

**LEGAL FRAMEWORK TO REGULATE
NUTRACEUTICALS IN MALAYSIA**

BY

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degree of Master of Comparative Laws**

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ABSTRACT

The growing consciousness among consumers on the importance of health has resulted in the mushrooming of various nutraceuticals products in the market. Nutraceutical products have become widespread phenomenon for proclaimed benefits they seem to offer. To define what nutraceutical is, has always been confusing in certain jurisdictions especially Malaysia. Legally, they cannot be considered as mere food, and they are not pharmaceutical drugs either. The issue arises is in relation to the absence of proper regulation that controls the production of nutraceuticals products. One of the main problems is the fact that nutraceuticals products in itself is not a standalone category. In Malaysia, nutraceuticals can be classified either as food or drugs and be regulated by different regulatory agencies depending on its classification. This creates a double standard treatment as different agencies have different standard procedures to govern the product. Due to uncertainty in its categorisation, nutraceutical manufacturers have taken advantage in producing and marketing those products to consumers. Social media has been effectively used as a platform to market these products. It is observed that some online seller in attracting customers' attention has advertised numerous claims. To some extent, there are sellers that claim that their product able to cure diseases that science had yet to find cure for such as cancer and diabetics. The popular marketing strategy by displaying the testimony of the users allows the producers to make profit out of the unproven claims of their products. As Malaysia is aimed to be the world class-leading supplier for nutraceutical products under the Economic Transformation Programme's Agriculture National Key Economic Area, there is a need to upgrade the local herbal supplements in the sense that any health claims must be supported by clinical evidence. Thus, a proper regulation in restraining such producers from advertising unsupported health claim is highly needed and required in protecting the consumers' interests. This study aims to examine regulatory issues pertaining to the production and marketing processes of nutraceuticals to ensure safer consumption. This study propose that there is a real need to have a specific, standard procedure to safeguard and protect consumer's interest in the long run. The study adopts a qualitative approach that includes doctrinal analysis and semi-structured interviews with relevant authorities. It is proposed that for local atmosphere, governmental intervention is required to assure safer consumption of nutraceutical products so that consumers may truly benefit from them. Self-regulation as practiced at present has to some extent, placed the nutraceutical industry in a very complacent position, resulting in consumers' safety at stake.

خلاصة البحث

إنّ عمليّة ازدياد الإهتمام بين المستخدمين بالصحة أدى إلى زيادة المبيعات المتعلقة بالأغذية الدوائية، وذلك للفوائد التي يعتقد في امكانية جنيها من استخدامها، ولكن من الناحية القانونية فإنه من الصعب تعريف مصطلح "الأغذية الدوائية" وخصوصاً في ماليزيا. وذلك لأنه لا يمكن تصنيفها على أنها غذاء فقط أو دواء، ولذلك لانعدام القوانين التي يمكن أن تنظم انتاج تلك الأغذية الدوائية التي لا تصنف في ماليزيا على أنها فئة مستقلة بذاتها، وعمليّة التصنيف تقع تحت اختصاص هيئات متباينة، مما أدى إلى ازدواجيّة تقييمها لأن لكل هيئة معاييرها الخاصة لها في عمليّة تقييم المصنفات، ولهذا السبب فإن منتجي هذه الأغذية الدوائية يستغلون هذه الفقرة القانونية لإنتاج منتجاتهم والترويج لها بين المستهلكين عبر وسائل التواصل الاجتماعي، حيث يدعى بعضهم دون التحقق أن لهذه المنتجات لها الفوائد الكثيرة، وكما أنّها يمكن أن تعالج أمراضاً عجز عنها الطبّ الحديث كالسرطان والسكري ويستشهدون ببعض العينات من البشر الذين قاموا باستخدام هذه الأغذية الدوائية، ممّا يمكنهم من جني الكثير من الأرباح باستخدام هذه الطريقة. ولأن ماليزيا تهدف إلى أن تصبح في مصاف الدول المتقدمة في صناعة الأدوية تحت خطة التحوّل الاقتصادي في مجال الزراعة بإعتبارها أحد دعائم الاقتصاد، فإن هناك حاجة ماسة لتحسين إنتاج الأعشاب المستخدمة في صناعة الأغذية الدوائية وذلك بالتحقق من فوائدها عن طريق الأبحاث الطبية، وهو ما يستلزم إطاراً قانونياً يمنع المنتجين من ادعاء فوائد غير محقق منها؛ وذلك من أجل حماية المستهلكين، فإن هذه الدراسة تهدف إلى دراسة المسائل القانونيّة المتعلقة بإنتاج وترويج الأغذية الدوائية للتأكد من سلامتها، وعدم إضرارها بالمستهلكين، وذلك عن طريق إيجاد إجراءات محددة تنظم هذه العملية، وقد استخدم الباحث المنهجية النوعية، حيث أجرى تحليلاً قانونياً ومقابلات شخصية شبه منظمة مع الجهات ذات الإختصاص وتوصى الدراسة بتدخل حكومي لتنظيم عملية إنتاج وبيع الأغذية الدوائية حتى يستفيد منها المستهلكون؛ ولذلك لأن هذا الأمر حالياً متروكاً للرقابة الذاتية للمنتجين وقد يضر هذا الأمر بالمستهلكين.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master of Comparative Laws.

