Regulatory Outlook on Vegetable Protein

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ABSTRACT

Vegetable protein products are increasing in use in the U.S. diet, especially in substitutes for the traditional animal-protein foods: meat, seafood, poultry, eggs and cheeses. This is occurring despite an ample protein supply which permits U.S. consumers to eat about twice the recommended protein levels. Cost, dietary preferences and the functionality of vegetable proteins appear to assure further increases. In order to permit continued development of these products, while at the same time assuring their nutritional adequacy and providing informative labeling, the U.S. Food and Drug Administration recently issued comprehensive tentative regulations. The regulations prescribe that the primary products be named as vegetable flour, vegetable protein concentrate and vegetable protein isolate when they contain less than 65%, 65% up to 90% and 90% or more protein respectively – except that gluten products may be referred to as such. When vegetable protein products are used as protein sources in whole or partial substitution for meat, seafood, poultry, eggs or cheese foods, the name of the substitute food must include the term vegetable protein product. Such substitute foods must be nutritionally equivalent to the original foods to avoid being called imitation. Imitation products must also be named to indicate the nature of the products, such as their use of vegetable protein ingredients. Nutritional equivalency is defined by nutrient profiles for six classes of foods: breakfast or lunch meats; seafood, poultry and other meats; eggs; cream cheeses; cottage cheeses; and natural cheeses. Fortification of substitute foods to meet nutritional equivalency requires their nutrition labeling. The FDA regulations also require that the PER of substitute foods containing vegetable protein products at more than 30% when combined with meat, seafood, poultry, eggs or cheeses shall be at least 100% that of casein. At 30% or less, the required PER is 80% that of casein. Specific USDA rules or FDA regulations such as the proposed standards for milk, cream or cheese substitutes take precedence over the general vegetable protein regulations. It is FDA intent to finalize the vegetable protein regulations as soon as possible.

INTRODUCTION

Development of plant or "vegetable" protein products, although varying as to their stimulus, progress and nature from country to country, has been a worldwide phenomenon. Vegetable proteins have been utilized in many developing countries in mixtures with staple foods to improve nutritional levels of diets for low-income groups. Elsewhere, they have found multiple applications in bakery products and have been used as thickeners in soups and sauces, as binders and extenders in meat products and as replacements in meat, seafood, poultry, egg and cheese analogs.

Recognition of the worldwide importance of vegetable protein products resulted in the establishment of the Codex Committee on Plant Proteins during the April 1978 meeting of the Codex Alimentarius Commission in Rome. The charge given to this committee was to elaborate definitions and worldwide standards for plant protein products and to develop guidelines for utilization, nutritional requirements, safety and labeling.

In the U.S., vegetable, and particularly soy, protein products are finding increasing use in the food supply. This increasing use does not stem from any protein shortage for, unlike some other parts of the world, there is an ample overall supply of protein in the U.S. The current supply permits U.S. consumers to eat about twice the recommended protein levels on a per capita basis, and a large proportion of the population do in fact consume protein well in excess of requirements.

The availability of soybeans, the financial capability of that industry and the extensive functionality of soy protein products have led to the current predominance of soy-based products in the marketplace. These conditions also point to further increases in soy protein utilization. Development of other plant protein products is similarly indicated primarily because of broad functionality, but also, increasingly, because of cost and dietary preference factors.

As is also the case in Canada and Europe, popular attitudes toward nutrition and changing lifestyles in the U.S. create a favorable environment for development of vegetable protein products. The U.S. Dietary Goals proposed by the McGovern Committee (the Senate Select Committee on Nutrition and Human Needs) reflect popular concern about consumption of saturated fats and cholesterol. Pertinent also is the fact that over half of the U.S. food supply is processed before distribution, and over one-third of food expenditures are for prepared items purchased and/or consumed away from home. This latter situation reflects the growing acceptance of convenience foods. The nutritional and functional properties of vegetable protein products fit in remarkably well with these current popular attitudes.

Paralleling the worldwide technological development of vegetable protein products has been associated worldwide activity in the regulatory arena. Regulatory approaches and progress have also varied from country to country. In general, though, the impetus has been to provide clearly for these products in the food supply and to establish definitions, labeling requirements and nutritive characteristics. U.S. regulatory activity has been directed toward these same objectives but is still in the developmental stage.

