VOL. 21, NO. 12 DECEMBER 1966

Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

December, 1966
Volume 21 • Number 12

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . December, 1966

VOLUME 21 NUMBER 12

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

Editor of Comments: Franklin M. Depew

Editor of Canadian Law: Robert E. Curran, Q. C.

Editor of Foreign Law: Julius G. Zimmerman

Associate Editor for Europe: Ernst Abramson, M. D.

Scientific Editor: Bernard L. Oser

REPORTS

TO THE READER

Now That the Fair Packaging and Labeling Act Is Law.—Some disadvantages of the Fair Packaging and Labeling Act are discussed in the article beginning on page 632. The author, *Cornelius B. Kennedy* is a member of the Illinois and District of Columbia Bars and was formerly an Assistant United States Attorney in Chicago and counsel for the Minority Members of the Senate Judiciary Committee. After tracing the development of the Act, Mr. Kennedy concentrates on analysis of Section 4, the labeling section, and Section 5, the packaging section. He notes that the problems in these sections arise primarily from ambiguities in wording, and from difficulty in applying some requirements to certain commodities.

The Packaging Industries and the Food Additives Amendment of 1958—It's Time for a Change in the Law.—In an article beginning on page 647, *Jerome H. Heckman* takes issue with the concept of the 1958 Food Additives Amendment as it relates to packaging materials. He discusses the procedure, prior to 1958, whereby the packaging supplier gave assurance to the food processor that his product was considered safe for its intended use, and he compares this procedure to the present one. It is the opinion of the author that the present regulatory scheme is unnecessarily complex, restrictive, and in need of change. Mr. Heckman is a lawyer with Keller and Heckman of Washington, D. C.

Factory Inspection Under the Federal Food, Drug and Cosmetic Act (Section 704).—Much uncertainty as to the soundness and scope of Section 704, providing for factory inspection, is rooted in its historical and legal background according to the article on page 673 by *James F. Hoge*. He contends that because the law itself is indefinite, industry is uncertain of its rights and unable to counteract the unlimited inspection sought by FDA. Mr. Hoge is General Counsel of the Proprietary Association and a member of the New York Bar.

The Advantages of, and Need for the Establishment of Uniform Guiding Principles and Model Standards for Food.—The need for the harmonization of national food laws is stressed throughout the article beginning on page 680. *Dr. Paul M. Karl* of Brussels discusses various organizations active in the field of food law. Believing that there is more confusion in harmonization activities than in the food laws, he suggests that one international body should carry out harmonization activities with the help of subsidiary regional groups.

Food Additives Article.—In the November issue, Dr. Bernard L. Oser, our scientific editor, presented excerpts from a valuable review of food additive developments by *Mr. Howard J. Sanders,* Associate Editor of the magazine *Chemical and Engineering News,* in which the complete article originally appeared. We regret that the presentation in this journal failed to make clear the fact that Mr. Sanders is the author of the article, and we join Dr. Oser in attempting to correct this oversight.

Index.—An index begins on page 687 for all the articles published in the 1966 issues of the JOURNAL. The articles are indexed according to author and title, and also under appropriate general subject headings.

VOL. 21, NO. 12 DECEMBER, 1966

Food·Drug·Cosmetic Law Journal

Now That The Fair Packaging and Labeling Act is Law

By CORNELIUS B. KENNEDY

Mr. Kennedy Is a Practicing Attorney in Washington, D. C.

ON NOVEMBER 3, 1966, before more than 100 people assembled in the East Room of the White House, at 5:30 in the afternoon, President Johnson said:

> We have met this evening to fulfill two obligations to the American family.
>
> —We are here to defend truth.
>
> —We are here to avoid tragedy.
>
> The two laws I sign this evening will help the American housewife to save her pennies and dimes—and the American mother to save the lives of her children.
>
> The first law is the Fair Packaging and Labeling Act. Its purpose is to uphold truth. Its target is labels that lie—packages that confuse—practices that too often deny the consumer a fair test and a clear choice in a shopping place.
>
> This is a strong and simple law.[1]

That law was born almost five and one-half years earlier, on June 28, 1961, in the lofty, paneled hearing room of the Committee on the Judiciary of the United States Senate, at 9:35 o'clock in the morning, when Senator Philip Hart said:

> The Committee will come to order.
>
> Today we are beginning hearings on packaging and labeling practices of food and household products as they affect consumers.
>
> The consumer has a right to be able to find out what he is buying, how much he is buying, what it is costing on a per unit basis.
>
> * * *
>
> Sen. Kefauver . . . has asked me to head this inquiry.[2]

[1] *Weekly Compilation of Presidential Documents,* November 7, 1966, p. 1599.

[2] *Hearings on Packaging and Labeling Practices,* Senate Committee on the Judiciary, Anti-trust and Monopoly Subcommittee, June 28, 1961, p. 1.

The intervening years were the formative years. There were lengthy hearings and extended consideration of a number of proposals to provide for government regulation of the packaging and labeling of items appearing on the shelves of neighborhood stores.

Two Packaging and Labeling Bills

Finally, on June 9, 1966, the Senate of the United States, by a 72-9 vote, passed a packaging and labeling bill which contained about every feature which industry had charged would not be in the best interest of the American consumer. That bill contained provisions permitting the government to create mandatory standardization of package weights and quantities. It contained a provision permitting the government agencies to establish and define the net quantity of a product which shall constitute a serving. It contained a provision permitting the regulation of the placement of "cents-off" and other price advantage labels upon any package. A Senate Committee report indicated that the power to regulate included the power to prohibit.

One week before the Senate passed that bill, the Chairman of the Committee on Interstate and Foreign Commerce of the House of Representatives had introduced a bill which contained all of those features and in addition, a provision permitting government agencies to prevent the distribution of commodities "in packages of sizes, shapes, or dimensional proportions which are likely to deceive retail purchasers in any material respect as to the net quantity of the contents thereof . . ."[3]

Compromise Packaging and Labeling Bill

Less than five months later, on October 19, 1966, the Senate of the United States accepted a compromise version of a House-passed packaging and labeling bill which not only deleted the government mandatory standardization of weights and quantities, the authority of government agencies to determine the size of servings, the authority in the government agencies to prevent the distribution of commodities in packages of sizes, shapes or proportions which they deemed likely to deceive, but also, in the House Commerce Committee Report accompanying the bill, interpreted the "cents-off" provision as permitting the regulation *but not the prohibition* of such offers.[4] That bill had been approved in the House by an overwhelming 300 to 8 vote.

[3] H. R. 15440, 89th Congress, Section 5(c)(5).

[4] Report 2076, House of Representatives, 89th Congress, p. 7.

The House-passed bill has been appraised in many ways. Congressman Staggers, the Chairman of the House Commerce Committee, commented that the bill had been reported from the Committee without a dissenting vote; that it was a good bill; that it was a housewives' bill, but that "if they had controlled the fate of this bill, I am sure it would be about 10 times as strong as it is."[5] Congresswoman Leonor Sullivan, who was for a much stronger bill, said that there was so little in the bill which did anything of any great importance that any opposition to it was tilting at windmills. She said, so far as foods, drugs and cosmetics are concerned, the bill "is a re-stating of the present law . . . to do what Congress thought it gave the government the right to do 28 years ago."[6] Representative Devine, who said he opposed the original bill as proposing to create a "monstrous bureaucracy . . . designed to further regulate the free-enterprise system of this country," agreed with Congresswoman Sullivan that the bill, as it came to the House for that 300 to 8 vote, "does practically nothing."[7] Representative Younger described it as a "reduced bill" which he could support although he reserved the right to oppose any attempt to go back to the language of the Senate-passed bill.[8] Representative Rosenthal was critical of the House version and called it "only half a truth-in-packaging bill," which "lacks the very elements which would assure protection of the consumer's interest."[9]

On the other hand, when he signed it into law with only a few very minor changes, President Johnson described it as "a strong and simple law" which will protect the housewife. And the President's legislative specialists, Postmaster General Larry O'Brien and the White House aide, Joseph Califano, in their report to the President of the 30 most important pieces of legislation passed in the second session of the 89th Congress—those "of landmark and historic significance"—put the Truth-in-Packaging Bill in second place. In their list it outranks Urban Mass Transit, Aid to Education, Minimum Wage, Child Safety, Demonstration Cities and many other measures. Interestingly, its rank in second place on that list cannot be chronological because it was passed after most of the other bills; and they reverted to the old name of the bill "Truth-in-Packaging."[10]

---

[5] *Congressional Record,* October 3, 1966, p. 23858.
[6] *Congressional Record,* p. 23860.
[7] *Congressional Record,* p. 23863.
[8] *Congressional Record,* p. 23862.
[9] *Congressional Record,* p. 23865.
[10] *Presidential Documents,* October 31, 1966, p. 1546.

Members of the Senate split in their appraisal of the bill. Senator Magnuson, Chairman of the Senate Commerce Committee, stated that the Senate had accepted the House version of the bill with great reluctance; that the House bill was not a packaging bill. He said that the House bill failed to recognize the need for and the importance of the Senate provision on product standards, and he concluded:

> We need a strong packaging provision. Testimony before the Senate Commerce Committee amply demonstrated the confusion which has been caused by proliferation of package sizes and by the use of awkward and fractionalized sizes.[11]

On the other hand, Senator Hart, the sponsor of the original legislation, said:

> I consider the Truth-in-Packaging Act to be strong, effective, and historically significant legislation.
>
> In saying this, I realize my remarks may be interpreted as an attempt to justify the efforts of a Senator who originated this legislation and worked 5 long years for its passage.
>
> From a historic point of view, I believe this legislation will have much the same significance regarding Federal responsibility for assisting consumers as the Employment Act of 1946 has had regarding Federal responsibility for economic planning.

And with respect to the mandatory provisions, which most House members said did little or nothing, he said:

> If this legislation contained nothing but these mandatory provisions alone, it would be a great advance over present law and would be considered significant and worthwhile legislation.[12]

Some cartoonists went to work on the bill—Herblock and Crocket, for example. Crocket showed the House with a pair of scissors snipping the sides, top and bottom out of the Truth-in-Packaging Bill, with the caption "There it is—holds nothing, says nothing, means nothing."[13]

These various appraisals are significant because the bill is something which industry must now take into account in its planning.

Analysis of the Labeling Section

Let us start with Section 4. It has been called the Labeling section, and it did not get as much fame as Section 5 which deals with packaging. But note that the servings provision was moved from Section 5 to Section 4 by agreement of the Conference Committee;[14] that the authority for exemptions from Section 4 has al-

[11] News Release, Sen. Warren G. Magnuson, October 14, 1966.

