



Vegetable Protein Legislation : An Industry Perspective

L.H. ROBERTS, Food Protein Division,
Ralston Purina Company, St. Louis, MO USA

ABSTRACT

Regulatory development governing vegetable protein in foods is well underway on a global scale. Although the regulatory development for vegetable protein usage has been affected by differing national, economic, and political factors, there seems to be a common thread of issues that has undergone vigorous debate. Principal among these issues are: (a.) the internationalship between existing food standards and the allowance of vegetable protein; (b.) the issue of labeling; and (c.) the issue of nutrient fortification. Historically, food standards have either precluded or greatly limited participation of vegetable protein in the world food supply. This preclusionary effect is examined along with the two regulatory approaches (vertical vs. horizontal legislative action) that have been undertaken to alleviate the restrictiveness of standards. Fundamental to the elaboration of proper labeling regulations for foods containing vegetable protein is an understanding of the applications and uses for vegetable protein in traditional food products. Differing labeling rules need to be established depending upon whether vegetable protein is used as a functional ingredient replacement, protein supplementation or fortification, or a partial or complete replacement of traditional characterizing protein ingredients. Recognition and consideration of these three types of uses will assist in developing labeling guidelines that achieve the delicate balance between labeling which informs consumers and labeling requirements that prejudiciously influence purchasing decisions. Much regulatory attention throughout the world has been focused on the issue of whether or not vegetable proteins should be fortified with vitamins and minerals and/or amino acids. There is considerable international divergency in approaches within this area. Two principal regulatory issues discussed are *when* should vegetable proteins be fortified and *what* should be the fortification requirements.

INTRODUCTION

It is obviously fitting that this Conference give attention to world regulatory developments governing vegetable protein – if only because these developments are well underway currently on a global scale.

In the United Kingdom, we find a proposed legislative framework for the usage, labeling and nutrition on vegetable protein (1).

On April 15, 1975, the Canadians issued one of the most elaborate sets of regulatory provisions governing the usage of vegetable protein in meat and poultry products (2).

On August 27, 1975, the French Government issued its first provisions governing the definitions and labeling of vegetable protein (3).

And the list goes on. Sweden, Netherlands, Norway and Japan are all in the process of elaborating national legisla-

tion for vegetable protein. Spain recently has joined the ranks of others in the global challenge of developing national regulatory policies on the same.

Mrs. Anne Brincker, our fourth speaker in this session, presented an excellent review of these national regulatory developments that are occurring in Europe.

Closer to my home, we find one of the most dynamic efforts occurring in the development of both direct and ancillary food law policies on vegetable protein usage. Regulatory development regarding the use of vegetable proteins has been a matter of continuous review by the United States Department of Agriculture and by the United States Food and Drug Administration (FDA). On July 14, 1978, FDA issued a comprehensive tentative final regulation on vegetable protein (4). Among other things this regulation established both labeling and nutritional guidelines for vegetable proteins used in meat, seafood, poultry, eggs, and cheese products. Dr. Howard Roberts presented the details of this U.S. regulatory development.

Independent of the issue of vegetable protein, there are many food law issues that are currently undergoing vigorous debate in the United States, that although ancillary in nature, will impact directly upon the ultimate evolution of U.S. vegetable protein legislation. Among these developments are the debate on FDA's safe and suitable optional ingredient concept, nutritional labeling regulations, the imitation labeling policy, policies governing nutrient fortification, and probably most important, the present debates and deliberations that are now addressing the efficacy of establishing strict recipe-type standards of identities for processed foods. Historically, these recipe standards have either precluded or greatly limited participation of vegetable protein in traditional products.

The regulatory challenge for vegetable protein has already gone beyond any of the previously mentioned national efforts. Several international regulatory bodies and functionaries have now given this subject matter a new priority.

Mr. Kinch presented the vegetable protein legislative developments within the E.E.C. Commission.

The highlight of this international regulatory inertia on vegetable protein took place on April 26, 1978. It was in Rome, during the Twelfth Session of the Codex Alimentarius Commission, that international agreement was reached that a new, independent subsidiary body within the Codex framework should be established in order to "elaborate definitions and worldwide standards for vegetable protein products" (5). Mr. Hutchinson presented details on this new Codex development.

The respective regulatory approaches undertaken by these different national and international communities are affected necessarily by differing political and economic factors. In addition, different governments will afford varying degrees of consumer protection by the food regulatory mechanisms.

