Functional food development: concept to reality

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Introduction

Functional food development has enjoyed heightened interest by commercial, academic and governmental sectors over the past decade. Food products with health claims attesting to functional capacity to promote health which extends beyond provision of essential nutrients are eagerly accepted by consumers and likely results in decreased morbidity and mortality, and increased quality of life in the general population. However, despite numerous important advances in functional food development, the reputation of the field has been tarnished on account of at least two reasons. First, inconsistent data have resulted in overt inconsistencies regarding the impact of certain food ingredients on health indices. Examples of inconsistencies include the controversy for vitamin E (Miller et al., 2005) and beta carotene (Patrick, 2000; Pryor, Stahl, & Rock, 2000). The absence of unequivocal evidence supporting diet—disease relationships has posed a challenge for the public to place their faith in nutritional messages. Second, the potential for financial gain has resulted in many unsupported claims for nutritional ingredients by commercial enterprises whose interests lie more in profit rather than sound science. Seemingly this is the case with the policosanol trials (Berthold, Unverdorben, Degenhardt, Bulitta, & Gouni-Berthold, 2006; Varady, Wang, & Jones, 2003). Indeed, industry sponsored trials are generally not ranked highly by consumers. For these reasons, nutritional sciences have suffered a credibility gap over past decades. Despite these drawbacks, several substantial diet—disease links have been forged over the past 50 years in nutritional science which have been important in the introduction of functional foods to the commercial market. The potential negative role of saturated fat in the diet was likely one of the original discoveries in the 1950s (Hu & Willett, 2002). More recently the evolution of concepts surrounding dietary fibre (Erkkila & Lichtenstein, 2006) and plant sterols (Katan et al., 2003) in relation to disease prevention reflects examples of the positive aspects of nutritional sciences and functional foods which have contributed to the wellness and longevity prolongation of populations. Although knowledge of the scientific underpinnings to the diet—disease link is critical for health promotion, the process of improving nutrition involves further aspects that reach into domains of regulatory and commercial interests. Indeed, for science-based nutritional knowledge to morph into improved population health requires a series of steps which culminate in a functional food developed to help enhance public health. The purpose of this article is to explore the process of translation of nutritional concepts into improved population health through this series of successive stages. The specific aim of this review is to explore the fundamental mechanisms through which evidence-based research can promote the development of foods and nutritional products which confer health

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benefits. By dissecting the components that underpin this dynamic science supporting the growth of the functional foods and nutraceuticals industry, a better sense can be obtained of how various stakeholders work together synergistically to improve public health and wellness.

The cycle of innovation

Concept testing

The process through which innovation in nutritional science occurs develops through intersecting alliances of various stakeholders as depicted in Fig. 1. Involved are research, industry, regulatory and consumer sector interests. Although the process of initiation of the cycle depicted in Fig. 1 can commence at any point, the most likely facet of the cycle to finally drive the remaining sequence is the creation of an idea of a novel diet—disease concept. Clearly, far more concepts emerge that fail to complete the innovation cycle than do, however, a logical nutrition—health concept exists as a central defining feature of the process. More often than not, such concepts originate from academic research performed in industrial or university laboratories. Occasionally, such concepts are derived de novo, however, more likely they arise from amassed evidence. Industry often initiates this part of the cycle; indeed these concepts are often spurned from previous similar successes. Innovative concepts may also emerge from academic researchers; however, although cognizant of the science, academic researchers are often not aware of the myriad of issues which come into play in translating diet—disease concepts into marketable food products. However, with the maturation of academic based offices of research services university researchers are become more fully aware of issues of concern in working with industry. Indeed, teams of academics working with business interests provide the grounds for a sharing of views on what would make an optimal concept product to take forward through the successive elements of the innovation cycle. Such alliances are increasingly being realized as food companies work ever more closely with academics through the formation of scientific advisory boards.

