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.

Next we must recognize three basic facts of existence under the new law.

1. We cannot go back from technological advances even if we were foolish enough to want to do so, so as to relieve ourselves of governmental controls. Without food additives we could not produce, distribute, and sell the vast array of delicious foods so much in demand today. All the convenience foods would disappear from the grocery shelves almost overnight. This would include the frozen foods, concentrated foods, dry mixes, brown-and-serve bakery items, and numerous other foodstuffs.
2. The Food Additives Amendment of 1958 is the law and we cannot make it go away by ignoring it.
3. Administrative procedures are necessary for the orderly administration of any law and we must learn to adjust to reasonable controls.

What then is the responsibility of a food manufacturer for conducting an operation within the ambit of the law? Of paramount importance is an initial survey of one's current operations to see if his company is conducting its activities within the terms of the act. Each company must, and I emphasize *must,* have one central source of determination regarding policy on food additives. This is imperative in order that the company may have uniform interpretation, uniform purchasing policies, and uniform labels. In short, if any question regarding the law should arise, the policy must be uniform to avoid complete confusion, and to insure full compliance. It almost goes without saying that such policy determination must be put in the hands of one who is competent to know the law, or to draw on sources that do know the law, and who is also thoroughly cognizant of all the ramifications of the business involved.

Next, a continuing effort needs to be made to determine from all available sources whether or not all the ingredients of each of the foodstuffs produced and of the packaging materials used are suitable for such use within the meaning of the act. No one can rely solely on the guaranty received from his supplier as being sufficient. Thus, to the extent that you know the actual composition of any of the ingredients or packaging materials used, you can check such items against the various lists published by the F.D.A. in the Federal Register. To the extent an ingredient is unknown, an inquiry must be directed to the supplier to ascertain if he has knowledge which establishes the status of such ingredient. If there is any uncertainty, either in your own mind or that of the supplier with regard to the information available to the supplier, it is necessary that you communicate with the F.D.A. in writing and they will clear up the matter in due course. Incidentally, discretion is needed with respect to "clearing" items with the F.D.A., for if the F.D.A. has to act as a clearing house on all items a situation will arise which is administratively impracticable. In any event, all supplies need be checked for safe status and any which are not cleared for safety should be removed from use and a substitute sought pending action taken to clear the substance.

Having established the status of all the ingredients and the packaging materials used, the company should devise a system to disseminate the information thus obtained to all interested divisions. It is essential that all divisions, research, engineering, purchasing, operations, and sales, know what can be used and why. Only with such knowledge available can they be expected to operate within the law. Certainly, it is fruitless to attempt to conduct a research program with reference to products which almost certainly cannot be used in foodstuffs. Obviously one's sales force ought to know that the products which it handles meet all the requirements of the law in order to be able to answer the many questions which their customers are going to make. Indeed, it almost goes without saying that a purchasing department must be particularly alert to the pitfalls of the act.

While we may expect that our suppliers will label their products correctly, it is only a matter of ordinary prudence to expect the suppliers to answer a few simple inquiries. Is the ingredient in question on a safe list, on an extension list, on a prior sanctioned list, or has an application for exemption been favorably acted upon? What designation must we, as a user, put on our labels to indicate the presence of the particular ingredient? Have any levels been set limiting the use of a particular ingredient?

No attempt need or should be made to delve into trade secrets or patent rights. In fact, the supplier should be encouraged to clear his product with the F.D.A. directly, although we must all cooperate by advising the supplier or the F.D.A., as the case may be, as to the prospective use of any questioned item.

Conversely each of us ought to be willing to establish or help to establish the suitability for use of our product in food. To this end, full cooperation must be given our customers or the F.D.A., as the case may be. We would not want our customers to inadvertently violate the act so every effort must be made to help them comply with the act. This of course means giving full disclosure of all information available to us regarding satisfaction of the legal requirements with reference either to an ingredient of a foodstuff or a packaging supply which we are selling.

The same careful survey must be made with reference to any new item which is to be incorporated in food or food packaging materials. If the material is purchased, then the supplier must establish the safety of such ingredient for its intended use. When the company's own research department develops a new ingredient or new product, its safe status has to be cleared before the item can be put to use or sold.

If the new item is added during processing but is removed by such processing so that no residue remains within the food, no food additives problem exists. If the item becomes part of a packaging material and becomes bound in so that it does not migrate into an enclosed foodstuff, no food additives problem exists. Here then is step No. 1. An exact determination must be made as to whether or not there is a residue of any new ingredient used in food or food packaging material. It is almost unnecessary to observe that migration studies are extremely difficult because there is a lack of precision in determining amounts of the migrating substance.