Although the regulatory development for vegetable protein usage has been affected by these differing national factors, there seems to be a common thread of issues that have undergone consideration. Three principle issues have

been: 1) the interrelationship between existing food standards and the allowance of vegetable protein in products governed by these standards; 2) labeling; and 3) nutrient fortification.

I will attempt to provide a perspective on these issues, a perspective that I trust is shared by the segment that I represent — industry — and a perspective that I hope will be shared by others represented at this Conference.

FOOD STANDARDS

Most national communities, be they developed or not, have established food regulations to provide varying degrees of consumer protection. There appears to be a common, evolutionary, regulatory process among national governments wherein food laws have gone through a maturation process — starting with the promulgation of general hygienic guidelines and finally evolving to a regulatory framework that encompasses more complex legal concepts like prevention of compositional, nutritional and economic adulteration. These three consumer protection objectives have been accomplished principally by the establishment of standards of compositions. These standards attempt to restrict the compositional variation among foods bearing the same product name. Proponents of strict recipe standards often advocate that these standards provide assurances to the consumer that a given identifiable food contains only wholesome and safe ingredients, formulated in a manner that would provide the expected level of nutrition, and that would reflect its economic worth. To argue against these seemingly worthy objectives would be like arguing against "Motherhood and Apple Pie." However, when food standards have the effect of creating competitive barriers protecting current technologies and precluding food product innovation, one begins to look for other regulatory alternatives to provide the same needed assurances that the consumer will be protected.

Prior to the demand for and development of food processing, there was little need for any type of food standard — a peanut was a peanut and corn was corn. However, marketing demands called for new products, and processing techniques were developed to provide safe, convenient, economical and nutritious foods. Compositional standards for these new products were established. It is at this point that the paradoxical limitations of food standards began. For history has shown that once these food standards were established, application of newer technology would be forever prohibited or, at best, made much more difficult in terms of market participation. In some respects standards have also stigmatized new ingredients. There appears to be an emotional and political attachment toward the "protected" ingredients of standardized foods, thereby creating polarized attitudes toward new and alternative food ingredients.

It is against this background that one could begin to appreciate the unique regulatory plight for vegetable protein. In most national communities, food standards have been established for processed foods long before vegetable protein made its appearance in human foods. Historically these standards have either precluded or greatly limited the participation of vegetable protein in traditional processed food products.

I can vividly recall in 1973 in Munich at a World Conference similar to this one where participants from all over the world expressed serious concern for the future of vegetable protein. The regulatory web at the time appeared to be strangling any hopes of vegetable protein becoming a viable supplement to the world food protein supply. However, since 1973 great strides have been made by food law makers in responding to the challenge of untangling the regulatory web that was preventing the economical, nutritional and functional contribution of vegetable protein to

the world food supply. There is no question that the challenge to ingenuity in the construction of new food laws and regulations was not simple. Issues of nutrition, labeling, and preexisting standards had to be resolved and reconciled before innovative regulatory developments could occur.

Early regulatory attempts to allow for vegetable proteins were "vertical" in nature. In other words, the preclusionary effect of food standards upon vegetable proteins was attacked directly. A number of (very few) individual food standards were amended to reflect the addition of 1-3% vegetable protein addition. Regulators were self-extolled with these early actions, for they were helping to feed a protein-deficient world; industry applauded these early minor "vertical" amendments, for they gave the industry new hope for its destiny, and finally, consumers were confused. It soon became evident that the "vertical" approach of amending individual food standards was too time-consuming, cumbersome, and too complex for full public involvement.

An alternative regulatory approach for vegetable protein usage began to emerge. This new approach accepts as its theoretical basis a given set of food standards, and attempts to allow for vegetable protein usage by labeling and nutritional guidelines. This approach differs from the previously discussed approach in that it is "horizontal" rather than vertical in operation. In other words, horizontal legislation does not deal with standardized products in particular, but all foods (or classes of foods) in general. Hence, its orientation is generally more encompassing in scope and not necessarily limited to meat products or standardized foods.

Labeling guidelines which establish rules for adding vegetable proteins to otherwise standardized food products are examples of horizontal legislation. In addition to labeling guidelines, hygienic guidelines on the vegetable protein itself (as a good ingredient) is a typical component of this type of regulatory approach. Also, in certain countries, nutritional guidelines have been considered a facet of the horizontal approach, particularly when a portion of an otherwise required level of traditional characterizing protein ingredient has been substituted by vegetable protein.