[12] *Congressional Record,* October 19, 1966, pp. 26563-26564.

[13] *The Evening Star,* Washington, D. C., October 6, 1966, p. A-14.

[14] Report 2286, House of Representatives, Servings, p. 10.

ways been a part of Section 5;[15] and, most importantly, note Section 2 which states that "packages *and their labels* should enable consumers to obtain accurate information as to the quantity of their contents *and should facilitate value comparisons.*" Therefore, Section 4 is *not* unimportant. It is a part of the device in the Act to foster "value comparisons."

The first question about Section 4 is: When does it become effective? Section 13 states that the Act shall take effect on June 1, 1967, provided that the effective date may be postponed with respect to particular consumer commodities for an additional 12-month period on the basis of a finding that such a postponement would be in the public interest.

Effective Date of Section 4

Therefore, it is necessary to look at what provisions in Section 4 may become effective on July 1st of 1967, and at whether there could be any review of the determination of a government agency to postpone, or, more significantly in this case, not to postpone upon request the effective date of the Act, because of the requirement that the postponement would have to be in the public interest. On this point, consider the recent decision of a three-judge Federal court in the case involving the 1963 merger of the Crocker-Anglo National Bank of San Francisco and the Citizens National Bank of Los Angeles. In its opinion, the court said that the determination of whether a merger is in the public interest was beyond judicial authority, and essentially an administrative or legislative decision.[16]

The next question is whether there are any provisions of Section 4 which become effective on July 1, 1967. Section 4(a) prohibits persons from distributing consumer commodities in commerce unless in conformity with regulations which "shall be established" by the appropriate government agency. So regulations are necessary before Section 4(a) comes in effect. However, Section 4(b) says simply: "No person subject to the prohibition contained in Section 3 shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or phrases appear in conjunction with the separate statement of net quantity of contents required by subsection (a) . . ."

Section 4(b) does not mention regulations, so is the prohibition in Section 4(b) effective upon the effective date of the Act? If so,

[15] S. 985 (P. L. 89-755); Exemptions, Section 5(b).

[16] *U. S. v. Crocker-Anglo National Bank, et al.*, D.C.N.D. Cal., Civil No. 41,808 (CCH TRADE REGULATION REPORTER, ¶ 71,898).

conduct in violation of Section 4(b) is unlawful from that time forward. However, note that the prohibition in Section 4(b) is directed to "qualifying words or phrases . . . *in conjunction with* the separate statement of net quantity of contents" which is required by Subsection (a) to be in conformity with regulations. Can you continue to use a qualifying word or phrase in conjunction with a statement of net quantity of contents after July 1, 1967, until such time as regulations are promulgated concerning the separate statement of net quantity of contents required by Section 4(a)?

Provisions for Stating Quantity and Identity of Commodities

Consider next the requirement in Section 4(a) that the identity of the commodity must be stated. Will the regulations issued by the agencies provide for an exception in those cases where the commodity is easily identified through the wrapper, as the Model State Regulations do?[17] How about the requirement that the net quantity be "accurately" stated? Will reasonable variations be permitted? The Model State Law specifically allows such variations, but the Federal Act does not contain a comparable provision.[18] Furthermore, in view of the statement in the House Report that the dual standard of weights was adopted to "facilitate the computation of costs per ounce,"[19] it would appear that any standard of "reasonable variation" which permitted variations greater than the variation in cost per ounce between competing products would run the risk of failing to meet the intent of Congress in providing for the dual weight statement.

The requirement that the net quantity of contents be stated "in a uniform location"[20] on the label has caused perhaps the greatest concern up to this time, due to uncertainty as to whether the agencies will interpret the provision as requiring a uniform location on all labels and containers, regardless of their shape. In effect, this could regulate out of existence any shapes of containers or labels which do not permit the statement of net quantity to be in the required "uniform location."

The requirement that net quantity be stated in both ounces *and* pounds and ounces applies only if the quantity is stated in terms of weight or fluid measure.[21] A question can be raised as to whether

[17] Model State Regulation Pertaining to Packages, as amended through 1965, Section 3.1. See also, Model State Law, Section 26.

[18] Model State Law on Weights and Measures, as amended through 1965, Section 26.

[19] House Report 2076, p. 11.

[20] S. 985 (P. L. 89-755), Section 4(a)(2).

[21] S. 985 (P. L. 89-755), Section 4(a)(3)(A)(i).

this provision would apply if the quantity is stated in terms of dry measure, such as a fraction of a bushel, or a measuring cup. If so, the manner in which the net quantity is stated can determine whether or not a particular package is covered by this provision, and a manufacturer could avoid the consequences of the provision merely by stating the net quantity of contents in dry measure.

On the other hand, the provisions relating to packages labeled in linear measure and area measure are far more inclusive because they apply regardless whether the quantity in the package is small or large. There is no cut-off comparable to "4 lbs. or 1 gallon." Therefore, the net quantity of contents of every package labeled in terms of linear measure or area must be stated both in inches (or square inches, as appropriate) *and* in terms of the largest unit of yards (or square yards), or feet (or square feet).[22] Where a large quantity is involved, this may produce some astounding figures in terms of inches, unless such a statement of quantity has been customary in the trade. It is also noteworthy that the 100 ft. ball of twine will be a thing of the past because 100 feet will not be an authorized measure of length. Instead, the quantity must be stated as 1,200 inches and as 33 yards and 1 foot.

The requirement that the statement of ounces must contain an "identification as to avoirdupois or fluid ounces" has become of substantial importance to the packaging industry.[23] The question has been raised in the case of packages where there can be no ambiguity, as to whether it is necessary to identify the ounces as avoirdupois, as well as whether it is necessary to spell out the full word "avoirdupois." This provision requiring the insertion of the word avoirdupois on such labels would be extremely expensive to the consumer because it would require a change in the printing plates and designs of almost every label.

A number of other problems also arise with respect to the statement of net quantity. For example, is the area of tissues sold in two-ply form to be doubled because there are actually two thicknesses?[24] Will a statement of quantity such as "not less than 10 oz." be permitted, as it is by the Model State Regulations?[25] Is a standard measuring cup a permissible form of fluid measure in view of the fact that the Act refers only to quarts and pints?[26] Will the regula-

[22] S. 985 (P. L. 89-755), Section 4(a)(3)(A)(iii) and (iv).

[23] S. 985 (P. L. 89-755), Section 4(a)(3)(A)(i).

[24] S. 985 (P. L. 89-755), Section 4(a)(3)(A)(iv).

[25] Model State Regulation, Section 3.8.

[26] S. 985 (P. L. 89-755), Section 4(a)(3)(A)(i).

tions issued under the Act require, permit or prohibit the inclusion of the weight of the propellant in the statement of net quantity on an aerosol container?[27]

Provisions for Type Size

There are equally hazy areas with respect to the printed matter on the label. The Model State Regulations require that the statement of quantity be "boldly presented."[28] It is not clear whether this will be the same or a different standard than "in conspicuous and easily legible type" required by the Federal Act.[29] While this problem can be dealt with by specific regulations, the next phrase which requires the statement of quantity to be set out "in distinct contrast . . . with other matter"[30] will have to be determined on almost a case-by-case basis because of the many color combinations.

It is not yet clear what meaning will be placed on the statutory provisions with respect to type size. The Act requires that they "be (i) established in relationship to the area of the principal display panel of the package, and (ii) uniform for all packages of substantially the same size."[31] Is this a direction to the regulatory agencies to take into account *only* the area of the display panel, or may consideration also be given to the shape of the display panel? It is possible that this provision could result in requiring the principal display panel to be uniform in area for all packages of substantially the same size, regardless of the commodity enclosed. This could come about because type size is not only established in relationship to the area of the display panel but must be uniform for all packages of substantially the same size; therefore, reasoning back, all packages of the same size may have to have the same size type, which will require a display panel of a given area. This provision is to be contrasted with the provision in the Model State Regulations which relates type size only to the area of the principal display panel.[32]

Stating the Net Quantity of Each Serving

One of the few changes made in the House-passed bill by the Conference Committee was to move to Section 4 from Section 5 the provision which requires the net quantity of each serving to be stated if the label of a package states the number of servings in the pack-

[27] Compare Model State Regulations, Section 3.2.

[28] Model State Regulations, Section 6.4.2.

[29] S. 985 (P. L. 89-755), Section 4(a)(3)(B).

[30] S. 985 (P. L. 89-755), Section 4(a)(3)(B).

[31] S. 985 (P. L. 89-755), Section 4(a)(3)(C).

[32] Model State Regulations, Section 6.5.

age.[33] Where the commodity in the package is the commodity which will constitute the serving, compliance with this provision may not be difficult. However, take the case of stuffing mix. Other ingredients must be added to that stuffing mix, and the actual serving itself also comprises a portion of fowl. How is the net quantity of that serving to be stated: in the weight of the stuffing mix per serving, the weight of the stuffing mix and other ingredients per serving, or the weight of the stuffing plus the fowl per serving? It will be necessary for the packaging industry to consider carefully whether provisions of this Act will permit the printing of recipes on the package where the recipe includes a statement of the number of servings that are to be prepared from the commodity contained in the package, unless the weight of the serving is also given in each case.

The provision in the Federal Act with respect to random packages is treated quite differently from the comparable provisions in the Model State Law.[34] The principal use of this provision in the Model Law is to require that if a number of similar items of varying weight are packaged together and the total price is stated, then the price per ounce must also be stated.[35] If that is meant to be the purpose of the random package provision in the Federal Act, then the purpose is not clear. That provision was added in the House and the House Report states that it was inserted "in order to accommodate computerized automatic weighing machines,"[36] but it provides only that the weight of a random package may be expressed in terms of pounds and decimal fractions, which does not achieve the same results as the Model Law.

Importance of Clarity in Labeling Provisions

In what ways are these uncertainties with respect to the labeling provisions important? There are several points to be considered.

Take the difference between a "package" and a "label." They are separately defined in Section 10. "Package" means container or wrapper in which a commodity is enclosed. "Label" means any written or printed matter affixed to any consumer commodity. Now turn to Section 6(d), which provides that no regulation under the Act shall preclude the orderly disposal of packages in inventory or with the trade as of the effective date of such regulation. This should include packages, and labels which have already been affixed to the packages, but does it include an inventory of labels, thousands upon

[33] S. 985 (P. L. 89-755), Section 4(a)(4).
[34] Model State Law, Section 27.
[35] Model State Law, Section 27.
[36] House Report 2076, p. 11.

thousands of them stored in warehouses? The answer to this is probably that it does not. If the labeling provisions were clear and specific, this would not be important because it would be a simple matter to make any necessary changes in labels in advance and avoid having a substantial inventory of non-complying labels.

