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Introductory Chapter: Dietary Supplements, Definitions, Role in Human Health and Regulatory Issues

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1. Introduction

National dietary guidelines are the ideal way to meet all the nutritional requirements for a healthy life. However for genetic, health or lifestyle-related activities, not everyone can follow these dietary guidelines. Not following the dietary guidelines can result in individuals not being able to meet their nutritional requirements leading to health-related issues. In the belief that they may not be meeting the required levels of nutrients, either justified or not, they take 'supplements' as insurance towards nutrient adequacy and good health. A common understanding of dietary supplements is presented in **Table 1**. **Figure 1** shows a typical dietary supplement fact of a commercial product [1]. Traditionally, the focus of dietary supplements is essential vitamins and minerals. However, in recent years, other biologically active components of foods have also been identified as playing an important role in human health [2, 3]. Although technically they are not 'nutrients', they are referred to as 'phytonutrients', 'nutraceuticals', functional ingredients' and 'bioactive beneficial compounds'. They include compounds such as carotenoids, polyphenols, dietary fibre and many more from plant and animal kingdoms. Nutritionists and other health professionals now believe that consuming these phytonutrients as part of a

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- A dietary supplement is a product that is manufactured with the aim of supplementing one's regular diet. They are not intended to treat, diagnose, prevent or cure diseases.
 - They are either natural compounds extracted from food sources or synthetic.
 - Traditionally they include vitamins and minerals in the form of multivitamin and mineral preparations.
 - May also contain fibre, amino acids and fatty acids.
 - May also contain other nonessential substances claimed to have beneficial health effects such as plant pigments, polyphenols and other biologically active compounds, including animal-derived compounds.
 - May also contain animal-derived compounds such as collagen.
 - They may be marketed individually or as a combination.
 - They often contain health claims such as supporting heart, brain, eye health and bone strength.
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Table 1.
Understanding what a dietary supplement is.

Suggested use: As a dietary supplement, take two (2) gummy vitamins per day. Chew thoroughly before swallowing.

Supplement Facts			
Serving Size 2 Gummy Vitamins			
Amount Per Serving	% Daily Value for Pregnant & Lactating Women	Amount Per Serving	% Daily Value for Pregnant & Lactating Women
Calories	20	Folic acid	800 mcg 100%
Total Carbohydrate	4 g **	Vitamin B-12 (as cyanocobalamin)	8 mcg 100%
Sugars	3 g **	Zinc (as zinc chelate)	3.8 mg 25%
Vitamin A (as retinyl palmitate)	4000 IU 50%	Choline (as choline chloride)	10 mg **
Vitamin C (as ascorbic acid)	30 mg 50%	Omega-3 fatty acids (from fish oil)	65 mg **
Vitamin D (as cholecalciferol)	400 IU 100%	DHA (Docosahexaenoic acid)	50 mg **
Vitamin E (as d-alpha-tocopheryl acetate)	15 IU 50%	Other Omega-3 fatty acids	15 mg **
Niacin (as inositol niacin)	20 mg 100%		
Vitamin B-6 (as pyridoxine HCl)	2.5 mg 100%		

** Daily Value not established.

Other ingredients: Glucose syrup, sucrose, water, gelatin; less than 2% of: citric acid, colors (blueberry and carrot concentrates, purple carrot juice concentrate), fumaric acid, lactic acid, and natural flavors. **Contains: fish (tuna).**

This product uses high quality, purified fish oil that has been tested for mercury and PCBs.

Figure 1. Typical dietary supplement facts of a commercial product [1].

daily diet is beneficial to maintain good health and avoiding diseases. However, being a new area of research, in most cases, there are no recommended levels of their intake except to advise consumers to include foods that are good sources of these phytonutrients as part of their healthy diet. This concept of taking supplements has gained popularity in recent years. Recognising the potential for a business opportunity, business sectors around the globe are now offering a wide range of dietary and nutritional supplements. This increase in the intake and sales of supplements has raised serious concerns among health professionals and government regulatory agencies. Questions are now being raised regarding the validity of the scientific evidence in support of supplements and possible misuse leading to adverse effects. In view of the importance of the issue of dietary supplements, several review articles have been published over the years [4–8], and it was felt that there was a need for a book on this topic to provide current knowledge on the research that is being conducted and provide science-based opinions relating to the use of supplements.

2. Challenges and future research

Undoubtedly, nutrient deficiencies such as vitamin A, iron, folic acid and vitamin D, to name a few, have been documented to affect the health of infants, children and childbearing women in the developing parts of the world. However, they are not restricted only to developing countries but also to industrialised countries. The reasons could include genetic factors, insufficient access to proper food, insufficient knowledge of nutrient requirements and their sources, and lifestyle factors. Dietary supplements, therefore, have a rightful place in providing the needed nutrients and other beneficial bioactive compounds to at-risk needy consumers. As a result, sales of these supplements have increased globally, indicating the awareness of the need for these compounds to maintain good health. However, there are still many challenges that the scientific community, consumers, manufacturers and regulatory agencies face in ensuring that the supplements being marketed and consumed are safe and indeed provide the healthy benefits claimed on the label [5].

As more and more new information is available relating to dietary supplements, one of the first challenges facing consumers and regulatory agencies is to define and understand what a dietary supplement is and differentiate them from medicines. Two important aspects of being considered are the intended use of the product and the claim(s) the product is associated with [6, 8]. In countries like the USA, Canada and

Australia, dietary supplements are considered as being self-selecting with limited claims in support of overall health and wellness and not requiring a prescription from a medical practitioner [5]. However, these guidelines are not always universally applied and vary from country to country. As mentioned in their article by Dwyer et al. [5], melatonin is regulated in the USA as a dietary supplement, in Canada as a Natural Health Product (NHP), and in Australia as a prescription medicine. As more and more marketing of dietary supplements is becoming a global issue, a clear and well-defined definition is essential to minimise confusion.

Another challenge is to have good science-based evidence in support of the claims that are often associated with dietary supplements. The two considerations that are important relate to the compound itself that is being evaluated and the design of the study being used. With respect to the compound itself, its source, purity and scientifically valid analytical procedures for its evaluation are important. With regard to the study design, it is absolutely essential that it is in accordance with scientifically accepted procedures of being double-blind with appropriate controls. If it is a clinical trial, the nature of the subjects participating, their health status, gender and age, length of administration of the compound being administered, procedures used to evaluate end results, and statistical procedures used in arriving at the results. In other words, the results derived from the study followed all the scientifically accepted procedures.

In addition to the challenges mentioned above, one of the most important challenges is faced by the regulatory agencies [5]. Unfortunately, no one regulatory model is used globally based on their regional priorities and needs. However, one common consideration of the different regulatory models used globally is to assure the consumers that the dietary supplements are safe and meet the claims made by the manufacturers. We have come a long way in developing a regulatory framework to achieve the goals of safety and applicability. However, as more and more new compounds are now being identified as beneficial for good health and marketing, much more work needs to be done in the future.

This introductory chapter aims to provide readers with a better understanding of the need for dietary supplements, what they are and the challenges faced by the industry, consumers, scientists and regulatory agencies. The common goal of all these stakeholders is safety and good health.

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