The Effect of Food and Drug Laws on Producers of Paper and Paperboard used for the Packaging of Food

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THE EFFECT OF FOOD AND
DRUG LAWS ON PRODUCERS
OF PAPER AND PAPERBOARD
USED FOR THE PACKAGING OF FOOD

by

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A thesis presented to the
Faculty of the School of Graduate
Studies in partial fulfillment
of the
Degree of Master of Business Administration

Western Michigan University
Kalamazoo, Michigan
December 1962
ABSTRACT

In 1958 the Food Additives Amendment to the Federal Food, Drug and Cosmetic Act was adopted causing a great deal of concern on the part of producers of packaging material. Any ingredient of the package that might migrate or transfer to food contained in the package became, by definition, a food additive subject to regulation and prior approval of the Food and Drug Administration.

Other acts and regulations have been adopted since 1958 indicative of increasing concern by the Federal Government for consumer welfare. This activity can be expected to have far reaching effects on manufacturers who must depart from some of the traditional ingredients used in their products and in the marking or labeling of their products.

Since 1958, there have been several industry committees in the paper and paperboard industry which have done tremendous amounts of work in evaluating chemicals used in their industries, meeting with Food and Drug officials and otherwise attempting to reach an understanding as to the effect of these new laws and to insure compliance by the members of their industries.

This paper is a survey of the basic legal problems in this field for those concerned with food packaging material made from paper and paperboard.
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INTRODUCTION

The purpose of this paper is to explore and discuss the various laws affecting producers of food protection packaging material and, particularly, manufacturers and converters of paper and paperboard used to make food containers.

The importance of food is self-evident. As a nation, we claim that our people are the best fed in the world. A trip through any modern supermarket will testify to this proposition, but it will also demonstrate the importance of food packaging materials. As an agrarian society, each family raised its own food. Even 50 years ago, fresh foods were sold from open containers and could be inspected by the consumer. However, as the food processing industry grew and developed, foods were processed and packed far from the place of sale. We now have foods that are canned, frozen, concentrated and dehydrated. They often have preservatives, colorants, sweeteners, thickeners, and other chemicals added to preserve them in the period until they are consumed.\(^1\)

We have come a long way from the illustration of the candy maker's assistant in England in 1858, who brought back arsenic of lead instead of sulphate of lime, causing the death of twenty customers and the severe illness of two hundred others. This negligence did not violate any laws of England and it wasn't until 1868 that Parliament passed the first poison labeling law. This was the start of our labeling laws.

Food production is now a highly complex, technical industry and the packaging industry devoted to food protection has developed with it. Paper and paperboard manufacturing in themselves are highly technical and a great deal of sophisticated chemistry is involved in making a food wrapper or carton. The combination of these two industries make the consumer an amateur when it is necessary to select a food item from a store shelf. The old legal doctrine of "caveat emptor" meaning "let the buyer beware" is meaningless and out-of-date when it comes to determining the wholesomeness of a food grown in one part of the country, processed or packed in another, and offered to the buyer in a sealed, tamper-

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proof container with nothing but a picture and a label to indicate the contents. The basis for governmental regulation and control is obvious.

The statutes involved are primarily Federal enactments promulgated under the general authority of the Federal government, as provided in the Constitution, to regulate interstate commerce. Because of the sizable investment in paper and paperboard making equipment, and the large volume produced by even a single-machine mill, it is safe to assume that no primary producer's activities are confined to intrastate commerce. Nevertheless, since some converters of paper and paperboard are small with a localized distribution and since many food packers serve a single state area, the existence of state laws and municipal ordinances affecting food sold within their boundaries must be recognized.

However, the primary concern of the larger producers and of this paper are the Federal laws which (except for a few relatively limited acts) begin with the original Federal Food and Drugs Act of 1906 (commonly known as the Pure Food and Drug Act or the Wiley Act). The enactments since then include the Meat Inspection and

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2 U. S., Statutes, c. 34, secs. 768-772; 21 USC 1 et seq.
3 34 Stat. 1260, 21 USC 71 et seq. (1907).
Poultry Products Inspection Acts\textsuperscript{1} administered by the Department of Agriculture, the Federal Food, Drug and Cosmetic Act of 1938 (often referred to as the Copeland Act),\textsuperscript{2} the 1958 Food Additives Amendment\textsuperscript{3} and several additional new acts, regulations and proposals for legislation and regulation of food ingredients and labeling.

After following this field for over five years, the writer has been unable to find an up-to-date, comprehensive survey of this field. It is believed that a survey of this type will be a contribution to the packaging industry and might well serve as a primer on the basic legal problems with which not only students, but managers, technical personnel and legal counsel working with paper and paperboard, either as a producer or a user, should be acquainted.

Very simply stated, papermakers were aware of the early Federal laws, used their own judgment over the years as to what was suitable for contact with food and had little contact with the Federal government. With the enactment of the Food Additives Amendment in 1958, all

\textsuperscript{1}46 Stat. 689, 21 USC 451 et seq. (1957).
\textsuperscript{2}52 Stat. 1040, 21 USC 301 et seq.
\textsuperscript{3}72 Stat. 1784, 21 USC 348.
this was changed. Industry groups organized committees to study the significance of this new legislation and through the efforts of their technical and legal personnel, working with governmental personnel, have substantially satisfied the newly imposed requirements. However, more regulation looms on the near horizon.

It is the intention of this paper to look into the earlier laws as to their legislative histories, the aspects of packaging they regulated, the case law relating to the liabilities of package and container manufacturers, and some of the state laws in this field. Congressional activity leading up to the enactment of the Food Additives Amendment will be reviewed, along with its provisions and regulations issued by the Food and Drug Administration (FDA). Additional recent (since 1958) regulations and enactments having an effect on the paper and paperboard packaging industry will be surveyed. This will then be followed by a more detailed discussion of the practical effects of these laws on the industry, the steps taken to comply therewith and the liabilities assumed by producers.

Some of the proposals in Congress and the current probe of packaging and labeling will be commented upon, followed by some observations and conclusions.

The references relied upon in this paper to a large extent are papers delivered at industry meetings by Food
and Drug Administration officials and by technical and legal experts in the packaging industry. A glance at the bibliography appended to this paper will reveal that Commerce Clearing House is the principal publisher of those articles that have been printed. It might be parenthetically observed that the food industry and others concerned with this subject should applaud this publisher's commendable effort to keep them informed in this somewhat specialized, technical, but highly significant, field of law and regulations.
CHAPTER I

BACKGROUND

According to one writer\(^1\) the efforts of the state to prevent food and drug adulteration date back to early Athens and Rome, where provisions against the adulteration of wine were enacted. In this country, the first efforts were state laws passed in the early nineteenth century to maintain the purity of medicines.\(^2\)

The first food law, enacted in 1883, was a Federal law designed to prevent the importation of adulterated and spurious teas.\(^3\) This was followed by legislation aimed at specific commodities, and general measures passed by several states.\(^4\) In 1890, a Federal law prohibiting the importation of adulterated or unwholesome food, drugs, or liquor was adopted\(^5\) and finally in 1906, the first national Pure Food and Drug Law was passed.\(^6\)

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\(^2\)loc. cit., p. 9.

\(^3\)loc. cit., p. 10.

\(^4\)ibid.


\(^6\)Supra, p. 3.
Pure Food and Drug Act of 1906

The original 1906 Federal Food and Drugs Act was designed to prevent the manufacture, sale or transportation of adulterated or misbranded, poisonous, or deleterious foods, drugs, medicines, and liquors. Although there were some problems of constitutionality as applied to manufacturing in a state, the commerce clause of the Constitution supported the prohibition of introducing such items into interstate commerce. 1

As pointed out by Dunn, 2 this was the third major law enacted by Congress to regulate interstate and foreign commerce (following enactment of the Interstate Commerce Act in 1887 and the Sherman Antitrust Act in 1890).

