1. Introduction

1.1 MOTIVATION

With ageing and increasingly affluent populations, there is a growing awareness and recognition of the link between diet and health. For consumers, this means seeking out food products with new or enhanced health attributes and navigating through the sometimes confusing maze of food health claims. For the food industry, this creates opportunities for product differentiation and drives incentives to invest in the research, development and commercialization of healthier foods. For regulators, this creates challenges in designing appropriate regulatory frameworks to encourage investment and facilitate innovation, while protecting consumers from fraudulent or misleading health claims. These issues form the backdrop to this book. The primary objective of the book is to examine the policy and regulatory environment governing the health foods sector internationally and examine key trends and industry developments in leading markets.

In researching the book, it became evident that the ‘health foods sector’ is a diverse concept: it is defined differently, is regulated differently and encompasses different types of products, in various countries. As will become clearer in the material that follows, the terms ‘functional foods’, ‘nutraceuticals’, ‘supplements’, ‘natural health products’, ‘medical foods’ are used variously and interchangeably across different countries to refer to products with health-enhancing attributes. The inconsistencies in definitions across countries is more than merely pedantic: it affects how these products are regulated and positioned in the market, determines what health claims are permissible and creates complexities for firms seeking to navigate export markets. For the purposes of this book, therefore, we have taken the deliberate decision to refer to these products under the catch-all term of ‘health foods’.

In this chapter we lay out the primary issues that are dealt with in more detail in subsequent chapters. Before doing so, it is useful to consider the factors that have driven interest in the health foods sector.
1.2 DIET AND HEALTH: DRIVERS OF INTEREST IN HEALTH FOODS

Science has shown fairly clearly that diet affects human health and, therefore, healthy diets help promote good health. Conventionally, the primary role of the human diet has been the biological provision of nutrients to maintain metabolic function and wellbeing. Scientific evidence increasingly suggests, however, that some foods and food ingredients provide physiological benefits over and above that of conventional foods (ADA, 2004; Health Canada, 2009b; IFIC, 2009). Examples include food products with enhanced levels of omega-3 fatty acids for heart health or foods enhanced with probiotics for digestive health, or calcium for bone health. Previous studies have pinpointed several drivers of the interest in health foods, which can be loosely grouped into four categories: (1) health drivers, including increased incidence of chronic diseases such as diabetes, cancer, cardiovascular diseases (CVD) and respiratory diseases; (2) lifestyle drivers, including sedentary lifestyles, which lead to an increase in lifestyle-related diseases, ageing populations and rising consumer incomes; (3) scientific advances, including new research and development (R&D) applications that create opportunities for product differentiation in the food industry; and (4) economic factors, including rising public health care costs and awareness of the link between diet and health.

A number of indicators related to disease, obesity rates, life expectancy and health expenditures set the scene for increased global interest in the health foods sector. According to the World Health Organization (WHO, 2013), CVD are the leading cause of death worldwide, with an estimated 17.3 million deaths caused by CVD in 2008, predicted to rise to 23.3 million by 2030. The majority of these deaths occur in low- and middle-income countries. Lifestyle factors, including tobacco and alcohol use, but also unhealthy diets, obesity and physical inactivity are leading contributory factors of CVD (WHO, 2013). Indeed, rising levels of obesity continue to present health challenges, with the WHO estimating that the worldwide prevalence of obesity doubled between 1980 and 2008. High levels of obesity are concentrated in the Americas, with around 30 per cent of the United States of America (USA) population over the age of 20 now considered obese. Globally, the WHO estimates that 2.8 million people a year die as a result of being overweight or obese, with many more developing diet-related diseases and long-term health problems (WHO, 2012a).
With improvements in life expectancy, nutrition and disease reduction, the world population continues to age; the number of people aged 60 and over has doubled since 1980 and is forecast to reach 2 billion people by 2050 (WHO, 2012b). This places an ever-increasing burden on health care systems, particularly in high-income countries. Global expenditures for health are estimated to top US$6.5 trillion, with the highest total spending per person per year on health occurring in the USA at US$8362 in 2012. These expenditure levels are in sharp contrast with the lowest spending per person per year of only US$12 in Eritrea. The disparity in global health spending worldwide is reflected in the fact that Organisation for Economic Co-operation and Development (OECD) countries, representing just 18 per cent of the world’s population, account for 84 per cent of the world’s total financial resources devoted to health (WHO, 2012c).