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CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF THE STUDY

The worldwide cost of allopathic cure is increasing nowadays and Malaysia is not exempted from the situation. In 2016, Frost & Sullivan had reported that “Malaysian healthcare expenditure could rise as high as USD20 billion by 2020 and the per capita spending on healthcare is expected to continue its upward trajectory.”¹ It has been further asserted in the report that the increment of healthcare cost is due to the rising incidences of chronic diseases such as diabetic and cancer as well as vector borne diseases like dengue. In addition to that, the usage of new and upgraded technology such as Computerized Axial Tomography (CAT scan) and Magnetic Resonance Imaging (MRI) as well as the expensive price of drugs/medicines also contribute to the soaring price of healthcare. With the increment of the healthcare cost, people started to resort to the concept of “deriving health from food” that emphasizes on prevention rather than treatment of disease. Hippocrates, the father of modern medicines who advocated the principle “let food be thy medicine, and medicine be thy food”² had emphasized on consuming appropriate foods in order to gain their therapeutic benefits. As allopathic medicines are associated with a variety of side effects, people started to

¹ Frost & Sullivan, “Frost & Sullivan: Malaysia – The 20 by 2020 Inevitability,” <https://ww2.frost.com/news/press-releases/frost-sullivan-malaysia-20-2020-inevitability/> (accessed 20 December, 2017)

² Baby Chauhan, Gopal Kumar, Nazia Kalam, and Shahid H. Ansari, "Current Concepts and Prospects of Herbal Nutraceutical: A Review", *Journal of Advanced Pharmaceutical Technology & Research*, vol. 4, no. 1 (2013): 4–8.

resort to natural alternative in maintaining a healthy lifestyle. Consumers have started subscribing to a diet regimen that they believe can reduce the risk of chronic disease.

The concept of nutraceuticals evolved due to the fact that there is a recognition link between nutrition and health. The word nutraceutical has often been used to describe “a broad list of product sold under the premise of being food components, but with the expressed intent of treatment or prevention of disease.”³ The word is a “combination of ‘nutrition’ and ‘pharmaceutical’ which refers to extracts of foods claimed to have a medical effect on human health.”⁴ Nutraceuticals are food that contain phytochemicals where these biologically active compounds which are normally found in plants, have a wide range of therapeutic effects against a number of diseases like diabetes, heart disease, common cold, arthritis, cancer, hypertension and many more.⁵ Nutraceutical products are said to pose a high potential to improve the long-term health of populations through disease prevention in cooperation with healthcare professionals.⁶ Consumption of nutraceutical products is considered as a form of nutritional therapy where it can be part of healing system as a food can provide medicinal benefits in addition to its function as sources of nutrients and energy.⁷ Nutraceuticals challenge the traditional notion that foods nourish and entertain, while drugs prevent or treat disease.

