INCREASING REGULATIONS FOR NATURAL HEALTH PRODUCTS: AN INVESTIGATION OF TRADE EFFECTS

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ABSTRACT

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Natural health products (NHP) have been experiencing strong growth in consumer demand, both domestically and in foreign markets. The nature of NHP and the small sector of the population that used them in the past, has allowed them to "slip between the cracks" of regulatory bodies. As NHPs have become mainstream and have been marketed and distributed through major agri-food supply chains, governments have had to become more active regulators. New *Natural Health Product Regulations* came into force in Canada on January 1, 2004 to regulate these product which had been generally regulated under the *Food and Drug Act*. Canada is not alone in its regulatory reform and other countries have begun to create new and often more rigorous regulations for NHP.

It as often the case that domestic regulations have unintended and sometimes trade restricting side effects. The current restructuring and focus on regulations of NHP, and the potential importance of trade within this sector, suggests that a better understanding of the non-tariff barriers that may arise could be important for the development of the industry in Canada and elsewhere. Analysis of trade effects arising from standards and regulations is not an easy task. Non-tariff barriers to trade tend to have product-specific effects making it difficult to find general results. Using a review of current approaches to address technical barriers, an analytical framework has been selected and applied to case studies.

The cases studies examined the welfare effects of regulations as they pertain to three products with different characteristics; flax omega-3 supplement, elk velvet, and a probiotic supplement. The case studies identified a range of non-tariff barriers arising from international regulatory divergence. The results suggest that trade barriers are likely to arise in the NHP industry and that they will differ from product to product. As a result, there is unlikely to be a single policy prescription that will facilitate the removal of barriers to international market access. Suggestions are made as to how barriers could be

eliminated or reduced through formal trade negotiations or less formal bilateral discussions.

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Chapter 1: Introduction

1.1 Background Information

The market for Natural Health Products has emerged as a growing and important segment of consumer spending around the world. A new focus on health and the acceptance of other cultural healing practices has fuelled this growing market. Modern markets for natural health products are most developed in high-income economies such as the European Union (EU), the United States (US), and Japan. Canada accounts for a small percentage of the global market but the dollar value of the industry is considerable.

There is no agreement on internationally standardized terminology for the industry, which leads to considerable confusion. The term "natural health product" was created by Canadian regulatory bodies and is unique to the Canadian market. The differing terminology stems from different regulatory approaches that define specific terms for a given market. Although, these products are by no means new to the marketplace, when they were cottage industries regulatory bodies largely ignored them. The regulatory environment in the natural health product industry typifies that of any fast growing industry – policy, institutions and regulation have yet to catch up with rapidly evolving consumer demands. It is still the case that many jurisdictions have poorly defined regulations or are in the early stages of development and implementation.

In terms of international trade, this assortment of regulatory regimes creates uncertainty and increased risk. Increased costs to firms, both financially and in terms of time and effort, occur as a firm undertakes the task of becoming familiar with and learning about the regulatory environment of foreign markets. There is a clear lack of harmonization and standardization in regulations governing natural health products. International regulatory standards bodies have yet to fully address this sector. The regulations arising in different markets vary considerably and firms have identified regulations as a major barrier to trade in the industry. The differing regulations and nature of some of the current regulation may, in turn, be acting as a hidden technical barrier to trade. As a result, international trade and its benefits may be inhibited.

Due to the growth in global and domestic markets, the issue of the impact of regulations within this sector has arisen. The differences in regulatory regimes and their effect on allowable claims for natural health products could be inhibiting the development of international markets and growth of the domestic industry. Firms that wish to export and import may face a series of barriers due to different regulatory approaches. Some in the industry question the impacts of the diverging regulatory system and the effect that may have on trade. Others believe that perhaps this is a perceived barrier and there is more to gain from increasing regulatory action. It is often difficult to assess technical barriers to trade that stem from standards and regulations. In addition, regulations also have the potential to increase benefits from trade. Economists find it difficult to produce conclusive analyses of the trade effect of regulations, as empirical methods are hindered by poor data access and collection.

1.2 Problem Statement

There has been considerable economic research that suggests non-tariff barriers, such as standards and regulations, are having an increasingly important role in inhibiting trade. Previous investigations suggest that these types of barriers could be more damaging than their tariff counterparts. However, that being said, economists find it increasingly difficult to deal with technical barriers to trade, both at the applied and theoretical levels. As of yet, little is known about the trade effects of technical barriers, and empirical analysis is rare. There have been no conclusions as to whether regulations and standards reduce trade by virtue of compliance costs or increase trade through increased consumer confidence in the safety and quality of imported goods.

It is important to understand the potential trade effects of the growing trend of more stringent and diverging regulatory systems within the natural health product industry. Additionally, the potential regulatory hurdles a firm must face to market a natural health product both domestically and for export, must be addressed.

In order to evaluate the potential trade effects of regulations in the natural health product industry, an analytical framework is presented and modified to examine three specific case studies. It is often the case that domestic regulations are put in place with the local issues in mind but can have unforeseen effects on trade. Natural health product

regulations are not strictly trade-limiting instruments, as both domestic and foreign firms must meet their requirements. However, these regulations can be described as trade obstacles that firms must overcome. The natural health product industry has become one that is facing a variety of different regulatory systems together with significant adjustment to past regulatory approaches.

There has been little research addressing the obstacles that firms face when marketing products internationally within this growing industry. This study addresses the potential technical measures that firms must overcome to effectively market natural health products. It also classifies the measures, and examines the trade effects of the current standards and regulations.

1.3 Proposition

This thesis proposes that increasingly stringent, and a growing variety of, regulations for natural health products may hinder firms' abilities to internationally market their products. These regulations may, in turn, act as trade barriers that could benefit domestic firms. However, the welfare effect for consumers is an interesting dilemma between the potential gain of surplus from increased information about natural health products and potential loss in gains from trade due to regulations. The case studies are used to assess domestic regulations for a given product and a foreign set of regulations for the same product. The framework is applied for the three specific products and provides insight into the regulatory hurdles a firm marketing various natural health products may face.

1.4 Objective

To assess the proposition that regulations may be negatively affecting a firm's ability to market natural health products internationally, research is undertaken into different regulatory systems, their nature and the effect of regulatory measures for natural health products. This research includes: a description of the natural health product industry and the current regulations in Canada, the United States (US) and the European Union (EU); a review of different approaches to addressing technical barriers, where an

appropriate framework will be chosen and described; and in-depth case studies of the regulations for three products using the framework.

1.5 Thesis Outline

The thesis is presented as follows. Chapter 2 will provide background information regarding the natural health products industry. It will define the important terms used in the industry.

Chapter 3 consists of a literature review of agreements that oversee technical measures and different approaches to analysing technical barriers. From this review, an analytical approach is chosen that is best suited to assess the proposition in the absence of suitable data to undertake a full empirical inquiry. The limitation of examining this industry is that there is little to no data available and this limitation was a major consideration when choosing the analytical approach. This constraint leads to a qualitative approach and the use of the framework to examine case studies.

Following the literature review, chapter 4 examines the proposed framework and its major components. Classification is important to the framework and is discussed in relation to three different characteristics. Next, the framework pulls together five previously published papers to build the model to examine the trade effects of technical barriers that the regulations can cause.

The beginning of chapter 5 provides an overview of the Canadian *Natural Health Product Regulations* and its component parts. Likewise, an overview of the regulations in the US and the EU for similar products is developed. This leads the way to a comparison of the three regulatory approaches. Next chapter 5 presents the three case studies: a flax omega-3 supplement, an elk velvet antler supplement, and a combination probiotic supplement. Each case identifies the regulations that must be met to market the given product in Canada and in one market abroad. A classification of the regulations a product faces is conducted, and finally the effects on trade are discussed for each case. The cases are compared in the conclusion and the potential effect for natural health product firms is discussed.

Lastly, Chapter 6 provides a summary and a discussion of the key results. Topics for future research are suggested.

Chapter 2: Natural Health Products Around the World

2.1 Introduction to Natural Health Products

Traditionally, the agriculture sector has focused production on commodities providing nutrition as well as some fibers. These tend to be markets with a high degree of substitutability among the outputs of farms, and few barriers to entry. As a result, profits tend to be competed away quickly. Product differentiation is often seen as one way to raise and maintain farm incomes and has highlighted the need for alternative products for the agricultural sector. Recently, a new focus has emerged on agricultural products intended to enhance human health; this includes functional foods, nutraceuticals, and natural health products. Attention and enthusiasm from governments, the agri-food sector and the research community in Canada have created a focus on functional foods, nutraceuticals and natural health products (NHP).

There is a dearth of reliable statistics on the current and potential size of the international markets for natural health products and functional foods; further, there is even less data that can be used to provide estimates of sub-sector sizes.[1] However, depending upon definitions used, the 2002 annual global consumptions of NHP and functional foods were estimated to be between US $70 and US $250 billion (NFFA 2002). In 2001, Canadians purchased approximately $4.2 billion of dietary supplements, nutraceuticals and functional food products as compared with $3.9 billion in 2000 (Anon 2001). This accounts for three percent of the global market, which was estimated in 2001 to be approximately $145 billion (Anon 2001). The industry identified that the primary markets for NHP and functional foods are the United States, Europe, and Japan as they account for 90 percent of global sales (Anon 1998). It is clear that these countries represent potential export markets for Canadian NHP and functional foods. Statistics Canada surveyed 576 companies that participate in the functional foods and NHP sector. One quarter of these companies were involved with both functional foods and NHP, while 45 percent of them were only involved in NHP activities. This survey showed the industry was gaining momentum, with about 17 percent of companies having revenues of

[1] It is very difficult to find statistics that will separate the category of functional foods, nutraceuticals, and natural health products. This problem is compounded by the lack of clear definitions.

$10 million or more in 2002. Exports are very important, as more than one half of all Canadian firms exported functional foods and/or NHP in 2002. Just over three-quarters of exported products were shipped to the United States (Statistics Canada 2003). The ability to capture foreign markets is an important determinant of the contribution the NHP industry can make to Canadian agriculture and to the wider Canadian economy. Imports will also be important as they can provide Canadian consumers with greater access to a wider variety of NHP. At the heart of this concern pertaining to import and export markets is a set of challenges and opportunities that all involved with this industry will face.

Functional foods and NHP have been in the marketplace for many years and some products have traditionally been used to enhance health. Increasing demand is causing a transition from a relatively small "cottage industry" to one of considerable commercial interest. Access to foreign markets is vital to the success of this transformation because it will allow these current niche markets to expand to the point where economies of scale can be realized. The nature of these products and the small sector of the population that used them in the past have allowed them to slip under the radar of regulatory bodies. As NHP have become mainstream and have been marketed and distributed through major agri-food supply chains, governments have had to become more active regulators (Hobbs 2002).

Policy makers have been faced with many difficult decisions as to regulate this industry. Often, these products are associated with numerous health claims that entice the buyer to purchase and try them. Consumers have a choice to purchase these products but it is often the case that the health claim has not been scientifically proven. The costs associated with proving claims are often prohibitive for the producers and/or manufacturers. Governments have recognized the need to protect consumers from fraudulent claims and to ensure their safety. A set of strict regulations will limit consumer choice and will most likely be accompanied by high enforcement costs. At the other end of the spectrum, leaving the industry to "the buyer beware" principle will expose consumers to products with little or no efficacy and that are, in some cases, unsafe. The balance between these positions is a fine line. Further complicating these difficult regulatory questions is the absence of an international consensus on the best regulatory

approach to take. The different regulatory systems evolving in individual countries can act as technical barriers to trade. As well, it is often difficult to distinguish between a genuine regulation and those put in place to extend protection to domestic producers (Gaisford and Kerr 2001).

It is often suggested that regulatory harmonization is the key to technical barriers to trade. However, harmonization is often fraught with difficulties, as agreeing on global standards is not a simple task (Gaisford and Kerr 2001). As yet, there seems to be no effort to internationally harmonize the current regulations surrounding NHP and functional foods. This leaves the development of this segment of the market vulnerable to non-tariff barriers to trade. These types of barriers are much less transparent and can often be more trade inhibiting than tariffs.

In terms of industry participants wishing to export and import, regulatory uncertainty represents a major risk that may threaten products that have been exported and imported easily in the past. The lack of knowledge of regulations in destination markets creates unforeseen costs associated with learning the regulatory environment. In addition to the learning costs, a firm may face others costs such as, reformulation, repackaging, or relabelling costs to comply with regulatory standards. With many different products, and destinations, this cost can prove to be significant – sometimes to the point of thwarting international transactions. Thus, different regulatory environments increase costs and risk to firms involved in trade. These types of costs are often referred to as transaction costs. Firms participating in the market will employ resources to acquire information on regulations; this activity comes under the general classification of information costs. Information costs are incurred *ex ante* to transactions and can include everything from the time allocated to finding trading partners, understanding the local regulations, identifying product qualities, and gathering price and currency information. When the costs of making a transaction becomes too great, a firm may decide that the sale is not worth the amount spent on completing the transaction. It is important for the NHP sector that complicated and strict regulations do not increase transaction costs to a point where industry development will suffer. Most policies are created with local interest (both consumer and producer) in mind, these interest are more able to effectively lobby their local governments and influence policies than potential foreign suppliers. In

turn, domestic firms are often left with an advantage relative to foreign firms. Currently, policy institutions and regulators need to catch up with the growing consumer demand for these products.

Across the globe, NHP are poorly defined and in early stages of regulatory development. Often through different approaches, national regulatory bodies are trying to create and enforce new legislation surrounding NHP. The focus of this chapter is NHP and the regulations that govern them within Canada and abroad. It is not the intent to capture issues surrounding functional foods. These two product categories are often lumped together, however, and there will be some mention of functional foods. Understanding the approach taken in Canada and how it differs from our major trading partners, the EU and the US will facilitate examining the potential challenges for those wishing to trade NHP. What follows here is a general overview of the differing regulatory approaches. More details on the regulations are provided in chapter 5.

2.2 Natural Health Product Regulations

2.2.1 Canada

In Canada there has been a significant effort to create a consistent and reasoned set of regulations for NHP. It is important, however, to first understand the definitional issues surrounding nutraceuticals, functional foods and NHP in Canada. These definitions are vital to understanding the regulations and to interpreting the current and proposed legislation. Unfortunately, there is no commonly accepted definition of these products. Categories and terminology are often quite different worldwide. This will become obvious in the discussion of the different approaches to regulation in Canada, the EU, and the US. Thus, beginning with Canada, the Bureau of Nutritional Sciences, of the Food Directorate of Health Canada, has proposed the following definitions (Health Canada 1998):

> A *nutraceutical* is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease. Examples include fish oils, soy isoflavones and canola phytosterols.
>
> A *functional food* is similar in appearance to, or may be a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological

> benefits and/or reduce the risk of chronic disease beyond basic nutritional functions. An example of a functional food with a disease-fighting ingredient would include omega-3 fatty acids found in fish, flaxseed, soybean, hempseed, and canola oil.

Health Canada and the Natural Health Products Directorate have defined the term NHP (NHPD 2004):

> A *natural health product* is naturally occurring substances that are consumed for the purpose of diagnosing, treating or preventing illness or maintaining or promoting health. Natural health product substances include plant, algal, fungal, or animal materials or extracts thereof; vitamins; minerals; amino acids; essential fatty acids and probiotics. Natural health products are usually sold in dosage form (capsule, pill, tablets or liquid extracts). Since nutraceuticals are sold in medicinal form and not consumed as food, they are classified as natural health products.

The natural health product definition includes traditional medicines and homeopathic preparations but excludes drugs and foods, among other substances (tobacco and illegal drugs). Thus, due to its definition, it does include nutraceuticals but does not include foods and is not intended to capture the food medium.

In the past, nutraceuticals and functional foods were generally regulated under the Canadian Food and Drug Act. The act was not properly designed to deal with these specific types of products and was a hindrance to the development of the industry. As a result, Health Canada undertook a review of health claims for these products. This review resulted in a policy document that recommended that a new regulatory framework be developed to govern allowable health claims and establish appropriate scientific standards of evidence and a monitoring and enforcement mechanism to ensure compliance (Health Canada 1998).

Consequently, Health Canada began regulatory reform focusing on separating functional foods from NHP. Canada's office of the NHP was formed in March 1999 to establish and implement a new regulatory framework for NHP. This parallel and equal department to Health Canada's Food Directorate and Therapeutic Products Programme was renamed the Natural Health Products Directorate (NHPD) in 2001. Nutraceuticals are responsibility of the NHPD but it is not the intention for the directorate to oversee

functional foods as well. Functional foods are being treated as a separate legislative area and are the responsibility of the Food Directorate.

In December 2001, proposed regulations for NHP were published in the Canada Gazette Part I as the first step to amending the Foods and Drug Act to reflect the needs of NHP (Natural Health Product Regulations 2001). The main components of the regulations include NHP definitions, product licensing, adverse reactions reporting, site licensing, good manufacturing practices (requirement for product specifications - identity, purity, potency; premises - equipment, personnel, sanitation program; operations-quality assurance, stability; records - sterility, lot or batch samples and recall reporting), standards of evidence for safety and health claims, and labelling and packaging (Fitzpatrick 2003).

2.2.2 United States

The regulatory environment in the US differs significantly from that of Canada. It is important to note that due to location and the size of the market, the US is the most promising foreign market for NHP trade with Canada. The primary difference is that NHP are considered dietary supplements and are regulated by the Food and Drug Administration (FDA). FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and over-the-counter). There is a separate act to cover this area called the Dietary Supplement Health and Education Act of 1994 (DSHEA). The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with the FDA nor get FDA approval before producing or selling dietary supplements (FDA 2003).[2] Manufacturers must make sure that product label information is truthful and not misleading. Despite common use in the market place the terms functional foods and nutraceuticals do not receive official recognition. FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and

[2] Domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are required to register their facility with the FDA. This is not a complicated process and the FDA estimates that this would take about three hours to read and fill out the document.

product information, such as labelling, claims, package inserts, and accompanying literature.

Traditionally, dietary supplements referred to products made of one or more of the essential nutrients, such as vitamins, minerals, and protein. However, in 1994 the DSHEA broadened the definition to include, with some exceptions, any product intended for ingestion as a supplement to the diet. This includes vitamins; minerals; herbs, botanicals, and other plant-derived substances; and amino acids and concentrates, metabolites, constituents and extracts of these substances (DSHEA 1994). It is easy to identify a supplement in the US because DSHEA requires manufacturers to include the words "dietary supplement" on product labels. Dietary supplements do not need FDA approval before they are marketed, except in the case of a new dietary ingredient in which case a pre-market review for safety is required. The law also requires data as proof.[3] As well, in the case of a new ingredient, the burden of proof for the safety of the substance is the responsibility of the FDA and not the marketer. While prescription and over-the-counter drugs and food additives must meet the FDA's safety and effectiveness requirements, dietary supplements that are marketed with medical claims can bypass these regulations. Dietary supplements can go to market with essentially no testing for efficacy, thus skipping the years-long process that drugs must undergo. It is interesting that the FDA is also prohibited from taking a dietary supplement off the market unless the agency can prove that using the supplement will create a medical problem.[4]

2.2.3 European Union

The EU market is perhaps the most uncertain and unpredictable regulatory environment as it is fraught with a myriad of national legislation as well as EU-wide legislation. As the EU strives to become a single market, companies have had to adjust to

[3] Dietary supplement manufacturers that wish to market a new ingredient (that is, an ingredient not marketed in the United States before 1994) have two options. The first involves submitting to FDA, at least 75 days before the product is expected to go on the market, information that supports their conclusion that a new ingredient can reasonably be expected to be safe. Safe means that the new ingredient does not present a significant or unreasonable risk of illness or injury under conditions of use recommended in the products labelling. The information the manufacturer submits becomes publicly available 90 days after FDA receives it. Another option for manufacturers is to petition FDA, asking the agency to establish the conditions under which the new dietary ingredient would reasonably be expected to be safe. To date, FDA's Centre for Food Safety and Applied Nutrition has received no such petitions.

[4] This is the author's interpretation of the legislation in the US for Dietary Supplements.

changing regulations and adapt products to a combination of national and EU-based regulations.

In 2002, the EU Directive on Food Supplements was passed. This piece of legislation is concerned only with vitamins and minerals and it establishes a range of general principles and labelling requirements affecting NHP containing other ingredients. The legislation has three major impacts on the marketing of NHP in the EU: (1) new EU labelling rules for all food supplements; (2) harmonized EU rules on the type of vitamins and mineral substances used and; (3) potential changes in national notification and registration systems. The directive (2002/46/EC) defines and limits the ingredients (vitamins and mineral salts) of food supplements to a positive list, as well as the combination of those ingredients within a product. The directive further regulates the labelling, presentation and advertising of food supplements (Official Journal of European Union 2002). This has been a controversial policy and has seen a great deal of resistance in the United Kingdom. Some feel the positive list was too conservative and has limited the number and range of ingredients. Critics (some manufacturers) of this legislation point out that many synthetic variants were included in the list and not the organic forms. Unsurprisingly, consumer groups as well as some manufacturers and retailers are opposed to the directive. In February 2004, the High Court in London ruled that the case should be referred to the European Court in Luxembourg. The court found that there was "an arguable case" that the directive was unlawful and would unfairly affect millions of people, threatening both health and trade (Functional Foods and Nutraceuticals Staff 2004). Only the European Court can challenge the directive. The future of regulations for vitamins and dietary supplements lies therefore with the Court. A decision is expected in June 2005 and, interestingly enough, only one directive has ever been overturned by the Court.

The second piece of legislation that will impact the industry in the EU is the Traditional Herbal Medicinal Products Directive (THMPD) that was adopted by the EU Parliament and published in the Official Journal of the European Union on the 30th of April 2004. The Directive requires all Member States to comply with the Directive by the 30th of October 2005. The purpose of the directive is to establish within the EU a harmonized legislative framework for authorizing the marketing of traditional herbal

medicinal products, involving a simplified registration procedure (Official Journal of the European Union 2004). The objective is to remove the differences among member states, which creates difficulties for the free movement of medicinal products within the EU, while ensuring protection for public health. The legislation requires that member states introduce the simplified registration procedure.

There is a clear lack of legislation that encompasses all NHP and regulates claims attached to the product. Currently, member states have freedom to interpret the labelling, presentation, and advertising provisions of the Foodstuffs Directive as they see fit. This has led to numerous voluntary agreements until further legislation is adopted (Hill and Knowlton Co. 2000). However, there is a clear divergence in the approaches to regulating NHP. This makes the EU perhaps the most difficult to analyze and clearly the most difficult for NHP trade. It is necessary to examine a specific country as a market destination due to the lack of a common European policy on food supplements and herbal medicines. This further increases the resources a firm must allocate to transact within the EU market and perhaps makes it the most challenging market of the three discussed.

2.3 Conclusion

Clearly, there is no consensus on the approach to regulating NHP across the globe. Canada has chosen a tightly regulated path for NHP. Its NHP regulations are very comprehensive and complex. This may be a deterrent for potential foreign suppliers and may create an export focus for domestic producers. The new NHP regulations in Canada have not been in place long enough to judge their effectiveness and for all the possible areas of conflict to become apparent. In contrast, the US regulations under DSHEA are more permissive and are an attractive and logical market of choice for many manufacturers of NHP. However, there is a push in the US to impose additional regulations pertaining to dietary supplements. As of yet, the EU cannot be treated as a single market and is therefore complicated and laden with intensive market specific regulatory related information costs for firms to ensure that a product can comply with regulations on a country-by-country basis. There are industry efforts to foster harmonization of the regulatory framework for NHP between the majors markets, but as with most attempts at harmonization, it is hampered by differing views on the correct

balance - allowing consumers to access NHP and the need to protect consumers' interests. Canada may have created a "first mover" advantage by setting a high regulatory standard, but these standards may be nearly impossible for less technically capable countries to meet.

There are many different reasons for the growing interest in regulating NHP. Firstly, safety and efficacy are areas where regulations will have an impact. In addition, there are questions concerning information and labelling when examining NHP. There is potentially a situation of incomplete information when neither the manufacturer nor the consumers can be sure whether the product will live up to its claims. Increased information may be the intent of the new NHP regulations in Canada that are taking a more scientifically intensive approach to claims and NHP. In the US, the FDA is becoming more involved by trying to further the implementation of the DSHEA act that governs dietary supplements.

Within Canada, some products may have to undergo clinical trials similar to that of pharmaceuticals and will have greater proof to support the claims attached to the product. It may be possible that stricter rules on efficacy of NHP may give Canadian producers an advantage when marketing in foreign markets. However, varying foreign regulations on NHP claims may restrict the scientifically proven Canadian products from making stronger health claims than similar domestic products. A major issue that will affect trade in these products is the difference between how Canada and the US have decided to define and regulate like products. The major difference is that in Canada NHP is a sub category of drugs, while in the US they are considered a sub category of food. This difference may have unforeseen effect for firms participating in trade.

When implementing these regulations, countries are inadvertently creating technical barriers to trade. This will affect the trade of NHP. It can be difficult to examine and quantify technical barriers to trade, as they are not transparent and require an understanding of how the regulations operate and their intent. As regulations become more complicated, so does the process of examining the effect on trade, and this will be central to the thesis. The next chapter will review literature on the analysis of technical barriers to trade.

Chapter 3: Literature Review

3.1 Introduction

In the past, reducing barriers to international trade has been focused on tariff reduction. Through trade negotiations at the General Agreement on Tariffs and Trade (GATT) and subsequently the World Trade Organization (WTO), as well as in regional trade organizations and bilaterally, countries have been relatively successful at tariff reduction to facilitate trade. Tariffs on OECD imports of manufactured goods, which account for two-thirds of world trade, average only 3.8 percent, with duty free treatment applying to a full two-fifths of these trade flows (Baldwin 2001). With this success, a new focus has arisen centred on non-tariff barriers that can inhibit trade and be just as, if not more, trade restricting than their tariff counterparts. This is by no means a new realization. Baldwin (1970, p.2) described the situation as follows: "The lowering of tariffs has, in effect, been like draining a swamp. The lower water level has revealed all the snags and stumps of non-tariff barriers that still have to be cleared away." He believes that over the past 30 years we have witnessed the swamp draining, but the stumps have started to grow through three decades of ever tighter regulations on goods, most of which were adopted for purely domestic policy aims but, in the process, have escalated regulatory protection in international trade (Baldwin 2001). It is interesting to note that OECD data cited by Lawrence and Bradford (2003) revealed that among a group of seven advanced industrial economies[5], the gaps between the highest and lowest average prices are substantial.

Ferrantino (2003) believes that the benefits of international trade, which are supposed to come largely from providing consumers with the benefits of cheap goods in distant locations, are nowhere near being fully realized. It would be a mistake to entirely attribute price differences to non-tariff policies but liberalizing non-tariff barriers could play a major role in changing trade patterns and moving toward price equalization. The current danger within the international trading system is that as industries lose the protection once provided by tariffs, governments will use non-tariff measures to continue or expand protection. The effect of the increased use of non-tariff barriers may be more damaging than tariffs as these measures tend to be less transparent and because it is more

[5] Australia, Belgium, Canada, Germany, Japan, the United Kingdom, and the United States.

difficult to distinguish between legitimate or protectionist measures. It is important to note that domestic regulations of many types can inhibit international trade and is open to abuses in regulatory design and administration (Gaisford and Kerr 2001).

Among non-tariff, barriers there is a particular subset of barriers, - standards and regulations - that are becoming increasingly contentious regarding their effect on international commercial activities. Both developed and developing countries have expressed concern that their exporters find it ever more difficult to comply with regulations and safety standards set by importing nations (Maskus and Wilson 2001). These types of barriers come under the category of technical barriers to trade (TBT). Technical trade barriers are measures that sometimes restrict imports to prevent entry into the market of products that fail to meet health, quality, safety, compatibility, or environmental standards of importing countries (Roberts 1998). Technical barriers to trade are the result of norms (regulations and standards) that control the sale of goods in a particular market by specifying required product characteristics or production processes (Baldwin 2001). Within the category of TBT there exists a subset of barriers entitled sanitary and phytosanitary measures (SPS) which are measures adopted to protect human, animal, or plant life and health. Thus, for members of the WTO, technical barriers to trade are administratively divided into those that fall under the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures and those, which are governed by its Agreement on Technical Barriers to Trade. Thus, knowing the objective of a measure is critical to determine which disciplines are relevant. An example helps to illustrate the difference: a measure, which prescribes the use of an additive, might be adopted as a safeguard to human health (an SPS measure) or to ensure the compositional integrity of a product[6] (a TBT measure) (Roberts 1998).

There is an increasing realization among economists that dealing effectively with the issues of technical barriers to trade, both at the theoretical and applied levels, is difficult. Many complications arise when attempting the difficult task of analyzing technical barriers to trade. As yet, little is known about the trade impacts of TBTs and

[6] Ensuring compositional integrity of a product could be additives used to prevent the product from becoming denatured and no longer effective. Thus the additive is not for human health as the product without it would not be a health threat but it is a technical measure to ensure that the product is working effectively.

empirical analysis is rare. Economists cannot say with confidence whether such restrictions tend to reduce trade by virtue of raising compliance costs or expand trade by increasing consumer confidence in the safety and quality of imported goods (Maskus and Wilson 2001). Despite the lack of analysis, the Members of the WTO have set out rights and obligations of members regarding TBT and SPS measures. This chapter will provide an overview of the agreements within the WTO that regulate both TBT and SPS measures.[7] In addition, the strengths and weaknesses of these agreements will be discussed. It is important to take an in-depth look at different approaches taken in the past to analyze technical barriers to trade, both empirical and theoretical. This chapter gives an overview of approaches taken in the past. This helps to shed light on the difficulties and obstacles that arise when attempting an analysis of the effects of technical barriers.