Upon analysis, one would recognize that the horizontal approach is the underlying basis of FDA's recently issued vegetable protein regulation (4). The horizontal approach is also an approach which is conducive to international harmonization of divergent national legislation, since it need not deal with individual national food standards. Indeed, it is the horizontal approach that has formed the basis of the EEC Study Groups' recommendations on vegetable protein legislation (6). Finally, it is believed to be the only feasible approach for future Codex efforts (7).

LABELING OF FOODS CONTAINING VEGETABLE PROTEINS

The subject of labeling is a central regulatory issue when alternatives to standards of compositions are being considered. When we move away from a system of product standards, the consumer is no longer guaranteed a prescribed or required composition. It is, therefore, absolutely essential that the consumer receive sufficient label information in order to assure that fair and informed purchasing decisions are made. A seemingly straightforward principal, and yet there has been a considerable amount of global debate and controversy over the last few years regarding the labeling of foods containing vegetable protein. From the industry side, the debate has been intense. Unfortunately, industry's position has often been misrepresented as one which advocates labeling rules that will allow vegetable protein to be hidden within a given food product. It is hoped that given the matured state of the industry that I represent, along with the documented evidence of the wide

consumer acceptance of vegetable protein, industry's concern regarding the issue of labeling has substance beyond any notion of hiding vegetable protein from the consumer. Rather, the concern is one which recognizes the often delicate balance between labeling which informs consumers and labeling requirements that prejudicially influence purchasing decisions. The final gauge of effective labeling for foods containing vegetable protein is whether the consumer can determine *how*, *why* and to *what extent* vegetable protein is being used in a food product. If the labeling requirements result in any confusion with the "whats," "whys," and "hows," then the result is not only misinformation but also prejudicial information.

Fundamental to the elaboration of proper labeling regulations for foods containing vegetable protein is an understanding of the applications and uses for vegetable protein in traditional foods. Failure to place these applications into a proper regulatory perspective can only frustrate practical attempts to develop well conceived labeling guidelines for vegetable protein usage.

TYPES OF VEGETABLE PROTEIN USES

There are three basic types of uses for vegetable proteins in traditional foods today: 1) replacement of traditional noncharacterizing ingredients that are in foods at low levels for their functional rather than nutritional contribution; 2) fortification of foods to increase protein levels; and 3) partial or complete replacement of traditional (characterizing) proteins -- proteins that make a nutritional contribution to foods.

Examples of the first type, (functional replacement) are milk and/or eggs in bakery products, and caseinates in whipped toppings and coffee whiteners. The replacement of traditional binders in meat products (e.g., nonfat dry milk) with vegetable protein is another example of this functional replacement utilization.

When vegetable protein is added to a food to supplement its protein content, its use is referred to as fortification. With fortification applications, vegetable protein is an addition to the normally available protein that is provided by a given food.

In many countries the standards for traditional foods specify a requirement for a minimum level of a characterizing ingredient that gives the product its character and value. When vegetable protein is used to replace a portion or all of the *required* level of characterizing ingredient, then we have an example of the third type of use for vegetable protein, e.g., replacement of the characterizing ingredient. An example of this use in the U.S. would be using vegetable protein as a substitute for a portion of the 40% meat that is required by the standard for the product called "chili."

The most effective way to avoid prejudicial labeling is to treat the inclusion of vegetable protein in a food product consistent with conventional labeling guidelines that are operative for traditional ingredients within a given country. Typically, this would *not* require a change in the product's traditional name or any other major front panel declarations where vegetable protein is used as a functional replacement or used in a fortification application. In most countries conventional regulations would, however, require the declaration of vegetable protein in the ingredient statement according to its relative predominance in the total food formulation.

Major front panel changes, like a change in the product's traditional name, or a requirement for descriptive terminology continuous with the product name, are justifiable when vegetable protein is used to replace a characterizing protein ingredient that is otherwise required by an applicable standard. Requiring these major label changes beyond this type of use tends to be prejudicial since it exaggerates to the consumer the relative prominence or role that

vegetable protein is playing in a given food product.

Some have advocated that whenever vegetable protein is used, regardless of the level or role in a given food product, its presence should be clearly stated with or in close association with the product name. This type of requirement tends to be highly prejudicial, particularly at the point of purchase. To understand this prejudicial effect, we must consider some basic economic-marketing ramifications of food product labels.

