Soy Protein in Foods: Their Use and Regulations in the U.S.[1]

JOSEPH RAKOSKY, Chemurgy Division, Central Soya Company, Inc., Chicago, Illinois 60639

ABSTRACT

Soy proteins have been used at an ever increasing rate in various food systems because of their beneficial functional properties and low costs. Their use was limited because of taste, regulatory restrictions, and prejudice on the part of many. As technology advanced and as consumer needs changed, these limiting factors became less of a restriction. Flavor and functionability were improved through the introduction of new products or altered processing. The greatest change in regulatory attitude did not come about until after the White House Conference on Nutrition, when it was recommended that the consumer be given the advantages found in the new technologies that were being advanced. In making these changes, a number of new problems have been encountered. These problems, as well as the apparent trend in regulatory action, are discussed.

INTRODUCTION

Although soybeans and their products have been used as foods by the Orientals for centuries, it was not until the turn of the present century that the Western World recognized soybeans for their human food value. At first, it was the oil that gained wide acceptance; later, we recognized that the high protein containing residual product had value in various food systems. Unfortunately, it was considered a by-product, and, as such, its treatment in processing was not the best. It had a poor flavor and its cost was very low—this led to abuses by many who attempted to use it. The end result was a build-up of many prejudices on the parts of the consumer, the food processor, and regulatory agencies.

It was realized eventually that soy protein products had many advantages that could be of benefit to the processor and to the consumer. However, to utilize these benefits most effectively, special soy processing technology had to be learned and followed to produce quality products. Even though these superior products were available to the food processor, it was difficult to overcome the prejudices that had been entrenched. It was also necessary to overcome some of the discriminatory-type food regulations that were in effect.

Although the widespread use and acceptance by the food processor and the consumer were taking place steadily, certain recent events triggered a change in attitude from simple acceptance to demand.

The White House Conference on Nutrition was the pacesetter for all subsequent events. The consumer, the food industry, and the regulatory agencies were encouraged to take advantages of the new technologies that were coming to light. Soy products were playing a part in most of these new technological developments.

In August 1970, the Secretary of Agriculture published the Department's "Postion Statement on Engineered Foods" (1). This set the stage for a change in attitude within the USDA, first with the Child Nutrition Division of the Food and Nutrition Service and secondly with the Meat Inspection Division.

It was in the meat applications area where the greatest change in attitude had to take place, because there were so many restrictions. However, it was in the meat applications area where the change most likely would take place because of ever increasing meat costs.

In the case of school lunch, the meat portion of the Type A lunch was a significant part of the cost. Since many students were receiving free lunches, the increasing costs of the meals were placing heavy financial burdens upon those concerned with the school lunch program. Following the guidelines put out by the Secretary of Agriculture, USDA issued Bulletin FNS-219 (2) which permitted up to 30% replacement of the meat requirement in the Type A school lunch. This notice permitted one to use up to 30% hydrated textured vegetable protein or hydrated granular soy protein concentrate in the meat portion of the lunch.

The third step in changing attitudes occured at the retail meat counter. At a time when the homemaker was boycotting meat because of high prices, a retail store in Minneapolis offered a mixture of ground beef and a hydrated soy protein product at a reduced cost. The response was immediate. Mrs. Homemaker bought it and came back for more. Once one retailer took the step, others followed the example, and general acceptance became the rule.

The three events mentioned above were not the only ones that were taking place, there were others of a subtle nature that were occurring over the years. For example, in the portion-control business, patties were being made with soy protein supplementation in an effort to keep costs down.

In the early days when supplementation of meat took place, there was little spread between the cost of an all-meat product and the supplemented product. Such a spread was of little interest to the homemaker, but it was of great interest to the institutional trade who was dealing in volume. A fraction of a cent/portion was significant, making it appealing to those dealing in volume. It was not until later when the price-spread between the all-meat items and the supplemented items became greater that the consumer became interested.

Thus, it can be seen that a significant change in attitude and acceptance had taken place and is continuing to take place. This is not only true in the U.S. but all over the world. With this change in attitude, the regulatory agencies are responding to the consumers' acceptance and demand for these products.

USE OF SOY PROTEIN IN FOODS

It was recognized that the basic soy products (meal, grits, and flours) were high in protein, they were good from the nutrition standpoint, and they were inexpensive. Because of these reasons, they first were used to extend various products. Unfortunately, the feeling soon became evident that "if little was good, more was better." As was stated earlier, this led to abuses that prejudiced the consumer, the food processor, and the regulatory agencies.

