Session C Round Table Discussions

Nutrition and Product Identity Issues Regarding Vegetable Protein Legislation

M. FONDU, Associate Director, Food Law Research Center, University of Brussels, Belgium

It is classic to say that the legislation of the foodstuffs must respond to two main goals: 1. the protection of the health of the consumers; 2. the protection of fair commercial transactions.

And to fulfill both those obligations, a number of problems have to be examined when a legislation is established: (a) composition of the foodstuffs as regards the eventual presence of antinutritional factors such as antitrypsine factors, anti acetylcholine esterase factors; (b) fabrication of the foodstuff, if new compounds are formed during the processing, compounds which could be harmful if present at a too high level; (c) use of additives, qualitatively and quantitatively; (d) presence of contaminants such as pesticide residues, heavy metals, and mycotoxins; (e) composition of the foodstuffs as regards their ingredients to prevent unfair competition (e.g., % fat in mayonnaise, in margarine). (f) in a number of cases, when the food takes part to the basic elements of the diet (such as bread, meat, dairy products, etc.) the composition of the foodstuff to assure the consumer as regards the nutritional properties of what he buys.

However, in recent years (sooner in U.S.A. than in Europe) other problems have been added to those classic goals: the information given to the consumer in two main ways, labeling (and these pertain to eventually nutritional labeling), and publicity.

To be complete, it must be said that other factors, even if they do not appear as such in the texts, play an important role in the elaboration of the legislations regarding foodstuffs. The first one is the protection of the eating habits of the populations. The perception of this element is not always very clear, but it is evident that, when the problem of regimentation for basic foodstuffs is examined, nutritionists have always in mind maintaining, or at least not too rapid modification of the eating habits of the population.

There is a second factor, and that is the probelm of the economical consequences of the introduction of a meat-like product on the market. Here also there is a trend, at least in some countries, to avoid too rapid changes in the agricultural and economical structures.

And finally, a more general problem. When a foodstuff is intended, even partly, to replace a basic food, is it not necessary to add this foodstuff the elements, such as vitamins, amino acids, and minerals, needed to give this food almost the same nutritive value as the other one? Is this necessary to avoid having the consumption of important amounts by a part of the population lead to a disturbance in the nutritive balance of this group of population? A classic example of this is the obligatory addition of vitamins A and D in margarine in some countries.

All those elements are involved, at different degrees, in the elaboration of the legislation regarding the vegetable proteins. And their combination with local and national factors such as different agricultural policies, different eating habits, and different philosophical approaches of the problem will probably lead to the elaboration of divergent legislations in the European countries. As Mrs. Brincker explained in Plenary Session C, we have just started in Europe with the elaboration of legislation regarding the use and purity criteria of vegetable proteins.

Let us hope that the excellent working paper prepared for the European Communities and that the establishment of a new Codex Committee on Vegetable Proteins will focus energies on this problem affording the possibility to the different countries to adopt not too divergent legislations on these kinds of products.

The United States Labeling Regulations for Vegetable Proteins: An Historical Perspective

EUGENE I. LAMBERT, Partner, Covington & Burling, Attorneys at Law, Washington, DC USA

On July 14, 1978, the United States' Food and Drug Administration issued what it denominated a "tentative final order" to establish common or usual names for vegetable protein products and substitutes for meat, seafood, poultry, eggs, or fish which contain vegetable protein products as sources of protein. This tentative conclusion to a 1974 labeling proposal has its immediate roots in turn in a 1970 proposal to establish a standard of identity for a class of foods to be known as "textured protein products." That proceeding had its antecedents in petitions first from separate companies and then jointly by two members of industry to establish standards of identity for those foods produced from vegetable proteins and intended either to substitute for or to "extend" meat food products. Thus, for over a decade, industry has been urging action to regularize the use of these nutritious foods.