The most notable of the provisions in this Act were those directed against misbranded, as well as adulterated, foods, drugs and liquors. 3 As applied to food containers, labeling was not mandatory, but any labeling was required to be true and not misleading. 4

3 Ibid.
Amendment of 1938

Difficulties in administering the 1906 law became apparent almost immediately and as early as 1911, a new law was advocated. As the food and drug industries progressed to more complicated products, and the consumers literally got further away from the farm, the cry for consumer protection increased. Although a few minor acts were passed to plug loopholes, it wasn't until May of 1935 that the Copeland Bill passed the Senate and, over a year later, the House, with amendments. Finally, a Conference Committee rewrote an acceptable bill, which became law on June 25, 1938, as Public Act No. 717 of the Seventy-Fifth Congress.

The revisions provided by the 1938 amendments included labeling of foods and drugs, authority for the promulgation of definitions and standards of identity for foods, the establishment under certain conditions of tolerances for poisonous and deleterious substances in foods, the mandatory pretesting of new drugs, obtaining permission of the Secretary of Agriculture to market new drugs, and the inclusion of cosmetics as subject to control and regulation.

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1 Stephen Wilson, op. cit., p. 72.
3 ibid.
The provisions of interest to the packaging industry are the definitions of adulteration\(^1\) and misbranding\(^2\) of food.

The Food and Drug Administration

The original responsibility for enforcement of the 1906 Act was placed in the Secretary of Agriculture. Penalties were fixed for violations and authorization given for the sampling of foods, inspection of premises and shipping records, seizures and condemnation of adulterated and misbranded foods and drugs, and trial of offenders in the United States District Courts.\(^3\)

The 1938 amendment provided for the issuance of administrative decisions by the Food and Drug Administration, subject to appeal to the U. S. Circuit Court of Appeals.\(^4\)

The Food and Drug Administration, as we know it today, grew out of the Bureau of Chemistry of the Department of Agriculture. Its chief, in 1906, was Harvey W. Wiley, who spearheaded the drive for the 1906 Act.\(^5\) The Bureau's personnel in 1906 numbered 110 and its appropriation for

\(^1\)Sec. 402 (reprinted in full in Appendix).
\(^2\)Sec. 403 (reprinted in full in Appendix).
\(^4\)ibid.
\(^5\)Stephen Wilson, op. cit., pp. 11-44.
the fiscal year of 1906 was $130,920.¹

With the establishment of the Department of Health, Education and Welfare, enforcement and administration of the Food and Drug Act was transferred to the Secretary of Health, Education and Welfare.² Today, although still a relatively small governmental agency, the FDA staff has grown to 2,260 and its budget for fiscal year 1961-1962 was $26,328,000.³ A new headquarters building is currently under construction in Washington. The agency's authorized strength in 1962 was approximately 3,200-up from 1,400 just prior to the passage of the Food Additives Amendment.⁴

FDA administers, in addition to the Food, Drug and Cosmetic Act, the Tea Importation Act,⁵ the Import Milk Act,⁶ the Federal Caustic Poison Act,⁷ the Filled Milk Act⁸

¹loc. cit., p. 47.
⁵29 Stat. 604, 21 USC c. 2.
⁶44 Stat. 1101, 21 USC 141-149.
⁷44 Stat. 1406, 15 USC 401 et seq.
⁸42 Stat. 1486-87, 21 USC 61-64.

The FDA is similar to other governmental agencies which have grown up during the last 30 to 40 years. However, FDA has been a career agency with a minimum of change in personnel and policy despite political changes in Washington. Its decisions on safety of products offered to the public have, until recently, generally been accepted without challenge. Drawing on the experience of handling new drug applications, the General Counsel of the FDA opined in 1958\(^2\) that formal hearings and judicial review of FDA decisions and actions under the Food Additives Amendment would be a rarity indeed.

However, it should be noted that recently the FDA has been severely criticized for its handling of the drug thalidomide and the anti-cholesterol drug Mer/29.\(^3\) Following these outbursts and the very recent report of the Citizens Advisory Committee, appointed in 1961 to study FDA, it is expected that the agency will be re-organized in the near future. The report of the sixteen

\(^{1}\)Public Law 86-613, 74 Stat. 372.


\(^{4}\)loc. cit., October 26, 1962.
man Citizens Advisory Committee headed by Dr. George Y. Harvey of the Department of Political Science of the University of Missouri, recommended, among other things, that the top posts of FDA be filled by scientists and not primarily by persons with backgrounds as inspectors. It severely criticized the emphasis on "investigation and prosecution" and urged more preventive and educational measures. It also recommended improvement of FDA-industry relations.  

Meat Inspection Act

The Federal Meat Inspection Act became law in 1907 and under it interstate and foreign commerce in meat has been rigidly controlled by means of Federal inspection of livestock before entering any slaughtering, packing, meat canning, rendering or similar establishment, and the inspection of meat and carcasses after slaughter. The use of dyes, chemicals, preservatives or ingredients which render meat or meat products unsound, unwholesome, unhealthy, or unfit for human food is banned. The Secretary of Agriculture is authorized to issue regulations specify-

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3 op. cit.
Packaging materials used in federally inspected plants must meet the approval of the Meat Inspection Division of the Department of Agriculture.

Poultry Products Inspection Act

The Poultry Products Inspection Act, approved August 28, 1957, became effective January 1, 1959. It applies not only to poultry and poultry products produced and moving in interstate commerce, but also to those moving in major consuming areas regardless of whether or not they move across state lines. Such consuming areas are designated by the Secretary of Agriculture.

This Act prohibits processing, sale or transportation in interstate commerce, or in any designated consuming area, of any poultry not inspected and stamped with approval under the Act. Federal inspection of poultry processing plants is provided under the Act and packaging materials used in such establishments must have the necessary approvals.

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2 op. cit.
Federal Trade Commission Act

Another act affecting one aspect of food is the Federal Trade Commission Act, as amended on March 21, 1938, by the Wheeler-Lea Act. One of the major purposes of this amendment was to broaden the powers of the Federal Trade Commission over unfair methods of competition by extending its jurisdiction over unfair or deceptive acts or practices. More specifically, section 12 (a) of the Amendment was aimed directly at false advertisement of foods, drugs, devices and cosmetics.

The distinction between the Wheeler-Lea Act and the Federal Food, Drug and Cosmetic Act is that the former is concerned with false advertising of food, drugs, devices and cosmetics, while the latter deals with adulteration, packaging and labeling of the products.

Although there are several additional statutes affecting food, they are not particularly concerned with packaging and probably need not be singled out for comment here.

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1 38 Stat. 717, 15 USC 41.
2 52 Stat. 111.
3 Reprinted in full in Appendix.
Product Liability

As modern mass production methods made it possible to prepare food in factories more efficiently and at less cost than at home, and more items were sold in cans and bottles, occasionally some foreign substance would get into the finished product. Thus began the deluge of exploding bottles, mice in beverages, and similar cases known as product liability cases.

Product liability law is the principal legal avenue for the recovery of damages for personal injury resulting from food or its container.

As a legal proposition, one of the earliest obstacles was the fact that there was usually no contractual relationship between the producer of the product and the ultimate consumer, due to the intervention of middle men (wholesalers, retailers, etc.). In product liability cases based on the theory of negligence, the leading American case, followed today by most states, is MacPherson v. Buick which put aside the notion that liability can grow only out of a contractual relationship.

In addition to negligence theories, product liability cases are often based upon theories of warranty,

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1 Food Drug Cosmetic Law Reporter, op. cit., p. 20,401.
2 217 N. Y. 382, 111 NE 1050 (1916).
either expressed or implied. In fact, under the Uniform Commercial Code, there are implied warranties of merchantability\(^2\) and of fitness for a particular purpose\(^3\) that may be invoked in a legal action. It is the writer's view that any producer of paper and paperboard packaging material warrants, upon its sale, that it may legally be sold and that it is suitable for the use for which it was produced or for uses to which it can reasonably be expected to be applied. This, of course, implies that the producer of the material knows, or should know from the nature of the goods, the use to which they will be put. This is not an unreasonable assumption, since most packaging material is printed to indicate the product it will contain.

