Authorizations and Restrictions on Soy Protein in Foods in the U.S.

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ABSTRACT

The Food and Drug Administration makes the basic decisions on what materials will be permitted in U.S. foods. The U.S. Department of Agriculture then selects those items which it will allow in meats and poultry products. The Food and Drug Administration is in the process of developing definitions for soy products and issuing the regulatory controls over their uses. Care is being taken not to impose burdensome regulatory restrictions on a technology that is in a rapid state of development.

INTRODUCTION

It is obviously fitting that this Conference give attention to the regulatory climate regarding soy protein in the U.S., partly because the size of our country gives it more than ordinary significance in commerce, and partly because as one of the major sources of soybeans, we will tend to have an influence outside our national boundaries by the ways in which our products are prepared and offered. We are not so vain as to think that our regulatory approaches have any unique virtue, if only because they are based upon the laws of our country and the laws of other countries present a different foundation on which to build. On the other hand, we have to cope with attitudes among consumers and among members of industry that have many elements in common, regardless of the language in which they are expressed. Consequently, the ways in which we are proposing to solve some of our problems may be useful, at least, in stimulating the thinking in other countries.

LEGAL BACKGROUND

Because our regulations are only a mechanism to define and extend the application of our laws to particular situations, it is necessary to start out with a look at the legal background and some of the philosophies entering into our present position. We may start with the fact that in our country the Department of Agriculture has regulatory jurisdiction over meat and poultry products. The Food and Drug Administration (FDA) regulates all other foods. Harry Mussman will discuss in more detail the approach of the Department of Agriculture toward the use of soy protein in meat products, but for the present let me say that the Department of Agriculture tends to regulate meat and poultry products in much closer detail than the FDA does other foods. As a general working rule, however, the FDA, as a part of the Public Health Service which in turn is a part of our Department of Health, Education, and Welfare, makes the basic decision as to what materials will be permitted in the U.S. food supply. From this shopping list, the Department of Agriculture selects those items that it chooses to permit in meat and poultry products. As a consequence, it is important that we cooperate closely in our approach toward the regulation of food constituents.

The operation of what is now the FDA began with a unit of the Department of Agriculture which was given responsibility to enforce the newly enacted Food and Drugs Act of 1906. This Act gave the U.S. government the authority to act against contaminated and adulterated foods in U.S. commerce. The burden of proof of harmfulness, however, lay on the government.

The inadequacies of this Act became sufficiently apparent that it was thoroughly overhauled and transmuted into the Federal Food, Drug, and Cosmetic Act of 1938. By this time the FDA had been created as a separate entity in the Department of Agriculture. The 1938 Act, among other things, gave the FDA the authority to establish standards of identity, quality, and fill for foods. It also provided that all foods not covered by such standards should bear on their labels a list of ingredients, ordinarily in decreasing order of predominance. The commissioner of food and drugs was authorized to designate which of the optional ingredients of standardized foods also should be declared on the label. Ingredients required by the standards did not and do not to this day have to be declared. There is presently under discussion in the Congress, however, a bill to remove this exemption.

The authority to develop and promulgate standards gave the FDA its first opportunity to review the safety of food ingredients before they were used instead of impugning their safety afterwards. As a consequence, the standards tended to be written in rather closely defined recipe fashion with only those ingredients listed in the standard permitted for use in that particular food. It should be pointed out, however, that the standards were not unilaterally imposed by FDA on an unwilling economy, but rather were developed through a public hearing process. It eventually became apparent that this mechanism was too cumbersome, particularly when the standards were noncontroversial. Therefore, the law was changed to permit the publication of a proposal for comment, followed by a final order taking into account the comments, with a hearing to be held only if there were valid objections to the final order. This is the mechanism now in force.

Eventually it became apparent that the standards mechanism too left something to be desired, because, although the standards covered the commodities in largest volume of consumption, there were and are thousands of items on the shelves for which there are no standards. Even now there are less than 500 standards in effect, and it is estimated that a typical large supermarket will contain as many as 8000 items. Accordingly in 1958 a Food Additives Amendment was added to the law. Leaving out certain exceptions that are relatively minor and irrelevant to the present discussion, this amendment provides that a food additive is any substance which is or might become a component of food or affect its characteristics, unless this substance is generally recognized as safe by experts qualified through training and experience to judge its safety.