3.2 Technical Barriers to Trade and the TBT Agreement

Technical barriers to trade result from regulations and standards that control the sales of goods within a market. The sheer volume and technical complexity of these regulations and standards makes it difficult to speak of TBT as a whole. Thus, it is helpful to define two distinct aspects of their control: (1) content of the norm, and (2) testing procedures necessary to demonstrate that a product complies with the norm (Baldwin 2001). Technical regulations and standards set out specific characteristics of a product - such as size, shape, design, function and performance, or the way it is labelled or packaged before it is put on sale (Mattson *et al*. 2004).

The provisions of the GATT 1947[8] contained only a general reference to technical regulations and standards. A GATT working group was set up to evaluate the impact of

[7] The foundations of the WTO are the central GATT 1994 agreement and the 15 annexed agreements. All these agreements together establish rules and disciplines for international trade affecting a wide range of economic activity. The most relevant to understanding the regulations governing Natural Health Products will be the Agreement on Technical Barriers to Trade (TBT Agreement) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement).

[8] GATT 1947 was the set of original rules that governed trade from January 1, 1948 until The WTO supplanted the GATT in January 1995. These rules only governed trade of goods and were subject to numerous changes over the many years they were in place. GATT 1947 is longer in place, having been replaced by the GATT 1994.
Information on GATT 1947 is available at www.wto.org

non-tariff barriers including technical barriers to international trade. The GATT Contracting parties signed a plurilateral agreement[9], called the Standards Code[10]. The GATT Standards Code laid down the rules for preparation, adoption, and application of technical regulations, standards and conformity assessment procedures. In 1994, the TBT agreement, which has strengthened and clarified the provisions of the Standards Code, was signed as an integral part of the new WTO Agreement. In the process, the regulation of technical barriers to trade moved from having a voluntary plurilateral membership to being part of the commitments of all (multilateral) members of the WTO.

The principles of the TBT agreement are as follows: (1) avoidance of unnecessary obstacles to trade, (2) non-discrimination and national treatment, (3) harmonization, (4) equivalence of technical regulations, (5) mutual recognition of conformity assessment procedures, and (6) transparency. For example, members shall accord equal treatments for other members on technical regulations, standards and conformity assessment procedures to all products, including industrial and agricultural products. The agreement also requires that members use relevant international standards or use relevant parts of them, if they exist, as a basis for their technical regulations, standards and conformity assessment procedures (WTO 1994a). [11] Specifically, Article 2.2 of the TBT agreement specifies that legitimate objectives of a technical regulation include: national security requirements, prevention of deceptive practices, and the protection of human health or safety, protection of animal and plant life or health or the environment (WTO 1994a)[12]. In general, it can be said that the Agreement deals with two broad categories of rules: technical regulations and standards. The first category contains mandatory, binding rules,

[9] For the most part, all WTO members subscribe to all WTO agreements. However, in the past, particularly in the Tokyo Round there were "plurilateral agreements", which had a narrower group of signatories. Most plurilateral agreements became multilateral obligations (i.e. obligations for all WTO members) when the World Trade Organization was established in 1995. After the Uruguay Round, however, there remained four agreements, which were originally negotiated in the Tokyo Round. The four were: travel in civil aircraft, government procurement, dairy products and bovine meat. The bovine and dairy agreements were terminated in 1997.

[10] After years of negotiations (1973-1979) at the end of the Tokyo Round, 32 GATT Contracting Parties signed the plurilateral Agreement on Technical Barriers to Trade (TBT).

[11] The TBT promotes the adoption of international standards such as the International Organization for Standardization (ISO).

while the latter category contains rules created by institutions other than the government. Standards are not binding *per se*, but very often become dominant in a particular industry and thus rise to the level of being *de facto* binding, simply because an economic operator cannot meaningfully do business without adhering to these standards.

One of the major areas where the TBT agreement has an impact on the consumer's right to be informed is labelling and the language of the label. Beyond the normal label information such as ingredients and nutritional information, this aspect of the agreement may be extended to provide information on how a product was produced (Gaisford and Kerr 2001). It is often the case that a label is the most efficient method to provide consumers with information on credence attributes. For example a consumer cannot know for sure by looking at an apple whether it was organically grown but a label can help express that the apple is organic – it turns a credence attribute into a search attribute[13].

It is reasonable to allow member countries to legislate domestic regulations and policies as provided for in the TBT agreement. However, it can be very difficult to distinguish between legitimate regulations and those whose purpose is protectionist. The way domestic regulations are constituted can be used as a means of protection for domestic producers and can become technical barriers in a number of ways. First, they may add directly to the cost of production (Gaisford and Kerr 2001). This can be attributed to numerous effects such as ongoing testing costs or higher marginal production costs that stem from small scale production – that is, being prevented from achieving economies of scale in production (Baldwin 2001). The lower scale of productions may be caused by such annoyances as line breaks to change label settings that comply with different market destinations. Technical barriers can also affect trade

[12] Regulations that apply to human health, animal health and plant health will be also subject to the SPS agreement specifically designed to handle these cases.

[13] In the case of uncertainty there are three quality attribute to consider- search, experience and credence attributes. Search attributes are known if a consumer conducts a pre-purchase inspection and the cost of inspection is negligible. An example would be in a pair of trousers that can be examined and tried on in the store before purchase. This is a case of full information. Thus, search attributes are known before consumption. Experience attributes become known post consumption and effect repeat purchases. That is only after consuming a steak can a consumer judge its tenderness. Finally, credence attributes are characteristics of a nature that a consumer cannot judge the quality even after consumption. The classic example of this is an organic carrot as it is impossible to judge how a carrot was produced by consuming it. Credence attributes leave the consumer with incomplete information and vulnerable to exploitation.

through one-time up front information costs involved with learning the regulations pertaining to a given market and bringing the product into conformity. This may not seem significant, but when a single firm has many export destinations this cost can be sizeable. These costs could also deter the entry of the firm into many market destinations if, to meet product conformity; facilities must be tailored to meet the requirement of one export market.[14] Another type of cost increase that may act as a barrier is providing proof for claims on labels. Some markets in less developed countries may lack the institutions available in the developed world that certify claims. It is often the case that many domestic regulations depend on testing and certification to ensure the product quality and claims. Without institutions to fulfill this need, it will leave less developed nations at a disadvantage and represent a substantial trade barrier.

3.3 Sanitary and Phytosanitary Measures

Issues surrounding food safety and other aspects of a population's health and security are complex. Protecting the health and safety of citizens is seen as a fundamental role for governments and they guard this aspect of their sovereignty carefully (Gaisford and Kerr 2001). From the point of view of policy makers, there are few events more politically damaging than a breakdown in the food safety system. Numerous examples demonstrate this point. Perhaps the crisis caused by the occurrence of 'mad cow disease' in North America in 2003 illustrates that governments will act swiftly and forcefully in the face of a food safety crisis. The WTO recognizes this role of government but also understands that SPS measures can also be used for nefarious purposes through the imposition of barriers to market access. As a result, during the Uruguay Round a new agreement on the Application of Sanitary and Phytosanitary Measures (SPS) was negotiated. This agreement is to oversee measures that are adopted to protect human, animal or plant life and health. Thus, SPS measures are a subset of the larger class of TBT that cover health-related and safety related aspects of products. They are particularly distinguished by their agricultural and food safety focus (Hooker and Caswell 1999). The SPS agreement can be viewed as an attempt to discipline the "seemingly never-ending demand for further regulation of the food system to protect

[14] Both fixed and marginal costs are affected by technical measures.

public health" (Henson and Heasman 1998). The challenge in negotiating this agreement was to strike the proper balance between rules that allow protection for human, animal, and plant health, while deterring regulatory protectionism. It is commonly accepted that domestic interests can capture regulatory processes with vested interests limiting competition (Roberts and Orden 1997). In the 1994 WTO agreement the historical progression of successive rounds of negotiations was continued and rules disciplining the use of technical restrictions on imports were considerably strengthened (Roessler 1996).

The negotiation of the SPS Agreement during the Uruguay Round was motivated by inadequacy of the provisions included in the previous rounds to discipline the use of SPS measures. According to Roberts (1998), although language in GATT and the Standards Code documents pronounced that measures could not be "applied in a manner which would constitute… a disguised restriction on international trade" or "create unnecessary obstacles to trade", the consensus was that the GATT and the Standards Code had failed to curtail the disruption of trade caused by technical restrictions. In the view of some members, one of the more visible failures of the pre-Uruguay rounds was the unresolved dispute betweens the U.S. and the European Union (EU) over the EU's ban on imports of hormone-treated beef during the 1980s (Stanton 1997).[15] Roberts (1998) identifies three flaws in the pre-Uruguay Round legal infrastructure that dulled the effectiveness of disciplines on SPS measures and other technical barriers: (1) the lack of a single integrated rule system (sometimes referred to as "GATT à la carte" which is manifest in plurilateral agreements); (2) the GATT's consensus-based dispute settlement process; and (3) the arguable exemption of production and process standards from many of the disciplines of the Standard Code. In addition, prior to the Uruguay Round, not all signatories of the previous GATT agreement had signed the Standard Code, effectively prohibiting some standards-related disputes from being brought before a GATT panel for

[15] The EU's ban on importation of beef produced using growth hormones is a highly discussed case. The EU decided to ban the use of hormones for domestic beef production and, to protect the integrity of their market, banned imports of beef products that used hormones during production. The hormones had been deemed safe for use in production in major beef producing countries, including the US and Canada. The US claimed the EU measure was unscientific and, along with Canada, took the case to the WTO dispute settlement system. The WTO found in favour of the US and Canada. The result is complex but the basic element that decided the case was the EU did not provide sufficient scientific evidence that animals produced using hormones represented a health risk, and the EU was applying a risk standard that was contradictory with other risk standards applied in the EU (Roberts, 1998).

resolution.[16] However, even if two countries had signed the Standards Code, the consensus based dispute settlement process effectively allowed either country to block a request to convene a panel or block adoption of a panel report (Roberts 1998).

At the conclusion of the Uruguay Round negotiations, all members became parties to the WTO's single integrated "rules" system, which included both the SPS and TBT Agreements as well as GATT 1994. Another major step was the new Dispute Settlement Understanding (DSU), where it is no longer possible for a single country to block a dispute ruling or a request for a panel. The new TBT agreement stipulates legally binding rules for "related processes and production methods" and the SPS Agreement imposes several new substantive and procedural controls for a wide variety of health and environmental measures (Roberts 1998).

The current SPS agreement consists of provisions aimed at preventing abuse of member rights to use SPS measures. Firstly, it encourages countries to base their SPS measures on existing international standards, guidelines and recommendations. The SPS agreement recognized certain international standard setting bodies (*Codex Alimentarius*, the International Organization of Epizootics, and the International Plant Protection Convention) as providing benchmarks or minimum standards, which would assure compliance with the Agreement. However, it does provide countries with an alternative to harmonized standards. Countries may introduce SPS measures that result in a higher level of protection than provided by those based on international standards if there is scientific justification for the departure, or if the country determines on the basis of an appropriate risk assessment, that a higher level would be appropriate (Oyejide *et al*. 2003). That is, the SPS agreement creates a regulatory floor but not a ceiling (Isaac, 2004). The SPS agreement seeks to encourage international harmonization by persuading importing countries to accept the SPS measures of exporting countries as equivalents, if they provide the same level of surety. This is often referred to as mutual recognition and can be found in article 4.1 of the SPS agreement. Isaac (2004) showed that, provided that the national treatment provision is met, the agreement is silent on limits on regulations substantially above those of other members, and thus mutual recognition is unlikely. A

similarly important provision of the SPS agreement arises when deciding among alternative SPS measures that provide the same level of food safety or animal and plant health. Countries are encouraged to apply those standards that least restrict trade, provided they are technically feasible.[17]

Another principal provision of the SPS agreement is that members must ensure SPS measures are based on scientific principles and not maintained without sufficient scientific evidence (Article 2, SPS Agreement) (WTO 1994b). This is by no means as simple as it sounds. The WTO's goal was to de-politicize decision making in the complex area of human, animal and plant health by relying on science. On the surface, science seems to be a clear-cut subject: mixing an acid with a base causes a reaction. When dealing with health and more complex science, however, scientific uncertainty exists. The SPS agreement has assumed that a scientific consensus can be reached and that scientists are making decisions independent of (protectionist) political influences (Kerr 2003). Other assumptions that affect the ability to rely on science are whether there is sufficient information to formulate a hypothesis and whether there is a willingness among the population to defer to the judgment of scientific experts. Kerr (2003) concludes that scientific consensus must be reached on three issues: (1) the scientific basis of the need for a trade restriction; (2) the risk arising from not imposing a trade restriction, and (3) when sufficient science has been done. Relying on science may have seemed like a convenient approach but it is not surprising that grey areas have come to light within the science-based system.

Assessment of risk is another controversial issue within the SPS agreement. There is ambiguity pertaining to the role of socio-economic considerations in risk assessment (Isaac 2004). The agreement permits members to establish SPS measures based on scientific assessment and other broader ways of assessing risk. By default, most SPS risk assessments are not quantitative predictions of the expected level of damaging effects but rather binary assessments of whether a particular level of a stressor is safe or unsafe (Powell 1997).

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[16] Members were permitted to select which Agreement they wished to sign and this was part of GATT à la carte. This was seen as impairing the dispute settlement mechanism.
[17] Agreement on Sanitary and Phytosanitary Measures, Article 5.4.

The Hormone dispute between the EU, US and Canada is often citied as an example where the SPS agreement served its purpose. The United States and Canada argued that the EU ban on imports of beef produced using growth hormones violated disciplines found in Article 2 (Basic Rights and Obligations), Article 3 (Harmonization) and Article 5 (assessment of Risk and Determination of the appropriate level of Sanitary and Phytosanitary Protections) of the SPS Agreement. The WTO Panel that heard the dispute found that the EU ban was inconsistent with four provisions in the SPS agreement, and recommended that the EU bring its measures into conformity with its obligations under the agreement. The case was complex but the EU maintained that the ban afforded a higher level of protection than provided by the international standards, a right protected by the SPS agreement. Throughout the proceedings, the US and Canada had drawn attention to the possible economic motives behind the ban. It is significant to note that the EU invoked the "precautionary principle" at several points in its defence of the ban.[18] This long-standing dispute has yet to draw to a close. The EU chose to accept retaliation and maintain the ban rather than pay compensation.

3.4 Analyzing Technical Barriers to Trade

One of the main focuses of recent work in the area of TBT is testing numerous methodologies to model and quantify the effect of barriers. The difficulty lies in the heterogeneous nature of these types of barriers, thus making it impossible to apply a unifying methodology. The quantification of the economic effects of SPS measures and technical regulations has been identified as an important step in the regulatory reform process that OECD countries have been involved in since 1997 (Beghin and Bureau 2001). This type of analysis will help inform governments of the costs of their domestic policies and provide the tools necessary to define more efficient regulations (Antle 1995). It is very important to address the effect of technical regulations and SPS measures on the developing world. Several sectoral studies have suggested that technical regulations are a considerable obstacle in developing countries for agricultural and food exports

[18] The precautionary principle is a notion which supports taking protective action before there is complete scientific proof of risk; that is, the action should not be delayed simply because full scientific information is lacking.

(Beghin and Bureau 2001). Several authors have conducted surveys focusing on policy relevant issues pertaining to the SPS (OECD 1999a; Orden and Roberts 1997).

When attempting an analysis, there is an important distinction between these types of barriers and other traditional barriers such as, tariffs. Unlike other barriers, SPS measures and technical regulations have the potential to increase welfare. As Kramer (1998) points out, SPS measures have gained such a secure and problematic position as non-tariff barriers to trade, precisely because of their ambivalent and non-transparent nature. However, they are one of the few types of trade barriers that have a potential benefit to consumers. Benefits can include increased confidence in the safety of imported products and greater access to information through labelling. There is no simple answer to the analysis of technical barriers, and almost all of the literature agrees that they are a difficult conceptual and empirical topic. It may be some time before key questions about optimal policies are resolved (Roberts *et al.* 1999).

There is a distinct line drawn between models that rely on the measurement of trade impacts only (such as methods based on price-wedge estimations, surveys and gravity model[19] and other methods that are grounded in welfare economics and measure non-tariff barriers through a larger range of effects than trade alone (such as methods based on comparative statistics, cost-benefit analysis and general equilibrium). Welfare–based approaches are believed to be superior as they capture a larger range of effects (they account for positive externalities of a regulation) (Beghin and Bureau 2001). However, this is not to say that the impact on the volume of trade for countries is not an important focus. Examining the various approaches that currently exist will help to reveal the most appropriate method depending on the goals and limitations of a particular case.

[19] A gravity model is a considered a spatial interaction model based on Newton's "Law of Universal Gravitation". In 1962 Jan Tinbergen proposed that roughly the same functional form of the Newton's Gravity Model could be applied to international trade flows. It has since been applied to a wide variety of interaction including migration, tourism, and foreign direct investment. The basic principles of a gravity model are explained by Head (2000).

3.4.1 Price Wedge Method

This technique assumes that a barrier can be gauged in terms of its impact on the domestic price in comparison to a reference price. This method can also be thought of as a tariff equivalent. Operationalizing the use of this method is seldom easy and it is conceptually orientated to measuring trade impacts. This method can be used in combination with a partial or general equilibrium model that could focus on welfare effects. This method relies on estimating a tariff equivalent by calculating the price wedge between the imported goods and the comparable product in the domestic market. The correct measure would be to compare the price that would prevail without the barrier to the price that would prevail domestically in the presence of the barrier if the price paid to suppliers remained unchanged (Deardoff and Stern 1997). However, these prices are usually unobservable, and actual measures focus on a comparison of domestic and foreign prices in the presence of the barriers.

Several studies have used this method. Campbell and Gossette (1994) used such a method for a large number of sectors. The U.S. International Trade Commission (USITC) uses this method on regular basis. Calvin and Krissoff (1998) estimated tariff rate equivalents of the technical regulations in the apple sector. They compared landed prices including freight and insurance costs of U.S. apples in a foreign country with wholesale prices in the foreign market. They assumed the price gap consists of the tariff and the technical barriers tariff rate equivalent. They focused as much as possible on the price of like apples (same variety, grade and size) during the same time and at a similar place in the marketing chain. Their study led to the conclusion that the price-wedge method can provide useful estimates of the tariff equivalent of technical barriers but other authors have been pessimistic about the practical validity of the method (Beghin and Bureau 2001). The price wedge method, as with any method, is not without its flaws. Using this method it may be possible to quantify the effect of a set of technical barriers on a given market but rarely can it identify what the barriers are precisely. In addition, this method relies heavily on the assumption that imported goods are perfect substitutes for domestic goods, which may not always be the case. The problem identified with this method is the practical limitations that exist (Beghin and Bureau 2001; European Commission 2001). Data are often too aggregated to reflect differences in the quality of the imported goods; a

basic requirement for this type of study. Due to data limitations, it is believed that this method can be applied to only a limited number of cases in which the products are standardized.

3.4.2 Frequency Method

The frequency method, also referred to as the inventory-based approach, has the potential to be used in either a quantitative and/or qualitative way to assess the direction and magnitude of domestic regulations as trade barriers. It is possible to construct a variety of measures that can indicate the frequency of regulations. This is possible through the use of various forms of data ranging from the number of regulations that exist to construct proxy variables, to the frequency of detentions at a given border, and the number of complaints from the industry on discriminatory practices. Using this type of data, frequency measures may include: (1) the number of restrictions; (2) frequency ratios (the number of product categories subject to technical barriers as a percentage of the total number of product categories in the classification); and (3) the import coverage ratio, constructed as the value of imports of each commodity subject to a technical barrier, as a percentage of imports in the corresponding product category (Beghin and Bureau 2001). Other ratios can be constructed but are subject to tenuous assumptions (Beghin and Bureau 2001). Data on detentions at the border is also a relevant source of information for the frequency method.

The frequency method has recently gained momentum and data is becoming more readily available (Mattson *et al.* 2004). Bora (2003) uses the frequency measures to demonstrate that, worldwide, non-tariff measures are more prevalent for agricultural and fishery products than for manufacturing products. Swann, Temple and Shurmer (1996) used counts of voluntary national and international standards recognized by the UK and Germany in an econometric study where the authors regressed British net exports, exports and imports over the period 1985-1991 on variables including the frequency indicators of standards. Moenius (1999) also used the frequency method as an input in an econometric approach. Both these studies used counts of binding standards in a given industry as a measure of stringency of standards. Otsuki, Wilson and Sewadeh (2000) went further and employed a direct measure of the severity of food safety standards

expressed in maximum allowable contamination. Data on border detentions have been used for other studies rather than the number of regulations. For instance, Lux and Henson (2000) studied border detentions in the United States and performed an analysis to assess how EU exports could be harmed by import procedures and border inspections. Their analysis showed that problems tend to be sector specific, and in particular the dairy sector tended to be greatly affected. Henson et al. (2000) have studied sanitary and technical barriers by focusing on import rejections by the United States of products coming from Africa, Asia, and Latin America.

The frequency method does have some drawbacks. The number of standards or the number of pages of standards can be a poor proxy for the trade restrictiveness of the whole regulatory regime. There has been no evidence that there is a clear correlation between the number of standards and the effect on trade. That is to say, the frequency method cannot provide a quantification of the effect of a regulation on trade, but it may be an indication of sectors and countries where regulations are more likely to be found and, thus, possibly problematic. Their use as a proxy variable in econometric models (i.e. gravity models) is a method that deserves more exploration. Gravity models rely on Newton's "law of Universal Gravitation" and have preformed relatively well but have lacked theoretical foundations in the past (Beghin and Bureau 2001). Gravity models examine the residuals in an economic regression of trade flows on the various determinants of trade. An interesting application of this model is to estimate how much trade is foregone because of "border" effects only. A study by Moenius (1999) is one of the most direct. It attempts to measure the trade impact of technical barriers to trade (TBT) using a gravity-based analysis of bilateral trade volumes. He focused on the trade impact of standards (voluntary norms) rather than on regulations due to data limitations.

3.4.3 Survey-Based Approaches

Surveys are a useful method of providing information (such as ranking the importance of the measures on a scale) to analyze the effects of technical barriers. Surveys have shown that important barriers include labelling, quality assurance, quarantine, lack of transparency, discrimination in the application of standards and excessive documentation. Slow customs clearance, lack of predictability, arbitrary

enforcement of rules and lack of harmonization and simplification of clearance procedures are also important (Bora 2003). Many different organizations such as the U.S. Trade Commission, the European Commission and the OECD all conduct surveys to provide information on regulations and for input into econometric models. For example, the OECD (1999b) conducted a survey of 55 firms in three sectors in the U.S., Japan, The United Kingdom, and Germany on export hindrances. Likewise, the United States Department of Agriculture (USDA) conducted a survey to provide a cross-sectional accounting of technical barriers in U.S. agricultural exports. This survey led to several studies that attempted to quantify the trade impact of questionable technical barriers (Roberts and DeRemer 1997; Thornsbury *et al.* 1999). Survey based methods are very useful, as it is often the case that other sources of information are lacking. They can also shed light on the important issues regarding technical barriers facing firms. The survey method is able to identify barriers that can be difficult to measure otherwise, such as administrative barriers. However, as with any type of survey, the cost of this method can out weigh its benefits. Firms questioned are likely to be biased if it is perceived that the survey is being conducted for policy purposes. Also it is important to obtain a large enough sample to be representative. This method is best suited to cases where no other information is available.

3.4.4 Analytical Frameworks

One way to assess a technical barrier is to measure the effect on the volume of imports at world prices. More general effects of the technical barrier can be accounted for by assessing the effect on welfare. This can be done by analyzing how a given regulation affects overall equilibrium in the sector or in the economy. Roberts, *et al.* (1999) propose an analytical framework for analyzing technical barriers that summarizes other approaches. This begins by distinguishing three economic effects: (1) the "regulatory protection" effect (the fact that a regulation provides some rents to domestic producers); (2) the "supply shift" effect, this focuses on the effects of imports on the domestic supply and the cost of enforcing compliance; and (3) the "demand shift" effect, which takes into account the possibility that a regulation may provide information and increase consumer demand for the product. Using comparative statics in a partial

equilibrium framework, the authors illustrate the effects of these three components of technical barriers, and in particular the welfare effects.

Compliance with a regulation involves a cost to foreign suppliers, which acts like a trade tax, resulting in a deadweight loss in the importing country, as well as transfers from consumers to producers. As there is no tariff revenue, the welfare loss is potentially greater than with a tariff equivalent. This point suggests that the method of applying tariff equivalents is only appropriate for measuring trade flow and not welfare. The supply shift component of a technical barrier captures both the effects of the imports on the domestic supply and the potentially beneficial impact of the regulation. Other features can be added to this method, in particular the cost of regulations affects small and large firms differently, and regulations modify the structure of the competition or the size of the relative market, affecting mark-ups and rents (Neven 2000; Fisher and Serra 2000). It is also possible to account for the fact that standards can impose a fixed cost of entry that affects competition and may lead to multiple equilibriums, an effect well known in the literature on industrial organization (Granslandt and Markusen 2000). It is also possible to account for the discriminatory nature of regulations towards imported products through a relative shift in the excess supply curve of the exporting country and excess demand curves in the importing country (Makus, *et al.* 2001).

The framework allows for the fact that regulations can affect domestic demand. It is also the case that there may be shifts in supply. This opens the possibility that the regulation could be welfare enhancing and offset the "regulatory protectionist" effect. Casella (1996) and Fisher and Serra (2000) explicitly account for the public good effect of regulations. In addition, it is possible to account for the potential reduction in transaction costs induced by some regulations. The framework by Roberts, *et al.* (1999) can be extended to the multimarket case, in which it is possible to include extra effects of regulations (Beghin and Bureau 2001). This could include the fact that standards may in some cases raise the elasticity of substitution in demand and bring network externalities, and even economies of scale, by permitting producers to provide a limited range of product characteristics or processes, or other forms of transaction facilitation (Harrison, *et al.* 1996; Maskus, *et al.* 2001).

3.5 Conclusion

Technical barriers can be significant barriers to trade. The WTO has been successful at reducing tariffs, which has exposed the numerous non-tariff barriers that impact trade. Technical barriers to trade are perhaps one of the most interesting and complicated types non-tariff trade barriers. Whether a technical barrier put in place for SPS reasons or with other policy goals in mind, the barriers all have the potential to affect trade flows. Regulations are all different and it is impossible to lump them into the same category for analysis. Due to the difficulties with analyzing technical barriers, case studies are often used, but results are limited to the specific sector. Harmonization may have a role to play in the reduction of these types of barriers, but this is by no means an easy task, and in the meantime it is important to inform policy makers on the consequence of regulatory policies.

Agreements to oversee issues of TBT and SPS measures are in place at the WTO. These are a step in the right direction but are not without their flaws. The reliance of the SPS agreement on science has not been as simple as hoped. Without a regulatory ceiling some countries are still left with much more stringent regulatory regimes. The TBT agreement is not black and white, and there exist grey areas, which need to be addressed. As more disputes are brought forward on the basis of violations to both the TBT and SPS agreements, additional information on the effects of regulations on trade flows is needed. There are many approaches that exist for analyzing such impacts. Due to the heterogeneous nature of regulations there is no one unifying method to approach all cases of technical barriers. It is important to examine the case at hand and choose the method most appropriate. The next chapter proposes an analytical framework.

Chapter 4: Analytical Framework

4.1 Introduction

This chapter focuses on the framework that is used to analyse the various cases in the following chapter. It will begin by discussing the importance of classification and different criteria that are proposed for classification. The classification section will end with a matrix of regulatory regimes that will be used to classify the barriers that are relevant to the cases being analyzed. Next is a modelling framework for assessing trade effects of technical trade barriers. The framework is composed of three elements (regulatory protection model, supply-shift model and demand shift model). The chapter ends with concluding remarks.

4.2 Classification

One of the major challenges that economists face when attempting to analyse technical barriers is the specific nature of these policy tools. The nature of technical barriers creates a situation of diversity that can make it difficult to systematically examine technical barriers. Classification is therefore a necessary step in an examination of technical barriers. Many different taxonomy approaches have been developed to provide a theoretical foundation for assessing technical barriers; to guide the specification of economic models used to gauge the trade and welfare effects of these measures; and to provide policy makers and analysts with a framework for discussing and possibly negotiating international guidelines for their use (Roberts, *et al.* 1999). The method of classification used in this thesis follows Roberts, *et al.* (1999) and begins by classifying technical barriers by policy instrument and by scope[20]; the classification provides a framework for evaluating these measures as if they were standard trade barriers (tariffs, import quotas and tariff rate quotas). Technical barriers are then classified by regulatory goal. Insight into the regulatory goal can help provide information and understanding of how the effect of the technical barrier differs from other barriers. Lastly, Roberts, *et al.* (1999) propose a matrix of technical barrier regimes that take into account both regulatory goals and policy choice among instruments.

