.S.</th>
<th>U.S. Midwest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>221</td>
<td>190</td>
<td>187</td>
<td>192</td>
<td>316</td>
<td>294</td>
<td>337</td>
<td>219</td>
<td>209</td>
</tr>
<tr>
<td>Ratio to Cost in U.S. Midwest</td>
<td>1.06</td>
<td>0.82</td>
<td>0.90</td>
<td>0.92</td>
<td>1.52</td>
<td>1.41</td>
<td>1.62</td>
<td>1.05</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Source: Fang and Fabiosa 2002; Midwest Agribusiness Trade Research and Information Center 2002; Japan Development Institute and Global Development Solutions, LLC 2006.
Note: MT = metric ton.

Labor Costs

The difference in labor is significant. To produce one metric ton of soybeans in China requires 76 staff days compared with 0.32 staff days in the United States (see table 11). However, even with a wage rate that is 462 percent higher in the United States than in China, labor cost in China is still 378 percent higher for soybean production than in the United States.

Seeds

China’s seed cost to produce soybeans is 44 percent higher than in the United States; however, in the northeast region of China, it is a only 4 percent higher. Seed cost throughout China is generally higher than in the United States. U.S. producers primarily use Roundup Ready, a GM seed that, as it grows, is impervious to glyphosate, which is a nonselective herbicide (Midwest Agribusiness Trade Research and Information Center 2002). American farmers agree to pay a higher price for Roundup Ready seed and further agree not to save it for additional planting. Chinese farmers use non-GM seed varieties that are inexpensive. The higher unit seed cost in China (US$22.53 versus US$17.3 for the United States) results from the fact that the quantity used per hectare is higher and the yield is lower in China’s soybean production areas.

Land

The U.S. land productivity advantage is offset by higher land rent costs in the United States. As a result, China has a substantial land cost advantage. Table 12 shows that the area required to produce a metric ton of soybeans is much lower in the United States at 0.36 hectares than in China at 0.57 hectares. However, total land cost in the United States of US$69.25/MT is much higher than in China of US$42.80/MT (Midwest Agribusiness Trade Research and Information Center 2002). The cost of land will continue to be a major determinant in the comparative competitiveness of the United States and China in the production of soybeans in the future. Some expect that the acreage of land required to produce soybeans in the two countries may be narrowed in the future as China draws closer to the level of productivity of American farmers.

However, the potential scale and speed at which China can catch up in the productivity of soybean production may be exaggerated, particularly
Table 9  Major Components in Cost of Production of Soybeans, Comparing China and the United States (US$/MT)

<table>
<thead>
<tr>
<th></th>
<th>China</th>
<th>Northeast</th>
<th>North</th>
<th>East</th>
<th>Pastoral</th>
<th>South</th>
<th>West</th>
<th>U.S.</th>
<th>U.S. Midwest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Land</td>
<td>42.80</td>
<td>34.86</td>
<td>39.19</td>
<td>49.83</td>
<td>49.52</td>
<td>35.40</td>
<td>28.91</td>
<td>69.25</td>
<td>73.09</td>
</tr>
<tr>
<td>Power</td>
<td>113.42</td>
<td>71.54</td>
<td>90.72</td>
<td>95.63</td>
<td>156.78</td>
<td>199.47</td>
<td>206.06</td>
<td>77.92</td>
<td>68.76</td>
</tr>
<tr>
<td>Total fertilizer</td>
<td>24.52</td>
<td>31.21</td>
<td>16.28</td>
<td>11.50</td>
<td>44.63</td>
<td>33.33</td>
<td>36.95</td>
<td>7.73</td>
<td>6.75</td>
</tr>
<tr>
<td>Seeds</td>
<td>22.53</td>
<td>16.95</td>
<td>19.31</td>
<td>23.15</td>
<td>33.65</td>
<td>24.70</td>
<td>39.78</td>
<td>17.3</td>
<td>15.71</td>
</tr>
<tr>
<td>Bag/Sell/Transport</td>
<td>15.23</td>
<td>5.50</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>21.1</td>
</tr>
<tr>
<td>Labor</td>
<td>85.98</td>
<td>33.87</td>
<td>75.14</td>
<td>81.65</td>
<td>104.6</td>
<td>171.47</td>
<td>179.79</td>
<td>17.99</td>
<td>15.95</td>
</tr>
</tbody>
</table>

<p>| | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio to Cost in U.S. Midwest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Land</td>
<td>0.59</td>
<td>0.48</td>
<td>0.54</td>
<td>0.68</td>
<td>0.68</td>
<td>0.48</td>
<td>0.39</td>
<td>0.95</td>
<td>1.00</td>
</tr>
<tr>
<td>Power</td>
<td>1.66</td>
<td>1.04</td>
<td>1.33</td>
<td>1.40</td>
<td>2.30</td>
<td>2.94</td>
<td>3.04</td>
<td>1.13</td>
<td>1.00</td>
</tr>
<tr>
<td>Total fertilizer</td>
<td>3.64</td>
<td>4.27</td>
<td>2.42</td>
<td>1.71</td>
<td>6.63</td>
<td>4.95</td>
<td>5.48</td>
<td>1.15</td>
<td>1.00</td>
</tr>
<tr>
<td>Seeds</td>
<td>1.44</td>
<td>1.04</td>
<td>1.23</td>
<td>1.48</td>
<td>2.13</td>
<td>1.58</td>
<td>2.53</td>
<td>1.10</td>
<td>1.00</td>
</tr>
<tr>
<td>Bag/Sell/Transport</td>
<td>0.72</td>
<td>0.26</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>1.00</td>
</tr>
<tr>
<td>Labor</td>
<td>5.39</td>
<td>2.12</td>
<td>4.71</td>
<td>5.12</td>
<td>6.56</td>
<td>10.75</td>
<td>11.28</td>
<td>1.13</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Source: Fang and Fabiosa 2002; Midwest Agribusiness Trade Research and Information Center 2002; Japan Development Institute and Global Development Solutions, LLC 2006.
Note: MT = metric ton.
considering that many farmers already use high-yielding varieties and have relatively high fertilizer use. Furthermore, the land costs in each country are largely driven by their respective policy regimes. In China, for instance, the low land cost is artificial and reflects government controls in land use and the lack of a free land market. All farmers interviewed rented their land from the government, as did all farmers in the region. In the United States, with government farm support capitalized into higher land values, land cost is

<table>
<thead>
<tr>
<th>Table 10</th>
<th>Fertilizer Use and Cost of Soybeans</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>China</td>
</tr>
<tr>
<td>Chemical</td>
<td>80.23</td>
</tr>
<tr>
<td>Fertilizer use/area (kg/ha)</td>
<td>45.96</td>
</tr>
<tr>
<td>Chemical</td>
<td>18.64</td>
</tr>
<tr>
<td>Fertilizer use/output (kg/MT output)</td>
<td>24.52</td>
</tr>
<tr>
<td>Chemical</td>
<td>2.77</td>
</tr>
<tr>
<td>Fertilizer cost (US$/MT)</td>
<td>3.64</td>
</tr>
</tbody>
</table>

Source: Fang and Fabiosa 2002; Midwest Agribusiness Trade Research and Information Center 2002; Japan Development Institute and Global Development Solutions, LLC 2006.
Note: h = hectare; kg = kilogram; MT = metric ton.
<table>
<thead>
<tr>
<th></th>
<th>China</th>
<th>Northeast</th>
<th>North</th>
<th>East</th>
<th>Pastoral</th>
<th>South</th>
<th>West</th>
<th>US</th>
<th>U.S. Midwest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor requirement</td>
<td>76.6</td>
<td>30.5</td>
<td>71.1</td>
<td>63.66</td>
<td>108.97</td>
<td>120.01</td>
<td>176.12</td>
<td>0.32</td>
<td>0.28</td>
</tr>
<tr>
<td>(days/MT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wage (US$/day)</td>
<td>1.12</td>
<td>1.12</td>
<td>1.05</td>
<td>1.29</td>
<td>0.96</td>
<td>1.42</td>
<td>1.02</td>
<td>56.96</td>
<td>57.31</td>
</tr>
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<td>Labor cost (US$/MT)</td>
<td>85.98</td>
<td>33.87</td>
<td>75.14</td>
<td>81.65</td>
<td>104.6</td>
<td>171.47</td>
<td>179.79</td>
<td>17.99</td>
<td>15.95</td>
</tr>
<tr>
<td>Power cost (US$/MT)</td>
<td>113.42</td>
<td>77.54</td>
<td>90.72</td>
<td>95.63</td>
<td>156.78</td>
<td>199.47</td>
<td>206.06</td>
<td>77.79</td>
<td>68.9</td>
</tr>
</tbody>
</table>

<p>| | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor requirement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(days/MT)</td>
<td>274.4</td>
<td>109.26</td>
<td>254.7</td>
<td>228.05</td>
<td>390.34</td>
<td>429.9</td>
<td>630.88</td>
<td>1.13</td>
<td>1.00</td>
</tr>
<tr>
<td>Wage (US$/day)</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.02</td>
<td>0.99</td>
<td>1.00</td>
</tr>
<tr>
<td>Labor cost (US$/MT)</td>
<td>5.39</td>
<td>2.12</td>
<td>4.71</td>
<td>5.12</td>
<td>6.56</td>
<td>10.75</td>
<td>11.28</td>
<td>1.13</td>
<td>1.00</td>
</tr>
<tr>
<td>Power cost (US$/MT)</td>
<td>1.66</td>
<td>1.03</td>
<td>1.33</td>
<td>1.39</td>
<td>2.29</td>
<td>2.93</td>
<td>3.04</td>
<td>1.13</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Source: Fang and Fabiosa 2002; Midwest Agribusiness Trade Research and Information Center 2002; Japan Development Institute and Global Development Solutions, LLC 2006.
Note: MT = metric ton.
artificially high. As government support is reduced in the United States and as land use policy is liberalized in China, land costs in both countries are expected to move toward parity—land cost in China is expected to increase while land cost in the United States will decrease (Midwest Agribusiness Trade Research and Information Center).

<table>
<thead>
<tr>
<th>Table 12</th>
<th>Land Use, Price, and Cost of Soybeans</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>China</td>
</tr>
<tr>
<td>Cost (US$/MT)</td>
<td>42.8</td>
</tr>
<tr>
<td>Use (ha/MT)</td>
<td>0.57</td>
</tr>
<tr>
<td>Price (US$/ha)</td>
<td>74.71</td>
</tr>
</tbody>
</table>

Source: Fang and Fabiosa 2002; Midwest Agribusiness Trade Research and Information Center 2002; Japan Development Institute and Global Development Solutions, LLC 2006.

Note: h = hectare; MT = metric ton.
8. Integrated Value Chain Analysis of Soybean Farming in India

Summary of Findings

Despite its robust growth over the last 25 years, with more than a tenfold increase in production from 1981–82 (0.46 million MT) to 2004–05 (5.85 million MT) and acreage from 0.622 million hectares in 1981–82 to 7.67 million hectares in 2005–06 (see figure 6), soybean production in India returns persistently low yields. From 1981 to 2005, in general, the yield’s trend has remained around 800 kilograms per hectares (kg/ha). The prevailing low soybean yields are symptomatic of a set of constraints that inhibit the sector’s competitiveness. An IVCA of soybean farming and processing has been undertaken in the large, central Indian state of Madhya Pradesh, where the bulk of soy is grown, to identify the major barriers to competitiveness.

Options for Growth

While many functional foods have proliferated in the developed markets, not all of them have established health benefit credentials. In the United States, for

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**Figure 6  Area Under Soybean Cultivation, India**

![Area Under Soybean Cultivation, India](source:SOPA)
example, the FDA establishes the labeling rules for health claims made by functional food producers and supported by scientific evidence available. In contrast to many functional foods, soy protein has an established record of health benefits and is one of the few foods recognized as such by the scientific community and regulators such as the FDA. Annex 1 provides examples of functional food components and their potential health benefits.

Because of soy protein’s established health benefits, an initial emphasis on soy-related products, such as soy milk, is an appropriate strategy for growth in the functional foods industry in India. Moreover, major Indian functional food processors believe that—

health awareness in India is phenomenal and the soy market is expected to grow at a rate of 200 per cent per annum. Also, about 50 to 60 per cent of the Indian population is lactose intolerant and a large number of the population is vegetarian to whom soy milk can provide the alternative for a high-protein, low-calorie nutritional supplement (Rekha 2004).

Notwithstanding the potential of soy as a functional food, soy milk plants operate at very low capacity. For example, the installed capacity of ProSoya Foods is around 20 million liters per year, of which it utilizes only 5 percent of its capacity. This suggests that diversification in the soy milk category itself (for example, through the introduction of multiple flavors) and into other products such as soy milk powder could increase the utilization levels of plants. This affects cost of production and the ability to produce a cheaper product may improve the growth prospects of the soy milk market in India.

