The Pure Food and Drug Law as it Applies to the Oil and Fat Industry[1]

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THE PUBLIC generally, as well as a large part of our scientific community, has only a vague understanding of the pure food laws, their mode of operation, and their limitations. A clearer understanding of the responsibilities placed on industry and government alike under our present laws is necessary if the American consumer is to continue to profit by scientific endeavor.

Supreme Court Justice Frankfurter stated in a decision involving the 1938 Food and Drug Act that "the Foods and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated foods and drugs out of the channels of commerce. By the Act of 1938 Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of peoples which, in the circumstances of modern industrialism, are largely beyond self-protection." Justice Frankfurter's statement was made in 1943. Tremendous advances have been made in food technology since that time, with the opportunity for self-protection steadily decreasing.

First, some of the ground rules of Federal food and drug law enforcement may be of interest. The Food and Drug Administration is charged with enforcement of the F. D. and C. Act and as such is a law-enforcement agency. The Food and Drug Administration does not have authority to padlock a violative plant or to arrest an individual. It is neither judge nor jury, but rather plaintiff representing the consumer. Regulatory actions are brought to the Federal Courts through the Department of Justice.

Briefly the sole objective of the law is to insure the consumer of wholesome, unadulterated, and truthfully labelled foods, drugs, and cosmetics. The law is written in general terms and as such is equally applicable to all products. Few foods or classes of products are singled out for special attention.

The Federal Food, Drug, and Cosmetic Act was passed in 1938, and several important amendments have been made to the law during the intervening 22 years. Generally these amendments have not changed the basic provisions of the Act. Some of the amendments clarified the meaning of the law while others have provided for procedural changes. The basic premise that the consumer is entitled to unadulterated, wholesome, and truthfully labelled foods, drugs, and cosmetics remains unchanged. These amendments have been made to provide additional protection.

THERE ARE three major fields of consumer protection. In order of importance they are health, sanitation, and economic and will be discussed in reverse order.

Economic violations include such cheats as short weight or short volume, substitution of a cheap ingredient in whole or in part for a more expensive one, such as the addition of water to shucked oysters, or the adulteration of olive oil with teaseed oil. The list is endless, but this problem which antedates Christianity needs little comment. In passing we note that the penalties invoked by our less civilized ancestors were of a more severe and lasting nature than the temporary embarrassment and financial penalty imposed by our modern laws. The loss of an ear or a right hand was a permanent reminder of the serious nature of the offense.

In the matter of sanitation the crude vegetable oil industry was given little attention for a number of years. An investigation into these plants some 10–15 years ago revealed a shocking lack of application of the most elementary principles of sanitation in the production of a staple food item. It was almost unbelievable that such primitive conditions could exist in this country. No one will knowingly eat food containing insects, or food which has been defiled by rodents or subjected to pollution by human excrements. All of these conditions were commonly found to some degree in the crude oil industry of 10–15 years ago. It is gratifying to report that this condition now exists only as an exception to the general rule. A moment's reflection on the difference between clean food and laundered food is suggested to those who point out that the vegetable oil is refined and undergoes considerable processing. The industry has cleaned house effectively and comparatively rapidly. This program was carried out in an atmosphere of mutual respect and understanding by industry and government. There were relatively few court actions. This attitude will continue to benefit the consumer and industry in considering food additives and pesticide residues.

THE MOST important aspect of food law control is public health. Section 402(a)(1) of the Food and Drug Act passed in 1938 states: "a food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health . . ." Section 402(a)(2) in similar language deals with added poisonous or deleterious substances for which tolerances may be established.

Basically this second section provides exceptions under certain specified conditions from the original prohibition of poisonous and deleterious substances. The rules for the tolerances are stated in other sections of the law, Sections 408 and 409. The pesticide amendment and the food additive amendment are a part of Section 402(a)(2).

There is one additional legislative matter to be brought to your attention, the Delaney clause which deals with cancer-producing substances. Essentially, this clause prohibits establishing a tolerance for additives which have been found to produce cancer when ingested by man or animal.