[20] Scope is used to describe who the measure is applied to. For example, if the scope is universal both domestic and foreign producers must comply with the measures.

4.2.1 Classifying Technical Trade Barriers by Policy Instrument

Governments have a considerable choice from a wide array of policy instruments to correct for market failures. Governments often favour regulatory trade measures, such as import bans and technical specifications, when risks associated with generic products are large, delayed or imperfectly known, and when an efficient legal system is missing[21] (Mahè 1997). Along with political economy factors risk concerns explain governments' extensive recourse to technical barriers in the form of bans, mandatory technical specifications, or information requirements to correct market failures (Roberts, *et al.* 1999) (see table 4.1).

Table 4.1: Classification of technical barriers

By policy instrument

Import bans
Total bans
Partial bans
Technical specifications
Packaging standards
Process standards
Product standards
Information remedies
Labelling requirements
Controls on voluntary claims

Source: Roberts, et al. 1999

Import Bans

The first general category of technical measures is an import ban, which is mostly adopted in situations of high risks or uncertainty that can cause harm and an alternative

measure cannot effectively reduce the risk.[22] This category is further divided into two groups, total bans and partial bans. The total ban is obviously the most restrictive type of technical measure as it completely blocks market access to the product. A total bans is most often used in cases where plant, animal and native species need protection from foreign pests and disease (Roberts, *et al.* 1999). A recent example of a total import ban would be when Bovine Spongiform Encephalopathy (BSE) was detected in Canada. The US, Japanese and a host of other countries borders immediately closed and initially, a total ban was in place on Canadian exports of cattle and beef. These types of bans have also been adopted world wide to protect endangered species (Krissoff, *et al.* 1996). Total bans are barriers that are allowed under the SPS agreement and implementing them would be justifiable within the WTO commitments.

Partial bans differ in that they do not completely restrict the entry of a given product from the exporting country. Partial bans include seasonal and regional bans, which are similar to total bans in that they are most commonly used to protect fauna and flora from pests and disease (Roberts, *et al.* 1999). However, in cases of seasonal and regional bans, more information is usually known about the nature of the pest or disease that permits seasonal and regional allowances. Thus, the targeted ban can effectively reduce the risks to an acceptable level. Roberts, *et al.* (1999) for example, suggest that authorities may implement a seasonal ban for horticultural products that allows for imports for part of the year if they have detailed knowledge about the effects of climatological factors on the biology of an identified pest. Regional bans are based on the idea that a country is not necessarily infected or pest/disease free but that different regions within the country may have different disease and pest statuses. Regional bans are likely to increase as they are included in the WTO Agreement disciplines on SPS measures. The SPS agreement requires that countries consider imports from sub-national areas, which the exporting country claims, are free of pest or disease.[23]

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[21] When citizens find it impossible, costly or slow to prosecute claims related to imported goods under property or product liability law it can be said that there is a lack of an efficient legal system to deal with these concerns.

[22] There are many cases where technology for monitoring and detection cannot distinguish between hazardous and non hazardous products, or effective treatments and eradication programs do not exist, and thus an import ban is necessary.

Technical Specification

The second broad category of policy instrument is that of technical specification. This category is of considerable importance when examining natural health products. This category encompasses requirements that an exporter must meet to gain entry into a foreign market. It is noted that, in principle, any firm in any country willing to allocate resources to meet necessary conditions can export to a target foreign market. In practice, however, some firms may be prevented from doing so because of the absence of satisfactory private or public sector certification services (Roberts, *et al.* 1999). This point is important in the case of natural health products and will be further examined within the application of the framework to the given cases. There is doubt among economists whether technical specification or partial bans are more trade restrictive (Roberts, *et al.* 1990). This is an empirical question where measurement is often difficult or data are not available. It is usually the costly nature of compliance that firms face that causes technical requirements to become restrictive. When foreign standards are strict, and also when standards vary considerably among markets, those costs to firms increase considerably. Technical specifications are subdivided into three types of standards, as seen in table 4.1. Firstly, packaging standards regulate a wide range of container attributes, from safety features to dimensions and biodegradability, which are in place to realize a range of different policy goals.[24]

Process standards (sometime referred to as production methods standards) prescribe the means and method (inputs and/or production technology) that a firm must follow to realize different regulatory targets. This is an interesting area, as the WTO does not allow products to be differentiated by process and production methods unless they change the final product in a way that can be identified by consumers. Lastly, are product standards, which specify the ends (characteristics of the product that can relate to numerous attributes but without specifying how a firm reaches the end product) (Roberts, *et al.* 1999). An example of a product standard in the natural health sector may be that the supplement is free of contamination, a status that could be checked by an importing

[23] Agreement on Sanitary and Phytosanitary Measures, Article 5.2.
[24] These standards can range from safety seals on pharmaceuticals, to requirements for environmental friendly packing standards. To reach certain environmental policy goals, some European countries require biodegradable packaging.

country. Alternatively, a process standard to reach the same regulatory goal could be to institute good manufacturing practices that ensure a low risk of contamination.

Economists usually agree that product standards are a more efficient regulatory tool than their counterpart of process standards. This is because the former allows firms to choose the technology that minimizes their costs to achieve the regulatory goal and the latter does not (Antle 1996). However, MacDonald and Crutchfield (1996) suggest that this is not always the case and sometimes process standards are the more efficient regulatory approach. They remark that Hazard Analysis and Critical Control Point (HACCP) systems, which are flexible process standards to reduce microbial contamination in food, might be superior to a product standard as there are large expenses associated with testing for microbes and the recurring nature of the pathogen hazards.

Information Remedies

The third broad category of technical barrier is that of information remedies. In many cases market failures arise as a result of information failures and, hence, information remedies may be preferred over other measures to correct the inefficiency. There are two basic types of policy instruments in this category: labelling requirements and controls on voluntary industry claims. These are important because, when combined with credible institutions for certification, they can transform experience and credence attributes of a natural health product into a search attribute. This category of government regulation has been viewed as the least burdensome (Roberts, *et al.* 1999). However, when assessing whether a labelling requirement is burdensome one must consider the cost to firms involved in numerous markets that require different labels and the cost of maintaining distinct inventories for each market (Sykes 1995). Recent concerns about labelling have come to the forefront of debate over genetically modified (GM) products. Given there is no evidence that GM products are harmful, labelling might unjustly stigmatize the products and reduce consumer purchases (Roberts, *et al.* 1999).

4.2.2 Classifying Technical Trade Barriers by the Scope of the Measure

The framework proposed suggests that it is important to classify the barriers by scope in addition to policy instrument. Roberts, *et al.* (1999) identify three types of scope:

uniform, border (universal) and border (specific). The first type of scope – uniform - may increase the cost for domestic as well as foreign producers (table 4.2). An example would be a product standard that applied regardless of the source, domestic or foreign, of the product. A uniform measure will increase compliance costs and will shift the aggregate domestic supply curve up/back, as well as affecting foreign excess supply curves. The magnitude of the shift in the excess supply curve will depend on whether the new measure differs substantially from international norms and standards (Roberts, *et al.* 1999).

Table 4.2: Classification of technical barrier by scope

	Uniform	Border (universal)	Border (specific)
Measure directly affects:			
Domestic Production	Yes	No	No
Imports	Yes	Yes	Some

Source: Roberts, et al. 1999

Sometimes these technical measures are applied only to imported goods. This is the universal border group and their legitimate use is limited under WTO agreements (Roberts, *et al.* 1999). Roberts, *et al.* (1999) provide the example of maximum residue levels (MRL) for a particular pesticide that is widely used in countries that export a given product but that is not registered for use in the importing country. The border specific measures are used to manage risks posed by imports from different sources. Within this group of technical barriers, an importing country will have numerous measures, which may range from border inspections to a complete ban, to reduce the risk from a particular product source.

The scope of the measure is important for determining who bears the cost of the regulation. Roberts, Josling and Orden (1999) present four cases that illustrate this effect. They begin with the assumption that the action of one specific country will have little or no effect on the world market (small country assumption). In the first case, one importer imposes a barrier on one exporter; both can avoid the cost by choosing an alternative source (importer) or alternative outlet (exporter). When one importer imposes a barrier on all exporters, the importer will bear all of the cost. Alternatively, if all importers target one exporter, the cost will fall solely on the exporter. Lastly, if all importers

impose a regulation on all exporters, the small country assumption will no longer hold and the cost will be shared by exporters and importers as the price received by suppliers falls and the price paid by consumers rises. These barriers may segment international markets in some instances and alter the nature of competition. There is extensive literature on incentives for producers to lobby for socially sub-optimal measures that even raise their own unit costs if such regulations limit competition (Roberts, *et al.* 1999).

4.2.3 Classifying Technical Trade Barriers by Regulatory Goals

This chapter has examined the first two criteria of classification. These two would be sufficient to gauge the effects of a technical barrier. However, changes in domestic demand and supply due to externalities of trade require further classification (Roberts, *et al.* 1999). As a result, technical barriers can also be classified by the regulatory goal by which policy makers justify the measures. This classification shows how and why domestic demand and supply can change as a result of the success or failure of a technical measure (Roberts, *et al.* 1999). This is key to the analysis of technical barriers as this can determine whether a measure is welfare enhancing or decreasing.

Classification by regulatory goal begins with the recognition that there exist three broad societal objectives of technical measures that effect trade: protecting the economic interest of producers, protecting the health and economic interest of consumers, and protecting the environment. These three categories can be further divided into those that are in place to reduce biological and toxicological risks and those that do not but which serve some other public goal (table 4.3).

To begin, commercial animal and plant health protection exists to reduce the risk that producers/processors face from imports that may carry pests and disease that could be detrimental to local production. Compatibility does not reduce a biological risk factor but is sometimes necessary to increase the efficiency of the marketing channel. Compatibility refers to the capacity of a product to function in association with others, such as mandatory dimensions for produce containers to ensure compatibility with handling equipment. Food and drug safety measures are in place to reduce involuntary threats that are associated with the consumption of food and drugs. When aiming to enhance consumers' ability to make sensible and informed choices with respect to

experience and credence attribute in the market, it is vital to have measures (labelling) that convey quality attributes. Policy makers recognize the potential for biological hazards and will put in place measures with the goal of protecting the natural environmental from harmful non-indigenous species (HNIS). To finish, conservation measures change the utilization of natural resource stocks.

Table 4.3: Classification of technical barriers by regulatory goal

Societal Interests	Risk-reducing measures	Non-risk reducing measures
Producers/Processors	Commercial animal and plant health protection	Compatibility
Consumers	Food/Drug Safety	Quality attributes
Environment	Protection of natural environment from harmful non-indigenous species	Conservation

Source: Roberts, et al. 1999

Roberts, *et al.* (1999) state that this classification highlights some of the relative distinctions in the evaluation of technical trade barriers. They note that commercial animal and plant health protection and compatibility measures could be studied largely with observable market data for prices and quantities of private goods. This could facilitate an evaluation of these categories and would gauge whether losses in consumer surplus caused by restricting trade were offset by the prevention of negative external (infestation of pests or disease) effects of foreign production on domestic production, or the attainment of economies of scale (Roberts, *et al.* 1999). The food/drug safety and quality attributes groups are measures that could cause or prevent demand shifts that could counterbalance the losses (gains) associated with restricting (liberalizing) trade. An evaluation of environmental measures must consider whether the losses from restricting trade exceed the benefits from providing public environmental goods for which prices are rarely available (Roberts, *et al.* 1999).

Risk Reducing Measures

When discussing risk, it is important to consider how one defines risk. This framework relies on the USDA definition of risk, which is, the product of the quantified

likelihood and magnitude of the adverse consequences. It is often the case that regulators will put in place measures to moderate the varied "public risk" associated with imported goods (Roberts, *et al.* 1999). Huber (1986) defined public risks as risks that are centrally produced, generally distributed, often temporally remote, and often outside an individual risk bearer's direct understanding and control. This definition has the implication that public risks are in fact involuntary and can often threaten human health and safety. Regulatory authorities have adopted an array of measures to mitigate different forms of public risk: (1) high probability, low consequence risks (some food additives) and (2) low probability, high-consequence risks (pest infestations) (Roberts, *et al.* 1999). One of the factors that make it most difficult to analyse regulations aimed at reducing risk is the heterogeneous nature of regulations. Roberts, *et al.* (1999) address the source of heterogeneity among countries in risk-reducing measures by attributing them to differences in actual risk factors, the degree and level of uncertainty about the risk factors, and differences in risk tolerance that might reflect variations in, among other things, incomes, experiences and tastes.

It is important in our case to focus on food and drug safety. Under Canadian legislation, natural health products are a sub category of a drug. Like food, drugs are consumed by humans and the measures that regulate them are similar to food safety measures, and thus they are categorized together. Canadian regulations aimed at food and drug safety try to reduce risk from both biological stressors, such as microbial contaminants, in addition to chemical stressors, such as additives, to protect consumers from involuntary risks (Roberts, *et al.* 1999). The demand curves will implicitly reflect risks associated with a given product when health risks are known and public. If formerly unknown or new risks are identified and made public, consumers may adopt private risk reducing strategies that shift or rotate domestic demand curves (Van Ravensway and Hoehn 1996). Consumers will evoke different strategies to reduce personal risk such as product avoidance and brand switching. Roberts, *et al.* (1999) point out that if food/drug safety measures are successful and mitigate public risk, the frequency and magnitude of private risk reduction will be diminished. Successful food and drug safety measures are crucial to averting serious disruption to markets.

Non-Risk Reducing Measures

Technical measures that are non-risk reducing and affect producers, consumers, and the environment are identified in the third column of table 4.4. Firstly, conservation measures are aimed at preserving natural resources. Measures in this category will not have a significant bearing on the natural health product sector but have been a relatively important issue when discussing trade and the environment.

Compatibility is the capacity of products to function in association with others, such as mandatory dimensions for produce containers that ensure compatibility with handling equipment (Roberts, *et al.* 1999). Product incompatibilities that arise from divergent national standards have the potential to increase production costs and reduce variety in the marketplace. Manufacturing different products for different markets may prevent a firm from realizing economies of scale in the production of these products, which may lead some firms to choose to exit markets (Roberts, *et al.* 1999).

Quality attributes, on the other hand, most definitely play a role in the regulations surrounding natural health products. Quality attributes are characteristics of a product other then safety that might enter a consumer utility function (Roberts, *et al.* 1999). Characteristics identified as quality attributes include health benefits (e.g. nutrition, energy), efficacy (e.g. scientific proof), hedonic (e.g. fresh, genuine), and ethical (e.g. free-range) attributes (Roberts, *et al.*1999). Satisfying diverse preferences regarding quality is an important asset of a market because not all consumers are willing to pay the same for particular product attributes (Roberts, *et al.*1999). It is often the case that because it is costly to a fabricate high quality products, that poor-quality products can out compete the high quality products and the market equilibrium may entail production of a suboptimal share of low-quality products (Akerlof 1970). Information regulations and standards lower the transaction costs of obtaining relevant product information to help correct market failures from imperfect information (Roberts, *et al.*1999).

4.3 Matrix of Regulatory Regimes

The three classification criteria consider above (instrument, scope and goal) suggest the multi-dimensional characteristics of technical barriers that make their economic quantification and evaluation particularly time-intensive and complex (Roberts,

*et al.*1999). Thus, Roberts, *et al.* (1999) propose a useful two-dimensional classification system of technical barriers that partition the measures into a set of distinct regulatory regimes taking into account both the goal of the measures and the policy instrument. Each column of the matrix indicates different instruments to achieve the same regulatory goal (table 4.4).

Table 4.4 Matrix of regulatory regimes and examples of measures that affect trade

	Risk reducing measures			Non-Risk reducing Measures		
Regulatory goal/ Policy instrument	Food/Drug Safety	Commercial Animal and Plant health protection	Protection of natural environment	Quality Attributes	Compatibility	Conservation
Import bans						
Total ban	Ban on ingestible product harmful to human health	Ban on imports to exclude pests and disease	Ban on imports that may introduce foreign flora and fauna	Ban on imports of natural health products that are of low efficacy	N/A	Ban on imports that threaten global endangered species
Partial ban	Ban on imports of a individual variety of ingestible product harmful to human health	Regional ban on imports to minimize risk of pests and disease	Seasonal ban on imports to reduce risk of introduction of pests and disease that threaten native flora and fauna	Ban on imports of "inferior" varieties of natural health products	N/A	Seasonal ban on imports that threaten stock of endangered species
Technical Specification						
Process standard	Measures that require specific good manufacturing processes	Required treatment of products to prevent introduction of pests	Ban on imports of bio-engineered products because of risk to native environment	Animal Welfare measures	N/A	Required harvesting techniques for imports of non-renewable resources
Product standard	Measures that specify dose of active ingredient in a natural health product	Threshold levels for presence of disease causing organisms that threaten crops or livestock	Threshold levels for presence of disease causing organisms that threaten natural environment	Measure that regulate size, appearance and other attributes	N/A	Measure that require harvested product to reach a certain size to prevent depletion of natural resources
Packaging standard	Specification of packaging technology that minimizes probability of contamination	Sealed containers requirement to minimize probability of infestation of production areas	Sealed containers requirement for goods to minimize probability of harmful non-indigenous species	Regulations that prohibit misleading fraudulent packaging	Mandatory dimensions for containers	Requirements that packaging material are biodegradable

Table 4.4 con't: Matrix of regulatory regimes and examples of measures that affect trade

	Risk reducing measures			Non-Risk reducing Measures		
Regulatory goal/ Policy instrument	Food/Drug Safety	Commercial Animal and Plant health protection	Protection of natural environment	Quality Attributes	Compatibility	Conservation
Information remedies						
Labelling requirements	Requirements for labels to indicate safe handling and use procedures	Required labelling of individual items to minimize risk of infestation	Required labelling for safe handling of bio-engineered products	Measures that mandate labels to indicate medicinal ingredients or whether contain GM ingredients	N/A	Mandatory eco-labels
Controls on voluntary claims	Measures that govern health claims	N/A	N/A	Measures that govern claims such as organic	N/A	Measure for claims on goods produced with renewable resources

Source: Roberts, *et al.* 1999, some examples have been altered

The classification system proposed by Roberts *et al.* (1999) facilitates an analysis of technical barriers. It can be a time consuming process but due to the nature of technical measures it is essential to fully understand the measure in place and be able to classify it. This approach takes into account both regulatory goals and policy choice among instruments to facilitate a further understanding of how their effects differ from other barriers. Classification is the first step in the framework, and allows for discussion and evaluation of technical measures.

4.4 A Modelling Framework for assessing the trade effects of Technical Trade Barriers

It is generally accepted that trade is affected by regulations. What is unclear is the extent of the effect and how it alters gains from trade. Due to the fact that this is a relatively understudied area, the true significance of regulations and what should be changed to reduce the effects caused by regulations remains to be seen. Regulations indirectly affect trade and it is hard to pinpoint their exact effect but it is safe to state that regulations create addition expenses by means of compliance costs. A firm must devote resources in order to comply with regulations and this in turn increases the firm's costs. It is clear then that the production function is affected by regulation in place for a firm's given product. Likewise it is relatively easy to see that regulations will affect consumption decisions. Additionally, the import demand and export supply curve can also be shifted due to regulatory measures.

The task of studying regulation begins with detailed knowledge of the regulations. The earlier part of this chapter addresses the importance of knowledge in the classification section. When beginning by classification one must understand the measure and its instruments and goals. It is also important to understand the implications of non-compliance, how firms choose to comply and different approaches to complying with the same regulation. The framework proposed by Roberts, *et al.* (1999) is based on a synthesis of the different approaches taken in five papers published since 1996.[25] Each paper is important and emphasizes one aspect of the relevant issues. The

[25] The five papers are summarized in Roberts, *et al.* 1999. The first paper (Krissoff, *et al.* 1997) examines the US apple market and technical barriers in Japan, Korea and Mexico, this piece calculated tariff

trade framework complements the classification of technical measures and is flexible and general enough to be customized to each specific case study in the following chapters. The framework includes three different but combinable components drawn from five of the studies.

The first element is regulatory protection. This is the idea that sometimes regulations will provide rents to the domestic sector. It is rare for a regulation to be purely protective; there is almost always some technical justification for the measures. The second component of the framework developed is a supply-shift element that focuses on the effect of imports on domestic supply and the cost of enforcing compliance at the border (or in the supplying country). This element introduces the rationale for the trade barrier but that does not mean the measure is the most appropriate for the circumstance (Roberts, *et al.*1999). The demand shift element is the third part of the framework. When regulations impart information they may increase (decrease) consumer demand for the product. The information can be related to quality (that an imported good meets a certain standard) or geographic origin. The model covers the scenario where unregulated imports have a negative impact on consumption, if not through actual harm to consumers then by causing consumers to change consumption patterns. In Roberts, *et al.* (1999) the information provided by the regulation causes consumers to increase demand, but in the case of natural health products we would also consider that information could decrease consumer demand. One of the goals of the new natural health product regulations in Canada is to provide reputable claims on the uses and applications of natural health products. It may be the case that as information is imparted, consumers may lose confidence in certain natural health products and decrease their demand.

To summarize the framework presented in this thesis, the first element of regulatory protection is similar to analysis of traditional trade barriers where the measures are assumed to have no other purpose than to protect domestic producers at the expense

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equivalents. The second piece by Sumner and Lee (1997) modeled the import regulations in Asia that affected US vegetables. This paper focused on the different ways that regulations increase costs at different points in the marketing chain. Next, Orden and Romano (1996) developed a model that focused on the effect of imported pests on domestic production costs. The consumer reaction was analyzed in a model of information by Thilmany and Barrett (1997). Lastly, Paarlberg and Lee (1998) addressed foot and mouth disease and trade in beef from countries where the disease is widespread.

of consumers. However, the supply-shift and demand-shift components allow for the regulation to have a beneficial impact (Roberts, *et al.*1999).

The scope of the technical barrier to trade was discussed earlier and is included in the analysis. For each model element, the situation is considered from the viewpoint of the exporter and the importer, taking into account the range over which the measure operates. In the classification section technical measures were distinguished by those that apply to all exporters (exporter-universal) and those that apply only to a certain exporter (exporter-specific). Likewise, measure applied to one importer (importer-specific) and those that are generally applied (importer-universal) need to be differentiated. This step is needed to address the cost of compliance with the import regulation. Table 4.5 illustrates the four possible combinations of scope for the regulations.

Table 4.5 Scope of measures from importer and exporter perspective

	Exporter specific	**Exporter universal**
Importer specific	Either can avoid compliance costs by selling to or buying from other markets. "Potential" rather then actual trade impediment.	Importer bears cost of compliance as the cost becomes built in to selling prices by all exporters
Importer universal	Targeted exporter bears cost of compliance as importers can choose to buy from other sources.	Importers and exporters share the cost of compliance as the world market price adjusts to the cost. Price to buyers goes up and to sellers goes down.

Source: Roberts, et al., 1999

4.4.1 The Regulatory Protection Model

The regulatory protection model is based on the simple small country case where a foreign supplier must comply with a regulation for importation of their goods. Compliance involves a cost and this acts like a tariff on the quantity of trade (unlike a tariff, there will be no tariff revenue). The result of the regulation is the importing country will suffer a loss as they forgo the benefits that arise from the gains of trade. Domestic producers will gain as imports are cut off and consumers pay both for the producer gain and the cost of a useless regulation. It is also the case that consumers pay

indirectly for the distortion in consumption and production decisions (the traditional deadweight loss triangles).

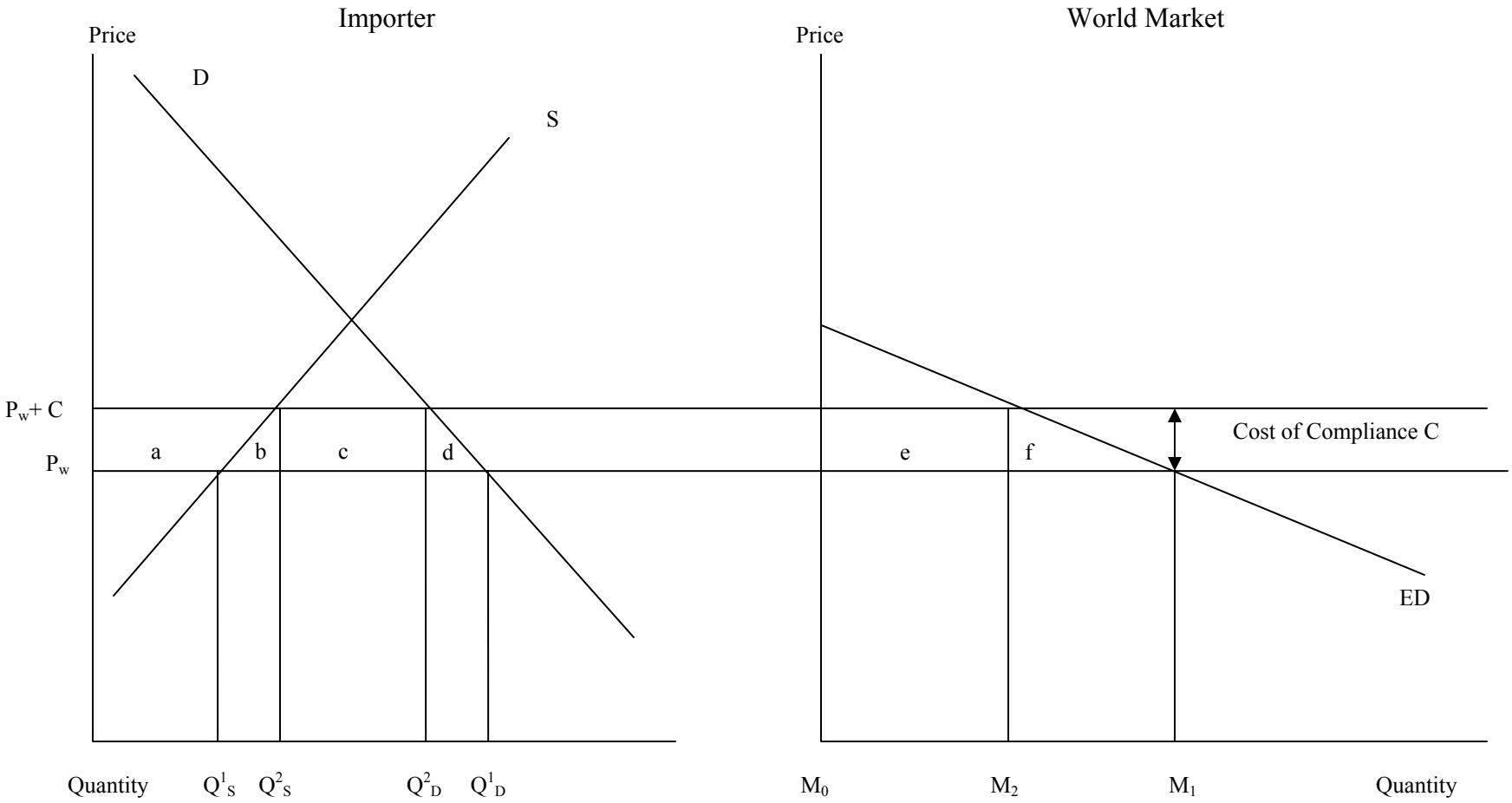

Figure 4.1: Regulatory Protection with no trade Externalities: Importer Perspective
Source: Roberts, et al., 1999

The regulatory protection model that addresses regulations with the goal of giving advantages to domestic producers. There is no real sanitary risk present and the goal of the measure is to raise the costs of foreign producers.

Importer Perspective

It is helpful to analyse this case from the importer perspective as seen in figure 4.1. This model incorporates the following assumptions: (1) the regulation applies to all exporters to the importing country (exporter-universal); (2) only this importer applies the regulation (importer-specific); and (3) the level of imports is small relative to the total world market (small country assumption). Let's begin with the unregulated market. Figure 4.1 shows an initial world price of P_w and at this price quantity demanded is Q^1_d and likewise the quantity supplied is Q^1_s. The difference between Q^1_d and Q^1_s is the quantity imported which is equal to M_1. Once the regulation that is intended to protect domestic producers is adopted and applied to all exporters (universal) by the importing country, the world and import price will increase to P_w+C; this is the original world price plus the costs of compliance. The rise in price will decrease imports to M_2 (this is the difference between Q^2_d and Q^2_s). Consumers will lose surplus area a+b+c+d, while domestic producers will gain area a. The reduction in the gains from trade relative to the free trade equilibrium is represented by the area e+f. If the importing country were to institute a total ban, imports would drop to zero, M_0. The interesting difference between the regulatory protection case and that of a tariff to protect domestic producers is that the welfare loss is not just triangle f but also the rectangular area e, which depends on the level of imports and the height of the compliance cost. Thus, the potential welfare losses from unwarranted regulatory protection exceed those from tariffs (as a tariff will generate revenue of area e). However, area e could be viewed as a transfer to the suppliers of compliance inputs.[26]

[26] Compliance inputs suppliers could be private or public certification institutions that are needed for firms to comply with regulations.