A further basis for product liability is for violation of a state or municipal pure food law. In the next section of this chapter, brief comments will be made on these laws.

Manufacturers have sought to limit their liability by disclaimers and by attempting to shift the burden to

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1 Food Drug Cosmetic Law Reporter, op. cit., p. 20,153.
3 loc. cit., sec. 2-315.
1 retailers. But particularly in nationally advertised, brand name items, the courts have looked with disfavor on these devices. As a practical matter, it is believed that most manufacturers (except possibly the largest who may be self-insurers) carry product liability insurance to cover liability for damages caused by their products. The tendency is to place the burden of strict liability on any seller of food in a defective condition, making him liable for any bodily harm caused to the consumer even though the seller exercised all possible care and despite the absence of any contractual relationship. 

State Food Laws

The passage of revised Federal legislation in 1938 started a movement for a Uniform State Food, Drug and Cosmetic Act. A model uniform act was accepted and endorsed in 1940 by the Executive Committee of the Association of Food and Drug Officials of the United

1Food Drug Cosmetic Law Reporter, op. cit., p. 20,161.


States. All fifty states have some type of food or drug law and forty-two of them have patterned their laws on the Federal Act of 1938. In general, these laws require labeling to show the source of the product, the ingredients and the presence and quantity of imitation or artificial color and flavoring. If the container is a so-called measure container, the weights and measures laws of several states require special marking.

Although the writer is unaware of any legal action involving paper or paperboard packaging material under state laws, this could become a most troublesome area if the various states adopted variations of the 1958 Food Additives Amendment. In addition, the various state laws present real problems to the food packers who often have to have special copy printed on their food containers to meet state labeling or weights and measures requirements. This involves extra costs for press stops in the printing of cartons or wrappers.

A complex legal issue involving the doctrine of Federal pre-emption can arise whenever a conflict arises between a state's law and the Federal. The only

\[1\] ibid.

\[2\] loc. cit., pp. 25,001-25,004.
practical solution, according to one of the legal specialists in this field, is uniform state laws.¹

CHAPTER II

THE FOOD ADDITIVES AMENDMENT OF 1958

The Food Additives Amendment of 1958 amended the basic food and drug law passed in 1938. The old law prohibited any food additive which was a poisonous or deleterious substance, except where it was required in the production of food or could not be avoided by good manufacturing practice. However, the 1938 law did not reach an unsafe additive until the food containing it was sold and injuriously consumed. As pointed out in the report by the House Committee on Interstate and Foreign Commerce concerning HR 13254:

"The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory

1 op. cit.


3 ibid.

4 loc. cit., pp. 9-10.
experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies."

In the early (1952) Report by the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics (known as the Delaney Committee) the scope of the problem was presented as follows:

"The number of chemicals entering the food supply of the Nation has increased tremendously in the last decade. Chemical substances are being introduced into the production, processing, storage, packaging and distribution of food at an ever-increasing rate. There is hardly a food sold in the market place today which has not had some chemicals used on or in it at some stage in its production, processing, packaging, transportation or storage. These foods include those items eaten by every family, ranging from staples like bread to such luxury items as the maraschino cherry. Some eminent pharmacologists, toxicologists, physiologists and nutritionists expressed the fear that many of the chemicals being added to food today have not been tested sufficiently to establish their toxicity and suitability for use in food. These scientists are not so much concerned with the acutely toxic compounds, whose harmfulness can readily be detected, as with those chemicals which may produce harmful effects only after being ingested for months or perhaps years.

"The indirect addition of chemicals to our food supply also raises serious problems. For example, cattle are being treated with antibiotic drugs in the control of mastitis, anthrax and other diseases. There is a question whether

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1 loc. cit., p. 89 (House Report No. 2356, 82nd Congress, 2d Session).
the presence of small amounts of antibiotics in milk and milk products has any effect on the consumer; that is, whether the consumer develops a sensitivity or resistance to these chemicals."

For this reason a law requiring pretesting of food additives and permitting the use of additives at safe levels was urged.

Legislative History

As summarized by Dunn, the Congress began an investigation in 1950-1952 by the House Delaney Committee which held public hearings and thereafter recommended that the Food, Drug and Cosmetic Act be amended to require an industrial safety pretesting of such additives similar to that required for new drugs. As a result in 1954, the Congress enacted an amendment to provide for the safety of pesticide chemical residues in natural food. Additional house bills were introduced during the 83rd and subsequent Congresses. During the second session of the 84th Congress, five days of hearings were held on 10 bills dealing with chemical additives in food and in the 85th Congress 11 days of hearings were held.

1 loc. cit., p. XI.

2 Public Law No. 518, 83rd Congress, approved July 22, 1954.

on 9 bills. As a result of the hearings and after consideration of the various bills, the Chairman of the Subcommittee on Health and Science, Congressman John Bell Williams of Mississippi introduced a "clean" bill\(^1\) which was reported unanimously by the subcommittee to the full committee. The full House Committee unanimously reported the bill out with one amendment and thereafter added the so-called Delaney cancer amendment. The House and Senate unanimously passed the bill with further amendments increasing the salary of the Commissioner of Food and Drugs, and another minor amendment. The President approved the bill on September 6, 1958, when it became law.\(^2\)

Mention of packaging material is found in the report of the Delaney Committee\(^3\) as follows:

"Nor is the problem confined to inadequately tested insecticides or other chemical substances added to foods. Paper, fiber, and plastics are becoming increasingly popular as food containers and food handling equipment. These, together with the use of chemicals in wrappers, may create a hazard to health. It is obvious that the toxicity and potential dangers of these materials should be studied before their use in the food industry is permitted."

\(^1\) HR 13254, 85th Congress, 2d Session.
\(^2\) Dunn, Legislative Record ..., op. cit., p. XI.
\(^3\) House Report No. 2356, op. cit.
The amendment itself is long and technical containing numerous sections and totalling six printed pages. However, its principal provisions will be outlined.

Definitions. The amendment first provides the citation name of the "Food Additives Amendment of 1958" and then broadly defines the term "food additive"\(^1\) as:

"... any substance the intended use of which, results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include ---

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a

\(^1\)Sec. 201 (s).
sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 USC 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 USC 71 and the following)."

This definition is presented in full since it sets forth the distinction between an intentional additive (covered by the Amendment) and an accidental additive (not covered by its provisions). It also clearly brings packaging materials within its scope if they contain ingredients which may reasonably be expected to become a component (or otherwise affect the characteristic of any food) under the conditions of their intended use.

The definition further provides for the exclusion of materials generally recognized as safe (GRAS) by qualified experts or, if used in food prior to January 1, 1958, has proved to be safe through either scientific procedures or common use.

It also excepts those items approved for use under the Meat, Poultry, and Pesticide Acts.

Thus, in the case of a food additive, the question of safety must be determined scientifically if it has not been determined by the experience of common use in the case of old food additives used before January 1, 1958. In the case of a substance accidentally added to food, it remains regulated by the prohibition contained in the Act
against any food that bears or contains any poisonous or deleterious substance which may render it injurious to health.¹

Prohibitions. The Amendment adds to the Act a new Section 409 which makes a food additive, or a food bearing or containing an additive, adulterated within the meaning of the Act and therefore outlawed from interstate and foreign commerce if it is unsafe within the meaning of that section. This is considered to be the basic regulatory law of the Amendment.² The procedure for petitioning for an administrative regulation, the standards by which the FDA shall act on the petition, and procedures for judicial review are spelled out in this section also. As Dunn³ summarized the law, it provides that after the manufacturer of a food additive, or a food bearing or containing it, completes the required safety pretesting, he must file a petition with the FDA regarding it. This is a petition that proposes the issuance of an administrative regulation prescribing the conditions under which such additive may be safely used. The FDA is directed to publish the regulation proposed by such petition in general terms within

¹Sec. 402 (a)(1).
²Dunn, Legislative Record . . ., op. cit., p. XVI.
³loc. cit., p. XXI.
thirty days after it has been filed.