Now, for example, consider that provision: "in a uniform location upon the principal display panel of that label."[37] Who knows what "uniform location" will finally be selected? Will it be the same for all consumer commodities? Will the uniform location be different for rectangular labels than for triangular labels or round labels?

As it is not likely that any major manufacturer can afford to operate with a very small supply of labels in order to avoid having a large inventory of labels on hand when the determination of uniform location is finally made, it is probable that many manufacturers will have substantial inventories of labels which may not comply with the regulations. Section 6(d) will raise the question of whether the statute permits any flexibility in the administration of the Act to permit the orderly disposition of labels under such circumstances. A giant guessing game may occur if the agencies construe the Act as preventing them from delaying the effective date of the regulation in order to permit such orderly disposal of labels, on the ground that Congress made the label provisions mandatory, although it could have provided for an orderly disposition of labels as it had provided for an orderly disposal of packages.

The administration of this Act is divided between the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA), each with its own authority to promulgate regulations on the same topic but for different consumer commodities.[38] Will this lead to chaos or can some system be devised for appropriate uniformity in the regulations of the two agencies?

What will be the effect of this Act on the Model Weights and Measures Laws and regulations of the States? Section 12 of the Act declares that it is "the express intent of Congress to supersede any and all laws of the States or political subdivisions thereof insofar as they now or hereafter provide for the labeling of the net quantity of contents of the package of any consumer commodity covered by this Act which are less stringent than or require information different from the requirements of Section 4 of this act or regulations promulgated pursuant thereto." It is not difficult to determine whether

[37] S. 985 (P. L. 89-755), Section 4(a)(2).

[38] S. 985 (P. L. 89-755), Section 5(a).

the information required by this Act is "different from," but what does "less stringent than" mean? Will it be possible to conform the State laws and regulations to the Federal laws and regulations so as to continue to give validity to State uniform laws?

Section 6(a) requires regulations promulgated by the Secretary of Health, Education and Welfare under Sections 4 and 5 of the Act to be promulgated pursuant to the provisions of Section 701 of the Food, Drug and Cosmetic Act. Does this also apply to the finding which is necessary under Section 5(b) before the Secretary can promulgate regulations exempting a commodity from the requirements of Section 4?[39]

An interesting question arises from the requirement in Section 4 for across-the-board regulations for all consumer commodities under the Act.[40] Will it be possible for the FTC and the FDA to develop regulations applicable to *all* commodities of *all* varieties with *all* types of labels in a *wide* range of sizes and still be sufficiently specific? Or will the agencies, in order to deal with such a broad problem, treat it in generalities, and thus leave industry to proceed at its peril?

Problems of Section 5

Section 5 has its own set of problems. It contains a provision permitting federal government agency regulation of size characterization.[41] Will the FDA and the FTC be as generous as the Agriculture Department, which recently issued a regulation classifying green olives Subpetite, Midget, Small, Medium, Large, Extra Large, Mammoth, Giant, Jumbo, Colossal and Super Colossal, in that order?[42] Equally important, whose "large" size will become the standard large size, and so on?

One of the more intriguing provisions in Section 5 authorizes the agencies to make regulations "to prevent non-functional slack-fill of packages containing consumer commodities."[43] Slack-fill is defined in the statute as filling "to substantially less than its capacity for reasons other than (A) protection of the contents in such packages or (B) the requirements of machines used for enclosing the contents in such packages."[44] Suppose the "requirements" of machines used by one company are different from the requirements of

[39] S. 985 (P. L. 89-755), Section 5(b).
[40] S. 985 (P. L. 89-755), Section 4.
[41] S. 985 (P. L. 89-755), Section 5(c)(1).
[42] *Federal Register*, November 4, 1966, p. 14250.
[43] S. 985 (P. L. 89-755), Section 5(c)(4).
[44] S. 985 (P. L. 89-755), Section 5(c)(4).

machines used by another company for the same enclosing function? Suppose one company packages a breakfast food in a plastic pack while its competitor packages substantially the same item in a box? How will the agencies deal with these problems in regulations applicable to the same commodity marketed by many manufacturers? Further, does the statutory definition of slack-fill cover settling, moisture absorption, hand packaging space requirements and similar problems?

Then there is the ingredient provision which requires the listing of the common or usual name of each ingredient in order of decreasing predominance in commodities other than food.[45] It could be that each person has a different idea of what "decreasing predominance" means. Does it mean predominance by weight, by quantity, by dollar value, or by benefit to the consumer? Does it include inert as well as active ingredients? Then, too, how long will the list of ingredients be with respect to those commodities which contain many ingredients with polysyllabic names? If the agencies do not require too large a type size, it might be possible to get all the names on a 20 pound box, but how about on a tube of lipstick?

Consider the "cents-off" provision. Does the power to regulate include the power to prohibit, as indicated by the House Report, or not?

Under the voluntary standards provision, what is the Secretary of Commerce to use as his basis for determining whether or not there is "undue proliferation" of the quantities in which any consumer commodity is offered for sale, and what should be considered as "reasonably comparable consumer commodities" which are also to be included in his determination?[46]

Meaning of "Value Comparison"

This leads, of course, to one of the most intriguing points of the entire bill—what does "value comparison" mean in the declaration of policy, and elsewhere? Senator Hart told the Senate on October 19, 1966, that this declaration of policy may be "as significant as the provisions of the legislation itself." He suggests that "it opens the door to consideration of legislation such as grade labeling and government testing of consumer products."[47] Two days later, on October 21, 1966, the Congressman who offered this amendment, Representative Gilligan, told the House that:

[45] S. 985 (P. L. 89-755), Section 5(c)(3).

[46] S. 985 (P. L. 89-755), Section 5(d).

[47] *Congressional Record*, October 19, 1966, p. 26564.

I find myself in disagreement with the distinguished Senator from Michigan, however, over his interpretation of the House amendment changing the phrase 'price comparison' to 'value comparison' in the statement of policy and elsewhere throughout the act.

Then Representative Gilligan went on to say:

Obviously what constitutes value is highly subjective. It is a decision that must be made by each individual and is a personal judgment of the kind the Federal Government is ill-equipped and should not be asked to make for the consumer. In sponsoring the change from price comparison to value comparison it was never my intention to intrude the Federal Government into quality determinations, or grade labeling and government testing of consumer products, as Senator Hart has suggested.[48]

Problems for Industrial Solutions

The differing appraisals of the Hart bill, as it was passed, will greatly complicate the task of those in corporate offices and law offices who must determine in the near future the type and extent of any action which must be taken to comply with the law. Although this article raises many questions, it does not mean that there are no answers to the questions, but only that the answers have not yet been determined. To determine the answers will require the combination of a close familiarity with the intent of the Congress as it dealt with this legislation and a full gathering of all the relevant facts.

This is not a task which can be deferred with prudence. As he signed the bill into law, the President said:

We are going to put this law to work right away. I am directing John Conner, the Secretary of Commerce, to proceed immediately to call in those industries where the Congressional hearings have shown protection to be the most needed.[49]

The FTC and the FDA also are already working on the implementation of their authority. The extent of their activity and the degree to which it is coordinated may pose serious problems for industry if industry is unprepared.

In looking ahead, industry might also consider the prospects for additional government controls in this area. On this point, Senator Magnuson, the Chairman of the Senate Commerce Committee, has said:

The Senate conferees have accepted the House version of the Fair Packaging and Labeling Act. We did so with great reluctance . . . the House was adament in its position. It would not compromise even on minor issues.

[48] *Congressional Record,* October 21, 1966, p. 27536.

[49] *Presidential Documents,* November 7, 1966, p. 1599.

We need a strong packaging provision, . . . It is regrettable that the House failed to recognize the need for and the importance of the Senate provision on package standards.[50]

In a news release Senator Magnuson also said:

The interests of the American consumer have been too long subordinated to the interests of special groups. The American consumer today has its champions in the Congress. The Commerce Committee will vigorously pursue legislation in the next session of Congress to enact a comprehensive and meaningful packaging bill.[51]

And Senator Hart said at the close of his statement to the Senate:

True, it is a beginning, not an end—but it is a proud beginning.[52]

A beginning of what? Is it a beginning of the route suggested by the Honorable Wilbur J. Cohen, Under Secretary of the Department of Health, Education, and Welfare, when he testified at the House Commerce Committee hearings:

I think you are absolutely correct when you talk about eliminating or removing the confusion that this bill does not do that in 100 per cent fashion.

I think you are absolutely correct that that cannot be completely done unless in addition to this bill you were to have price regulations per ounce or per unit and unless you had quality determination . . .

I think this [bill] takes a step, a large step, not a complete step in that direction, but to take the ultimate step, I think you would have to absolutely regulate price per unit. You would have to determine what, and I think that at this time would be undesirable, so I hope that the point that you made would not mean that something that is good and in the right direction could not be achieved unless we reach the millenium all at once, and I don't see that we can do that.[53]

The fact that consideration is being given on this level of government to additional government controls in this area makes industry's response to the Fair Packaging and Labeling Act of great significance. This is particularly true concerning the course of action which industry takes in respect to voluntary standards. Should industry wait until the Secretary of Commerce acts under his powers, which become effective July 1, 1967? If so, should industry willingly accede to the Secretary's requests for voluntary standards, regardless of the scope or direction of the Secretary's requests, or should it take a positive position of its own? Or, on the other hand, should industry take its own steps to implement voluntary standards before the Secretary of Commerce acts?

---

[50] *Congressional Record,* October 19, 1966, p. 26562.

[51] News Release, Sen. Warren G. Magnuson, October 14, 1966.

[52] *Congressional Record,* October 19, 1966, p. 26565.

[53] *Hearings on H. R. 15440,* S. 985, House of Representatives, Committee on Interstate and Foreign Commerce, July 28, 1966, pp. 181-182.

There are many questions concerning possible anti-trust implications in taking any of these courses of action. Even more important, there are substantial competitive problems which must be dealt with because any voluntary standard which reduces "proliferation" is likely to have serious adverse consequences for those members of the industry who are "standardized out."