The significant increase in lifestyle and diet-related diseases poses a challenge to governments around the world seeking effective ways to reduce health care costs and improve citizens’ health. At the same time, opportunities are burgeoning in the health foods sector as the relationship between diet and health is becoming increasingly important in the context of ageing populations, particularly in the developed world. As healthier diets today may lead to fewer diseases tomorrow, the consumption of health-enhancing foods provides an avenue for improving the welfare of citizens.

The importance of the health foods sector is evident in the growth of the industry worldwide. Available food technologies, scientific discoveries and increased consumer desires/interest for healthier food products provide opportunities for the development of healthier food products, while industry foresighting analysis suggests a continued upward trajectory for the industry (Arias-Aranda and Romerosa-Martinez, 2010; Hobbs, 2002; IFT, 2005). With the caveat that robust estimates are notoriously difficult to come by in part due to differences in the definition of the health food category, the global market size for the health foods sector is estimated to have ranged from US$30 to US$60 billion in 2004, representing 1–3 per cent of the total food market (Kotilainen et al., 2006). The sector has continued to grow. More recent estimates put the global health food market at around US$151 billion in 2011, with the sector forecast to grow to US$207 billion by 2016 (BCC Research, 2011). Currently, the leading markets are the USA, the European Union (EU) and Japan.

A burgeoning literature on health-enhancing food products indicates strong prospects for the health foods sector. There is growing evidence of consumer acceptance of these products and willingness to pay a premium
for their benefits. Consumer acceptance is critical and should in turn lead to additional R&D and product development. Increased consumption of nutrient-enhanced products (for example, trans fat-free designer eggs, high conjugated linoleic acid (CLA) dairy products, golden rice, probiotics, functional cereals, phytoalexin-enriched foods and high oleic oil peanuts) offer potential health benefits and improvements in areas where considerable public and private sector health spending occurs (including CVD and cancer).

The health foods sector is not without its challenges, which include resources for product development, transparent and enforceable property rights systems to protect patents, regulations that differ across jurisdictions with respect to the number of permissible health claims, slow and cumbersome approval processes and maintaining consumer confidence in the face of a proliferation of products and health claims. These issues are examined in later chapters.

1.3 ISSUES EXPLORED IN THE BOOK

The book covers three main themes: the different approaches to defining the health foods sector; policy challenges and the regulation of health claims and new product approvals; and drivers of industry growth and consumer acceptance.

1.3.1 Defining ‘Health Foods’

A central objective of this book is to provide an overview of the policy and regulatory environment governing the health foods sector internationally. This regulatory environment, particularly with respect to health claims and new product approvals, is evolving at different rates internationally. Various countries permit health claims declaring an association between a food or food ingredient and a health benefit; however, different definitions, terminologies and regulations are in use. Chapter 2 provides a comprehensive discussion of the terminology used to define health foods in various countries. Below we provide a broad overview.

Generally speaking, the health foods sector is characterized by two broad categories of products: so-called ‘functional foods’ and ‘supplements’ or ‘nutraceuticals’. The term functional food has become a fairly widely accepted term to describe enhanced foods. Functional food usually refers to food that is intended to be consumed as part of a normal diet and contains ingredients that have the potential to enhance human
health or reduce the risk of disease beyond basic nutritional functions (ADA, 2004; Health Canada, 2009b; IFIC, 2009; Stein and Rodríguez-Cerezo, 2008).

Nutraceuticals, also known as food supplements, or natural health products (NHPs), are products that have been isolated or purified from food and may include ingredients such as amino acids or vitamins; they are often marketed in the form of pills, powders, capsules or tablets. Nutraceuticals/supplements are intended to have a physiological benefit or to provide protection against chronic disease (EFSA, 2010; Health Canada, 1998).