With more than 1 billion people, the Indian market is a very good avenue for growth of the functional foods industry because Indians spend between 42 and 63 percent of household income on food. Increased household income, especially in the urban middle class; strong and robust growth of the retail sector; and urbanization contribute to good prospects for growth of functional foods business. A closer look at Indian household expenditure (see figure 7) shows that 7 percent of consumer expenditures in urban India and 8 percent in rural India are spent on the milk and milk-based products categories. Although this category is a direct competitor for soy-related products, soy milk has the distinct advantage of not requiring an effective cold chain, which is needed for milk products. The growth of the soy milk industry domestically most probably is going to hinge on its ability to accomplish one or more of the following:

- Provide consumers with credible (cost and quality wise) substitutes for milk;
- Deliver to consumers credible (cost and quality wise) substitutes for milk-related products, such as yogurts, creams, cheeses, ice creams, and so forth; and
- Diversify into the larger share of “other food” consumer segments by introducing products that provide substitutes to drinks items, such as beverages and shakes, and create entirely new product categories, such as energy bars.
Integrated Value Chain Analysis of Farming

For the purpose of this analysis a farmer in the Sehore district of Madhya Pradesh was selected. Typical for this soybean cultivating region, this farmer’s cultivation area is approximately 2 hectares. The farmer owns two bulls and generally uses rented equipment for planting. The farmer shares the tubewell and motor pump with village relatives. He mainly uses Jawahar Soybean 335 (JS-335) seed variety with a maturity period of 85 to 100 days. He also uses Samrat and Gold seed varieties and generally is known as an early adopter of improved varieties.

According to the value chain analysis, the farm-to-market cost of delivering a kilogram of soy is dominated by the cost of fertilizer (29.7 percent), followed by planting (26 percent), and plant maintenance through thinning (14.8 percent) (see figure 8). The farming production cost per hectare of yellow soybean delivered at local Mandi market is estimated at Rs 13,001 (US$284.49/ha). The average marketable yield is estimated at 1,480 kg/ha, thus making the delivered cost of soy Rs 8.77/kg (US$0.19/kg).

Fertilizing

Table 13 illustrates the cost and usage structure of fertilizer in this particular farm with the highest cost attributed to biofertilizer fertilizers.

The bulk of fertilizer used is biofertilizer obtained from the farmer’s animals and from other farmer’s animals. The biofertilizer available meets only one-third of total requirements at the current usage level. Traditionally, self-prepared compost fertilizer, mainly from animals, has been the first preference. Currently, such fertilizer is not readily available because growth of the livestock population in Madhya Pradesh has been negative for cattle and very weak for...
buffalo and other animals. The same holds for other states with major livestock population as well as countrywide (see table 14).

In Madhya Pradesh, for example, between 1997 and 2003, there were 13 percent fewer cattle and buffalo to support the supply of manure for the growing area planted (see table 15). As a result, biofertilizer is increasingly in short supply.

To compensate for the diminishing availability of biocompost, the smallholders have to turn to chemical fertilizers, but there are problems. First, the distance to market is generally 30 kilometers or more. Second, smallholders are generally cash deprived and the cost of chemicals, including the cost of approximately Rs 30 to transport three to four 50 kilogram bags over a distance of 10 kilometers, is most probably prohibitively expensive for most farmers.

<table>
<thead>
<tr>
<th>Table 13 Fertilizer Cost and Usage, Indian Soy Farm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
</tr>
<tr>
<td>DAP</td>
</tr>
<tr>
<td>POTASH</td>
</tr>
<tr>
<td>SSP</td>
</tr>
<tr>
<td>BIO</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006.

Note: BIO = biofertilizer; DAP = diammonium phosphate; ha = hectare; kg = kilograms; POTASH = potassium and soil; SSP = single super phosphate.
While a full comparative survey would be needed to highlight the yield differences in fertilized versus nonfertilized plots, the value chain analysis suggests that there are clear benefits to using fertilization in terms of yields. For example, this particular farmer, who has relatively good fertilization levels, has yields of 1,480/ha and in some years up to 2,220kg/ha for seed variety JS-335. As figure 9 illustrates, these yield levels are superior to average country levels. The yield potential of the JS-335 variety is estimated at between 2,500 and 3,000 kg/ha, which suggests that the degree of importance of improved farm nutrient intake is probably the highest among variables that influence yields.

Investment measures, such as genetic, nutritional, and health improvements for livestock that lead to increased livestock populations, would provide the necessary levels of biofertilizer for soybean farmers and, as a result, would positively impact yield levels. Together with an improved livestock situation, strategies that would make chemical fertilizer more accessible to smallholders with limited cash resources could also be expected to close the gap between the actual and potential soybean yields in India.

Table 14  Livestock Population, India, 1997–2003 (in millions)

<table>
<thead>
<tr>
<th></th>
<th>1997</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cattle</td>
<td>Buffalo</td>
</tr>
<tr>
<td>Madhya Pradesh</td>
<td>19.5</td>
<td>6.6</td>
</tr>
<tr>
<td>Uttar Pradesh</td>
<td>20.0</td>
<td>19.0</td>
</tr>
<tr>
<td>West Bengal</td>
<td>17.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Total India</td>
<td>198.8</td>
<td>89.9</td>
</tr>
<tr>
<td>Growth 97–03</td>
<td>-7%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Source: Compiled by Japan Development Institute and Global Development Solutions, LLC 2006, from the Indian Ministry of Agriculture.

Table 15  Main Manure Animals per Soybean Area Planted, Madhya Pradesh

<table>
<thead>
<tr>
<th></th>
<th>1997</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cattle (million)</td>
<td>Buffalo (million)</td>
</tr>
<tr>
<td></td>
<td>19.5</td>
<td>6.6</td>
</tr>
<tr>
<td>Variance (%)</td>
<td>-3</td>
<td>+15</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006.  
Note: ha = hectare.  
*Assuming the 2003 share of Madhya Pradesh’s planting area of 55 percent of the total Indian soybean area planted.
Planting

Planting is the second-highest value added component to the cost of soybeans. As noted in table 16, the cost of seed accounts for more than 74 percent of the total cost of planting, with equipment rental accounting for 18.2 percent and labor accounting for the balance. Although most farmers have historically used their own seeds in the cultivation of their crops, the Indian Seed Act of 2004,\textsuperscript{12} when it comes into effect, will overhaul the seed regulatory system. The Act may prevent or eliminate such sourcing options in the future through the regulatory requirements that seed must be registered and certified before it can be used (see box 6 for details of registering and certifying seed as proposed under the Act). The government says that the objective of the law is to regulate the seed market to ensure that “quality” seeds are readily available to the farmer. The seed law is designed to harmonize with seed laws around the world and to open the Indian seed market to foreign competition.
Therefore, the proposed Indian Seed Act of 2004 will restrict the “use of retained hybrids” at farm level, forcing farmers to purchase private or state-produced seeds, which come at a higher price.

The farmers interviewed reported spending around Rs 25/kg of seed. This is in contrast to the potential cost of Rs 9/kg (the farmer’s production costs) for using retained hybrids. Therefore the farmer, by being required to purchase commercial seed instead of retained hybrids, has a cost of production that is Rs 1,650 higher than it would be if he or she purchased only retained hybrids.

**Plant Maintenance**

Plant maintenance is the most labor-intensive part of soybean farming, and it is estimated at Rs 1,925/ha. All costs associated with plant maintenance are for labor, which is mostly involved in thinning and weeding. About 20 to 60 workers are needed to perform plant maintenance. The wage rates differ during the plant cycle. Depending on weather conditions, the daily wage rate is between Rs 20 and Rs 90, with the wage rate increasing depending on weather conditions; in periods of rain, for example, the effort required to maintain the plants increases and the wage rates also increase to an estimated Rs 90 per day. For the most part, plant maintenance is a 30- to 45-day job for any individual worker. The value chain analysis has not identified any major bottleneck in this part of the value chain.

### Box 6  India: Seed Registration and Certification

A distinction needs to be made between registering a seed and certifying a seed under the proposed Indian Seed Act of 2004:

**Registering a seed:** This is compulsory for all seed sold. The criteria for registering a seed are the Value for Cultivation and Use (VCU). This would involve growing the variety over a number of seasons (three seasons in the Seed Act) and testing for their ability to be of commercial use.

**Certifying a seed:** This is an optional extra to register a seed and the criteria are established in the “Indian Minimum Seed Certification Standards” from 1988. There are six phases of seed certification:

1. Receipt and scrutiny of application;
2. Verification of seed source, class, and other requirements of the seed used for raising the seed crop;
3. Field inspections to verify conformity to the prescribed field standards;
4. Supervision at postharvest stages, including processing and packing;
5. Seed sampling and analysis, including genetic purity test and/or seed health test, if any, to verify conformity to the prescribed standards; and
6. Grant of certificate and certification tags, tagging, and sealing.

*Source: Indian Seed Act of 2004.*

**Other Issues: Trading at Mandi, the Government-Run Market**

After threshing and bagging, the farmers bring their product to the Mandi, the markets sponsored and administered by state governments. Seeds are
auctioned openly. Farmers are generally price-takers, because they need funds to finance the subsequent harvest, and the trader provides the necessary liquidity in the market. In this particular example, the farmer’s delivered price of soybean was estimated at Rs 12.5/kg, thus making the farmer’s estimated gross profit of Rs 3.72/kg. The trader rebags the soybeans, increasing the transaction cost of business. In addition, an estimated 7.5 percent of the auction price is spent on a range of fees and charges at Mandi (see table 17).

As table 17 shows, marketing charges in the range of 9.8 percent are added to the soybean value chain before soybean reaches the processor and exclude the trader’s margin. Depending on the time the trader sells to processors, this margin can be reduced by storage costs charged by Mandi, which are at 4 percent of the auction price per month. In the best-case scenario, in which the trader sells within days of purchasing from the farmer, and based on the estimated nonpeak delivered price of soybean to processors at the price of Rs 17/kg, the trader’s margin can be 19 percent. However, soybeans usually are sold within two to three months from the auction and this time gap reduces the profit margin to 10 percent. Margins vary as the trader’s increased cost of storage can either be compensated if prices increase during the storage period or compounded if prices fall.

Table 17  Marketing Charges, Mandi Auction

<table>
<thead>
<tr>
<th>Rs/kg</th>
<th>Percentage of Auction Price (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auctioned Price (Yellow JS-335)</td>
<td>12.50</td>
</tr>
<tr>
<td>Rebagging cost</td>
<td>0.18</td>
</tr>
<tr>
<td>Mandi (trading) tax</td>
<td>0.28</td>
</tr>
<tr>
<td>Sales tax</td>
<td>0.50</td>
</tr>
<tr>
<td>Entry tax</td>
<td>0.06</td>
</tr>
<tr>
<td>Municipal tax</td>
<td>0.01</td>
</tr>
<tr>
<td>Weight charges</td>
<td>0.05</td>
</tr>
<tr>
<td>Brokerage fee</td>
<td>0.04</td>
</tr>
<tr>
<td>Labor</td>
<td>0.10</td>
</tr>
<tr>
<td><strong>Total Fees and Charges</strong></td>
<td><strong>1.22</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Soybean Cost Price, Post Auction</th>
<th>Storage (Rs/kg)</th>
<th>Percentage of Auction Price (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trader’s Cost Price, 1 week storage</td>
<td>13.84</td>
<td>0.12</td>
</tr>
<tr>
<td>Trader’s Cost Price, 1 month storage</td>
<td>14.22</td>
<td>0.50</td>
</tr>
<tr>
<td>Trader’s Cost Price, 3 months storage</td>
<td>15.22</td>
<td>1.50</td>
</tr>
</tbody>
</table>

**Delivered Price of Soybean** 17.00–20.00

*Source: Japan Development Institute and Global Development Solutions, LLC 2006.*
*Note: kg = kilograms; Rs = rupees.*
With peak and off-peak volatility of soybean prices delivered at the processor’s gate ranging between Rs 17/kg (off-peak) and Rs 20/kg (peak), investments that would improve the efficiency of Mandi markets are needed to bring down the transaction costs, which are eventually passed down the value chain to processors. In this respect, the value chain analysis suggests that storage charges of publicly run Mandi markets are excessive and need to be addressed. In addition, traders pay a trading tax to Mandi in the range of 4 percent, and they are charged additional nontransparent/opaque fees, such as an entry tax. These fees increase the cost of doing business.

*High Tariffs on Soybeans and Related Products*

The Indian Government has imposed high tariffs on the import of soybeans and related products, supposedly to protect soybean farmers, most of whom are smallholder farmers working with limited resources to use techniques associated with modern farming, such as irrigation. The tariffs for soybean seed, meal, and oil are higher in India than in any of the other major soybean-producing and -consuming countries in the world (see figure 10 for details).