The question may well be asked, why was it necessary to amend the law if provisions for tolerances were already authorized? For one thing, under the 1938 law, chemicals could be added to foods without any advance testing to establish the safety now required under the food additive amendment, and for another the amendment permits the use of new additives at safe levels to advance food technology whereas the 1938 Act had banned deleterious ingredients in any amount unless they were required or could not be avoided in good manufacturing practices.

In the case of food additives these procedures really are not new to many in the food industry. Many representatives of the industry have been bringing problems of this nature to the Food and Drug Administration and taking steps to be sure that the substance being considered was safe. Those who took these precautions are in a most enviable position because they have prior sanctions for the substances cleared in the past.

Although the food additives amendment does not fundamentally change the concept of complete safety of foods, the amendment places the responsibility and burden of proof on the shoulders of the person who desires to use the substance. This responsibility extends to the development of practical analytical methods for determining the quantity of the substance in the food and includes any substances formed in the food as a result of its use.

THERE ARE some substances so generally recognized as safe that they are not subject to the procedures of the amendment. Sugar, cottonseed oil, salt, citric acid, and the like are examples of substances widely used and known

[1] Presented at 51st annual meeting, American Oil Chemists' Society, at Dallas, Tex., April 5, 1960.

DALLAS WORKERS—Not around for the general committee picture were T. S. McDonald (left), publicity, and Stuart G. Johnson, plant tours.

PAQUIN KEY—N. D. Embree (left), outgoing president of the American Oil Chemists' Society, receives the key from T. C. Law, charter member.

BOND MEDAL—H. M. Teeter is the winner of the Bond award for 1959. With him is W. O. Lundberg, chairman.

to be safe. To be subject to the amendment, the substance must a) become a component of the food or otherwise affect the characteristics of the food under the intended conditions of use, and b) not be generally recognized by qualified experts as safe under the intended conditions of use. Several lists of such substances have been published, which include a number of antioxidants for use in fats and oils. Both old and new additives are subject to these criteria. Substances having approvals for use prior to January 1, 1958, under the Food, Drug, and Cosmetic Act or the Meat Inspection Act or the Poultry Products Inspection Act are not subject to the amendment. Pesticide chemicals on the raw agricultural crops or in the processed foods resulting from the legal use of pesticides on crops are also exempt from the procedures. When pesticide residues occur in processed foods due to the use of raw agricultural commodities that contained lawful pesticide residues, the processed food will not be regarded as adulterated so long as good manufacturing practice has been followed and the food, when ready to eat, does not contain residues in excess of those permitted for the raw agricultural commodity. Residues resulting from application of the same agent to the processed food are subject to the provisions of the food additives amendment.

Experimental data are required for approval of a food additive. The petitioner for a food additive is required to give the name and all pertinent data concerning the substances, including the chemical identity and composition where possible; a statement concerning the conditions of proposed use; pertinent data concerning the effect the additive is to produce and the amount required to produce the effect; full reports on the investigation concerning the safety of the substance. The food additive amendment specifically requires a description of practical methods for determining the quantity of the additive in the food and any substance formed in the food because of its use.

The antioxidants, used in the preservation of oils and fats, are good examples of the chemicals being used in our modern scheme of food production and distribution. They are necessary in order under some circumstances to have sound, ready-to-use foods available for consumption, thousands of miles from the production area and months beyond the date of maturity. Many of the antioxidants are exempt from the requirements of the amendment at common levels of usage and have been cleared for use on the grounds of general recognition of safety.

The food additives amendment has received considerable attention in the public press as a result of aminotriazole in cranberries, stilbestrol in poultry, and chemicals in foods generally. Aminotriazole is a pesticide for which no residue tolerance has been established. The amounts of the substances involved are small. They are measured in parts per million in a food, and in many instances the food involved is not eaten in large quantities. The small quantities involved have led some to conclude that there is much ado about nothing. Further consideration of this reasoning will uncover the pitfalls.