The FDA tentative final order is both complex and ambiguous. Reading the explanatory material to the order,

generally called the "preamble," only reinforces the conclusion that the order represents only a partial solution to a larger, an unresolved regulatory proceeding. To understand why this should be the case - why it should take an executive agency of government more than a decade to establish a labeling policy where the industry has offered itself up for regulation - one must have an appreciation of the historical setting in the United States within which vegetable protein products are regulated.

The regulation of vegetable protein products essentially is divided between two noncoordinating executive departments of government and one independent agency having principal responsibility to the Congress and nominally, if not in fact, independent of executive authority. Countries more familiar with the parliamentary form of government and the close responsibility of executive agencies to the legislative branch and their control within the cabinet may well look aghast at the inherent conflicts that the U.S. system breeds. Both the conflicts and the constituencies of the various agencies form an intrinsic part of the United States' food regulation.

Both of the basic pieces of legislation governing the United States' food supply were originally enacted in the first decade of this century, and were initially administered in the same executive department. The Federal Meat Inspection Act passed as a result of scandals involved in the supply of meat to United States Armed Forces during the Spanish-American War at the end of the 19th Century. The Food and Drug Act of 1906 was passed largely through the self-publicizing tactics of Dr. Harvey Wiley and his self-administering "Poison Squad." Although quite different in their legislative approach, the administration of both Acts was lodged within the Department of Agriculture.

The Federal Meat Inspection Act is a licensing statute. No meat food product can move in interstate commerce other than from an establishment licensed by the Secretary as meeting standards of cleanliness and in accordance with individual product licenses reflecting label approvals and recipe control. In complete contra-distinction, the Food and Drug Act was a police statute containing prohibited acts that were policed in essence as would be any misdemeanor or felony through police action of inspection and criminal or civil penalties.

The major upheaval in this regulatory pattern occurred at the end of the decade of the thirties. The Food and Drug Act was replaced by the current Federal Food, Drug, and Cosmetic Act of 1938, and while its administration was initially lodged with the Department of Agriculture, it was soon transferred to the newly created Federal Security Agency (now the Department of Health, Education and Welfare) and thus divorced from even nominal supervisory control and coordination within a single agency along with the Meat Inspection Act.

At the same time as the Federal Food, Drug, and Cosmetic Act was enacted, major amendments were made to the regulatory authority of an independent commission that was not directly responsible to executive control, the Federal Trade Commission. Originally created as an anti-monopoly vehicle, in 1938 the Commission's charge and jurisdiction were substantially expanded to include specific supervisory control over the advertising of foods, drugs, and cosmetics.

Until the technology involved in current day vegetable protein products emerged during the 1960s, the two prncipal federal regulatory agencies - FDA and USDA - had quite satisfactorily regulated the products within their respective jurisdictions with very little regard for each other's practices and the inconsistencies that readily developed. The U.S. Department of Agriculture regulated meat food products, and the Food and Drug Administration regulated everything else.

There were essentially no products that crossed jurisdictional lines so as to cause confusion or competition between the agencies for their regulation.

It is notable that, after four decades of rather distant relations and indeed at times virtually arm's length negotiations, the three agencies - the Food and Drug Administration, that component of the Department of Agriculture charged with meat inspection, and the Federal Trade Commission - are for the first time in 1978 undertaking a coordinated and cooperative examination of Federal policy relating to food composition, labeling, and advertising.

Both USDA and FDA took a very traditional attitude toward the products they regulated. In the case of the Department of Agriculture, this was a not unnatural consequence of their close relationship in the licensing and inspection of establishments and products with the meat food industry, principally represented by slaughtering houses and packing houses.

FDA's traditional approach is based both on the concepts imbedded in the 1938 Federal Food, Drug, and Cosmetic Act and the attitudes of many of its administrators reflecting the trauma through which the United States had just lived known to those of us who live in that country as the "Great Depression." I trust in this gathering I can be forgiven the parochial attitude that reflects toward what was a worldwide depression having significant and portentous political consequences here in Europe.

