with reduction or less commonly reduction alone. These organisms were not identified.

No Salmonella or Shigella were recovered from any sample.

The conclusions of this preliminary report are that: (a) the products are contaminated during fabrication by hand, and (b) growth of the initial contaminants takes place at least in the salad type sandwiches as a result of being held at ambient air temperatures (23°-30°C) for 17-20 hours (which may be extended up to 30 hours for late afternoon sales) prior to sale.

The initial contamination level has not been determined, although it is believed to be no higher and probably considerably lower than the counts from the "dry" sandwiches. This growth is strong evidence for the potential danger of food poisoning from the "wet" or salad type sandwiches. Care should be taken not to assume that the "dry" type sandwiches are free from danger. The potential danger of this type sandwich is not so clear and more work must be done to ascertain their potential; however, it is assumed to be much less than the "wet" type. There seems to be no reason why sandwiches from other producers, made from similar materials and under similar conditions of fabricating and holding, should not show similar patterns of growth. However, this requires more thorough study before a definite assertion can be made.

The foregoing would indicate that a great deal has yet to be done to improve the sanitary quality of commercially prepared, wrapped sandwiches as received by the consumer. This probably should be centered around control of bacterial growth in the product.

REFERENCES


THE EFFECT OF THE FOOD ADDITIVES AMENDMENT ON FOOD PROCESSORS AND OTHERS

BY FRANKLIN M. DEPEW

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In order to evaluate the tremendous impact of the Food Additives Amendment on the regulated industries as well as on the Food and Drug Administration, I sketch a brief history of the events leading to its enactment. This history shows the law to be part of a creative evolution whereby government and industry are continuously working together to better protect the public health.

Some years ago the Congress became concerned about the increased use of chemicals in the manufacture of food and the increased development of pesticide chemicals which might leave residues in food. The great technological advance since the War made available an infinite variety of new substances for preserving and improving food. The food industry had spent millions in improving the handling of raw materials and in food processes to produce cleaner and safer foods. They had also spent millions in testing new substances used in food but questions were raised as to whether these tests were adequate. Investigations of these new substances were commenced by the House Delaney Committee which held public hearings in 1950-52. Subsequently the House Commerce Subcommittee on Health and Science held hearings during 1955-58 and unanimously recommended that a law be passed requiring that food additives be pretested in a manner analogous to that required for new drugs.

This recommendation was made even though there was no evidence to show that any responsible food processor was using a harmful substance. There was a general conviction that despite this the public was in need of protection against small, irresponsible ele-
ments, as well as against the possible inadvertent mistakes of reputable food processors.

The recommendation for pretesting was supported by the food industry generally. The industry concluded that it was essential to resolve all doubts in favor of protecting the integrity of food products. Thus in deference to the national welfare, the members of the industry voluntarily recommended the relinquishment of some of their individual rights. By doing so they gave up the privilege that had been exercised by manufacturers through recorded history—the right solely to determine the safety of the food they manufactured in the manner it had been determined in the past, i.e., by relying on the exercise of discretion and scientific judgment of their experts that it did not contain a poisonous or deleterious substance.

Prior to the enactment of the Amendment such a poisonous or deleterious substance might properly have been called a food additive within the meaning of the then existing law. That law prohibited the food processor from using any poisonous or deleterious substance (i.e. a food additive) except that if the substance was required in the production of a food or could not be avoided in good manufacturing practice, its quantity was not to exceed the limits of an administrative safety tolerance for it. During some twenty years no food additive was found to meet this exception in the law. As a result where there was any question as to whether or not a new substance was poisonous or deleterious the food processor usually reviewed his expert's conclusions with the Food and Drug Administration (FDA). Thus, these technological advances since the War had created a situation where the food processor, as a practical proposition, frequently felt he should not rely entirely on his own experts. Accordingly, with respect to such practices the Amendment has but legally required the substantial equivalent of that which was theretofore done voluntarily.