*Integrated Value Chain Analysis of Soy Milk Processing*

Once the processor purchases soybean, at the price range of Rs 17/kg to Rs 20/kg depending on the time of purchase, there are five stages of production involved in producing soy milk, namely the following:
- Soaking
- Grinding

---

**Figure 10  Applied Soybean Tariffs for Major Producers and Consumers (Ranked by 2002–04 Average Production)**

Source: Agricultural Market Access Data base (AMAD).
- Cooking
- Pressing and filtering
- Packing

For the purpose of this analysis, an established processor of packaged fruit drinks, Bhopal, in the capital city in Madhya Pradesh was selected. The processor operates the soy milk-processing unit while using some of the synergies with the existing fruit drinks plant, but the value chain analysis suggests that the processor produces only at 5 percent of its full capacity of 4,000 liters/hour. According to the value chain (see figure 11), with soybean priced at Rs 17/kg, the production cost of a liter of soy milk packaged in 1 liter Tetra Pack cartons is estimated at Rs 34.56 (US$0.75/liter).

Figure 11 illustrates that financing, energy costs, and packing material costs are the main drivers of soy milk production. Considering that soy milk competes with milk in Bhopal markets at the price range of Rs 15/liter to Rs 16/liter, soy milk at Rs 36/liter will have difficulties in penetrating the local market in so far as substitution at relative price parity is concerned. In addition, the retail price is before any distribution and retailing margins are included.

Most soy milk is marketed in 200 milliliter (ml) packs, and the value chain analysis suggests (see figure 12) that the cost of soy milk sold per liter (five 200 ml packs as opposed to 1 liter pack) is 39 percent higher than 1 liter of soy milk sold in a 1 liter carton (Rs 48.16/liter or US$1.05/liter). This cost difference is driven by the fact that several packages are used to package the 200 ml packs versus the one package used for the 1 liter pack. Apart from
packaging cost variations depending on the type of retail packaging chosen, the fundamentals of soy milk processing are affected by high-energy, financing and packaging costs. As a result of the high price of the end product, volumes of soy milk sold are low, thus leading to extremely low plant capacity utilization and high per unit costs.

**High Financing Costs**

As shown in figure 12, at 30 percent, the cost of financing soy milk production is one of the highest cost components across the value chain. The Bhopal producer financed all of his equipment and as such was required to take out loans for millions of rupees at rates in the range of 12 percent to 15 percent. Therefore, the interest costs for the financing are high and this is coupled with the low capacity utilization, which makes his per unit financing costs much higher than it should be if the company were to produce at a 50 percent capacity. As the market grows and more production comes on line, this per unit financing costs should drop dramatically.

The result of this cost structure is that soy milk processors sell soy milk at or below cost price in their attempts to gain some market share. For example, this particular producer sells a liter of soy milk at Rs 46.80, which represents a loss of 3 percent of production cost. As table 18 illustrates, compared with the retail price of milk, the consumer in Madhya Pradesh would have to pay a price premium of 244 percent in case soy milk is chosen as a loose milk substitute. Although in developed markets soy milk is also at a premium, sometimes at retail multiples of 300 percent over and above the price of milk, judging by the low sales volume in India, even at below cost prices, it appears that the consumer’s purchasing power is not strong enough to justify the price differences between loose milk and soy milk.

*Source: Japan Development Institute and Global Development Solutions, LLC 2006.*
This suggests that marketing strategies that would not necessarily focus solely on promoting soy milk as a milk substitute (notwithstanding its clear health benefits) but also on soy milk in the beverage segments, such as healthy drinks, shakes, and so forth, could potentially create room for the expansion of soy milk sales.

<table>
<thead>
<tr>
<th>Table 18 Soy Milk Chain—Producer to Retail, Madhya Pradesh, India</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Producer’s sales price to wholesale(r)</td>
</tr>
<tr>
<td>Rs/liter</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>46.80</td>
</tr>
<tr>
<td>Wholesale(r) price to retailer</td>
</tr>
<tr>
<td>Rs/liter</td>
</tr>
<tr>
<td>48.89</td>
</tr>
<tr>
<td>Retailer price</td>
</tr>
<tr>
<td>Rs/liter</td>
</tr>
<tr>
<td>55.00</td>
</tr>
</tbody>
</table>

Source: Japan Development Institute and Global Development Solutions, LLC 2006.
Note: Prices inclusive of value added tax (4 percent) and transportation.
n.a. = not applicable; Rs = rupees.
9. Conclusion

The global functional foods industry has experienced growth over the last few years, emerging from mainly a fringe or niche market to one that is mainstream. The growth in China and India has mirrored that around the world. Both countries have experienced solid growth in a number of functional food categories, including yogurts (prebiotics and probiotics), energy bars, functional waters, soy-based products, juices, and other beverages. All of these are examples of areas in which significant growth and intense competition are taking place, although performance across national markets varies greatly. Other areas of rapid growth for functional foods include that of curative products such as gut health, cholesterol lowering, and bone health products. Gut health products find an especially attractive market in Japan; however, this particular market in India, China, and the United States remains small and provides opportunity for further development.

As the market for functional foods expands and develops, multinational companies and government regulators are increasingly involved in regulating and developing the functional foods markets. The size of the global market for functional foods is estimated at around US$63 billion and this is expected to grow to as much as US$167 billion by 2010 and even larger with the demographics of an increasing aging population interested in a healthy lifestyle in developed countries and growing middle classes in many developing countries with more disposable incomes (Hoggard n.d.). The current global growth rate for functional foods is approximately 14 percent, (Hoggard n.d.) and this is expected to continue for the next few years after which the market will see some maturity and the growth rates will slow accordingly. The best estimates are that the functional foods market will include approximately 5 percent of total expenditures made in the developed world on food by 2010 (Hoggard n.d.). Strong scientific evidence that demonstrates safety and efficacy of functional foods is critical in guaranteeing future consumer confidence and market success.

The market for functional foods is global, and the development of markets will depend on a number of factors such as the following:

- Growing consumer demand for new, supplementary foods designed to enhance health and general well-being;
- An established, competitive market for processed foods;
- Health benefits that are clear, understandable, and relevant to the target market, believed by the consumer, and regulated by the government;
- Functional foods products that are competitively priced and offer taste and convenience for their use (this would follow the experience of the early years of the health food sector and recent experiences with organic foods);
Relevant R&D that provides the consumer and the functional foods industry with information about benefits; and

Policies and regulations that are compatible with a changing market and support the development of the functional foods industries, particularly by adding to consumer confidence in the product.

As evidenced by the country case studies and the soybean and soy milk IVCAs presented earlier, India and China are in strong positions to be competitive players in the global functional foods industry provided that certain modifications are made to existing laws and regulations. Both countries are implementing legal and regulatory improvements that will help establish a solid foundation for building the functional foods industry in their respective countries.

However, as global growth in functional foods continues and as regulation increases, there is a danger that regulators will create barriers for the industry that stifle growth and opportunities for development. In the 1980s, Japan was able to create an appropriate balance with the establishment FOSHU and its regulatory environment that played a key role in the success of functional foods.

Sound regulatory foundations are vital to the functioning and sustained growth of the functional foods industry. The health and well-being benefits of functional foods must be substantiated by scientific research and certified by governments, and must be appropriately labeled. Growth in the functional foods industry will also benefit from information campaigns designed to educate the consumers about the benefits of functional foods.

Success in the development of the functional foods industry over the coming years can only come when all of the stakeholders join to promote truthful, healthful, quality products that meet the needs of consumers. These stakeholders include, among others, farmers, manufacturers, retailers, wholesalers, governmental regulators, and scientists working to better understand functional foods. The future success of markets for functional foods will be driven by the scientific research on nutrition and health, as well as how the manufacturers and marketers deliver the products of this research and how governments provide the regulatory framework to instill consumer confidence, improve infrastructure, and maintain a free market environment. As the research and knowledge of nutrition and health continues to develop, and as companies around the world create and sell their products on the basis of sound science in a climate in which regulations have been carefully thought out, functional foods will see substantial future growth.
Annex 1. Types of Functional Foods

There are a number of classes of functional foods that offer a variety of benefits. The following table lists some of them along with the source of the food and the potential health benefits.

<table>
<thead>
<tr>
<th>Class/Component</th>
<th>Source*</th>
<th>Potential Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Carotenoids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta-carotene</td>
<td>carrots, various fruits</td>
<td>neutralizes free radicals that may damage cells; bolsters cellular antioxidant defenses</td>
</tr>
<tr>
<td>Lutein, Zeaxanthin</td>
<td>kale, collards, spinach, corn, eggs, citrus</td>
<td>may contribute to maintenance of healthy vision</td>
</tr>
<tr>
<td>Lycopene</td>
<td>tomatoes and processed tomato products</td>
<td>may contribute to maintenance of prostate health</td>
</tr>
<tr>
<td><strong>Dietary (functional and total) Fiber</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insoluble fiber</td>
<td>wheat bran</td>
<td>may contribute to maintenance of a healthy digestive tract</td>
</tr>
<tr>
<td>Beta glucan**</td>
<td>oat bran, rolled oats, oat flour</td>
<td>may reduce risk of coronary heart disease (CHD)</td>
</tr>
<tr>
<td>Soluble fiber**</td>
<td>psyllium seed husk</td>
<td>may reduce risk of CHD</td>
</tr>
<tr>
<td>Whole grains**</td>
<td>cereal grains</td>
<td>may reduce risk of CHD and cancer; may contribute to maintenance of healthy blood glucose levels</td>
</tr>
<tr>
<td><strong>Fatty Acids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monounsaturated fatty acids (MUFAs)</td>
<td>tree nuts</td>
<td>may reduce risk of CHD</td>
</tr>
<tr>
<td>Polyunsaturated fatty acids (PUFAs): Omega-3 fatty acids—ALA</td>
<td>walnuts, flax</td>
<td>may contribute to maintenance of mental and visual function</td>
</tr>
<tr>
<td>PUFAs: Omega-3 fatty acids-DHA/EPA</td>
<td>salmon, tuna, marine and other fish oils</td>
<td>may reduce risk of CHD; may contribute to maintenance of mental and visual function</td>
</tr>
<tr>
<td>PUFAs: Conjugated linoleic acid (CLA)</td>
<td>beef and lamb, some cheese</td>
<td>may contribute to maintenance of desirable body composition and healthy immune function</td>
</tr>
<tr>
<td>Class/Component</td>
<td>Source*</td>
<td>Potential Benefit</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Flavonoids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anthocyanidins</td>
<td>berries, cherries, red grapes</td>
<td>bolster cellular antioxidant defenses; may contribute to maintenance of brain function</td>
</tr>
<tr>
<td>Flavanols—Catechins, Epicatechins, Procyanidins</td>
<td>tea, cocoa, chocolate, apples, grapes</td>
<td>may contribute to maintenance of heart health</td>
</tr>
<tr>
<td>Flavanones</td>
<td>citrus foods</td>
<td>neutralize free radicals that may damage cells; bolster cellular antioxidant defenses</td>
</tr>
<tr>
<td>Flavonols</td>
<td>onions, apples, tea, broccoli</td>
<td>neutralize free radicals that may damage cells; bolster cellular antioxidant defenses</td>
</tr>
<tr>
<td>Proanthocyanidins</td>
<td>cranberries, cocoa, apples, strawberries, grapes, wine, peanuts, cinnamon</td>
<td>may contribute to maintenance of urinary tract health and heart health</td>
</tr>
<tr>
<td><strong>Isothiocyanates</strong></td>
<td>cauliflower, broccoli, broccoli sprouts, cabbage, kale, horseradish</td>
<td>may enhance detoxification of undesirable compounds and bolster cellular antioxidant defenses</td>
</tr>
<tr>
<td><strong>Phenols</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeic acid, Ferulic acid</td>
<td>apples, pears, citrus fruits, some vegetables</td>
<td>may bolster cellular antioxidant defenses; may contribute to maintenance of healthy vision and heart health</td>
</tr>
<tr>
<td><strong>Plant Stanols/Sterols</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free Stanols/Sterols**</td>
<td>corn, soy, wheat, wood oils, fortified foods and beverages</td>
<td>may reduce risk of CHD</td>
</tr>
<tr>
<td>Stanol/Sterol esters**</td>
<td>fortified table spreads, stanol ester dietary supplements</td>
<td>may reduce risk of CHD</td>
</tr>
<tr>
<td><strong>Polyols</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sugar alcohols—xylitol, sorbitol, mannitol, lactitol</td>
<td>some chewing gums and other food applications</td>
<td>may reduce risk of dental caries</td>
</tr>
<tr>
<td><strong>Prebiotic/Probiotics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inulin, Fructooligosaccharides (FOS), Polydextrose</td>
<td>whole grains, onions, some fruits, garlic, honey, leeks, fortified foods and beverages</td>
<td>may improve gastrointestinal health; may improve calcium absorption</td>
</tr>
<tr>
<td>Lactobacilli, Bifidobacteria</td>
<td>yogurt, other dairy and nondairy applications</td>
<td>may improve gastrointestinal health and systemic immunity</td>
</tr>
<tr>
<td>Class/Component</td>
<td>Source*</td>
<td>Potential Benefit</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------</td>
<td>------------------</td>
</tr>
<tr>
<td><strong>Phytoestrogens</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isoflavones—Daidzein, Genistein</td>
<td>soybeans and soy-based foods</td>
<td>may contribute to maintenance of bone health, healthy brain, and immune function; for women, maintenance of menopausal health</td>
</tr>
<tr>
<td>Lignans</td>
<td>flax, rye, some vegetables</td>
<td>may contribute to maintenance of heart health and healthy immune function</td>
</tr>
<tr>
<td><strong>Soy Protein</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soy protein**</td>
<td>soybeans and soy-based foods</td>
<td>May reduce risk of CHD</td>
</tr>
<tr>
<td><strong>Sulfides/Thiols</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diallyl sulfide, Allyl methyl trisulfide</td>
<td>garlic, onions, leeks, scallions</td>
<td>may enhance detoxification of undesirable compounds; may contribute to maintenance of heart health and healthy immune function</td>
</tr>
<tr>
<td>Dithiolthiones</td>
<td>cruciferous vegetables</td>
<td>contribute to maintenance of healthy immune function</td>
</tr>
</tbody>
</table>


**Note:** ALA = alpha-linolenic acid; CHA = cholic acid; CHD = coronary heart disease; CLA = conjugated linoleic acid; DHA/EPA = docosahexaenoic acid/eicosapentaenoic acid; FOS = fructo-oligosaccharides; MUFA = monounsaturated fatty acids; PUFA = polyunsaturated fatty acids.

