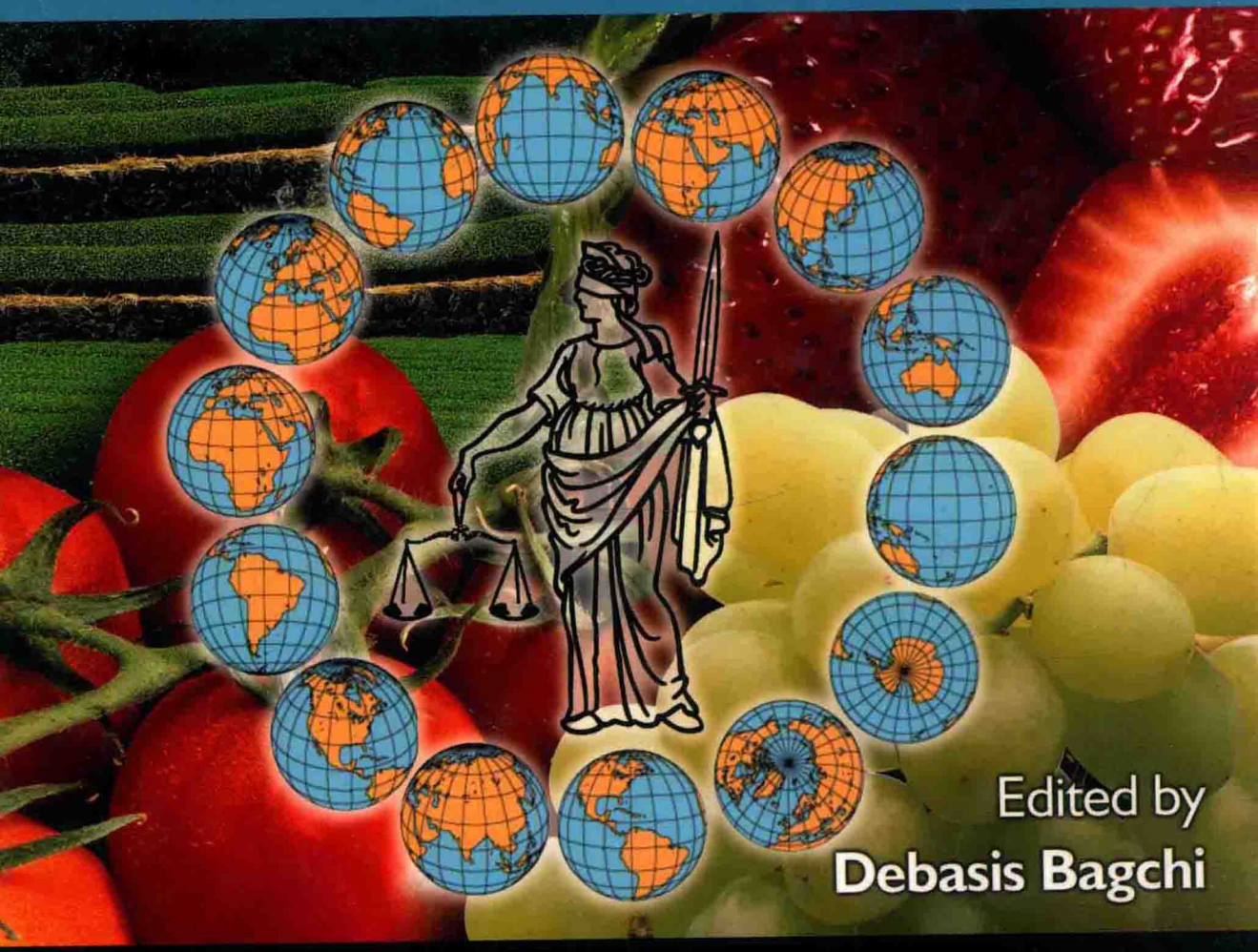
Nutraceutical and Functional Food Regulations

in the United States and Around the World



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Nutraceutical and Functional Food Regulations in the United States and Around the World

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NUTRACEUTICAL AND FUNCTIONAL FOOD REGULATIONS IN THE UNITED STATES AND AROUND THE WORLD

Food Science and Technology
International Series

A complete list of books in this series appears at the end of this volume.