I believe that most of the food processors will agree that up to the present time the Amendment has not greatly changed their operations, so far as they relate to ingredients and processing substances, because it has only made mandatory what was previously done voluntarily. The situation, however, has been different with respect to packaging items. Food processors have had to explore more carefully the substances used in packaging materials and thus they have brought to these suppliers a fuller realization of the law's requirements. I said "up to the present time" because the status of certain substances used in small amounts, such as many flavoring ingredients, is still unresolved. These substances are used in such small amounts they were not considered toxicological-

ly significant in the past. The cost of testing each of these substances seems to be out of all proportion to the price at which the substance can be sold. The solution of the problem has been postponed by the granting of extensions for most of these substances until next year. It has been suggested that the Amendment has presented FDA and industry with an insuperable problem in regard to these substances in that the requirements of the law may have outstripped our fundamental knowledge of toxicity. I do not believe that this will be the case. Much imagination and resourceful thinking may be necessary to solve the problem but I feel confident a satisfactory solution will be reached.

As it has turned out, not only must the members of the food industry conform to the provisions of the Amendment but the members of many other industries as well. It is doubtful that many of these other industries comprehended the manner in which the law would be applied to them. It is even doubtful that a portion of the food industry realized that the law would apply to those many substances present in foods in such small amounts they had been considered to be inconsequential from the standpoint of health hazard.

The definition of the term "food additive" necessarily had to be broad in order to accomplish the desired purpose. It is so broad that it is now recognized that a company supplying processing materials, handling equipment or packaging material—indeed, almost anything—may be supplying a substance that constitutes a food additive. This is so because of the possibility that some portion of any substance coming in contact with food may migrate to the food. If that substance or any substance resulting from the interaction is not generally recognized as safe, then both would constitute a food additive.

It seems obvious that it is mathematically possible for many millions of chemical reactions to occur almost daily as a result of the numerous contacts of various substances with food from the time the seed is planted until it reaches the consumer's table. In the past little consideration has been given to many of these possible reactions in the absence of any scientific warning that they constituted an imminent or even a potential danger to health. The new law has changed all this for it poses a basic problem to the food processor and his suppliers—that of determining whether these multitudinous substances, many of which present serious practical difficulties of analysis, are generally recognized by qualified experts as safe for their intended use.

The food and related industries have the primary responsibility of resolving this problem under the law. In order to answer the problem intelligently it seems
clear that all ingredients of all the processing and other materials must be disclosed to someone who is able properly to evaluate them and to determine whether the finished food does, or does not, contain or constitute an additive within the meaning of the law. At the outset this has presented the food processor with a vexing dilemma since the formulas for many of these items are regarded as industrial secrets of great value, which the proprietors are loath to reveal. So far as the exercise of this responsibility by the food processor is concerned, it is clearly essential that he be permitted a reasonable discretion in relying on the representations and guaranties made by his suppliers relative to the ingredients in the materials purchased even though a guaranty may not fully excuse him from liability. Once the food processor has collected this data, and has determined what all these materials are, it is still most difficult for him to find qualified experts who can evaluate the information.

It is most important to recognize however that the responsibility to solve this problem rests on management. In this connection it behooves the newly regulated industries, including the food industry, to reflect on the stern admonition of the case of United States v. Dotterweich, 329 U. S. 277 (1943). This far-reaching decision, rendered only five years after the enactment of the Federal Food, Drug and Cosmetic Act, emphasizes that the remedial purposes of the Act require that it be liberally construed. The case involved a Government prosecution against a drug jobber and its president and general manager. It charged that the corporation purchased certain drugs, repacked and labeled them in an adulterated and misbranded condition, and so shipped them in interstate commerce. The corporation was acquitted on technical grounds but the company officer was convicted. In the course of its opinion the Court said:

"The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirements for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. United States v. Balint, 258 U. S. 250. And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded (or adulterated), and that the article may be misbranded (or adulterated) without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares..." United States v. Johnson, 221 U. S. 488, 497-98."