But the most important question is the one industry must answer in order to make a decision concerning the steps which it must take to minimize or avoid the possibility of future adverse legislation or executive branch action in this area. The answer to this, as to the other questions, requires a careful and thorough development of the facts, a knowledge of the various proposals and arguments considered by the agencies and the Congress in the course of this legislation, and an understanding of the goals which those in the government seek through government involvement in this area. **[The End]**

FDA DEFERS VITAMIN REGULATIONS

The Food and Drug Administration has deferred the new Federal regulations on special diet foods and diet supplements. They were to become effective on December 15, 1966. A public hearing has been scheduled for early 1967.

The FDA announced several revisions in the regulations and proposed standards for three other classes of fortified foods—certain frozen dessert products, milk fortifiers and meal substitutes. The revisions include the modification of Recommended Dietary Allowances, which will replace the 25-year-old "minimum daily requirements," and the expansion of the table of Recommended Dietary Allowances to list separate nutritional allowances for infants, children, adolescents, adults, and pregnant or lactating women. The labeling and/or content of special diet foods and vitamin and mineral supplements were also revised. Other changes include the elimination of infant formulas, infant cereals and alimentary pastes from the list of vitamin and mineral-fortified food products.

The Packaging Industries and the Food Additives Amendment of 1958—It's Time for a Change in the Law

By JEROME H. HECKMAN

The Following Article Was Presented at the American Chemical Society Symposium on Safety Evaluation of Coatings and Plastics for Food Packaging in New York City on September 14, 1966. At the Time of Presentation It Was Entitled "Legal Status of Coatings and Plastics for Food Packaging." Mr. Heckman Is with Keller and Heckman of Washington, D. C.

MY PRIMARY AIM WILL BE to give you one lawyer's view of the impact of present Food and Drug Administration (FDA) regulation on those who manufacture and sell food packaging materials and food processing equipment, or components thereof.[1] This paper is a critique. It takes direct issue with the concept of the Food Additives Amendment of 1958 as it relates to packaging materials. Further, it poses the question of whether or not far too much government and industry time, and scientific attention, is being diverted from true public health problem areas by an unnecessarily restrictive and complex regulatory scheme for passing on the safety of packaging materials components.

Since the area of regulation at hand has its genesis in the Food Additives Amendment of 1958—the only law Congress has thus far passed giving the Food and Drug Administration direct regulatory

[1] In the remainder of this paper, reference is made only to packaging materials in most instances. This is simply a "shorthand" device; it is to be understood that, with rare exceptions, what is said about packaging materials regulation is applicable to the regulation of processing equipment where food contact is anticipated.

authority over packaging materials as such[2]—I will focus on the 1958 law and the regulatory scheme it has brought into being. There will be some mention of other agency regulations and the laws of other countries, but only as they relate to the Food Additives Amendment and its administration by FDA.

First, about all that can be safely said concerning the legal status of coatings and plastics food packaging materials is that most plastics and coatings substances now in use are either covered specifically under applicable FDA regulations, or are "exempt" from application of the special clearance requirements of the law because they may not reasonably be expected to become components of foods, or are "prior sanctioned" or "generally recognized as safe." Those old or new substances not already covered by Food Additive Regulations, or excluded by law from the necessity for such coverage are probably the subject of pending food additive petitions or intra-company soul-searching to decide whether or not the "flame is worth the candle."

While this two-sentence status observation is accurate enough, it is an almost valueless generalization. The status of every formulation really depends on the specific substances involved and all relevant facts about the precise nature of a composition and its intended use. Furthermore, a practical status analysis of a particular product requires reasonably close familiarity with a substantial portion of the hundreds of pages of FDA's Food Additive Regulations; an even closer acquaintance with the vagaries of FDA's policies where so-called "incidental additives" are concerned; and an appreciation of what the marketplace requires in the way of assurances to customers

[2] FDA does exercise considerable authority in the drug and cosmetic packaging materials fields, but unlike the case of food packaging materials, FDA does not "clear" drug or cosmetic packaging components by special regulations which are *sui generis,* and wholly direct. It regulates drug packaging only indirectly in passing on specific New Drug Applications where the packaging is considered in relation to how it might affect the drug. See, for example, Earl L. Meyers, "The Food and Drug Administrations Role in the use of Plastic Materials," presented at the American Association for the Advancement of Science Interdisciplinary Symposium in the Medical Sciences: Materials Science in Dentistry, Medicine and Pharmacy, University of California, Berkeley, California, Dec. 29, 1965.

As regards cosmetics, FDA exercises even less direct control since cosmetics themselves are subject only to FDA policing action, as, for example, where they are found to be misbranded.

Thus, little of what is said in this paper is properly applicable to the other major economic areas FDA regulates. The agency may be the same, and some important scientific and regulatory principles it employs may be pervading, at least for packaging materials suppliers; but the legal concepts and practical problems involved are significantly different.

that a substance is suitable for use in food packaging or processing applications.

Because marketplace requirements are often more demanding than the law itself, I will use them as both a jumping-off point and something of a touchstone for this paper. This approach, like all others, will leave important gaps in coverage, but it should at least provide a more down-to-earth framework for a discussion of my understanding of the law and the impact of its implementation by FDA to date.

Problems and Procedures Prior to 1958 Food Additives Amendment

Long before consideration of any type was given to the enactment of specific legislation to require some type of clearance of food packaging materials, those companies who were anxious to supply containers or implements for use in food contact applications were, as a practical matter, required by their food industry customers to provide reasonable assurance that the use of their products would not present any undue hazard of civil or criminal liability in the ordinary course of events. Thus, for example, the federally inspected meat plant insisted upon assurance that the use of a food contact material would not give rise to any difficulty with the Meat Inspection Division of the Department of Agriculture. Further, food processors had to be convinced that the use of a new package could not reasonably be expected to adulterate their products so that they might somehow be charged with a violation of the adulteration or misbranding provisions of the Federal Food, Drug and Cosmetic Act. These prospective customers were also keenly aware of the necessity for protecting themselves against potential civil liability for use of food contact materials that might in some way contaminate foods.[3]

It was immediately obvious to the package supplier, and to his customers that one very worthwhile way of "killing the two birds" of regulatory compliance and potential civil liability with the proverbial "one stone" might be to secure a written opinion of the ap-

[3] The most difficult problem usually faced by packaging suppliers today is not so much assuring themselves that the sale of a material will not create jeopardy of prosecution under federal law; it is the problem of being unable to sell products to customers without providing an acceptable type of assurance that use of a given package or component will have something tantamount to "federal approval." Often, under the guise of insisting on such assurance, customers try to demand from their packaging material suppliers all-encompassing guarantees, or similar written commitments approaching "insurance policies" against potential civil liability or criminal prosecution.

propriate federal authorities as to the safety of a packaging material or component for its intended use. It should be clearly understood that, until 1958, no law required any type of packaging materials pre-clearance; therefore, submitting data to federal officials and soliciting their reactions was a completely voluntary matter. The practice was, however, exceptionally widespread; almost all responsible companies followed it long before 1958.

Fortunately, the always highly-respected, competent scientific authorities in such agencies as the Meat Inspection Division of the Department of Agriculture, and the FDA, agreed that their statutory obligation to operate with public interest, convenience and necessity in mind made it appropriate for them to provide dispositive opinions in writing on data submitted to show the suitability of a material for a proposed application. Indeed, to this day, industry owes a great deal to such men as Mr. R. H. Philbeck of the Meat Inspection Division (MID) of the Department of Agriculture (now the Laboratory Branch of the Technical Services Division of the Department of Agriculture's Consumer Marketing Service), and Dr. Arnold Lehman of the Food and Drug Administration, for the objective, yet efficient way in which they handled requests for their opinions on the suitability, from the public health standpoint, of packaging and processing materials for food contact applications.

Because of this enlightened attitude of these agencies, a company manufacturing a chemical component or a packaging formulation to be used in a food contact application was able to submit all of the relevant information about its product to MID or FDA, and obtain a response setting forth the views of the agency on the proposed use.

"Acceptance" or "No Objection" Letters

Procedurally speaking, this regulatory activity before 1958 was generally informal. What happened is that a company submitted its data, perhaps after conferences with the appropriate government officials, and then received advice as to whether there was any objection to the proposed use, or whether additional data might be required. If more information was deemed necessary, it was supplied and, ultimately, once questions bearing on safety were resolved, the manufacturer received a letter or letters from the FDA, or the MID, or both, depending on who was asked. A typical MID letter would advise that a product would be deemed "acceptable for use in federally-inspected meat plants"; an FDA response would indicate that

the Food and Drug Administration "would raise no objection" to the use of the product in food contact applications.

In the opinion of many (including some present FDA staffers and the author of this paper) the pre-1958 approach and procedures used were, for the most part, far sounder than the present day counterparts employed by the FDA. Essentially, the old approach, although informal and voluntary, could be considered to constitute a type of "licensing," as distinguished from "rule-making," in the language of Administrative Law. All that FDA or MID were asked to pass upon was whether a very specific mixture or chemical compound, destined for a well-defined range of food contact applications, would be considered safe for such use. To obtain the desired response, considerable or very little data might have to be supplied, depending on the precise circumstances relevant to the specified packaging material. For example, if a mixture was described, and it was shown that no chemical compound of questionable toxicological status could be expected to migrate to foods *from the packaging material as it was actually made,* and in the intended use, "no objection" letters could be obtained rather readily. If migration of a chemical compound of unknown status was to be expected, satisfactory toxicological data might have to be secured first. The important thing, however, was that FDA was only being asked to give a very limited opinion on a very specific product made by a manufacturer who was "before the agency," and was ready, willing, able *and volunteering* to supply it with all information required for a complete opinion *on his product only.*

At this time before 1958, FDA was not attempting to devise "rules" or "regulations" of transcendentally broad application designed to give the "green light" to anyone who might make a product known by the same generic name as that used by a manufacturer who voluntarily asked for an opinion on his product. Thus, regardless of the amount of data the manufacturer might need to supply to demonstrate safety of his chemical compound or mixture—be it great or small depending on the precise factual setting involved—at least he was not called upon to guess at how someone else might make and/or market the product. Further, neither he nor FDA were forced to contrive complicated regulatory criteria or exotic test methodology as control devices to assure that some less scrupulous, or irresponsible company would not have a federal rule or regulation upon which to base sales of an unsafe compound or mixture.

Undoubtedly due to the fact that this sort of "rifle" instead of "shotgun" evaluation was all that was necessary at the time, obtaining letters of "no objection" from the Food and Drug Administration was not an inordinately time-consuming or expensive matter in the ordinary case. Where extensive delays took place, it was invariably due to the fact that there was a real need for additional scientific information to provide the necessary assurances of safety, about which the agencies were understandably scrupulous.

