SOYA PROTEIN-NUTRITION-Roundtable

discussions

Difficulties Arising from Legal Definitions of Nutrition – Uncertainty and Risk

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INTRODUCTION

Development of novel vegetable protein foods and their eventual commercialization require large investments which are based on an understanding of the attendant risks. In assessing risks, companies consider a number of internal and external factors and attempt to describe the past, present and future "condition" of these factors. The higher the degree of uncertainty surrounding a factor, the less confident one is of quantifying the risk of a new product venture, and the less likely one is to proceed with development. In the case of vegetable protein foods, government regulations are a major external factor which must be considered in assessing risks. Specifically, the legal definitions of nutrition now being proposed in the U.S. have created a degree of uncertainty which could result in the curtailment of innovative development programs. This paper gives an overview of investments required and the process of assessing risks in new product programs, and attempts to point out the difficulties posed by legal definitions of nutrition.

NEW PRODUCT INVESTMENT

Successful new products are ideas which have survived the rather tortuous process of screening, evaluation, concept testing, development, test marketing and commercialization (1). At each stage in the process, questions are raised which must be answered in order for a company to decide, with some degree of confidence, whether to proceed as planned, modify approaches or terminate the project. As the nature of the questions becomes more complex, the cost of finding answers increases. However, even with well-documented procedures for carrying out the various stages of new product programs, the success rate is still discouragingly low. In a recent study of 51 U.S. food companies, it was shown that out of nearly 60 new product ideas brought through the various stages, two reached test market and only one of these was successfully commercialized (2). We have estimated the investment costs of bringing a hypothetical new brand of retail food to the national market. The estimate is based on the experience of people in our organization who have been involved in the new products programs of a number of U.S. food companies. For a typical national brand with sales of \$20 million during the first year, the investment represents 90% of sales or \$18 million. The breakdown of investment costs is given in Table I. Notable is that the research and development costs are low compared to capital investment and nonrecurring marketing costs. Put another way, the technical development risk is small compared with the risk of building plants and marketing the product.

INTERNAL AND EXTERNAL FACTORS

The major internal and external factors which should be considered when a company embarks on a new product development program are listed in Table II. The importance given to each factor depends on, among other things, the nature of the company and the types of new products being developed. For innovative products, such as foods based on vegetable proteins, the weight assigned to regulatory considerations will be higher than that for a new product in an existing category. That is, regulatory considerations have a

TABLE I

Investment in a New Product Program

Stage	First year national sales ^a (%)	US \$
Pre-test market		
Marketing	2	400,000
Marketing research	3	600,000
Research & development	8	1,600,000
	13	2,600,000
Test markets ^b		
Research & development	2	400,000
Capital investment	2 7	1,400,000
Marketing (nonrecurring)	13	2,600,000
	22	4,400,000
National market		
Marketing (nonrecurring)	20	4,000,000
Capital investment	35	7,000,000
	55	11,000,000
Grand total	90	18,000,000

^aAssumes sales of \$20 million.

^bAssumes 2 products in test market with 1 failure.

TABLE II

Internal and External Factors in a New Product Development Program

Potential market size Product viability Competitive environment Regulatory considerations

greater impact on investment decisions regarding innovative foods as opposed to traditional foods.

UNCERTAINTY AND RISK

Risk is simply a description of the chances that a new product has of succeeding or failing commercially. It is derived by combining (with proper weighting) the probability of those occurrences associated with each investment factor. Whether a food company uses a formal system of risk analysis, the higher the degree of uncertainty surrounding each of these investment factors, the higher will be the risk associated with a project. For a more detailed discussion of uncertainty and risk in investment decisions, the reader is referred to an excellent paper by Hertz (3).

LEGAL DEFINITION OF NUTRITION AND UNCERTAINTY

Regulatory considerations, specifically, current legal definitions of nutrition of vegetable protein foods, may negatively affect development programs. These have greater weight in determining the risk associated with commercialization of vegetable protein foods than with more traditional foods. This is so because, in regulating "new" foods, the government, in its deliberations, is being more attentive in its approach and is attempting to strike a balance between practical, economical and nutritional considerations. The result of more than 10 years of deliberation among government, industry and other interested groups in the U.S. is the FDA Tentative Final Regulation of Vegetable Protein Products (4). This regulation defines the common or usual names of vegetable proteins; defines the nutritional equivalency profiles for vegetable proteins which replace various meats, poultry, seafood, eggs and certain cheese products and gives guidelines for finished product names. Setting aside the uncertainty associated with the effects of finished product names on consumer acceptance (a major consideration in its own right), let us examine why the nutritional definitions cause a great deal of uncertainty. The uncertainty arises from the following considerations:

- 1. Nutritional definitions are more art than science.
- 2. Since 1971 USDA has specified nutritional pro-

files and requirements for amino acid supplementation in the School Lunch Program which differ substantially from the new regulation.

- 3. FDA has jurisdiction over the manufacture of vegetable proteins but USDA regulates their use in meat, poultry, egg and dairy products.
- 4. Although there has been "close cooperation" between the agencies, the form and extent of adoption of these regulations by the USDA is unclear.
- 5. Regulations do not pertain to foods covered by existing Federal Standards, some of which allow the use of significant amounts of vegetable proteins.
- 6. USDA food standards have not been developed on a nutritional basis.
- 7. U.S. consumers currently are receiving conflicting dietary recommendations from government, health authorities and various consumer groups which makes future trends in food consumption difficult to predict.

These seven considerations are more than academic-they are kinds of issues raised when management considers whether to invest in "foods of the future." At this time, our inability to clearly relate the nutritional bases of the regulations to the realities facing food manufacturers makes ventures into innovative vegetable protein foods more risky. It will not be an easy task to resolve the issues raised in this paper. In an ideal world, one could suggest simply starting with a "blank sheet," but this is impractical. What is needed is an effort which uses common sense when solid nutritional information is unavailable, a better rationalization of nutritional definitions in light of existing food standards, unified application of regulations and clear delineation of jurisdictions. Until uncertainty is reduced, U.S. food companies will continue to invest their resources in less innovative development programs.

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- 4. Federal Register 43 (136) Friday, July 14, 1978.

Consideration of Regulations of Baby Foods Containing Soybeans in Venezuela

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ABSTRACT

Quality standards for industrially processed food products are being prepared by a joint committee composed of the private sector, government and universities. These standards include specific dispositions which, if necessary, allow utilization of different ingredientssoya protein derivatives among them- to improve the quality and quantity of the protein or to balance the amino acid profile. Despite these efforts, in Venezuela, there are no clear-cut regulations about the utilization of soybean proteins either as a supplement or as an ingredient in the manufacture of food products for human consumption and, as such, its use is limited to a few items. Several reasons can be cited to explain this low use: (a) the incipient/scarce domestic production of soybeans; (b) the high cost of imported protein derivatives (only soya flour is fabricated in the country from imported beans); (c) lack of interest (apathy) and absence of proper knowledge or insufficient advice of the private industry; (d) lack of proper incentives from the government; and (e) unnecessary complications or delays in the registration procedures of the new products. Baby foods containing soya proteins in Venezuela can be grouped into the following categories- 1: cereal-based products elaborated by the private sector; 2: different food items distributed by the Intituto Nacional de Nutrición; 3: milk substitutes; 4: high-protein preparations used in special diets; 5: soya protein-enriched commer-