The two responsible U.S. Government organizations, the Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have been working together for the last several years on vegetable protein regulations. In their 1970 regulations for the National School Lunch Program, USDA provided for the use of texturized soy protein in an amount not to exceed two ounces as a meat alternate for the Type A School Lunch. USDA has also authorized vegetable proteins for use essentially as binders in over 30

TABLE I

Nomenclature for Primary Vegetable Protein Products

Percent protein by weight	Product name (with protein source)
Less than 65	Flour e.g., "Soy flour"
65 to 90	Protein concentrate e.g., "Soy protein concentrate"
90 or more	Protein isolate e.g., "Soy protein isolate"
65 to 90 (glutens)	Gluten e.g., "Wheat gluten"

different standardized meat and poultry products and has prescribed provisional labeling requirements. FDA has been working on more general requirements for vegetable protein products but has not yet promulgated final regulations.

The lack of final FDA regulations has in no small measure been the consequence of the complexities involved. For example, when one considers different plant sources and possible processing variations, there is an almost endless set of potential primary plant protein products. These primary products can be formulated into foods substituting for a variety of existing products, such as meat, seafood, poultry, egg or cheese foods and can also be used to fabricate entirely new types of foods. The substitute foods can in turn be used in a variety of multicomponent foods such as casseroles and pizzas. Further, various types and levels of nutrient enrichment can be introduced at any stage in the process.

FDA's initial regulatory approach, in keeping with the treatment of traditional foods, was to propose in 1970 a standard of identity. The proposed standard, based on an industry petition, would have established a definition and standard of identity for a class of foods to be known as "Textured Protein Products". The comments received on the proposed standard, as well as our own evaluation, persuaded us to abandon that approach. We then worked out a "common or usual name" approach which was published as a proposed regulation in 1974 (Federal Register of June 14, 1974). That proposal would have established names for "Plant Protein Products" prepared predominantly from cereal and vegetable products and used as extenders or replacements for meat, seafood, poultry, egg and cheese foods.

Extensive comments were also received on the proposed common or usual name regulation. These led to some revision of the proposal and the publishing of a tentative final regulation earlier this year (Federal Register of July 14, 1978). Because of the elapsed time since the proposal and the complexities involved, a 60 day comment period was provided. The comment period was subsequently extended for an additional 60 days and will end on November 12, 1978.

The basic thrust of the tentative final regulation is to define the primary vegetable protein products and to provide for labeling these products in the names and in the ingredient statements of finished foods. For practical purposes, the regulation specifically addresses only those finished foods in which there is partial or total replacement of meat, seafood, poultry, eggs or cheese. However, it has been pointed out that when the primary vegetable protein products are used in other ways, they must be named as required in the ingredient statement of the finished food. Finished foods other than those specifically identified are subject to the general FDA common or usual name regulations (21 CFR 102.5).

In addition, the regulations address the nutrition aspects and provide nutritional equivalency criteria for each of the classes of food involved. Adherence to these criteria by manufacturers avoids the necessity for use of imitation labeling when the food substitutes for and resembles a major animal-derived protein food.

The basic components of the tentative regulatory provisions are described in the following.

NOMENCLATURE

The FDA regulations provide nomenclature for three basic classes of primary vegetable protein products and also provide for the labeling of finished foods containing the primary products.

Primary Products

Prescribed names for primary products are based on the terms which have become associated with soy protein products and correspond to a three-tiered structure. The basic names are illustrated in Table I. In each case the primary product name must include the source of the protein, e.g., "soy flour" or "peanut flour," "soy protein concentrate," etc. A specific exception is made in the case of the products commonly known as gluten. Since this term has become firmly established, its use is provided for, again with the requirement that the protein source be included, e.g., "wheat gluten."

The regulations do provide some flexibility in nomenclature within the context of the basic requirements. For example, in the case of vegetable flour, the physical form may be included in lieu of or in addition to the term flour. Thus, as appropriate, any of the names "soy flour," "soy granules," or "soy flour granules" could be used. Similarly, the physical form of concentrates and isolates can be referred to by the addition of "granules" or "bits," as appropriate, to the product name. The terms "textured" or "texturized" can also be added when appropriate to do so.

There are also certain restrictions regarding nomenclature. For example, "protein" cannot be used in the names of flours. The common or usual name of other flours are not permitted to make reference to protein. Hence, it was considered inappropriate and possibly misleading to make an exception in this particular case.