Consumption of products from either category provides additional health benefits beyond the supply of basic nutrients. We devote an entire chapter to explaining how these products are defined in various countries because this is an important context for the remaining chapters of the book. In particular, it underpins the discussion of the regulatory environments in developed and emerging markets in later chapters. As such, Chapter 2 presents the varying definitions used for these health food products in the USA, Canada, EU, Japan, Australia and New Zealand, Brazil, Russia, India, China, South Korea and Taiwan.

1.3.2 Policy Challenges: Health Claims and New Product Approvals

The health foods sector embodies the outcome of scientific discoveries and new technologies leading to the creation of new products. While this creates obvious opportunities for market growth, it also brings with it a set of policy issues including the process for new product approvals, the establishment of regulatory frameworks to govern allowable health claims for these products and determining whether the rules around the protection of intellectual property rights (IPR) provide appropriate incentives for innovation. Labelling and novel food registration procedures have a direct bearing on the incentives for firms to innovate. Different regulatory treatment of these products in different countries creates the potential for trade barriers; for example, if a product, an ingredient or a process is approved for use in one jurisdiction but not in another, or if a health claim is permitted on a product label in one jurisdiction but not in another.

Consumers seeking improved health will likely see food with health benefits as superior to food without health benefits, thereby providing opportunities for food innovations that meet consumer demands. In order for consumers to choose foods with health benefits over conventional foods, they must be provided with credible, useful information about a product’s health and nutrient benefits upon which to make informed
decisions. The role of credible information is therefore critical but susceptible to manipulation, hence many countries have moved to regulate health and nutrient content claims on food products. Such claims are usually permitted on labelling and in advertisements to inform consumers about the health benefits of the consumption of the food or the food constituent.

Recent policy responses include measures to better inform consumers about the nutrient content of foods to facilitate healthier eating choices – for example, the introduction of mandatory nutrition labelling on pre-packaged foods and the requirement to label the presence of trans fat in these foods. Enhancing the information provided to consumers is an important policy response to improving health by changing what consumers eat. Policies to encourage R&D into healthier foods also have a role to play. This may include changing the nutritional composition of diets by lowering the cost of producing food that is more nutritious and by improving the nutrient composition of existing foods. Policy issues are explored in Chapter 3, which also charts the evolution of regulatory frameworks in a number of countries through a review of the literature examining regulatory developments.

How do regulatory frameworks in key markets differ? This is the subject of Chapters 4 and 5, which describe the regulatory environments in key developed country markets and emerging markets, respectively. Specifically, Chapter 4 focuses on the USA, Canada, EU, Japan, Australia and New Zealand, with a particular focus on allowable health claims and the processes for new product approval. Chapter 5 presents a comparable analysis of the regulatory frameworks in Brazil, Russia, India, China, South Korea and Taiwan.

While Chapters 4 and 5 provide a detailed treatment of these topics, it is useful to provide a broad overview of the different types of health claims in use. Health claims can be either generic or product-specific. Generic claims usually specify relationships between a food constituent and a health effect and can be claimed by a food product so long as it meets the conditions for using the claims. Product-specific claims, on the other hand, can only be used by products that have undergone a registration process for use of the claim, which usually specifies a relationship between the food or food constituent and a health benefit (Subirade, 2007).

Beyond generic or product-specific distinctions, health claims are usually further divided into two different categories: disease risk reduction claims and structure/function claims (Subirade, 2007). A disease risk reduction claim usually specifies the relationship between the consumption of a nutrient and its effects on mitigating disease risk. For example,
several countries (USA, Japan, Canada, Australia and New Zealand) permit claims linking the presence of calcium and/or vitamin D and the reduced risk of osteoporosis. Structure/function claims, on the other hand, link the presence of a nutrient to normal growth, development or functioning of the human body. For example, several countries (Japan, Canada, Australia and New Zealand) permit claims linking the presence of calcium and/or vitamin D and proper bone structure.