The 1938 Act contained within it a major dichotomy in food regulation. It was assumed that there were basic foods whose composition was widely understood among the population and that had, if not a folk history, at least a common basis of understanding among the population at large. These foods were to be identified and standardized, and in general, no labeling requirements beyond the simple identity of the food - canned corn, bread, milk, chocolate - was to be required. Only where novel ingredients were incorporated into the product was labeling to be a requirement. Such novel ingredients might include an artificial flavor in chocolate or a chemical preservative in bread.

At the same time, Congress also took a perceptive look into the future and provided for all manner of foods that might be developed and could not at that time be foreseen. Those foods were to be identified by their common or usual name, if there was one, but in any event were to be labeled with all their ingredients so that consumers could have some understanding of the nature of the food they were buying.

The significnace of this dichotomy in approach to food controls was reflected in an FDA decision almost immediately after the passage of the Act to exempt numerous classes of foods from ingredient labeling, even though they were not standardized, on the ground that the agency intended to standardize them and there was no reason why they should not be treated as standardized from the inception of the Act.

This exemption was in fact not finally terminated until the 1960s when it was clear that many classes of foods would never be standardized, and that those that were should indeed still have descriptive ingredient labeling.

In addition to giving special stature to traditional products, the 1938 Act contained strong indications of the problems of poverty and scarcity during the Great Depression. Half of the adulteration provisions of the Act were concerned with the economic rather than poisonous adulteration of the food supply. In addition, labeling provisions raised specific concerns of palming off and imitation foods. The concern for cheapened substitutes being sold in place of the "real thing" was evident throughout the Act.

On to this scene of tranquil traditionalism burst vegetable proteins, posing challenges to both agencies and creting tensions and conflicts between them.

At the Department of Agriculture, licensing as it did

each product of the meat packing industry, those interested in using vegetable proteins had to go to the Department to seek approval for the incorporation of novel ingredients in the recipes licensed by the Department. Wholly without public proceedings, the Department developed a series of internal quidelines that governed and largely limited the introduction of vegetable proteins into meat food products.

Where they were permitted, however, in general the meat food product retained its original familiar and traditional name but carried along with it an announcement of the presence of the intruding ingredient. The process was, on the whole, one of negotiation and accommodation.

The situation at the Food and Drug Administration, which did not license either products or labels except through the laborious process of issuing food standards, faced significant difficulties with vegetable proteins. Where the Agency did have a food standard, existing law prohibited the addition of any new material without as elaborate a procedure as was gone through in the initial adoption of the standard. Where the vegetable proteins were formulated to simulate in appearance or flavor traditional foods, the question immediately arose whether they could be identified by their composition or whether they were to be labeled as simply a mimic - immitation - of the simulated food. FDA finally decided upon the latter course and seized some vegetable proteins that had been formulated to resemble and replace crushed bacon used as a garnish in salads and cooking. That action, taken in the mid-1960s was, in fact, the genesis of the tentative final order issued in July of this year.

And throughout the course of that proceeding, it has been the original FDA charge - that the food was an imitation of a traditional food - that provided the conceptual underpinning for the proceeding and the impetus for industry action. If the food could be standardized - if it could be given its own identity - if it could be identified by its own name - it would then escape the clutches of imitation and would be able to face the marketplace as an independent food item.

The notion of providing a food with its own niche so as to escape being an imitation is certainly not a new concept in U.S. food and drug regulation. Starch-based salad dressing was a Depression-borne alternative to expensive mayonnaise; each has its prescribed standard of identity. Margarine has an honorable hundred year history of escaping from the shadow of butter, aided in the United States by an independent standard of identity. The search for less expensive functional substitutes is certainly reflected in these standards for cheese foods and spreads, and the standards for chocolate-coating products.

But in this proceeding, a confounding factor has been the fact that foods produced under the supervision of one agency (FDA) are largely intended to be incorporated into other foods subject to the jurisdiction of a second agency (USDA). However strong the conceptual underpinnings were for control over vegetable protein foods that, without mixture with animal protein, resulted in foods resembling in their organoleptic characteristics meat food products, both the theory and practice of control were much more tenuous as applied to those vegetable protein products which bore no resemblance to any meat food product until actually mixed with the meat food product in an extended system. Even the tentative final order of July 1978 pays major, if confusing, obeisance to the concept of independent control over meat and vegetable protein mixtures in the hands of USDA.