Finished Foods

FDA's tentative regulations also address labeling of finished foods containing vegetable protein products as ingredients. Specifically covered are meat, seafood, poultry, egg or cheese substitutes which contain vegetable protein products as protein sources. Such foods are those in which one or more vegetable protein products are substituted in whole or in part for the major animal protein components. In these foods there is thus less of the meat, seafood, poultry, egg or cheese component than normally present or than appears to be present. Therefore, in these specific cases the common or usual name of the food must include the term, "vegetable protein product." It may also include the terms "textured," or "texturized," and "granules," or "bits" as appropriate, and "plant" may be used in lieu of "vegetable".

In addition to the requirements for the names of finished foods, the regulations also require that each primary vegetable protein product used in the finished food be individually listed in the ingredient statement. For example, a product containing both soy flour and peanut protein isolate would have to list each by name in the ingredient statement.

Flavor Labeling

Although existing FDA regulations cover the requirements for labeling of foods in which flavors are represented, these requirements are repeated in the vegetable protein regulations. Thus, for example, as appropriate, the name

TABLE II

Protein and Nutrients per Gram of Protein Requirements for Nutritional Equivalence in Vegetable Protein Substitute Foods

Nutrient	Food class[a]					
	1	2	3	4	5	6
Vitamin A (IU)	13.0	13.0	91.0	146.0	---	39.0
Thiamine (mg)	0.02	0.02	0.01	---	---	---
Riboflavin (mg)	0.01	0.01	0.04	0.02	0.01	0.02
Niacin (mg)	0.30	0.30	---	---	---	---
Pantothenic acid (mg)	0.04	0.04	0.22	---	0.02	---
Vitamin B_6 (mg)	0.02	0.02	0.02	---	0.01	---
Vitamin B_{12} (μg)	0.10	0.10	0.15	---	0.05	0.05
Iron (mg)	0.15	0.15	0.19	---	---	---
Magnesium	1.15	1.15	---	---	---	---
Zinc (mg)	0.50	0.50	0.22	---	0.06	0.24
Copper (μg)	24.0	24.0	14.0	---	---	---
Potassium (mg)	17.0	17.0	10.0	---	6.0	---
Calcium (mg)	---	---	4.3	9.0	4.0	28.0
Phosphorous (mg)	---	---	---	---	---	19.0
Vitamin E (IU)	---	---	0.15	---	---	---
Biotin (μg)	---	---	1.7	---	---	---
Folic acid (μg)	---	---	---	---	1.0	---
Protein (% by weight)	13.0	18.0	13.0	9.0	14.0	24.0

[a]For definitions of food classes, see text.

of a substitute product would be accompanied by terms such as "shrimp-flavored vegetable protein product," or "artificially ham-flavored vegetable protein product."

Vegetable-Animal Protein Mixtures

When dealing with substitute finished foods containing vegetable protein products, there are a number of labeling complexities. Several of these are specifically treated by the regulations. One such problem is a substitute food made from a vegetable protein product but containing an animal product added for functional or other purposes (e.g., a vegetable protein cheese substitute containing nonfat dried milk or a vegetable protein meat substitute containing beef fat). In order that the nature of such products be identified to the consumer, the regulations require that the name be accompanied by a statement noting the presence of the animal product, e.g., "contains beef fat" or "containing nonfat dried milk."

Multicomponent Foods

Another problem area arises when one of the vegetable protein substitute foods is used as a characterizing ingredient in another food (e.g., cheese substitute in a macaroni and cheese casserole). The regulations cover two situations for such foods, partial and total substitutions. If the finished food contains both the animal protein source and vegetable protein substitute(s), the name of the finished food must include both components according to predominance; e.g., "macaroni casserole made with cheese and vegetable protein product," or "macaroni casserole made with vegetable protein product and cheese." If the animal protein source is totally replaced by a vegetable protein product, that must also be indicated in the name of the finished food, e.g., "macaroni casserole made with vegetable protein product cheese substitute."

Nutritional Equivalency

The area of greatest complexity perhaps is that of nutrition. Not only are nutritional considerations important in their own right, but there are also certain constraints imposed by law and regulation. Any food resembling and substituting for another food must be termed imitation unless it is nutritionally equivalent to the food for which it substitutes. Thus, vegetable protein substitutes for meat, seafood, poultry, eggs or cheese foods would have to be termed imitation unless they were nutritionally equivalent. The question then arises as to what constitutes nutritional equivalence, especially when one considers the large variety of foods for which vegetable protein products might substitute. This is a complicated and controversial area. In order to regulate nutritional equivalency, standard nutrient profiles must be defined for everyone to follow. However, the very large number of products involved makes this impractical to do for each specific product. FDA, therefore, has approached this problem in the regulations by considering six classes of animal protein foods and defining a characteristic nutrient profile for each. These six classes resulted from consideration of average protein content as well as product nature and use. It is recognized that this approach, of necessity, will result in some nutrient levels in some foods. However, the nutrient levels overall within any one of the six classes will be similar between original and substitute foods. Further, this regulatory scheme is practical from the points of view of compliance and enforcement.