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Preface

Historically, plants have been used as a valuable source of prophylactic agents for the prevention and treatment of diseases in humans and animals. Hippocrates conceptualized the relationship between the use of appropriate foods for health and their therapeutic benefits in his renowned quote:

> Let food be thy medicine and medicine be thy food
>
> Hippocrates (460–377 BC)

This intimate relationship between food and drugs is even recognized in the American legal definition of a drug:

> §201(g)(1) The term 'drug' means…articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (*other than food*) intended to affect the structure or any function of the body of man or other animals… (1).

Within the last decade, consumers have made increasing reference to 'nutraceuticals' and 'functional foods', recognizing the relationship between nutrition and health, to the point of avoiding an overreliance on pharmaceuticals and regarding prescription drugs as often being unnecessary, too expensive and of dubious benefit once all the risks are considered. This combined with a more widespread understanding of how diet affects disease, health-care costs and an aging population, have created a market for functional foods and natural health products.

According to market statistics, the global functional food and nutraceutical market is growing at a rate that is outpacing the traditional processed food market. A poll conducted by the Council for Responsible Nutrition (CRN) reported that 52 percent of Americans identify themselves as regular users of dietary supplements in 2007, up from 46 percent in 2006 (2). In the USA alone, consumer expenditures on dietary supplements and functional foods reached a reported $22.4 billion and $31.4 billion sales, respectively, more than double the amount spent in 1994 (3).

Natural products industries face diverse challenges. In attempt to define efficacy and support marketing claims for the products, extensive safety studies including acute, subacute, subchronic, chronic and long-term toxicity studies, genotoxicity,

reproductive toxicology, teratogenicity, molecular mechanisms of action both in vitro and in vivo, should be complemented with supplementation studies in animal models and clinical trials for human efficacy for specified indication.

This book on *Nutraceutical and Functional Food Regulations in the United States and Around the World* formalizes an expert panel and provides descriptions of health food regulatory aspects from North America, the UK, Australia, New Zealand, Asia, Brazil, Africa, and other select countries in the Pacific Rim. Other topics include marketing insight, current good manufacturing compliance (cGMP), analytical validation, intellectual property, branding, trademark and regulatory approvals. Furthermore, the impact of World Trade Organization (WTO) regulations on the global food supply chain is reviewed. A special section on the safety assessment and assurance of nutraceuticals through obtaining generally recognized as safe (GRAS) status and the use of traceability technologies and nanotechnology is also discussed.

A highly impressive group of professionals has immensely contributed to the successful accomplishment of this special issue.

Part I: Introduction. A.L. Almada and Professors O. Hänninen and C.K. Sen discussed the scope and significance of global regulations on nutraceuticals and functional foods. Almada emphasized on market opportunities and future directions of nutraceuticals and functional foods.

Part II: Regulatory hurdles for marketing were examined by C. Noonan and W.P. Noonan, and A.V. Maher. Noonan and Noonan reviewed the common reasons for rejection of new dietary ingredient submissions and discuss some tactics to help improve the odds for successful marketing in the USA. Maher explains how the Federal Trade Commission (FTC) evaluates the adequacy of scientific substantiation and provides numerous examples of how the FTC has applied the standard in law enforcement actions.

Part III: Manufacturing compliance and analytical validation was reviewed by leading analytical researchers, Drs R. Crowley, L.H. Fitzgerald and D. Sullivan. Crowley and Fitzgerald emphasize the impact of cGMP compliance on consumer confidence in dietary supplements. Sullivan and Crowley give an overview of the development and validation of analytical methods for health foods and dietary supplements.

Part IV: Importance of safety assessment was discussed by Drs G.A. Burdock and Dr P.A. Lachance. Burdock et al. enlightened on the importance of GRAS to the functional food and nutraceutical industries. Lachance reviews the concept of traceability of nutraceuticals and pharmaceuticals to prevent the covert introduction of chemical and microbiological hazards as agents of terrorism or counterfeiting.

Part V: Regulations around the world was provided by a selected panel of world renowned professionals specialized in their respective country's legislation on dietary supplements and functional food regulations.

Drs J.E. Hoadley and J.C. Rowlands highlighted the Food and Drug Administration (FDA) perspectives on health claims for food labels in the USA.

Dr S. Agarwal, a leading nutrition scientist, and S. Hordvik and S. Morar, well renowned regulatory legal counsels, focused their discussion on the nutritional claims for functional foods and supplements in the USA.