³ M. Prasad Palthur, S.S. Sajala Palthur, and Suresh Kumar Chitta, "Nutraceuticals: Concept and Regulatory Scenario", *International Journal of Pharmacy and Pharmaceutical Sciences*, vol. 2, no. 2 (2010).

⁴ Vimal Patel, Paul Wilson, and Ram H. Singh, "Nutraceuticals of Antiquity" in *Handbook of Nutraceuticals, Volume 1*, edited by Yashwant Pathak (CRC Press, 2009).

⁵ Kiran Dahiya, "Nutraceuticals and Their Impact on Human Health", *Journal of Plant Biochemistry & Physiology*, vol. 1, no. 4 (2013): 10–12.

⁶ Roberto Giunta, Giovanni Basile, and Arianna Tibuzzi, “Legislation on Nutraceuticals and Food Supplements: A Comparison between Regulations in USA and EU,” in *Bio-Farm for Nutraceuticals: Functional Food and Safety Control by Biosensors*, edited by Maria Teresa Giardi, Giuseppina Rea, and Bruno Berra (Landes Bioscience and Springer Science Business Media, 2010), 322–328.

⁷ Dahiya, Nutraceuticals and Their Impact on Human Health.

It is interesting to examine the statement by Bernadette M. Marriott where he stated that:

“250 years ago, we might have said that lemon were drugs because, at that point in time, lemon cured this mysterious and deadly disease called scurvy. Many years after that, seamen were still carrying lemons on their voyage to cure this disease. Then many years later, vitamin C was identified as the phytochemical or nutrient that was found in lemons. We now consider lemons to be foods...We are now looking at other phytochemicals in lemons call limonenes and their potential to perhaps combat and prevent cancer. Thus, our thinking about food and drugs and everything between is somewhat cyclic and depends, of course, on how science is evolving.”⁸

Food and nutrient are very significant in maintaining one health and reducing the risk of various diseases. In relation to that, the nutraceuticals industry had started to recognize food as the ultimate delivery mechanism for medicine and health.⁹ The nutraceuticals revolution lead into a new era of medicine and health, in which the food industry is expected to become a research-oriented sector similar to the pharmaceutical industry.¹⁰ The growing consumer interest in health-enhancing product increases the demand for the nutraceutical products in the market. Since these products have been widely promoted in the social media, people started to pay recognition and put a considerable interest in it. Hence, supplementing diet with nutraceuticals are becoming a life style treatment for the health conscious consumer.

⁸ Bernadette M. Marriott, "Clinical Studies and Trials to Evaluate the Efficacy and Safety of Nutraceuticals and Dietary Supplements: Approaches, Stumbling Blocks and the Consumer Quandary" in *Examining the Science Behind Nutraceuticals*, (United States America: AAPS Press, 2001), 25.

⁹ Adesoji O. Adelaja and Brian J. Schilling, "Nutraceuticals: Blurring the Lines between Food and Drugs in the Twenty-first Century", *The Magazine of Food*, vol. 14 (1999): 35–40.

¹⁰ Palthur, Palthur, and Chitta, Nutraceuticals: Concept and Regulatory Scenario.

1.2 STATEMENT OF THE PROBLEM

Nutraceuticals is believed to be a powerful instrument in promoting good health and improving consumer's lifestyle. Thus, the quality of nutraceutical should not be compromised and should be the main concern by all the stakeholders. An effective regulation starting from the production of the product until it reaches the market is needed in order to protect the consumer's interest. Without a concrete regulation, fraudulent nutraceutical product will flood the market and it has the potential to jeopardize the wellbeing of consumers.

In Malaysia, the legal status of nutraceuticals is in a grey zone as there is a lack of a well structured regulatory framework for nutraceuticals. It seems that the term nutraceuticals is an alien to most of the stakeholders as the term itself is not recognized or being defined under any of Malaysian legislations. This creates a huge regulatory challenge and uncertainties of the actual type of products which can be classified as nutraceuticals. Absence of a proper legal definition poses some difficulties to immediately trace the responsible authority that handles and monitors the products. As such, it is a challenging task to determine the specific standards and guidelines that should be complied with by the manufacturers.