Let us assume for the moment that a residue of the ingredient is found in the food either as a result of migration tests or because the item was deliberately added to the foodstuff. The next step, then, is a toxicity study. First a careful survey should be made

of the literature. It may be that a study has been made in connection with other work which will throw real light in this area. A realistic appraisal should be made to determine whether there is reason to support toxicity based on such literature search. If toxicity is suspected, an informal discussion with F.D.A. should be held to ascertain if the material must be tested. If testing is indicated it can best be done on unknown items by use of a 90-day rat feeding test as a screening device. If this test reveals no evidence of toxicity, it may be that no further work will be required. If evidence of abnormality in the rats develops during the test, then further and more expensive testing will have to be done. Before making the more expensive testing which will take some two to four years, it will be necessary for the company to determine whether the item or process in question will yield a profit ratio sufficient to justify the expense of the test and the delay in marketing. Please observe that the 90-day screening test does not guarantee against a toxicity problem. It will reveal the existence of the more acute cases so that one can more easily determine the desirability of pursuing such case study further. Let it be assumed that the accumulated toxicity data appear satisfactory. At that point it would be wise to write to the F.D.A., setting forth all available information. It may be that the aggregate of the information in the F.D.A.'s files will justify clearance without further ado. If so, you will be advised. However the probabilities are that eventually a formal petition must be filed. Anticipating this eventuality, it would be wise to advise the F.D.A. of the additive's chemical identity and composition, the intended conditions of use, information on the effect the additive is supposed to produce and the quantity required, a description of a practical method for determining the quantity and the procedures which will be used to conduct the tests for safety. If the F.D.A. feels that such data are adequate, they will so advise. If not, they will suggest a procedure or protocol that meets their needs. After the work has been completed, a formal petition following the suggested format in Regulation 121.51 must then be submitted for a ruling.

You will observe that thus far no reference has been made to studies regarding the subject matter of carcinogens. Fundamentally, the same procedure is applicable to a determination of the question of carcinogenicity as is true of toxicity. It is apparent that it is easier to oversimplify these problems than it is to give a full and complete discussion of each and every step to be taken to resolve the problem. However time limitations on this discussion forestall any such effort.

Certainly it will readily be observed that the requirements of the Food Additives Amendment of 1958 will substantially change the nature of food research. Now the question of whether the new item or process will work to yield a profit is not enough. The item must be both profitable and safe. If the latter is in question, then to establish safety may be so expensive as to discourage any thought of profit. In such event, low volume food additives may fall by the wayside; their suitability or desirability yielding to the element of research cost.

By this time many of you may wonder if compliance is all burden and no benefit. While there are some negative effects incident to compliance with the act, the act itself has a very high yield of good and beneficial results.

Let us quickly acknowledge the burdens.

It is true that research will become more time consuming and costly. There also may be a tendency to avoid completely whole areas of study on the premise that no matter what information is developed, the item or process may not be used. For example, evidence would suggest that the F.D.A. appears to feel it is fairly well established that estrogenic substances are or may be carcinogenic and that the act expressly prohibits any tolerance level for carcinogens; therefore it would be unrealistic to study estrogens as possible food additives. In a very real sense, the Delaney Clause in the Food Additives Amendment of 1958 is a self-defeating proposition. Only by experimenting and testing will science ever determine definitely whether or not there are threshold levels for carcinogens. If, as indicated, no use may be made of test information because no tolerance may be set under the law, few tests will ever be made. Obviously the lack of an accumulation of information in this field will slow down the determination of whether or not threshold levels can be determined. For this reason the report and recommendations of Dr. Kiskiatowsky's Panel on Food Additives needs unanimous support.

There may also be a tendency to circumscribe research into new areas because of the possible expense involved in toxicity testing or the long delay before bringing new products onto the market. There may also be increasing dependence on governmental recommendations as to areas of further endeavor.

On the other hand, there are indeed some real plus values to be derived from the new law.

Your company will, in fact, know that the foods which it sells are safe for human consumption. All guesswork will be eliminated. Prior to the enactment of the new law, a consumer complaint alleging illness could and often did mean rather extensive laboratory testing after the fact to obtain sufficient information for evidence to defend the company position. Surely much of this will become unnecessary. Furthermore it is a historical fact that the safety for use of a particular substance was not always definitively known prior to the enactment of this law. Therefore the affirmative knowledge that your product is safe when it leaves your custody and control is a truly plus value. This will no longer be an assumption; it will be a fact. While consumer complaints will continue to exist, the elimination of even a few may well justify some of the more necessary research expense created by the new law.

Companies will begin a more realistic evaluation of their research programs. No longer will large sums of money be spent on gimmicks and gadgets. Real merit and value must be seen in a project or it will be abandoned in the face of the cost incident to toxicity testing. Perhaps the new law may circumvent "pure research" in new fields. It is too early to come to any conclusion on this subject. It is more certain, however, that it will require a realistic appraisal of product and process research, all of which may be quite beneficial in the long run.