The nutrient profiles for the six classes are shown in Table II. These classes include substitutes for: 1.) breakfast meats (e.g., bacon, sausage) and lunch meats (e.g., frankfurters, bologna, luncheon meat); 2.) seafood, poultry and meats other than those in class 1; 3.) eggs; 4.) cream cheese (Neufchatel and cream cheese); 5.) cottage cheese; 6.) natural cheeses other than those in classes 4 and 5.

The protein requirements listed in Table II refer to the percentage of protein by weight in the substitute product when formulated to resemble the traditional food. "When formulated" includes the water, fat or oil, colors, flavors and other substances added, prior to sale or by the purchaser, to the dry product to make it resemble the food for which it substitutes.

Nutrient requirements, as shown in Table II, are on a per gram of protein basis. The protein basis is employed rather than the caloric basis noted in FDA's proposed general principles for the addition of nutrients to foods because the plant protein products included are all significant sources of protein. The vitamins and minerals listed for each of the six product classes are primarily those recognized in FDA regulations [21 CFR 105.3(b)] which are present at an average level of two percent or more of the U.S. Recommended Daily Allowance per serving in the traditional product.

Because the average vitamin and mineral content, per gram of protein, for the breakfast and lunch meat class is so close to that of the seafood, poultry and other meats class, the same profile is used for both. Where differences in the

average vitamin and mineral levels did occur, the higher level was used in the common profile.

It should be noted that there are some differences between average vitamin and mineral levels found in these food classes and the enrichment requirements of Table II. Phosphorus is one example. Although there is currently an overabundance of phorphorus in the U.S. diet, phosphorus is listed for the natural cheese class because it is considered reasonable to maintain the calcium-phosphorus balance in thie important source of calcium. However, since the other classes contain little or no calcium, it was not considered necessary to add phosphorus in those cases. Another departure concerns zinc, which is listed at approximately twice the actual averages. This was done to compensate for the decreased bioavailability of zinc arising from the phytate content of plant components. Vitamin D does not occur in measurable amounts in most meat and poultry but does in some seafoods. However, because other sources of vitamin D are considered adequate, it is not required for the seafood meat and poultry class. Iodine is not required in any of the six classes, despite its occurrence especially in seafood, because current indications are that U.S. dietary intake of iodine is far in excess of the U.S. RDA.

Protein Quality

In addition to the protein quantity requirements noted for the six classes of foods, consideration must also be given to protein quality. Again the problems are complicated and controversial, but a uniform practical approach is needed for purposes of both regulation and consumer protection. The regulations, therefore, require a minimum biological quality for the protein in the substitute food depending on the level at which it occurs in the finished food. Specifically, if the vegetable protein substitute constitutes no more than 30% by weight of the finished food, the biological quality of the protein in the substitute must be at least 80% that of casein. Otherwise the biological quality must be 100% that of casein.

Although the regulations refer only generally to biological quality, currently protein quality is measured by the Protein Efficiency Ratio (PER). Should a new approach to protein quality measurement be found acceptable for regulatory purposes, that could be adopted without the necessity to change the current regulations.

It is fully recognized that currently available methods for measuring protein quality leave something to be desired both in terms of complexity and cost and in terms of direct applicability to human protein needs. Current research may lead to the conclusion that human protein quality requirements may differ significantly from the requirements of rodents – the conventional animal used to measure such quality. Hence, input from research findings which could lead to improvement in regulatory approaches to protein quality, not only for vegetable protein products but for all major sources of protein subject to FDA regulation, is solicited.

Nutrition Labeling

Existing regulations require that when nutrients are added to, or nutritional claims made about, a food, the food must be nutrition labeled. Thus, nutrient enrichment of a vegetable protein product to meet nutritional equivalency requirements necessitates nutrition labeling of the product. Indeed, any addition of nutrients to these products does so. Further nutrients added to plant protein products, whether or not those products meet nutritional equivalency requirements, must be listed both in nutrition labeling and in the ingredient statement.

