Problems and Outlook in Evolving Food Regulation[1]

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Abstract

Oil chemists and other food technologists are confronted by a rapidly changing food regulatory environment. New concepts of standards, procedures, tolerances, etc., are being reviewed amid the emergence of significant recent and foreseeable legislation. Designed foods such as margarine are significantly affected. Major changes involve a new federal food regulatory organization different from the traditional FDA, problems of interrelationship of FDA and USDA controls and procedures, a mixed situation in state regulatory work where federal law, funding and leadership is strengthening in some sectors, but where other phases of enforcement may become more state oriented. A definite new problem of uniformity and government intervention has emerged. Leadership personnel also is changing. Net, the responsibility of oils and food technologists is increasing. It is necessary to reexamine their relationships and goals in the regulatory field interest of continued development of food products and public acceptance of existing standards of preparation and handling.

Introduction

The purpose of this paper is to consider what can be expected in terms of evolving, i.e., future food regulation, particularly margarine regulation.

Regulation comes primarily in two branches of government, the legislative and the executive or administrative branch, and at two levels of government, the federal level and the state level. Regulation is effectuated at the federal level, legislatively through Congress and administratively through bureaus such as the Federal Food and Drug Administration, the Federal Trade Commission, the Departments of Agriculture and Commerce and many others. Regulation is also effectuated at the state level by state legislatures and by state departments of agriculture, public health or consumer protection, or any one of a number of similar departments. No food product has in the past been subject to as much regulation in any one of these four ways as margarine.

Federal Legislation

What does the future hold? First, consider the prospects for additional legislative regulation at the federal level. Next to death and taxes, the surest future prospect is for additional federal legislation affecting food products. Just since the basic Federal Food Drug and Cosmetic Act was passed in 1938 Congress has enacted the Hale Amendment, which facilitates the standards-making procedures, the very extensive food additive amendment, which changed the whole concept of the legal approach to items going into food, and the color additive amendment, all of which are very important and particularly relevant to the food industry. As to drugs, Congress has enacted a substantially broadened factory inspection provision, and the extensive Kefauver-Harris amendments of 1962. Congress has also adopted the Fair Packaging and Labeling Act of 1967 applicable to both food and drugs. Most important for purposes of this paper, is the 1950 margarine amendment to the federal act. This is one of the most comprehensive sections of the act, even purporting to regulate intrastate sales of colored margarine. Sec. 407 limits retail sales of colored margarine to one pound packages or less, requires that the word "margarine" be in type at least as large as any other word on the label, and requires 20 point type. The statute also regulates service of margarine in public eating places.

With this kind of historical background, what can be expected in the next few years? More rigid and more stringent labeling requirements are very likely to be enacted, although the margarine industry is relatively safe in this regard because it is already so strictly regulated. More strict factory inspection provisions, for example, authorizing inspectors to look at formulas, are probably also coming, as are additional bills regulating pricing and promotions, e.g., cents off labeling, two for the price of one, "this top of the box free if you buy the 8 ounces that are in the bottom of the box" and so forth.

Full time federal inspection of meat plants is now an accomplished fact. Very serious and hotly debated proposals for full time inspection of the drug industry are probably next and if that occurs, then the final step is proposals for full time federal inspection of the food industry.

There will probably also be proposals for amendments to the present act to change sectoin 403 (c) which now provides that a food shall be deemed to be misbranded if it is an imitation of another food, unless it bears the word "imitation" followed by the name of the food imitated. This is, of course, the section which the court held to be applicable to Demi imitation margarine. But the word "imitation" has become relatively meaningless. It can mean high fat or low fat, or it can mean vegetable fat or no fat, or it can mean high moisture, or low sodium, high sugar, no sugar, or any one of many different things which are important to the consumer, but which are really not at all described by a general term such as "imitation." As a matter of fact, this situation is so bad that the FDA has now proposed a standard for "imitation milk." The name of the food would be "imitation milk," which, of course, raises a very interesting prospect that sometime in the 1970's someone is probably going to come out with a product called "imitation imitation milk."

Another potential subject of legislation is further implementation of the Fair Packaging and Labeling Act, and that section of the act particularly which relates to standardization of package sizes. (Here again margarine is, of course, relatively safe because the present law is so restrictive.) The act itself directs the Secretary of Commerce to work with industry in a voluntary compliance program on package sizes primarily to eliminate odd sizes and "undue proliferation." The Secretary is directed, if industry does not cooperate properly or if industry does not reduce the number of package sizes, to report back to Congress so that Congress can presumably make further changes in the law to make certain that packages are more standardized.