It is important to note here that this type of informal procedure is still employed very satisfactorily by the Department of Agriculture where a material is to be used in a federally-inspected meat or poultry plant. Thus, in most instances Department of Agriculture letters on the acceptability of a food contact material for use in a federally-inspected meat or poultry plant may still be obtained within a month or less by any manufacturer who supplies proper and complete data relating to his particular product. The same is, incidentally, true in Canada for all food contact applications since the Canadians, in enacting their basic food additives regulations long after our law became effective in 1958, specifically exempted packaging materials from the type of regulation imposed on direct food additives.[4]

When the company which sought the opinions of FDA or the Department of Agriculture prior to 1958 did receive its "acceptance" or "no objection" letters, it was in a position to move ahead on the sales front. The great virtue of having such letters was that they served to provide food processor customers with the type of assurance they desired to allay their fears about possible government agency enforcement action or civil liability. The customer had the assurance that the government would not consider food products adulterated or misbranded because of the use of the packaging or processing material involved, and had the further assurance that if anyone brought a product liability suit against him, he would have in his defense arsenal a federal government finding that the product was considered to be safe for the intended use.[5]

[4] See Canadian Food and Drug Regulations, Section B.01.001(d)(v). It might well he said that the Canadians wisely recognized that food additives and packaging materials are simply not the "same breed of cats" and should not be admixed in a regulatory scheme, or even by the use of confusingly similar names such as "direct" and "indirect" food additives.

[5] See *Joseph H. Lewis v. Martha Baker, d/b/a Baker's Pharmacy and Richardson-Merrell, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5546 (Ore. S. Ct. 1966). Here is an excellent example of how very valuable an appropriate government agency finding on the safety of a product can be. In this case it was held that a drug manufacturer

(Footnote continued on next page.)

Actually, although this was not foreseen, the pre-1958 "Lehman letters," as the FDA "no objection" communications came to be called, were even more valuable than the recipients could possibly have known at the time. Their vital importance and great value was to become apparent only during and after the deliberations which led to the enactment of Public Law 85-929, the Food Additives Amendment of 1958, since the Lehman letters ultimately became the main basis for the "prior sanctioned" exemptions from the operative provisions of the law. This will be further explained below.

First, let me raise and comment briefly on the obvious question of why, if this system was working so well, was there any necessity for a change as far as FDA was concerned? Frankly, this is a question for which I, too, would like to have a valid answer. To this day my own feeling is that the so-called "informal system" whereby specific products or chemicals were given acceptable status was one of the best that could be devised. Indeed, it is noteworthy that our own Department of Agriculture and the Canadian government, despite the change which took place in the FDA regulatory scheme beginning in 1958, or perhaps because of the apparent deficiencies brought into the spotlight by FDA's administration of the Food Additives Amendment, have continued to regulate packaging materials in the same way as before Section 409 of the Federal Food, Drug and Cosmetic Act was adopted.

Delaney Hearings Lead to 1958 Amendment

The only rationale that can be advanced in a sensible way for FDA's move towards its present very restrictive regulatory scheme is historical, and flows from the so-called Delaney Hearings held from 1952 to 1956. These Hearings pointed up an FDA-avowed need for some new regulatory mechanism which would require "pre-clearance," that is, approval prior to use, of the amorphous classification of substances designated very unscientifically as "Food Additives." The entire record of the Delaney Hearings and FDA's expressions of pre-1958 experience dealt only with substances directly and intentionally added to foods, to the best of my knowledge. Yet the avowed necessity for new regulatory authority to control the intentional and

(Footnote 5 continued.)
could not be held strictly liable for a disability allegedly caused by its product at a time when the product had been found and was held by FDA to be reasonably safe for its intended use. The Court said strict liability principles were not applicable even though the FDA approval had been withdrawn on safety grounds before the suit was filed and tried.

direct addition of various chemicals to foodstuffs led the FDA to convince Congress that packaging and processing materials should be regulated in precisely the same way as substances deliberately added to foods.

The legislative path which led to the adoption of the Food Additives Amendment of 1958 was not unmarked by packaging industry warnings against the "indelicate" application of the proposed new food additives pre-clearance law to so-called "incidental additives" situations.[6] Indeed, I recall very vividly an appearance made with the Chairman of the Food Packaging Materials Committee of The Society of the Plastics Industry, John Kuniholm, to fervently urge the House Committee which considered the Food Additives Amendment proposals in 1956 and 1958 *not* to apply the same law to incidental additives.[7] Others also tried to dissuade Congress from an uninformed adoption of the FDA recommendations. We felt then, and I still feel, that FDA insistence on the same regulatory scheme for direct and indirect food additives was and is a serious mistake.

Unfortunately, we were unable to prevail in making the necessity for a distinction between the two classes of things FDA called "additives" understood, and the legislative "bandwagon," or perhaps I should say "combine," rolled in and scooped up incidental additives as soon as the leading chemical industry trade association, Manufacturing Chemists Association (MCA), gave its support to a slightly revised version of the Food Additives Bill sponsored by FDA. All during the legislative process, the Food and Drug Administration had insisted that no distinction should be made between substances intentially added to foods, and substances which might possibly find their way into foods as a result of migration from food packaging or processing materials. The superficially logical appeal of this position left no satisfactory means of convincing Congress that the problems in the two areas were substantially different and should not be treated in the same way. Perhaps industry and we lawyers should rightfully acknowledge a share of the blame here. I am afraid that we did not know enough at the time to call on you chemists to tell us and the Congress more about the impossibly speculative type of work you would have to do when FDA began to look for ways to prescribe

[6] *Statement of John G. Kuniholm on Behalf of The Society of the Plastics Industry, Inc.;* Hearings Before A Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, Eighty-Fifth Congress, On Bills to Amend the Federal Food, Drug and Cosmetic Act With Respect to Chemical Additives in Food, (Pages 145-152).

[7] See footnote 6.

"practical analytical methods" to determine how much of an "incidental additive" actually will get into a food, or the diet. We had no way of really understanding how critical, yet impossible this might be. Nor did we anticipate the type of almost unreasoning interpretation of the law by which one can now be required to do extensive toxicological work on a chemical compound if it appears that more than .01 parts per million of the compound may be found in a so-called food simulating solvent.[8] The type of practical regulatory experience we have *now* had might have been invaluable in arguing more convincingly for separate treatment of packaging materials on the Hill. Indeed, the day may yet come when a courageous effort to re-open the subject may be undertaken within the framework of this experience.

Events Since 1958 Amendment

In any case, in 1958 the Food Additives Amendment became a "fact of life," and the packaging industries embarked upon a new era of FDA involvement. Confusion reigned from the very beginning. Once it had its legislative mandate, the FDA was faced with the necessity of deciding how it would handle the myriad number of critical regulatory details. Could an orderly process be developed to bear out its original representations to Congress that the Food Additives Amendment would have only minor impact on food packaging material suppliers? Would the Food Additives Amendment truly find its major application in providing FDA with an effective tool for making certain that no intentional "food additives" were being unsafely poured into our food supply?

Among the matters FDA was forced to deal with in the food packaging area were the subtleties of how to interpret the basic

[8] See "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions" p. 8 available from the Food and Drug Administration Office of Public Information. A discussion of the true significance of finding the equivalent of 0.01 ppm of something extracted from a food packaging material in a solvent (which admittedly exaggerates food extraction capability severely) is beyond the scope of this paper or the competence of the author. It is suggested, however, that this might well be a fit subject for a chemist's evaluation in a separate treatise since, in most instances today, unless a manufacturer can show extraction of less than 0.01 ppm from a mixture or compound, he will be required to supply reports on two-species 90 day animal feeding studies to bring about issuance of a Food Additive Regulation for his compound. Even where the 0.01 ppm extraction might be of something other than the compound he seeks to clear (as where the extraction work is necessarily performed with a combination of cleared and uncleared materials such as a plasticized film), unless he can demonstrate that it is, it will be presumed that the extraction is of the uncleared material, and a request for toxicological data will probably be made by FDA.

"exemption" clauses built into the Food Additives Amendment. FDA had included certain "grandfather" or exemption clauses in H. R. 6747, the Food Additives legislation it successfully sponsored. However, it was generally understood that it did so with misgivings and that the clauses were provided primarily at the urging of industry which was understandably anxious to place some rational limitation on what would have to be FDA "cleared" by the Food Additive Petition-Broad Regulation issuance route. Thus, almost from the beginnings of the legislative activity everyone agreed that the coverage of the law should eliminate the need for Food Additive Regulations on substances which might not reasonably be expected to migrate to foods;[9] the arguments over this area were mainly as to the language to be used in the law. Also, the law was written to express a Congressional intent to provide similar exemptions for substances which were "generally recognized as safe" for their intended use by competent experts in the scientific world, and to exclude from the requirement for regulation coverage all materials which were "prior sanctioned," that is, previously held to be acceptable for use in their intended applications by means of the letters Dr. Lehman and others on the FDA Staff had written prior to September 6, 1958.

Remember that prior to September 6, 1958, our mythical salesman or his company could obtain the sort of FDA help needed to assure customers of a packaging material's suitability by the relatively simple device of supplying the required information and obtaining an informed opinion about a specific packaging product from unquestionably qualified FDA scientific personnel. Any FDA or MID letters so obtained prior to 1958 presumably gave a product so covered the preferred "prior sanctioned" status thereby eliminating the necessity for clearance under the new Food Additives Amendment.