*Examples are not an all-inclusive list.

**FDA-approved health claim established for component.

The 27 Health Claims Allowed by the Chinese Government

The functions are divided into two main groups. The first group comprises 16 functions related to the prevention of disease, relief of symptoms, and assistance in drug treatment, including lowering blood pressure, blood sugar, and blood lipids; facilitating digestion; improving constipation; and assisting lead excretion. The other group comprises 11 functions related to enhancing physical health and strengthening bodily conditions, such as enhancing the immune system, improving stamina, controlling obesity, improving skin moisture and skin oil content, and enhancing functions related to growth and development. Each functional food product can apply for certification of no more than two health functions. Therefore, if a product actually can prove to support more than two of the functions, the manufacturer must decide which of the functions are the best ones to use for marketing the product. Table A2-1 shows the 27 functions currently approved by the government.

<table>
<thead>
<tr>
<th>Table A2-1</th>
<th>The 27 Functions One Can Claim According to Chinese Law</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Enhancing immune systems</td>
</tr>
<tr>
<td>2.</td>
<td>Sleep improvement</td>
</tr>
<tr>
<td>3.</td>
<td>Alleviating physical fatigue</td>
</tr>
<tr>
<td>4.</td>
<td>Enhancing anoxia endurance</td>
</tr>
<tr>
<td>5.</td>
<td>Irradiation hazard protection function</td>
</tr>
<tr>
<td>6.</td>
<td>Increasing bone density</td>
</tr>
<tr>
<td>7.</td>
<td>Assisting liver protection against chemical injury</td>
</tr>
<tr>
<td>8.</td>
<td>Alleviating eye fatigue</td>
</tr>
<tr>
<td>9.</td>
<td>Eliminating acne</td>
</tr>
<tr>
<td>10.</td>
<td>Eliminating skin pigmentation</td>
</tr>
<tr>
<td>11.</td>
<td>Improving skin ability to retain moisture</td>
</tr>
<tr>
<td>12.</td>
<td>Improving skin oil content function</td>
</tr>
<tr>
<td>13.</td>
<td>Assisting blood lipids reduction</td>
</tr>
<tr>
<td>14.</td>
<td>Assisting blood sugar reduction</td>
</tr>
<tr>
<td>15.</td>
<td>Antioxidative function</td>
</tr>
<tr>
<td>16.</td>
<td>Assisting memory improvement</td>
</tr>
<tr>
<td>17.</td>
<td>Alleviating lead excretion</td>
</tr>
<tr>
<td>18.</td>
<td>Improving throat function</td>
</tr>
<tr>
<td>19.</td>
<td>Assisting blood pressure reduction</td>
</tr>
<tr>
<td>20.</td>
<td>Facilitating milk secretion</td>
</tr>
<tr>
<td>21.</td>
<td>Assisting weigh control</td>
</tr>
<tr>
<td>22.</td>
<td>Improving child growth</td>
</tr>
<tr>
<td>23.</td>
<td>Improving nutritional anemia</td>
</tr>
<tr>
<td>24.</td>
<td>Regulating gastrointestinal flora</td>
</tr>
<tr>
<td>25.</td>
<td>Facilitating digestion</td>
</tr>
<tr>
<td>26.</td>
<td>Facilitating bowel movement (regularity)</td>
</tr>
<tr>
<td>27.</td>
<td>Protection of gastric mucosa</td>
</tr>
</tbody>
</table>

Source: China State Food and Drug Administration 1995.
Note: Red: Animal study only
Green: Human study only
Black: Animal and Human studies are required.
The Nine Major Changes Incorporated into the New Regulatory Framework

In 2004, a comprehensive review on the regulatory framework for functional foods began. In April 2004, the State Food and Drug Administration (SFDA) issued the draft Regulation for the Registration of Health Food for consultation and sought comments from relevant departments in different parts of the country. Finally, on April 30, 2005, the new regulatory framework was put into place. The new regulation includes nine sections with 105 clauses. There are nine major changes from the previous framework. The changes are as follows.

1. The claim must now be accepted at provincial level, and the provincial SFDA will be the decision-making authority.
2. Chinese citizens and organizations are now allowed to apply for approval of a health food claim. Domestic applicants must be legal citizens, legal persons, or organizations, whereas foreign applicants must be legally registered health food manufacturers.
3. The technical requirements for claiming that a product is a functional food have been increased. The new regulations require that all claimants provide a completed application form, acceptable identification, a name that has not already been used for any other registered functional food, a guarantee that there are no intellectual property infringements, a research and development report (including methodology, function selection process, expected results, and so on), product formula and evidence of formulation, functional ingredients, contents, testing methods of the functional ingredients, manufacturing process, and a flow chart describing the process, product quality specifications, testing certificate issued by test institute, and a product package with labels, samples, and other documents that could support the claim.
4. New functions other than 27 previously allowed can be claimed if the applicant can prove that the food delivers the “new” function being claimed by providing scientific data with complete details of the research. The government mandates that full “evidence” be presented to support health food claims. This includes trials and tests on animals and/or humans. Although there is no specification of the length of time the trials must take place, informally it is understood that one year’s trial is required to establish appropriate evidence to support a health food claim.
5. Companies can now transfer production technology between one another through a specific transfer process that recertifies the health food claim for the new owner of the technology.
6. The certification expires five years from the date of official certification, and must be recertified. To prevent a break in certification, the applicant must notify the authorities at least three months before expiration of certification of its intent to recertify.
7. The certification process has been simplified with a detailed timeline provided to each applicant. The overall process takes approximately five months.
8. Before the claim is accepted by the provincial SFDA, any transactions between the applicant and the authorized testing institute(s) are the purview of the private parties. In this case, the private parties bear all financial and other risks, and the government has no responsibility or authority in this matter.

9. If a claim was rejected, the old regulation allowed the applicant to appeal the decision, but there were no clear details of the process for appeal. The new regulations, however, state very clearly the process, timeline, and contents for an appeal to be successful.

Discussion of the Functional Food Claim Process for Domestic Products

The domestic applicants for government certification of a functional food claim can be legal citizens, legal persons, or organizations. They must submit completed application forms to the appropriate Provincial State Food and Drug Administration (PSFDA), which is determined by the location of the scientist who or organization that developed the product. The completed application must be accompanied with a full set of evidence to support the claim. This includes the following:

- Applicant’s proper and acceptable identification;
- A trade name that is not already being used for any other registered functional food;
- A guarantee that there are no intellectual property infringements;
- Research and development reports, including methodology, product function, selection process, and expected results;
- Product formula and evidence of formulation;
- Functional ingredients and testing methods of the functional ingredients;
- Manufacturing process with a flow chart that describes the process clearly and in detail;
- Product quality specifications;
- Test certificate issued by an Authorized Testing Institute;
- Product insert sheets with health claims and specifications;
- Product packaging with all labels that will be used for the product in the marketplace;
- Samples of the product as they will be packaged and formulated for the market; and
- Any other documentation that can be used to support the claim.

At the time of submission, an application fee of RMB 100 and an inspection fee of RMB 8,000 are charged—this payment is made to the China International Trust and Investment Industrial Bank (CITIC). The receipts for these payments then must accompany the application form.
The PSFDA will give the applicants a response within five working days, which will state one of the following:

- The application has been accepted;
- The application has been rejected, with reasons stated for the rejection; or
- The application requires supplementary materials before a decision on acceptance or rejection of the application can be made.

If the application is accepted, the PSFDA will take samples at the site of manufacturing or the scientist’s laboratory within 15 working days of receipt of the application. The PSFDA will send all samples to and request inspection from an authorized testing laboratory. The laboratory has 50 working days to complete its testing and submit a report to the PSFDA, the national SFDA authority, and the applicants. At the same time that the PSFDA sends samples to the testing laboratory, it sends the applicant’s claim forms to the national SFDA.

The SFDA will form an expert committee to review the claim and the inspection reports from the testing laboratories. The SFDA has no experts on staff so they develop a roster of approximately 40 experts who are commissioned from the authorized testing and inspection institutes. Most of the experts come from the Chinese Center for Disease Control and Prevention and from relevant government ministry officials, such as the Ministry of Health. The Expert Committee will review all claims submitted to the SFDA to which the Testing and Inspection Institutes have submitted reports. The SFDA can make one of three decisions:

- Approve the claim in full;
- Reject the claim, in which case the applicant can begin the appeals process; or
- Demand that supplementary material be presented to support the claim.

The SFDA will approve or reject the claim within 80 to 110 days, depending on whether additional materials have been provided as part of the original review. If the SFDA requires supplementary materials after their original review, then the applicants have five months to provide the new evidence or documentation. The new information will be submitted to the SFDA, which will then complete its review within 80 days.

**Discussion of the Functional Food Claim Process for Imported Products**

For an imported good to be accepted and certified as such, the original application must be submitted directly to the national SFDA. The requirements are as follows:

- The application form for imported functional food;
- Product formula and evidence of formulation;
- Functional ingredients and testing methods of the functional ingredients;
- Manufacturing process with a flow chart that describes the process clearly and in detail;
- Product quality specifications (enterprise specifications);
- Test certificate issued by an Authorized Testing Institute;
- Product insert sheets with health claims and specifications;
- Product packaging with all labels that will be used for the product in the marketplace;
- Certified/notarized documentation that show the applicant is empowered to act on behalf of the submitting organization;
- Documents that show the product is allowed to be produced and sold in the manufacturer’s country or region of origin;
- Samples of the product as they will be packaged and formulated for the market; and
- Any other documentation that can be used to support the claim.

At the time of submission, an application fee of RMB 100 and an inspection fee of RMB 8,000 are charged—this payment is made to the CITIC. The receipts for these payments must accompany the application form.

The SFDA will give the applicants a response within five working days, which will state one of the following:
- The application has been accepted;
- The application has been rejected, with reasons stated for the rejection; or
- The application requires supplementary materials before a decision on acceptance or rejection of the application can be made.

If the application is accepted, the SFDA will take samples at the site of manufacturing or the scientist’s laboratory within 15 working days of receipt of the application. If the SFDA believes it is necessary, they will visit the overseas site(s) to take samples and inspect production processes. They reserve this right under the legal authority that establishes SFDA oversight for the health food claim process. The SFDA will send all samples to and request inspection from an authorized testing laboratory. The laboratory has 50 working days to complete its testing and submit a report to the national SFDA authority and the applicants.

The SFDA will form an expert committee to review the claim and the inspection reports from the testing laboratories. The SFDA can make one of three decisions:
- Approve the claim in full;
- Reject the claim, in which case the applicant can begin the appeals process; or
- Demand that supplementary material be presented to support the claim.

The SFDA will approve or reject the claim within 80 to 110 days, depending on whether additional materials have been provided as part of the original review. If the SFDA requires supplementary materials after their original review, then the applicants have five months to provide the new evidence or documentation. This new information will be submitted to the SFDA, which will then complete its review within 80 days.
Annex 3. India’s Experience with Genetically Modified Functional Foods—Golden Rice and HarvestPlus

In recent years, India has been trying to manage the various issues raised by the development of genetically modified (GM) foods. The debate over GM rice developed by the Swiss biotechnology company, Syngenta, called Golden Rice is an example of the issues under consideration.

The United Nations Children’s Fund (UNICEF) has estimated that child deaths in developing nations could be reduced by a third if children got enough vitamin A (Starling 2003b). The best way to combat vitamin A deficiency is through a balanced and varied diet rich in fruits, vegetables, and animal products. For those not able to attain such a diet, some researchers claim that nutrient-dense, GM foods are the best substitute. One particularly beneficial crop is Golden Rice, which is produced through a genetic modification designed to increase the amount of beta-carotene (ProVitamin A) present in the grain. Although beta-carotene is naturally occurring in the green tissue of the rice plant, it is not present in the edible part of the seed (Golden Rice 2006). First reported in 2000, this variety is being developed for consumption primarily by individuals living in developing countries who have vitamin A deficiency.