Federal Administrative Regulations

Federal administrative regulation, particularly by the Food and Drug Administration, as distinguished from legislative regulation by Congress will also increase in the future. In some areas this is, of course, clearly charted. FDA has issued good manufacturing practice regulations—GMP's—for the food industry. Good manufacturing practices regulations for the drug industry have been in effect for several years, with separate paragraphs covering buildings, equipment, personnel, records, etc. The "umbrella" food GMP's are less detailed, but are substantially similar. The purpose is to tell industry what FDA expects in terms of housekeeping, sanitation, production control and related matters. The umbrella GMP's cover the entire food industry without relating to any specific type of food.

To implement the umbrella GMP's, FDA is now preparing

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specific GMP's relating to a particular industry, and is also publishing what are called PEV's, Plant Evaluation Systems, a set of questions given to the inspector which the inspector asks when he goes into the plant. This can be very helpful to industry because industry will be on notice as to what the inspector is going to look for, and it will be an excellent guideline for a company which may not have the facilities or the technology or the know how in a particular area. FDA has indicated that the GMP's and PEV's are not directly related to each other, but in any event the GMP's and the PEV's are going to be an important part of industry life in the next 10 years. While the legal basis and the legal effect of the food GMP's and the PEV's is somewhat questionable, the practical effect is clear: many firms will be spending a substantial amount of money over the next few years to make certain they are clearly in compliance.

More regulations in the form of standards of identity are probably also forthcoming. For example, a group of Wisconsin dairies is proposing to file a petition for a standard for butterine, a 40% butterfat-40% vegetable fat spread. Present standards may also be changed significantly. For example, standards like the french dressing, salad dressing and mayonnaise standards which do not presently require an ingredient clause may be amended to include this requirement. Any such amendment should be accompanied by an amendment using generic terms such as "any safe and suitable emulsifier" or "stabilizer" in the make procedure provision of the standard.

One thing which must be reconsidered is the FDA hearing procedure, which has recently broken down rather seriously. This is a matter of mutual concern to the government and industry. The mozzarella hearings—and mozzarella is a relatively simple product—lasted for three weeks. The first orange juice standards hearing took 3434 pages of record. And there has been another orange juice hearing since then. From the time the original proposal was filed on ice cream 20 years elapsed before the standard was finally promulgated. The peanut butter hearing was long and unfortunately rather acrimonious, and resulted in litigation, as did the orange juice hearing. In the dietary hearings, motions were filed, among other things, to disqualify the hearing examiner who was specifically appointed for this purpose, and to disqualify the Commissioner of the Food and Drug Administration from making the final decision. So this is an area in which administrative reform and possibly legislative reform are sorely needed.

State Legislation

State regulation is becoming more and more important, and here again attention should be given to regulation in terms of statutory regulation and administrative regulation.

State legislatures over the last few years—and this is certainly going to be a continuing trend—are trying to upgrade the job that they do. There is a general movement in the country to strengthen our states. And one of the aspects of this is going to be increased state food and drug legislation. For example, the Illinois Legislature has passed an amendment to the model food and drug act to provide for automatic adoption of federal regulations governing pesticides, food additives, color additives, dietary foods and, most importantly, food standards. Under the new Illinois law, if FDA promulgates a standard for a food, that standard becomes automatically effective in Illinois without publication and without notice. In order to assure constitutionality, however, anyone in Illinois is given the right to file a subsequent objection and request for a hearing which automatically stays the proceeding until that person has an opportunity to be heard and to present his views for such changes as may be necessary or desirable for Illinois.

This has an immense advantage because there are so many federal regulations and amendments to the regulations that state officials can't even begin to get them typed, let alone publish notices and hold hearings. It is a fantastic job to try to follow on a state level everything that FDA with its many more employees and all of its expertise is accomplishing on the federal level. Hopefully, this kind of automatic adoption will be of substantial benefit to consumers and to industry in Illinois, as well as to our enforcement officials.

There are, of course, some clouds on the horizon of uniformity between the states and the federal government. Some of the states are going off a little bit more on their own. California is perhaps the prime example of this. The California legislature has turned into almost a full time operation, a well-paid, well-staffed, well-equipped, fine legislative body. One result, however, is that California is getting a substantial amount of food and drug legislation, some of which isn't so fine in terms of uniformity.

State Administrative Regulations

Another development which can be expected over the next several years is increased state administrative regulation. One form which this will take is more cooperation between the federal officials and the states, an extension of the present program. It is possible that more and more enforcement duties, including inspections, will be turned over to the states by FDA.

There is also a trend toward more professionalism and competence on the state level. This will undoubtedly result in more administrative regulation as problems develop over the years.

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