A COMPLETE LISTING of chemicals used in our food supply would be many pages long. Practically the entire food supply is subjected to or treated with chemicals, or at least exposed to situations, as in packaging, where the introduction of a chemical additive is possible. This means that everyone, the young and old, the sick and the well, are being continually exposed to these chemicals throughout their lifetimes. Consider, if you will, the number of foods in which antioxidants are used as intentional additives and, further, the number of foods in which antioxidants are incidental additives. What then is the total intake, daily or annually?

The susceptibility of individuals to any specific chemical will vary widely. Some will be very sensitive while others will be relatively insensitive to the effect whatever it might be. Even when genetically-controlled subjects, such as mice or fruit flies, are used, this susceptibility varies widely. This effect has been closely observed in the testing of carcinogens. The end result of one type of susceptibility is illustrated in the case of flies where continued exposure to the insecticide DDT has resulted in the development of resistant strains. The development of resistant strains of insects is becoming increasingly more common in crop control.

Apparently there is still some misunderstanding about the practical operation of the Delaney clause. G. Burroughs Mider, associate director in charge of research, National Cancer Institute, National Institutes of Health, prepared a report on "The Role of Certain Chemical and Physical Agents in the Causation of Cancers" at Secretary Flemming's request. This comprehensive report is most interesting, and Dr. Mider's statement that "no one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take to develop" deserves emphasis. In this report H. F. Blum, summarizing a study on the effect of ultraviolet radiation in producing cancer, states:

> Cancerization is in some way cumulative. If dosage is stopped, development continues at a retarded pace but steps up with renewal of dosage. Although there is evidence of a small degree of recovery, this is slight in over-all effect, and carcinogensis may be regarded as essentially irreversible.

THE SITUATION is somewhat analogous to the findings in the experiments on the effect of ionizing radiations on the mutation rate of fruit flies. The mutation rate is a direct function of the dose of ionizing radiation, and the important point to be observed is that the curve has its origin at zero. There is no threshold below which no effect is observed.

In discussing the practical operation of the anticancer clause, Secretary Flemming said:

> Some of the opposition to inclusion of an anticancer provision . . . arises out of a misunderstanding of how this provision works . . .
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> It has been suggested that once a chemical is shown to induce a tumor in a single rat, this forecloses further research and forever forbids the use of the chemical in food. This is not true. The conclusion that an additive "is found to induce

cancer when ingested by man or animal'' is a scientific one. The conclusion is reached by competent scientists, using widely accepted scientific testing methods and critical judgment. An isolated and inexplicable tumor would not be a basis for concluding that the test substance produces cancer.

It has also been suggested that when a compound shown to produce cancer in test animals has been modified in chemical structure so that it no longer produces cancer, it continues to be incriminated by its past history. This too is erroneous. The Food and Drug Administration would—and should—take a close look at the modified compound to be certain it did not have the same cancer potential as its parent. But once convinced that the cancer potential had been eliminated, the anticancer clause would not preclude use of the substance.

Finally doubt has been expressed about the authority of the Department to reverse a decision in this area. This, of course, is an unfounded doubt. When new evidence is presented, the Department has not only the right, but the obligation, to evaluate this evidence and determine whether a previous decision should be reversed.

This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

Chemists are accustomed to more precise data than can be obtained in experimental biology. In this area we must proceed with caution, and we must be guided by sound experimental procedures to determine the safety of our food additives. The translation of data from animal experimentation to man must be accompanied by a margin of safety, and the risks of its use must be weighed against the anticipated benefits. And it must be remembered that the consumer does not have a choice in this risk. The statement on carcinogen might be paraphrased in terms of almost any chemical additive. Before leaving this subject, mention should be made of the synergistic effect of different chemicals on man. A. J. Lehman, chief of pharmacology for the Food and Drug Administration, and his associates have described in detail the procedures to be used in a booklet, "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics," published by the Association of Food and Drug Officials of the United States in 1959.