Section 409 (b) (2) sets forth the requirements of the petition which shall contain: (A) the name and all pertinent information concerning the food additive, including, where available, its chemical identity and composition; (B) a statement of the conditions of the proposed use of the additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling; (C) all relevant data bearing on the physical or other technical effect the additive is intended to produce, and the quantity of the additive required to produce such effect; (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and (E) a full report of the investigation made with respect to the safety for use of the additive, including full information as to the methods and controls media used in conducting such investigation. Moreover, upon request, the petitioner must furnish a full description of the methods used in, and the facilities and controls used for, the production of the additive. ¹ Upon request, the petitioner shall also furnish "samples of the food additive, or articles

¹Sec. 409 (b) (3).
used as components thereof, and of the food in or on which the additive is proposed to be used.\(^1\)

The law further requires\(^2\) the FDA to fairly evaluate the pretesting and other data submitted and issue an order within 90 days after the petition is filed unless that period is extended, upon written notice to the petitioner, for further study and investigation of the petition. The order will either establish a regulation prescribing the conditions under which the additive may be safely used or deny the petition. The law further provides standards which the FDA must follow in promulgating its regulation.\(^3\) Further tolerance limitations may be imposed on the use of additives.

Upon issuance of an order or regulation, it shall be published\(^4\) and within 30 days, any person adversely affected thereby may file objections.\(^5\) A public hearing shall be held and by order, the FDA shall act upon the objections. Provision is further made for appeals to the U. S. Court of Appeals and, by certiorari, to the Supreme Court of the United States.\(^6\)

\(^1\)Sec. 409 (b)(4).
\(^2\)Sec. 409 (c).
\(^3\)Ibid.
\(^4\)Sec. 409 (e).
\(^5\)Sec. 409 (f)(1).
\(^6\)Sec. 409 (g).
Delaney Cancer Clause. One of the much discussed provisions of this law is found in the standards which FDA is bound to follow. It was added on to HR 132541 by the House Commerce Committee and has become known as the Delaney Cancer Amendment. It provides:

"That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, ..."

The comments on this clause are two-fold: first, that no tolerance limitations can be imposed where a carcinogen may be safe in small quantities; and second, that since medical experts do not know the cause of cancer, this clause seems administratively unworkable. As pointed out by one scientific group, 2

"The conservative position would demand that substances that produce cancer in experimental animals should be excluded from human foods as a precautionary measure, even though it is known that a substance carcinogenic in one species is not necessarily carcinogenic in others."

However, it should also be mentioned that the Senate Committee on Labor and Public Welfare, in its

1op. cit.

report on HR 13254 and its amendment\textsuperscript{1} commented:

"... We believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration."

\textbf{Guaranties}

In discussing the burdens added by the Amendment, Dunn\textsuperscript{2} points out that the responsibility for complying with the industrial safety pretesting requirements in the case of a chemical food additive normally resides in the manufacturer of the additive and secondarily resides in the manufacturer of a food bearing or containing this additive. But the food manufacturer may obtain a guaranty from the additive manufacturer as authorized by the Act,\textsuperscript{3} that a food bearing or containing his additive is not adulterated or misbranded within the meaning of the Act when it is used as directed by him. If a food manufacturer obtains such a guaranty in good faith from a responsible chemical additive manufacturer and uses his additive as thus directed, it is a legal

\textsuperscript{1}Senate Report No. 2422, 85th Congress, 2d Session, reprinted in Dunn, \textit{Legislative Record ...}, op. cit., p. 69.

\textsuperscript{2}Dunn, \textit{Legislative Record ...}, op. cit., p. XXI.

\textsuperscript{3}Sec. 303 (c) (2).
defense against a criminal prosecution of the manufacturer for using the additive. But, if the food manufacturer deviates significantly from the directed use of the additive or if he independently develops his own use of this or another chemical additive, he is subject to the safety pretesting requirements of the law. It should be noted that a guaranty, while a defense against criminal prosecution, is not a defense against seizure of the food or an injunction proceeding under the Act. As for guaranties from container manufacturers, this subject will be discussed further in Chapter IV.

Summary

It seems clear that by comparison with the earlier Food Drug and Cosmetic Act, the 1958 Amendment made substantial and fundamental changes in the food and drug law and in the procedural burdens when a new chemical is introduced into the food supply whether directly or indirectly. As one executive in the packaging field observed:

"...the packaging industry found itself directly concerned with some of the legal and safety

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aspects of the food and drug industries, its major customers. The law had defined a food additive as any substance directly or indirectly becoming a part of the food product. The package, thus, became a part of the finished product and had to be treated in a manner similar to the product itself from the viewpoint of potential health hazards."

It also put the Federal Government further into the activities of the food industry while at the same time placing severe burdens on the smaller food manufacturers that do not maintain the laboratories and personnel for extensive research and testing. The responsibility on chemists and the chemical profession is great to assure compliance with the law as well as safeguarding the nation's food supply.
CHAPTER III

RECENT ADDITIONAL LEGISLATION AND REGULATIONS AFFECTING FOOD PACKAGING

Since the passage of the Food Additives Amendment in September, 1958, there have been several events which indicate a continuing concern of the Federal government that the consuming public be protected and informed through regulation and labeling of the items it purchases.

Color Additives Amendment

One such enactment was the Color Additives Amendment to the Federal Food, Drug and Cosmetic Act, passed on July 12, 1960. As stated by the Department of Health, Education and Welfare in transmitting the proposed color additive bill to Congress, the objective of the legislation is as follows:

"The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded,

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1 Public Law 86-618, 74 Stat. 397.

provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer."

The pressure for this law came from the Food and Drug Administration following its decertification of Red, No. 32, a coal-tar derivative used for the artificial coloring of oranges. As pointed out by an FDA spokesman following the delisting of three coal-tar colors in urging new law:

"Further, there is a prospect of gradual removal of colors from the permitted list, with no indication that adequate substitutes will be developed which are suitable for acceptance on the list ... In such case, they will be unable to meet the stringent requirements of the present law that they be harmless for unrestricted use, although in the quantities needed to color particular foods they might be used under tolerance limitations..."

Under the old law, only harmless coal-tar colors could be used. Then FDA interpreted "harmless" to mean harmless in any amount and that no color could be used in limited amounts that were safe, if a greater amount were

1 ibid.
The Color Additives Amendment provides for regulation of all food, drug and cosmetic colorants and for regulations of acceptance. To the producer of paper and paperboard food packaging, the colors used in paper dyes or in printing inks that might transfer to packaged food should be selected from colors approved for use as a color additive.

Ice Cream Labeling Regulations

Under its authority to promulgate regulations for standards of identity and labeling, the FDA in 1960 issued regulations for the labeling of ice cream, ice milk, sherbets, water ices and quiescently frozen dessert products. These regulations had been under consideration for over eighteen years, during which public hearings were occasionally held. Of concern for the producer of ice cream packages, the regulations, as issued, provided for label statements of the presence of artificial flavoring or coloring in at least as large type as the name of the product (e.g., "Vanilla, artificial flavoring added, ice cream").

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These regulations brought forth an immediate response from the ice cream industry in the filing of four law suits challenging the reasonableness of the regulations. Pending the outcome of this challenge, the FDA suspended the effective date of the more burdensome provisions of the regulations. Negotiations have been under way between representatives of the International Association of Ice Cream Manufacturers and FDA in which some of the practical problems of carton design and printing have been brought out.

