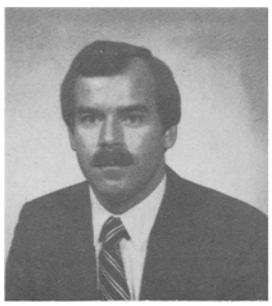
the consumer not be deceived or misled in any way by marketing or labeling practices used for foods. This is interpreted to mean that the consumer cannot be deceived about the composition or nutrient quality of foods. Therefore, if a traditional food is made with partial or total replacement with a new protein source, the consumer must be informed of that fact in the naming of the product. Further, if a new ingredient is added to a traditional food and thereby gives the appearance to the consumer that the product contains more of a valued ingredient than a product containing the same amount of the valued ingredients, the consumer should be informed about the addition of the new ingredient in the name of the product. Otherwise, the consumer might be deceived into believing the product containing the added new ingredient is higher in the valued product.

FAIR MARKETING PRACTICES

The regulation of fair marketing practices is not part of the Food and Drug Administration's mandates, but is a concern of the Federal Trade Commission. That agency has, in the past, taken action to prohibit practices in the marketing of new substances which were considered to be unfair to other products in the marketplace. Generally such practices also affect consumers and, therefore, the FDA would have a role.



Regulatory Approach of Industrialized Countries to Accommodate Use of Soy Protein

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ABSTRACT

Government bodies worldwide are moving toward accepting soy proteins in their food supplies. There is a trend toward food laws that allow countries to take advantage of unique nutritional, functional and economic benefits soy protein has to offer. This is a world precedent, soundly based on broad experiences and firmly backed by scientific research and development. There is no longer any need to postpone this important decision to allow soy protein in the food supply. The most critical question at this point should be: "What steps can be taken now to properly incorporate and take advantage of soy protein in the national food supply? Regulations recognizing the benefits of soy protein in the food system need not be complex. A reasonable approach to food legislation attempts: (a) to allow the production of properly labeled, safe, wholesome foods, recognizing new developments in modern food technology; (b) to ensure the nutritional value of foods; (c) to provide sufficient information and understanding to help the consumer make a wise purchase decision; and (d) to adopt controls as required to promote honesty and fair dealing in the marketplace.

Regulation of Soy Protein in Foods

Regulatory development to take advantage of how soy protein can benefit the national food supply and the nutritional and economical well-being of its consumers is underway on a global scale. The technological advancement and the nutritional and functional properties of soy protein has created a challenge for lawmakers in the formulation of new food regulations. The issues may seem difficult at first, but with careful consideration, these issues have been resolvable to satisfy the interest and expectations of all parties involved—the government, industry, and most importantly, the consumers.

The regulatory approaches presented here are based on experiences with national governments in their consideration of the use of isolated soy protein. Isolated soy protein represents the highest form of protein purification and is essentially free from the carbohydrate fraction found in other soy products. Being a relatively pure protein, isolated soy protein or soy protein, as it will be called in the remainder of this presentation, is the most technologically advanced soy product.

Numerous countries are successfully developing regulations which will allow them to take immediate and effective advantage of the quality, nutrition and economic benefits of soy protein. England, Sweden, Belgium, Canada, Spain, The Netherlands and the U.S. are examples. This paper focuses on the experiences of these and other countries regarding the regulation and use of soy protein in their food supply.

The approach to regulate soy protein is somewhat different in each country due to varying political and economic circumstances. Still, five basic considerations are common to all countries: (a) The decision to accommodate soy protein in foods through the establishment of official guidelines; (b) the relationship between existing food standards and the allowance of soy protein in products governed by standards; (c) labeling of foods containing soy protein; (d) nutritional requirements for foods containing soy protein; and (e) enforcement of compositional requirements for foods containing soy proteins.

Accommodating Soy Protein in the Food Supply

The present technology and continuing technological developments for soy protein will result in products that will enable food processors to offer effective responses to consumer demands for high quality, economical, nutritional food products. Studies have told us that consumers have positive opinions about soy protein and the advantages it offers. Consumers in growing numbers are not only accepting foods containing soy protein, but they also are beginning to understand the importance of this efficient source of protein that offers valuable nutrition to their traditional foods.

