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 profiles 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.

REFERENCES

1. Burns, J.S., Food Prod. Dev. 13:40 (1979).
2. "New Product Success Ratios 1977," The Nielsen Researcher 1:3 (1979).
3. Hertz, D.B. Harv. Bus. Rev. p.169 (Sept. 1979).
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 ingredients– soya 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-

cial flours. A general review of the composition, protein ingredients, presentation and availability of the different items within the five groups is presented and discussed. Emphasis is on the standards which regulate the commercial products in group 1. Comments are made about Venezuelan food habits and possible acceptance by consumers. Foods covered in group 2 include different types of biscuits, a Venezuelan bread (arepa) made with degerminated corn fortified with soya flour, and a ready-to-drink beverage. Group 3 covers a specific segment of the market and presently faces unavailability. Products under groups 4 and 5 could be used as a potential high-protein food for young children, although high costs of group 4 products present serious obstacles. Special reference is made to the soybean derivatives used in these products.

INTRODUCTION

Soya protein regulations in Latin America are scarce or nonexistent, Article 418 of the Latin American Food Codex (1) indicate the percentage composition of soybean (poroto de soya), and in the chapter on salad dressings, soya is mentioned among the ingredients. Soya flour composition is described in the Código Sanitario de Alimentos del Perú (2); some standards applicable to soya products also can be found in Central American countries and Brazil (3). In Venezuela, aside from the COVENIN Standard about soya oil (4) and the proposed Standard for soya meal (5), specific regulations do not exist for the use of either soya protein derivatives in foods or food products that contain such proteins. The purpose of this presentation is to review baby foods containing soya protein and current food regulations in Venezuela.

Classification of Foods Containing Soya Proteins

Industrially processed products containing soya protein intended for consumption by children, are either imported, produced locally or distributed by the government and can be grouped into the following categories: (a) cereal-based products manufactured by the private sector, (b) products distributed by the National Institute of Nutrition, (c) milk substitutes, (d) high-protein products, and (e) fortified cereal flours.

Cereal-Based Products Manufactured by Venezuelan Private Industry

The use of bottles, gruels and other table foods based on cereal flours for children is a widely accepted, popular custom in Venezuela. The commercial products used are made either of a single flour, mainly rice, or from a mixture of vegetable flours, which may be enriched with vitamins and minerals. For instance, in a 1970 survey made by the National Institute of Nutrition in several communities near Caracas, it was found that 83% of the families used cereal-based commercial products in preparations for bottle feeding (6). Similarily, the use of commercial cereals in the preparation of infant foods was mentioned by 43% of the families surveyed in Mother Crafts' Centers in the capital and by 42% of the families investigated in the Caracas survey in 1966 (7).

The protein content of selected cereal-based products available at the time of those surveys was, in the most cases, below 14%. Five of the 12 products tested contained less than 10% protein. Furthermore, in some samples, the actual protein value was found to be lower than the value listed on the container.

Protein quality of some products as determined by rat bioassay is presented in Table I. All rat bioassays were done during 1965-72 in the National Institute of Nutrition, Caracas, Venezuela. Protein efficiency ratio (PER), net protein ratio (NPR) and net protein utilization (NPU) values were low, a result expected from the composition of these products. The NPU parameter was calculated using the average nitrogen value for the Sprague-Dawley (8). Product FRX had the highest level of protein and was responsible for the best biological response. Its declared ingredients were precooked wheat, oat, and corn flour, skimmed milk, ground bones, yeast, vitamins and minerals. This product is no longer on the Venezuelan market.