Many ice cream cartons are produced for a specific customer and carry labeling specified by that customer, so that the labeling regulations are principally the ice cream producers' concern. However, the larger carton makers preprint cartons in a variety of what are termed "stock designs" which are sold to small ice cream producers who do not have their own carton designs.

1 loc. cit., p. 7139.

2 International Association of Ice Cream Manufacturers and High's Dairy Products Corporation v. Commissioner of Food and Drugs, USCA (D.C.); Food Adjuncts Association, Inc. v. Commissioner of Food and Drugs, USCA (D.C.); National Dairy Products Corporation v. Secretary, Department of Health, Education and Welfare, USCA (7th) filed October 14, 1960; Foremost Dairies, Inc. v. Secretary, Department of Health, Education and Welfare, USCA (9th) filed October 10, 1960.

3 Federal Register, November 3, 1960, p. 10532.
These stock design cartons are usually in series of compatible designs for the more common flavors. When ordered they are then rerun through a job press (usually one-color) to print the customer's name and address. Since the labeling under the proposed regulations might vary tremendously for even the same basic flavor of ice cream because of the ingredients used, the present practices of stock design cartons would be altered severely. It now appears that a compromise set of regulations will be adopted acceptable to both FDA and the ice cream manufacturers.

Other Labeling Requirements

Although not concerned with food items, packaging producers should be aware of the existence of the Federal Insecticide, Fungicide, and Rodenticide Act\textsuperscript{2} and the Federal Hazardous Substances Labeling Act.\textsuperscript{3} The former, administered by the Department of Agriculture, relates to the label declaration of ingredients, claims for the product and caution notices on certain products such as insecticides often found on the shelves of food markets. The latter, adopted in 1960, relates to

\textsuperscript{1} Food Chemical News, July 2, 1962, p. 8.

\textsuperscript{2} Public Law 104 (80th Congress) as amended by Public Law 86-139, 74 USC 135.

\textsuperscript{3} op. cit.
Labeling of products commonly found in the home which contain toxic or flammable substances, irritants, sensitizers or whose containers generate pressure. Such products include waxes, cleansers, and household items sold in pressure cans.¹

Labeling has been a major area of concern for food producers for some time and is a subject in itself for extensive review if one is interested, more as a producer of foods than as a producer of packaging material. In addition to those mentioned, there are both Federal and state laws, establishing food standards and the labeling to appear on foods meeting these standards and also, to prevent misbranding and deception, spelling out what a label must show, what it may not contain and what may optionally appear thereon.²


CHAPTER IV

EFFECT ON FOOD PACKAGING MATERIALS, THEIR COMPOSITION AND USE

To say that the Food Additives Amendment of 1958 created a large amount of confusion, uncertainty, and apprehension throughout the food and food packaging industry is a gross understatement. Industry trade journals predicted ruinously expensive and other drastic results from this legislation.¹

The amendment was to become fully effective on March 6, 1960, eighteen months after its enactment, and the Commissioner of Food and Drugs was given discretionary powers to grant further extensions up to an additional twelve months.² When it became evident that many testing programs could not be completed within these time limits, Congress passed the Food Additives Transitional Provisions Amendment of 1961³ to permit further extensions to November 9, 1961 by FDA under circumstances where testing programs were under way and

²Sec. 6 (c) (1).
³Public Law 87-19, 75 Stat. 42.
there was no undue risk to the public health. The paper and paperboard industries, in common with other segments of the packaging industry, found a number of new and confusing problems as a result of the new law. Paper and paperboard were early pioneers in the prepackaging of food and were instrumental in making the old cracker barrel obsolete. Over a long span of years in which billions of packages have been sold, there had been no instances of injury to health attributable to paper or paperboard packaging material.¹

As Kaufman² observed, a prime function of a food package is to combat the destructive forces of the many chemical, microbiological, climatic and physical abuses at work to render food either useless or at least unappetizing. The secondary function of a food package he states,

"... is to provide a measure of convenience, such as easy storage or means of carrying, and a means of identification, such as ingredient clauses, weights or measures, and manufacturer identity. In other words, a food package is food protection, food economy and food convenience all rolled into one."

¹Modern Converter, August 5, 1962, commenting on speech by E. B. Brookbank, Jr., before Packaging Institutes' 23rd Annual Forum.

Although paper is the most common packaging material of all, chemically speaking, it is one of the most complex. As Kaufman\(^1\) describes the paper making process,

"Wood is digested in a chemical bath of sulfides or sulfites, to free the cellulose for use in making paper. Fungicidal treatments may then be added to prevent the build-up of slime in the piping system of the paper-mill equipment. Any one of a dozen chemicals may then be added to bleach the paper or still other chemicals may be added to impart the 'whiter than white' effect, as we do with various laundry preparations. Later on are added the resins, rosin acids, starches, gums, waxes, rubbers, plasticizers of both natural and synthetic varieties, which are the sizes that make the paper printable or receptive to the additional coatings and treatments that will impart grease-proofing, gas-proofing and moisture-proofing properties to the paper. There are at least a hundred chemicals involved here which have been used and accepted for decades, conservatively speaking, almost all of which have no significant past toxicological history at this time."\(^2\)

As pointed out by Brookbank,\(^3\) the packaging industry is self-policing. Mis-applications are not accepted by the buying public. If a food item stains

\(^1\)loc. cit., p. 652.


\(^3\)Modern Converter, op. cit.
its container evidencing a transfer of food ingredients to the packaging material, or if the coloring matter (ink or dyestuff) from a package is visible on the contents, the esthetic appearance of the package or the contents is a deterrent to the continued use of that particular packaging material. This consumer veto power is strong enough to insure properly selected materials and properly designed packages.

To meet the problems posed by the new enactment and with encouragement from the Food and Drug Administration, the Biological and Chemical Research Committee of the National Paper Board Association joined with the Chemical Additives Committee of the American Paper and Pulp Association, forming a Joint Liaison Committee. This brought together the top technical and legal personnel of every major producer of paper and paperboard in the country in a unified attempt to comply with the new law.

The Liaison Committee did the major job of preparing lists and, in consultation with FDA officials, classifying the 350 principal chemical components used in manufacturing grades of paper and paperboard.

Considerable confusion followed the flood of petitions for approvals of materials used in proprietary mixtures (e.g., coatings and adhesives). The problem was further complicated by the fact that low-volume, low-
profit ingredients might require safety evaluation at a disproportionate cost. To preserve the confidential nature of some proprietary mixtures, independent laboratories were used in some of the studies. Other chemical suppliers cooperated in this program and a big portion of the biological testing, testing for transfer or migration of ingredients from one material to another, and development of analytical methods was handled by suppliers and their associations.

Although the cellulose fibers which are basic to any sheet of paper were given almost immediate clearance, the many paper making chemicals, such as wax and rosin sizes, starches, defoamers, slimicides, etc., in various grades, produced by several concerns, had to be listed and classified as to their safety.

To some extent paper making today is still an art and paper making formulas will vary from mill to mill and even from machine to machine in the same mill, which made the problem one of listing those chemicals used by several firms rather than considering every last item used by each producer. It also required, in some instances, new measuring techniques to meet new standards of precision.

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Reused Fibers

Among paperboard producers, a very significant problem was that of reclaimed or reused fibers. A large number of packaging grades of paperboard have traditionally used reclaimed fiber from wastepaper as the major, if not the sole, component of the fiber furnish. Such paperboard grades as chip, jute liner, patent coated, folding boxboard, bleached manila, cracker shell, and many specialties are based largely on reclaimed fibers.¹

The reclaimed fibers are obtained by repulping wastepaper. Wastepaper dealers sort and grade this waste into some forty-two² grades such as news, soft white shavings, hard white shavings, boxboard clippings, etc. Paper mills using reclaimed fibers select grades of wastepaper in accordance with the required properties of the board to be produced. With cylinder machines which produce paperboard built up of several layers, the inner plies may be a waste grade while the outer plies in contact with food are made from virgin pulp.