There are two situations when consumers perceive food products as new: 1) a product is introduced that was not previously sold, or an existing product is reformulated to the extent that its shape, appearance, taste and/or other organoleptic qualities are markedly changed; or 2) an existing product is reformulated without apparent change to the consumer except that a change in the label is required by regulations. The "meat analog" or "meatless meat" using vegetable protein is an example of a perceived new product as described in the first case above.

With respect to the second case, a food product may be reformulated to accommodate vegetable protein without marked change in the product. If the reformulation involves a significant replacement of the traditional characterizing protein in a standardized product, justification exists for a "regulatory forced" new product classification by requiring major label changes. If, however, vegetable protein is added at lower levels for fortification purposes and/or for functional purposes, or its addition does not result in the replacement of a required level of characterizing ingredient, then little, if any, justification exists for it being deemed a new food product. One must remember that products perceived to be new by consumers are expensive to introduce to the market place. The high costs associated with introducing new products to the market place may well prohibit many minor but beneficial uses for vegetable protein. In other words, not all applications or uses for vegetable protein in foods justify the cost burden associated with introducing new products.

The proper resolution of the labeling issue is the key to any practical attempt for the development of sound "horizontal" regulations for the usage of vegetable protein in foods. It is an effort that must take into consideration the manner in which the vegetable protein is used; that is, labeling requirements should accurately reflect the role vegetable protein is playing in the food system.

A well conceived set of labeling guidelines and policies will have to differentiate necessarily between the use of vegetable protein as a fortification or functional supplementation to foods, and the use of vegetable protein as a replacement of traditional proteins in foods consumed for their nutritional value.

NUTRIENT FORTIFICATION

Much regulatory attention throughout the world has been focused on the issue of whether or not vegetable protein, particularly soy protein, should be fortified with vitamins and minerals and/or amino acids, namely methionine. The two principal regulatory issues have been "when?" and "what?". *When* should vegetable proteins be fortified and *what* should be the fortification requirements? The issue of "when" is not to leave you with the assumption that all countries are in agreement that vegetable protein should in fact be fortified; that the only issue remaining is to determine in what food applications should fortification requirements be imposed. This assumption would be incorrect since there are differing viewpoints on the basic issue.

For example, the present legislative trend and thinking in Europe appears to be to regulate traditional products containing vegetable protein as new products consisting of a mixture of traditional and more novel food protein

ingredients (8). In other words, this European trend views the mixture of vegetable protein and traditional proteins from meat, poultry, dairy, etc., as products of their own identity and right. Concomitant with this European trend are the requirements for clear and informative labeling, thereby assuring, from a consumer standpoint, that these identities are maintained in the market place.

In Canada and in the United States, however, the trend and approach appears to be somewhat different. Traditional products containing vegetable protein are considered more as "reformulated" traditional products, borrowing their image from these traditional products. Consequently, the regulatory requirements for nutrient fortification is the trend in order theoretically to achieve "nutritional equivalency" to the traditional products.

The dichotomy of these differing national positions on nutrient fortification became apparent during the debates at the Codex Meeting on Processed Meat Products, held in Copenhagen in 1976. The minutes of that session reflected that the United States government stated that "its approach would favor fortification of vegetable protein so that if a vegetable protein product looked like a traditional product, it should be nutritionally equivalent to the product it simulates (9). However, other governmental delegations, particularly from Europe, expressed the view that it would be better to let these products stand on their own merit without fortification requirements subject to clear and informative labeling.

Going beyond the basic issue of whether vegetable protein should be fortified, there has been a considerable amount of global deliberation on when fortification requirements should be imposed. Hence, the issue is directed more at the scope of national nutritional guideline regulations. In other words, once fortification requirements are established, when should they be applicable or imposed on vegetable protein? Here again there has been a substantial divergence of approaches and notions in resolving this issue. For example, the Canadian legislation would require that vegetable protein be fortified with 12 different vitamins and minerals whenever it be added to a meat or poultry product, disregarding its use as a functional ingredient (at low levels) or its use as an animal protein alternate, or extender (2).

Under FDA's Vegetable Protein Regulation, the approach in the United States is to exempt vegetable protein from nutrient fortification requirements when they are used for technological purposes. Furthermore, the particular legal basis of the FDA regulation would seem to narrow further the scope or applicability of the proposed nutritional guidelines. The intent of FDA's nutritional guidelines appears to be to specify the nutritional qualities of vegetable protein substitutes for meat, seafood, poultry, eggs, and cheese, in order to avoid the necessity of their being labeled imitation (4). It would seem to follow, therefore, that the proposed nutritional guidelines would not be applicable to vegetable protein containing products which are *not deemed* to be imitation under the Imitation Labeling provisions of the Food, Drug and Cosmetic Act and its governing policies.