Although the products covered by the tentative regulations are subject to nutrition labeling requirements, producers are not precluded from making additional nutrition claims in labeling providing they are accurate, nonmisleading and consistent with other regulations.

Sodium-Potassium Labeling

In addition to nutrition labeling as prescribed by current regulations, there are other related requirements imposed by the vegetable protein regulations. There is wide interest by consumers in the sodium content of foods, and vegetable protein-containing substitutes may be higher in sodium content than their traditional counterparts. Therefore, the requlations require sodium content labeling for all of the vegetable protein substitutes for meat, seafood, poultry, eggs and cheese. Sodium content is required to be stated in milligrams per serving as part of nutrition labeling. Although there is as yet no U.S. RDA established for potassium, the tentative regulations require its presence at the levels listed in Table II. Further, potassium content is required to be stated in milligrams per serving immediately following the sodium content listing.

Related Regulations

With respect to protein quality, it should be noted that FDA issued in June of this year (Federal Register of June 27, 1978) a final food additive regulation which provides for the use of N-acetyl-L-methionine as an additive for vegetable protein-containing foods other than infant foods or foods containing added nitrites or nitrates. It is anticipated that this action will assist in overcoming the technological difficulties previously associated with the addition of methionine to soy-based protein products for purposes of increasing protein quality.

In the Federal Register of September 19, 1978, FDA issued proposed standards of identity for milk, cream, and cheese substitutes. The proposed standards include composition and labeling requirements and specify nutrient profiles defining nutritional equivalence in order to avoid imitation labeling. Briefly, the proposal would require that, if the substitute is nutritionally equivalent to the traditional product and meets composition requirements, the name of the product be " substitute," the blank being filled in with the name of the traditional product being simulated. An example would be "cheddar cheese substitute." In the case of cheese substitutes, when the corresponding standard of identity permits variation in fat and moisture content (e.g., process cheese products), or when the fat and moisture content of the substitute varies from that of the natural cheese, the name of the substitute must include the world "product." An example would be "process cheddar cheese product substitute". It is also required that a descriptive phrase accompany the name to identify the nonmilk ingredients used to replace the milk protein, e.g., "made with vegetable protein product." Milk substitutes must meet the milkfat and milk solids-nonfat requirements of the standard of identity for the traditional product. When required by the standard of identity for the traditional milk product, the substitute product name must be accompanied by a statement of the amount and type of fat. Because cheese substitutes are permitted to vary in fat content, their names must always be accompanied by a declaration of the amount and types of fat, e.g., "30% vegetable fat and milkfat." For milk and cream as well as cheese substitutes, the ingredients must be listed in accordance with existing regulations. Thus, when the vegetable protein product regulations become final, they would govern the listing of such ingredients in milk, cream and cheese substitutes.

Since statutory authority for meat and poultry products resides with the U.S. Department of Agriculture, FDA has closely coordinated the development of the vegetable protein regulation with that Agency. In addition, the FDA regulation specifically provides that none of its provisions shall supercede any existing federal regulation. Thus, a specific USDA regulation or an FDA regulation such as the

proposed standards for milk, cream and cheese substitutes would take precedence over the more general vegetable protein regulations.

In general, prescribing the labeling and nutritional composition of any class of food is at best a difficult process. This is especially true of vegetable protein foods because of their varied nature and developmental status. However, it is necessary that there be uniform provisions for such foods which are already in the marketplace. Therefore, it is our intent to finalize the tentative vegetable protein regulations as quickly as possible. In enforcing these regulations, advice as to proper composition and labeling will be given to any who solicit it. Should specific exemptions to or modifications of the regulations be warranted, these can be accomplished through existing FDA administrative procedures.

The tentative regulations have two simple purposes. One is to bring uniformity into nomenclature, primarily to minimize consumer confusion. The second is to protect consumers so that when they purchase foods which resemble and clearly substitute for conventional animal-derived protein foods, they are assured that the quality of these substitute foods is as close as is technologically feasible to the foods they are replacing. It is also important to point out that the tentative regulations are not designed to regulate purely technological uses of vegetable protein products, but rather only to provide for proper nomenclature. Finally, the regulations address only those foods clearly replacing meat, seafood, poultry, eggs, and cheese. They are not intended to govern the innumerable other possible uses of vegetable-derived protein products, and FDA has no desire to thwart orderly and innovative research, development and marketing aimed at expansion of the role of these protein sources in either our domestic or the international human food supply.