During the past few years, we have learned the importance of energy in our lives. We tend to think of energy in

terms of fuel, limitations of its sources, and its costs. But the human system also demands energy from another source—food. The energy component of food costs is universal. The Commission of the European Community, in a study of vegetable proteins, found that "one unit of energy input may produce 90 times as much soy protein as meat protein." In the face of increasing pressure on traditional protein sources, the relatively low cost and versatility of soy protein affords decision makers in government a key option that will meet consumer demands for food protein. Government officials worldwide are making policy and program decisions that encourage the use of soy protein for savings in money and increased nutrition.

The basic philosophy of most food laws is that if a food is safe, wholesome and nutritious, and provided the food is properly labeled, there is no reason to prohibit the food from entering the country's food supply. Among the countries which have seriously evaluated the many advantages of soy protein, agreement has been universal that such products should be allowed as food ingredients. The real challenge, then, has become: to establish definitions and standards for the basic forms of soy products; to establish hygienic guidelines; to consider the soy protein uses; and to develop labeling and nutritional guidelines.

Food Standards

Most countries have established food regulations placing varying degrees of control on foods. Generally, these regulations are intended to ensure the safety, wholesomeness, composition and nutritional value of foods. These consumer protection objectives have been accomplished principally through the establishment of standards of composition. In most countries, however, food standards were established for processed foods before alternative protein sources were technically advanced as a compatible ingredient in foods; thus, provision for their use was not taken into consideration. For this reason, the challenge to lawmakers is to establish guidelines for the use of soy protein in standardized (traditional) foods.

Most of the early attempts to allow for soy protein were "vertical" in nature. That is, they allowed soy protein in the food supply on a product-by-product basis. This required developing standards for each product in order to allow soy protein as an ingredient. It soon became evident this approach was too time-consuming, cumbersome and too complex to be manageable in a practical manner.

An alternative approach has evolved that concentrates on the soy protein ingredient rather than individual food standards. This is called a "horizontal" approach. The basis of this is a practical set of labeling and, in some cases, nutritional guidelines. Again, "horizontal" legislation does not deal specifically with standardized products, rather with classes of foods in general. Its application is broader in scope, and it more effectively controls the use of soy protein. The key part of the horizontal approach is labeling guidelines establishing rules for including soy protein in otherwise standardized food products. It is the approach taken by most governments today to accommodate the use of soy protein. It is the basis of the European Economic Community (EEC) Study Group's recommendation, and it is generally believed to be the only feasible approach for the future efforts at the Codex Alimentarius Commission. Horizontal legislation for soy protein meets the most important objectives in regulating food to protect the consumer. This is especially true considering it covers all foods, even those for which a government has not established standards of composition.

Labeling of Food Containing Soy Proteins

Providing adequate information to the consumer about the nature of food products is the key to achieving the important goal of protecting the consumer. The importance of the consumer receiving proper label information to make an informed purchasing decision applies to all ingredients; soy protein is no exception. There has been worldwide discussion on how this may best be accomplished. Clearly, a worldwide trend is to provide labeling which informs consumers of the role of soy protein in a food, and to avoid labeling that negatively prejudices purchasing decisions.

To provide a labeling scheme that properly informs the consumer of the role of soy protein in a food, government officials have examined the three basic ways that soy proteins are used in food products: (a) replacement of noncharacterizing ingredients that are in foods at low levels for their technical use; (b) soy protein used as an optional ingredient (fortification), and (c) partial replacement of traditional characterizing proteins. It is important that these uses for soy protein are properly understood for the horizontal approach to be effective. The labeling rules depend largely on how and why soya protein is being used in a food product.

Characterizing ingredients are those that the consumer expects to receive based on his traditional perception of the food product. They are required by an applicable standard of composition. They form a basic part of the consumer's motivation in making the purchasing decision. Examples are meat in sausage products, milk in ice cream, or shrimp in shrimp cocktail. Noncharacterizing ingredients are those used for technical purposes and are not, per se, basic to the consumer's reason for purchasing the product. Examples of noncharacterizing ingredients are egg or milk in bakery products, or casein in sausage products.

When soy proteins replace noncharacterizing proteins in foods, the soy protein is being used as a technical ingredient. In this case, there is no need for special labeling—conventional labeling guidelines are normally adequate. This is also true when soy protein is used to increase the protein content of the final food (fortification). In most countries, these conventional guidelines would simply require a declaration of soy protein in the ingredient statement in the order of its predominance.

Most countries have standards for traditional foods that specify a requirement for a minimal level of a characterizing ingredient, such as meat in meat products, or that limit the amounts of nonmeat ingredients such as fat and water. When soy protein is used to replace a portion of the required level of a characterizing ingredient, this is an example of the third type of use. Some countries consider a change in labeling requirements justifiable when soy protein is used to replace a required or expected amount of protein in a food. For example, when soy protein is used to replace meat in a hot dog, the product name might be changed to "Hot Dog with Soy Protein."