Golden Rice has yet to be distributed and is still under vigorous study and debate. Critics have pointed out that Golden Rice would not supply nearly enough vitamin A to counter the deficiencies in most diets, because a person would have to eat 1.5 to 2 kilograms (kg) of Golden Rice per day to meet minimum requirements (Shah 2002). In 2005, a second generation of the grain, Golden Rice 2, was announced by a team of researchers at Syngenta. Reportedly, this new variety provides up to 23 times more vitamin A than the original Golden Rice and thus 144 grams (g) is estimated to satisfy the daily vitamin A intake requirements (Golden Rice 2006).

With the reported success of Golden Rice, the Bill and Melinda Gates Foundation has provided $50 million in funding to improve Golden Rice by increasing the level of or the bioavailability of beta-carotene, vitamin E, iron, and zinc, and to improve protein quality through genetic modification (Wikipedia 2006). This is in addition to the $100 million that has been spent thus far on the development of Golden Rice (Institute of Science in Society n.d.).

Critics of the Golden Rice Initiative abound and the reasons for criticizing are numerous. A detailed presentation of these criticisms is beyond the scope of this text. It is worth citing a few examples of the arguments. Some
groups, such as Greenpeace, are opposed to all GM foods and fear that Golden Rice will only lead to more GM foods. Other critics are more specific about their concerns, for example, fearing the loss of biodiversity in food crops. As claimed by Vandana Shiva, a leading Indian environmental activist,

\[
\text{The reason there is Vitamin A deficiency in India in spite of the rich biodiversity and indigenous knowledge base in India is because the Green Revolution technologies wiped out biodiversity by converting mixed cropping systems to monocultures of wheat and rice and by spreading the use of herbicides which destroy field greens (Shiva n.d.).}
\]

Shiva argues that through a diet of indigenous foods in India, people would achieve much better dietary results based on the diversity of intake. Other critics claim that the large multinationals are the ones to reap the benefits through long-term profits. However, the Golden Rice project initiator has rules for distribution of Golden Rice:

- It is free to subsistence farmers;
- There is a $10,000 cutoff level between humanitarian and commercial use;
- As long as a farmer or subsequent user of Golden Rice genetics does not earn more than $10,000 per year, no royalties need be paid to Syngenta for commercial use;
- There is no fee for humanitarian use of Golden Rice; and
- Farmers are permitted to keep and replant seed (Wikipedia 2006).

During interviews, Dr. S. R. Rao from the Council for Scientific and Industrial Research in New Delhi discounted the excessive press coverage surrounding Golden Rice by claiming that a naturally growing variety of rice has been discovered with a far greater vitamin A content than that achieved by the researcher of Golden Rice. This has once again highlighted the gulf between those who support traditional functional foods and those in favor modern science to develop modern, perhaps GM, functional foods.

**A Note about HarvestPlus**

Because the same arguments against Golden Rice are extended to the use of GM foods and their development in international research institutes, biofortification of foods raises similar issues. HarvestPlus is an initiative of the Consultative Group on International Agricultural Research (CGIAR). According to the HarvestPlus Web site,

\[
\text{HarvestPlus is an international, interdisciplinary, research program that seeks to reduce micronutrient malnutrition by harnessing the powers of agriculture and nutrition research to breed nutrient dense staple foods. . . . HarvestPlus was implemented on a full-time basis in January 2004. HarvestPlus is one of the CGIAR's Global Challenge Programs. Initially, six crops and three nutrients are targeted: beans, cassava, maize, rice, sweet potatoes and wheat.}^{14}
\]
As noted above, the same criticisms of Golden Rice can be extended to HarvestPlus. A critical article by Devinder Sharma (2003) presents the following arguments:

- Fortified crops cannot eradicate nutrient deficiency because the human body requires fats, conspicuously absent in the malnourished populations, to absorb nutrients.

- Food is abundant; distribution is poor. According to Sharma, “[In India] more than 30 million tons of wheat and rice (which was a record 65 million tons in 2005) are rotting in the open. The surplus food[s] contains an average of nine percent proteins—four to nine times more than any fortified GM crop that scientists have developed so far.”

- If the poor cannot afford to buy their normal dietary requirement of rice (or any other food) for a day, then how will they be able to afford the potentially more expensive Golden Rice?

Only a few points surrounding this controversial issue, about which many articles have been published, are presented above. An adequate analysis of the pros and cons of the issue are well beyond the scope of this study.\textsuperscript{15}
Annex 4. Integrated Value Chain Analysis

Methodology

The following is a detailed description of the methodology for the Integrated Value Chain Analysis (IVCS).

Creating a Product Value Chain

An important point of departure for conducting an IVCA is to understand how to break down and categorize various activities associated with the production of a good to be analyzed. The IVCA can be used for everything from agricultural commodities to complex engineered products. But the effectiveness of the IVCA is principally a function of whether an analysis is conducted using categorization of value-adding and non-value-adding activities associated with a product.

Creating a value chain requires products to be defined and categorized according to various production processes and procedures that capture all value-adding and non-value-adding activities associated with a final product. Depending on the complexity of the product and the level of detail required for an analysis, the number of categories of activity along a value chain can range from as few as 5 to as many as 25 or more. For example, a value chain for coffee has nine process categories clustered under two major value-adding activities, namely farming and postharvest. A sample of the process segmentation along a coffee value chain is presented in table A4-1.

<table>
<thead>
<tr>
<th>Value-Adding Activities</th>
<th>Transport-Related Activities</th>
</tr>
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<tbody>
<tr>
<td><strong>Farming</strong></td>
<td><strong>Postharvest</strong></td>
</tr>
<tr>
<td>Land preparation</td>
<td>Transport to processor</td>
</tr>
<tr>
<td>Fertilizer/manure</td>
<td>Drying</td>
</tr>
<tr>
<td>Pesticides</td>
<td>Hulling and grading</td>
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<tr>
<td>Plant maintenance</td>
<td>Bagging</td>
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<tr>
<td>Harvesting</td>
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</table>

*Source: Global Development Solutions, LLC.*
Each of the process segmentations represents important value-adding and non-value-adding activities needed to trace a product from its beginning until it reaches the final consumer.

**Integrated Value Chain Analysis**

The objective of a value chain analysis is to take a “snapshot” of a value structure that is representative of a particular product or industry. The IVCA is a dynamic model in which variables within a value chain can be adjusted to reflect changes in the market. To ensure that the analysis is adjusted for any data uncharacteristic of the market, emphasis is placed on cross-checking all firm-level data against other similar enterprises to help ensure that data used for the value chain analysis mirror realities facing local enterprises. The IVCA is a two-phased process involving (1) the fieldwork and (2) the data analysis, benchmarking, and report writing.

The fieldwork involves conducting interviews at every point along the value chain. Experience from working with the private sector in developing countries has allowed IVCA practitioners to develop an approach to interviewing in which selected interviewees will be forthcoming with the required information and data. For instance, interviewees who want access to the available benchmarking data will provide their data in return for the benchmarking data to which they have not had access in the past. The method of interviewing employed, plus the robust analytical tools that are used, ensure that the data collected are accurate and real.

**Data Collection**

Sector associations generally offer a good starting point for collecting sectorwide data, which often define the overall landscape of the sector under investigation. But the level and detail of information generally available through associations are too broad to be applied toward an IVCA. In this context, a personal interview approach with players along the value chain is the only sure way of guaranteeing data that reflect the actual situation in the market.

A principal challenge for developing credible industry- and product-level market analysis in any country is the acute absence of reliable baseline data. As a result, much of the raw data required to analyze industries and markets must be compiled through rigorous local research and individual in-depth firm-level interviews. Experience shows that intensive personal interviews tend to yield the detailed data and information required to develop a representative value chain analysis. The integrated value chain methodology does not rely on a survey mechanism because surveys do not yield the types and level of detail required to conduct an effective value chain analysis.

The IVCA relies on a standardized analytical framework for the data collected, which ensures that data collected for a particular product can be directly benchmarked against similar data from a competitor or another country. The interviewer does not follow a prescribed number of interviews to collect the necessary data, but stops only when a pattern in the data develops and
the deviation between figures along various stages of production is within an acceptable range. This difference reflects variation in management and administrative practices, variances in growing or production conditions, and other operational factors, which are generally accepted as normal deviations among players in a given sector. With this said, interviews with as few as 10 and as many as 50 individuals spread out between anywhere from as few as 3 or 4 to as many as 30 companies or farms are generally required to develop a robust database necessary for executing an IVCA.

The sequence of the interview tends to be a function of the sector being investigated. To ensure that the value chain developed reflects the actual flow of resources across an entire value chain, interviews are conducted along a supply chain that is currently operational. Specifically, in a soy farming to soy milk value chain analysis, interviews are conducted with individuals along the entire supply chain who actually sell goods or services to each other. This helps to ensure that the “delivered price of a good” traces each activity that actually takes place along the various stages of value addition.

Additional consideration relates to the size of companies and farms within a sector, which generally tends to vary widely. For example, small companies or farms tend to be labor intensive, while larger operations tend to exercise capital-intensive production practices, as will be evident in the comparison of soy farming in China versus the United States. In this context, unless the focus of the IVCA is specific to a particular size company or farm, the interviewer collects data from both small and large operations to analyze the difference in the delivered price of a good and the resource allocations along the value chain for the two types of operations.

In some countries, provincial or state governments have substantial authority over economic activities within their jurisdiction. As a consequence, provincial or state laws and regulations may differ substantially from province to province within a single country. This has an impact on the delivered price of a good and the resource allocations along a value chain, because different types of incentives and support services are offered at the provincial and state levels.

The same can be said of different cultural and ethnic enclaves within a country. For example, money-lending practices often vary between different cultural and ethnic groups, or supply chain relationships are closely guarded among individuals within the same cultural or ethnic group. These factors all impact the value chain in different ways.

The Analysis: Understanding the Distribution of Resources that Determines the Delivered Price of a Good

Whether it is an agricultural commodity or a food product, the ultimate objective of the IVCA is to estimate the delivered price of a good, reflective of a particular sector, and to break down this figure into various stages of production to identify critical bottlenecks and constraints. Generally, enterprises as well as farmers keep general production data according to
inputs, such as labor, electricity, water, material, and the corresponding unit output or yield rates. To estimate the delivered price of a good, the IVCA disaggregates the value of these inputs along various stages of the process so that it becomes possible to define the composition of value-adding activities.

The phrase “delivered price of a good” differs somewhat from product to product and from country to country. For example, in the case of an agricultural commodity, the phrase delivered price of a good is generally defined as the farmgate price. Depending on the nature of the industry and commonly recognized practice in the country, transport and market intermediary costs, such as broker or buying agent fees, are paid for by the farmer or the downstream buyer along the supply chain.

For an exportable good, the delivered price of a good can refer to either the freight-on-board (FOB) or cost-insurance-freight (CIF) price. Once again, the choice between applying FOB or CIF pricing reflects the practice generally recognized in the sector and in the country under investigation. In the case of FOB pricing, a separate analysis is conducted to determine the export transaction cost, which includes such items as freight forwarder charges, documentation charges, customs fees, and other standard charges incurred by an exporter to deliver a good to a client. In addition to the standard charges, whenever possible, the IVCA also attempts to capture undocumented charges, such as payment of bribes. For example, bribes are often paid at weigh stations to customs officials, as well as to the port authority, to help expedite the clearing and loading process. These hidden or unofficial payments are categorized as “other costs.”

Figure A5-1 Area Under Harvest: China and India

![Graph showing area under harvest for China and India from 1961 to 2005.](image)

Source: All data were extracted from FAOSTAT (accessed June 12, 2006).

Figure A5-2 Area Under Harvest: China and India Compared with the United States and the World

![Graph showing area under harvest for China, India, United States, and the world from 1961 to 2005.](image)

Source: All data were extracted from FAOSTAT (accessed June 12, 2006).
Figure A5-3  Average Soybean Crop Yields

Source: All data were extracted from FAOSTAT (accessed June 12, 2006).

Figure A5-4  Yearly Production: China and India

Source: All data were extracted from FAOSTAT (accessed June 12, 2006).
Figure A5-5  Yearly Production: China and India Compared with the United States and the World

Source: All data were extracted from FAOSTAT (accessed June 12, 2006).
Annex 6. State Food and Drug Administration
Decree No. 19

August 2005

China—Interim Administrative Measures for Health Food Registration
(Original link In Chinese)

Reviewed and approved by the State Food and Drug Administration (SFDA), the Interim Administrative Measures for Health Food Registration was hereby promulgated and shall go into effect as of July 1, 2005.

Zheng Xiaoyu, Director
April 30, 2005

Chapter I – General Principles

Article 1. These Measures are formulated in accordance with the Food Hygiene Law of the People’s Republic of China and the Administrative Licensing Law of the People’s Republic of China to standardize the registration of health food, ensure the quality of health food, and guarantee the human food safety.

