The Food and Drug Laws as Viewed by Regulatory Agencies

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THIS SUBJECT is an intriguing one because of the uncontroverted fact that, at least in theory, our food and drug laws go hand-in-hand with technology. As new products, new processes, new uses for old products are developed, there comes the need for revision of our food and drug laws to deal with the problems created by those new products, processes, and other developments. In theory, we should have these new laws available so that we would have an up-dating as soon as needed. In fact, this is not always possible.

The original Federal Food and Drugs Act was, at the time of its enactment in 1906, a good law, a law that was needed and a law which, as it was enforced, accomplished much of value in the regulation of our food and drug supplies. As the years went on however, it became most apparent that it was sorely deficient in a number of respects. While a few amendments were made to try to up-date that law, it was not until 1938 that the new Food, Drug, and Cosmetic Act came into being. In addition to strengthening the provisions of the old law as it applied to food products and dealing with the problem of new drugs, the law, for the first time, encompassed cosmetic products. The law set about to deal with poisons in our food supply, set up a basis for establishing standards of identity, quality, and fill of food products, provided specific labelling directions and, as had been shown to be needed, established higher penalties for violations of its provisions. In the drug field, comparable improvements were made.

Perhaps some of the most widely hailed provisions of the new law were those dealing with the addition of poisonous and deleterious substances to our food supply. These provisions provided, in effect, that no poisonous or deleterious substance could be added to our food unless and until it could be shown that the added substance was necessary or unavoidable in the production of the food and that the Government had carefully considered all of the data about the substance and had established a safe legal tolerance for its presence.

Thus any food containing an added poisonous or deleterious substance for which no tolerance existed or which contained the substance in excess of the tolerance would be clearly adulterated and thus contraband in the eyes of the law.

ON ITS FACE, this would, in fact, appear to be a provision which was clearly and unequivocably beneficial to consumers generally, especially from the standpoint of health and well-being. Among the first items to be considered under this provision was the matter of the presence of pesticide chemical residues on raw agricultural commodities. In those days this involved principally arsenic, lead, and fluorine. There could be a showing that the chemicals were needed in the production of food and that certain residues were unavoidable. The problem however became more difficult in dealing with foods generally. While the Government was able without too great difficulty to deal with the addition of chemicals which could be readily classed as acute poisons, such as the monochloroacetic acid preservative in beer and some other drink items and thiourea as a preventive of the darkining of frozen peaches, what could be done about added substances, which were not themselves actually toxic when given in large amounts but for which there was no real information available as to the effect of small amounts of these substances in the diet over long periods of time?

Admittedly, reputable manufacturers would not introduce such new substances without seeing to it that they obtained the necessary pharmacological data of safety. Many of these discussed their proposals and data with the pharmacologists of the Food and Drug Administration before placing such products on the market. The law however did not require that this be done. Where a manufacturer elected to add a new substance to his food without first seeing to it that it had been adequately tested, the Food and Drug Administration had the burden of finding out about the addition, arranging for the necessary long-term pharmacological experiments which might take several years and then take action to remove the food from the market if the substance was found to be hazardous. The principal weakness of all this was that consumers would have been eating this food with the particular additive included during all the time it had taken the Government to ascertain the facts and to take steps to stop the practice.

Thus it was not long before we in the Food and Drug Administration recognized that those particular provisions of the law, fine as they seemed to be on paper, just were not working out to the end expected and that the consumer had need for much better protection.

In 1950 the House of Representatives appointed a group known at the Delaney committee to look into the whole question of chemicals in foods (and cosmetics as well). The testimony at these hearings pointed up the need for new methods of handling not only the additives in processed foods but, because of the great strides which had been made in technology in the pesticide chemical field, for new methods of dealing with that problem as well.

The first concrete result of this was the enactment of the Pesticide Chemicals Amendment to the law in 1954, which set up a sound basis for establishing safe legal tolerances founded on pharmacological, chemical, and experimental data plus a certification from the Department of Agriculture on whether the chemical was useful in agriculture and whether the use data had demonstrated that the residue tolerances requested could be met.

It is pertinent to point out that this law, while providing for the establishment of tolerances, included a section which authorizes the establishment of a tolerance of zero where the facts so warrant. So

far, we have established tolerances for more than 100 different chemicals covering more than 2,000 uses. In our opinion, the law is working out very well. It is, of course, our obligation to police the shipment of raw agricultural commodities to determine whether they do contain permitted residues within the legal limits.