MANY PESTICIDE tolerances and chemical additive tolerances have been established under these procedures. As the scientific studies continue, these are subject to review and re-evaluation. Two examples of recent origin are stilbestrol in poultry and heptachlor. In the case of stilbestrol, by improved analytical techniques the estrogen was found to be deposited in the skin and livers of chickens. The approved use of this substance in poultry processing was predicated on a no-residue basis in the finished product. Heptachlor epoxide results from the weathering of heptachlor on forage crops. This poses a problem in milk particularly because the epoxide, unlike heptachlor, is deposited in the milk of cows. Since no residues of this type are permitted in milk, it was necessary to change the tolerance established for heptachlor to zero. This may be of interest from the standpoint of residues remaining in the by-products of the vegetable oil industry that are used for animal food and subsequently raise problems with the human foods derived from the animals. The case of nitrogen trichloride, which was eliminated as a bleaching agent for flour after the development of data showing harmful effects on dogs, and the withdrawal of coumarin as a flavoring agent when data showed harmful effects on test animals are other examples where new scientific evidence required a change in previously-accepted practices.

In addition to the intentional or incidental additives, technological changes bring on new problems. For example, the investigations into the changes in the chemical, nutritional, and toxicological properties of heated fats and oils have been under way for several years. Substances toxic to rats have been isolated from over-heated cottonseed oils. The chicken edema disease is related to the splitting of fats. These substances (and the present evidence is that they are not the same) have not been completely purified and identified.

NEW YORK DELEGATION—Scouting for ideas at Dallas are some of the convention committee for the fall meeting: D. S. Bolley, chairman; W. C. Ault, program; J. E. Preston, registration; and E. I. Marshack, entertainment.

The fatty acids are significant in the food additive field, particularly as emulsifiers, stabilizers, and in the packages used for food containers. The presence of a toxic substance in these fats and fatty acids is cause for concern, but not alarm. Suitable procedures for preventing the formation of or removing the toxic substance can probably be devised after its identity is established. Present specifications for determining the quality of food fats are not satisfactory for detecting these factors. Tests, chemical or biochemical, must be devised for use in detecting and measuring such substances.

In these particular problems the industry and the Food and Drug Administration are working together in an effort to resolve the matter. An atmosphere of mutual respect, recognition of the problems, and a coordinated approach to their solution is necessary for the consumer to continue to enjoy the fruit of scientific endeavors.

[Received April 5, 1960]

• *New Books*

CHEMICAL ANALYSIS, AN ADVANCED TEXT AND REFERENCE, by H. A. Laitinen (McGraw-Hill Book Company Inc., 611 pp., 1960, $12.50). This book constitutes an impressive addition to the McGraw-Hill Series in Advanced Chemistry. The physical format (6 x 9¼ in.) is noteworthy for the durable two-tone binding, quality of paper, and legibility of type face. The index is comprehensive. Copious literature references in the text are listed at the bottom of each page and are readily available without searching for the end of a chapter. The literature is thoroughly covered, up to and including 1958, with at least one 1959 citation.

The book contains 27 chapters. A random selection of chapter titles will convey some idea of the material covered. For example, there are excellent individual chapters on the solubility, formation, colloidal properties, aging, and contamination of precipitates. There are additional chapters on the various types of titrations: acid-base, precipitation, complexometric, and oxidation-reduction. Important oxidants receive individual treatment in separate chapters. Other chapters describe methods of separation by precipitation, electrolysis, distillation, extraction, chromatography, and ion exchange. The book closes with a chapter each on statistics in quantitative analysis and sampling.

The author has endeavored to describe the fundamental principles involved in chemical analysis and does not give detailed procedures for specific analytical determinations. The emphasis of the work is on the "classical" or "wet chemical" methods, but in addition it contains much background material directly applicable to instrumental methods.

The book has been written primarily with the advanced undergraduate and beginning graduate student in mind but will, unlike some books so directed, be found of inestimable value to all workers in analytical chemistry, whether engaged in industry or in institutional activities.

The reader requires only a general knowledge of mathematics to cope with the book. Illustrative numerical examples abound throughout the text, all carefully worked out. Problems (with answers) follow most of the chapters. The last two chapters, on statistics in quantitative analysis and sampling, present more of a mathematical challenge, but