Nutrition content claims or nutrition claims can also often be made on food and sometimes on supplements/nutraceuticals. Nutrition claims simply describe the presence or absence of a nutrient. Permitted nutrition claims tend to indicate positive implications for health. In a way, nutrient content claims are implied health claims. For example, in some countries (for example, USA, EU, Japan, Canada), firms can claim a food to be ‘high in potassium and low in sodium’, both of which contribute to reduced risk of high blood pressure and CVD. Nutrition labelling regulations vary from country to country. Of specific focus are nutrition facts tables, which display information about levels of nutrients per serving. A number of countries (for example, USA, Canada, EU, Brazil, Russia, India) have implemented mandatory nutrition labelling. Labelling is deemed an essential means of imparting information to consumers about the foods they eat and also confirms that the claims that firms make on their health food products are not misleading.

Labelling requirements for the products categorized as nutraceuticals/supplements (see Chapter 2) often differ from that of food and vary from country to country. Some countries have implemented labelling that treats these products more like drugs than food (for example, Canada, Australia), while others have implemented the reverse. There are also broad regulatory differences across countries when it comes to functional food regulations. Some countries have a body that regulates the use of health claims (for example, the Food and Drug Administration (FDA) in the USA, the Ministry of Health, Labour and Welfare (MHLW) in Japan, Health Canada in Canada, the Ministry of Food and Drug Safety (MFDS) in South Korea, the State Food and Drug Administration (SFDA) in China). Historically, some governments permitted health claims but allowed private interests to regulate their use (United Kingdom). Other countries have developed regulations cooperatively on health and nutrition claims (EU, Australia and New Zealand). All countries examined in this book no longer permit self-regulation. Future regulatory trends appear to be leaning towards regulatory cooperation between countries, which will be particularly important in countries with close trade relationships.
A final regulatory hurdle to new health food products may be novel food approval. If a food meets certain conditions (for example, it lacks a history of safe use as a food), then it may be subject to novel food registration before entering the market, which generally requires a safety assessment. Details of the novel food registration procedures in several countries are also provided in Chapters 4 and 5.

1.3.3 Drivers of Industry Growth and Consumer Acceptance

The health foods sector has experienced rapid growth, with an increasing array of products available in the marketplace. Chapter 6 charts the growth of this sector in four markets – the USA, EU, Japan and Canada – in terms of size, market trends and research directions. Ultimately, it is consumers that determine the long-run market success of these products, therefore understanding the factors that influence consumer acceptance of products with new health attributes is critical. These issues are explored in Chapter 7, which draws upon a growing body of literature examining the receptivity of consumers to new health attributes in food products, their willingness to pay (WTP) for these attributes and the drivers of trust in health claims. The chapter reveals growing evidence that consumers are willing to pay a premium for health benefits provided by foods and by supplements. An understanding of consumer attitudes towards health foods, including the extent to which traditional influences on consumer acceptance – such as convenience and taste – remain relevant, is important to the long-run growth of the sector.

1.4 ROADMAP

As outlined in more detail above, this book is organized into eight chapters. Chapter 2 explains the terminology used within the ‘health foods sector’ internationally and forms the backdrop for the subsequent discussion of policy and regulatory issues. Chapter 3 outlines key policy issues surrounding the health foods sector and charts the evolution of regulatory frameworks through a review of relevant literature. Chapters 4 and 5 discuss health claims regulations in selected developed and emerging markets, respectively. Chapter 6 examines industry trends in selected developed markets. Chapter 7 explores consumer responses to the health foods category and is informed by a comprehensive review of consumer literature in this area. Chapter 8, ‘Through the looking glass’, offers a synthesis and concluding thoughts with respect to common themes and differences in regulatory environments for the health foods sector.
sector globally and future issues that are likely to arise as new food innovations emerge. We invite the reader to grab a (healthy) bran muffin, pour a glass of omega-3-enhanced orange juice and read on.

NOTES

2. Obesity is defined as a body mass index $\geq 30$ kg/m$^2$ (WHO, 2012a).