These abuses brought out the objectional properties of the then existing products. As time went on, the soy processor learned how to make products that corrected many of the problems that arose. New technologies also developed entirely new products which were improvements over the parent substances. These developments included the production of concentrates, isolates, and textured products. It was now possible to try various products that would overcome an objection that a food processor might have for another food ingredient, a related soy product, another grain product, or even an animal product. Concurrent with these developments was the recognition of various functional properties. Here too, technological developments allowed the processor to enhance some of the desired proper-

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ties through special techniques.

In considering the present day usage of soy products in various food systems, we need to recognize the regulatory agencies as they apply.

Those food companies engaged in interstate activities are regulated by the federal agencies, including the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare (HEW), and the Animal and Plant Health Inspection Service (APHIS) of the USDA. APHIS has jurisdiction over all-meat and poultry products, and the FDA regulates all other foods. Although the FDA is not directly concerned with meat and poultry operations, it does decide what is considered safe as additives in all foods, including meats. Thus, APHIS will not consider any ingredient that does not have FDA approval.

FDA is concerned with two aspects of the Food and Drug Law, adulteration and mislabeling. Adulteration includes contamination of any type that is a threat to health, e.g. pathogenic microorganisms, toxic substances, or material that may cause injury, such as glass and metal particles. An important aspect of the law is that FDA need not prove the existence of contamination. They need only prove that adulteration is possible under the conditions the food is being handled.

The mislabeling responsibility given to FDA by the law allows the agency to regulate that aspect whereby the consumer should be fully informed of what he or she is buying. If, in naming the product, it is not obvious to the consumer what that product is, then the label must have information to inform the buyer fully, such as an ingredient statement which lists (in descending order of concentration) those items included in the food product. Presently, the FDA also establishes standards of identity, quality, and fill for foods. Although standard foods are not required to have an ingredient statement, the present trend is to include an ingredient declaration.

In regulating foods and food additives, FDA does have a problem differentiating between the two. Under one set of conditions, a product can be considered a food, while, under another set, it can be considered a food ingredient or an additive. In all cases, the item must be considered safe. Presently, there are regulations affecting additives. They can be considered generally recognized as safe (GRAS), or they can establish their status as a regulated food additive. In the latter instance, there usually are limits and conditions set in the use of the food additive.

Every food additive legally in use in the U.S. has had its safety established through appropriate tests. As V.D. Wodicka pointed out: "It should be obvious . . . that no demonstration of safety is ever permanent, because ideas of safety change; and it is necessary to review these determinations from time to time" (3).

The FDA presently is reevaluating all additives and foods. An additional category of additives also is being examined and that is "distillates, isolates, extracts, concentrates of extracts, or reaction products of substances considered to be GRAS" (3).

Presently, whole soybeans and full-fat flour are considered GRAS. Because of their long history of usage, soybean oil, meal, and defatted soy flour also are considered GRAS. Thus far, this is not the case with soy protein concentrate, isolated soy protein, and texture vegetable protein. Wodicka noted that "these materials are indeed generally recognized as safe by experts, even through this fact has not yet been legally affirmed by the FDA. Accordingly, they may be used right now and the only need for a regulation is to make this a record" (3).

APHIS administers the Federal Meat Inspection Act and the Federal Poultry Inspection Act (4). In so doing, the consumer is assured that he is getting wholesome and properly prepared products. In addition, the consumer is assured that the products are labeled properly. APHIS also regulates all ingredients, including vegetables, sauces, additives, and other substances. APHIS carries out its duties in several ways. The first is on-site inspection and the other is prior label approval.

In approving labels, certain guidelines and procedures must be followed. As a first step, the local inspector reviews a proposed label and indicates his acceptance. As part of the information that the processor includes in his application is a disclosure of the complete formulation and processing procedure. If the product is a standard item, it must conform to all requirements. The label for which approval is sought must have five essential features (A) name of the product; (B) ingredient statement if two or more ingredients are used; (C) name and place of business of the manufacturer, packer, or person for whom the product is prepared; (D) net wt statement; and (E) inspection legend.

The inspection legent not only indicates that the processing plant is federally inspected, it contains an establishment number which also identifies the plant and its location.