Article 2. Health food in the Measures refers to food claiming that it has certain health improving functions or is able to supply vitamins and mineral. It is good for a particular group of people and able to adjust body functions. But, it is not used to cure certain diseases. It will not have any form of harm whether it is acute or sub-acute or chronic.

Article 3. The Measures apply to the registration of domestic and imported health food within the territory of the People’s Republic of China.

Article 4. Health food registration refers to that further to the application filed by the applicant, the State Food and Drug Administration, in accordance with the legal procedure, conditions, and requirements, conducts a systematic review of the safety, effectiveness, and quality control of health food and the content of the instruction. The State Food and Drug Administration decides whether to permit it to enter the process of examination and approval of its registration. It includes examinations and approvals of applications for product registration, alteration, and technology transfer product registration.

Article 5. The State Food and Drug Administration is responsible for the regulation of national health food registration and examination and approval of health food.

Drug (Food) administrative departments in provinces, autonomous regions, and municipalities entrusted by the State Food and Drug Administration, are
Health Enhancing Foods

responsible for examining domestic health food registration application package, checking the experiments of health food that applies for registration and sample experimental production, and arranging for the examination of samples.

The examination agencies designated by the State Food and Drug Administration are responsible for the health food safety toxicology test, functionality test (including animal test or human trial test), effective or marker ingredient test, hygiene test, and stability test. They will carry out the sample product test and reexamination test.

Article 6. The administration of health food registration should follow the principles of being scientific, open, equal, fair, effective, and convenient.

Chapter II – Application, Examination, and Approval

Section One: General Provisions

Article 7. A health food registration applicant refers to the one who files health food registration application, bears corresponding legal responsibilities, and is granted the health food approval certificate after the application is approved.

A domestic applicant is a legally registered citizen, legal person, or other organization in China.

An overseas applicant refers to a legitimate foreign health food manufacturer. When an overseas applicant intends to handle the imported health food registration, it should be done by its representative office or authorized agent in China.

Article 8. A health food registration application includes applications for product registration, alteration, and technology transfer product registration.

Article 9. The State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions, and municipalities should publish the items of application materials for health food registration and the sample of relevant registration application forms at the place where the application is processed.

Article 10. Health food registration applicants should submit standard and complete documents and report on a true basis as required, and should be responsible for the authenticity of the submitted documents and other materials.

Article 11. Applicants are allowed to correct the mistakes in submitted application materials if they can be corrected immediately.

Article 12. When materials submitted by applicants are not complete and in compliance with statutory format, drug (food) administrative departments in provinces, autonomous regions, and municipalities and the State Food and Drug Administration should, immediately or within five days, advise the applicants of all the materials that should be added and corrected. If the notification is overdue, the day when the application materials are received is
taken as the day of acceptance. If the application is denied for acceptance, the applicant should be notified in writing of the reasons.

Article 13. In the course of examination, if any further materials are required, the State Food and Drug Administration should inform the applicant at one time. An applicant should submit satisfactory additional materials as required within five months after receiving the notification. If the applicant fails to do so, the examination will be terminated. Under special circumstances where an applicant is unable to supply the additional materials in due course, the applicant should file written application to the State Food and Drug Administration and make explanations. The State Food and Drug Administration should respond with a decision within 20 days.

Article 14. If any additional materials are required for registration application, the original examination period is extended by 30 days. In case of alteration application, it is extended by 10 days.

Article 15. If the product is granted registration after examination by law, the State Food and Drug Administration should issue a health food approval certificate to the applicant for registration within the period as stipulated, and send it to the applicant within 10 days. If the application is denied, the State Food and Drug Administration should inform the applicant of the denial and explain the reason of rejection within the period as stipulated, and advise the applicant of the rights to apply for reexamination or administrative reconsideration or file administrative litigation in accordance with laws.

Article 16. The State Food and Drug Administration and drug (food) administrative authorities in provinces, autonomous regions, and municipalities should give notice to the interested parties, if it is found in the course of examination of health food registration application that the application directly involves the material interests of others. Applicants and interested parties may submit written opinions to make a statement and argument, or request for a hearing in accordance with laws.

Article 17. The State Food and Drug Administration should provide relevant information in connection with the acceptance of health food registration application, examination process and health food approved for registration on its official web site.

Article 18. Based on the development and requirement of science and technology, the State Food and Drug Administration should make adjustments of function, scope, evaluation, and testing methods for health food as well as technical standards of evaluation, and should make an announcement thereof.

Section Two: Product Registration Application, Examination, and Approval

Article 19. Product registration applications include domestic health food registration application and imported health food registration application.

Domestic health food registration application refers to the registration application for health food that the applicant intends to manufacture and sell in China.
Imported health food registration application refers to the registration application for health food which has been manufactured and sold overseas for more than one year and the applicant intends to market within the territory of China.

Article 20. An applicant, before applying for health food registration, should make relevant searches.

After such research has been completed, the applicant should provide samples and test related materials to the testing agencies designated by the State Food and Drug Administration for corresponding testing and examination.

If the functions of health food submitted are within the scope published by the State Food and Drug Administration, the applicant should supply a product research and development report to the designated testing agency.

If the functions of health food submitted are out of the published scope, the applicant should conduct its own animal test and human trial test and supply a function research and development report to the designated testing agency.

The product research and development report should include information on basic concept of research and development, function screening process, and expected effects. The function research and development report should include information on the name of function, reason for application, function test, evaluation methods, and test results. If it is impossible to conduct animal test and human trial test, the applicant should articulate reasons why it is impossible to do so in the function research and development report and supply relevant information.

Article 21. Receiving the sample and relevant materials supplied by an applicant, the testing agencies should, in accordance with health food examination and evaluation technical norms published by the State Food and Drug Administration and the testing methods issued by other related departments or provided by the enterprise, carry out safety toxicology tests, function tests, effective or marker ingredient tests, hygiene tests, and stability tests of the sample. If the function of health food submitted are out of the scope published the State Food and Drug Administration, the testing agencies should also check its function tests and evaluation methods, as well as test results, and issue a test report.

Article 22. Only after the testing agencies have issued a test report, the applicant may apply for health food registration.

Article 23. To apply for domestic health food registration, an applicant should complete the Application Form for Domestic Health Food Registration as required and send the application materials and sample products to local drug (food) administrative departments in provinces, autonomous regions, and municipalities.

Article 24. After receiving the application materials and sample products, drug (food) administrative departments in provinces, autonomous regions, and municipalities should review whether the format of application materials
are standard and complete and give an acceptance or rejection notice within five days.

Article 25. For satisfactory registration application, drug (food) administrative departments in provinces, autonomous regions, and municipalities should, within 15 days after the application is accepted, check testing and sample production sites, choose samples to be used for tests, and give examination opinions that are reported to the State Food and Drug Administration along with the submitted materials. Meanwhile, drug (food) administrative departments in provinces, autonomous regions, and municipalities should send a notification of the test to the designated testing agencies and provide the samples for testing.

Article 26. The samples required for health food registration application should be produced in workshops that conform to Good Manufacture Practice for Health Food and the course of processing thereof should also be in compliance with the Good Manufacture Practice for Health Food.

Article 27. Within 50 days after receiving the test notification and sample products, the testing agencies should carry out sample and recheck examinations of the chosen sample products and send a test report to the State Food and Drug Administration and make a copy for drug (food) administrative departments in provinces, autonomous regions, and municipalities that give the test notification to the applicant. In exceptional cases where the test agencies are unable to finish the work in due time, the test agencies should report to the State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions, and municipalities on a timely basis, and attach written explanations.

Article 28. After receiving the examination opinions, application materials, and sample products from drug (food) administrative departments in provinces, autonomous regions, and municipalities, the State Food and Drug Administration should arrange food, nutrition, medical, pharmaceutical, and other technical personnel to perform technical evaluation and administrative examination of the submitted materials that meet the requirements and make a decision after the examination within 80 days. If registration is granted, a Domestic Health Food Approval Certificate should be issued to the applicant.

Article 29. Applying for imported health food registration, an applicant should complete the Application Form for Imported Health Food Registration as required, and send the application materials and sample products to the State Food and Drug Administration.

Article 30. After receiving the application materials and sample products, the State Food and Drug Administration should review whether the format of application materials are standard and complete and should give an acceptance or rejection notice within five days. For satisfactory registration application, the State Food and Drug Administration should provide a test notification and sample products for tests to the designated testing agencies within five days after the application is accepted. If necessary, the State Food and Drug Administration may examine the production and testing sites of the product.
Article 31. Within 50 days after receiving the test notification and sample products, the testing agencies should carry out sample and recheck examinations of the sample products and send a test report to the State Food and Drug Administration and make a copy for the applicant. In exceptional cases where the test agencies are unable to finish the work in due time, the test agencies should report to the State Food and Drug Administration on a timely basis, and attach written explanations.

Article 32. After accepting the application, the State Food and Drug Administration should arrange food, nutrition, medical, pharmaceutical, and other technical personnel to perform technical evaluation and administrative examination of the submitted materials and make a decision after the examination within 80 days. If registration is granted, an Imported Health Food Approval Certificate should be issued to the applicant.

Article 33. The health food approval certificate will be valid for a period of five years. The format of registered number of approval for the domestic health food is as follows: GuoShiJianZi G + 4-digit year number + 4-digit serial number. The format of registered number of approval for the imported health food is as follows: GuoShiJianZi J + 4-digit year number + 4-digit serial number.

Section Three: Alteration Application, Examination, and Approval

Article 34. Alteration application refers to the application by an applicant for change of items stated on health food approval certificate and its attachment.

Article 35. An applicant applying for alteration should be the holder of a health food approval certificate.

Article 36. Items such as function name, raw and supplementary materials, manufacturing techniques, eating instruction, expansion of applicable population, or reduction of inapplicable population for the health food stated on the health food approval certificate that might have an impact on safety and function should not be altered.

Article 37. The health food involved in the application for reduction of applicable population, expansion of inapplicable population, precautions, function items, change of dosage, product specifications, best before date, or quality standards should be the product that has been manufactured and sold. The newly added function items must be those within the scope published by the State Food and Drug Administration.

Article 38. Applying for altering the contents of Domestic Health Food Approval Certificate and its attachments, an applicant should complete the Application Form for Domestic Health Food Alteration, and send relevant materials and statements to local food (drug) administrative departments in provinces, autonomous regions, and municipalities where the applicant is located.

Article 39. Drug (food) administrative departments in provinces, autonomous regions, and municipalities should examine whether the format of application materials are standard and complete and give an acceptance or rejection notice within five days after receiving the application materials.
Article 40. In relation to alteration application for change of product name, best before date, dosage, reduction of applicable population, expansion of inapplicable population, precautions, and function items, drug (food) administrative departments in provinces, autonomous regions, and municipalities should give examination opinions and report to the State Food and Drug Administration along with the submitted materials within 10 days after accepting the application.

The State Food and Drug Administration should, within 40 days after receiving the examination opinions and application materials, arrange food, nutrition, medical, pharmaceutical, and other technical personnel to perform technical evaluation and administrative examination of the submitted materials and make a decision after the examination. If alteration is granted, an Approval for Domestic Health Food Alteration should be issued to the applicant and copied to drug (food) administrative departments in provinces, autonomous regions, and municipalities.

Article 41. In relation to application for alteration of product specifications and quality standards, drug (food) administrative departments in provinces, autonomous regions, and municipalities should give examination opinions and report to the State Food and Drug Administration along with the submitted materials within 10 days after accepting the application, and meanwhile provide a test notification and sample products for test to the designated testing agencies.

Within 30 days after receiving the test notification and sample products, the testing agencies should carry out sample examinations and send a test report to the State Food and Drug Administration and make a copy for drug (food) administrative departments in provinces, autonomous regions, and municipalities that give the test notification to the applicant.

The State Food and Drug Administration should, within 50 days after receiving the examination opinions, application materials, and sample products, arrange food, nutrition, medical, pharmaceutical, and other technical personnel to perform technical evaluation and administrative examination of the submitted materials and make a decision after the examination. If alteration is granted, an Approval for Domestic Health Food Alteration should be issued to the applicant and copied to drug (food) administrative departments in provinces, autonomous regions, and municipalities.

Article 42. Applying for altering the contents of Imported Health Food Approval Certificate and its attachment, an applicant should complete the Application Form for Imported Health Food Alteration, and send relevant materials and statements to the State Food and Drug Administration.

Article 43. The State Food and Drug Administration should check whether the format of application materials are standard and complete and give an acceptance or rejection notice within five days after receiving the application materials.
Article 44. In relation to the alteration application for change of product name, best before date, dosage, reduction of applicable population, expansion of inapplicable population, precautions, and function items, the State Food and Drug Administration should arrange food, nutrition, medical, pharmaceutical, and other technical personnel to perform technical evaluation and administrative examination of the submitted materials and make a decision after the examination within 40 days after accepting the application. If alteration is granted, an Approval for Imported Health Food Alteration should be issued to the applicant.

Article 45. In relation to alteration application for change of product specifications and quality standards as well as the overseas production location by the producer of imported health food, the State Food and Drug Administration should provide a test notification and sample products for test to the designated testing agencies within five days after accepting the application. If necessary, the State Food and Drug Administration may examine the production site of the product.

