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Considerations in Development of Regulations for New Protein Sources

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ABSTRACT

In the development of regulations for new protein food sources, considerations are given to such factors as product definition, product safety, nutritional quality, consumer perceptions and fair marketing practices.

In the U.S. the food additive status of any new protein source would have to be considered. A determination would be necessary, depending on the type and use of the product, as to whether a new protein product has GRAS (generally recognized as safe) status or whether a food additive petition would be necessary before marketing. A new product would be considered GRAS if there is general agreement that a product is safe for human consumption and no concerns exist that the product could cause harm if consumed by any segment of the population. Although a manufacturer can make this determination on his own, generally, it would be best for the manufacturer to review his findings with the Food and Drug Administration (FDA) prior to marketing the new protein product to be sure that the agency agrees with his determination. Should the manufacturer or the FDA find unanswered questions about a product's safety, then a food additive petition would be required.

PRODUCT DEFINITION

The first consideration in regulation of a new protein source is the same as for any other food additive—that of defining the product. In general, two approaches have been used to describe a new product source. The first and most preferred is to describe the physical and chemical properties of the end item. Such a description should be as complete as possible to distinguish the product from other products in the marketplace. The description should contain information about the complete chemical profile of the product, including levels of all nutrients and contaminants found.

A second method for defining a new protein product is to detail the way in which the product was produced. This approach is generally less desirable because it requires records on production and disclosure of processing techniques. A manufacturer who wishes to describe a product in this manner may elect to file a food additive petition, even if he thinks the product is, in reality, GRAS. Many new products are described on the basis of a combination of these approaches. In such cases, the manufacturer elects to provide information on both production techniques and composition of the end product. For example, a general outline of the production process is provided, in which the starting products are specified, the processing steps are listed and the acceptance criteria used for the end product are stated. It is obvious that approval to market a new protein source or any other food additive requires a reasonable basis on which the product can be identified in the marketplace.

PRODUCT SAFETY

After a new product has been adequately defined, the next consideration is an assessment of its safety. Traditionally, the agency has required a so-called 100-fold safety factor for approval of new food additives. This strategy permits the use of 1% of the highest level shown to have no adverse biochemical or physiological effect in man or

animals. In the case of macronutrients such as proteins, it is obvious that this strategy is not applicable. Consequently, other techniques must be employed, such as the use of metabolic balance studies and growth and longevity studies in animals, together with metabolic balance studies in man. Even after a new protein source has been approved for human use, continuous monitoring of the consuming population for adverse health effects is accomplished through cyclic reviews of GRAS and food additive substances.

Part of the safety evaluation of a new protein source should include a consideration of the safety of the levels of any contaminants found in the end product. Concerns include, but are not limited to, such substances as pesticides, herbicides, and the so-called heavy metals (arsenic, lead, cadmium). In those instances where a contaminant has been found for which tolerance levels have not been established, the manufacturer will be requested to provide appropriate data to demonstrate safety. Of particular concern for new protein sources are the indirect food additive compounds formed as a result of processing, e.g., lysinoalanine, ornithinoalanine and lanthionine are formed as a result of alkali treatment of protein. Lysinoalanine has been shown to cause renal lesions in rats.

Naturally occurring toxicants are another safety consideration. Such substances as gossypol, found in cottonseed and trypsin inhibitors, hemagglutinins, goitrogens and estrogens found in raw soybeans, and possible other high protein seeds are examples. Maximal levels for such substances may be established wherever a chance exists for these compounds to reach the consumer.

NUTRITIONAL QUALITY

The primary objectives of the development of new protein sources are to replace, either partially or completely, protein sources which are more costly to produce, less abundant, or lack an appropriate balance of amino acids for human needs. Therefore, a regulatory concern must be that the new protein source provide adequate quality to meet human needs. Furthermore, because most traditional protein sources provide other nutrients in addition to protein, the regulatory scenario must take into account the potential impact of these nutrients, as well. Finally, consideration must be given to the impact of new protein sources on the utilization of nutrients from other sources in the diet.