Supplementation of NNA, MNA and FFV with different levels of soya flour increased their protein quality, as can be appreciated in Table II. Soya flour was mixed with the product in the indicated proportion prior to diet elaboration. MNA with 4% Venezuelan soya flour showed the poorest weight gain and protein quality, probably due to an inadequate amino acid profile. ,

By 1970, we had the following facts: there existed a very popular and widely accepted group of commercial products based on cereals marketed with emphasis on infant and child feeding. At the same time, its protein quality and, in most cases, quantity were very low. This situation led the Ministry of Health (the National Institute of Nutrition), the Official Venezuelan Bureau of Standards (COVENIN) and the private sector, to prepare "Standards for the composition of vegetable based food products for infant feeding"

TABLE I

Protein Quality of Selected Cereal-Based Products Prior to the Quality Standards (1965-71)

Product	Protein in diet (%)	PER	NPR	NPU
NNA	9.4	0.81	1.32	28
MNA	10.1	0.66	1.18	18
NTM	10.8	0.20	0.90	21
PBM	10.6	1.24	1.63	29
FRX	10.3	1.73	2.17	47
Casein	10.6	3.70	4.03	66

TABLE II

Protein Quality of Selected Cereal-Based Products with Added Soya Flour

Product	Protein in diet (%)	PER	NPR	NPU
NNA + 10% soya flour[a]	9.4	2.25	2.67	43
NNA + 10% soya flour[b]	8.9	1.87	2.27	36
NNA + 4% soya flour[a]	10.0	1.03	1.39	23
MNA + 4% soya flour[b]	10.0	0.81	1.28	18
FFV + 30% soya flour[b]	8.5	2.93	3.36	58
Casein	10.6	3.70	4.03	66

[a]F-200, A.E. Staley Mfg. Co. Decatur, IL.

[b]Soya-50, Extractora Nacional de Oleaginosas, S.A. Valencia, Venezuela.

TABLE III

Protein Quality of Some Cereal-Based Products Adhering to the Quality Standards

Product	Protein in diet (%)	PER	NPR	NPU	RPV
GBN - S[a]	10.1	2.23	2.73	51	49
GBN - A[a]	10.1	2.33	2.90	50	52
GBN - C[a]	10.2	2.48	2.98	49	52
NNA - 1[b]	10.2	2.76	3.30	59	–
NNA - C[b]	10.1	3.07	3.59	65	–

[a]Soya flour produced in the country as main protein ingredient (1976).
[b]Calcium caseinate as main protein ingredient (1970).

TABLE IV

Soya-Containing Foods Distributed by the National Institute of Nutrition, Venezuela (1980)

Product	Age group (years)	Jan. - March	Apr. - June
Biscuits (wheat & soya flour)	1- 6	2,238,917	6,825,296
Beverage ("chicha," 200 ml/serving)	7-14	1,238,127	3,666,554
Arepa (8% soya flour)	7-14	3,569,167	5,974,769

Source: Dirección Operativ INN. 1980.

(Gaceta Oficial No.29,802 del 12-05-72) and the "Standards for foods based on cereals for children" (9). These regulations were officially published in 1972 and 1979, respectively.

As a result of the application of these regulations, the quality of cereal-based baby foods has markedly improved. For instance, a minimum of 16% protein is now required by law if the product is intended to be marketed for infant feeding and a level of no less than 25% protein is compulsory for a product to be called "high-protein cereal." Several protein sources can be used to increase the protein level and thus fulfill the requirements. Among the sources permitted are soya protein derivatives. It should be pointed out, however, that these quality standards regulate only the identity and composition of this particular group of food products in Venezuela but does not refer specifically to soya-protein-containing foods, or to the utilization of soya protein derivatives in cereal foods.

Table III shows the protein quality of some products adjusted to the regulations. As can be appreciated, values of PER, NPR, NPU and RPV, RPV calculated only in GBN products, were higher compared with the ones studied previously. Products identified as NNA-I and NNA-C, which were voluntarily adapted to the standard before implementation as early as 1970, reached 16% protein with calcium caseinate but later shifted to soya protein isolates because of economics. This practice continues today and the manufacturer is the only one in the industry using soya protein isolates to supplement cereal flours, thus achieving the desired protein level.