Product development

Following generation of a novel diet—disease concept, the next natural stage in the innovation cycle is to develop a real-world test product that embraces that concept. For instance, production of a probiotic enriched yogurt, a cheese enriched with omega 3 fats or a spread containing plant sterols reflects translation of diet—disease concepts into functional commercial products. Often rendering of the concept into a marketable, acceptable product represents a considerable challenge. In many instances substantial hurdles surround proper matrixing, formulation, as well as ensuring that the product possesses acceptable hedonic qualities. Foods which incorporate entities with the fewest taste, mouth-feel, stability or intestinal side effect attributes will hold the greatest possibility of seeing a concept translated into a successful product.

Omega 3 fatty acids (FA) have garnered substantial commercial interest due to their potential heart healthy properties (Breslow, 2006). The worldwide market for omega 3 fatty acid ingredients was valued at more than US$700 million in 2005 (Turner, 2006). Omega 3 FA have been added to commercial products including milk, cheese, yogurt, bread and juice. However, a recent report by Frost and Sullivan show that omega 3 FA are still viewed negatively by the food industry with some of the major concerns being that omega 3 FA may be sensitive to oxidative damage as well as possessing adverse taste and smell qualities (Seaton, 2006; Staff reporter, 2006). Fortunately, technological advances such as microencapsulation have made incorporation of omega 3 FA into food much easier and acceptable (Whelan & Rust, 2006).

Plant sterols exist as another key player in the functional foods market and have been shown to effectively lower blood cholesterol levels (Plat & Mensink, 2005). Plant sterols are found in several formats with the most popular being yogurts and spreads. In a recent report by Frost and Sullivan, European markets for plant sterols were valued at $184.6m in 2005, and are estimated to reach $395.2m by 2012 (Daniells, 2006a). With plants sterols being so widely used and possessing such a positive safety profile, the National Cholesterol Education Program (2002) has incorporated a recommendation of using 2 g/day of plant sterols as a therapeutic lifestyle change to lower LDL cholesterol levels.

Probiotics represent another category of functional compounds which have seen an upward trend in consumer interest for their potential benefits in disease conditions including gut health, cancer and allergies (Reid, Jass, Sebulsky, & McCormick, 2003). The probiotic market is one of the fastest growing sectors in fresh dairy market with a retail growth of about 12% (Daniells, 2006b). Many probiotics products are yogurt based. Similar to issues faced by omega 3 formulation, incorporating probiotics into foods presents technological challenges. Main concerns over addition of probiotics to foods include what type or form of ingredient/probiotic should be

![Fig. 1. Functional foods and health promotion: cycle of success.](Image)
selected, how much must be added to have a beneficial effect, and whether supplementation changes sensory properties (Champagne, Gardner, & Roy, 2005).

Efficacy/safety and evidence

Expression of a nutrition—health concept through development of a product needs to be followed by verification that the product will mirror the original concept through the testing of biological efficacy. Although it is possible to assume that biological action and safety of a given candidate product can be supported adequately by the preexisting body of evidence, more often it is required that efficacy and perhaps safety assessment of individual test matrices be undertaken. Reasons for the need to test specific matrices of bioactive ingredients are several. Placing a bioactive component into a particular food matrix may affect its efficacy. As an example, it has been demonstrated that plant sterol efficacy differs across various matrices. Clifton et al. (2004) studied plant sterol enriched milk, bread, cereal and yogurt and discovered that although LDL cholesterol was lowered by all four food types, the milk matrix was almost three times more effective than in bread or cereal. Failure to properly disperse the bioactive principle within the food delivery system is another potential reason for reduced efficacy. This has been demonstrated in earlier low fat formatting of plant sterols into juice (Jones, Vanstone, Raeini-Sarjaz, & St-Onge, 2003). Moreover, failure to achieve a threshold dosage may limit the biological efficacy of the bioactive material of interest. This is seen especially with probiotics where Champagne et al. (2005) noted that the survival of probiotic bacteria during passage through acidic conditions of the stomach exists as a major concern to manufacturers. Thus, for various reasons it is vital to confirm the efficacy of any product developed on a theoretical diet—disease concept.