Accordingly, the effect of this amendment is to divide our food supply into two categories, one of them consisting of food additives and the other of substances generally recognized as safe. The law permits a food additive to be used only after the FDA has promulgated a regulation permitting its use and setting forth any limiting conditions applying to its use, such as levels, specifications of purity,

etc. Before the FDA is permitted to issue such a regulation, the person proposing the use of the substance must submit convincing evidence of its safety when used as intended. Accordingly, every food additive legally in use in the U.S. has had its safety established through appropriate tests. It should be obvious, of course, 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.

I know of no one who has come up with a satisfactory definition of food additive for rigorous application to regulatory affairs. Logically it is obvious that a food additive is something one adds to food. This means that the difficult question is, what is not a food additive? For instance, salt is a pure inorganic chemical, and sucrose is a pure organic chemical. Are these food additives? The legal definition of food, even setting aside the distinction from food additives, becomes a substantial challenge; and our law has not set a shining example in this respect.

When the added problem of distinguishing between food and food additive is imposed, the job becomes unmanageable, if a sharp distinction is sought. In our law, and consequently in our regulatory operations, there is no distinction between food and food additive, nor is the distinction between food and drug a sharp one. There are substances on record which are considered as both foods and food additives and others that are considered as both foods and drugs and regulated accordingly. It would be theoretically possible for a substance to be all three.

When the Food Additives Amendment became law, the regulatory status of a number of substances, particularly minor functional ingredients of foods, became doubtful. Accordingly, as a public service, the FDA prepared and published in the *Code of Federal Regulations* a list of substances generally recognized as safe through formal surveys of experts who were considered qualified to make such decisions. The FDA made it clear, however, that this list was not intended to be exhaustive. This should be obvious, because, if it were, it would have to include the whole food supply that is not covered by food additive regulations.

Standards of safety now have reached the point that it costs upwards of a quarter of a million dollars to establish the safety of a component of the food supply through formal animal test procedures. Consequently, most food formulators today will not use an ingredient on which the safety status has not been ruled upon by the FDA. Accordingly in December 1972, the FDA issued a new procedural regulation (§ 121.40) establishing a mechanism by which it would affirm that a particular substance generally is recognized as safe. In this way the regulatory status of a substance not covered by a food additive regulation can be made a matter of permanent record. Previously in July 1971, § 121.3 had been issued to set forth the rules by which such an affirmation would be made.

The July 1971 regulation, to avoid the overwhelming burden of affirming the safety of most of the food supply, provided that, "any substance of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without detrimental effect when used under reasonably anticipated patterns of consumption . . ." would be considered generally recognized as safe without a regulation promulgated in the *Federal Register*. This status also would apply to such foods that had been modified by conventional processing practiced prior to that date. The date was chosen to correspond to the passage of the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. On the other hand, certain categories of food ingredients were designated as requiring review of evidence followed by an appropriate regulation to determine regulatory status. One of these categories consists of "distillates, isolates, extracts, concentrates of extracts, or reaction products of substances considered as GRAS." Such substances would be covered by regulation either affirming that generally they are recognized as safe or establishing their status as regulated food additives.

U.S. REGULATIONS PERTAINING TO SOYBEANS

In accordance with these regulations, whole soybeans and full fat soy flour generally would be recognized as safe without mention in regulations. In view of the fact that the removal of oil was long established as a safe process before 1958, soybean oil meal and defatted soy flour also would be generally recognized as safe without an implementing regulation. When fractionation procedures are applied to the soy flour and texturizing procedures beyond that, the regulations would require their affirmation as generally recognized as safe through an implementing regulation. Such regulations are now in preparation. In the meantime, these materials are, indeed, generally recognized as safe by experts, even though 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 matter of record.

The regulatory status of soy protein preparations, however, involves more than safety considerations and their appropriate regulatory classification in this regard. The law also requires the product to bear a label showing the common or usual name of the food. If there is not a common or usual name, the FDA may issue a regulation to cope with the situation. There is already a bewildering diversity of products made from the soybean which then fan out into an even larger diversity of uses. Undoubtedly more of both may be anticipated, although some of them now in the marketplace may well drop by the wayside. In brief, the present commercial situation is dynamic. In view of such a situation what shall we do about nomenclature?

One approach that might be taken is to issue a standard of identity to cover these materials. As indicated earlier, the FDA has authority to issue such standards to promote honesty and fair dealing on behalf of the consumer. In fact, such a standard was proposed most recently on December 5, 1970, and has been under active discussion ever since. It is uncertain whether such a standard will now be issued.