Products Distributed Free by the National Institute of Nutrition

Among the soya-containing foods intended for children, this group is second in importance to the previous one. The foods covered here are a biscuit made of wheat and soya flour; a typical Venezuelan bread known as "arepa" made of ground corn enriched with 8% soya flour; and a ready-to-drink beverage called "chicha."

Initially produced by a well-known Venezuelan enterprise, the biscuits are presently produced in Colombia for the National Institute of Nutrition. This product is packaged in polyethylene bags with a net weight of 468 g, containing 18 small packages of 4 vanilla flavored biscuits each.

The ingredients of the "chicha" per 100 ml are: 5 g rice flour, 4 g soya flour, 5 g skim milk, 13 g sugar, vegetable fat, vitamins and minerals. This product is distributed in 200 ml "pure-pack " containers and provides 3.6 g protein and 95 cal/100 ml.

Light yellow in color, the soya-enriched corn flour is produced by a Venezuelan Company, at a rate of ca. 100 tons/month with a cost of ca. $0.45/kg (O. Ibarra, personal communication). The results and conclusions of these developments (D. Johnson and O. Rodriguez, personal communication) were presented later in Nutritional Improvement of Corn, a conference held at the National Institute of Nutrition of Central America and Panama (INCAP), Guatemala in 1972 (10).

The consumption of these supplementary foods containing soya protein, corresponding to the first semester of 1980, is indicated in Table IV. An increase in the consumption by type can be observed in the months of April-June. This consumption covers the whole country with the exception of the "chicha," which due to logistics is produced and distributed only in the West Central part of Venezuela (11). All of these products use soya flour as an additional source of protein. In the "chicha" and arepa flour, all production uses imported soybeans and is done by only one manufacturer. The biscuits produced abroad are made of a foreign product. None of these products are intended to be sold in the market presently, but are distributed free within the programs of the National Institute of Nutrition (14).

Soy-Based Preparations As Milk Substitutes

Considered as Foods for Special Dietary Uses by the Codex Alimentarius and by Venezuelan legislation, these commercial products are sold in pharmacies and supermarkets and are registered as foods and not as pharmaceutical specialties. Presently, three products are marketed: ISML, fabricated in Holland, PSBE from Canada and ALXY, produced

in Venezuela. The first two products utilize soya protein isolate as the only protein source and the Venezuelan product is made with soya flour that is produced domestically. These products are purchased by people with milk intolerance. This group of soya-protein-containing products have no specific regulations affecting their production. However, the COVENIN Standard 909-79 "Infant Formula" (13), in the section dedicated to Essential Composition, allows the use of ingredients other than cow's milk, either from animal or vegetable origin, deemed suitable for infant feeding. Also, in products based on soya proteins, only specific amounts of some additives, e.g., certain thickening agents, are permitted.

High-Protein Foods

These products also are treated as Food for Special Dietary Uses by Venezuelan regulations (14) and can be registered either as foods or pharmaceutical specialties. About 20 products of this kind can be found in the Venezuelan market, but only two are of interest from our point of view. These are SPRL and GVRL, which have 36 and 60% protein, respectively. Probably because of adverse organoleptic properties, inadequacies in marketing, competition from other similar products not containing soya proteins, and less flavor appeal, these two products have an uneven consumer demand.

Soya Protein-Enriched Flours

This group comprises the precooked corn flour fortified with 8% soya flour, which at the present, is only distributed by the National Institute of Nutrition. Designed as a food for the general public, this product is not yet available on a commercial basis. Some unpleasant flavor and aroma of the resulting dough, uncertainty of the Venezuelan market and fixed prices of the finished products negatively affect commercial production. (O. Ibarra, personal communication).

Other commercial products, including hot dogs and sausages containing soya proteins, are also consumed in variable proportions by older children but cannot be considered within the general scope of this approach, as time does not permit a detailed discussion of these products.