The current situation in Malaysia is that nutraceutical can fall under the category of either drugs or food. The categorization of nutraceuticals is made through examining the ingredients in the product. It is observed that, if a product belongs to the category of drugs, the authority which is responsible to govern it is the National Pharmaceutical Regulatory Agency (NPRA). On the other hand, the Food Safety & Quality Division (FSQD) is responsible to regulate all the nutraceutical products that fall under the food category. It is the task of the industry players to determine under which category their product belongs to base on the clear guidelines incorporated in the Drugs Registration

Guidance Document (DRGD) which is provided by the NPRA. When there are two different agencies to control and regulate the nutraceuticals product, there surely exist different standards and procedures to be complied with by the industry. As both authorities enumerate their own standard procedures, it causes the same category of product being treated differently which later gives rise to various issues that revolve around the product efficacy, safety and quality upon human consumption.

In terms of product registration, nutraceuticals that falls under the purview of the NPRA is made mandatory to be registered. Registration of a product enables it to be evaluated in the aspect of safety. On the other hand, food product is a non-registrable product as it is presumed to be safe because it is possible to extrapolate from a known history of exposure to them, whereas a drug that has no such widespread exposure history cannot be presumed to be safe. Consequently, food product can reach the market without any evaluation made by the authority. Thus, the safety standard of the said product is vague and can only be traced or inspected upon complaint from the consumer. NPRA prescribed that product registration could only be done if the product is manufactured in the facilities that comply with GMP standard. Compliance with GMP standard is very important to ensure that the product is safe, effective and reaches the minimum quality. This is crucial to prevent uncontrolled manufacturing operations which lead to the production of fraudulent product that can be detrimental to the health of the consumers. It is in fact a form of quality assurance standard that ensures that the product is consistently manufactured and the quality is controlled according to the intended use as required for the purpose of product registration. However, since there is no registration requirement for food product, manufacturing it in the GMP premises is highly encouraged but it is not obligatory to do so.

Although nutraceuticals contain biologically active compounds that derived from plant and have a wide range of therapeutic effects against a number of diseases, a thorough clinical study need to be conducted in ensuring that it can really benefit the consumers. The increase in use may expose consumers to often inherent problems of quality and potentially increase the risk of individual self-medicating for serious disease instead of seeking the correct medical attention. Clinical study is important to determine the safety and efficacy of the product. Furthermore, it also enables the manufacturer to develop a proper health claim for the product. However only certain category of product under the supervision of NPRA has to undergo a laboratory test before marketed and the test is to determine the ingredients contain in the product and not the efficacy of the product, while food product does not require any clinical or laboratory test.

It is observed that the trend of selling a nutraceutical product based on testimony from the consumer is growing in the social media. Unfortunately, most of the testimonies are not supported by any clinical study and only based on one's personal experience. This poses a risk to consumers upon consumption of the product as not all people will experience the same effect upon consumption of the same products. As some might adjust and suit to the product, others might not so. It seems more like the manufacturers are taking advantage of the consumer's behaviour and changes in lifestyle when they use the social media to commercialize their product. The marketing strategy that is based on user's testimonial leave a big question as regard to its genuinity. As advertised those products can be made through various distribution channels especially through the internet based sale such as Facebook, Instagram, website, it is hard for the authority to monitor the advertisement. People can write anything in promoting their product through their own social media account which includes

unproven health claim or uncertain testimony. Thus, a mechanism of control to this issue is highly warranted

As nutraceuticals could either fall under the purview of FSQD or NPRA, it seems that the former appears to be less strict compared to the latter in terms of regulatory power and control. This fact somehow makes the industry to be more complacent to have their product regulated by the FSQD. Since the classification of a product is based on its formulation and ingredient, it is possible for the industry that is the manufacturer for instance, to manipulate and alter the ingredients so that its product is governed under the food law. Consequently, the manufacturer may avoid all the hassle and strict requirements as stipulated by the NPRA in the DRGD. The “double standard” treatment and requirements open up the opportunity for manufacturers in having the preference to label their product as food. The end result could be the consumer is paying a lot more for a ‘make believe product’ when the product is not curing instead deteriorating the health of the consumer. The safety concerns of the governmental authorities lag behind the marketing strategies of distributors. More and more product with scarce scientific evidence of their medicinal potency and their side effects being introduced to the market. Furthermore, a risk management or action plan for nutraceuticals by governmental authorities is widely missing. At the end of the day the consumer health is at stake. In response to the problems, this study propose to suggest that the government need to establish a solid regulatory framework to govern the flourishing of nutraceuticals product.