Now, however, our salesman and his company were being faced with all sorts of new and surprising regulatory roadblocks, even in obtaining desired reconfirmations about previously secured sanctions. They soon found out that, unless they could get someone at FDA to make and enunciate in writing a sort of legal-scientific judgment that a product and/or its identifiable components could be considered a "non-additive" because of coverage by one or more of the exemption

[9] Here again, hindsight indicates that testimony from expert chemists should have been elicited and might have provided a more valuable legislative definition of "not reasonably expected to become a component of foods." Certainly FDA's present interpretation of this criterion seems wholly unreasonable, but perhaps this is due to a failure in the legislative stages to foresee the type of evaluation that might become necessary.

clauses written into the Food Additives Amendment, they would probably have to file a Food Additive Petition, and wait as long as two or more years for a clearance that had to be tailored to cover a chemical substance, or group of substances, not just the company's particular packaging product. Worst of all, from September 6, 1958 on, FDA's administrative staff seemed to have a compulsion for finding means of construing the Congressionally bestowed exemptions from the law as narrowly as possible. This pervading philosophy found its impact on the "generally recognized as safe" (GRAS) and "prior sanctioned" exemptions in some very strange ways.[10] Of even greater consequence and impact on our salesman, however, was the way in which FDA ultimately found a line of reasoning whereby, as a practical matter, it virtually did away with the exemption re-

[10] A basic truism about the body of materials or substances which have "GRAS" or "prior sanctioned" status should be mentioned here only because we have had so much continuing evidence of misunderstandings in the area. "GRAS" and/or "prior sanctioned" status is a fact, to which a legal status, that is, exemption from coverage of the operative provisions of the Food Additives Amendment, attaches; neither of these statuses is simply a reversible legal position, notwithstanding a good deal of confusion created in this regard by various FDA rulings, formal and informal. A substance is either "generally recognized as safe" for its intended use by the scientific community, or it is not. Likewise, a substance is either "prior sanctioned" for a specified use or class of uses because there was some type of pre-1958 approval of it by FDA, or it was not. If either of these statuses is established as a matter of fact, the law operates automatically to provide exemption from the operative provisions of the Food Additives Amendment and the necessity for filing a Food Additive Petition to obtain clearance.

Confusion about the legal concept involved has been engendered primarily because FDA has entertained and acted upon petitions for Food Additive Regulations on "GRAS" or "prior sanctioned" substances and has, indeed, encouraged the filing of such petitions despite an apparent lack of legislative authority to do so. The agency has then often "boot-strapped" by taking the position that a substance loses its "GRAS" or "prior sanctioned" status if it is made the subject of a Food Additive Regulation. This, we submit, is wholly fallacious.

This entire area has been further confused to some extent by the fact that, shortly after the Food Additives Amendment was enacted, FDA published lists of "GRAS" and "prior sanctioned" substances as Food Additive Regulations (see, for example, sections 121.101 and 121.2001 of the Food Additive Regulations). No substantial additions have been made to these lists since about 1960 despite early indications that they would be supplemented from time to time, thereby eliminating the need for excessive correspondence on status questions. To the best of our knowledge, the only reason that there have been no additions to the lists is FDA preoccupation with other matters. It should be understood, however, that the published lists are by no means all-inclusive and, in fact, there are probably a great many more "GRAS" and "prior sanctioned" substances not included in the FDA "GRAS" and "prior sanctioned" listings, than are included.

lating to materials which might not reasonably be expected to become components of food—the so-called "no-migration" exemption.

Limitations of "GRAS" and "Prior Sanction" Exemptions

Looking first at the way this attitude affected the "prior sanction" and "GRAS" interpretations, let us see what sort of approaches our mythical salesman encountered. Prior to 1958, once FDA had provided a basic "no objection" letter acquiescing in safety for the use of a particular packaging material, supplementary acquiescenses for related uses or innocuously varied mixtures could be rather readily obtained. Now, the trend was to deny acquiescence in "prior sanctioned" or "GRAS" status if there was any possible way to do so.

From the very beginning under the new law it became evident that the "GRAS" and "prior sanctioned" exclusions would be delimited by FDA as severely as possible, even where this might require the use of exceptionally tenuous interpretive and administrative processes.

Thus, for example, a company inquiring about the status of a product, and hopefully expecting that FDA would agree that a component or components were "prior sanctioned" or "GRAS," would often receive a response to an inquiry wherein it was told something like: "To the best of our knowledge, we [FDA] know of no 'prior sanction' for the product in its intended use, do not agree that it has 'GRAS' status, and, hence, can only provide an official opinion allowing the use of the product upon the filing of a Food Additive Petition complete with all of the data required in such a petition."

In many cases letters reading along these lines written by the Food and Drug Administration Staff amounted to nothing more than use of the classic "negative pregnant" technique. In other words, FDA, without necessarily making this entirely clear, was advising that it would not or could not search its files to see if there was a basis for "prior sanctioned" status; so that unless the inquirer could cite some explicit reference for believing there was such status, FDA could only conclude that a petition would have to be filed to obtain a clearance for the given substance as a regulated indirect additive.

In other cases FDA was actually taking the position, again often without adequate explanation, that "GRAS" or "prior sanctioned" status (that is, exemption from the clearance-by-regulation provisions of the law) might exist for the component in some applications but would not be extended to allow other uses, regardless of the reasonableness of such an extension. For example, there were and are

cases where it is entirely clear that a substance is "GRAS" or "prior sanctioned" for a direct (intentional) additive use, but FDA will not agree that a packaging use involving the smallest possible potential migration to food, or perhaps no apparent potential migration, can be held to be covered by the "GRAS" or "prior sanctioned" status.[11]

In other peculiar cases, since the early Lehman letters, which actually formed the bases for the "prior sanctions" exemption, were sometimes written on an entire formulation rather than a single component, FDA would and does take the position that the prior sanction allows the use of the component only when it is employed in precisely the same physical mixture of compounds and does not cover the component's use in a slightly altered mixture. Some of you may even have been exposed to situations where FDA has held that a particular component, conceded to be "prior sanctioned" when mixed with some substances, will not be considered "prior sanctioned" in another physical mixture or use, even if the newer mixture would be with more innocuous compounds or in a far less critical application. If the rationale for this type of holding is scientific, I confess that, for me, it remains in that area that I have come to call FDA's "scientific mystique" for I believe it defies understanding. Actually, my own conclusion is that the treatment is neither scientific, nor rational, but is simply a part of the pervading regulatory philosophy designed to compel the filing of petitions for everything with all of the delays and complications this involves.

"No Migration" Clause Treatment

So much for some of the treatments afforded the "GRAS" and "prior sanctions" exemptions. What about the so-called "no migration" escape clause. Despite the packaging industries' severe misgivings about being subjected to the rigors of the Food Additives Amendment, at least some fears were laid to rest during the legislative proceedings by (1) FDA assurances that the incidental additives problem would be the minor one under the law, as opposed to the

[11] Typically, FDA personnel would allege a legal, rather than a scientific public safety basis for such conclusions. Interestingly enough, however, the decisions were made by non-legal personnel without readily available legal advice as to whether sound statutory or regulatory construction demanded such unimaginative treatment. FDA is actually most unique in the fact that, unlike almost all other federal agencies, FDA's day-to-day "legal decisions"—at least on Food Additives matters—are made by administrative personnel with no advice from government attorneys readily available to them.

regulation of direct additives, and (2) the generally held industry belief that limiting application of the law to substances which "may reasonably be expected to become components of food" would at least provide a basis upon which FDA would be able to act promptly in concurring in "non-additive status" on the basis of data tending to show that no extraction of a food packaging or processing material was apt to occur.

Indeed, for the first two years of FDA's administration of the Food Additives Amendment, it appeared that the "no migration," or perhaps more accurately "no significant extraction into food simulating solvents" exemption would at least limit the application of the Food Additives Amendment within some rational bounds *vis a vis* the public health interest the Congress sought to advance. Until 1960 the Food and Drug Administration followed a policy of concurring in writing in situations where companies submitted extraction data which was satisfactory to demonstrate that migration of a finished packaging material or component to food was not reasonably to be expected. In accordance with the provisions of Section 121.2(c) and (d) of the Regulations, in many instances letters were sent to FDA setting forth a packaging material formulation on a confidential basis, and FDA was requested to respond with a letter passing on contentions that all of the components of the formulation were either (1) cleared under applicable existing regulations, (2) GRAS, (3) prior sanctioned, or (4) shown unlikely to become components of food by appropriate extraction studies. As a matter of fact, even to this day, FDA public pronouncements advise the agency's "constituents" in industry to perform extraction studies first to determine whether or not they really have a food additives problem before they undertake the acquisition of much more time consuming and expensive toxicological work, or undertake to file a food additives petition.[12]

Securing FDA concurrence in no migration, therefore "non-additive," status was often a very satisfactory means of obtaining the type of customer assurance indication needed to do business with food processing companies. Unfortunately, FDA suddenly came to the conclusion that providing the no-migration concurrence letters was creating allegedly difficult administrative problems for it so that, in a talk at an FDA-Food Law Institute (FLI) Conference in 1960, then Assistant FDA Commissioner J. Kenneth Kirk announced that,

[12] See, for example, E. B. Detwiler, "Synthetic Polymers and the Federal Food, Drug and Cosmetic Act," *SPE Journal*, Jan. 1965, pp. 61-64.

henceforth, FDA would no longer respond in an unequivocal, direct way to requests for such concurrences, regardless of the soundness of the supporting data submitted. The Kirk pronouncement, as later amplified during question and answer sessions of the FDA-FLI Conferences in 1960 and 1961, is perhaps best and most briefly summarized by quoting from a response to a question given by Mr. Kirk in the 1961 FDA-FLI Conference panel discussion.

Mr. Kirk: The situation has not changed since last year's meeting. At that time, we discussed the very situation where we had been receiving reports of extraction studies which did not show any migration to the food. We wrote letters stating that we agreed that these items were not food additives. After many of these had issued, we found they were being used as sales promotion pieces, often to the detriment of other firms who had the same items, and had properly made up their minds without consulting us that the Food Additives Amendment did not involve their items. As a result, we concluded that we could no longer issue that kind of letter. Additionally, there were instances where small amounts of migratory substances were, in our opinion, properly classed as food additives. As a result of our reconsideration of the situation, we stated that we would, if requested, review data submitted to us and if this represented the right kind of work, I say right, as recommended by Mr. Ramsey's article, for example, and showed no migration, we would issue a letter which, unfortunately, would not be a letter suitable for advertising. Essentially, the letter would say: "You made your mind up. You have a perfect right to do so and even though you didn't give us any reason to say that you're wrong, we still have no facts of our own on which to agree."

The other alternative is that if you want a "letter," the way to get it is to submit a petition for a Food Additive Regulation. If we can find that the product and the use involved are safe, then we can issue a regulation which will be there for all to see and will apply to everyone who has the same product for the same use.[13]

Obviously, the thrust of Mr. Kirk's statement was to the effect that, regardless of the type of data FDA might be given, it would no longer provide any statement as to non-additive status based on "no migration" which would be helpful in allaying customers' questions. We respectfully submit that this FDA policy is an abuse of government discretion, a violation of FDA's own rules,[14] and con-

[13] "Panel Discussion of Questions Submitted to the 1961 FDA-FLI Conference," 17 FOOD DRUG COSMETIC LAW JOURNAL 79 (Jan. 1962).