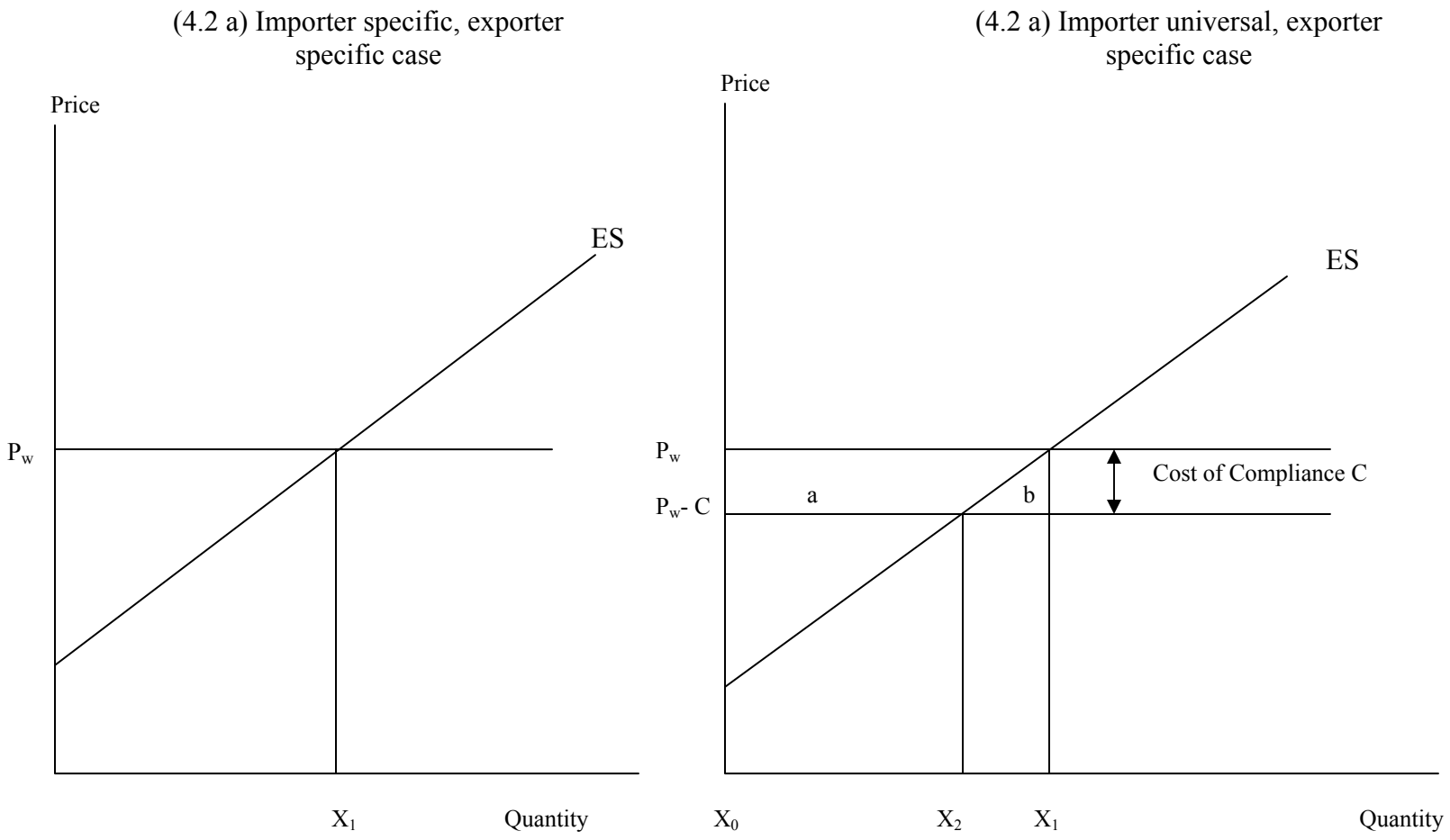

Figure 4.2: Regulatory Protection with no trade externalities: exporter perspective
Source: Roberts, et al. 1999

The easiest way to illustrate the trade effects of regulatory protection policies is to use the concept of a tariff equivalent (Roberts, *et al.*1999). A tariff that would restrict trade to the same extent as the regulatory measure would be the tariff equivalent. In a simple case it can be equal to the cost of compliance. The effect on trade volume of the regulation can be computed with knowledge of supply and demand. It should be remembered that the welfare effect of a technical barrier could be different than a tariff equal to C. That is to say, the tariff equivalent is appropriate for comparing trade volumes not the welfare effects (Roberts, *et al.*1999).

Exporter perspective

If the technical measure is imposed by only one importer, and the importer does not affect the world market price (small country assumption), the exporter in general should not notice the effect of the technical measures (Roberts, *et al.*1999). This would cause the world market to shrink but by an amount too small to be noticed and other importers will buy the displaced goods. The exporter may still experience costs in searching for alternative markets and could incur costs when selling to a sub-optimal market. Bilateral trade flows are modified and individual firms can be disadvantaged, but the aggregate impact is insignificant (fig. 4.2a). Thus, the exporter will continue to export volume X_1 but the destinations will change. However, in the targeted case that is exporter specific (fig. 4.2b), the exporter will bear the compliance cost and will face a lower world price of P_w-C. This will result in exports declining to X_2 and the gains from trade declining by area a. The example from the exporter's perspective reinforces the importance of understanding who the barrier applies to and whether it is universal or specific.

4.4.2 The Supply Shift Model

Many SPS trade barriers are put in place to protect local production from unwanted pests or diseases that might accompany the imports. The supply shift model examines a ban on an importing country's goods to prevent the spread of disease or pests. The effect of a harmful pathogen on domestic production would increase production costs (shifting up the supply curve) or cut production from a part of the country (shift back the

supply curve). The supply shift model is important to address SPS measures that affect raw goods.

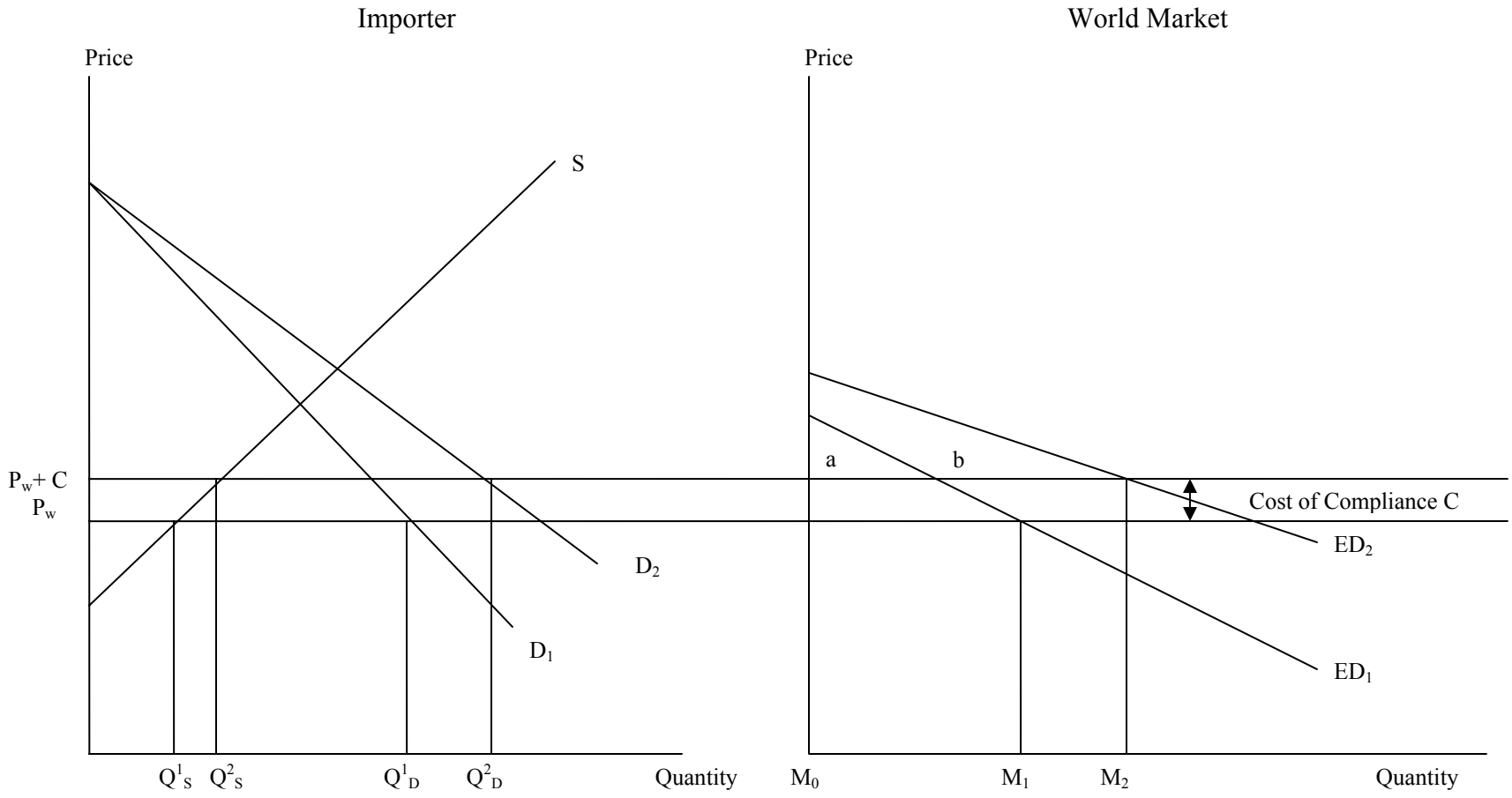

Figure 4.3: Demand Shift Model

Source: Roberts, et al., 1999

The supply shift model is less relevant to natural health products and would only come into play when shipping raw ingredients or perhaps herbs. The situation presented compares a ban versus testing to prevent the spread of the pathogen. Due to its non-applicability to natural health products, this part of the model will not be elaborated upon.[27]

4.4.3 The Demand Shift Model

Regulation can impart information and, in turn, affect domestic demand as consumers benefit from knowing what to expect from the goods as the result of the regulation. In effect, the demand curve is assumed to reflect limited information about foreign supplies. The demand shift model is helpful to analyse quality attributes/mandatory labelling systems. In Figure 4.3, the model begins in the absence of technical regulations. Imports are M_1, while excess (or import) demand is ED_1. The regulations are put in place and due to increased confidence, domestic demand increases to D_2, in addition the domestic price increases to price P_w+C due to compliance cost C. Imports are now at M_2, which can be above or below M_1, depending on whether or not the cost of compliance outweighed the demand shift. In this case the domestic cost of production remains the same. Gains are definitely larger (area a + b) than without the demand shift and with increased compliance costs (area a).

Importer Perspective

If a firm decided not to conform to the regulations this would cause confusions among consumers and it would result in decreased trade. The net welfare effect of the technical trade regulations (versus trade without the regulation) is ambiguous. This is a question of whether the consumers' benefits from the regulation are greater than the cost of providing the information. The assumption in this model is that the information makes

[27] Roberts, *et al.* (1999) were focused on addressing issues for agricultural products where the supply shift model has an important role. This can be seen through the recent example (BSE cattle and beef in Canada) where an import ban was put in place to protect other production regions from the spread of the harmful disease. Since natural health products are processed, the SPS measures that apply are more likely to be product standards to protect human health and not ones that are in place to prevent spread of disease and pests for local producers.

imports more valuable. Later, when evaluating the cases this assumption may be relaxed to consider a case where the information makes the imports less useful. The demand shift model can also be useful for examining consumer "scares". If true demand were at D_2 and unregulated products caused uncertainty, and demand decreased to D_1, then uncertainty spoils the market for both domestic and foreign suppliers. Enforcing the regulation to restore consumers' confidence will cause demand to recover to D_2.

Exporters Perspective

In a case where one small importer (import specific) introduces an information regulation applicable to all exporters (universal), it will not change world price and has no measurable effects on the exporters. The compliance costs are borne by the importing country. However, if all importers impose the regulation on one exporter (importer-universal, exporter-specific) then the exporter will have to bear the costs of compliance. This case the exporter has no choice but to comply as all importers have imposed the regulation.

4.4.4 World Price Effects

The models thus far have relied on the small country assumption that world price was not affected by the action of one country, as it was too small to have an effect. Contrastingly, if a country was a large enough player in the world market and did affect world price, or if all importers uniformly imposed a barrier against all exporters, the small country assumption no longer holds. A terms-of-trade effect, which will affect gains from trade, must be included. The terms-of-trade effect can be thought of as apportioning the cost of compliance. When a single importer faces a single exporter, the cost of compliance becomes a wedge between the price that the importer pays and the price the exporter receives, net of compliance costs (Roberts, *et al.*1999). The ratio of the elasticities of excess supply and excess demand can determine the rate. The less flexible side of the market bears the larger part of the cost.

4.5 Summary

This chapter has highlighted the importance of understanding technical regulations to fully analyze their effect. It is clear from both the classification and modelling sections that an understanding of the details of the barrier, who it affects and how it is applied is central to the question of its trade effect. Case studies will be useful to address these issues and reveal some of the challenges associated with analyzing technical barriers to trade and regulations.

Chapter 5: Case Studies

5.1 Introduction

This chapter provides three cases to examine the regulatory effects facing the natural health product industry. Initially, the chapter gives a detailed overview of the regulations in Canada, the US and the EU. The chapter presents each case and the product being examined and then the regulations it faces in Canada and in one market abroad. Each case is examined according to the framework developed in chapter 4 to examine the trade effects of the regulations.

The first case examines the simple case of a product that faces little regulatory distortion. This case is a flax omega-3 supplement. The next case examines a product that is significantly affected by the regulatory regime and has its own unique characteristic due to its animal tissue origin. This case focuses on elk velvet antler, which is also unique as is origins are rooted in traditional Chinese Medicine. The last case differs again and examines a potential microbial natural health product that is not considered a traditional medicinal product. The probiotic combination product highlights the increased requirements for combination products, which are common in the NHP industry. This case has important subtle differences from the elk velvet antler case. The US and UK are used as comparison regulatory regimes. Finally the conclusion summarizes the cases, the significant differences and the potential trade effect of the regulations.

5.2 Overview of Regulation Requirements

This is brief overview of the main requirements of the regulations that apply to all three cases. It will begin by discussing the two main requirement of the Canadian regulations, the product and site licenses, and enforcement. It is followed by a discussion of the US and the EU.

5.2.1 Canadian Regulations

Product License

The first major component of the NHP regulations is the product license. A product license is a document that sets out the specific product characteristics that the

NHPD has authorized for sale for the natural health product, such as its brand name or names, recommended dose, dosage form, recommended route of administration, source, the use or purpose, quantity, and, when applicable, potency of the medicinal ingredients, as well as the product number (NHPD 2003d). All individuals must obtain a product license before they can sell a natural health product in Canada. A product license application must include sufficient data to allow the NHPD to evaluate the safety, quality and efficacy of the NHP when used under recommended conditions. Product market authorization requires one of the following: (1) reference and adherence to a natural health product monograph (published by the NHPD); (2) submission of evidence of safety, efficacy, and quality of the finished product; (3) or reference to one of the homeopathic pharmacopoeias listed in the Evidence for Homeopathic Medicines Guidance Document (NHPD 2005a). Obtaining a license requires detailed information on the product including medicinal ingredients, source, potency, non-medicinal ingredients and recommended use.

There are five types of applications that may be made for a product license: compendial, traditional claim, non-traditional claim, homeopathic, and transitional drug identification number (DIN) product (NHPD 2005a). A compendial application would be for a product that has one or more medicinal ingredients contained in a monograph for a single or combination of medicinal ingredient(s) in the NHPD *Compendium of monographs*. The compendial application type will cite a monograph in the NHPD's *Compendium of Monographs*. A monograph is a written description of particular elements on an identified topic, for example, aloe has a monograph. The compendium is a compilation of monographs based on natural health product ingredients. The NHPD developed the Compendium of Monographs to ensure a timely and efficient evaluation of the safety and efficacy of many commonly used medicinal ingredients that comprise natural health products. A compendial application will be processed within 60 days if the information on the product license is the same as the information on the monograph. The compendial application is meant to be timely and to reduce the cost of proving many commonly used NHP ingredients. The current compendium contains 30 monographs and there are 70 more nearing completion (NHPD, 2004).

A non-compendial application must be submitted when citing a non-monograph and this application requires additional information. There are two types of claims possible in a non-compendial submission: traditional claim or non-traditional claim. The evidence used in the application differentiates the claims. The traditional claim will refer to traditional use to support the health claim and this product application will be supported by two or more independent traditional references. The non-traditional claim application is for a product that does not fit any other application categories and will require an evidence summary report. The transitional DIN application is to handle products that previous were issued a DIN under the Food and Drug Act. These will not necessarily meet the new NHPD's requirements. Lastly, the homeopathic application is for a product in which all the ingredients are homeopathic.[28] Homeopathic Medicines (HMs) are medicines that are manufactured from or contain as medicinal ingredients only those substances or sources referenced in the *Homeopathic Pharmacopoeia of the United States* (HPUS), the *Homöopathische Arzneibuch* (HAB), the *Pharmacopée française* (PhF) or the *European Pharmacopoeia*, as they are amended and that are prepared in agreement with these pharmacopoeias (NHPD 2003a).[29]

The non-compendial applications are given no information or guaranties on the application processing time. The NHPD could not provide an average time of processing and commented that licenses are judged on a case-by-case basis. Complete file

[28] The Homeopathic Pharmacopoeia of the United States describes homeopathy as the art and science of healing the sick by using substances capable of causing the same symptoms, syndromes and conditions when administered to healthy people. For example, if a child accidentally ingests certain poisons, you may be advised to administer Syrup of Ipecac to induce vomiting. If a group of healthy volunteers took this same substance the outcome would also be vomiting. Homeopathy attempts to stimulate the body to recover itself.

[29] Pharmacopoeias specify the ingredients and detailed procedures for the preparation of homeopathic medicines. The most widely accepted are the *Homeopathic Pharmacopoeia of the United States* (HPUS), La *Pharmacopée française* (PhF) of France, the *Homöopathische Arzneibuch* (HAB) of Germany, and the *European Pharmacopoeia* of Europe. All these different pharmacopoeias operate on the same principle and specifically, the HPUS is a list of products which contain active ingredients that are official Homoeopathic Drug Products. The standards in order for a product to appear on the HPUS are established by the Homœopathic Pharmacopœia Convention of the United States. This is a non-governmental, non-profit scientific organization composed of experts in the fields of medicine, arts, biology, botany, chemistry and pharmacy who have had training and experience in the principles of homeopathy. The Convention works closely with the FDA and homeopathic organizations most notably the American Institute of Homeopathy and the American Association of Homeopathic Pharmacists.

applications may move very quickly and submission with deficiencies may take an exceptionally long time.

All types of applications require a firm to fill out an application form (NHPD 2005a). This form has five main parts, beginning with application and contact information. This is followed by the submission type. Information regarding the site is part 3 of the application, followed by part 4- product information. The product information includes details about both the medicinal and non-medicinal ingredients and recommended conditions of use. Lastly, part 5 of the application is the submission of content and attestation.

The license applications are processed by the NHPD and are subject to four steps in the process overview: verification, processing, assessment, and decision. At each level of processing there are different personnel involved to assess the product license application. Once submitted, the licensing process begins by the NHPD. Firstly the NHPD will screen the application for the company and contact information. If there are deficiencies in the company information these will be outlined in the notice of acknowledgement. The applicant must respond within 15 calendar days. Level two of the submission will be processing. The NHPD checks verified applications for completeness to ensure the appropriate information is submitted in an acceptable format. If deficiencies are identified, the NHPD will issue a processing deficiency notice, requesting the missing information or clarification. Applicants have 30 calendar days from the date the notice is issued to respond. The next step is assessment and when the application reaches this level, it is assessed for compliance with the *Natural Health Product Regulations*. If clarification is needed an information request is sent that will include all areas that require further clarification. Applicants have 30 calendar days to respond. Lastly, a decision will be issued whether the application was accepted or refused based on the requirements set out by the regulations (NHPD 2005a).

Once a product has been assessed by NHPD, the product label will bear a product license number preceded by the distinct letters NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM (NHPD 2005a). The number is issued once the Natural Health Products Directorate authorizes a product for sale in Canada. The product license number on the label will inform consumers that the product has been reviewed and

approved by Health Canada for safety and efficacy. Applying for a product license is by no means simple and there are long guidance documents to aid firms to properly meet the requirements of the applications. The length of approval time for a product license depends on the application type.

Site License

The next major component of the NHP regulations is site licensing. All businesses in Canada who wish to manufacture, package, label or import a NHP for sale must have a site license (NHPD 2003e). A business involved in manufacturing, packaging, labelling or importing a natural health product may choose to apply for one site license for all business operations (i.e. at multiple buildings or locations) or for individual site licenses for the respective buildings or locations. A site license gives the licensee authorization to manufacture, package, and label or import natural health products. These activities must be carried out according to the good manufacturing practices (GMP) in Part 3 of the NHP Regulations. GMP is to be employed to ensure product safety and quality. GMP requires that appropriate standards and practices regarding product manufacturing, storage, handling and distribution respecting natural health products be met. The provisions cover: specifications (product), premises, equipment, personnel, sanitation program, operations, quality assurance, stability, records, sterile products, lot or batch samples, and recall reporting (NHPD 2005b).

The submission requirements for a site license depend on the role of the applicant. Site licenses require an application and this must be submitted when initially licensing the site, notify the NHPD of changes in information relating to a building or process when amending a site license and to renew a site license (NHPD 2005b). The application form is long, detailed and is divided into five parts. Part 1 is simple licensee information and likewise part 2 is simple submission information. Part 3 of the site license application involves Canadian site information, while part 4 deals with foreign sites. Lastly, part 5 is an attestation by a qualified quality assurance person who confirms that buildings and procedures used in the facility comply with GMP as set out in part 3 of the NHP regulations.

In addition to the site license application form, each site requires a quality assurance report (QAR) form (NHPD 2005b). The QAR is perhaps the most detailed part

of the site license procedure. This requires an inspection that can be a self-inspection, third party audit, regulatory agency, or any other type of audit. However, the inspection must be completed by a person who has the necessary qualifications to assess the operation of the facility. The necessary qualification must be presented in the quality assurance personnel qualification form, where details of quality assurance activities, education, training and experience must be provided.

The QAR submission requires exact information on places, people, processes, and product. This submission must demonstrate that the operations of the facility are in line with the GMPs outlines in the NHP regulations. Standard operating procedures (SOPs) are also submitted in the QAR submission. SOPs are authorized written procedures giving instructions for performing operations and are not necessarily specific to a given product or material but more a general nature (NHPD 2005b). If a firm is involved in homeopathic medicines then a supplementary quality assurance report form must also be submitted. The NHPD will assign a submission number to the application and a company file number to each application. The license will be issued when the applicant meets all the regulatory requirements outlined in the NHP regulation, any and all of the additional information requested has been submitted and the application contains no false or misleading information. The site license is independent of the product being manufactured and it is the product license that will be product specific (NHPD 2005b).

The site licenses must be renewed every year for the first three years, then every second year for the next six years, and finally every three years after holding a site license for nine years. The Natural Health Product Directorate (NHPD) will process the site license by first verifying the information. The NHPD will send out an acknowledgement notice to the applicant confirming the submission. If the NHPD has noticed deficiencies in the submission, these will be outlined in the acknowledgement notice and the applicant has 15 calendar days to respond. If there is no response from the applicant, the NHPD will consider the application withdrawn and the applicant must re submit the application in full. Next, the NHPD will process the application form and appropriate supporting data. If deficiencies are identified, the NHPD will issue a processing deficiency notice and will request missing information or clarification. The applicant must respond in 30 days from the date the notice is issued. Assessment is the

following step in the submission process flow. The application form and supporting data are assessed for compliance with the NHP regulations. Lastly, when the NHPD deems a site license fully compliant with the NHP regulations it issues a site license. If the NHPD refuses a site license the applicant receives notice stating the reason for the decision. The NHPD estimates that a complete site license application can be reviewed in about 30 days (NHPD 2005b).

Enforcement and Compliance

When a situation of non-compliance is identified by the Inspectorate or otherwise, it is the responsibility of the regulated party to take timely and appropriate action to comply with legislative and regulatory requirements. Compliance is normally achieved through cooperation between the regulated party, the Inspectorate, and the NHPD. However, when this is not possible there are a number of enforcement options available to respond to infractions of the *Natural Health Product Regulations*.

The Inspectorate will determine the most appropriate actions to be taken. This depends on the circumstances of each case and consideration of many different factors, including: risk to health and safety, compliance history, whether the regulated party acted with indifference or premeditation, the degree of cooperation offered by the regulated party to the Inspectorate officials, likelihood of reoccurrence, need to maintain public confidence, and the Health Products and Food Branch priorities and available resources.

One or more of the following actions may be taken to achieve compliance for violations of the regulations (HPFB 2001):

Voluntary Disposal – This is a decision by the regulated party to destroy a non-compliant product.

(1) Voluntary Detention – This is an agreement between a regulated party and the Inspectorate to prevent distribution of a particular product. This may be appropriate in the Inspectorate is confident the regulated party will comply with the conditions of the agreement.

(2) Recall – A recall with respect to a product is an action taken by the regulated party to correct or remove from the market a non-compliant product that may represent a risk to the health and safety of consumers.

(3) Negotiated Compliance – In a case where the Inspectorate informs a regulated party of non-compliance of which the regulated party was not aware, and the regulated party is willing to comply with the requirement, the Inspectorate will negotiate with the party to establish an appropriate time frame for achieving compliance.

(4) Warning – A warning letter may be issued when it is believed that non-compliance has occurred or is continuing and the risk to human health or safety does not warrant stronger enforcement action.

(5) Stop Sale – The Inspectorate may request that a regulated party stop sale of its product(s) if the product has not received the appropriate marketing approvals.

(6) Customs Look Out/Alert – The Inspectorate may request that Canadian Customs and Revenue Agency (CCRA) target and detain for examination, a specific shipment that has been identified as non-compliant with regulatory requirements.

(7) Import refusal – The Inspectorate may recommend to the CCRA that a product be refused entry into Canada.

(8) Suspension or Cancellation of Product License – When a party is not complying and a significant health risk exists and there is no indication the party will comply, the Inspectorate can recommend that steps be taken toward suspending or cancelling a product license.

(9) Suspension or Amendment of Site License – The Inspectorate may suspend a site license where there are reasonable grounds to believe any provision of the regulations have been disregarded, or that the licensee has made a false or misleading statement in its application for a site license.

(10) Formal Hearing – this is an official meeting with the regulated party to discuss issues of non-compliance. Such a hearing may be appropriate when previous enforcement options (eg. Warning) have not been effective, or prior to initiating more serious enforcement options.

(11) Seizure and Detention – This is an immediate enforcement tool for controlling non-compliance. The Inspectorate may take control of non-compliant articles.

(12) Prosecution – This is legal proceeding in which the courts determine whether the applicable legislation has been disregarded, and if so, apply an appropriate penalty.

(13) Injunction – this is a judicial order prohibiting or ordering specific activities.

(14) Public Warning – When there is an imminent health hazard associated with a product or group of products is present, the Inspectorate may inform the population at risk by means of public warning.

(15) Public Advisory – This is appropriate to inform the population when a product or group of products present in the market place is/are considered a potential health hazard or a non-imminent risk, especially in situations where it would be difficult to reach the consumer via the distribution chain.

It may be the case that some of the Inspectorate decisions will be disputed by the regulated party, in which case an internal appeal process is available to facilitate the resolution of contentious issues. Any of these measures may be utilised to enforce compliance with the *Natural Health Products Regulations*.

The above is just an overview of the NHP regulations in Canada highlighting the major aspects of these regulations. These regulations are by no means simple; there are 75 pages of legal requirements, which can be somewhat difficult to interpret and which are accompanied by numerous guidance documents. There are detailed requirement for GMP and clinical trials involving human subjects. The cases explored in this thesis reveal the intricacies of the regulations and the potential cost to firms that must comply with the regulations.

5.2.2 US Regulations

Under DSHEA, it is the responsibility of the firm to determine that the dietary supplements it manufacturers or distributes are safe, and that representations and claims surrounding the dietary supplement are substantiated by adequate evidence to show they

are not misleading or false. The FDA does not approve dietary supplements before they are marketed in the US. The only exception to the rule is new dietary ingredients, which require a pre-market review for safety data and other information required by law.

Manufacturing dietary supplements does not require registering the product with the FDA before producing or selling. In addition, there are no FDA regulations that are specific to dietary supplements that establish a minimum standard of practice for manufacturing. The manufacturer is responsible for establishing its own manufacturing practice guidelines to ensure that the dietary supplements it produces are safe and contain the ingredients listed on the label. Under DSHEA, once a product is marketed it is only then that the FDA has the responsibility for showing that a dietary supplement is unsafe, before it can take action to restrict the products use or removal from the marketplace. The FDA may investigate when numerous adverse reaction have been reported to the FDA. It is only the difference in allowable claims that may concern firms. In the US only structure/function claims can be made, these are claims that relate the product to the normal functioning of the human body and are allowable on food products as well as dietary supplements. Statements relating to the prevention, diagnosis, treatment, cure or mitigation of disease are forbidden (unless the statements are specifically reviewed and approved by the FDA).