Within 30 days after receiving the test notification and sample products, the testing agencies should carry out sample examination and send a test report to the State Food and Drug Administration and make a copy for the applicant.

Within 50 days after accepting the application, the State Food and Drug Administration should arrange food, nutrition, medical, pharmaceutical, and other technical personnel to perform technical evaluation and administrative examination of the submitted materials and make a decision after the examination. If alteration is granted, an Approval for Imported Health Food Alteration should be issued to the applicant.

Article 46. In relation to the change of an applicant’s own entity name, address, and representative agency in China, the applicant should complete the Record Form for Domestic Health Food Alteration or the Record Form for Imported Health Food Alteration as required within 20 days after the subject item has been altered, and should report to the State Food and Drug Administration for recording such change [along with relevant supporting materials.

Article 47. The valid period of the Approval for Health Food Alteration is identical to that of the original health food approval certificate. Upon the expiration of the valid period, application for re-registration should be performed for both them.

Article 48. Requesting for reissuing of health food approval certificate, an applicant should send written application to the State Food and Drug Administration and make explanations. Applying for reissuing as a result of loss, an applicant should submit the original lost property notice published on a national newspaper; applying for reissuing as a result of damage, an applicant should return the original health food approval certificate. If qualified after examination, the Health Food Approval Certificate will be reissued with the original registered number of approval and the valid period
will remain the same as before. The reissued Health Food Approval Certificate should bear the original date of approval and the printed word of “Reissued.”

Section Four: Technology Transfer Product Registration Application, Examination, and Approval

Article 49. Technology transfer product registration application refers to the act that a holder of the health food approval certificate transfers the right to produce and sell its products and the production technology to another producer of health food, and jointly apply with that health food producer for the issuance of a new health food approval certificate to the transferee.

Article 50. The domestic health food producer as a transferee must be an enterprise that has obtained the health food sanitation license in accordance with law and is in compliance with the Good Manufacture Practice for Health Food.

The foreign health food producer as a transferee must be in compliance with corresponding local standards of production quality control.

Article 51. The transferor should conclude a contract with the transferee to transfer all of the technical information to the transferee and direct the transferee to product three batches of products in a row that meet the quality standards for the product.

Article 52. In case that more than one applicant jointly owns the health food approval certificate, they should cosign the transfer contract at the time of technology transfer.

Article 53. When health food with the Domestic Health Food Approval Certificate or Imported Health Food Approval Certificate is transferred within China, the holder of the health food certificate and the transferee should jointly complete the Application Form for Domestic Health Food Technology Transfer Product Registration or the Application Form for Imported Health Food Technology Transfer Product Registration, and send relevant materials and sample products to local drug (food) administrative departments in provinces, autonomous regions, and municipalities where the transferee is located, along with the transfer contract.

Article 54. Drug (food) administrative departments in provinces, autonomous regions, and municipalities should examine whether the format of application materials are standard and complete and give an acceptance or rejection notice within five days after receiving the application materials.

For the satisfactory application for technology transfer product registration, drug (food) administrative departments in provinces, autonomous regions, and municipalities should give examination opinions and report to the State Food and Drug Administration along with the submitted materials within 10 days after accepting the application, and meanwhile provide a test notification and sample products for test to the designated testing agencies.

Article 55. Within 30 days after receiving the test notification and sample products, the testing agencies should carry out sample examinations and send
a test report to the State Food and Drug Administration and make a copy for
drug (food) administrative departments in provinces, autonomous regions,
and municipalities that give the test notification to the applicant.

Article 56. The State Food and Drug Administration should make a decision
after the examination within 20 days after receiving the examination opinions,
application materials, and test report of the sample product. If registration is
granted, a new Domestic Health Food Approval Certificate should be issued
to the transferee with a new registered number of approval, while the period
of validity of the new certificate will remain the same as the one it is replacing.
Meanwhile, the original Domestic Health Food Approval Certificate or
Imported Health Food Approval Certificate previously obtained by the
transferor should be collected and cancelled.

Article 57. When health food with the Imported Health Food Approval
Certificate is transferred outside China, the holder of the health food
certificate and the transferee should jointly complete the Application Form for
Imported Health Food Technology Transfer Product Registration, and send
relevant materials and sample products to the State Food and Drug
Administration, along with the transfer contract.

The State Food and Drug Administration should check whether the format of
application materials are standard and complete and give an acceptance or
rejection notice within five days after receiving the application materials. For
the satisfactory application, the State Food and Drug Administration should
provide a test notification and sample products for tests to the designated
testing agencies within five days after the application is accepted. If necessary,
the State Food and Drug Administration may examine the production site of
the transferee.

Article 58. Within 30 days after receiving the test notification and sample
products, the testing agencies should carry out sample examinations and send
a test report to the State Food and Drug Administration and make a copy for
the applicant. The State Food and Drug Administration should make a
decision after the examination within 20 days after receiving the test report of
the sample product. If registration is granted, a new Imported Health Food
Approval Certificate should be issued to the transferee with a new registered
number of approval, while the period of validity of the new certificate will
remain the same as the one it is replacing. Meanwhile, the original Imported
Health Food Approval Certificate previously obtained by the transferor
should be collected and cancelled.

Chapter III – Raw Materials and Supplementary Materials

Article 59. Raw materials of health food refer to the primary materials that
have a connection with the functions of health food. Supplementary materials
of health food refer to other additional materials that are used to produce
health food.

Article 60. Raw materials and supplementary materials used in the production
of health food should comply with national standards and hygiene
requirements. In the absence of national standards, industry standards or self-stipulated quality standards should be provided and information on the raw materials and supplementary materials should be supplied.

Article 61. Raw materials and supplementary materials used to produce health food should be safe and harmless for human health. In case of materials with a limit on usage, the use level should not exceed the limit set by relevant state regulations.

Article 62. Raw materials and supplementary materials that are not allowed to be used in health food or prohibited for use by the State Food and Drug Administration and other government departments should not be used as the raw materials or supplementary materials of health food.

Article 63. Raw materials and supplementary materials that are allowed to be used in health food as announced by the State Food and Drug Administration, eatable as announced or approved by the Ministry of Health, or used in the production of general food can be used as the raw materials and supplementary materials of health food.

Article 64. If the raw materials and supplementary materials used in the production of the health food involved in registration application are not covered under Article 63 of these Measures, the applicant should, in accordance with relevant stipulations, provide the relevant test report of toxicological evaluation of safety for the raw material and supplementary material and the related information on food safety.

Article 65. Based on the development and requirement of science and technology, the State Food and Drug Administration should, on a timely basis, publish a list of raw materials that are allowed or prohibited for use in health food.

Article 66. Raw materials and supplementary materials used in the production of imported health food should comply with various Chinese regulations on the use of raw materials and supplementary materials in health food.

**Chapter IV – Labels and Instructions**

Article 67. In the course of product registration application for health food, an applicant should submit the draft sample of product instructions and labels.

Article 68. The draft sample of labels and instructions of the health food involved in the registration application should include product name, main raw (supplementary) materials, effective/marker ingredients and their content, health care functions, applicable population, inapplicable population, dosage and usage, specification, best before date, storing method, and precautions.

The label of the health food produced and marketed after approval should comply with relevant state regulations.

Article 69. Naming of health food should comply with following principles:

1. In compliance with relevant national laws, regulations, standards, and requirements;
(2) Reflecting the true nature of the product, clear, easy to understand, and in compliance with the convention of Chinese language;
(3) Drug name that has been approved and registered should not be used as general name.

Article 70. Name of health food should consist of three parts—brand name, general name, and attribute name. They must comply with the following requirements:

(1) The registered trademark or other names of the product can be used as the brand name;
(2) The general name should be accurate and scientific, words that indicate therapeutic effect, whether expressly or impliedly, or exaggerate its functions and effects are not allowed to be used;
(3) The attribute name should indicate the authentic configuration of the product, and its representation should be standard and accurate.

Article 71. The State Food and Drug Administration should examine the draft sample of labels and instructions according to relevant national standards, regulations, product application materials, and sample test results.

Chapter V – Test and Examination

Article 72. Safety toxicology test means that the testing agencies, in accordance with the procedures of toxicological evaluation of health food safety and the testing method issued by the State Food and Drug Administration, carry out animal tests of the sample product submitted by the applicant to verify its food safety. If necessary, human trial test could be carried out.

Function test means that the testing agencies, in accordance with the procedures of function evaluation of health food and the testing method by the State Food and Drug Administration or provided by the enterprise, carry out animal tests and/or human trial tests of the sample product submitted by the applicant to verify its health care functions.

Effective or marker ingredient test means that the testing agencies, in accordance with the testing method for effective or marker ingredients of health food issued by the State Food and Drug Administration and relevant departments or provided by the enterprise, test the content of effective or marker ingredients of the sample product submitted by the applicant and their content changes during the valid period.

Hygiene test means that the testing agencies, in accordance with the testing method issued by relevant government sectors or provided by the enterprise, test the hygiene and product quality related indicators (other than effective or marker ingredients) of the sample product submitted by the applicant.

Stability test means that the testing agencies, in accordance with the testing method issued by relevant government sectors or provided by the enterprise, test the change of hygiene and product quality related indicators (other than effective or marker ingredients) of the sample product submitted by the applicant during the valid period.
Sample test means that the testing agencies, in accordance with the quality standards submitted by the applicant, carry out a full examination of the sample product provided by the food and drug administrative department.

Recheck test means that the testing agencies carry out an examination to recheck the testing method for effective or marker ingredients in the quality standards submitted by the applicant.

Article 73. The State Food and Drug Administration is responsible for designating the test agencies for health food tests, sample tests, and recheck tests. The detailed measures will be formulated separately.

Article 74. The designated testing agencies should, in accordance with the health food testing and evaluation technical norms published by the State Food and Drug Administration and the testing and evaluation methods issued by other relevant departments, carry out tests and examinations and provide test and examination reports within the stipulated or agreed time. Health food testing and evaluation technical norms should be formulated and published by the State Food and Drug Administration.

Article 75. The designated testing agencies should, in accordance with the national service standards and charging standards and the conditions stipulated according to law, provide secure, convenient, stable, and reasonably priced services to the applicant and fulfill the obligations of universal service.

Article 76. The designated testing agencies should act in accordance with law to ensure that the tests and examinations are scientific, standard, open, fair, and just. They must not provide false reports.

Article 77. Applicants should provide food and drug administrative departments with relevant information required for sampling and cooperate in selecting samples for test to provide standard substance to be tested.

Article 78. Sample test and recheck test of the health food involved in the registration application should not be conducted by the testing agencies that are responsible for the tests of the product.

Chapter VI – Re-registration

Article 79. Health food re-registration refers to the process of examination and approval of application for extending the valid period of the Health Food Approval Certificate upon its expiration by the State Food and Drug Administration according to an applicant’s application and statutory procedures, conditions, and requirements.

The applicant for health food re-registration should be the holder of the Health Food Approval Certificate.

Article 80. If extension of the valid period of the Health Food Approval Certificate is required upon its expiration, the applicant should apply for re-registration three months in advance prior to the expiration of the valid period.

Article 81. To apply for domestic health food re-registration, an applicant should complete the Application Form for Domestic Health Food Re-registration as
Article 82. Drug (food) administrative departments in provinces, autonomous regions, and municipalities should examine whether the format of application materials are standard and complete and give an acceptance or rejection notice within five days after receiving the application materials.

Article 83. For satisfactory re-registration applications, drug (food) administrative departments in provinces, autonomous regions, and municipalities with the authorization of the State Food and Drug Administration should provide examination opinions and report to the State Food and Drug Administration for examination within 20 days after accepting the application.

Article 84. The State Food and Drug Administration should make a decision after the examination within 20 days after receiving the examination opinions. If there is no notification of denial of re-registration issued within 20 days, drug (food) administrative departments in provinces, autonomous regions, and municipalities should issue a re-registration certificate to the applicant. In case of denial of re-registration, the State Food and Drug Administration should notify the drug (food) administrative departments in provinces, autonomous regions, and municipalities to give a notification of denial of re-registration and reasons for it to the applicant.

Article 85. Applying for imported health food re-registration, an applicant should complete the Application Form for Imported Health Food Re-registration as required, and send the application materials to the State Food and Drug Administration.

Article 86. The State Food and Drug Administration should check whether the format of application materials are standard and complete and give an acceptance or rejection notice within five days after receiving the application materials.

Article 87. For satisfactory re-registration application, the State Food and Drug Administration should make a decision after the examination within 20 days after accepting the application. If qualified, re-registration will be granted and a re-registration certificate will be issued to the applicant. If unqualified, a notification of denial of re-registration will be provided to the applicant and the reasons for it will be given.

Article 88. In case of any of the following circumstances of health food, re-registration will be denied:

1. Failure to submit the re-registration application within the specified time;
2. Cancellation of the health food approval certificate in accordance with relevant laws and regulations;
3. Raw materials, supplementary materials, and products with food safety problems;
(4) Materials or manufacturing techniques used for the product is incompatible with the existing regulations;
(5) Other circumstances that are incompatible with relevant state regulations.