Although a fair amount of information is needed for label approval, the form used was designated for key punchers to get information into a computer. In addition, a procedure is in effect that permits the USDA to approve a label in less than 48 hr after its reception at the office (5).

In giving label approval, the Labels and Packaging Staff often consults with the Products Standards Staff. As the need arises, they may even consult with other agencies of the government, such as the FDA.

Meat products produced outside the U.S. for consumption in the U.S. also must go through the procedure.

As to the approval of additives for use in meat products, here too, a number of requirements must be met before approval is given. Obviously, first and foremost, safety is essential, and, as stated earlier, the additive also must be safe in the eyes of FDA.

Next, it is necessary to demonstrate a need for the additive, and it must be effective for its intended purpose. The additive must be used only at the level necessary to accomplish this intended purpose.

A number of meat items has a standard of identity in which additives are permitted in maximum specified amounts. In cooked sausage and bologna, as an example, soy flour and soy protein concentrate are permitted at a level of 3-1/2%, whereas isolated soy protein is restricted to 2%. Breakfast sausage follows the same guidelines.

In the case of chili con carne, all soy protein products, with the exception of textured vegetable protein, may be used at a level of 8%. Meatballs and salisbury steak permit these same ingredients at a 12% level. For meat products that do not have a standard identify, regulations concerning additives simply state the level permitted be "sufficient for purpose" (6). Nonspecific loaves and patties fall into this category.

In all cases where isolated soy protein is used, regulations require that the product be tagged with 0.1% titanium in the form of titanium dioxide (7). This is done to allow APHIS to determine the amount of isolated soy protein present in the meat products in question.

As far as textured vegetable protein is concerned, greater restrictions are exercised. This is done because the agency feels that the consumer might be deceived, i.e. it would appear that a greater quantity of meat is present than actually is there. The present labeling policy is based upon the relative proportions of fresh meat to dry analogue. For products that have 13 parts of fresh meat or more to 1 part of dry analogue, the label need only make known the fact that the analogue is present by listing it in the ingredient statement. For those products that have less meat, i.e. between 13:1 to 10:1, the label should read "textured vegetable protein added" or something equivalent. For products having greater than a 10:1 ratio, the analogue name should be included in the name of the product, e.g. "beef and

TABLE I

Proposed Levels of Usage of Large Particle Textured Vegetable Protein in Meat Products (4)

Product class	Amount (%)	Examples
High meat products not	5	Meat loaves for baking, meatballs, meat toppings for pizza, salisbury steak, patties
Meat with gravy or sauce	4	Beef and gravy, beef burgundy
Sauce or gravy with meat	3	Chili, gravy with beef, barbecue sauce with beef
Meat salads or hashes	3	Ham salad, roast beef hash
Sauce or gravy with meat and vegetables	2	Beef pie, chili with beans, beef stew
Starch (pasta) or beans with meat in sauce	1	Spaghetti with meat in sauce, macaroni with meat in sauce, chili macaroni, beans with bacon in sauce
Meat sauces	1/2	Spaghetti sauce with meat, chili sauce with meat, hotdog chili sauce with beef

textured vegetable protein stew" (4).

At the present time, APHIS is considering guidelines for textured vegetable protein having a particle size of 16 mesh or larger. The maximum amount of large particle textured vegetable protein in various products is shown in Table I. The levels shown are the upper limits permitted without declaring the ingredient in the product name.

As an example, chili con carne contains 8% soy flour, concentrate or isolate, or combinations of these products. When textured vegetable protein is used, only 3% may be used as an upper limit without including it in the name of the product. Five percent of the other materials then may be used. However, in no case is the total allowed to be greater than 8%.

Following the recommendations of the White House Conference on Nutrition, the USDA recognizes the fact that present technology is capable of formulating foods that are complete imitations of another. They further recognize that the word "imitation" would be wrong, especially if that product is equal to or superior to the product being imitated. For this reason, the department will allow the use of a fanciful name. Both FDA and APHIS now feel that, if the product is nutritionally inferior to the product being imitated, then it should be called "imitation." If it is nutritionally equal or superior, then a fanciful name would be permitted.