In practice food boards are made from lighter colored, better grades of wastepaper or from new pulp.

¹Modern Converter, op. cit.
Also, in the manufacture of paperboard, the selected waste is defibered in water, washed and screened before being made into paperboard on the board machine. Nevertheless, the Food and Drug Administration was concerned about the chemical content of paperboard made from wastepaper and particularly the heavy metal content and possible bacterial contamination that might be present.

This last point (bacterial contamination) was fully answered to the satisfaction of FDA officials from projects conducted by the Institute of Paper Chemistry and from work conducted in Germany. These had shown complete destruction of pathogenic bacteria in the dryer section of the paper machine, even when the wet web was inoculated with copious quantities of pathogenic cultures. As pointed out to FDA officials,

"Vast quantities of water (approximately 12,000 gallons per ton of paperboard) and extremely high temperatures (280-300°F) are used in making paperboard. Under these conditions, bacteria are killed and contaminants washed out."

However, there was no data available on the presence in paperboard or migratory characteristics

1 Modern Converter, op. cit.


3 Letter from National Paperboard Association to Dr. Arnold Lehman, Food and Drug Administration, Washington, D.C., December 3, 1959.
of such metals as lead, mercury and arsenic.

To provide the scientific data required before FDA would clear reclaimed fibers for direct contact with food, the National Paper Board Association sponsored three different research projects which are described in the August 5, 1962, issue of Modern Converter.¹

The first of these projects, conducted by Syracuse University Research Corporation, was a heavy metals analysis of paperboard. Methods for digestion, separation and analysis, with sensitivities in the microgram range, were adapted and developed. Then 87 different samples of various types of paperboard were analyzed for arsenic, cadmium, cobalt, copper, mercury and molybdenum. The work showed that the quantities of arsenic, cadmium, cobalt, copper, mercury and molybdenum present in paperboard made from reused or reclaimed fibers are, in general, about the same as found in agricultural commodities and in water supplies. While the lead content varied, further work on migration indicated the presence of lead to be of no practical significance.

A second project carried out by Hazelton Laboratories, Inc. investigated the possible leaching

¹ op. cit.
and migration of heavy metals from paperboard. In this work, standard FDA solvents were used in contact with the paperboard under investigation and also samples of lean beef and chocolate were exposed to surfaces of each of the test boards for 7 and 14 days. The tests indicated no detectable transfer of lead and mercury to moist or fatty foods even under exaggerated use conditions.

The third project, carried out by the Institute of Paper Chemistry, involved abrasion studies to determine the amount of paperboard which might enter the packaged food under severe shipping conditions. In this study, cartons were filled with either a purified sand or special reagent grade sodium chloride and shipped by rail on round trips from Appleton, Wisconsin, to Kansas City and to Seattle, Washington. After shipment, analysis of the salt and sand for paperboard fragments showed that no detectable amount of paperboard enters the test material under ordinary conditions of handling even though the traveling distance is greatly exaggerated.

When the three research programs were completed, a petition proposing the issuance of a regulation to provide for the safe use of pulp from reclaimed fibers in the manufacture of paper and paperboard for food packaging was filed jointly by the National Paperboard Association and the American Paper and Pulp Association.
The petition was accepted by FDA on May 13, 1961, and on August 9, 1961, a notice of the filing was released for publication. After several extensions to allow for further consideration of the submitted data, the FDA on July 4, 1962\(^1\) published its regulation covering the use of pulp from reclaimed fiber as a component for containers for food.\(^2\) To date, (November, 1962) the only adverse reaction to this regulation has been a letter from a consulting engineer in the packaging field\(^3\) criticizing FDA for approving pulp from reclaimed fiber. There are no indications that his views are finding any support in Congress, in the Food and Drug Administration or elsewhere.

**Other Ingredients**

Although the regulation answered the questions concerning the base paperboard, further work was done on the dyes and pigments used to color paperboard. One can take the position that in the use of colored packaging materials, where there is no intent to color the food product contained in the package, the Food

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\(^1\) *Federal Register*, Wednesday, July 4, 1962, p. 6328.

\(^2\) Reprinted in full in Appendix.

\(^3\) *Food Chemical News*, July 9, 1962, p. 16; August 6, 1962, p. 13.
Additives Amendment, rather than the Color Additives Amendment, controls. FDA has taken a practical approach and accepted in principle the test that absence of visible transfer of color to food is sufficient evidence of no significant transfer, provided a migration test or dye solubility data is used to evaluate materials used with colored food.

In addition to colors in paperboard and paper, many different chemicals are used in coatings for paper and paperboard, in inks for printing them, and are present in materials, such as cellophane, polyethylene, polypropylene and foil, used in combination with paper and paperboard to produce a functional and esthetically pleasing appearance in the final package.

As of September 1, 1962, some 230 substances, including coatings, remained to be cleared. The Joint Liaison Committee is continuing its work with FDA officials to establish regulations for their use.

Many questions asked by food packagers, according to Brookbank, involve the use of paper and paperboard where the direct contact of the paper and board with the food product is not involved. The food product is

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1 Letter from Food Additives Subcommittee to Mr. Einar T. Wulfsberg, Food and Drug Administration, Washington, D. C., September 1, 1962.

2 op. cit.
frequently prepacked in another material or there is an impervious layer, such as wax or polyethylene, between the food and the surface of the paper or paperboard. The provisions of the Food Additives Amendment certainly do not apply to corrugated shipping containers for products packed in metal cans or glass bottles. Nor do they apply, under present FDA interpretation, 1 to paper cups and plates sold without food items packaged therein. Since cups and plates are not food containers, when moving in interstate commerce, they cannot contain food additives.

Other questions are not so easily answered. Can a substance migrate from paperboard into dry tea packed in porous tea bags? Not if the package remains dry and a wet package of tea bags is not normally a saleable product. 2

It will be obvious that to establish compliance with the Food Additives Amendment of 1958, it is necessary to examine each packaging application individually. Not only is it necessary to know the components of the paperboard and other package components,


2Modern Converter, op. cit.
but it is also necessary to know what food products are involved, and, in some cases, conditions of temperatures and humidity and time periods to which the packaged food will be subjected before it is consumed.

As one FDA official explained:

"...whenever a new wrapping material is developed, even though it be composed entirely of substances which have been tested and found to be safe individually or in other combinations, extraction studies should be made and the extractables looked at from the standpoint of the food-additives amendment. Unless the substances which may migrate to food are generally recognized as safe for their intended use or their presence conforms with a pre-existing approval or order under the amendment, a petition seeking an order authorizing their addition to food is necessary."

Labeling and Deceptive Packaging

Although the Food Additives Amendment caused the biggest stir in packaging and the most concentrated effort to insure compliance, there has been renewed interest in the labeling provisions of the Act. In

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this area common sense and the exercise of judgment play an important part in decisions as to the conspicuousness and prominence of label declarations as well as the intent to deceive.¹

The food packaging producers are watching very closely the labeling requirements proposed by FDA and opposed by the International Association of Ice Cream Manufacturers.² Another potential area of legislative difficulty is the outcome of the hearing on deceptive packaging. For example, if fractional weights of food are outlawed, package sizes will have to be adjusted to some standard weight. On the other hand, if an attempt is made to regulate package size, such as "small", "large", "economy", the weights will be adjusted to size.

Guaranties

As mentioned in Chapter II, the basic Food and Drug Act provides for the use of guaranties to avoid the criminal penalties of the Act.

Many food processors, including some of the major chains, requested guaranties from their suppliers of


² Supra, pp. 33-35.
packaging materials immediately after the Act was passed. This put suppliers in a nearly untenable position. They did not have guaranties from the manufacturers of the various ingredients used in their own products but were sometimes threatened with loss of orders if they did not give a guaranty. The penalty for giving a false guaranty is the same as for a violation of the Act for adulteration of food, misbranding, etc.\(^1\)

Further, the legal counsel of the National Paperboard Association, stated his opinion\(^2\) that a written guaranty from a packaging producer is of no practical benefit to protect the food processor from the penalty provisions of the Federal Food, Drug and Cosmetic Act. To use his example, the written guaranty is designed to protect a box broker or wholesaler who doesn't do anything to the product or make it into some final article for sale. When the product is made into a box, is filled with an item or is otherwise changed and then sold, it is not the same article which is purchased.