Essentially, the FDA is required to oversee safety, manufacturing and product information (claims included on a label, or insert, or accompanying literature). It is not the responsibility of the FDA to authorize or test dietary supplements. DSHEA also gives FDA authority to establish good manufacturing practices, or GMPs, for dietary supplements but has not yet decided whether to pursue mandatory industry wide GMPs. Besides the FDA, individual state governments have the authority to restrict or stop the sale of potentially harmful dietary supplements within their jurisdictions. For example, prior to the FDA ban on dietary supplements containing ephedrine alkaloids (ephedra), Florida had already banned some products containing ephedra.[30]

[30] Dietary supplements containing ephedrine were promoted for aiding weight control and boosting sports performance and energy. The FDA found that available data showed little evidence of ephedra's effectiveness except for modest, short-term weight loss without any clear health benefit, while confirming that the substance raises blood pressure and otherwise stresses the circulatory system. These effects are linked to significant adverse health outcomes, including heart attack and stroke. The FDA found these

The FDA is not responsible for regulating the advertising of dietary supplements as this comes under the responsibility of the Federal Trade Commission (FTC). The separation of these powers can lead to discrepancies between regulations and enforcement. Under DSHEA and previous food labeling laws (the Nutrition Labelling and Education Act of 1990 (NLEA), supplement manufacturers are allowed to use, when appropriate, three types of claims: nutrient-content claims, disease claims, and nutrition support claims, which include "structure-function claims."[31]

The FTC requires truth in advertising by law and this can be boiled down to two main points: (1) advertising must be truthful and not misleading; and (2) before disseminating an advertisement, advertisers must have adequate substantiation for all objective product claims (FTC 2004). Unfortunately, the FTC may not always monitor whether claims advertised are allowable under DSEHA but are mostly concerned with whether they are true. In addition, the FTC does not approve all advertising prior to its use but instead will investigate complaints of false advertising. This makes it relatively easy to put any claims that may enhance the sale of a product on the label.

The key element of the US legislative environment is the decision of the manufacturer regarding how to position their product. Whether it is positioned as a conventional food, a dietary supplement, or a product fitting into another regulatory category is central to determining how the FDA will regulate the use and accompanying labelling claims (IACFO 1998). This means that NHP are subject to a great deal of varying regulatory environments depending on the category they are placed in (e.g. food, dietary supplement, medical food or drug).

Facilities in the US, and abroad, exporting to the US, are subject to a form of facility registration. The Public Health and Security and Bioterrorism Preparedness and

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products to be too risky and warned consumers not to take them, and the FDA removed them from the market (FDA 2004b).

[31] While the Act, as amended by DSHEA, requires substantiation for such claims, it does not define the term (DSHEA 1994). However the FDA does provide this explanation: structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or they may describe general well-being from consumption of a nutrient or dietary ingredient.

Response Act of 2002 (The Bioterrorism Act) requires that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the US register with the FDA. The Bioterrorism Act includes the manufacturing of dietary supplements. This application is available on-line and just requires basic information from the manager. The FDA estimates that it will take one or two hours of a manager's time to understand the regulations and about 45 minutes to fill out the application and another 15 minutes of an owner, operator or agent in charge to certify the registration. This is the only requirement regarding the facilities. However, the FDA announced that they intend to fully implement the DSHEA and required GMPs for dietary supplements. Currently, the announcement has been the only step and there are no GMPs available from the FDA for dietary supplements.

However, it is important to note that in 2004 the FDA announced major initiatives for dietary supplements (FDA 2004a). This announcement was to further implement DSHEA via three main components – regulatory strategy, open public meetings, and a draft guidance document for the industry. In the first initiative, a regulatory strategy, FDA will work collaboratively with its federal and other partners to improve the evidence base FDA uses to make safety and enforcement decisions about dietary ingredients and dietary supplements. Also, a public meeting was held to seek comment on the type, quality, and quantity a manufacturer should provide the FDA for new dietary ingredients. The third initiative reflects FDA's commitment to fully implement DSHEA by asking for comments on a draft guidance document on the amount, type and quality of evidence a manufacturer should have to substantiate a claim.[32] The guidance document for the industry will include information on evidence for structure-function claims, warning and advisory letters to distributors and marketers of products making unsupported claims, closer scrutiny of new dietary ingredients and adverse events, speedier and more punitive treatment of unsafe products, implementation of long-awaited GMPs and random supplement-content testing.

Enforcement and Compliance

[32] There has been no formal guidance document produced as of May 22, 2005.

In the US when violations are discovered by the FDA there are many regulatory procedures available. Adulterated or misbranded products may be voluntarily destroyed or recalled from the market by the firm, or may be seized by US Marshals on orders obtained from the FDA. Persons and firms responsible for violations may be prosecuted in the Federal courts and, if found guilty, may be fined and/or imprisoned. Continued violations may be prohibited by Federal court injunctions and violations of an injunction are punishable as contempt of court. Any or all types of regulatory procedures may be employed, depending on the circumstances.

In addition, civil money penalties may be pursued for certain specific violations. Injury from unsafe products can be considered an actionable tort in the US. The potential for civil liability may in fact create greater incentives to market safe products. As firms aim to avoid damages that can involve significant amounts of money.

5.2.3 EU Regulations

The EU market is not yet uniform it in application of regulations for NHP. Companies must deal with changing regulations and combination of national and EU based regulations. There are two major directives that have been passed in the EU that will affect the marketing of NHP. The first is the Directive on Food Supplements, that specifically targets vitamins and minerals. The second piece of legislation that will influence NHP is the Traditional Herbal Medicinal Products Directive. This directive mainly covers a wide range of herbal products that are used as NHP. Specifically, in the case study the UK is used as the foreign market. The UK has begun steps to comply with the Traditional Herbal Medicinal Products Directive. They have begun to implement a new system for herbal medicinal products that more closely mirrors the system in Canada as compared to the system in the US. There is pre-market product approval and facility registration involved.

The EU is a varying market and is hard to compare with the US and Canada without using a specific country with in the EU. Many of the measure for marketing NHP are specific to the destination as the EU has yet to completely unify it approach to the NHP. Enforcement and penalties are difficult area as countries within the EU have different court systems and enforcement procedures. In addition to the separate legal

system within the member states, there exist a higher EU court. Discussing penalties would also be a country specific situation.

5.2.4 Comparison

It is helpful to compare the different regulatory regimes. Table 5.1 reveals the numerous differences between the three countries. The table lists the main components of the NHP regulations in Canada and list similar measures in the US and EU when present. This table will assist with understanding the case studies and the analysis of difference transaction costs among different market, as well as, the potential for technical barriers to trade.

Table 5.1: Regulation Comparison Canada, US and EU

	Canada	United States	European Union
Product Category	• Sub Category of Drug	• Sub Category of Food	• Sub category of Drug or food
Product Licensing	• Pre-market review-assessed for, safety, efficacy, and quality • Must submit evidence to Health Canada by means of product license application (one per product) • No fee for application	• No registration of products • No pre-market approval from FDA (exception of new dietary ingredients not marketed before October 15, 1994)	• Positive List of acceptable food supplements • Individual countries can continue exiting national restrictions and bans • Regulations on purity criteria (some annexed in the Directive 2004/24/EC and some remain country specific)
Site Licensing	• Require site licenses for sites that manufacture, import, label, package, distribute, and/or store NHP • Must demonstrate above practices are conducted in manner that is congruent with the requirement of GMPs for NHP • Requires trained quality assurance person or 3rd party auditor for application • No fee for application	• Registration of facility with FDA • Requires basic information (name, address, etc) • No 3rd party audit	• N/A for EU • Some country Specific
Clinical Trials	• Registration of clinical trials involving humans • Requirements designed to protect participants • Document not yet available	• N/A	• N/A

Table 5.1 con't: Regulation Comparison Canada, US and EU

	Canada	United States	European Union
Good Manufacturing Practices	• Sets standards and practices for product testing, manufacturing, storage, handling and distribution • Specific requirements for places (premises, equipment) • Specific requirements for people (personnel, quality assurance) • Specific requirements for processes (sanitation programs, operations) • Specific requirements for products (specifications, stability, samples, records, recall reporting, sterile products)	• DSHEA grants the FDA the right to establish GMPs for preparation, packing and holding • As of yet have not established GMPs	• N/A
Labelling and Packaging	• Label must be submitted with product license application • Meet labelling requirement (Appendix 1)	• Restrictions on claims (See Appendix 1) • Ingredients labelling (See Appendix 1) • Label is not submitted to FDA for approval	• Must be submitted to competent authority in the area • Restrictions on claims (See Appendix 1) • Ingredient labelling (See Appendix 1)
Importing	• Importer must be licensed • Onus is on the importer to provide evidence that imported products come from sites that meet Canadian GMPs or equivalent standards	• N/A	• N/A
Exporting	• No stipulation but section 37(10 of the Food and Drug Act does have requirement for exported products	• N/A	• N/A

5.3 Introduction: Flax Omega-3 Supplement Case

Flax is being touted by some as the next nutritional superstar. Scientific support for the health benefits of flax is increasing and there has been considerable interest shown by the media. Flaxseed contains healthy amounts of both soluble and insoluble fiber. Scientists at the American National Cancer Institute singled out flaxseed as one of six foods that deserved special attention (Flax Council of Canada 2005b). The reason: flaxseed shows potential cancer-fighting ability. Flax has also gained attention for its ability to help reduce coronary heart disease. The scientific research on flax and its health benefits is extensive and wide-ranging, covering numerous aspects of the benefits of a diet rich in flax seed and oil.

This case study of flax, specifically an omega-3 fatty acid concentrate, is expected to be relatively straightforward. It is expected that NHP that are derived from flax when it is a capsule of concentrated ground flax or in a concentrated liquid oil form will encounter little distortion from regulatory barriers. The scientific support should easily allow these forms of product to penetrate both the domestic and a given export market. In addition, flax is found on the Natural Health Products Compedium of Monographs, which should ensure that a natural health product based on flax (excluding any non-approved non-medicinal ingredients) would quickly be able to receive a product license in Canada.

The flax case will begin with background on flax and omega-3 fatty acids and then discuss their health benefits. The case study examines some scientific support for the health claims that accompany this type of product. An examination of regulations faced by a domestic producer and foreign producer in Canada and the United Kingdom (UK) follows. The examination includes a classification scheme of the regulations. Lastly, the potential demand and supply shift effects of the regulations will be analyzed to determine the welfare effects of regulations within the natural health products sector.

5.3.1 Flax

Flax is an ancient crop that has been grown since the beginning of civilization. Flax is grown for two main purposes - seed and fibre. In North America the majority of

flax that is produced is of the oilseed variety (Flax Council of Canada 2005a). Canada is the world's leader in flax production and exports. According to Statistics Canada the ten-year average (1986-1995) for Canadian production is about 710,000 tonnes of flax seed on about 1.5 million acres. Agriculture and Agri-food Canada identified Canada as producing 40% of the world's flax in the 1996/97 growing season (Flax Council of Canada 2005a). Saskatchewan is the main producer of flax in Canada followed by Manitoba and Alberta. There has been both consumer and public policy interest regarding the potential health benefits of flax. Flax contains both omega-3 fatty acids and soluble fibre, which have both been shown to favour healthy blood lipid patterns. In addition, its high levels of lignans make flax of interest to the natural health product sector.

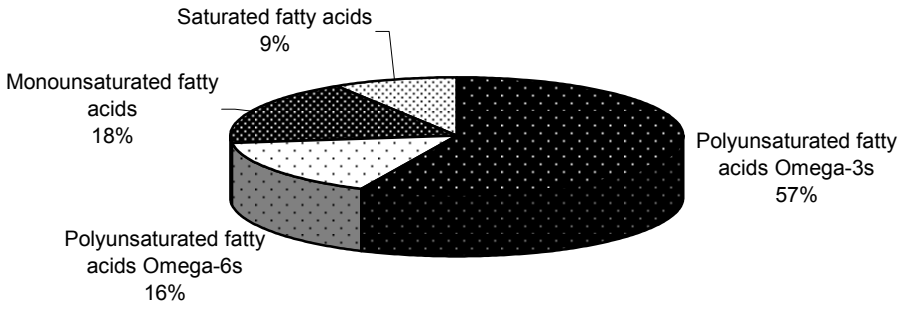

Figure 5.1: Fatty Acid Composition of Flaxseed Oil
Source: Flax Council of Canada (1998a)

Many consumers are turning to flax products for their potential health benefits. Flaxseed is naturally low in saturated fat and provides a moderate amount of monounsaturated fat. Figure 5.1 shows that roughly 73 percent of the fatty acids in flaxseed are polyunsaturated. Flax is particularly rich in the omega-3 fatty acid called alpha-linolenic

acid (ALA) and a lesser amount of the omega-6 fatty acid commonly called linloeic acid (LA). There is a growing concern that diets in Western countries are too high in linloeic acid and some leading experts recommend replacing omega-6 fatty acids with those from the omega-3 fatty acid family (Flax Council of Canada 1998a). It is clear that flaxseed is a very rich source of ALA, an essential fatty acid (EFA) of the omega-3 family. Omega-3 fatty acids have been shown to regulate gene transcription and expression, thus altering enzyme synthesis (Clarke and Jump 1994), and to modify several risk factors for coronary heart disease, including reducing serum triglycerides and blood pressure (Schmidt *et al.* 1994). Populations with higher intake levels of ALA have been observed to have low risk of cardiovascular diseases such as coronary heart disease (CHD) and stroke (Flax Council of Canada 1998b). These long chain omega-3 fatty acids have been shown to reduce blood triglycerides, increase blood high-density lipoprotein (HDL) cholesterol[33], reduce blood pressure, reduce platelet reactivity and reduce neutrophil activity – all actions that help lower CHD risk (Flax Council of Canada 1998b).

In clinical trials, ALA was shown to produce positive effects on blood lipids. One study of 10 young, healthy men and women found that plasma total cholesterol was reduced 6 percent and LDL-cholesterol was reduced 9 percent following daily consumption of flax seed muffins providing 50g flaxseed for four weeks. Plasma HDL-cholesterol and triglycerides did not change during the flaxseed supplementation period (Cunnane *et al*. 1995). In five hyperlipidemic men and women who had just completed a study on the effect of vitamin E supplementation on serum lipids oxidation products, the addition of 15g milled flaxseed to their daily diets produced significant reduction in blood total cholesterol (-7%) and LDL-cholesterol (-11%) without changing HDL-cholesterol levels. Blood triglycerides decreased slightly but not significantly during the trial (Bierenbaum *et al.* 1993). Overall, the finding from clinical studies examined by the Flax Council of Canada suggest modest reductions in total cholesterol and LDL-cholesterol can be achieved, without a change in HDL-cholesterol levels, by adding flaxseed to the diet.

[33] High-density lipoprotein (HDL) carries about one-third to one-fourth of the blood's cholesterol. The HDL carries the cholesterol away from the arteries and back to the liver where its passed from the body. HDL cholesterol is known as the "good" cholesterol because a high level of HDL seems to protect against heart attack (American Heart Association 2005).

Two other important omega-3 fats exist that are called eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). EPA and DHA are found mainly in fatty fish like herring, salmon, mackerel, and blue fin tuna and fish oil supplements made from them. There is debate as to whether flax or fish is the better source of omega-3 fatty acids. Both offer good nutrition and are important to a healthy lifestyle. Fish oil capsules are the most concentrated form of omega-3 fatty acid and contain all ALA, EPA and DHA. However, a health alert has been raised about the level of polychlorinated biphenyls (PCBs) in fish oil supplements (Flax Council of Canada 2004). Fish oil is the main competition for flaxseed oil in the realm of omega-3 fatty acids.

The FDA has been conservative regarding statements about Omega-3 fatty acids. The following statement was approved by the FDA: the scientific evidence about whether omega-3 fatty acids may reduce the risk of CHD is suggestive, but not conclusive. Consumption of omega-3 fatty acids may reduce the risk of CHD. Studies in the general population have looked at diets containing fish and it is not known whether the diets or the omega-3 fatty acids found in fish may have a possible effect on a reduced risk of CHD. It is not known what effect omega-3 fatty acids may or may not have on the risk of CHD in the general population (FDA 2002).

Similarly, there is growing evidence that increasing dietary intake of omega-3 fatty acids may help prevent arrhythmias. Arrhythmias occur when there is a disturbance in the electrophysiologic properties of the cardiac muscle. By enhancing the electrical satiability of the heart cells and increasing their resistance to becoming "hyperexcitable" omega-3 fatty acids appear to protect against arrhythmia (Flax Council of Canada 1998c).

Research continues on the benefits of flaxseed oil and other sources of omega-3 fatty acid such as fish oil. The National Centre for Agri-food Research in Medicine (NCARM), located in Winnipeg, is an organization devoted to the study of natural health products. NCARM is involved in numerous research projects involving flax including clinical trials and cellular level projects.[34] Positive results from clinical trials like these

[34] Some current research projects on flax include: Effects of flaxseed consumption on vascular function and atherosclerosis, Cellular basis for the anti-arrhythmia and cardio-protective action of flaxseed, and a comparative analysis of the effect of fish oil, flaxseed oil and hempseed oil supplementation on lipid profile, and platelet function in healthy volunteers (NCARM 2002a).

and others will have the ability to satisfy Canadian regulatory requirements for clinical trial evidence.

The evidence may not be conclusive but with further research perhaps the true benefits of flaxseed oil will become apparent. However, there is enough evidence to induce some consumers interested in improving their health to purchase and use flaxseed oil. Flaxseed oil products are considered to be a market growth category for natural health products.

5.3.2 Regulations

Regulations are important to the marketing of natural health products. Flaxseed oil must adhere to regulations established for the given market. This discussion will begin by examining the Canadian market place regulation that applies specifically to flaxseed oil. First, the case of a domestic producer is examined, followed by the case of a foreign producer. Accordingly, an examination of the regulations in the UK and how they affect foreign and domestic producers is undertaken. Then a comparison highlights potential technical barriers which will then be classified according to the framework.

5.3.2.1 Canada

This section discusses the main component of the Canadian *Natural Health Products Regulations* that must be met to sell a flax omega-3 supplement. The two main parts of the regulations that apply are that of the site license and the product license. These two regulations were discussed earlier in detail at the beginning of this chapter. Each regulation is discussed from the perspective of the domestic and foreign producer.

Domestic Production

Site License

The first element that is relevant for a domestic firm is the site license. Any firm manufacturing, packaging, labelling or importing NHP must obtain a site license. When marketing a flax capsule, the appropriate sites must be licensed.[35]

[35] A detailed description of the site license procedure is found earlier in section 5.2.

Product License

As mentioned, the product license is specific to a given product and in our first case the product is an omega-3 supplement derived from flax. The flax product examined is a compendial application. This is the simplest of monographs and according to section 6 of the NHP regulations will be reviewed in 60 days after the day of submission. Flax does have a monograph in the NHPD's *Compedium of Monographs* and is listed as a plant extract. The case study involves an oral pill and can be stated as being a source of essential fatty acid for maintenance of good health. For a product such as a flax pill, a completed product license application form is required.

The product license application form has five main parts, beginning with application and contact information. The submission type follows, which in our case is a product license application - compendial. Information regarding the site is part 3 of the application, followed by part 4- product information. The product information includes details about both the medicinal and non-medicinal ingredients and recommended conditions of use. Lastly, part 5 of the application is the submission of content and attestation. In addition to the application form, the proposed label text must be included.

Foreign Production

Site License

NHP that are imported from foreign sites require the importer to be licensed. That is to say the onus is on the importer to provide evidence that imported goods come from sites that meet Canadian GMPs under part 3 of the *Natural Health Products Regulations*, or equivalent standards. An importer must submit a complete site license application, quality assurance report, or evidence of GMP compliance for each foreign site. Consequently, one of the following must be provided:

- A quality assurance report signed and dated by a quality assurance person who has training, experience and technical knowledge relating to the activity conducted in order to assess compliance with GMPs
- An audit, inspection report or equivalent, based on memorandum of understanding or mutual recognition agreement between the foreign regulatory agency and Health Canada, when applicable

- A license from the accepted regulatory authority in a designated country or association of countries which are recognized under the current Guidance Document on Drug Establishment Licenses and Establishment Licensing Fees, that are therefore considered to meet standard equivalents to Canadian GMP requirements.[36]

An importer will be issued a site license for a foreign site only after the information has been provided.

Product License

The product licensing regulations also apply to a foreign manufacturer. A product license must be obtained before selling a flax omega-3 capsule in Canada. The product license application will be identical to that of a domestic producer and should in theory be as simple to obtain if all the correct information is provided.

5.3.2.2 The UK

In the UK, the key distinction to make before marketing the flax omega-3 supplement is to determine if the product is considered a food or a medicine. Both of these paths lead to further scrutiny and some complicated regulatory procedures. Our case will consider the flax product to be an herbal medicine, in-line with the list provided by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA). The UK needs to comply with EU commitments and has produced the forthcoming Traditional Herbal Medicines Registration Scheme (THMRS) as required by Directive 2004/24/EC on Traditional Herbal Medicinal Products. The THMRS will not come into force until October 2005 and current products on the market will have a seven-year transition period. THMRS will apply to manufacturing (including those that manufacture for export), importers and wholesale dealers of medicinal products covered by the scheme, which are marketed in the UK. Similar to the Canadian regulations, a product license is required

[36] The Health Products and Food Inspectorate Branch have memoranda of understanding (MOU) related to GMP with the following countries: Australia, Switzerland, Sweden, France and United Kingdom. An inspection report from the regulatory authority of one of these six countries would be considered appropriate data to establish that a drug has been fabricated, packaged/labelled, or tested against equivalent standards to requirements of part 3 of the *Natural Health Products Regulations*.

and, depending on the role played by the firm, another license is required (manufacturer's license (ML), wholesale dealer's license (WL), or wholesale dealer's (import) license (WI)).

Domestic Production

Manufacturer and Wholesale dealer's license

To obtain a manufacturer's license (ML), a firm will need to meet approved standards of Good Manufacturing Practice and submit a manufacturer's license application form. The ML is required only for UK manufacturers and the wholesale dealer's import license covers product from foreign markets. The application form should be completed and submitted to the MHRA. It should be signed by the applicant and the relevant pages should be signed by the nominated Qualified Person.[37] The principle guidelines for GMP include quality management, personnel, premises and equipment, documentation, production, quality control, contracting out, complaints, product recalls, and self-inspection. In addition to the manufacturer's license application a firm must submit a site master file to the MHRA, which contains information about the production and control of manufacturing operations carried out. This is similar to the information provided in the site license application in Canada. Granting of a license is subject to the finding of an inspection by the MHRA. All manufacturing sites listed on the manufacturer's license are subject to regular inspections.

If a firm is importing products from within the EU then the firm will require a wholesale dealer's license. To obtain the license you must meet the standards of Good Distribution Practice (GDP) and submit an application to the MHRA. The application needs to be filled out by the applicant and signed by a responsible person.[38] Once again

[37] The duties of the qualified person include: ensuring that Good Manufacturing Practice (GMP) has been adhered to, the requirements of the product registration and of the manufacturer's license have been met, manufacturing and testing processes have been validated, all necessary quality control checks and tests have been conducted. In addition the qualified person should ensure legal requirements for imported products have been met. For products imported from outside the EU or European Economic Area (EEA) the qualified person should ensure testing within the EU/EEA to requirements of the product registration and any other tests to assure quality of the products, unless a Mutual Recognition Agreement exists between the EU and the third country concerned ((Medicines and Healthcare Product Regulatory Agency 2004b).

[38] The responsible person will be responsible for safeguarding product users against potential hazards arising from poor distribution practices for example from the purchase of suspect products or poor storage.

UK sites listed on the wholesale dealer's license are subject to routine inspections. These take place approximately every three years depending on the size of the operation.

Product Registration

The final product registration procedure has not yet been completed but pre-application notification is available. The precise format of the dossier for the application is not yet decided but it will be based on common technical document format, which is currently used in applications for marketing products, meeting requirements of safety, efficacy, and quality. The format is not decided but the following information will be required (MHRA 2004a):

- Application form
- Sample patent information leaflet
- Summary of product characteristics (name of the product, strength, pharmaceutical form, quantity of active ingredients, method of administration, indications, contraindications, excipients, shelf life and any special warnings and precautions for use etc.)
- Information about the experts providing evidence of safety of claims of traditional use
- A dossier on the quality of the finished herbal product
- Bibliographical review of safety data
- The application will need to be accompanied by bibliographic or expert evidence that the medicinal product or a corresponding product has been in medicinal use throughout a period of 30 years.

Each product will require its own product registration. Even the same product but with different formulations and strengths will require separate product registration.

Foreign Production

Wholesale Dealer's License

They will be required to ensure that the conditions of the wholesale dealer's license are met and that the guidelines on GDP are complied with (Medicines and Healthcare Product Regulatory Agency 2004c)

If a firm is importing products from outside the EU it will require a wholesale dealer's import license. To obtain one a firm must meet approved standards of GDP and the relevant elements of GMPs in respect of batch release. This license application must be signed by a qualified person. A list of licensed products imported should be submitted with the information on product name, license and country of origin. The qualified person must ensure that each production batch has undergone: (1) a full qualitative analysis; (2) quantitative analysis of all active ingredients; and, (3) all other tests and checks to ensure the quality of the product. The license can be subject to inspection and a site master file of the manufacturing site in the foreign country needs to be provided.

Production registration

Products must be registered and are subject to the same standards as domestic products. The flax omega-3 herbal product must be registered to be sold in the UK. The application procedure is the same as that for a domestic product. Product registration is an involved procedure and will require large amounts of information. The precise format of the dossier for product registration has not yet been determined. The THMRS states that required data for the dossier would take significant preparation, particularly for firms that are not accustomed to meeting regulatory requirements related to medicines. The application will include information on: product characteristics, expert information, quality, safety and traditional use.

5.3.3 Classification

The first and essential step of the framework proposed by Roberts, *et al.* (1999) is that of classification. Governments have a wide choice among numerous policy instruments to correct for market failures. The first order of classification is that of technical barriers by policy instrument. The barriers that apply to the case of flax omega-3 supplements for Canada and UK will be classified by policy instrument.

Table 5.2: Classification of technical barriers for flax omega-3 supplements by policy instrument

	Canada	United Kingdom
Import bans		
Total ban	N/A	N/A
Partial ban	N/A	N/A
Technical Specifications		
Packaging Standards	GMPs packaging materials/procedure requirements to avoid contamination	GMPs packaging materials/procedures Requirements to avoid contamination
Process Standards	Operations and sanitation standards included in GMPs	GMP production standards
Product Standards	Product license requirement standards for safety, quality and efficacy	Product registration evidence of safety, efficacy and quality.
Information remedies		
Labelling requirements	Inner and outer label requirements and bilingual text requirements	Requirements for label and user package leaflet
Controls on claims	Must provide evidence for claims	There are requirements for permitted indications

When examining table 5.2, the flax product in Canada faces similar policy instruments to the flax product in the UK market. This could infer that the cost of accessing the market for like products in Canada is relatively similar to accessing the market in the UK. Particularly, the technical specifications involved in selling the flax omega-3 supplement in the Canadian market are similar to those in the UK.

The framework continues by examining the scope of the technical measures encountered by the flax omega-3 supplement. Scope is important as it determines who bears the cost of the regulations. The UK regulations are uniform in that they are applied

equally to foreign and domestic producers. The Canadian technical measures are for the most part uniform in that both domestic and foreign firms must obtain site and product licenses. The importer of flax omega-3 supplements in Canada is required to ensure that the foreign site of manufacturing, labelling and packaging is in accordance with the GMPs set out by the regulations. Likewise, the importer in the UK must provide an application to ensure GMPs are carried out in the foreign site and they can be subject to inspection. These measures could be considered border specific as they apply to foreign product specifically.

For example, retailers selling flax omega-3 supplement in Canada do not have to worry about site licenses for a domestic producers. It is the responsibility of the domestic manufacturer to obtain the site license and incur the cost of meeting all the GMPs requirements. If the retailer decides to import the flax omega-3 product, it then becomes responsible for the site license and the quality assurance report that necessitates trained quality assurance personnel, third party audit or a government authority with a MOU. Considering that a MOU does exist with the UK, the product has the support of the equivalence agreements. This means that there is an exchange of compliance information and exchange of inspection reports. An inspection report from the regulatory authority in the UK would be considered appropriate data to establish that the NHP has been fabricated, packaged/labelled, or tested against equivalent standards to the requirements of Part 3 of the *Natural Health Product Regulations*. The importers could pass the cost on to the foreign manufacturer but this cost may make the transaction not as profitable as expected. The existence of MOUs may cause the regulations to be border specific, as countries with MOUs will more easily enter the Canadian markets and other foreign countries may face additional barriers and resistance.

Lastly, the framework proposed a classification of technical barriers by regulatory goal. The main social objective of the NHP regulations is protecting the health and economic interest of consumers. It is not the intent of the regulations to protect producers and processors from imports or to protect the environment. The regulatory goal is both one of risk reducing and non-risk reducing. The policy goal for safety of the consumers of NHP is aimed at reducing risk due to potential harmful products. The regulations that specify quality standards such as efficacy do not reduce risk but are important for

consumer confidence. Likewise, under the Directive 2004/24/EC on Traditional Herbal Medicinal Products and the scheme by the UK to meet the directive's requirements, the main policy goal is that of protecting consumer health and safety.