Article 89. In case of denial of re-registration, the State Food and Drug Administration should make a public announcement to cancel its registered number of approval for health food.

Chapter VII – Reexamination

Article 90. If an applicant disagrees with the refusal made by the State Food and Drug Administration, the applicant may submit a written application for reexamination to the State Food and Drug Administration and provide reasons for reexamination within 10 days after receiving the notification of denial of re-registration.

Article 91. After receiving the request for reexamination, the State Food and Drug Administration should, in accordance with the time limit and requirements of examination for the original application items, conduct the reexamination and make a decision after that. If the denial of registration is withdrawn, a corresponding health food approval certificate should be issued to the applicant. If the original decision is maintained, no more application for reexamination will be accepted. However, the applicant may apply with the State Food and Drug Administration for administrative reconsideration or turn to the People’s Court for administrative litigation in accordance with relevant laws.

Article 92. The scope of reexamination is confined to the original application items and application materials.

Chapter VIII – Legal Liabilities

Article 93. In any of the following circumstances, the State Food and Drug Administration may, on the basis of the request of the interested parties or its function and power, take actions in accordance with the provisions of Article 69 of Administrative Licensing Law after verification:

(1) A staff of administrative departments abuses his or her powers to grant registration;
(2) Exceeding one’s statutory authority to grant registration;
(3) Violating legal procedures to grant registration;
(4) Granting registration to an applicant who is unqualified for application or does not meet the statutory requirements;
(5) Other circumstances where the health food approval certificates could be cancelled in accordance with law.

Article 94. In any of the following circumstances, the State Food and Drug Administration should cancel the corresponding registered number of approval for health food:

(1) A holder of health food approval certificate applies for cancellation;
(2) It is confirmed that the product has potential safety concerns;
(3) As a result of violation of laws and regulations, the health food approval certificate should be cancelled;
(4) Other circumstances where the certificate should be cancelled according to law.

Article 95. In the process of health food registration, if the State Food and Drug Administration and drug (food) administrative departments in provinces, autonomous regions, and municipalities and their working personnel violate the provisions of these Measures, it should be handled in accordance with Articles 72, 73, 74, and 75 of the Administrative Licensing Law in case of any of the following circumstances:

(1) Refusal to process a health food registration application which meets the legal requirements;
(2) Refusal to publish the items of application materials for health food registration at the place where the application is processed;
(3) Failure to fulfill the legal obligation of advising applicants in the course of processing and examining health food registration application;
(4) In case of incompleteness and noncompliance with the statutory format of the health food application materials submitted by applicants, failure to advise the applicants at one time of all the materials that should be added and corrected;
(5) Failure to explain reasons why the health food registration application is refused to be processed or rejected in accordance with law;
(6) Granting registration to health food registration application that does not meet the conditions stipulated in these Measures or granting registration beyond the legitimate authority;
(7) Refusal to grant registration to applications that comply with these Measures or failure to grant registration within the time limit specified in these Measures;
(8) Charging without authorization or out of accordance with the standards for statutory items;
(9) Asking for or taking bribery, or seeking for other interests.

Article 96. During the process of health food registration, the State Food and Drug Administration should provide compensation according to the state compensation law if it causes damage to the lawful rights and interests of the parties concerned as a result of its violation of these Measures.

Article 97. If an applicant hides relevant information or provides false materials or sample products to apply for health food registration, the State Food and Drug Administration will refuse to process the application or grant registration and will give a warning to the applicant. The applicant will not be allowed to file registration application for the health food again within one year.

Article 98. If an applicant obtains the health food approval certificate by cheating, bribery, and other illicit means, the State Food and Drug Administration should cancel its health food approval certificate and registered number of approval for the health food. The applicant will not be allowed to file registration application for the health food again within three years.
Article 99. If the designated testing agencies violate the provisions of Article 75 of these Measures, the State Food and Drug Administration should order them to make corrections within a definite time. As for fees charged in violation of law, the State Food and Drug Administration or other relevant government departments should order them to refund the amount; the Qualification Certificate for Health Food Testing will be revoked in serious cases.

Article 100. If the designated testing agencies fail to conduct test or examination in accordance with these Measures or make errors in the process of testing and examination, the State Food and Drug Administration should give a warning and order them to make corrections within a definite time; the Qualification Certificate for Health Food Testing will be revoked in serious cases.

Article 101. If a designated testing agency issues a false test or examination report, its Qualification Certificate for Health Food Testing will be revoked; illegal gains will be confiscated, if any. In the event of constitution of a crime, the criminal liability will be investigated in accordance with law.

In case of losses as a result of untruthfulness of test or examination results provided by a designated testing agency, it shall bear the corresponding legal liabilities.

Chapter IX – Supplementary Provisions

Article 102. Working periods mentioned in these Measures are calculated on the basis of working days, excluding statutory holidays.

Article 103. Packaging materials and containers that have direct contact with health food should comply with the state requirements for that of food or medicine and the standards for ensuring human health and safety.

Article 104. The State Food and Drug Administration should be responsible for the interpretation of these Measures.

Article 105. These Measures shall go into effect as of July 1, 2005.

Regulations on health food registration issued prior to the implementation of these Measures should be terminated since the date of implementation of these Measures if in conflict with these Measures.
Annex 7. Application Items for Product Registration

1. Application Items for Domestic Health Food Registration

1) Application Form for Health Food Registration.
2) Photocopies of an applicant’s identity card, business license, or certificates for legal registration with other government agencies.
3) Provision of reference information proving that the general name of the health food involved in the registration application is not the duplication of a drug name that has been approved and registered (searching the online database of the State Food and Drug Administration).
4) Letter of guarantee that the applicant does not constitute an infringement of the patents already obtained by others.
5) Provision of trademark registration certificate (not required if trademark is not registered yet).
6) A product research and development report (including basic concept of the research and development, function screening process, and expected effects).
7) Product formulation (raw materials and supplementary materials) and its basis; sources of raw materials and supplementary materials and basis of their usage.
8) Effective/marker ingredients, content, and testing methods for effective/marker ingredients.
9) Diagram of production process and its detailed explanation and relevant research materials.
10) Product quality standards and explanation for their preparation (including quality standards for raw material and supplementary materials).
11) Category, name, quality standards, and selection basis of packing materials that have direct contact with the product.
12) Test reports issued by testing agencies and their related materials, including:
   A. Test Application Form;
   B. Notification of test acceptance by the testing agencies;
   C. Safety toxicology test report;
   D. Function test report;
   E. Test reports on stimulant, illegal drugs, etc. (registration application for functions including alleviation of physical fatigue, losing weight, and improving growing functions);
   F. Effective ingredient test report;
   G. Stability test report;
   H. Hygiene test report;
   I. Other test reports (including examination report on raw material, test report on bacterial virulence).
13) Draft sample of product labels and instructions.
14) Other materials contributing to product evaluation.
15) Two sealed samples in minimum sales package.

Notes:
a. In terms of registration application for products made from fungus, beneficial bacterium, nucleic acid, enzyme preparation, and amino acid chelate, relevant application materials should be provided according to pertinent regulations in addition to the abovementioned materials.

b. In terms of registration application for products made from wild animals and plants that are restricted for use by the state, the certificate issued by relevant government departments to the supplier of raw materials for development and utilization of such raw materials and the purchase-and-sale contract made by and between the supplier of raw materials and the applicant should be provided, in addition to the abovementioned materials.

c. In terms of registration application for health food aiming to supply vitamins and minerals, the test report on animal function evaluation and/or human trial test report and function research and development report are not required.

d. In terms of registration application for functions that are out of the scope of function items published by the State Food and Drug Administration, in addition to provision of the abovementioned materials on the basis of use of raw materials, the following materials in connection with the new functions should be provided: (1) Function research and development report, including function name, reasons and basis for application, function evaluation process and testing methods and research process and relevant data, basis for the establishment of function evaluation process and testing methods, and scientific documentation. (2) Self-examination report on function evaluation test of product by an applicant in accordance with the function evaluation process and testing methods. (3) Test report on function evaluation of product in accordance with the function evaluation process and testing methods and verification report on evaluation of test methods that are issued by the designated testing agencies.

e. In terms of registration application for different dosage forms of the same product by the same applicant, if one of those dosage forms has gone through all the tests as required and the testing agencies have issued their test reports, the registration of other dosage forms could be exempt from function and safety toxicology tests; however, photocopies of those test reports should be provided. Material change in production process that has an impact on product safety and functions should be excluded.

2. Application Items for Imported Health Food Registration
In terms of registration application for imported health food, in addition to provision of materials on the basis of use of raw materials and functions and
in accordance with the requirements of application materials for domestic health food, the following materials should be provided:

1) Documentary evidence issued by relevant authorities of the country of production to prove that the producer complies with corresponding local standards of production quality control.

2) If the registration issue is handled by a foreign producer’s representative office in China, the photocopies of Registration Certificate of Foreign Enterprises’ Representative Offices in China should be provided.

If the registration issue is handled by a representative agency in China with the authorization of a foreign producer, the original notarized letter of authorization and the photocopies of business license of the authorized representative agency should be provided.

3) Documentary evidence proving that the product has been produced and marketed in the country of production for more than one year, which should be notarized by a notary organ of the country of production and confirmed by the Chinese Embassy or Consulate in that country.

4) Relevant standards of the country of production or international organizations that are in connection with the product.

5) Samples of packages, labels, and instructions of the product marketed in the country of production.

6) Sample products from three consecutive batches, three times of the quantity required for test.

The aforesaid application materials should be prepared in Chinese with the original text. Materials in foreign languages could be attached for reference. The Chinese translation should be notarized by a domestic notary organ to ensure its consistency with the original. Quality standards of the product to be registered (Chinese version) should be in conformity with the format of quality standards of Chinese health food.
Endnotes

1 Values based on 2005 data.

2 There are a number of terms used around the world. These include, among others, health food, health-enhancing food, nutraceuticals, supplements, fortified foods, and functional foods. For the purposes of this report, the term functional foods will be used throughout, even when referring to food in a country that uses different terminology.

3 Depending on the source, the number of manufacturers is reported between 3,000 and 4,000 companies.

4 An interesting point is brought to light by Jungbeck and Benkouider (2004): “Foreign players such as Nestlé and Fonterra were among the first to introduce health and wellness characteristics to dairy products in China, thanks to their strong research and development capabilities, and extensive product portfolio. However, pricing, limited nutrition awareness and logistics issues hampered the range and sophistication level of functional products that Nestlé and Fonterra brought into China. This allowed domestic players such as Yili and Mengniu to swiftly introduce products with similar health benefits and erode the competitive advantage enjoyed by their foreign competitors.”

5 Values based on 2005 data.

6 Fortified through various means, including both genetically modified and genetically engineered processes.

7 A survey report claims that for those Indians who are aware of functional or fortified foods, 37 percent cited their children’s health as the reason for buying organic foods, 55 percent said they bought whole grain, high-fiber products, and 31 percent bought fortified fruit juices (Watson 2006).

8 India has recently fortified sugar with vitamin A. The Indian Life Sciences Institute is also sponsoring a project to fortify salt with iron (salt is already fortified with iodine). In the United States, oils and margarines are the newest sector to be fortified with vitamin E, whereas this trend is already well established in India (Patton 2006).

9 Current disposable income per head in India, in dollar purchasing price parity terms, is $2,303, but this number is expected to grow to $3,033 by 2008 (Ismail 2006).

10 The law actually so tightly defines a particular food item that it is overwhelmingly difficult to introduce new foods. To give an example, the law describes ice cream down to the amount of fat and other ingredients it must contain to be called ice cream, so if a firm produced a low-calorie, low-fat ice
cream, it could not legally call it ice cream because it goes against what the law says ice cream must contain.

11 It is worth noting that there is often misunderstanding about the difference between a supply chain analysis and a value chain analysis. The supply chain focuses on the activities involved with acquiring raw materials and subassemblies, and then getting them through the manufacturing process. The value chain describes the full range of activities that are required to bring a product or service from conception, through the different phases of production, to delivery to the final consumer. The phases of production involve a combination of physical transformation and the input of various producer services.

12 The Indian Seed Act of 2004 is still being debated in Parliament and society and had yet to become law as of May 2006.

13 This is the original team of researchers, but Syngenta has acquired the rights to the project.

14 For complete information regarding HarvestPlus, please refer to the official CGIAR Web site for the program (www.cgiar.org/); also see http://www.harvestplus.org.

15 Although not presented in this report, an interesting article was written by Bill Gates and published in Time magazine (“Will Frankenfood Feed the World?” June 19, 2001). Gates states his reasons as to why GM foods are necessary but also states that GM foods are not the sole solution to the problem of malnutrition. This article can be accessed at http://www.agbioworld.org/biotech-info/topics/dev-world/frankenfood.html.
References


Institute of Food Research Web site. 2006. Available at www.ifrn.bbsrc.ac.uk.