A notable trend in most countries is to require labeling which provides the consumer with information on the role of soy protein in a food. It has shifted away from placing maximal levels on the amount that can be used in a food, or restricting the foods to which soya protein can be added.

Nutritional Guidelines for Foods Containing Soy Proteins

Much regulatory attention has been focused on the issue of whether soy protein should be fortified with vitamins and minerals and/or amino acids. While not all countries have approached this subject in the same manner, the trend is definitely toward recognizing the soy protein as a highly

nutritious protein in itself. Recent studies clearly demonstrate that it is of comparable protein quality to milk, meat and egg protein.

Enforcement

Several methods are used worldwide to control the use of soy protein to prevent fraud or abuse. The ability to determine the presence of soy protein in foods has been a concern of governments. At the same time, these governments strongly believe the technical problems associated with this concern should not delay or prevent the regulatory development for the use and recognition of soy protein in foods. Countries such as Canada, Denmark, United Kingdom, France, the U.S. and Spain, and world food bodies such as the Codex Alimentraius Commission under FAO/WHO, and the EEC Section of Food Legislation are all committed to solve this concern, and still have recognized through regulation or policy the unique benefits and advantages of soy protein.

In some countries, the need or desire to determine analytically the presence and level of soy protein in foods has been expressed. These countries feel that an exact analytical method is necessary in order to ensure that the product composition is as represented on the label. Considerable research effort has been devoted to the qualitative and quantitative analysis of soy protein in meat products. "Qualitative" refers to detection of the presence of soy protein; "quantitative" refers to detection of the presence and level.

Several methods are being considered today for analyzing food products for their soy protein content. These methods include microscopic examination, and immunological and electrophoresis tests.

While other methods are still in various degrees of development, the electrophoretic method looks very promising. It is workable and is being used or considered by several governments for the detection of soy protein in meat products.

The use of a tracer such as titanium dioxide as an analytical method should only be adopted if other analytical methods are found to be too complex. Although it is generally recognized as a safe food additive, it does not contribute to the biological or physical enhancement of the food. For this reason, there is a general trend against the use of tracers in many countries.

A requirement to determine the exact composition of foods containing soy protein is thought to be regulatory excess in countries that have recently considered the question such as Canada, Spain and France. Compositional and labeling regulations state the requirements the food manufacturer must follow. The requirements to keep and disclose formulation records for products assist the compliance effort.

Restrictions on Using Soya Proteins in Foods in Latin America and the World

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ABSTRACT

Potential applications of soybean protein in developing countries are generally very different from those in industrialized countries with the exception of foods demanded by state feeding programs. Hence, the way restrictions affect usage and consumption of soya proteins varies greatly in the two types of regions. This paper discusses those factors that can restrict the soybean protein usage related to acceptability, price and legislation. A general discussion of these factors is given, followed by a brief analysis of experiences in Latin America. This analysis illustrates the interactions existing among the three factors under consideration, and the important role that market development techniques and integrated food and nutrition policies may play in the promotion of highly nutritious and relatively low-cost foods that use soya proteins.

It seems appropriate to begin this presentation with a brief analysis of the potential applications of soybean proteins in industrialized (IC) and developing countries (DC). Table I lists some of the market possibilities in DC. The food service market (restaurants and others) is growing rapidly in the U.S., where 30% of the consumer's budget is spent for food service (1) and in France, 6 million meals were eaten outside the home in 1980 (2); in DC, however, this market has serious income restrictions. Institutional food services also find restrictions due to lack of a cold chain or appropriate handling equipment as elementary as meat-mincing machines in central cooking facilities.

The greatest market for soya proteins and products no doubt has been in the state feeding programs, school lunches and target-group-oriented food distribution programs. Under U.S. Title PL 480 for fiscal year 1974, 60,750 tons of soya flour were used (3), an amount equivalent to two-thirds of the milk included in the EEC food aid program the same year (4). Developing countries hope to replace partially or totally these tonnages with locally grown products. In several cases, the replacement is done with locally grown soybeans and locally produced products.

The ingredient market is strong and diversified in IC. Applications in DC are mainly limited to cereal enriching and fortifying, or to wheat or milk extenders, two commodities that are in great deficit in tropical areas.