To understand the situation, it is necessary to examine the considerations underlying the original proposal. First of all, in view of the fact that we are dealing with essentially a new component in the food supply, it is necessary that there be uniformity of nomenclature to avoid confusion of many different names for closely similar products in the marketplace. Accordingly, a major purpose of the proposed standard was to establish a standard nomenclature. Secondly, it is obvious that one of the major purposes of marketing a variety of products based upon soy protein is to substitute protein of plant origin for protein of animal origin and thereby reduce the cost of the end product. This cost reduction is obviously in the public interest, given two conditions. First, the public must know that the substitution is taking place, so that it can make a decision whether or not to buy the substitute product. This condition would be taken care of by the standardized nomenclature. The second condition is that the substitution must be accompanied without significant deterioration of the nutritive value of the food supply. This condition is harder to meet. The attempt was made in the proposed standard by choosing a rough average of the foods of animal origin for which the soy protein would be substituted and by prescribing a nutritive value for the standardized food corresponding to this average. The proposed standard, however, provided only one name and one composition.

As time wore on, several things happened. First, it

became obvious that there were many different products made from soybeans, and they differed in flavor, texture, and nutritive value. It would impede communication with the consumer to call them all by the same name. It is likely that they all have uses, but the uses are not necessarily the same for the different products. Accordingly, the consumer should be able to distinguish.

Secondly, some new regulatory mechanisms were developed while this standard was under consideration. One of these regulatory mechanisms provides for the establishment by regulation of a common or usual name for a commodity. A common or usual name may be established upon petition by any interested person or upon the initiative of the commissioner of food and drugs without petition. Such a regulation may be looked upon as a substitute for a standard of identity for use when it is not necessary or often not even desirable to restrict too closely the variations among products bearing the same name. The purpose of such regulations is to establish rules of nomenclature whenever there may be confusion or undesirable inconsistency in the use of generic names for products. Such a regulation is now under consideration for various product types based upon soy protein.

The second regulatory mechanism that makes it possible to use a common or usual name regulation instead of a complete standard for protein products is one in which nutritional quality guidelines are established. Here again we are dealing with a substitute for a food standard. Nutritional quality guidelines are established for classes of foods rather than individual foods; and they are only recommendations, not requirements. If a food marketer supplies a food that follows the guidelines and has its nutritive value presented on the label, although not necessarily on the principal display panel, he may then say on his label, "this product provides nutrients in amounts appropriate for this class of food as determined by the U.S. government." This statement would be on the principal display panel and also may be repeated on the information panel, along with the nutrition labeling. This regulatory mechanism is so new that we do not have any experience to report on its usefulness. We are confident, however, that marketers who are eligible to make use of this label statement will do so.

If we decide to travel the route of a regulation establishing common or usual names instead of a standard of identity and quality, it will be accompanied by a regulation establishing nutritional quality guidelines for the product classes involved.

One final regulatory development bears on the status of soy protein products. This is the handling of the designation "imitation." The Federal Food, Drug, and Cosmetic Act provides, "a food shall be deemed to be misbranded if it is an imitation of another food, unless its label bears in type of uniform size and prominence the word 'imitation' and immediately thereafter the name of the food imitated." The law does not go on to define the word imitation, leaving that to regulations to be issued by the FDA.

The FDA, on the other hand, never issued implementing regulations; and, through the years, it has not been entirely consistent in the enforcement actions it has taken against various foods. Largely because of the relevance and importance of questions arising from the substitution of plant proteins for animal proteins in the food supply, the FDA decided that it would have to establish a policy on this matter. Because the word imitation is inherently a pejorative term denoting inferiority, a regulation has been issued which exempts a food from the requirement to be labeled as an imitation when offered in resemblance to another if it is not nutritionally inferior to the food resembled and if it is truthfully and informatively labeled with regard to its composition. This policy ensures that the consumer is neither misinformed regarding the composition of the food nor cheated with respect to nutrition. Accordingly, we believe that it establishes a consistent policy which carries out the intent of the statute.

Looking back at the regulations which are in various stages of issuance, one may see a pattern and in that pattern discern a philosophy. The FDA is trying to make available to the consumer a variety of plant protein products with, of course, soy protein being the most important member of the family. It is doing so with the expectation that many consumers eventually may be priced out of the market for protein products of animal origin. As this takes place, we must be certain that the products available are wholesome, nutritious, and honestly represented. At the same time we do not wish to impose burdensome regulatory restrictions on a technology that is in a stage of rapid development. We hope and believe that the family of regulations described here will meet these requirements.