CONCLUSIONS

Venezuela produces a limited variety of processed foods containing soya protein, some of which are imported and some that are produced locally. At the same time, clear-cut regulations do not exist concerning the utilization of soybean proteins either as a supplement or ingredient in the manufacture of food products for human consumption. The following points of view could partially explain this situation. The private sector has, for some reason, shown a degree of apathy or perhaps absence of proper knowledge from insufficient advice in the field of appropriate utilization and application of soya protein technology. Also, Venezuelan health authorities have demonstrated, thus far, little interest and low receptivity to the advantages of this technology and toward the elaboration of specific regulations and standards. The lack of reliable and effective methods of analysis to control the use of soya protein in food is, in their point of view, a serious obstacle to consider the full-scale implementation of this technology. Furthermore, the scarcity of incentives from the government and the unnecessary complications and delays in the registration procedures of any new product are setbacks.

On the positive side, it is worthwhile to emphasize the efforts made in Venezuela by private organizations to promote and disseminate knowledge of soya protein utilization in human foods. For instance, several demonstrative talks and conferences have been offered at different levels by the American Soybean Association (the most recent in Caracas during April 1980). Similarily, the Ralston Purina Company, through its Venezuelan branch, Purina de Venezuela, sponsored the "Symposium about Soya Protein Isolate and Its Use in Human Food in Venezuela," held in Caracas during September 1979. Despite thorough publicity and excellent organization, the attendance of the official sector was meager and, in my opinion, the expected goals were not fully achieved.

Finally, I do believe there is great potential for the use of soya protein in my country. Venezuela is a developing country with peculiar characteristics not common to other developing countries either in this hemisphere or in other parts of the world. It cannot afford to lose the benefits derived from the wise and appropriate use of soya protein for human nutrition.

REFERENCES

1. Código Latinoamericano de Alimentos, Segunda Edición, Octavo Congreso Latinoamericano de Química, Estab. Gráfico "Sidus" S.R.L. República Argentina, 1964.
2. Código Sanitario de Alimentos, Ministerio de Salud Pública y Asistencia Social, Lima, Perú, 1963.
3. Olszyna-Marzys, A., Legislación Alimentaria Latinoamericana en su efecto sobre alimentos de proteina de soya, Primera Conferencia Latinoamericana sobre la Proteina de Soya, México, 1975.
4. Norma COVENIN 744-78 "Aceites y Grasas Vegetales: Aceite de Soya Comestible," Venezuela.
5. Anteproyecto IA COVENIN 10:003 "Alimentos para Animales: Harina de Soya, Requisitos" Venezuela.
6. Encuestas Efectuadas en Pablaciones del Departamento Acevedo, Estado Miranda, Instituo Nacional de Nutritión, Venezuela, 1970.
7. Estudio de Caracas, Volumen VII, Tomo 1, Ediciones de la Biblioteca, U.C.V. Caracas, 1971.
8. Pellet, P.L., Brit. J. Nutr. 21:609 (1967).
9. Ministerio de Fomento COVENIN 1452-79" Norma Venezolana: Alimentos Elaborados a Base de Cereales Para Niños," 1979.
10. Chávez, J.F., "Mejoramiento Nutricional del Maiz," Publicación INCAP L-3, 1972.
11. Informe de las Unidades de Nutrición, Archivo de la Dirección Operativa, Instituto Nacional de Nutrición, Venezuela, Sept. 1980.
12. Consideraciones sobre alimentación y nutrición en Venezuela, Consejo Técnico del Instiuto Nacional de Nutrición de Venezuela, June 1980.
13. Ministerio de Fomento, COVENIN 909—79, "Norma Venezolana: Fórmulas Alimenticias para niños de Pecho," 1979.
14. Resolución sobre Alimentos para Regímenes Especiales, Venezuela, Gaceta Oficial No. 31, 106 de fecha, Nov. 1976.