In the past 10 years, there has been much scientific discussion about the regulatory requirements with regard to new protein sources. There have been views expressed that too-high standards have been set for human needs and that the methods used to assess protein quality do not accurately reflect human needs. On the question of quality standards, there still is a concern that criteria for regarding a food as a protein source should be based on adequacy of meeting human needs. Although there seems to be general agreement among scientists that methods for assessing protein quality need to be changed, there still is a lack of consensus as to which method would be best. Several reasons for these positions are based on both public health concerns and the prevention of consumer deception. Even in countries such as the U.S., where there is an abundance of protein from a variety of sources, many individuals frequently consume a limited variety of foods. This is particularly true among those who live alone, and is compounded when economic resources of the individual are limited. For example, the elderly/retired frequently have limited food supplies on hand and purchase and consume one single protein source at a time. The same pattern of activity can be found for some young adults who live alone and have limited resources. Protein quality standards are paramount for infant formulas, formulas used in diet therapy, and other foods designed for use as the sole source of nutrition for an individual.

In the U.S., the requirement for the protein quality of infant formula is that it must equal or exceed that of casein as measured by the protein efficiency ratio (PER). This requirement has been established by the Infant Formula Act of 1980 which was signed into law Sept. 1980.

Prior to the enactment of this law, FDA regulations permitted proteins having biological quality of 70% of that of casein or more if additional amounts of protein were provided to compensate for the reduction in quality below that of casein.

Regulatory considerations about the impact of new protein sources on nutrients other than proteins are more complex. It is true that a combination of protein isolates from vegetable sources can, in some instances, equal the protein quality of animal-derived sources, or at least meet human needs for animo acids.

However, many protein isolates have lost accompanying mineral elements and vitamins. In some instances, the existing mineral elements have been replaced by sodium or potassium. Furthermore, these new protein sources replace protein sources which also provide needed vitamins and minerals to the human diet. It is possible, as we have recently seen, that the use of a protein isolate to replace a traditional protein source can result in an acute deficiency of a nutrient as ubiquitous as chloride. It is, therefore, imperative that consideration be given to replace all the nutrient losses which are meaningful when making a substitution of a traditional protein source. A level of 2% of the US-RDA has been established as a meaningful amount. Fortification technology has advanced to a point at which added nutrients, in most cases, do not impact significantly on the organoleptic quality of most new protein sources. The major problem will be to establish a nutrient profile of the traditional protein sources which are being replaced. With gaps in our knowledge about the levels of many nutrients such as chloride, the task of identifying accurately the levels of lesser known nutrients such as selenium, molybdenum and chromium is formidable; of course, common sense must prevail. If the consumer's diet is already too high in a nutrient such as sodium, there is no rational reason to require nutrient equivalency.

The impact of substances contained in new protein sources which have detrimental effects on the absorption and utilization of other nutrients in the diet must also be considered. For example, the phytate content of some protein concentrates and isolates is very high because this substance is concentrated with the protein. The negative impact of phytate on the absorption of copper, zinc and other trace elements has been well documented in the scientific literature. A regulatory consideration, therefore, must be that either the phytate level be reduced or that increased amounts of the trace elements affected be added to the new protein source. It is possible that other as yet unidentified substances which would interfere with the absorption of some nutrients could be contained in a new protein source. Therefore, careful assessment of the nutritional status of animals used to evaluate new protein sources must be made. For the same reason, long-term evaluations of the nutritional status of humans consuming new protein sources should also be accomplished and appropriate adjustments in composition and use be instituted, should a loss in nutritional status occur.

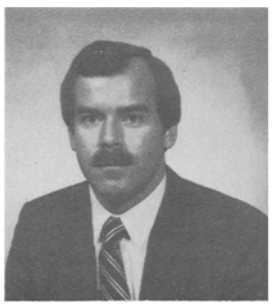
CONSUMER PERCEPTIONS

In the U.S., the Food, Drug and Cosmetic Act requires that

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