5.3.4 Assessing the Trade Effect

Comparing these two markets, one could conclude that the regulations, although not identical, are rather similar. The omega-3 product in Canada will most likely be easy to register, as it is the simplest type of application. That being said, there will be a positive list that will aid registration in the UK, but it is not yet available. An equivalence agreement has been negotiated between the two countries, as they require many similar standards and pieces of evidence. The likelihood of regulatory protection and technical barrier for firms wishing to market within these two regions seems small. The equivalence agreement should act to decrease barriers, as it is a form of harmonization. There will be costs involved in submitting the various applications required but the equivalence agreement will help facilitate the processing of the applications. Both the regulations in Canada and the UK regulations are rather complex and require the time of personnel to fully understand them to ensure they meet the requirements. However, they are similar enough that a firm once having met the requirement of one market should easily be able to fulfill the standards of the other.

This leads to the discussion of the trade effect. For this case it seems that the most relevant trade effect will be that of the demand shift, as regulatory protection does not seem significant.

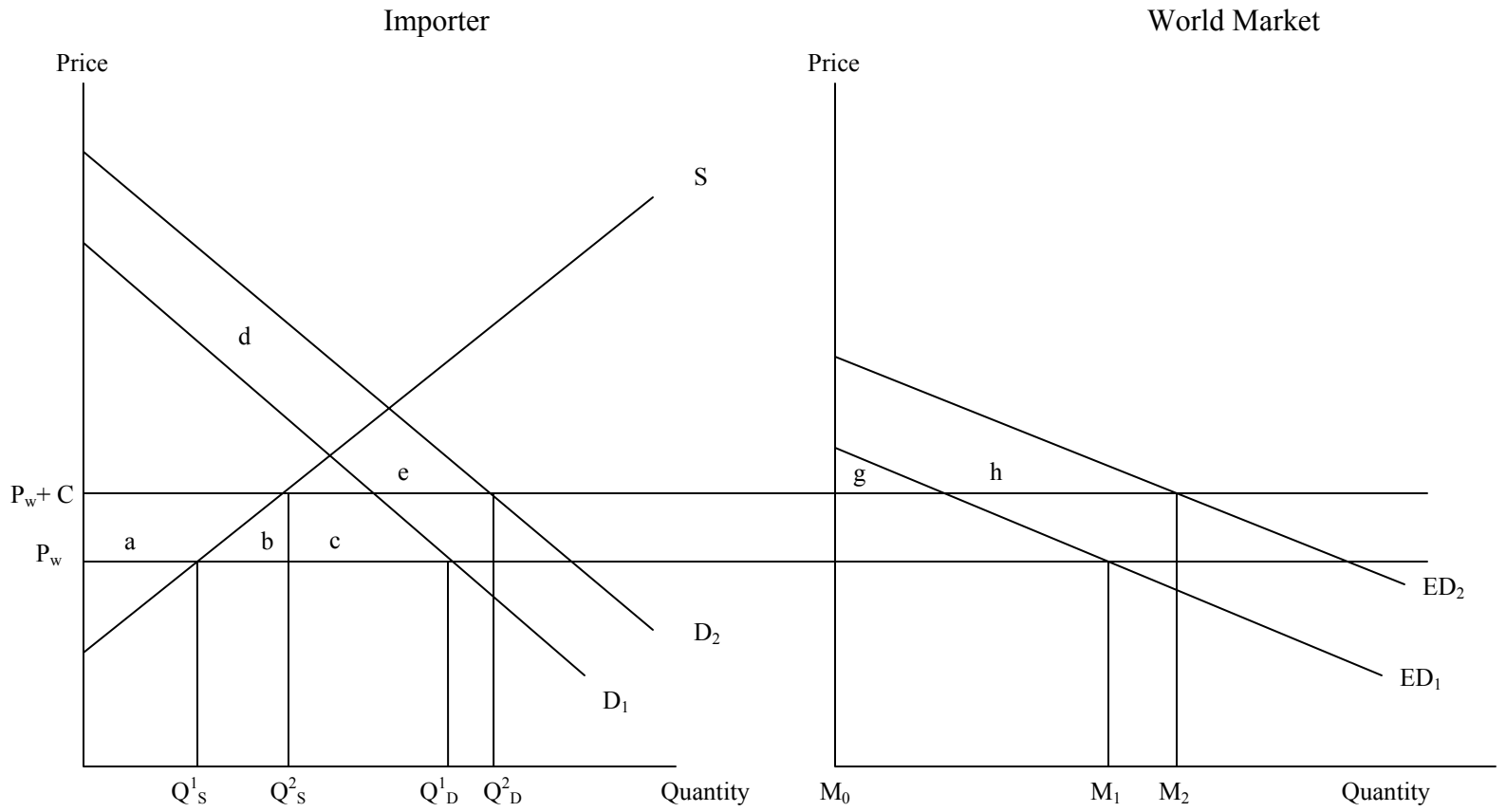

Figure 5.2: Demand Shift Model: Flax Case

This Figure illustrates the trade and welfare effects in the demand shift model, viewed from the perspective of the importing county. Trade in absence of the information provided by the regulation is given by M_1, corresponding to the import demand curve ED_1, which is derived from domestic demand D_1 and supply S. Enforcing the regulation raises demand to D_2, but the costs of compliance C is incurred, which raises the domestic price in the importing country to P_w+ C. This leads to trade of M_2 and domestic supplied is assumed to remain constant. The consumers will lose surplus area a+b+c, but will gain area d+e. The producers will gain surplus area a. In the world market the gains from trade are represented by area g+h.

The Demand Shift Model

The regulations governing the flax omega-3 supplement does, in fact, impart information and can, in turn, affect domestic demand as consumers benefit from knowing what to expect from products and have greater trust in the safety of the product. The demand shift model will show the benefits that accompany regulations. For the case of flax, the fact that the regulations have imparted positive information about the safety and effectiveness of the product is assumed. The importer in this case is the UK and the exporter is Canada. In figure 5.2, the model begins in the absence of technical regulation, and imports are at M_1, while excess (or import) demand is ED_1. The regulation is put in place, and due to the positive effect on consumers, the domestic demand increases to D_2. The price will increase from P_w to P_w+C due to the compliance cost of the technical measures. This, in turn, increases imports to M_2 (this could be above or below M_1).

Importer Perspective

If the producer decided not to conform to the regulation it could cause confusion and would result in decreased trade. The net welfare of the technical regulations (versus trade without regulations) is ambiguous. The net welfare outcome is the question of whether the consumer benefits are greater than the cost of providing the information. However, the gain from trade is definitely larger (area g+h) than without the demand shift (area g).

Exporter perspective

In view of the fact that only one importer is applying the regulations to all exporters, it will not affect world price and has no measurable effects on the exporters, the compliance costs are borne by the importer.

5.2.5 Conclusion: Flax Omega-3 Case

When comparing the UK regulatory regime and Canadian regulatory regime, the flax omega-3 products are regulated fairly equally. Although the regulations in the UK are not fully in effect and implemented, new products will need to meet their specifications. The fact that flax, as an omega-3 supplement, is cited as a monograph in Canada reduces the transaction costs involved with product licensing due to an

equivalency agreement between the two countries. The UK regulations currently do not have that same allowance, but, with the emergence of the positive list as is proposed, it may help alleviate the cost involved with product registration. With the new regulatory format that requires scientific evidence to substantiate health claims made by an omega-3 supplement, the potential for increased consumer demand and potentially large gains from trade seems likely.

5.4 Introduction: Elk Velvet Antler Supplement

It has been common practice in Asia for more than two millennia to use deer and deer parts as a source of medicine. The elk velvet antler (EVA) industry is growing in North America and Europe, although its main markets have been in Asia (Cooney 2001). Some consumers may consider this product a cure all as it has been linked to numerous different uses for a wide variety of aliments. Firstly, in traditional Chinese medicine EVA was used as all-purpose preventative tonic for general well-being and revitalization. Further, it has also been alleged to have more specific health and wellness effects including enhancing sexual function, lowering blood pressure, reducing cholesterol, slowing aging, promoting healing, reducing inflammation, boosting the immune system and increasing vitality. It has also been used for the treatment of numerous conditions such as: anemia, arthritis, impotence, insomnia, amnesia, external wounds and pain (Cooney 2001). However, there is some concern that there is a lack of peer reviewed scientific evidence to clearly assess the affects of EVA on health and well-being (NCARM 2002b; Natural Medicines Comprehensive Database 2005).

The EVA case study focuses on EVA and is expected to be more heavily regulated and complicated than the flax case. EVA is considered a traditional product, and to further complicate the regulatory environment, it contains animal tissue, which carries an additional set of concerns. Some scientific backing and traditional medicinal support exist but this product is not supported by the NHPD's *Compedium of Monographs* and consequently its application procedure in Canada is different from the flax case.

The case study starts with a background on EVA and its alleged health benefits. It examines the support for its health claims and some of the issues EVA currently faces.

This is followed by an analysis of the regulations EVA must comply with in Canada and the US. Classification of these regulations that apply to the EVA product are also discussed. Lastly, the trade effects of the technical measures are analyzed and discussed.

5.4.1 Elk Velvet Antler

Velvet antler products are derived from immature antlers of male members of the deer family. In North America, velvet antler is mostly obtained from elk. For the most part EVA is ground into a powder that is processed through various methods and sold in different NHP forms (gel capsules, chewable capsules or liquid extracts). It is still ambiguous which of the elements of EVA are responsible for its supposed pharmacological effects (NCARM 2002b). However, it is known that EVA contains several components including protein, collagen, proteoglycans and glycosaminoglycans (chondroitin sulfate), phospholipids, and a variety of minerals (calcium, phosphorous, magnesium). Some velvet antler preparations may contain growth factors (insulin-like growth factor 1, epidermal growth factor) and hormones (testosterone). Different velvet antler products may vary significantly in composition. Factors that may influence the chemical composition of velvet antler preparations include: which species of animal the antlers are taken from, what that animal is fed, when the antlers are harvested (degree of calcification) which part of the antler is used and how it is processed (NCARM 2002b).

First, EVA is said to enhance sexual functioning for men and women. The EVA industry and some traditional references have suggested that EVA supplements have a hormonal effect on testosterone and estrogen levels. In Cooney's review of scientific literature on the health benefit of velvet antler there was one article cited to support this use (Cooney 2001). However, in a search for referenced articles from western medicine sources there were no available articles. There has been much made of EVA and physical performance. Preliminary studies from Russia and New Zealand suggest that supplementation with velvet antler may improve athletic performance. The studies from New Zealand and Russia would have to be evaluated for credibility to be used as evidence for the Canadian regulatory procedure (NHPD 2003c). Next, EVA is promoted as having the ability to increase production of both red blood cells and white blood cells

(Alberta Elk Commission, 2005a). This reported use is linked with the apparent ability of velvet antler to increase oxygen uptake to the brain, liver and kidneys.

It is also claimed that EVA can help reduce blood pressure due to velvet antler's ability to increase dilation of the peripheral blood vessels. Protection against stress is another alleged benefit of EVA. Likewise, the Alberta Elk Commission lists anti-aging abilities, stimulation of growth and aid in recovery from traumatic injury as some of the potential advantages of EVA (Alberta Elk Commission 2005a). Despite the long history of use of EVA, there is little peer-reviewed scientific research that supports the therapeutic use of velvet antler. Most of the research on velvet antler has been conducted in Russia, China, Korea and New Zealand and does not meet the rigorous standards of methodology and reporting of the North American medical community (NCARM 2002b). When searching for articles in the North American medical community, few articles were found. One article examined the use of topical elk velvet antler cream applied externally to healing wounds in diabetic rats. This study did conclude that wound healing was accelerated with EVA use, and further research was suggested (Mikler, *et al.* 2004).

Recently, there has been anecdotal evidence that suggests EVA is effective in controlling symptoms of rheumatoid arthritis, particularly pain, but like most other alternative therapies, the effectiveness of EVA has not been studied scientifically (Alberta Elk Commission, 2005a). Velvet antler contains active ingredients, including omega 3 and 6 fatty acids, which have been shown to contribute to the health of joints and, perhaps, decrease inflammation, resulting in less tender and swollen joints. Velvet antler is also said to contain a fatty acid called prostaglandin, which has an anti-inflammatory effect (Ewwashkiw and Allen 2001). The University of Alberta is undertaking an in depth study, that began in January 2001, to determine the effectiveness of EVA in controlling symptoms and improving quality of life in persons with rheumatoid arthritis (University of Alberta 2001). The results of this phase-II clinical trial were reported in a journal article. The article concluded that EVA can be taken safely in conjunction with a number of rheumatoid arthritis medications and should be studied further to assess efficacy (Allen *et al.* 2002).

More recently, there has been a marketing push for the use of EVA to enhance pet health. In North America millions of pets suffer from chronic arthritis and other aging

diseases. There is a vast array of conventional drugs used to treat animals but the side effects have led animal health care providers to explore alternative medicines. Some of the benefits of EVA for pets are similar to that for humans while some differ. These benefits include: improved hair coat, improved kidney function, improved reproductive performance, and accelerated wound healing (Alberta Elk Commission 2005b). There is little to no scientific support of the use of EVA for pet health. One article was found that examined the use of EVA for the treatment of osteoarthrosis in dogs. This clinical trial found that the EVA was effective in alleviating the condition in arthritic dogs (Moreau, *et al.* 2004).

It is important to note that there is little scientific data on the long-term safety of EVA use. However, based on historical evidence, the use of EVA does not seem to produce any immediate side effects. Other than the possibility of allergic reaction, there is little mention in scientific literature of significant side effects from EVA use. It is recommended by the National Center for Agri-food Research in Medicines that a health care provider be consulted before beginning treatment with EVA (NCARM 2002b).

An issue that must be discussed when considering the safety of EVA is Chronic Wasting Disease (CWD). CWD is an untreatable, fatal neuro-degenerative disease that affects elk and deer alike. CWD belongs to a group of diseases called the Transmissible Spongiform Encephalopathies (TSE), a group which also includes Bovine Spongiform Encephalopathy (BSE) ("mad cow" disease), which affects cows, Scrapie, which affects sheep and Creutzfeldt-Jacob Disease (CJD), which affects humans (NCARM 2002b). At present, there is no direct evidence that CWD is a threat to humans. Nonetheless, the World Health Organization (WHO) advises that animals and humans should not consume products coming from animals infected with, or exposed to, CWD. Both the United States Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA) state that products derived from elk or deer that are known to be infected with CWD are not allowed to enter the food chain, but continue to allow the EVA product on the market. However, the largest market for EVA, Korea, closed is border to North America exports of EVA because of the existence of CWD in the region. This was a significant shock to the industry and caused prices to plummet (Curry 2003).

The evidence may not be conclusive for the benefits of EVA but its traditional role will help justify its current use. The discovery of CWD in Canada has had a detrimental effect on the EVA sector. When Korea closed its border to North American velvet antler it left producers relying on domestic and other North American destinations for their products. EVA was a product with a growing market in the natural health product sector and the industry believes it can overcome the hurdles caused by the detection of disease (Alberta Elk Commission, 2005a).

5.4.2 Regulations

Regulations are particularly important for natural health products, especially in the wake of a disease scare and with uncertainty surrounding transmission. This section begins by discussing the regulation this product would face in Canada. This differs from the last case as EVA is not cited as a monograph and is derived from animal tissue. Comparatively, the EVA product is discussed in terms of regulations it faces in the US. Once again, the regulatory hurdles are discussed in terms of a foreign and domestic source for the product.

5.4.2.1 Canada

This section discusses the regulation one must follow to market EVA in Canada. The main components of regulations pertaining to marketing the product are the site and product license.

Domestic Production

Site License

Once again it is necessary that any firm manufacturing, packaging, labelling or importing NHP must obtain a site license. The first step for a firm involved in manufacturing, packaging, labelling or importing EVA is to obtain a site license. Without a site license the firm is illegally operating and for a product license you must submit your site license number.[39]

Product License

[39] The details of the site license were provided in section 5.2.

Each product will have to meet different requirements for a product license depending on the characteristics of the product. The EVA application will be a traditional claim application. This means that this product is a long-used Asian remedy, classifying the product as traditional. In the traditional use classification, the firm is required to submit a completed license application. In addition to the application form, the proposed label text must be included. The proposed label text must also be presented with the application.

In addition to the product license application, a summary evidence report must be submitted. All relevant information, both favorable and unfavorable is required to be included in the evidence summary report. An overall analysis of all the evidence is required and favorable evidence must outweigh the unfavorable evidence. Products are divided into two categories according to the claims: traditional and non-traditional. The NHPD identifies that "traditional medicine represents the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" (NHPD 2003c). The NHPD considers traditional use to be the use of a medicinal ingredient within a cultural belief system for at least 50 consecutive years. In this case the EVA is a part of traditional Chinese Medicine. A traditional use claim is required to be prefaced with "traditionally used …" and this will inform the consumer that traditional evidence was used to support the claim.

The evidence summary report in the case of EVA must cite a minimum of two traditional references (e.g. text books) to support the use of the product. This includes details on the reference and what they support. There are numerous alleged benefits of EVA supplements and a firm may desire numerous claims for its product. This would require the firm to present two references for each use, or two references encompassing all the uses the firm intends to claim. However, the sources must be from two different reliable sources. The NHPD provides a list of suggested reliable references, which includes: referenced texts, pharmacopoeias, monographs, and journals with peer-reviewed research articles.

The two references are the first requirement. Following the references the firm must provide the details of its literature search strategy, complete with keywords used and limits, along with a rationale for excluding irrelevant information. After completing the search strategy and deciding which papers are relevant, the application must include a complete listing of evidence. This provides key information for particular citations and gives the NHPD an "at a glance" view of the results of relevant references to support the claim and conditions of use. Next the applicant must identify the types of evidence used (e.g. traditional, Pharmacopoeia, existing monographs, etc). Lastly, the applicant must include a critical overview, which is an analysis of the information from the line listing and other references to support the use of the medicinal ingredient, according to the recommended conditions of use. The critical overview is a summary of all relevant results supported by references and takes into account both favorable and unfavorable data. The applicant must also provide a comparative analysis of the traditional use claim and the non-traditional use claim when relevant, and any variations must be justified. Also, the critical overview must include a section with all relevant information on the pharmacology and toxicology of the medicinal ingredient based on the effects seen in humans and from animal and/or *in vitro* studies. Lastly, a dose and direction section is included that provides information on the dose, dosage form, route of administration, duration of use (if any) and frequency and the references that provided this information must be provided after each direction.

Firms wanting to sell EVA products must also submit a safety summary report. This report must identify any safety concerns about the ingredients, from references to traditional use, adverse reaction reports or published scientific literature. Each report will have four component parts (NHPD 2003c):

- All risk information from the two independent references used for traditional evidence claim and any risk information from the scientific literature;
- A review of scientific literature for information on risks regarding toxicological testing, adverse reactions, known interactions with food, drugs, or herbs, contradictions/warnings/cautions, or other information relevant to safety must be provided;

- Responses to a list of "safety factor" questions with regards to the ingredients; and
- Any additional information: previous market experience, including adverse reaction report when available.

Similarly, a quality summary report must be submitted. This report requires six major parts: (1) description of the manufacturing process; (2) sterilization and irradiated processes; (3) analytical procedures; (4) validation of analytical procedures; (5) justification of specifications; and (6) template for finished product specifications (NHPD 2003b). Due to the fact that EVA is extracted from a non-human animal it is important to describe the steps used to extract the product in the first section of this application (manufacturing process). The analytical procedures must describe testing methods used for the EVA supplement.

Lastly, because EVA is taken from a non-human animal material, a completed animal tissue form must be included in the application. This form is used to assess the risk before a product license is given. It basically specifies the type of animal used, the age, and the part of the animal used. In addition this form identifies the country of origin of the animals used.

All of these parts: product license application, evidence summary report, safety summary report, proposed label, quality summary report, and the animal tissue form make up the application dossier that must be submitted to license an EVA supplement. It is interesting to note that in the previous omega-3 flax case only a product application form was required.

Foreign Production

Site License

NHP that are imported from foreign sites require the importer to be licensed. That is to say, the onus is on the importer to provide evidence that imported goods come from sites that meet Canadian GMPs under part 3 of the *Natural Health Products Regulations*, or equivalent standards. An importer must submit a complete site license application, quality assurance report, or evidence of GMP compliance for each foreign

site. The site license application involves information and monitoring costs for the importing firm.

Product License

The product licensing regulations apply to foreign manufacturers as well. A product license must be obtained before selling an EVA capsule in Canada. The product license application will be identical to that of a domestic producer and a foreign producer will have to submit all the same documents that were required for EVA.

5.4.2.2 United States

This section discusses the regulations faced by an EVA product in the US market. It differs considerably from the Canadian approach to NHP and highlights a very different approach to regulating like products. Under DSHEA, dietary supplements are defined, in part, as products (other than tobacco) intended to supplement the diet that bear or contain one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or concentrate, metabolite, constituent, extract, or a combination of any ingredient mentioned above. In addition, dietary supplements are products intended for ingestion, are not represented for use as a conventional food or as a sole item of a meal or the diet, and must be labelled as dietary supplements (FDA 2005). As EVA is a capsule that includes minerals, proteins, collagen, proteoglycans and glycosaminoglycans, and phospholipids, and as is not a product that is intended for ingestion as a conventional food, it is appropriate to classify EVA as a dietary supplement.

Domestic Production

Facility Registration

As required by the Bioterrorism Act domestic and foreign facilities must register with the FDA. Facility registration appears to be simple and takes little time to complete.[40]

Product Registration

As discussed in section 5.2, there is no need for pre-market registration of products with the FDA. This means that the EVA product as it is not considered a new dietary ingredient, does not need FDA approval. A firm may market this product without confirmation from the FDA.

Foreign Production

Facility registration

Foreign sites are required to be registered under the Bioterrorism Act of 2002. The application procedure is exactly the same as that for domestic sites except that foreign site must have a US agent. A US agent is a person residing or maintaining a place of business in the US whom a foreign facility designates as its agent for the purpose of the registration regulation. The agent acts as a communication link between the FDA and the foreign facility for both routine and emergency communication (FDA 2003).

Product Registration

There are no distinctions between product registration for foreign and domestic producers. The FDA still requires no pre-market authorization for the sale of the EVA dietary supplement, as it is not subject to the new dietary ingredient clause. The EVA product can be easily marketed with little FDA involvement and with little to no paperwork. The FDA does require that import documents including an entry notice and an entry bond, be submitted to US Customs Service. The FDA will determine if they desire to inspect the imports at the border prior to entering the US. They may decide to inspect and will sample the import and possibly send it to their laboratories for testing. Import documents are general import procedures for FDA regulated products and inspection is to ensure the products are in compliance with the governing Acts.

5.4.3 Classification

Classification of the measures helps to compare the regulations and is essential to the analysis.

[40] Details of the Facility registration are found in section 5.2.

Table 5.3: Classification of technical barriers for EVA supplements by policy instrument

	Canada	US
Import bans		
Total ban	N/A	N/A
Partial ban	N/A	N/A
Technical Specifications		
Packaging Standards	GMPs packaging materials/procedure requirements to avoid contamination	N/A
Process Standards	Operations and sanitation standards included in GMPs	N/A
Product Standards	Product license requirement standards for safety, quality and efficacy; including extensive documentation	N/A
Information remedies		
Labelling requirements	Inner and outer label requirements and bilingual text requirements	Nutrition and Ingredient label standards
Controls on claims	Must provide evidence for claims	There are requirements for permitted claims

The first type of classification proposed is that of classification by policy instrument. A classification of the measures for the US and Canada is examined by policy instrument. When examining Table 5.3 it is easy to see that the product in Canada faces many more policy instruments than the same product in the US. Thus, it is easy to conclude that there are greater transactions and production costs involved with marketing the EVA product in Canada versus that of marketing in the US. Particularly, there are

many more technical specifications that must be met for EVA in Canada versus that of EVA in the US.

The framework continues by a classification of the measures by scope. Scope is important as it determines who bears the cost of the regulations. The US regulations are very few and uniform, in that they are applied uniformly to foreign and domestic producers. The Canadian measures are for the most part uniform, in that both domestic and foreign firms must obtain site and product licenses. The importer of EVA in Canada is required to ensure that the foreign site of manufacturing, labelling and packaging is in accordance with the GMPs set out by the regulations. The foreign site measure could be considered border specific as it applies to foreign product specifically.

Finally, one must consider the regulatory goal of the measure. Again, as in the case of the flax product, the main goal for the regulations in Canada is protecting the health and economic interest of consumers. It is not the intent of the regulation to protect producers and processors from competition from imports and the natural environment does not play a major role in these regulations. The goal of the US regulations is also consumer safety, and the main part of this goal is achieved through their requirements for labelling. There are limits on claims and strict labelling standards. The FDA will permit a health claim if: (1) the FDA has issued a letter stating the conditions under which they will consider exercising enforcement discretion for the specific health claim; and (2) the qualified claim is accompanied by an agency-approved disclaimer.

A product can state a claim as long as it states that the claim has not been approved by the FDA. However, these three types of structure and function claims are allowable:

- A statement that claims a benefit related to a classic nutrient deficiency disease and that discloses the prevalence of such disease in the U.S.;
- A statement that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, or characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; or,
- A statement that describes the general well-being arising from consumption of a nutrient or dietary ingredient.

Sometimes the difference can be ambiguous. Firms must decide what type of claims they want to make and how they are classified according to the regulations in the US. There are four other areas of claims that include: nutrient content claims, antioxidant claims, high potency claims, and percentage claims.[41] One product can present numerous claims.

5.4.4 Assessing the Trade Effect

The technical measures have been classified and this leads to assessing the trade effects of the technical barriers. The classification of both regulations in Canada and the US reveals that the US has little to no regulations that will cause an increase in cost due to compliance. Exported products from Canada do not have to meet the *Natural Health Product Regulations* and are not subject to any of the requirements of the *Natural Health Product Regulations*. For this reason, Canada is considered the importer because there are more significant trade effects. Trade is affected by the regulations and it will be the goal of the section to discuss the effect of the regulation in the Canadian and US market for EVA. This section initially discusses the regulatory protection model from the perspective of the importer and the exporter. Then it is followed by a discussion of the demand shift model that is based on a link between trade and domestic demand through information imparted by the regulations.

Regulatory Protection Model

Compliance with the regulation involves a cost, and because the regulations are applied domestically, local and foreign producers will incur this cost. However, it can be argued that because the regulations differ significantly between the US and Canada, the magnitude of the shift in domestic supply will be smaller than that of excess supply. This model assumes the small country case where the foreign supplier to Canada must comply with the regulations. The result will be that the importer will suffer a loss as they forgo the benefits that arise from trade. Consumers will lose as imports are cut off and, due to

[41] A percentage claim is a statement that characterizes the percentage level of a dietary ingredient for which a reference daily intake or a daily reference value has not been established (e.g. "40 percent omega-3 fatty acid, 10 mg per capsule").

regulation, the domestic supply also decreases. In the framework, the model examined the example where the policy had only the goal of increasing costs to foreign producers.

It is clear that there may be valid SPS considerations but it is debatable if the approach taken by Canadian regulatory authorities is the least trade distorting. However, considering the differences in the regulatory approach in Canada and the US it is important to take into account the recommended international standard in this area. The Codex Alimentarius Commission, or Codex, was created in 1963 by two U.N. organizations, the Food and Agriculture Organization and the World Health Organization. Its main purpose is to protect the health of consumers and to ensure fair practices in international trade in food through the development of food standards, codes of practice, guidelines and other recommendations. The Codex has produced draft guidelines for vitamin and mineral supplements. However, there are no recommendations for other health products such as herb botanicals. The US regulations are generally broader in scope and less restrictive then the Codex recommendations. The Canadian regulations also govern more than vitamins and minerals and are broader in scope. The Canadian regulations could be considered of a higher standard than the Codex recommendation. The difference in the regulated product scope is also significant. Vitamins and minerals are considered by the Canadian regulatory authorities to be in the lowest category of risk and for the most part included on the list of monographs. This means that vitamins and minerals will face less regulatory requirements in Canada. The other products included in the scope of the Canadian regulations, however, may merit increased regulatory requirements. Thus, there are no clear international standards that cover the array of products regulated by both the *Canadian Natural Health Product Regulations* and DSHEA. It could be viewed that regulations in Canada are a higher standard than scientifically needed and create a trade barrier for products imported from the US dietary supplement industry. Perhaps the regulations in the US produce the same end result with less regulatory involvement. The current international standards for these products are not that strict and probably do not regulate EVA as a product because it is clearly not a vitamin or mineral. The Canadian regulation may be creating high cost of compliance that is unnecessary. US firms may be able to argue that the regulations in Canada are more restrictive than needed.