Dr O.I. Aruoma summarized the impact of WTO and food regulation on the food supply chain.

Drs S. Martyres, M. Harwood, and E.R. Nestmann reviewed the basic principles of Canada's regulations and examples of major issues faced by the Natural Health Products Directorate.

Dr P. Coppens, M.F. DaSilva and S. Pettman, and Drs O.P. Gulati and P.B. Ottaway, two well renowned professional teams, discussed in detail the legislation governing enrichment of foods and health claims made on botanical-sourced, functional and fortified foods and food supplements in the European Union.

Dr S.A. Ruckman provided an understanding of European and UK food law and how they apply specifically to nutraceuticals and functional foods.

Drs D. Ghosh, L.R. Ferguson and M.A. Skinner presented a succinct discussion on the roles of Therapeutic Goods Administration and the Medicine and Medical Devices Safety Authority in Evaluating Complementary and Alternative Medicines in Australia and New Zealand.

Drs H. Ohama, H. Ikeda and H. Moriyama provided a detailed overview on Japanese regulations for health foods and foods, as well as intricate aspects of Foods for Specified Health Uses regulations.

Korean FDA representatives J.Y. Kim and D.B. Kim, in collaboration with Professor H.J. Lee of Seoul National University gave a thorough update on Korean Regulatory aspects.

A. Roberts and R. Rogerson discussed the regulations and requirements for regulatory approval within the Chinese market.

Victor A. Tutelyan and Boris P. Sukhanov reviewed biologically active food supplements (BAFS) as well as food supplement quality, safety, efficacy and regulating the registration process in the Russian Federation.

Drs. K. Shelke and C. Hewes gave an in-depth narration of the historical background and the current status of Indian nutraceuticals and regulation foods regulations. The authors concluded the chapter with an outlook of the regulatory challenges that lie ahead in the nutraceuticals and functional foods industry in India.

Drs T. Bahorun and O.I. Aruoma focused on the regulatory status on botanical drugs, nutraceuticals and functional food in the African continent.

Drs M.C. de Figueiredo Toledo and F.M. Lajolo described the legislation that is relevant in the marketing of supplements and functional foods in Brazil.

Dr J. Zawistowski provided an extensive review on the regulatory system for functional foods in the eight countries of the Pacific Rim: Taiwan, Hong Kong, South Korea, Malaysia, Indonesia, Singapore, Philippines and Thailand as well as their diverse acts, regulations, and guidelines.

Part VI. Intellectual property, branding, trademark and regulatory approvals in nutraceuticals and functional foods were discussed by L.K. Chong, L.J. Udell and B.W. Downs. Further discussion on the challenges of IP and branding were reviewed by the well known legal group at Marshall, Gerstein & Borun LLP.

Although nutraceuticals and functional foods have significant promise in the promotion of human health and disease prevention, health professionals, nutritionists and regulatory toxicologists should strategically work together to derive appropriate regulations to provide the optimal health and therapeutic benefits to mankind.

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1. 21 U.S.C. 343(r)(4) emphasis added.
2. http://www.nutraingredients-usa.com/news/ng.asp?n = 80363-crn-ipsos-survey.
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Contents

PART 1

Introduction

1

An Overview on the Scope, Importance and Market Opportunities of Nutraceuticals and Functional Foods: A Special Emphasis on the Future Directions

Anthony L. Almada
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Abstract

Nutraceuticals and functional foods (NFx) present an economically robust opportunity on a global scale. However, manufacturers and marketers of these products are confronted with the Herculean task of developing finished goods that exhibit excellent hedonics, create sustainable revenues, yield attractive investment returns, and give birth to multinational legions of brand zealots. The dearth of NFx products that enjoy a reputable evidence base affords a compelling opportunity for industrial and academic alliances that integrate consumer relevance—instantly understood, evidence-based, and confidence-inspired health benefits. Creation of an intellectual property composite from the inception point, cognizant of global markets and demographics, is critical to prolonging the product life cycle and maximizing market share. The provision of consumer nutritional goods that elicit preventive, therapeutic, or quality of life enhancing effects—substantiated by validation in relevant human target populations—can inject consumer confidence into a sector viewed with diffidence by both consumers and the life sciences and biomedical communities, while elevating industrial growth through science-driven revenues and valuable intellectual assets.

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