Efficacy assessment is an essential element of establishing the credibility of functional food entities and can be performed using in vitro or in vivo systems. Cell systems provide basic biological information regarding nutrient—biochemical process interactions. However, to assess biological activity on a whole body physiological basis, use of animal or human systems is preferable. Animal systems enable a high degree of control of diet, environment and genetics, although, many instances exist where animal models fail to adequately mimic the normal physiological responses of humans. Numerous differences exist in lipid metabolism among various species which should be considered when assessing the relevance in humans of research findings from various animal models (Bergen & Mersmann, 2005). As such, properly conducted human trials are more desirable than those in animals. Confirmation of efficacy, particularly in a human system, also provides a strong basis on which to argue allowing a health claim for that specific product.

Demonstration of clinical efficacy for a functional food product represents a critical point of the innovation cycle, as at this stage the credibility gap narrows for both the diet—disease concept, as well as the product claim itself. Clinical efficacy credibility is strengthened by the presence of parallel studies with related products. Evidence also needs to be provided by parallel studies conducted across several jurisdictions and conducted in both academic and private sector institutional laboratories. Indeed commercial enterprises conduct extensive responsible and sound FF research from a scientific point of view, both in their independent labs and in collaboration with academics. Even multiple clinical studies attesting to biological efficacy of a functional ingredient have limited utility if all such studies emanate from a single source and other laboratories fail to reproduce the same diet—health marker relationship.

Publication

The optimal path for dissemination of biological efficacy data is through publications in peer-reviewed journals, generally accepted as the most authoritative route of dissemination of leading edge science. However, journals are increasingly aware of the positive impact that published positive results can have in terms of marketing of pharmaceutical or nutraceutical ingredients, thus, have become more stringent and restrictive over potential conflict of interest of authors. Many journals now publish disclosure statements concerning linkages of authors with the study funding sources. Journals are also less willing to publish studies containing negative findings which can result in obfuscation of overall distribution of the literature, favoring sometimes erroneously an overly positive position for a given functional food ingredient. It is equally important that negative, as well as positive, efficacy and safety results be disseminated through peer-reviewed publication in order to provide a balanced evaluation of the true merits of that ingredient.

Health claims and regulatory review

The next stage of the innovation cycle involves communication of the health messages generated through active research and regulatory review of a specific food product to the general public. Regulatory review is required in order to translate peer-reviewed published data supporting the efficacy and safety of a given bioactive product within a novel food matrix or capsule into policy changes consistent with approving products for sale of functional food products. Either the supportive data can be used directly in promotion of material, or indirectly in securing a health claim. For health claims to be approved through the regulatory review process, functional food products must be thoroughly evaluated for efficacy and safety through the stages of the cycle of innovation defined in Fig. 1. Unfortunately in certain jurisdictions, restrictive health claim environments have resulted in substantial challenges in terms of communication of food/health relationship to the general public. Globally, regulatory systems vary widely with some countries such as Japan allowing over 500 functional foods (Yamaguchi, 2005), while other countries such as Canada
allow a much more limited number of health claims. Such restrictions have been challenged successfully in courts of law. As an example, the successful Pearson versus Shalala landmark health claim lawsuit petitioned against the Food and Drug Administration, which resulted in the present series of qualified health claims in the US.

Although the number of claims allowed varies widely across jurisdictions, the process of regulatory review shares some common features. Normally the benchmark of successful regulatory review rests in provision of sound peer-reviewed data, which are compared to a set of criteria necessary for permission of any given claim. Normally, a certain threshold of evidence is required during the course of regulatory review to enable a claim to be made for a specific or generic functional food category.

Industry growth

Securing specific messages on foods attesting to their health benefits represents a vital part of the cycle of moving a functional food from concept to a marketing success story. Given that consumers are both interested and informed about foods that confer health benefits beyond simply providing nutrients (Heller, 2006) the presence of an informative, authoritative claim on a food will stimulate the market share penetration of that product within its sector. Such an increase in market share will promote further growth by leading to additional “concepts/theories” to be elaborated and tested thus reinitiating the cycle. Ultimately the successful development of any successful FF will stem from a balance between the obstacles surrounding regulation and available science versus the demands of the commercial market.

Summary

Functional food development is a multistage process that requires input from commercial, academic and regulatory interests, with a critical need to achieve acceptance by consumers. It is only through these partners working cooperatively through the multiple elements of the continuum from concept to successful marketing of functional foods that this sector will see continued growth and sustainability.

References