The act has a very real and almost hidden benefit only just being realized. A company can learn of markets it did not know existed. For example, I

know of a company which has been selling an industrial chemical for years for a very specialized use. Subsequent to the Food Additives Amendment, it received an inquiry from one of its customers as to the suitability for use of this chemical in the manufacture of food packaging materials. Here was a sales area not known to exist. Fortunately, adequate data were in the files of the manufacturer-supplier which supported the suitability for use of this chemical in food packaging material. Needless to say, the sales force has now instituted an aggressive campaign in the area of food packaging materials. We at Armour and Company are reappraising our many sales areas to determine whether a number of the chemicals which we produce are suitable for use in foodstuffs. We trust that this new unexpected market will assist us materially.

Of additional real value will be the increased consumer confidence in our food products. I personally have never had an opportunity to see so much distortion of fact, or lack of fact, accumulated in one place as is to be found in Mr. Longgood's book "Poisons in Your Food." As a journalist, he deserves the Pulitzer Prize for fiction. Nevertheless the misguided and misinformed have been hashing and rehashing the substance found in his book in various forms and at various forums for years. It is to be hoped that the public will cease being deluded and will develop the same confidence in all foodstuffs that they have had in U. S. inspected meats. Such confidence can have incalculable value to the food manufacturer.

THUS FAR, the discussion of industry's responsibility under the new law has been in terms of compliance. There is another large and very real area of responsibility, namely the response to administration of the act by the F.D.A. We hear so much about how the government doesn't give realistic consideration to the problems of business, how business is hampered by a disregard for its needs, etc., etc. Frankly, respect for ideas and actions must be earned and it must be mutual. To this end, we in the food industry must extend to the Food and Drug Administration every help, provide complete and truthful data, and deal with the representatives of the F.D.A. just as we would with our own good customers.

Cooperation must be extended in all areas. Nothing clears the air like truth. Nothing speeds work to conclusion like cooperation. We have a right to urge the validity of our thinking, our data, our protocols, our procedures, our conclusions. However we must learn that mutual cooperation may mean some deviation from our previously conceived plans. An attempt to understand and to solicit explanations for any changes requested by F.D.A. can only be beneficial. After all, it just may be that they are right.

We must all reflect on how long it takes each of us to answer a question. If we have all the facts available there still may be a long delay while the matter is considered through channels in most companies. If we don't have all the facts available, there will be a long delay while various personnel are scurrying to obtain sufficient data on which to base an answer. Furthermore size alone is often justification for some delay. With this in mind, we may reasonably expect anything but an immediate answer from F.D.A. and should plan accordingly. One must understand that F.D.A. is an extremely large organization and it may be seeing, for the first time, data with which you have been well acquainted for many years. And of course your inquiry is only one of literally scores of inquiries which are before the F.D.A. Responsibility under the act does contemplate some patience.

On the other hand, while we in the food industry must provide information, respect, cooperation, and patience, we in turn may expect some reasonable degree of reciprocity from the F.D.A. The completeness of information supplied may be the subject of a question. The integrity of the conclusions reached by our scientists should not be a matter of debate. We should expect that the administration of the act will be based on a scientific approach and not something dictated by political expediency or favoritism. To insure that this is the case, no special privilege should be solicited directly or indirectly.

While it is true that we must wait patiently for an answer, we would have a right to a reasonably prompt response to any responsible inquiry.

It could well be observed that the act needs some slight amendment in order to make it a more workable instrument for both industry and the F.D.A. I find it extremely difficult to understand opposition to amending the Delaney clause. It would seem to me that the Food and Drug Administration has a right to the exercise of scientific discretion with reference to cancer just as it must exercise scientific discretion with reference to any of the other causes of illness to man or animal. On the other hand, it is equally difficult to recommend numerous changes in the act until we have given the act a reasonable opportunity to work. This requires some time, some patience, and some cooperation on the part of all.

In short, let's give the act an opportunity to work. Let's see first whether people are going to be harmed before we claim they are without substance to our claim. For if we find the act unworkable, it would seem that the cooperation of both the F.D.A. and industry would be forthcoming to obtain a more workable food law. Certainly, everybody is extremely interested in producing good, nutritious, safe, wholesome foods for sale and distribution.

Let us now consider whether the worst has happened. The evidence seems to be that it has not. It is true that some people have experienced the need to make an additional effort, expended more money, and experienced some delay in clearing their products. On the other hand, many hundreds of items are cleared, many more are allowed to be used temporarily, and work is progressing on all fronts. It would appear that relatively few items have been forced off the market. We have reason to believe not only that the worst has not happened but also that it may never occur.