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Review

A current look at nutraceuticals – Key concepts and future prospects



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ABSTRACT

Background: Nutraceuticals exist in a legal limbo and the existing legislative efforts remain confusing, complex and not harmonized throughout the many regions of the Globe. These compounds are believed to contribute to improvements in physical and/or mental health and to ameliorate or avoid disease or health-related conditions. However, the promised food and health revolution is yet to come. Although some of these compounds have been shown to improve health, similar claims made for others have not been unequivocally demonstrated.

Scope and approach: Herein, we explore the different definitions of nutraceuticals, associated legal definitions and constraints, while evaluating some of the facts and fictions surrounding these compounds. Lastly, we speculate on how the industry can evolve and how nutraceuticals can, in fact, make good on their promised health benefits.

Key findings and conclusions: The high value market potential has led government agencies to establish regulatory requirements for the design, testing and marketing of these products, though much remains unregulated. Biologically, the often contradictory available data are based on the fact that the beneficial effects of a given chemical, agent or substance when consumed in food does not automatically translate into an enhanced health effect if consumed in concentrated forms or in higher quantities. How the nutraceutical industry will respond to the current lack of knowledge of these compounds, increasing demands of regulatory agencies and to the growing awareness of the general audience may very well determine the evolution of the industry and, to some extent, the health of their customers.

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1. Introduction

“Nutraceuticals”, “(dietary) supplements” and “functional foods”, as well as other terms, are all used interchangeably, though these have significant differences – albeit not always evident (Hardy, 2000). Dietary supplements contain nutrients derived from food products and are commonly concentrated in capsule, powder, liquid or pill form (Meštović, 2015). Kalra defined “functional food” as a product containing the necessary nutrients – including vitamins – for survival, while “nutraceuticals”, in accordance with the previous definitions, not only are complementary to the diet, but also aid in the prevention and/or treatment of disease and/or health disorder(s) (Kalra, 2003), with the exception of anemia, as most functional foods act, to some degree, as anti-anemic. Nutraceutical, a portmanteau of the words “nutrient” and “pharmaceutical”, was coined by Stephen DeFelice, who defined nutraceuticals as “foods (or part of a food) that provide medical or health benefits, including

the prevention and/or treatment of a disease” (DeFelice, 1995). The European Nutraceutical Association (ENA) defines nutraceuticals as substances that markedly contrast pharmaceuticals, which are “synthetic substances or chemical compounds formulated for specific indications”.¹ Nutraceuticals are, hence, “nutritional products that provide health and medical benefits, including the prevention and treatment of disease” (Pandey, Verma, & Saraf, 2010).

The definition of nutraceutical is largely based on the alleged Hippocratic principle “let food be thy medicine and medicine be thy food”, a phrase that, contrary to what is believed by the general public and by scientists, is nowhere to be seen in *Corpus Hippocraticum*, the compilation of the existing knowledge of Hippocrates’ medicine (Jones, 1945). Though it may seem innocuous, such literary fabrication has led to the essential misconception that, in Hippocratic medicine, food was synonymous of medicine, even if food was certainly considered to be closely associated to both

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health and disease (Cardenas, 2013). Currently, however, the term “nutraceutical” applies to a wide range of products, from dietary supplements (Venhuis et al., 2016) and isolated nutrients (Jacobs & Tapsell, 2013), to herbal products (Nworu et al., 2014), as well as specific processed foods and beverages (Udenigwe & Aluko, 2012).

There has been a considerable rising interest in nutraceuticals, as illustrated by the ever growing number of scientific publications (including patents), depicted in Fig. 1. This interest stems not only from their potential nutritional and therapeutic effects, but also from their prospective market value, expected to reach the US\$ 250 billion mark by 2018 (Nasri, Baradaran, Shirzad, & Rafieian-Kopaei, 2014), a projection made in the late 90's (DeFelice, 1995). However, two decades later, the industry, while still present, continues to battle for a significant share of the mainstream food market, while simultaneously facing challenges that threaten both growth and long-term viability (Finley, 2016). This is partly due to a lack of definition, which is reflected in a confusing and complex set of regulations, frequent changes in dietary guidance values and a generalized skepticism over product efficacy. This confusion is further exacerbated in the annual market growth projections, which may encompass nutraceuticals alone or may also include dietary supplements and functional foods, as market research companies tend to consider the overall inclination, by consumers, towards natural ingredients. Hence, market projection values range anywhere between \$US 45.58 billion by 2022 at a mean annual growth rate of 7.6% (M&M, 2015, pp. 116–126) to a whopping \$US 278 billion by 2021 at a mean annual growth rate of 7.3% (TMR, 2015, pp. 25–30), with some additional intermediate estimates (NutraIngredients.com, 2015; Pandal, 2014).

In the following section, the most prominent types of nutraceuticals are defined and, later, some of the key issues pertaining to these compounds, including alleged health benefits, facts and fictions and how they are currently regulated (or not) are critically appraised. Lastly, what the future holds for these promising and highly lucrative substances are discussed.