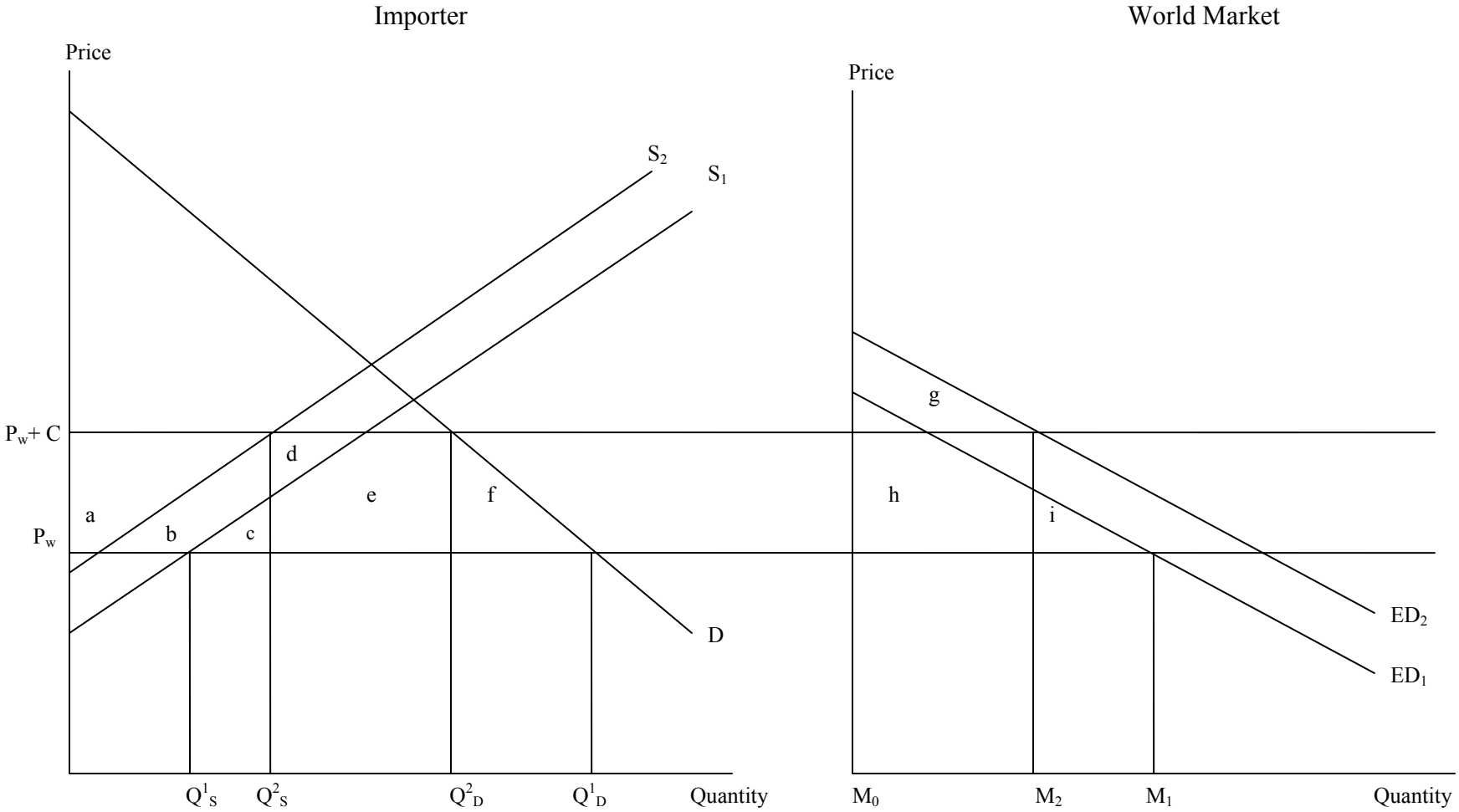

Figure 5.3: Regulatory Protection: EVA Case

This figure illustrates the trade and welfare effects in the regulatory protection model for EVA, viewed from the perspective of the importer (Canada). Assume the "small country" case for the importer, with domestic producers and consumers facing the world price, P_w. At this price quantity demanded is Q^1_D, and quantity supplied by domestic producers is Q^1_S, and the difference between these is the quantity imported M_1. When the importer adopts the regulation the price increases to P_w+ C, and due to increase costs domestic supply is shifted to S_2 and in turn the excess demand increases to ED_2. In this case imports have decreased to M_2. Consumer surplus falls, by area a+b+c+d+e+f, while producer surplus increases by area by area a. Producers do not gain area b+d due to the supply shift. There is a reduction in gains from trade of area h+i but the is a gain of area g due the excess demand shift.

Importer Perspective

The importer in our case is Canada, having applied numerous regulations that will increase costs in order to comply. This creates a more interesting analysis as considering Canada the exporter to the US there are little compliance costs involved. The model (figure 5.3) begins with these three assumptions: (1) the regulation applies to all exporters to the importing country, (2) only this importer applies the regulation, and (3) the level of imports is small relative to the total world market (small country assumption). At the outset, the unregulated market is as shown in figure 5.3, where the initial world price is P_w. At this price, the quantity demanded is Q_d^1 and the quantity supplied by the domestic market is Q_s^1 and the rest of demand is filled by imports of M_1. The regulation is applied to both domestic and foreign firms and increases the world price to P_w+C. The EVA case differs from the framework in that the domestic firms must also comply with the regulations. The domestic suppliers shift supply leftward (S_2) due to the stricter regulations, and likewise excess demand shifts from ED_1 to ED_2 because there is less EVA products supplied than is demanded by the domestic market. The increase in cost outweighs the increase in excess demand and imports fall to M_2. The quantity supplied in the domestic market increases from Q_s^1 to Q_s^2 and quantity demanded has decreased at the higher price to Q_d^2.

The consumer surplus loss represented by area a+b+c+d+e+f, while the domestic producers gain area a, they lose potential area b+d. Figure 5.3 could be very different by changing the magnitude of the shift in price and supply. However, it is fairly safe to assume the supply shift in the domestic market will not be as large as the price shift in our case. Numerous EVA supplements are produced in Canada and many of the larger NHP companies have been aware of the regulatory changes and, have had input on the regulatory approach and have been able to comply readily with the new regulations.

Exporters Perspective

The technical measure in our case is applied by one country only (importer specific) and because of the small country assumption the importer does not affect world market price. Consequently, the exporter, in general, should not notice the effect of the technical measures. The world market may shrink by an amount too small to notice and

other importers will buy the displaced goods. In practice, exporters usually are observed to care when even small markets are denied. It may be the case that the *ex post* effect on total export earnings may be insignificant but for each firm wishing to enter the market each barrier appears significant. Thus, it has been said that the exporter's concern may be a political reality even if it is an economic illusion (Roberts, *et al.* 1999). The exporter may incur costs of search for an alternative market but these may be less than the cost to comply with the regulations.

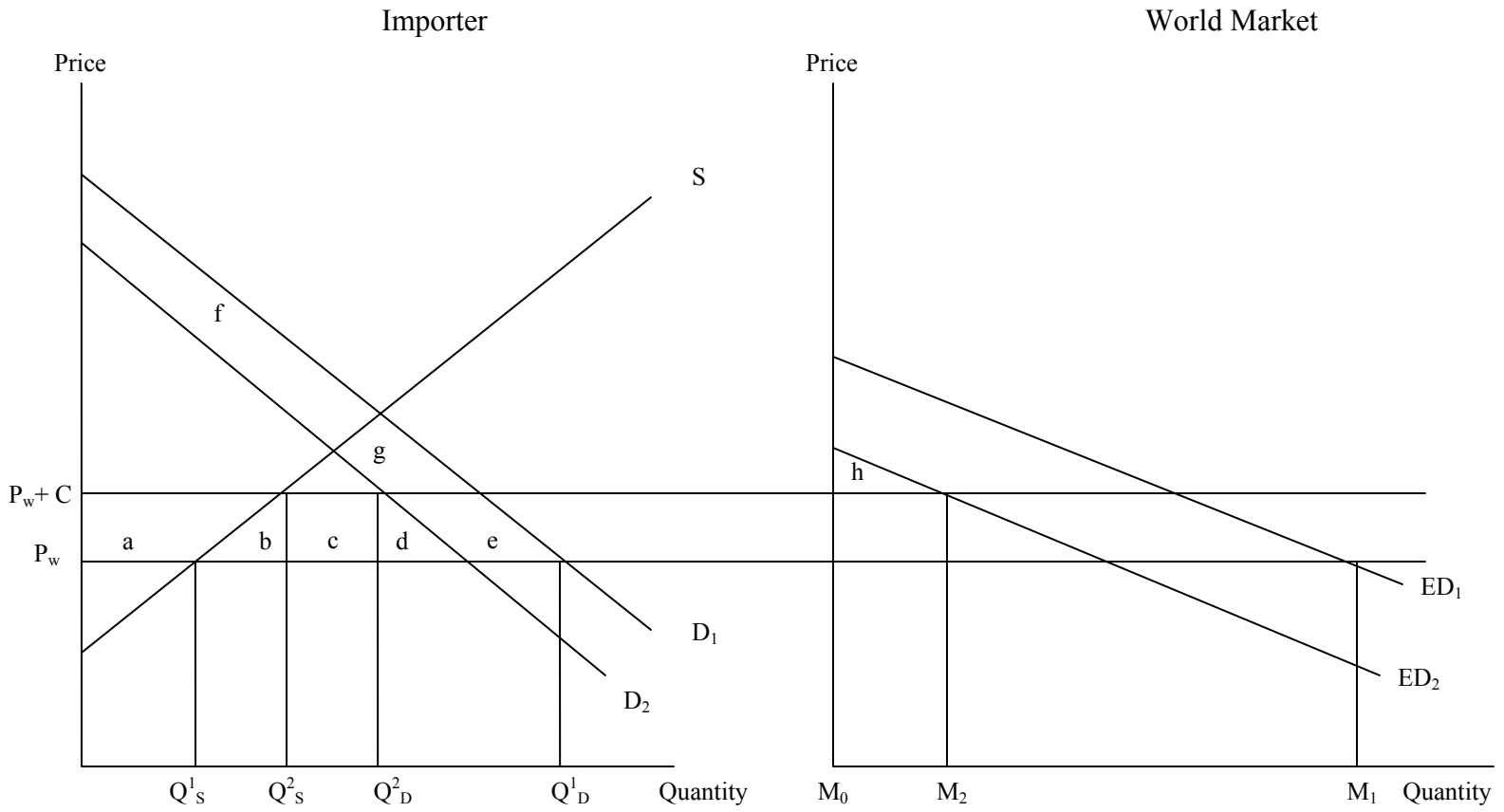

Figure 5.4: Demand Shift Model: EVA Case

This Figure illustrates the trade and welfare effects in the demand shift model, viewed from the perspective of the importing county (Canada). Trade in absence of the information provided by the regulation is given by M_1, corresponding to the import demand curve ED_1, which is derived from domestic demand D_1 and supply S. Enforcing the regulation decreases demand to D_2, and the costs of compliance C is incurred, which raises the domestic price in the importing country to P_w+ C. This leads to import trade of M_2. Domestic supply is assumed to remain constant. The consumers will lose surplus area a+b+c+d+e+f+g. The producers will gain surplus area a. In the world market the gains from trade are represented by area h, which is considerably smaller than what it would be without the regulation.

The Demand Shift Model

The link between trade and domestic demand affected by regulations that enable consumers to benefit from knowing more information is relevant to the trade effects. In the case of EVA it is unlikely that all claims will be justified through the application procedure. The credibility of the required evidence needed for the proof of efficacy for different EVA, uses may prove to be insufficient. Some of the current claims for EVA products may not pass the rigorous requirements of the Canadian regulations. The EVA product is potentially a case where increased information may in fact decrease demand for the EVA as product claims are weakened. The initial demand for the EVA can be illustrated in figure 5.4 by the curve D_1. The D_1 curve is assumed to reflect limited knowledge about the product. The imports are at M_1 and the excess demand is ED_1. Once the regulation is put in place and consumers are informed that many of the product claims are unjustified the demand decreases to D_2. It could be the case that the references to support all of the current uses of EVA are not available or are not considered credible, strong enough, or are considered to be of poor quality. This in turn decreases the excess demand and the level of imports to ED_2 and M_2, respectively. In addition, due to the regulation, the price has increased by the amount of the compliance cost. The Canadian regulations have spoiled the market for both domestic and foreign suppliers. The consumers left in this market are not as well off as before the regulations because the greater demand and lower costs left them with much greater surplus than in the case with the regulation. However, the pre-regulation level of benefit was illusionary being based on faulty information.

5.3.5 Conclusion: Elk Velvet Antler Case

There are major differences in the manner that the US and Canada have decided to regulate natural health products and specifically EVA. The US has taken an uninvolved, more self-monitored approach with some restrictions on claims but with a built in loophole that a firm can include claims as long as they state they are not approved by the FDA. In contrast, Canada has taken a fully hands on and active governmental role in the assessing of the market for EVA products. The difference in compliance costs between the US and Canadian markets seem significant. The information cost to register

a product in Canada is high as the procedure is complicated and time consuming. It may be the case that US firms will be deterred by the transaction costs of participating in the Canadian market and choose to sell their products outside of Canada. The new regulatory procedures in Canada will make it increasingly difficult to advertise or label the numerous claims that now accompany EVA. A company could position itself as a solely an exporter and will not have to comply with any of the Canadian *Natural Health Products Regulation.* Exporters exclusively could be attractive as the domestic in Canada is relatively smaller then the US and other market abroad. The EVA market was operating when completely focusing on exports to Korea. However, with the discovery of CWD, the market was devastated and this revealed the problem with solely exporting when a safety concern arises and firms are left with few market opportunities.

5.5 Introduction: Probiotic Supplement Case

Scientists are continually learning more about the numerous health benefits that products with live active bacteria cultures, also known as probiotics, can provide. Probiotics were defined by a group of experts convened by the Food and Agriculture Organization of the United Nations (FAO) as "live microorganisms administered in adequate amounts which confer a beneficial health effect on the host" (FAO and WHO 2002). Most probiotics are bacteria, which are small, single celled organisms that are most commonly categorized by scientists with genus, species, and strain names. The roots of probiotics lie in centuries of folklore that suggested fermented dairy products containing live active cultures were healthy (US Probiotics 2005c). Recently, more controlled scientific investigations have supported the view that probiotics can have positive health effects.

This chapter studies a probiotic combination product that incorporates different strains of bacteria to form a combination product. This product is not considered traditional and is studied as a combination product, whereas the last two cases were single active ingredient products. This case begins by discussing the role of probiotics and health. It examines some of the scientific research that has supported the possibility that probiotics can increase wellness. The necessary steps to register and market this

product in Canada as well as the US follows. The regulations are classified and examined according to the framework.

5.5.1 Probiotics

As noted, probiotics are live microorganisms that can lead to positive health effects for consumers. The question of how probiotics work lies in the microbiology and physiology of the human gastrointestinal tract. Humans and animals are host to many types and high numbers of microbes that live on our skin, in our mouths, in women's vaginal tracts and in our gastrointestinal tract. It is estimated that there are more microbes associated with the human body (about 10^{14} bacterial cells) than human cells in the body (about 10^{13}). In addition to the vast amount of microbes carried by the human body there is a large diversity of bacteria and it is estimated that more than 400 different bacteria make their homes in humans (US Probiotics 2005b). Most of the bacteria are not harmful and in fact contribute positively to normal human growth and development. However, some bacteria can have negative influences and it is important to maintain the balance of microbes such that the beneficial bacteria outweigh the potentially harmful ones.

The observation that some bacteria may be helpful to human health is by no means a new idea. Elie Metchnikoff, Nobel Prize winner for Physiology or Medicine, noted in some of his research during the 19th century that people in the Balkans who ate yogurt and other cultured foods lived longer (Encyclopedia Britannica 2005). Probiotics, a word that is derived from Greek and Latin words meaning "for life", are a century old but recently has become the focus of scientific scrutiny. Probiotics are area of the natural health product industry that is viewed as expanding and gaining popularity. Grant Ferrier, the editor of the Nutrition Business Journal, was quoted in a USA Today article as saying he estimates that U.S. sales of probiotic supplements have increased 10 percent to 15 percent annually over the past five years, reaching US$170 million in 2002 (Rubin 2003).

A large body of literature exists pertaining to the health benefits of probiotic cultures. A search of the bibliographic database, Medline[42], shows how the science has

[42] Medline is bibliographic database covering clinical medicine, including: internal medicine, general medicine, primary care, family medicine, and general practice. This database contains reference to articles

grown over that past 15 years. Prior to 1990, only five citations appeared in a search for "probiotic" with zero citations for probiotic when the search was limited to clinical trials. This is a complete contrast to a search of publications including the past fifteen years, which returned 1189 probiotic citations and 102 citations when limited to clinical trials. When examining the results of scientific research on probiotics, it is important to recognize that different strains, species and genera of bacteria may have different effects. For the most part, it is imperative to consider the research specific to the study and type of probiotic tested. The following discussion of the health effect of probiotics should be taken as general description of probiotic activity and one must keep in mind that any one effect may have been documented with only one or a limited number of probiotic strains.

Many types of diarrheal illnesses, with many different causes, can disrupt intestinal function. Perhaps the most substantiated benefits of probiotics are the ability to decrease the incidence or duration of certain diarrheas. A paper published in *Pediatric* in 2002 reviewed nine studies on the effect of lactobacillus (a probiotic) as therapy for diarrhea in children. This paper concluded that lactobacillus is safe and effective as a treatment for children with acute infectious diarrhea (Van Neial *et al.* 2002). This study does combine data from different species and strains of lactobacillus into one analysis and could be criticized on this basis, but the positive conclusions suggest that, at least for the strains studied, the results are useful. Also focusing on children, a double blind, placebo controlled, randomized trial was conducted to investigate the effect of two different probiotics in preventing infection in infants attending childcare centers. Both bifidobacterium lactis (BB-12), and lactobacillus reuteri (American Type Culture Collection 55730), or lastly no probiotics were administered in the infant formula. The conclusion was that the childcare infants fed a formula supplemented with L reuteri or B lactis had fewer and shorter episodes of diarrhea, with no effect on respiratory illnesses, however, these effects were more prominent with L reuteri (Weizman, *et al.* 2005).

Another common use of probiotics is to counter the side effects associated with individuals taking antibiotics. The purpose of antibiotics is to kill harmful bacteria but unfortunately they frequently kill benficial bacteria as well, and use of the antibiotic can

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from more than 3500 journals. Medline is considered the primary source in the US for information from the biomedical literature.

result in a disruption of the bacterial flora leading to diarrhea and other intestinal disturbances. Reintroducing beneficial bacteria during and after antibiotic therapy seems to minimize disruptive effects of antibiotic use. Another meta-analysis[43] looked at the impact of probiotics (*Lactobacillus rhamnosus* GG or *Saccharomyces boulardii*) on antibiotic-associated diarrhea. This paper concluded that the evidence suggests that probiotics can be used to prevent antibiotic associated diarrhea, but that no strong effect on the ability of probiotics to treat diarrhea exists (Cremonini, *et al.* 1995).

Another area of health where probiotics may prove to be effective is the fight against irritable bowel syndrome (IBS). IBS is a functional bowel disorder that can be characterized by symptoms of abdominal pain, cramps, gas, bloating, diarrhea and constipation (US Probiotics 2005a). The US probiotic organization reports that only a few controlled studies have been conducted evaluating probiotics and IBS and some symptom relief (mostly for diarrhea and abdominal pain or bloating) has been reported in studies published to date (US probiotics 2005a). Likewise, inflammatory bowel disease, such as ulcerative colitis and Crohn's disease are serious intestinal diseases that can lead to the removal of the colon, is another area of research into probiotics. Some studies have shown that high levels of certain probiotics strains can extend the disease free remission period. Studies also have documented this effect on remission of pouchtis. After undergoing a surgery for ulcerative colitis to remove the colon and form an ileal pouch that serves as the fecal reservoir and is connected to the anus, there are often complications. Inflammation of the ileal pouch, or pouchitis, is the most common long-term complication from this surgery. One study used a combination product of numerous different probiotics and found that there was a statistically significant improvement demonstrated by the probiotic product. Probiotics can be an effective treatment for the prevention of the onset of acute pouchitis and improves the quality of life in patients with ileal pouches (Gionchetti, *et al.* 2003).

It has been hypothesized that probiotic cultures might be able to decrease exposure to chemical carcinogens that are known cancer-causing agents. Probiotics may be able to: (1) detoxify ingested carcinogens; (2) alter the environment of the intestine

[43] A meta-analysis is a method to integrate and summarize the findings from a body of research. This has been referred to as an analysis of analyses and is a statistical analysis of a collection of individual studies.

and thereby decease populations or metabolic activities of bacteria that may generate carcinogenic compounds; (3) produce metabolic products which improve a cell's ability to die when it should die (a process known as apoptosis or programmed cell death); (4) produce compounds that inhibit the growth of tumor cells; or (5) stimulate the immune system to better defend against cell proliferation (US Probiotics 2005a). There have been some preliminary tests done on animals where the results suggest that probiotic cultures may positively influence the gastrointestinal environment to decrease the risk of cancer (US Probiotics 2005a). However, there must be more research to demonstrate the effect in humans that will be expensive to conduct.

The human immune system provides the body with its primary defense against microbial pathogens that have entered the body. The immune system is complex and involves both cell-based and antibody based responses to potential infectious agents. Probiotic cultures have been shown in a variety of test systems to stimulate certain cellular and antibody functions of the immune system. Many studies have begun to examine this relationship and the results accumulated so far suggest that probiotics may provide an additional tool to help the human body protect itself. When searching the Medline database, 75 referenced articles were found on the subject of probiotics and immune system stimulations.

The next area of health effects that has been documented for probiotics is their role in alleviating vaginosis. The vagina is a finely balanced ecosystem of different microbes and disruptions of this ecosystem can lead to a microbiological imbalance and symptoms of vaginosis. Vaginosis used to be considered a mere annoyance but it is now being examined for a role in serious conditions including pelvic inflammatory disease, pregnancy related complications, and increased susceptibility to AIDS infection. Probiotics can maintain a favorable pH in the acidic range and inhibit pathogens. The result of one study that examined 64 healthy women found that the combination of probiotics used was not only safe for healthy women but it can reduce colonization of the vagina by potential pathogenic bacteria and yeast (Reid *et al.* 2003).

Lastly, the other potential health effect of probiotic use is associated with allergies. Allergies are on the rise in industrial nations and it is estimated that the incidence of asthma in the US doubled between 1980 and 2000 (US Probiotics 2005a). There has

been considerable debate regarding the causes for increased levels of allergies. One hypothesis, known as the "hygiene hypothesis", is based on the observation that lower allergy incidence is associated with environments that have greater number of microbes, such as day cares, farms, or in homes with siblings or pets. This is by no means the only thought on the issue and there are many reports taking an opposite view. However, this hypothesis led researchers in Finland to conduct a study evaluating the effects of a Lactobacillus strain on the incidence on atopic eczema in 132 infants at high risk of developing eczema. The study was double blind and placebo controlled, where pregnant mothers two-to-four weeks before delivery and newborn babies through six months of age were given Lactobacillus rhamnosus GG. The infants were followed to two years of age and the incidence of recurring atopic eczema was recorded. The study reported a 50 percent drop in incidence of recurring atopic eczema in the group receiving the probiotic supplement. A follow up study of these same children at four years of age indicated that these same trends were still present. These results suggest that exposure to the right types of microbes early in life may decrease the risk of allergy (Warner 2003).

Other health effects have been linked to probiotic use but are of less importance and less publicized. Lactose intolerance may be aided with the use of probiotics. As well, there has been some investigation of the link between probiotics and hypertension. Likewise, there is research into the links between small bacterial overgrowth and probiotics. Also, results suggest that manipulation of gut flora with the right probiotics may have a positive impact on causes of kidney stones. Lastly, there has been some research into probiotic use and their effect on serum cholesterol levels. All these areas are explored by the US probiotic organization in the health effects section (US Probiotics 2005a).

There seems to be strong evidence that support the use of probiotics. Probiotics are a growing sector and the scientific community seems to support their use. There are many different areas where probiotics have been found to be useful and this may complicate the regulatory process. The probiotic case continues with a discussion of the regulations facing a combination probiotic supplement and the steps the firm must pursue to license and sell the product.

5.5.2 Regulations

This section discusses the regulations that a combination probiotic product would face in both the Canadian and US markets. The US was chosen as it was identified by Statistics Canada as the primary destination for Canadian NHP exports (Statistics Canada 2003). The case is an examination of a probiotic that consists of different quantities of five bacteria: *Lactobacillus rhamnosus, Bifidobacterium breve, Bifidobacterium longum, Lactobacillus sporogenes,* and *Lactobacillus acidophilus*. This product will face different set of regulations in the two markets and these differences may act as technical barriers to trade.

5.5.2.1 Canada

Canada is the first market of discussion and entails a look at the steps necessary to market a combination probiotic supplement in Canada. The major components of the regulations that a firm must comply with are the site license and the product license.

Domestic Production

Site License

Like the previous two cases the first requirement for marketing the probiotic supplement is the site license. Without a site license a firm will not be able to operate for the sale of domestic products.[44]

Product License

As previously mentioned, the *Natural Health Product Regulations* require individuals to obtain a product license before they can sell a natural health product in Canada (Natural Health Product Regulations, Section 4 2001). To obtain a product license, individuals must submit a product license application to the Natural Health Products Directorate (NHPD). This application must include sufficient data to allow the NHPD to evaluate the safety, efficacy and quality of the NHP when used under the recommended conditions of use. The requirements of the application will depend on the type of product that one wishes to license. Of the five types of application, this case will be considered a non-traditional claim submission. A non-traditional calim requires a

product license application form, the label text, evidence summary report with a minimum of two pieces of evidence (per claim) to support the product (e.g. clinical trials), a safety summary report, and a quality summary report (finished product specifications).

In addition to the product license application, a summary evidence report must be submitted. The amount of evidence needed to substantiate a claim will depend on the claim and the severity of any named symptoms or conditions. The application must provide references to support all the conditions of use. The types of evidence that are allowable are: reference to scientific evidence, reference from expert opinion reports, reference from reputable regulatory authorities[45], reference to clinical studies and references to previous marketing experiences. The NHPD will evaluate the evidence on its credibility, strength and quality. Likewise, the probiotic product application must also include a safety summary report. The safety summary report must identify any safety concerns about the ingredients, from references to traditional use, adverse reaction reports or published scientific literature.

Due to the fact that the case is a combination product, it must be shown that the combination is safe and that each component contributes positively to the claimed intended effects. There must also be a clear rationale for the combination. In the case of the probiotic, it could be that some strains have different effects and the combination will lead to a stronger product that is more effective. Also, there is a specific section that pertains to probiotics that must be completed. Probiotics differ from other NHP, as one cannot use conventional toxicology and safety evaluation, as it is not considered sufficient to evaluate the safety of probiotic microorganisms. The main function of the probiotic is that it is a live culture and is supposed to survive or/and grow in order to benefit humans, which makes the use of these conventional tests ineffective for probiotics, as the testing may kill the bacteria and leave it ineffective. Therefore, a multi-disciplinary approach is necessary to examine the pathological, genetic, toxicological, immunological, gastro-enterological, and microbiological aspects of the safety of probiotic strains. This approach is based on the FAO/WHO's "Guidelines for the evaluation of probiotics in

[44] Details of the site license application and requirements are provided in section 5.2.
[45] Reputable regulatory authorities are not identified but referred to in general (NHPD 2003c).

food - Report of a joint FAO/WHO working group on drafting guidelines for the evaluation of probiotics in food" (NHPD 2003c; FAO and WHO 2002).

Similarly, a quality summary report must be submitted. As with the EVA case, this report requires six major parts: (1) description of the manufacturing process; (2) sterilization and irradiated processes; (3) analytical procedures; (4) validation of analytical procedures; (5) justification of specifications; and (6) template for finished product specifications (NHPD 2003 b).

All these parts combined are necessary for the submission if the NHPD is to begin the process of approving a product license for the combination probiotic supplement.

Foreign Production

Site License

Once again, NHP that are imported from foreign sites require the importer to be licensed. An importer must submit a complete site license application, quality assurance report, or evidence of GMP compliance for each foreign site.

Product License

The product licensing regulations apply to a foreign manufacturer as well. A product license must be obtained before selling the probiotic combination supplement in Canada. The product license application will be identical to that of a domestic firm. All the same documentation must be submitted by the foreign firm as is required for the domestic firm.

5.5.2.2 United States

This section discusses the probiotic supplement and US regulations. First, in the US it is important to note that probiotic bacteria are sold in two different formats: food and dietary supplements. Food products containing probiotics are almost exclusively dairy products, capitalizing on the traditional association of lactic acid bacteria with fermented milk. Probiotic enhanced fluid milk and yogurt, are the common products associated with probiotic bacteria in the US. On the other hand, the dietary supplement market for probiotic cultures seems to be a more diverse and active market than probiotics for dairy. The supplements market contains many different product formats and contents, including

capsules, liquids, tablets and food-like formats. These dietary supplements are purchased mainly at health food stores or natural food grocery stores. For our case, the probiotic capsule is considered a dietary supplement. As defined by Congress in the Dietary Supplement Health and Education Act (DSHEA), which became law in 1994, a dietary supplement is a product (other than tobacco) that (DSHEA 1994):

- Is intended to supplement the diet;
- Contains one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents;
- Is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and
- Is labeled on the front panel as being a dietary supplement.

As our product is a capsule it is appropriate to define it as a dietary supplement.

Domestic Production

Facility Registration

Facilities are required to register with the FDA under the Bioterrorism Act. Facility registration was previously discussed in section 5.2.

Product Registration

Under DSHEA, it is the responsibility of the firm to determine that the dietary supplements it manufacturers or distributes are safe and that representations and claims surrounding the dietary supplement are substantiated by adequate evidence to show they are not misleading or false. The FDA does not approve dietary supplements before they are marketed in the US. The only exception to the rule is that new dietary ingredients, which require a pre-market review for safety data and other information required by law. Since the component ingredients of the probiotic supplement were sold in the US prior to October 15, 1994, it is not considered a new dietary ingredient and requires no pre-market review.