THE NEXT result was the enactment of the Food Additives Amendment in 1958. That law classes as a food additive any substance which may reasonably be expected to become a part of a food or otherwise affect its characteristics that is not generally recognized as safe by experts qualified to evaluate the safety of food additives, is not covered by a prior sanction for a particular usage, or is not a pesticide chemical residue on a raw agricultural commodity.

This amendment serves to correct the situation which I mentioned earlier in that it places squarely upon the manufacturers and shippers of food the responsibility for being sure that each and every ingredient of their foods, whether added as such, formed in the manufacturing process, or made a part of the food through migration from machinery or packing material, is safe. If any such substance is not covered by one of the exemptions in the law, it is a food additive and may not be used unless and until an appropriate regulation has been issued making provision therefor under such conditions as may be necessary. This regulation is to be obtained in much the same way as is the pesticide chemical regulation in that the petitioner must submit full information about the product, what it is, how it is used, what effect it has, how much is needed to achieve that effect, and the pharmacology of the substance and methods for its detection. One of the items which has so far caused difficulty with a number of products is the lack of methodology.

Certainly the Food and Drug Administration cannot issue any regulation authorizing the addition of a limited amount of any food additive in a food if there is no good way by which it can be determined whether or not the limitation for it has been met.

This Food Additives Amendment served to bring into contact with the Food and Drug Administration many firms which heretofore had not previously considered that they had any obligation to deal with us. The amendment was scheduled to become fully effective on March 6, 1960, subject to extension not to exceed one year on individual items where it could be shown that the extension was necessary and would present no undue hazard to the public health during that additional period. So far, we have extended the effective date of the law for well over 800 different items and classes of items, used either as direct additives or in packaging materials or manufacturing equipment.

It cannot be emphasized too strongly that all of these exemptions will expire on March 6, 1961, and the law does not contain any provisions for further extensions. It is, of course, conceivable that at least some of the packaging items on the extension list will be found not to migrate to the food in which case, of course, there would be no food additive problem.

Where there is such migration however and the migratory substance is not generally recognized as safe, there is the need for the establishment of an appropriate authorizing regulation. We know that much work is being conducted to ascertain the facts. We urge everyone concerned to get to us in good season petitions for any regulations which may be needed so that these can be issued in advance of the March 6, 1961 deadline.

IN THE FIELD of fats and oils perhaps the greatest concern under the Food Additives Amendment arises in the case of such items as stearic and oleic acids. Last January at a meeting of the Fatty Acids Producers Council in New York, I discussed at some length our data and our views on these items in the light of the provisions of the Food Additives Amendment. Since then we have extended the effective date of the Food Additives Amendment for both stearic and oleic acids used in food manufacture where those products have been made from edible fats and oils and there is freedom from the chick edema factor. Some of you may know that the use of the word "edible" in that extension notice has been the subject of concern by some groups. Perhaps we could have used a better word although I do not know at the moment what that might be. In this context we are using the work "edible" to make plain what is not regarded as a suitable fat or oil for this purpose. First, this rules out fats from animals which have died by other means than slaughter or which were diseased. This, of course, merely points up one provision of the basic Food, Drug, and Cosmetic Act which classes as adulterated any food which is "in whole or in part the product of a diseased animal or of an animal which has died otherwise than by slaughter."

Then also ruled out are filthy materials. It is intended that fats and oils used to produce food ingredients will be prepared and handled with that purpose in mind.

We are given to understand that industry is actively engaged in the development of data that will permit the preparation of appropriate petitions for regulations for oleic and stearic acids. We are looking forward to the receipt of such petitions.

Two other developments took place on July 12, 1960, when the president signed the Color Additives Amendment to the Food, Drug, and Cosmetic Act and the Hazardous Substances Labeling Act.

Until that date, coal-tar colors were specifically regulated under one section of the act calling for certification of such colors where it could be shown that they were harmless. Other colors in or on foods were to be dealt with from the standpoint of safety under the Food Additives Amendment. The old coal-tar color provisions did not provide authority for limiting the amount of the color, and when some of the colors formerly thought to be suitable for food use were tested, using modern-day pharmacological techniques, and shown not to be "harmless," it was necessary to remove these from the list of colors eligible for certification for food use.