2. Types of nutraceuticals

There are numerous classifications and categorizations of nutraceuticals, functional foods and dietary supplements. Previously, they have been categorized as either potential or established nutraceuticals (Pandey et al., 2010), on the basis of the food material and nutrients (Kalia, 2009; Kokate, Purohit, & Gokhale, 2002; Singh & Sinha, 2012) or in terms of their effects on the body (Das &

Sen, 2014, pp. 13–39; Prabu, Suriyaprakash, Dinesh, Suresh, & Ragavendran, 2012). Most commonly, however, their classification is based on the chemical constituents and/or active ingredients (Espín, García-Conesa, & Tomás-Barberán, 2007; Srivastava, Sharma, & Kumara, 2015; Tapas, Sakarkar, & Kakde, 2008), as described in detail in Table 1.

These are not, nonetheless, the sole classes of nutraceuticals currently studied and marketed. For example, fatty acids, namely, monosaturated (MUFA) and polyunsaturated fatty acids (PUFA), have been described as having pronounced health benefits. MUFAs, commonly found in olive oil and nuts, have effectively been shown to lower cardiovascular disease (CVD) and metabolic syndrome (MS) (Kastorini et al., 2011) and PUFAs, of which the most recognizable are omega 3 and 6 fatty acids, are involved in the prevention or delay of the onset of Amyotrophic Lateral Sclerosis (Fitzgerald, O'Reilly É, Falcone, & et al., 2014), reduction of CVD and MS (Lorente-Cebrián et al., 2013), improvement of immune function (Miles & Calder, 2012), and may also play a key role as a preventive agent against neuronal atrophy-related depression (Larrieu et al., 2014).

Another type of compounds commonly referred to as “nutraceuticals” which also present a nutritional value are pre- and probiotics (Burgain, Gaiani, Linder, & Scher, 2011; Douglas & Sanders, 2008). Both beneficially affect the host by “selectively stimulating the growth and/or activity of one or a limited number of bacteria” in the digestive tract, thus improving the host's health (Gibson & Roberfroid, 1995). Prebiotics and probiotics differ in the fact that the former refers to non-digestible, fiber compounds. These pass undigested and act as a substrate for the growth of beneficial bacteria, with concomitant positive health contributions that may range from energy balance, bowel function and immunologic function to sensory perception, pressure regulation and glycemic control (Delzenne, Neyrinck, Bäckhed, & Cani, 2011; Hord, 2008; Rajat et al., 2012; Scholz-Ahrens et al., 2016). It should also be noted that, in the specific case of prebiotics, the term does not apply only to the effects on the gut microbiome, but also on that of other areas of the body, such as skin, as it has been shown that certain moisturizers can actively contribute to the improvement of the skin microbiome (Schloss, 2014). These, however, are a group of diverse ingredients that are still not fully understood in regard to their modes of action, effects and required dosages for measurable health benefits (Douglas & Sanders, 2008).

Hence, the vastness of compounds and active ingredients and their presence, to different extents, in a wide variety of foods, foodstuffs, supplements and pills, as well as their alleged impacts in health, make the regulation of these substances a necessity. However, as discussed in the following section, and in spite of the current overwhelming daily presence of nutraceuticals, legislative bodies and regulatory agencies continue to be, to a large extent, incapable of adequately regulating these compounds, as companies continue to profit from marketing such products. Additionally, it becomes necessary to distinguish which, if any, of these potentially listed benefits do hold to the test of science, as later addressed.

3. Legislation and regulations

As foods and/or food ingredients, these substances are regulated by the FDA under the authority of the Federal Food, Drug, and Cosmetic Act (P.L.75-717, 1938), though they are not specifically defined by law. In fact, the only legally-defined term is that of “dietary supplements” (Finley, 2016). Because, according to the FDA, no drug may enter the food market and food is defined as “used for food or drink (or) components of any such article” (Finley, Finley, Ellwood, & Hoadley, 2014), this has complex implications not only in the creation and development of new products with

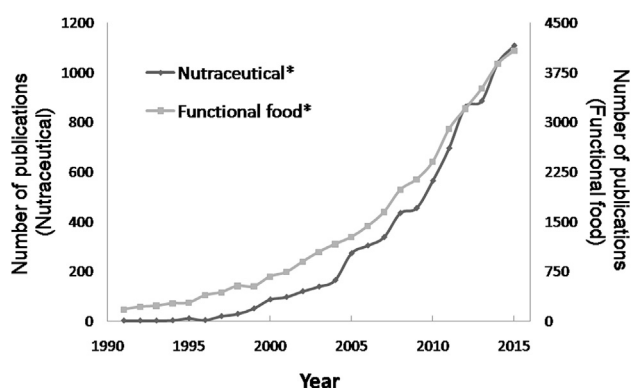


Fig. 1. Number of publications pertaining to either “nutraceuticals” or “functional foods”, from 1991 to 2015, using Scopus (Boyle & Sherman, 2005). Queries included “nutraceutical*” and “functional AND food*”, in the Title, Abstract and/or Keywords. Searches were performed using the “*” symbol, to include word variations, such as “nutraceuticals” and “functional foodstuffs”, among others.

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