Presently, USDA is considering the nutritional labeling of meat products. The proposal is patterned after the FDA Nutritional Labeling Regulations. In both cases, if a claim is made in advertising that a product is improved from the nutritional standpoint, i.e. lower in calories, higher protein content, or fortified, etc., then the label must conform to the nutritional labeling regulations. In following the regulation, certain guidelines are laid down. The aspect of the USDA proposal that presently is being debated is the amount and type of analytical substantiation needed.

SCHOOL LUNCH PROGRAM

Since soy protein products are becoming increasingly important in the school lunch program in the U.S., it would be well to discuss this subject briefly. In 1946, Congress passed the National School Lunch Act "to safeguard the health and well being of the nation's children and to encourage the comestic comsumption of nutritious agricultural commodities and other food" (8). The Act also is designed to teach nutrition and to improve food habits.

At first, the program was geared to feeding children at lunch time. The meal was to contain one third of the recommended daily allowances of the various nutrients considered important. Since its inception, the program has expanded to the inclusion of other meals. For purposes of discussion, we will concern ourselves only with the Type A school lunch and those areas where soy is concerned.

The Type A pattern includes a minimum of 1/2 pint of milk, 2 oz cooked lean meat or its equivalent, 3/4 cup serving of 2 or more vegetables or fruits, a slice of enriched bread, and a teaspoon of butter or fortified margarine.

The most expensive portion of the meal is that containing animal protein, particularly meat. Two regulations were introduced with the publication of two notices, FNS 218 (9) and FNS 219 (2). The first provides for the use of a protein fortified macaroni to be used in combination with meat, poultry, fish, or cheese. The second was to allow the use of hydrated textured vegetable protein product or a hydrated granular soy protein concentrate product to supplement the meat up to 30%.

In the case of the macaroni product, the protein content content was boosted to 20% over the usual 12%. Not only was the level increased, but the protein efficiency ratio was increased from ca. 1.1 to ca. 2.4. Obviously, this was designed to improve the child's nutrition at a slightly higher cost.

In the case of FNS 219, the notice provides for equal nutrition at a reduced cost. In allowing for the supplementation of the meat portions of the meal, it was necessary for processors to meet certain nutritional specifications; thus, it provided for the fortification of these products to meet the specifications. Before the products are permitted in school lunches, they are required to be analyzed in an outside laboratory, the findings then are forwarded to the Food and Nutrition Service in Washington for approval. A list of approved products then is published.

An important consideration in this is the fact that here was a positive step taken in food summplementation that gave the approach a degree of confidence which was picked up by others. A significant savings was realized, and the supplemented products were acceptable.

Until recently, the School Lunch Guidelines did not, as a rule, provide for one item supplying all of the nutrients normally supplied by another component. It was recognized that pizza could well provide nutrients normally contained in other components of the Type A meal, i.e. it is equivalent to 2 oz cooked meat (meat allotment) or 2 oz of cheese, a serving of bread and a teaspoon of butter or fortified margarine. This category was classified as CN Type 2 Pizza. The CN Type 1 Pizza category also would include 1/4 cup vegetables in addition to the above. Presently, pizza meeting these requirements also must be approved and listed as approved by the Food and Nutrition Service (10).

It can be seen that, over the past several years, significant changes have taken place in technological developments and in the eyes of the various regulatory agencies as they are concerned with soy. As we overcome the several disadvantages yet remaining and work out new technologies, we will see even more significant changes in all types of foods.

REFERENCES

1. USDA, "Position Statement on Engineered Foods," USDA, Washington, D.C., 1970.
2. Food and Nutrition Service, USDA, Bulletin FNS-219, USDA, Washington, D.C., 1971.
3. Wodicka, V.O., JAOCS 51:105A (1974).
4. Mussman, H.C., Ibid 51:104A (1974).
5. Anonymous, The National Provisioner, p. 12-16 (July 21, 1973).
6. Rakosky, J., J. Agric. Food Chem. 18:1005 (1970).
7. Rakosky, J., JAOCS 51:123A (1974).
8. USDA, "National School Lunch Program," CMS-USDA, Washington, D.C., PA-19, May 1965.
9. Food and Nutrition Service, Bulletin FNS-218, USDA, Washington, D.C., 1971.

10. Food and Nutrition Service, "Guidelines for the Formulation of CN Pizzas (Type 1 and Type 2) for Use in the Food and Nutrition Service," Child Nutrition Programs, FNS-USDA, Washington, D.C., July 1973.

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