That Agency had its own complexities, for in addition to the part of it that directly regulated the meat food industry (by now including the poultry industry) there was another portion responsible for the supervision and funding of programs designed to provide school children throughout the country with adequate nutritious lunches. This venture inevitably faced the pressures of increasing costs and the desire to provide nutritious lunches while stabilizing the funding expenditure.

Vegetable proteins in this context provided a major opportunity to achieve nutritional goals while supplementing expensive animal protein with less expensive vegetable protein. The need to achieve this meant that a nonregulatory agency was forced to adopt standards to permit its clientele - school districts throughout the United States - to spread their money further; so was developed the first specific requirements for a nutritional profile for vegetable protein products to be incorporated into meat food products. From that point on, that element of the Department of Agriculture became an integral part of the regulatory negotiations with respect to the development of requirements for vegetable protein products.

What do we see in the tentative final order of July 1978? We see nutritional demands based on a Depression-borne fear of a nutritional dilution of the food supply - a nutritional Gresham's law where, without adequate warnings or proscriptions, watered down substitutes would drive good food from the market.

We see the difficulty of accommodation between independent agencies having no common overseer in a regulation that on its face is sufficient to cover all food products but must acknowledge a lack of jurisdiction with respect to the central group of foods that are in reality produced in the marketplace.

And finally, we see past this tentative final order to the other regulatory agency so mired in its traditional licensing exercises that it as yet has not been able to deal publicly with the consumer issues presented in the combined use of animal and vegetable proteins.

While the United States' experience presents perhaps some unique elements reflecting our nonparliamentary governmental system, the traditional prejudices that have impinged on the development of a uniform approach to the utilization of vegetable food proteins is hardly unique, as Mrs. Brincker's paper demonstrated. The new joint hearings now being conducted by the Food and Drug Administration, the Department of Agriculture, and the Federal Trade Commission present for the first time an opportunity for a coordinated policy on food labeling, including those rules applicable to vegetable protein products. One can only hope that the total regulatory framework so carefully enunciated in Dr. Ward's paper is reflected in the deliberations and recommendations of the hearing parties, rather than any of the diverse interests enumerated in Dr. Ward's paper being given a role of primacy to which all else must be subservient.

If one is to turn away from the prescriptive and restrictive concepts borne of a hunger economy and depression and look forward as indeed the Congress did in part in 1938, one can foresee the development of uniform labeling requirements that will not discriminate against the utilization of vegetable protein products in food classes regardless of traditional concepts. The Food and Drug Administration has only recently, without fanfare, and perhaps indeed without even self-realization, taken the first important step for the Agency to the implementation of that approach.

As Mr. Leonard Roberts has carefully noted, food standards have a prescriptive effect, limiting the addition of new ingredients to foods. In order to resolve a controversy with respect to a quite minor item in the diet - raisin bread - FDA recently in effect lifted the prescription that had been judicially approved since the 1940s. It ruled that one could market, outside a standard, a food product bearing the name of the standardized food so long as the name was modified to reflect the added ingredients and so long as the controlling qualities of the standardized food were not otherwise diminished. While, within the framework of the United States' statute, the Food Protein Council is urging

an even more flexible pattern for the use of vegetable protein products, this step by FDA does, in the United States, represent a major step forward in the permitted use of vegetable protein products without restriction of existing food standards. One can only hope that the Department of Agriculture in its regulation of meat food products will follow a comparable approach.