These words of the court warn of the extent to which management is held responsible for violations of the Federal Food, Drug and Cosmetic Act. They merit most careful consideration at this time because of the new and difficult duties imposed on management by the Food Additives Amendment and the Color Additive Amendments.

The following further quotation from the Dotterweich decision gains increased significance in the light of these amendments:

"The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should influence construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

The Dotterweich decision is a precedent for the belief that the management of a corporation, as well as the corporation itself, which causes or allows a food additive to become a part of food are responsible for the adulteration of the food, even though they may have no personal knowledge of guilt. The law thus places great responsibility on management.

It has been said that even the most perfectly planned democratic institutions are no better than the people whose instruments they are. We see from the history of the Food Additives Amendment that it was framed in a democratic manner to further the public welfare. But the many unexpected problems created by its enactment leave some doubt about the perfection of its legislative planning from the viewpoint of the many hazards involved in determining compliance. It is clear, however, that the language relative to "generally recognized as safe" expresses the philosophy that the amendment was not intended to make the law one of governmental permissive control. The success or failure of this new law will depend to a great extent on the measures taken to implement it by the officials responsible for its enforcement and by the management of the regulated industries. The FDA has responded admirably to the problems created by this enactment. Its regulations and interpretations demonstrate a helpful recognition of the difficulties which confront industry. Its "white lists" have been a major contribution in aiding industry to solve many of these problems. We believe this is what could be expected from this expert professional agency with its long record of distinguished administrative success.

However, the purpose of the Amendment will not be achieved in time to come unless government and the regulated industries continue to use this same
high degree of statesmanship in determining how compliance with its provisions can best be accomplished. We firmly believe that the regulator and the regulated have recognized that this is the case and thus we conclude that the basic impact of the Amendment has been to bring about a realization that it is necessary for all concerned to exert every effort toward making the Amendment function in such a way that these multitudinous problems will be solved justly, fairly and effectively, and with a minimum of conflict. We believe the law is largely and best self-enforced by industry on a voluntary basis and that every effort should be made to promote voluntary industry compliance through educational means before more drastic enforcement action is taken. The problems are so intricate and perplexing for scientists, as well as for lawyers, that they must be approached in a spirit of cooperation. If a dispute arises as to whether a substance is generally regarded as safe it should only be carried to the courts with a sound appreciation by both sides of the issues involved. If the issue reaches the courts it should then be determined impartially in accordance with our long established history of fairness and justice. We believe we can look forward to the continued prudent exercise of responsibility and power which is so needed to make the law bring forth those ends which the Congress intended. We have faith that the result will be in accord with the creative evolution which brought about the enactment.

In this connection it should not be forgotten that a major contribution in the past to the successful enforcement of the Federal Food, Drug and Cosmetic Act has been the FDA’s program of education and cooperation. The program has included FDA’s “open door policy” whereby voluntary industry compliance has been promoted by exchange of ideas about the interpretation of various provisions of the law. This program has been highly praised by all concerned with the problems of enforcement.

The FDA has deliberately adapted this tested policy to furthering compliance with the Food Additives Amendment. Not only has FDA cooperated with The Food Law Institute in holding national FDA-FLI conferences on this subject but it has also expanded its “open door policy” to invite full and free discussion with its experts and other key personnel. These meetings have clearly demonstrated that a full explanation of all the facts relating to a problem, if presented in a spirit of cooperation, almost inevitably produce a satisfactory solution.

We of FLI commend the FDA for this policy as the democratic way in which to develop respect for and compliance with any law. Such cooperation is in complete accord with the philosophy of our free institutions and it should continue to have the full support of government and industry alike. One of the basic reasons why The Food Law Institute was created was to develop the needed knowledge about this and other aspects of the food and related laws by research studies, by university education and by other educational means. The FLI program of education will continue to be a bulwark of support for this method of law enforcement. We believe it is a privilege to participate in furthering this creative evolution by working together in this manner.

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