This view was supported by the Assistant General

\(^1\)Sec. 301, 303 (a).

\(^2\)National Paperboard Association, Releases No. 1 and 3 on Legal Matters, January 7, 1960 and April 15, 1960.
The requests for guaranties have nearly stopped since the efforts of the paper and paperboard packaging industries in gaining approval for their products and their ingredients are far more meaningful in giving to food packers, the Government and the public the assurance of a safe food supply. The warranty provisions of the Uniform Commercial Code referred to in Chapter I will, when given greater recognition, undoubtedly make guaranties unnecessary.


CHAPTER V

PROPOSED LEGISLATION AFFECTING PACKAGING

Any person who reads the newspaper, with a little reflection, will realize that our Federal Government in Washington is concerning itself more and more with the care and protection of our people. This is evident in not only proposals for increased Social Security benefits and medical care for the aged, but the Senate investigations of drug prices and deceptive packaging. Proposals have been put forth to provide a consumer representative adviser on the White House staff of the President. Another proposal has been the creation of a new cabinet level post to concern itself with consumer affairs. On July 11, 1962, the Secretary of Health, Education and Welfare announced the formation of a Departmental Committee for Consumer Protection to carry forward the consumers' rights to safety, to be informed, to choose and to be heard.\(^1\) This is indeed a fertile field for Government extension and regulation and, since everyone buys food, this particular area can easily

become, if it hasn't already, a battleground of emotional propaganda, charges and counter-charges.

The Government's position as to its role was made very clear recently by the Commissioner of Food and Drugs, who said:

"As our society becomes more complex, the evolution of technology requires more safeguards for the consumer. As much as we admire the rugged individualist, when you have 90,000 firms dealing in over $82 billion worth of food each year, you can't have each going his own merry way. Processors who are hundreds of miles from the point at which their product will be consumed have to have standards of operation to live up to and somebody has to see that the processor does in fact live up to them. We believe that you and we together have to do the job the individual housewife would do if she were preparing a product in her own kitchen. And really the food plant is just an extension of the home kitchen. Since the housewife can't go several hundred miles or more to assure herself of the quality of raw products used, the sanitary conditions of the commercial kitchen, the methods of handling and preparing the food, and the additives that are employed in its preparation, we are supposed to do this job for her." (emphasis added.)

Factory Inspection Amendment

One way in which the FDA hopes to pursue its goal is by increased authority for factory inspections. To


2Ibid.
this end, a bill\(^1\) was introduced before the Congress in May, 1962, by Representative Oren Harris to broaden the investigatory powers of FDA inspectors, to inspect not only the factory premises, but any consulting laboratory, including,

"... all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls and facilities) ..."

The National Canners Association\(^2\) and others\(^3\) have opposed this legislation as being an unwarranted expansion of FDA's inspection powers with no demonstrated need to go beyond the present inspection provisions. One of the principal objections is the opening up of trade secrets and financial information to FDA agents.\(^4\)

Although "killed" in 1962, it can be expected to be reintroduced in 1963.\(^5\)

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\(^4\) National Canners Association, op. cit.

Senate "Truth in Packaging" Bill

Either the FDA or the Federal Trade Commission will likely be given further authority to regulate food and food packaging as the result of the recently concluded investigation conducted by a Senate sub-committee headed by Michigan's Senator Philip A. Hart and the so-called "Truth in Packaging" bill introduced in the 1962 session of the 87th Congress.

FDA is aiming at what it calls "the problem of inconspicuous display of required label information and the related problems of slack-fill and short weight of package contents". It sees this as a problem due to the fact that the public, in its opinion, is buying "by the package" instead of the pound, pint or peck as it used to.

During the period from 1938 to 1949, four or five

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2 U. S. Senate, S-3745, 87th Cong., 2d Session, introduced September 24, 1962.


4 Ibid.
charges of deceptive packaging reached the courts.  

These cases basically concerned packages in which the food content occupied 33 to 60 percent of the space in the package. If there were laudable reasons (e.g., protection of the contents) for the package design, the courts generally found no deception.

More recently, the Food and Drug Administration seized 174 cases of Delson thin mints, alleging that containers in which chocolate thin mints occupied only forty-five percent of the interior space, the rest being largely occupied by hollow dividers, were misleading to the public. The Federal District Court for New Jersey ordered the seized goods returned holding that the dividers protected the contents and that the case was lacking in proof that the average adult would be deceived. FDA appealed to the Court of Appeals and the case was remanded to the District Court for further findings of fact. The District Court again found the accused package was not misbranded or misleading and again the FDA appealed. The Court of Appeals this time

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3 287 F. 2d 246 (CA-3,1961).

affirmed the District Court.¹

It is the writer's personal opinion that the final decision of this case was a blow to the FDA and has much to do with the present pressure for new legislation on deceptive packaging.

Senator Hart described his legislative plans outlining a three step approach, to the National Conference on Weights and Measures in Washington:²

"First: A ban across the board of practices which by their nature are subject to a high degree of abuse because the manufacturer has no control over the final pricing of his product. Such practices, of course, include 'cents off promotions' and 'economy size' designations.

"Second: Establishment of standards applicable to all products regardless of their particular problems and differences. This would include guides requiring the net weight or content designation to be in a specific type size and face in proportion to the main panel of the package, positioned in a location where it can easily be seen, unadorned by qualifying phrases.

"Third: Promulgation of standards on a product line basis in those categories of practices which require separate and individual treatment. The areas where this may be necessary . . . include serving designations; meaningful size designations; product efficiency measurement where net weight or content is not meaningful in this regard; undue proliferation of weights and sizes (this would necessitate some modified kind of standardization); distorted package proportions; relationship between package size and package contents."

¹ 302 F. 2d 724 (CA-3, 1962).
One authority has warned that standardized packaging legislation proposals, if passed, will cause the demise of some products unless customers are willing to pay a higher price to cover the cost of new equipment or altering existing operations.

This promises to be a controversial subject since economical packaging requires some uniformity of package size. As foods vary in bulk or density, it is necessary to either vary the percentage of fill, use fractional weights, or use non-uniform sizes of packages.

Labeling of Dietary Foods

Recently, FDA published its proposed rules for labeling of dietary foods. According to an FDA release:

"The regulations would cover vitamin, mineral, and other dietary supplements, baby foods, foods for the elderly, low sodium foods, low calorie and artificially sweetened foods, protein supplements, hypoallergenic foods, foods for use in dietary management of disease, and all other foods represented as having special dietary properties."

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2 Federal Register, June 20, 1962, pp. 5815-5818.

According to Commissioner Larrick:

"The proposed regulations are designed to provide the consumer with complete and reliable labeling information which will enable him to select and purchase special dietary foods of all kinds. This will help to eliminate false and misleading claims."

The increasing popularity of "Metrecal" type products, vitaminized cereals and so-called low calorie breads and desserts probably prompted the Food and Drug Administration to up-date the regulations in this area.

Comments on the impact these regulations will have on the packaging and package designs for this large group of food items have not been extensive. However, there are no provisions in these regulations comparable to those in the Ice Cream Labeling Regulations requiring any particular size of type or conspicuous placement of the required information. The only provisions are that the information be set forth on a separate part of the label, in easily readable style of type on a contrasting background and no information not required by the regulations is to be comingled with required information.