1.3 RESEARCH OBJECTIVES

This study embarks on the following objectives:

1. To identify the suitability and practicability of applying existing regulations on food and drugs to nutraceuticals product in Malaysia.
2. To assess the effectiveness of existing regulations on food and drugs in protecting consumers from the risk of unscientifically proven health claims in nutraceutical product.
3. To examine the strength and weaknesses of the regulations on nutraceuticals product in other countries including United States, Japan and India.
4. To make recommendation and propose the best and most effective model regulation on nutraceutical products that can be adopted in Malaysia.

1.4 RESEARCH QUESTIONS

This study attempts to answer the following research questions:

1. Whether the existing regulations in relation to food and drugs should be applicable to nutraceutical products?
2. Whether the current laws regulating food and drugs are sufficient to protect consumers from the risk of unscientifically proven health claims in nutraceutical product?
3. Which country has the most effective regulations on nutraceutical to benchmark?

1.5 HYPOTHESIS

Unregulated nutraceutical products that flooded the Malaysian market have the potential to bring health risks to the consumers. Therefore, an effective regulation is

needed to ensure consumers are protected and producers to be liable for any harm caused by the nutraceutical products.

1.6 SCOPE AND LIMITATION OF THE STUDY

The study aims to investigate the current status of nutraceuticals in Malaysia. It seeks to analyse the relevant laws and regulations that govern nutraceuticals products in Malaysia and to examine whether the current legal mechanism is adequate in relations to the protection of consumers rights and interests.

This study attempts to emulate the best and the most feasible policy from other jurisdictions regarding nutraceuticals in order to be adopted in Malaysia. A comparative study on the legal framework of nutraceuticals in other jurisdictions such as United States, Japan and India has been conducted. Those countries were selected after a comprehensive literature review. United States were selected because this is where the term nutraceuticals was first coined by Stephen L. DeFelice, M.D. the founder and chairman of Foundation for Innovation in Medicine. However, it is interesting to note that the term itself is not recognized under the United States law as nutraceuticals were regulated under the heading of dietary supplements. In Japan, nutraceuticals were regulated under the category of Food for Specific Health Use (FOSHU). FOSHU system as it is based on the approval system. As the main priority is to safeguard the consumers, product can only be released to the market once it obtained the approval from the authority. Meanwhile, India was chosen because it had recently passed a regulation that not only legally defines the term nutraceutical but also provide specific procedures on how to regulate nutraceuticals.

The constraint in this study is that most of the jurisdictions do not have a formal definition of the term nutraceuticals making it hard to determine exactly under which

categories nutraceuticals might fall. Since there is no unanimous definition of the term nutraceuticals, comparison between countries is never easy.

1.7 RESEARCH METHODOLOGY

The research was conducted using qualitative method. This method was selected in order to get in-depth and detail understanding about the subject matter and issues of this study without being constrained by pre-determined categories of analysis. It focussed on obtaining data through various instruments which include which includes content analysis and field work (semi-structured interviews).

1.7.1 Content Analysis

Content analysis involved summarizing any form of content in order to enable more objective evaluation of the subject matter. This includes a thorough review of the existing literature from text books, journals, articles, newspapers and periodicals. In addition, various websites from the internet were also useful in gathering all the needed information. A gap analysis of the existing legal framework relating to nutraceuticals was done in order to gather extensive data in addressing the issues and problems concerning nutraceuticals. Doctrinal analysis of the regulations and case law pertaining to nutraceuticals in Malaysia includes browsing through the online data bases such as Lexis Nexis, LawNet and HeinOnline. A comparative study of the Malaysian legislations on nutraceuticals with other countries such as United States, Japan and India is carried out in order to select the best legal framework for bench marking purposes.