On this legal basis, it would appear that vegetable protein would be exempt from nutritional guidelines when used for functional or technological purposes or added to foods which are not subject to a standard of composition; or when added to foods whose existing standards allow for a specified level of vegetable protein inclusion by law. In each of these situations, the issue of imitation labeling never arises.

Another way of viewing this is to sort through all the debates on the use of vegetable protein in their various forms and multiplicities of uses. The only rational situation where nutritional equivalence would seem to be applicable is when vegetable protein is used to replace a portion of the

traditional protein that is otherwise expected or required by the national food law structure. When vegetable protein is used for a technological purpose, or used in products wherein the resulting level of required traditional protein is not specified and/or not diminished, then the imposition of nutrient fortification requirements is difficult to justify. In each of these situations, the practical nutritional efficacy of the traditional food product has not been altered.

It also must be emphasized again that not all countries have imposed nutrient fortification requirements on vegetable protein. In fact, of the eighteen countries that have developed some national regulatory policy or regulation on vegetable protein, only one country *currently* requires nutrient fortification. That is Canada. However, the current thinking in the United Kingdom and the United States favors nutritional guidelines that would necessitate nutrient fortification of vegetable protein.

With respect to the nutritional guidelines themselves, (the "what" question) the international divergence is absolute. In other words, no two countries are in agreement, both in terms of vitamin and mineral guidelines or on guidelines concerning protein quality. These differences appear to be based more on differing national legal principles and/or on the lack of a uniform nutritional data base on vegetable protein rather than on a determined nutritional need of the national population in question.

The differences in protein quality guidelines on vegetable protein are of particular concern since they are compounded by the lack of an agreed upon method for assessing it. PER, NPU or other methods are now under active consideration by various international governments (11).

It is because of these current differences in protein quality and their potential impact on the future regulatory destiny for vegetable protein that the nutritional subject matter covered at this Conference is both timely and critically important. New legal dimensions are being formulated that may determine the nutritional worth and future of vegetable protein. It is no longer sufficient that vegetable protein be a good source of high quality protein. Legal theories and principles such as the imitation food labeling laws in the U.S. are becoming, in essence, the theoretical basis for protein quality guidelines on vegetable protein. Consequently, the nutritional value inherent with vegetable protein itself may be subordinated to its nutritional value as measured by the food to which it is added. It, therefore, becomes paramount that continued nutritional research on vegetable protein be conducted in an effort to assess accurately the true relationship between vegetable protein and other traditional protein in the context of human dietary requirements.

REFERENCES

1. Food Standards' Committee of the United Kingdom, Report on Novel Protein Foods, London, Her Majesty's Printing Office, 1974.
2. Canada, Food and Drug Regulations, Regulation Excerpts and Guidelines - Part 13, April 15, 1975.
3. Definitions and Uses of Vegetable Protein, French Minister of Agriculture, The "Circulaire" of August 27, 1975.
4. U.S. Food and Drug Administration, "Common or Usual Name for Vegetable Protein Products," Federal Register, Vol. 43, No. 136, July 14, 1978.
5. Report of the 12th Session of the Codex Alimentarius Commission - Alinorm 78/41, Codex Alimentarius Commission, FAO, Rome.
6. Report of the Study Group on Vegetable Proteins in Food Stuffs for Human Consumption, Commission of the European Communities, Brussels, 1978.
7. FAO/WHO Food Standards' Program report on Vegetable Protein, Twelfth Session, Codex Alimentarius Commission, Kapsiotis, Alinorm 78/32, Rome, April 1978.
8. Brincker, A., "Review of European Legislation on Vegetable Proteins in Meat Products," World Conference on Vegetable Food Proteins, Amsterdam, p. 211, 1978.

9. Codex Alimentarius Commission, Report of the Ninth Session of the Codex Committee of Processed Meat Products, Alinorm 78/16, para. 77, 1976.
10. The Federal Food, Drug and Cosmetic Act, Chapter IV, Section 403 (C).
11. Wilcke, H.L., D.T. Hopkins, and P.H. Waggle, "Keystone Conference - Soy Protein and Human Nutrition," Academic Press, New York, 1978, (in press).