5.5.3 Classification

It is essential to classify the measures to compare them and hopefully identify areas that may be susceptible to misuse as technical barriers to trade. The first type of classification proposed is that of classification by policy instrument. A classification of

the measures that the probiotic supplement faces in the US and Canada is examined by policy instrument. Classification by policy instrument is best illustrated by table 5.4 which is a side-by-side comparison. An examination of Table 5.4, makes it clear that the Canadian regulatory framework has more specific policy instruments in place to regulate the product. However, the hard work to prove efficacy may have its benefits in Canada, as the product may then be able to carry more claims in the US market. The use of claims may be very beneficial in the probiotic case, as it seems there are a considerable number of credible references for the health benefit of the probiotic strains that are the indigents of the probiotic combination product.

The next step of the framework examines the scope of the measures in place. Scope is important as it determines who bears the cost of the regulations. The US regulations are uniform in that they are applied uniformly to foreign and domestic producers. The Canadian measures are, for the most part, uniform in that both domestic and foreign firms must obtain site and product licenses. The importer of probiotic supplements in Canada is required to ensure that the foreign site of manufacturing, labelling and packaging is in accordance with the GMPs set out by the regulations. This measure could be considered border specific as they apply to foreign product specifically. A retailer that supplies the product to the consumer may prefer a domestic supplier for the product thereby avoiding the regulations and the costs associated with compliance.

Finally, one must consider the regulatory goal of the policies in place. Once again, it is the case that the Canadian regulations most likely are in place to protect the health of consumers. This does not mean that the regulations could not be manipulated to benefit local firms. Often the manner that the regulations are administered could be influenced to the benefit of local firms. The US regulations are also in place to protect consumers' health by restricting health claims that may not be suitable for given products.

Table 5.4: Classification by policy instrument of technical barriers for a probiotic supplements

	Canada	US
Import bans		
Total ban	N/A	N/A
Partial ban	N/A	N/A
Technical Specifications		
Packaging Standards	GMPs packaging materials/procedure requirements to avoid contamination	N/A
Process Standards	Operations and sanitation standards included in GMPs. Product testing and record keeping. Stability and storage requirements important to probiotics.	N/A
Product Standards	Product license requirement standards for safety, quality and efficacy. Including extensive documentation and specification for probiotics	N/A
Information remedies		
Labelling requirements	Inner and outer label requirements and bilingual text requirements	Nutrition and Ingredient label standards
Controls on claims	Must provide evidence for claims	There are requirements for permitted claims

5.5.4 Assessing the Trade Effect

Successfully classification is the first step to examine potential trade effects. The classification of both regulations in Canada and the US reveals that the US has a less involved regulatory system as compared with the intensive pre-market evidence approach in Canada. The difference between the two countries leads to many possibilities when considering the trade of natural health products between the two countries.

Regulatory Protection Model

Although it may not be the intent of the regulation, there may be underlying regulatory protection involved with the Canadian NHP regulations. It is fairly clear that to comply with the regulations a firm must allocate resources and, in the case of the Canadian regulation this could become a significant cost. The US regulations are less restrictive for process and product specifications. The difference between the markets may, in turn, cause US firms to view the Canadian market as a "hassle" that bogs them down with regulatory measures and they may decide to find alternative markets that more closely mirror the US regulation with which firms are familiar. Likewise, the market in Canada may not be viewed as large enough to incur the costs associated with meeting the regulations in place and firms will turn elsewhere. The cost of compliance could, in the short run, decrease imports to Canada and perhaps give domestic firms the chance to establish their brands and dominate the market. However, if international regulatory bodies continue to suggest increased stricter regulations, and other markets begin to follow suit and increase the regulations for natural health products, Canada may have a first mover advantage. However, because of the relatively small size of the Canadian market, it may not be able to induce changes in regulation in other major markets such as the US. If Canada is too small to induce others to follow suite, then there is not likely to be a first mover advantage. The consumers may end up losing, as the compliance cost involved with the regulation will be shifted to the price of the product and the consumers to lose surpluses that they previously enjoyed.

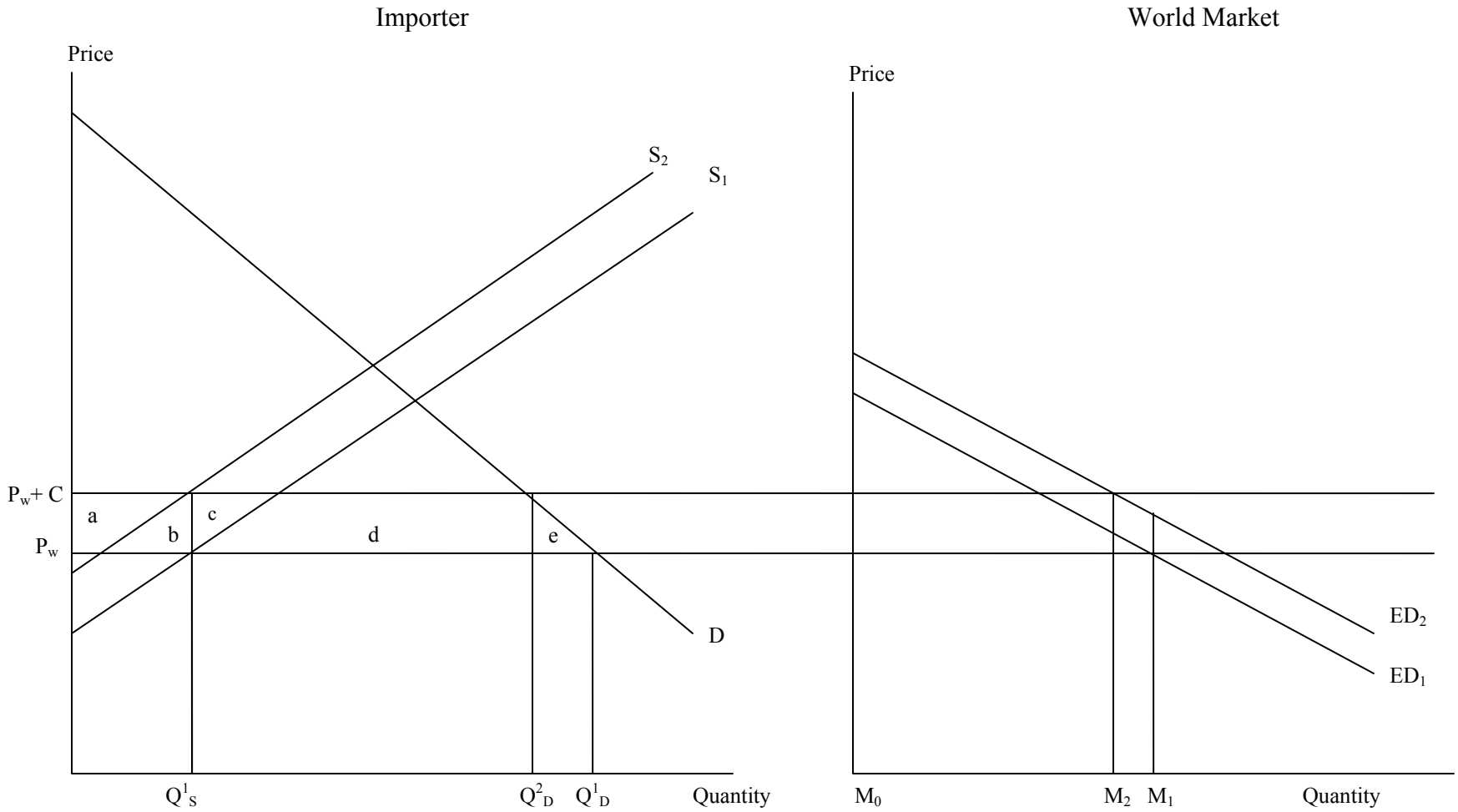

Figure 5.5: Regulatory Protection: Probiotic Case

This figure illustrates the trade and welfare effects in the regulatory protection model for the probiotic case, viewed from the perspective of the importer (Canada). Initially the world price is P_w.. At this price quantity demanded is Q^1_D, and quantity supplied by domestic producers is Q^1_S, and the difference between these is the quantity imported M_1. When the importer adopts the regulation the price increases to P_w+ C, and due to increase costs domestic supply is shifted to S_2 and in turn the excess demand increases to ED_2. In this case imports have decreased to M_2, however, due the relative magnitudes of the supply and price shift the quantity supplied by the domestic market has remained the same. Consumer surplus falls, by area a+b+c+d+e, while producers surplus increases by area by area a. Producers do not benefit by area b+c because of the supply shift.

Importer perspective

Canada is considered the importer, which has applied regulations that increased the price by the amount of compliance costs. Canada is used as the importer because it is important for the Canadian NHP industry to both import and export. As well, because the US has little compliance costs associated with its market for NHP and is not interesting to model. Once again the model begins with these three assumptions: (1) the regulation applies to all exporters to the importing country; (2) only this importer applies the regulation; and (3) the level of imports is small relative to the total world market (small country assumption).

In the absence of the regulation the domestic demand is D and the supply is S_1 (figure 5.5). The current price of the probiotic supplement is P_w and this causes excess demand of ED_1 and import levels of M_1. The regulations are put in place and are uniform and are applied to both domestic and foreign producers. This causes a supply shift in the domestic market from S_1 to S_2, as the regulation deters some firms and/or raises costs of existing firms.[46] In addition, the price increases to P_w+C. This price increase is represented as a large shift because the regulations are intense, complex and require a significant amount of a firm's resources. The excess demand in turn shifts up to ED_2 and the imports have decreased because the price increase outweighs the excess demand shift. Therefore, consumers will lose surplus area of a+b+c+d +e and the regulatory protection granted by the regulations have increased producer surplus by area a, however, there was also a loss in potential producer surplus due to the supply shift. It in interesting to note that this case differs from the EVA case because the shift were relatively smaller and the quantity supplied in the domestic market (Q^1_S) did not change as the supply shift and price shift cancelled one another out.

Exporter perspective

The technical measure in our case is applied by one country only (importer specific) and because of the small country assumption the importer does not affect the world market price. The world market may shrink but by an amount too small to notice and other importers will buy the displaced goods. In practice, exporters usually are

[46] It can be the case that both fixed costs and marginal costs are affected by the regulations.

observed to care when even small markets are denied. The exporting firm may have to incur cost to search for alternative markets for the displaced products. If suitable alternative market cannot be found then the exporter (if large enough) may be able to distort world market with excess supply.

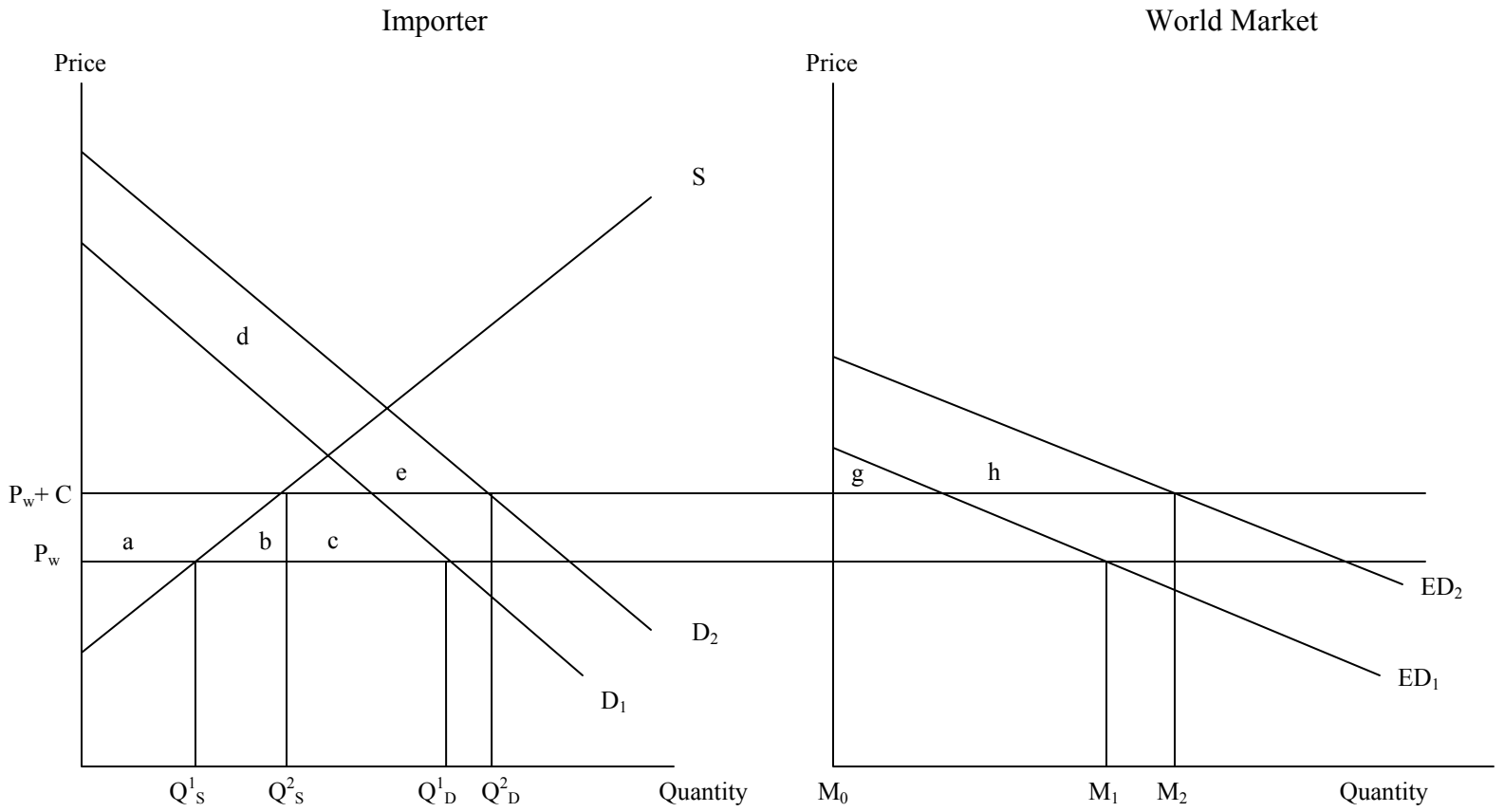

Figure 5.6: Demand Shift Model: Probiotic Case

This Figure illustrates the trade and welfare effects in the demand shift model for the probiotic case, viewed from the perspective of the importing county. Trade in absence of the information provided by the regulation is given by M_1, corresponding to the import demand curve ED_1, which is derived from domestic demand D_1 and supply S. Enforcing the regulation raises demand to D_2, but the costs of compliance C is incurred, which raises the domestic price in the importing country to P_w+ C. This leads to trade of M_2 and domestic supply is assumed to remain constant. The consumers will lose surplus area a+b+c, but will gain area d+e. The producers will gain surplus area a. In the world market the gains from trade are represented by area g+h.

Demand Shift

Predicting demand shifts for a given product is difficult. Whether increased allowable claims (one of the goals of the regulations during the preliminary stages of development) would in fact increase consumer demand for probiotics it is difficult to predict. There seems to be a significant amount of literature that supports probiotic use and there are already clinical trials, for these products that will provide evidence for the different areas of their health benefits. If indeed the demand curve is shifted rightwards, consumers that have acquired more information have led to a positive effect on demand. Whether the gains from the demand shift outweigh the potential protective effects is ambiguous, and therefore an empirical question. This is virtually the same situation as the flax case, which also modeled an increase in demand.

Importer Perspective

The assumption in this model is that the regulatory regime in Canada benefits consumers and makes the product more useful. As the regulations are put in place, the domestic demand increases from D_1 to D_2 (figure 5.6). This causes a shift in the world market as the excess demand also shifts from ED_1 to ED_2. The price has also increased to P_w+C because of the compliance costs associated with the regulations. The consumers have gained area d+e but in turn due to the increased cost of product because of the regulations, have lost area a+b+c. Whether the consumers are experiencing welfare gain is ambiguous and depends on whether the consumers' benefits from the regulations are greater than the cost of providing the information. The gain from trade (area g+h) is greater than in a case without an increase in demand, in which case the gain would only be area g.

5.4.5 Conclusion: Probiotic Case

It is clear that there are differences between the regulatory approach in the US and Canada. The manner in which the Canadian regulations are administered could either benefit (increased information) or disadvantage Canadian consumers who may have longer waits for up and coming products and may face higher costs as compared to their US counterparts. A comparison of the cases and a discussion of world trends for natural

health products may shed light on the difference between cases and markets. Probiotics seems to be a valid natural health product that could benefit many Canadians suffering from numerous aliments and it is important that regulations do not inhibit this market. The probiotic product in Canada may enable more substantiated health claims on the label. However, even when some claims may be restricted, there seems to be few deterrents in place to prevent consumers from using supplements for other purposes. The Internet is a convenient source of considerable information, some of which may be misleading for natural health product users and could affect the ability of the regulatory system to limit uses of the products.

5.6 Summary

The three cases all present different elements that affected the regulatory requirements for each product. Firstly, the case of the flax omega-3 fatty acid supplement is by far the simplest case mainly due to its inclusion in the Compendium of Monographs in Canada. This case is also examined in the UK where the regulations are at elementary stages but are taking shape in a form that is similar to Canada. The positive list of herbal medicines has not been released for the UK and inclusion on this list would aid the regulatory process for natural health products in that market.

The EVA case is complicated by being an animal tissue based product and a traditional product. The differences between these first two cases are significant. The regulatory requirements for the EVA supplement are far more in-depth and complicated. More information about the product is required and more research about the supplement was needed to obtain a product license in Canada. However, this case differs in that it looked at the requirements in our biggest trade partner for this sector, the US. The US approach is unique in that the firm is responsible for ensuring a safe product and there is no pre-market approval required by the FDA. The US regulation does limit the types of claims but allows firm to include health claims accompanied by an agency-approved disclaimer.

Lastly, the probiotic case is a microbial product that is not considered a traditional product under Canadian regulations. This product did require a significant amount of reference and research for a product license application in Canada. However, it does not

require an animal tissue report, as did the EVA case due to concerns about disease transmission from animal products. However, there are specifications included in the regulations about probiotics and some probiotics have been prohibited, none of which are included in the case product. Once again, for the third product it is necessary to closely examine the regulation to determine the requirements for the probiotic product.

Together these three cases shows that each product can vary significantly and firms with diverse product lines will be required to invest resources into each product application as they all differ (unless the product is the same but differs by dose in which case only one application is needed). When turning to international standards, there is little guidance. The Codex did produce a document for mineral and vitamin supplements but this does not encompass the range of products examined in this thesis. In addition, Canadian authorities view minerals and vitamins as low risk products. Vitamins and minerals are some of the last products to require product licenses in the implementation strategy for NHP regulation in Canada. Numerous mineral and vitamins are included in the Compendium of Monographs and will face less strict regulatory standards. Also, in the EU there is a separate directive for vitamins and minerals that differs from the one introduced for herbal medicinal products. The regulation for natural health products seem to be country specific and can differ significantly, as demonstrated by the difference between the US and Canada. The US industry is very supportive of the less restrict regulation in the US and will resist change to these regulations. However, if more foreign markets chose to actively regulate this sector, it will become increasingly difficult for US exporters. On the other hand, the resources allocated to proving the safety, efficacy and quality of NHP in Canada may not transfer to foreign markets that will have different regulations for product claims.

Chapter 6: Summary and Conclusions

6.1 Introduction

This chapter summarizes the findings of the research in this thesis. The motivation for the research is also discussed, along with key results of the research. The implications for the natural health product industry are presented and discussed. To finish, the research limitations are presented, along with recommendations for further areas of research.

The NHP industry has become the subject of increasing regulatory focus. Numerous countries are pursuing more active and specific regulation for NHP, which have remained under the regulatory radar in the past. These regulations have important implications for the industry and specifically for international trade of NHP. Understanding the regulations firms face and the possible implication for trade is useful for the industry and policy makers.

This thesis suggests that the increasingly stringent and growing variety of regulations for natural health products may hinder firms' abilities to internationally market their products. The case studies presented provide further insight into the research problem.

6.2 Summary of Research Findings

The primary conclusions of this thesis are drawn from the examination of the case studies as a whole. Nations have put regulations for NHP in place to address legitimate domestic concerns surrounding safety and efficacy. There does not seem to be evidence of import specific regulations aimed at limiting trade, as it is the case that both domestic and foreign firms must meet the requirements of the regulations. However, the regulations can be viewed as real trade obstacles that firms must overcome. Although all firms must comply with the regulations in all the studied markets (Canada, US and UK), domestic firms often enjoy an advantage in having easier access to information, procedures, decision making bodies, qualified inspection services, assistance, and in some cases less documentation. This could perhaps lower the transaction costs for domestic firms and alters the relative cost structure, competitive advantage, and therefore trade patterns.

In Canada the case studies have revealed that each product can be subject to significantly different regulatory measures. The difference among regulatory measures is a key finding that will increase transaction costs of firms significantly. Instead of a one-time up front cost of learning the regulations, each product will require sizeable amounts of investigation to determine the applicable measures needed to market a given product. The result may be a pattern of constant learning as firms extend product lines and market destinations. For both domestic and foreign firms, the length of time to pursue regulatory compliance may be significant. First, if production sites do not meet requirements, the process to obtain a site license could be lengthy and considerable. It could also entail a reorganisation of the method of operations used at a particular site.

Product licenses for each product require the firm to incur large information costs. As mentioned previously, there will be costs involved in learning the applicable measures that are required for given product. The cost of providing evidence for efficacy, safety, and quality will also increase information costs significantly. Each product requires different amounts of scientific support. In the case of the flax product, little evidence was required, unlike the other two products where considerable amounts of credible evidence were required. The current step-by-step guide for product licensing in Canada includes an appendix of common deficiencies in submission, which may indicate that firms are finding it difficult to correctly provide the required documentation. Also deficiencies can increase wait time to receive product licences and, in turn, add to costs as marketing of the product is delayed.

In comparison, the US took a very different approach and this market will be very attractive, as it will have significantly less transaction costs arising for firms participating in the NHP industry. The UK regulations are not completely clear as of yet, but it seem to be complicated and will also involve considerable transaction costs that may be comparable to the Canadian market. The differences among the regulatory system seem to indicate the potential for change in the way trade will develop. Also, the regulations have an important role in providing information and could have positive effects on the demand for NHP.

6.2 Implications for the Natural Health Product Industry

The results suggest that there will indeed be significant compliance costs to meet requirements in the UK and Canada. These compliance costs will have real trade implications and potentially affect trade patterns. Similarly, the relatively small size of the Canadian market combined with the regulatory requirements may deter investment. The US will dominate as a potentially attractive market and US consumers may enjoy greater access to a larger variety of products. On the other hand, they may be more at risk from safety issues and fraudulent claims that could impede the market. Market failures from safety issues and misleading labelling could create negative externalities.

Some may argue that Canada may have a first mover advantage by leading the way of increased regulations for NHP, however, the relatively small size of Canada in the world market may not induce other countries to take similar approaches. The first mover advantage may also be dependant on the approaches that international standards organizations take. If Canada is able to influence the international governing bodies for standards, then the Canadian market may experience a first mover advantage.

If firms are pursuing global markets for natural health products they must be prepared for considerable differences in regulatory approaches and be willing to invest time and money into meeting specific requirements. This could be extremely difficult for small to medium sized firms with limited resources, and larger firms may be more successful. Also, due to the significant differences involved in meeting requirements of assorted products, firms may chose to specialize in a certain product category. A policy implication could include policies aimed at education resources for firms to work in cooperation with the NHPD to fulfill the requirements of the regulations.

6.4 Limitations of the Research

A number of potential research limitations should be acknowledged. Only three products were studied that were specifically chosen for their differences; perhaps examining more products may provide additional insights into the effects of the regulations. Likewise, the examination of only three regions and their approaches to regulations for NHP may not be inclusive enough to make inferences about world markets. An in-depth look at many markets would have been too time consuming and

complicated given the scope of the thesis. Research into more product areas and markets could enhance the value of the results.

The framework used does not lead to specific results, as the magnitudes of the relative shifts in the curves are unknown. The results of the framework are necessarily subjective and the weakness of the method is that there is no actual data that could be used. Without data it is hard to draw firm conclusions regarding the trade effect of the regulations as conflicting economic forces lead to ambiguous results. Therefore, the framework was based on purely hypothetical demand and supply curves. In previous used of the framework, demand and supply elasticises were used to determine the effect of a given technical barrier. Given data limitations, this was not possible, but is a potential extension of this thesis. True consumer responses were unknown and this was key to the demand shift response in the framework. The shifts presented were based on the likelihood of allowable health claims, although this may not be the major preference attribute for consumers. Therefore, the consumer response to the regulations for a given product was hypothetical.

6.5 Areas for Further Study

There are many opportunities for further research into the effect of regulations on the natural health products industry. More research into the trade effect of domestic regulations, specifically sanitary and phytosanitary measures could provide useful information on both the positive and negative effect of regulations. A detailed before and after exploration of the trade patterns (exports and imports in Canada) since increased regulations for natural health products could help other nations facing the same regulatory issues.

Additional investigation of industry perceptions regarding the effect of the new regulations could help determine whether the benefits have outweighed the costs of the regulations. An industry survey could also specifically identify whether the regulations have indeed increased significantly. An industry survey could identify potential problems with the regulations and whether there are long processing waits for market approval and how firms believe the regulations have affected their cost structures. Also,

it would be useful to survey US firms to examine their response to the Canadian regulations.

In addition, export and import data for these products need to be collected to examine the trade effects and provide more insight into the effect of regulations. Research into the approval rate of products in Canada and product availability could perhaps provide more knowledge about the restrictiveness of the regulation in comparison to the US. Also, to further explore consumer demand effects, a possible extension of the thesis is to use stated or revealed consumer preference methodologies. A study of consumer demand could give better indications of the relative magnitudes of the demand shifts from the implementation of the regulations.

Lastly, research into different approaches of natural health products regulators around the world would help industry understand the differences. Further, research into the role and involvement of international standard organizations, such as the Codex, is needed to investigate the potential for reducing trade barriers through harmonisation or the granting of equivalence.

6.6 Conclusion

Global demand for natural health products is increasing and regulations have an important role in the industry. Trade may be inhibited by differing national standards and regulations for natural health products and some nations may experience welfare decreases due to their domestic regulations.

This study has taken the first step towards understanding the barriers that may be created by the new and sometimes more complicated regulations. This study is clearly limited in scope and further research is needed into the natural health product industry. There is a need for more data within this industry to facilitate further research.

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Appendix 1: Labelling Requirements, Canada, US and EU

Labelling Requirements for natural health products in Canada

There are two labels required for NHP: the outer label and the inner label. An outer label means the label on or affixed to the outside of a package of the NHP. An inner label means the label on or affixed to an immediate container of a NHP. An immediate container means the container that is in direct contact with a NHP.

Inner and Outer Label:

Front Panel (principal display panel):

- Brand name
- Dosage Form
- "Sterile", if it is sterile
- Net amount in the immediate container

Side Panel:

- Name and address of the product license holder
- Name and address of the importer, if any
- Medicinal ingredients: Proper name (common name) (source)…quantity, potency
- Recommended use or purpose
- Recommended route of administration, recommended dose, recommended duration of use, if any
- Risk information: cautions, warning, contraindications, known adverse reactions
- Recommended storage conditions, if any
- Expiry date

Outer Label Only:

- Non-medicinal ingredient: common name
- Quantity of mercury, if any

Bilingual Text:

- Recommended use or purpose

- Dosage form
- Recommended route of administration, recommended dose, recommended duration of use, if any
- Risk information: cautions, warning, contraindications, known adverse reactions
- Medicinal ingredients: Proper name (common name) (source)…quantity, potency
- Non-medicinal ingredient: common name
- Storage conditions, if any

Pressurized container:

- Single word, primary hazard statement
- Additional cautions

Cautionary Statements

- Must include any cautionary statements

Label Requirement for dietary supplement in US

Ingredient Label:

This label must include the name and quantity of each dietary ingredient or, for proprietary blends, the total quantity of all dietary ingredients (excluding inert ingredients) in the blend. The label must also identify the product as a "dietary supplement" (e.g., "Vitamin C Dietary Supplement"). Labeling of products containing herbal and botanical ingredients must state the part of the plant from which the ingredient is derived.

Nutrient Label:

This label must first list dietary ingredients present in "significant amounts" for which FDA has established daily consumption recommendations, followed by dietary ingredients with no daily intake recommendations. It is not necessary to list dietary ingredients that are not present in significant amounts. The nutrition labeling must include the quantity per serving for each dietary ingredient (or proprietary blend) and

may include the source of a dietary ingredient (for example, "calcium from calcium gluconate"). If an ingredient is listed in the nutrition labeling, it need not appear in the statement of ingredients. Nutrition information must precede ingredient statements on the product label.

Label Requirement for food supplements in the EU

Claims:

- Labelling, presentation and advertising must not attribute to food supplement property of preventing, treating or curing a human disease or refer to such properties.
- Labelling, presentation and advertising of food supplement

Label must include:

- Names of the categories of nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances
- Recommended daily dose
- Warning not to exceed the stated recommended daily dose
- A statement to the effect that the food supplement should not be used as a substitute for a varied diet
- A statement to the effect that the product should be stored out of the reach of young children