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1 ibid.
2 op. cit.
3 Federal Register, June 20, 1962, p. 5818 (Regulation Sec. 125.12).
In this paper, an attempt has been made to collect and collate the principal laws affecting food packaging materials made from paper and paperboard. To more thoroughly dissect and examine each law or subject would be a monumental task and would serve no useful purpose since interpretations and regulations are forever changing and any particular point would have to be re-examined in the light of the facts involved and the law current at that time. No attempt is made here to make legal experts out of the readers of these pages, but rather to give those interested in the subject the "feel" of what laws are involved, what they attempt to prescribe or regulate and when to seek legal or technical advice.

In Chapter I, the early enactments leading up to the passage of the Wiley Act in 1906\(^1\) were noted. The provisions of this original Federal food and drug act affecting packaging were discussed. The major revisions of 1938 in the Copeland Act\(^2\) were compared, as they related

\(^1\)op. cit.
\(^2\)op. cit.
to packaging, with the earlier law. Parallel, and in some ways over-lapping, laws such as the Federal Meat Inspection Act\(^1\) and the Federal Poultry Products Inspection Act\(^2\) were described and recognition given to state laws and products liability decisions.

In Chapter II, the Food Additives Amendment of 1958\(^3\) was more thoroughly considered as to its origin, its provisions and the way in which packaging materials were very suddenly brought under the strict surveillance of the Food and Drug Administration.

Chapter III deals with the response of the paper and paperboard industries to the 1958 legislation. The attempt is made to give some insight into the complex technical problems created in obtaining regulations approving the many chemicals used in paper and paperboard production and conversion.

Since 1958, additional legislation (e.g., the Color Additives Amendment\(^4\) and the Federal Hazardous Substances Labeling Act\(^5\)) have been passed and further regulations issued under existing laws. These are covered in Chapter

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\(^1\) op. cit.  
\(^2\) op. cit.  
\(^3\) op. cit.  
\(^4\) op. cit.  
\(^5\) op. cit.
IV and Chapter V follows with proposals for further laws now before the Congress (Factory Inspection\textsuperscript{1} and "Truth in Packaging"\textsuperscript{2}) from which it can be expected new laws will be enacted.

The great increase in Federal activity since 1958 in the regulation of the food industry and those that serve it will be apparent. Producers and converters of paper and paperboard can no longer hide behind the excuses that they produce only what their customers order and label copy is not of concern to those who merely act as printers. Today, between requests for guaranties of compliance with Federal, state and local law and the warranties attaching to any sale of goods, anyone producing merchandise without knowledge of the ingredients used in his products and their suitability for the intended use of those products is exposing his company to liability.

As in the case of stock ice cream cartons, some converters offer their products in a way that they must warrant their safety and that they meet legal requirements. In other cases, small food processors look to their larger suppliers for information as to what can be used. Although no supplier concern can put itself in the

\textsuperscript{1} op. cit.

\textsuperscript{2} op. cit.
position of rendering legal advice to its customers, as a practical matter it has a moral duty to point out that certain packaging materials have limitations as to the foods with which they may be appropriately used.

The thrust of this increasing regulation by Federal agencies in this area alone will undoubtedly be less than pleasing to contemplate by advocates of states' rights, less government control of business and balanced budgets. However, at the same time, it is obvious that with the interstate traffic in the food industry and in food containers that fifty different state laws and untold local ordinances cannot be known, much less observed, to the national enterprises that are a part of this huge part of our economy.

But we can and should ask if the Federal activities are steps in the right direction. The President of the Food Law Institute observed recently:

"The problem of safety clearance of incidental additives resulting from chemical residues in packaging materials (fibre or otherwise) has taken up the bulk of FDA's time and effort in the food additive field. Petitions for food additives regulations for such additives involved approximately 1,675 chemicals as of

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March, 1961 . . . It has also required large expenditures and intensive studies by industry which have not produced any evidence that any old or new packaging material would have been a serious hazard to health if the Food Additives Amendment had not been enacted. It has even been suggested that a vigorous effort be made to secure FDA's support for Congressional reconsideration of the Act insofar as it relates to incidental additives. These problems might possibly have been solved by expert panel determinations that the various substances were generally recognized as safe."

One writer suggests that "the food and associated industries are being over-regulated in fields where not even a remote possibility of hazard to public health has existed in fact". However, he goes on to point out that "details of the composition and production of packaging materials, can lining and other like materials are now known to FDA and their approval by this governmental agency should alleviate public fears about the unknown".

Another writer after reviewing events since 1958 expressed the view that "the present regulatory plan is imprudent when applied to incidental packaging additives" and urged Congressional reconsideration.

Unless the urgings of industry spokesmen are heeded by Congress, those in the paper and paperboard

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industry can look forward only to increased regulation and control. The managers, technical and legal personnel charged with the responsibility of compliance with these laws have a big task ahead of them and one which cannot be ignored. The praise for keeping one's company out of trouble will be scant compared to the scorn that will befall the adviser who overlooks a Federal requirement resulting in the seizure of the customers' goods and the notoriety that will result.

As Miller\(^1\) observed, those associated with industries close to the consumer must expect additional legislation of this nature and must develop the means for adjusting to it as it arises. One way he suggests is working together in technical areas. He also suggests trying to anticipate what future legislation might cover and making such changes within the business "to obviate the need, real or apparent, for the passage of this legislation."

\(^{1}\)op. cit., p. 43.
Adulterated Food.

Sec. 402. A food shall be deemed to be adulterated--

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) (A) if it bears or contains any added poisonous or added deleterious substance, other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive which is unsafe within the meaning of section 406, or

(B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a); or

(C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409; Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or
(4) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706 (a).

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except authorized coloring, harmless flavoring; harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.
Sec. 403. A food shall be deemed to be misbranded--

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as--(l) a food for which a standard of quality has been prescribed by regulations as provided by
section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or (2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: Provided, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribed as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: Provided, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a
pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical: Provided, however, That no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade. (Nothing in the amendments made by the first section of this Act (403 (k) and (l)) shall affect any requirement of the laws of any State or Territory.)

(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.

FEDERAL TRADE COMMISSION ACT
(15 USC 41 et seq.)

False Advertisement of Food, Drugs, Devices or Cosmetics.

Sec. 12 (a) It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement--

(1) By United States Mails, or in commerce by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in commerce of food, drugs, devices, or cosmetics.

(b) The dissemination or the causing to be disseminated of any false advertisement within the provisions of sub-section (a) of this section shall be an unfair or deceptive act or practice in commerce within the meaning of section 5.
Sec. 121.2546 Pulp from reclaimed fiber.

(a) Pulp from reclaimed fiber may be safely used as a component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of paragraph (b) of this section.

(b) Pulp from reclaimed fiber is prepared from the paper and paperboard products described in sub-paragraphs (1) and (2) of this paragraph, by repulping with water to recover the fiber with the least possible amount of nonfibrous substances.

   (1) Industrial waste from the manufacture of paper and paperboard products.

   (2) Salvage from used paper and paperboard excluding that which bears or contains, or has been used for shipping or handling any poisonous or deleterious substance which may have contaminated the paper or paperboard and which may reasonably be expected to be retained in the recovered pulp.
BIBLIOGRAPHY

Public Documents

U. S., Constitution, Article I.


U. S., Statutes, Chapters 29,34,38,42,44,46,52,72,74,75.


Books


Articles and Periodicals


"Crisis: The New Food Law." A series of three articles in Modern Packaging, vol. 32, nos.9, 10, 11; May, June and July 1959.


Hollander, Stanley C. "Problems and Puzzles in Trade Regulation." Business Topics, Michigan State University, Graduate School of Business Administration, vol. 10, no. 3, Summer 1962, 23-35.


Modern Converter, December 15, 1960; August 5, 1962.


Unpublished Material


Releases No. 1 and 3 on Legal Matters, January 7, 1960, and April 15, 1960.


"Progress Under the Food Additives Amendment of Interest to the Cereal Chemist." Paper read before the annual meeting of the American Association of Cereal Chemists, St. Louis, Missouri, May 20-24, 1962 (Mimeographed).