It was of interest to note that these investigations followed incidents where too much color was used in some products, resulting in the illness of many children. Similar action was taken in the case of colors for drugs and cosmetics where they could no longer be regarded as harmless.

The new amendment deals with all colors whether or not coal-tar, provides for batch certification where necessary, and also authorizes tolerances, should these be needed to insure the safe use of a color.

During its consideration by the Congress the Color Additives Bill was quite a controversial subject because it included the so-called Delaney Clause, which is essentially carried over from the Food Additives Amendment. In the case of the Food Additives Amendment, the Delaney Clause prohibits the establishment of any regulation for an additive which has been shown to induce cancer upon ingestion by man or animal or to induce cancer by other tests appropriate for the evaluation of food additives. The color bill carries a comparable provision taking into account, of course, that the tests will be appropriate for the proposed use of the particular color.

THE Hazardous Substances Labeling Act is not an amendment to the Food, Drug, and Cosmetic Act, but again we have a law which will touch the operations of a large number of firms and individuals which have not previously had contact with the Food and Drug Administration. That law, as its name implies, is designed to require that hazardous substances in certain defined categories as set forth in the statute will need to bear certain types of labelling to protect users. While this bill was before the Congress, there was presented ample evidence of the need for this law to replace the obsolete Federal Caustic Poison Act which, as many of you know, covered only a very limited number of caustic and corrosive items. The hazardous substances law became effective upon signature of the president but provides that there shall be no legal action to enforce it during the first six months. An extension provision is included along the lines authorized in the Food Additives Amendment for up to 18 months from date of signature where justification for such extension can be demonstrated.

In our enforcement operations it became clearly apparent many years ago that in preparing or packing drug products, compliance with the terms of the law could be assured only where a firm operated with a well designed and operated control system, including a properly equipped and staffed laboratory to examine products from the raw material to the finished article stage. As new, more complicated, drug products came on the market, the fact that such a control operation was essential became more and more apparent. In recent years the preparing and packaging of food products has become increasingly complex what with new uses, new processes, and new types of so-called convenience foods. We in the Food and Drug Administration are convinced that, to continue to prepare and market food products, proper factory and laboratory control of the entire operation is also becoming an essential part of the conduct of a food manufacturing plant.

Commissioner George P. Larrick has publicly urged all food manufacturers to take a most careful inventory of their own operations to determine whether or not their control operations are, in fact, sufficient to insure that the products they put out will be clean, sound, and wholesome.

Problems Posed to the Food Industry by the Food Additives Amendment of 1958

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BY NOW, most if not all persons who are actively engaged in any phase of the manufacture, sale, or distribution of foods are aware of the Food Additives Amendment of 1958, which amends the Federal Food, Drug, and Cosmetic Law. Literally reams of material have been written about this law and more words have been spoken on or about the subject than on all other food legislation in the last ten years. Nevertheless an appraisal of the effect of the law in action may have some value.

Many persons in the food industry have at times taken a rather defeatist attitude as to what effect the new act and its administration would have on industry. With the benefit of some hindsight, perhaps we can determine if the worst has occurred or will occur.

It would be well to bring the subject into focus. First, what is a food additive? Shorn of lawyers' language, a food additive is any chemical that either by intention or merely by inadvertence has found its way into and affects the characteristics of a food, and is not exempted from the clearance provisions of the act for one reason or another. The list of intentional additives is vast, including many natural or synthetic substances which are used to encourage efficient manufacturing processes, to make foods more nutritious, taste better, or appear more appealing, or to extend shelf life. Incidental additives are those substances used in the production of the raw materials from which foods are made, in processing operations, or in food packaging supplies, and which migrate into food.

A partial list of food additives includes the following broad categories of items:

Anti-foaming agents	Leavening
Anti-hardening agents	Neutralizers
Anti-mycotics	Nutrients
Anti-oxidants	Peeling agents
Anti-spattering agents	Pesticides
Anti-sticking agents	Plasticizers
Bleaches	Preservatives
Buffers	Propellants
Chill-proofing agents	Sequestrants
Container liners	Stabilizers
Firming agents	Sweeteners
Foaming agents	Thickeners
Glazes	Whipping aids
Humectants	Waterproofers

You will readily observe that this list could be expanded many times.