Comments on the Report of the Study Group on Vegetable Proteins for Human Consumption, in Particular Meat Products, by the Commission of the European Communities (April, 1978)

L. SCHUTTE, UniMills B.V., Lindtsedijk 8, 3336 LE ZWIJNDRECHT, The Netherlands

Recently an E.C. Study Group, chaired by Prof. Ward, has published recommendations for use of vegetable proteins for human consumption, in particular meat products. The spirit of this report is extremely positive, since it acknowledges specifically soy protein products as valuable food ingredients, of which the use should rather be regulated than restricted. Notwithstanding this positive attitude, some criticism on certain proposed rules is still possible.

1. The report recommends products in which more than 2% soy protein product is used should contain a minimum level of vitamin B1, B2, B12 and iron. If this would mean that these micronutrients should be added to the soy protein ingredients rather than to the end-product (the report is not clear about this), the following comments can be made:
   - I am opposed to addition of nicronutrients to ingredients. If, in view of nutritional requirements of a population, fortifications are necessary, this should be done in foods rather than ingredients. It is unfair to place the burden of adequate nutrition on one ingredient, just because it happens to be new.
   - Soy protein materials are by themselves wholesome and natural food ingredients which do not have to be modelled to equivalency of other food ingredients.
   - It is always debatable when a soy protein product should be regarded as a "replacer" of other foods, particularly in new or fancy products. Must spaghetti be regarded as a potato replacer and therefore be fortified to an equivalent nutritional value?
   - There are considerable technical (mixing) problems if soy flour and concentrates have to be fortified, which will lead to unnecessary cost increase.
2. I see no reason why, as the report states, substitution for meat in meat products should be limited to 30% as an initial precaution. Large scale nutritional trials carried out recently and once more reported during this conference do not indicate any nutritional reason for such a limitation. Taste problems, which some years ago made higher levels than 30% less acceptable, can be overcome with proper refining techniques. Limiting the usage level to 30% would disfavor the application of improved, refined materials.
3. In products of type *a*, application of soy protein products would be allowed up to a level of 2% as technical aid. I think that 3% would be a more realistic maximum level, since this is frequently used in practice.
4. In products of type *b*, a maximum substitution of 30% (or 35% on protein basis) is recommended for extended meat products. On this I have the following comments:
   - As stated above, a limit of 30% is rather arbitrary and based on an old technology where acceptability was limited. A more logical borderline would be 50%, since products with more than 50% meat are certainly rather meat than vegetable protein products,and products with less than 50% meat are clearly falling outside the meat product area. A borderline of 50% would be in line with existing opinions in Western Germany and Belgium. A 50% limit would encourage the use of refined materials, which would enhance the acceptability and would also offer the optimum consumer benefits in terms of economy.
   - I should therefore favor a regulation in which the products of type *b* (extended meat products) would contain at least 50% meat (or 50% of the minimum meat content), whereby the total protein content of the product should not be lower than expected in the nonextruded counterpart. Theoretically such a product could contain more vegetable protein than meat protein, when the end product is enriched in protein. The regulation proposed in the report, allowing for 35% of the total protein content being of vegetable origin, would encourage the use of ingredients with a low (48%) protein content, leading to uncontrolled addition of nonproteinaceous fillers.
5. I welcome the possibility of fancy products, products of type *c*, containing both vegetable protein products and meat as ingredients. It follows from the previous argument that in my opinion a borderline of less than 50% meat would be a logical limit, The category of type *d* products, with 97% vegetable proteins, seems to me redundant. Since ingredient listing is favored in all cases, there is hardly any risk for confusion if type *d* products are omitted as a separate category.
6. I am in favor of labeling regulations which are aimed to inform the consumer as to the nature of the product. Long and confusing names do not serve this purpose. Declaration of the source of vegetable protein in the product name leads to such a confusion, especially when more than one source is used. Moreover, the word "textured" is of no importance to the consumer, as it has no bearing on the composition of the product. The consumer can be informed adequately by mentioning the source of the proteins in the ingredient listing.

In spite of the above remarks, I should like to emphasize once more that the report must be considered as an extremely positive and valuable piece of work, which hopefully will lead to a desired uniformity in legislation in the E.C. and to increased possibilities of the use of vegetable protein ingredients in European foodstuffs.