[14] Section 121.3(d) of the procedural Food Additive Regulations specifically states that FDA will provide responses to status inquiries by advising whether or not a substance is a food additive. There can be no valid doubt but that, under this provision, industry is entitled to candid, complete, and direct responses, free of artful language to the greatest degree possible. Certainly it must be considered improper for FDA to provide unnecessarily nebulous responses for reasons which can only be understood by those so close to the regulatory field that they have special knowledge as to why a response is equivocal, and non-dispositive of a direct question. In actual fact, the FDA policy whereby a direct response is avoided in situations where the agency is asked to pass on food addi-

(Footnote continued on next page.)

stitutes grossly inequitable treatment. Industry is being deprived of the benefits of a frank government opinion on the status of its products. It is entitled to such opinions as a concomitant for its being very severely regulated if the status is other than one of exemption from coverage of the operative provisions of the law.[15]

Legal Objections to FDA's Regulatory Philosophy

To make this discussion of the no-migration concept reasonably complete, it should be noted that there were immediate objections to the newly announced "no migration" doctrine from the legal community. It was pointed out at various Bar Association and other meetings that, in the opinion of food and drug lawyers, FDA had an obligation under Section 121.3(d) of its procedural regulations to provide industry with sound and clear-cut advice as to the Food Additive Amendment status of products upon request.

Upon the advancing of this legal argument, a helpless industrial community was met with some most unusual counter-reasoning. The legal justification advanced for the FDA policy—that is as far as its refusal to concur in non-additive status for "non-migrants"—boils down to FDA avowal of the theory that it has a right to refuse to concur in proof of such an exempt status. Why? Because it can reason that if a company goes to the trouble of conducting extraction studies it must believe that some or all of its product "may reasonably be expected to become a component of food" and, hence, the product and/or its components are legally "food additives"! Under this theory, there really is no such thing as an exemption from the

(Footnote 14 continued.)
tive status on the basis of extraction data demonstrating no detectible migration constitutes a negation of Section 121.3(d). It would certainly seem that, whenever a policy is adopted which has this effect, the agency should at least amend its regulations so that they will not be misleading.

[15] The problem of having to satisfy customers demands for "federal approval" type assurance of product suitability cannot possibly be overemphasized in this connection. It is by no means an academic problem in any sense, particularly when one recognizes that various state, and even federal agencies, will flatly refuse to use any material or component in a food contact application unless the potential supplier can provide some written evidence of satisfactory status from the Food and Drug Administration. This means, of course, that one who chooses to rely on his own conclusions in a "no migration" situation simply cannot sell to an important group of customers unless he files a Food Additive Petition and obtains FDA clearance of what is really a "non-food-additive" under the law. The anomaly of this situation is obvious, but its practicalities are painful and have led to filings of many "Food Additive Petitions" for coverage of what, under any rational interpretation of the Statute, are "non-food-additives."

law for non-migrants as a practical matter because no manufacturer of integrity would conclude that his product is a non-food additive *without performing extraction studies.* Yet FDA takes the view that once such studies are undertaken, regardless of the results, food additive status is established and official clearance can be given only upon the filing of a Food Additive Petition.[16]

Recently, after hearing an explanation of this peculiar line of reasoning, a representative of industry was heard to remark: "This sounds like Alice in Wonderland."

On the possibility that it might be difficult for some of you to believe the avowal of the line of reasoning that I have attempted to outline here, let me simply document what I have said by quoting to you from an address given by the then Deputy Commissioner of the FDA, John L. Harvey, at Rutgers University on January 18, 1962. In pertinent part, Commissioner Harvey's remarks read as follows:

> We came to the conclusion that we had opened Pandora's box and had better find a way to close it before the situation got completely out of hand. We therefore re-evaluated our position after consultation with our legal counsel and came to the conclusion that basically, *if there was enough reason to run extraction studies on packaging or equipment materials, why shouldn't it be concluded that it would be reasonable to expect that the substances involved would, in fact, become a part of the food? Since the law refers to "reasonably to be expected" we then began to advise those who asked that we were not in a position to give them a letter which would absolve their product from any responsibility from under the Food Additives Amendment but instead suggested that they file petitions.* That is the present status of this item.[17] (Italics supplied by author.)

Let us leave aside for a moment the clear-cut situation involving a new packaging material or component which, on the basis of extraction work, may be expected to migrate to foods, so that a Food Additive Petition is obviously and properly required as long as the law stands as is. Where has the evolution of FDA's policies on the exemption clauses left the company which honestly believes its

[16] There are two relatively well defined exceptions to the general FDA policy on no migration situations. FDA will give useful letter responses in cases where inquiries are made requesting concurrence in non-additive status for components used in so-called "barrier" or "repeated use" applications. Thus, for example, FDA will usually concur in the non-additive status of printing materials for use on the outside of wrappers where data shows that the wrapper presents an effective "functional barrier" between the food and the substance. Likewise, FDA will often agree to non-additive status for components of processing equipment intended for repeated use where it is reasonably clear that anything that might be expected to migrate from such equipment will be "washed out," or otherwise exhausted, during pre-use cleaning or flushing.

[17] Harvey, "Food Additives and Regulations," 17 FOOD DRUG COSMETIC LAW JOURNAL 275 (April 1962).

product is covered by one or more of the exemptions, but cannot obtain FDA concurrence in its position for one of the reasons discussed above? The problem comes to bear in our very real marketplace because of the previously mentioned generally prevalent insistence of customers on some type of "general approval" in writing. Faced with the practical impossibility in many instances of obtaining written FDA concurrence in non-additive status under the law because of the agency's general anti-exemption attitude, the manufacturer has only the choice of filing Food Additive Petitions on every component of every product he makes that is not covered in an applicable Food Additive Regulation, or of taking the independent position, without FDA concurrence, that his product does not require Food Additives Amendment clearance.[18] Neither of the alternatives is attractive and the approaches actually used understandably have varied according to all sorts of circumstances, including the nature of a company's customers, and their familiarity with the vagaries of this peculiar law and its even more peculiar application by FDA.

By and large, my own opinion is that those companies which have satisfied themselves that their products present no real or legal hazard because their components are already cleared, or are exempt from the law because, for example, as a matter of fact, they are not likely to become components of food, have fared best. Where they have been willing to do the extra selling job of convincing their customers that no food additive regulation or government blessing by letter should be deemed necessary, these companies have probably avoided as much frustration as they have encountered in being unable to sell those customers who simply will not move without an FDA stamp of approval.

Difficulties in Filing a Food Additive Petition

The reason I say this is that the other alternative is to file a Food Additive Petition. Industry's experience thus far at least has indicated that the filing of such petitions for incidental additives imposes seldom anticipated, and almost unbelievably difficult burdens and costs. Despite FDA's early assurances that incidental food additives would present minor problems, the vast majority of Food Additive Regulations which have been promulgated since 1958 are "incidental additive" regulations, not direct additive regulations. It is estimated that at least 70% of the time of the FDA Staff spent on Food Additive Petitions is spent on incidental additive petitions. Other statis-

[18] See footnote 15.

tics that demonstrate the point are that action on basic incidental additive petitions calling for new, rather than amended Regulations, is seldom taken in less than a year or two, despite the statutory requirement for action within 180 days after filing. The fact is that some incidental additive petitions have been pending before the Food and Drug Administration for more than five years.[19]

What is it that makes the petition-regulation process so difficult? The answer to this question defies definitive analysis in anything less

[19] In the past several months FDA has been evidencing a new awareness of, and sensitivity to statutory time requirements. Until the early part of 1966, a Food Additive Petition would almost never be "Noticed for Filing" within the 30-day period called for by Section 121.51 of the Food Additive Regulations. Instead the Petition was circulated for virtually complete review by the Divisions of Food Additives and Standards, and Toxicological Evaluation, after which extensive inquiries were usually raised. The Petition was then "Noticed for Filing" only after almost complete substantive resolution of any problems that came to light in this "pre-acceptance" review process. Even so, FDA seldom took action to promulgate a requested indirect Food Additive Regulation within the 180-day statutory maximum time allowed for such action after a petition is "Noticed."

Since the beginning of this year, FDA has, generally speaking, established a policy of filing all petitions promptly (that is, within the time Section 121.51 provides) so long as the Petition is *prima facie* complete. This is undoubtedly what was originally intended by the procedural time-element safeguards set forth in the law and the regulations.

Unfortunately, however, the new FDA interest in complying with statutory standards and eliminating its huge backlog of petitions—mainly for indirect additives—has brought into play a new twist, perhaps more properly characterized as a "backlash." In its anxiety to eliminate its backlog and industry's complaints about delays, FDA is often advising petitioners, sometimes at what amounts to the eleventh hour (that is, just before a 180-day deadline expires) that a Petition Noticed for Filing cannot be acted upon favorably without some extensive new study or studies not previously requested in any way. Simultaneously it will be stated that, unless such data can be made available, the Petition will be denied or a request for "withdrawal without prejudice" may be filed within 30 days. In a number of these cases, the additional data requested might be a 90-day feeding study so that the Petitioner really has no choice but to withdraw the petition, and suffer any commercial consequences Federal Register publication of the withdrawal might bring about. These consequences can involve considerable loss of business, or, at the very least a need for some potent reselling. For example, a customer might be using the Petitioner's product on a "no migration" basis, having been satisfactorily convinced that such use would present no real problem during some interim time while a Food Additive Regulation was being sought to provide more tangible "federal approval" not otherwise obtainable because of the FDA "no migration" policy. Convincing such a customer that there is still no true safety problem, but only a procedural one, when a "Notice of Withdrawal without Prejudice" appears in the Federal Register relating to the substance he is using will be, at best, difficult, and could be impossible.

(Footnote continued on next page.)

than a book on the subject.[20] Suffice it to say here that once a company has decided to go the petition route, and despite any assurances it may have received previously that action on such a petition will be prompt and relatively simple to take, it is likely to be asked for data which would appear wholly irrelevant to it. For example, there will be cases where the petitioner will suddenly be asked for data about the degree of use of the component in which he is interested, in the overall market. This is because the regulatory philosophy FDA adopted by urging passage of the Food Additives Amendment is one which requires it to pass, not only on a particular manufacturer-petitioner's product, but also on the acceptability of the use of the component or package when it is made by others.

It must be recognized that filing a petition does not involve merely seeking clearance for your product in the way that you make it. It means that you are seeking clearance for the marketing of the product by anyone who can meet the regulatory criteria ultimately published. This may well demand that you devise very sophisticated analytical methods, and undertake all sorts of other di- or trichotomies to suggest to FDA as appropriate regulatory devices to assure that no one will make your product in a different way that might have problematical public health implications. In short, you will be called upon to justify your existence in the marketplace by providing FDA with assurance that no one with less integrity will be able to produce something called by the same generic name in a way that might lead to strange consequences. This, as we see it, is the basic

(Footnote 19 continued.)