1.7.2 Field Work

Field work includes semi-structured interviews with the relevant stakeholders as follow:

No.	Agencies	Date/Day	Officers
1	National Pharmaceutical Regulatory Agency (NPRA)	10th October 2017 (Tuesday)	Dr. Faridah Aryani Binti Md Yusof Mrs Azrina Binti Hassan Mrs Karen Wong Yoke Sim.
2	Food Safety and Quality Division (FSQD)	11th April 2017 (Tuesday)	Puan Nurul Hidayati Bt Mohd Nasir Senior Assistant Director
3	Institute of Pharmaceutical and Nutraceutical Malaysia (IPharm)	21st July 2017 (Friday)	Mr Syed Saberi Bin Syed Amirudin Registered Pharmacist Mr Azizairol Bin Md Mizan Assistant Executive Director of IPHARM

1.8 LITERATURE REVIEW

1.8.1 Development of Nutraceuticals

Nutraceuticals are being consumed by certain people as part of normal diet where it is an alternative for both nutrition and medicine.¹¹ This product can be easily bought as it is sold openly in pharmacies, supermarkets or online shops.¹² Surveys which were conducted in United Kingdom, Germany and France revealed the result that consumers were prone towards a proper diet in achieving a good health compared to exercise and other hereditary factors. The demand for nutraceutical products is increasing in line with the growing of consumer interest in the relationship between diet and health.¹³ Due to the increasing demand for nutraceuticals, the food industry is expected to become a

¹¹ Annemarie Koch, Sonja Brandenburger, Suzanne Türpe, and Marc Birringer, "The Need for a Legal Distinction of Nutraceuticals", *Food and Nutrition Sciences*, vol. 5, no. May (2014): 905–913.

¹² Prevesh Kumar, Nirdesh Kumar, and Tushar Omer, "A Review on Nutraceutical 'Critical Supplement for Building a Healthy World'", *World Journal of Pharmacy and Pharmaceutical Sciences*, vol. 5, no. 3 (2016): 579–594.

¹³ *Ibid.*, 579.

research-oriented sector similar to the pharmaceutical industry.¹⁴ The growth of nutraceuticals began when the benefits of calcium, fiber and fish oil were discovered through clinical studies in the early 1980s.¹⁵ In the United States, the concept of nutraceuticals started to take place in 1900s when the food manufacturer began to add iodine to salt in an effort to prevent goiter.¹⁶ Major food and pharmaceutical companies such as Kellogg, Heinz, M&M, Quaker Oats, Unilever, Cargill, Hormel, Glaxo-SmithKline, Warner-Lambert, Johnson & Johnson and Wyeth began to invest and take opportunity from the growth of the nutraceuticals industry.¹⁷ These companies commit major resources to discover health-enhancing activities within foods we eat and to change traditional food so they contain more of those active ingredients.¹⁸

1.8.2 Terminologies

Nutraceutical are being widely adopted as a catchall term to refer to vitamins, minerals, herbs and various other supplements.¹⁹ However, there are various terminologies used to describe nutraceuticals. Different jurisdictions used different terminologies to refer to nutraceuticals such as medical foods, designer foods, phytochemicals, functional foods and nutritional supplements.²⁰ The nutraceutical industry include three main segments which are functional food, dietary supplement and herbal/natural products.²¹

¹⁴ Palthur, Palthur, and Chitta, Nutraceuticals: Concept and Regulatory Scenario.

¹⁵ Kumar, P., Kumar, and Omer, A Review on Nutraceutical 'Critical Supplement for Building a Healthy World'.

¹⁶ Ibid.

¹⁷ Steven H Zeisel, "Regulation of Nutraceutical", *Science*, vol. 285, no. September (1999): 1853.

¹⁸ Ibid., 1853.

¹⁹ Palthur, Palthur, and Chitta, Nutraceuticals: Concept and Regulatory Scenario.

²⁰ Esther Bull, Lisa Rapport, and Brian Lockwood, "What is a Nutraceutical?", *The Pharmaceutical Journal*, (2000).

²¹ Adelaja and Schilling, Nutraceuticals: Blurring the Lines between Food and Drugs in the Twenty-first Century.