Under such circumstances the new FDA policies seem overly rigid and impose a very important additional jeopardy for potential petitioners to consider. They may well work to reduce the Petition backlog, not only by bringing about many withdrawals without prejudice, but also by discouraging the development of new products, or the filing of petitions for any reason. It is submitted that the approaches now in use exalt form over substance and should be re-evaluated bearing in mind that the statutory and regulatory deadlines were provided to protect industry from arbitrary inordinate delays, not to provide the government with a convenient procedural device to clear its petitions list without substantive determinations. As a minimum, FDA should exert every effort to review a petition promptly after it is Noticed for Filing, and advise promptly as to any and all additional data deemed necessary. In most cases this would give petitioners time to provide the data before the 180-day time allowed for action on a petition, and FDA would still have its full time allotment to act, especially in light of the provisions of Section 121.53 of its Regulations.

[20] A good indication of why petition preparation is so difficult can be gleaned from the newly published set of "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions." These Guidelines are now available through FDA's Office of Public Information.

difficulty with the regulatory philosophy FDA has now adopted, and is the best argument for a possible return to some form of the licensing type procedure used before 1958 in all cases except where the nature of anticipated migration of a substance to food warrants its treatment as a direct, intentional additive.

FDA's Lack of Procedural Safeguards

A more complete discussion of all of the implications and difficulties inherent in the present regulatory philosophy would unduly burden this already lengthy paper. However, there is a compulsion to note the sincere belief that the underlying concept of the Food Additives Amendment in its application to packaging is erroneous, and that administration of the law in this area is significantly defective. The administrative defects flow in large part from the fact that, unlike other regulatory agencies, FDA's power is virtually unfettered by adherence to the normal procedural safeguards required as a matter of law. For example, we are of the opinion that FDA violates—or more properly ignores—the Administrative Procedures Act almost daily by not proceeding according to requirements of the Act in its rule making activity. Furthermore, FDA has no clear-cut recognition of the distinctions between rule making and licensing, perhaps because it has no attorneys working on the regulatory aspects of its Food Additive Amendment activity at day-to-day Staff level. The failure to recognize such a distinction is what has led to the unfortunately unique "license by regulation" approach used under the Food Additives Amendment.

Indeed, the attention of the Food and Drug Administration, and especially that of its extremely able new Commissioner, who is so interested in meaningful reforms in FDA's management, might well be directed to the revisions of the Administrative Procedures Act now being considered by the Congress.[21] In the Senate report on these revisions the Committee on the Judiciary noted Justice Frankfurter's observation that "The history of liberty has largely been the history of procedural safeguards" and also quoted a Justice Jackson opinion where it was stated even more pointedly that ". . . procedural fairness and regularity are the indispensable essence of liberty."

My brethren at the bar engaged in practice before such other agencies as the Federal Communications Commission often wonder aloud how an agency like the FDA can possibly ignore such basic

[21] See Senate Report No. 1234, (89th Cong. 2d Sess.), which accompanies S. 1336, passed by the Senate on June 21, 1966.

procedural safeguards as those enumerated in the Administrative Procedures Act so that, even in recently issuing new hearing regulations, FDA did so by final order without so much as proposing the regulations first, and considering comments from interested parties. The answer to this question is a very simple though completely frustrating one, especially to those of us who are attorneys. The reason that FDA has seldom in any area, and never in the incidental food additives area, been taken to task for procedural inequity is because no company which must deal with the agency has the temerity to insist on its procedural rights for fear (reasonable or unreasonable) that it might be subjected to that sort of "trial by press release" which has so severely damaged the industrial community in the past.

Correcting the Problem—Hopeful Signs

Is there any hope on the horizon for remediation of the present incidental additives bottlenecks, or the general problem of fairer treatment for those who must deal with FDA? We suspect that the answer to this question lies now primarily with Commissioner James Goddard who, though he has thus far devoted most of his energy and attention to drug industry problems, has given evidence that he intends to do something about the general administrative chaos which has characterized FDA activity during the past several years when its regulatory responsibilities have multiplied. There are already some signs on the horizon which bear watching.

Firstly, many of you may have read about the joint study project the FDA has undertaken with Rutgers University to determine, among other things, whether or not FDA's present attitude on suitable packaging material migration studies is realistic. In embarking on this program, it was specifically stated that one purpose of the venture will be to determine whether or not "as a result of this work, broad classes of packaging materials may be exempt from further migration studies." Incidentally, you should know that among the materials which will be used in the Rutgers study are organo-tin stabilizers in which there is now so much interest because of the great hope that these stabilizers will bring polyvinyl chloride into the forefront as a plastics packaging raw material.

Other signposts which promise to bring about worthwhile changes are the facts that Associate Commissioner Kirk and Lessel Ramsey, both most knowledgeable about the incidental additives situation generally, are believed to be providing leadership in the direction of providing industry with better, more concrete informa-

tion about the type of data FDA needs. Primarily, at their urging, the new "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions" has been published. Although industry will certainly take exception to some of the requirements the "Guidelines" set forth, and it can be hoped that some day FDA, like other agencies, will propose such important, albeit technically informal, regulatory pronouncements and receive comments before they are finalized, such reductions of policy to writings available to the public are long overdue and constitute a significant step towards better understanding.

These recent moves may well be followed by closer FDA study of the possibility of revising its procedural regulations so that they will reflect what is actually being done, and those who must take some action because of the Food Additives Amendment will at least have a better idea of what considerations they must take into account. We may hope that there will be growing recognition that FDA is no longer just a body of scientists evaluating food adulterations and medical evidence about drugs. It now has exceptionally potent legal powers which, in our opinion, give it an obligation to be scrupulous in providing fair procedures based on solid legal approaches and advice. As we see it, FDA's promulgation of regulations and your dealings with FDA on such matters now necessitates the same type of legal-scientific teamwork so familiarly employed in other regulatory areas. From industry's point of view, since it is clear that your very *raison d'etre* can hang on an FDA decision, or the elimination of inordinate regulatory delays, we believe you should bring together all of the expertise in all of the different disciplines that have a bearing on how you are regulated whenever you have an FDA problem. What I am really saying here is "For goodness sake, consult your house counsel or other attorney before you get too deeply into any regulatory situation."

Suggestions for Advocating Changes in Present Regulatory Scheme

Finally, let me use the opportunity this paper provides to cast a little bread on the waters. Perhaps you or your company will someday be in a position to advocate changes in the present incidental additives regulatory scheme which we believe would be very much in the public interest, so I cannot pass this opportunity to give you some of our thinking for your consideration.

As we see it, the errors made by the Food and Drug Administration and Congress when the Food Additives Amendment was enacted

have led, perhaps unforeseeably, to some extremely far reaching and dire collateral consequences above and beyond the exemplary specific problems noted herein. Not the least of these consequences has been the fact that all over the world, with the exception of Canada, other countries have followed our lead in adopting similar, or even more restrictive regulatory approaches where packaging and processing materials are concerned. Even the European Economic Community is expected to adopt regulations which, in essence, will make it possible for you to sell your products in foreign countries only if all of the components you wish to use are set forth on a so-called "positive list." In some areas such regulation already presents a substantial "non-tariff trade barrier" which has come to exist because of our unfortunate example. Most foreign countries have taken our indirect additives regulatory scheme to an even more logical extreme because they are not fully aware or appreciative of the nature of such exemptions in our law as those provided for the GRAS, prior sanction, or no migration situations. Thus, they have proceeded along the path of adopting legislation which absolutely precludes the use of any chemical in a packaging material unless it appears on a positive list.

Rather than even attempt to dispute the philosophy behind such approaches in the face of our own government's position, or to try to convey some of the ameliorating nuances possible by proper interpretation of our laws, American company representatives overseas have simply been exerting most of their efforts in the direction of trying to assure coverage of their products by these positive lists. If they are successful prior to the publication of a first decree, statute or order, all is well and good until they have need to substitute an unlisted component. If they overlook a legislative movement in a foreign country, or develop a new component, the process of adding to the original lists overseas will almost always be even more difficult than is the case here.

This is just one side-effect of our incidental additives law although it is an important one for you to consider. It is enough, however, to make one wonder even more how the present situation came to be, and why it is allowed to continue to exist, especially when it is recognized that there never were any real health hazard "incidents" relative to packaging materials before 1958, and, to this day, FDA has never had to use its conventional enforcement powers to proceed against a packaging material. There are indeed only one or two reported situations where FDA, long ago, found it necessary to advise industry not to use some component in a packaging appli-

cation, and even these instances involved cases where the packages were intended to have an immediate direct additive type effect in food.

With this sort of "track record," and having in mind the severe hardship that has flowed from application of the Food Additives Amendment to the packaging industries, we are of the view that it is time for the Food and Drug Administration to go back to Congress and frankly "confess error" with a view towards having something done to change the law. In short, we should openly concede and take action to demonstrate to the world that it need no longer continue an unreasonable fear and over-regulation of packaging and processing materials.

It is perhaps too late to return to a completely informal preclearance type of procedure such as that used before 1958. Even if this is so, we can see no reason whatsoever for Congress to reject or delay enactment of remedial legislation which, as was suggested by The Society of the Plastics Industry in 1956, might require only that FDA be notified about packaging materials components so that their use would be permitted unless rational questions are raised about the intended application. In any case, the regulatory scheme that requires FDA to pass on the suitability of a substance taking into account all imaginable possible producers and uses, instead of those actually known, and factually before the agency, should be abandoned forthwith. If a simple notification system is deemed inadequate for some reason, FDA might at least look at a true licensing approach whereby the proponent of approval for a packaging material would be given authority to manufacture and sell it as he plans or proposes, with others left to seek the same authority for their products. We cannot believe that such licensing would require any more delay or hardship than is now extant, and it would have the impressive virtue of allowing for the making of narrow decisions with foreseeable consequences, instead of requiring the making of unbelievably broad decisions in areas where foreseeability is impossible.

Once again I caution you to understand that, as long as it is, this paper does little more than cover the subject matter superficially. Papers of equal length could easily be written to analyze the Food Additives Amendment, its many facets and "wheels within

wheels," from the viewpoint of the special problems of the chemist,[22] the toxicologist, the pharmacologist, and the legal practitioner dealing with product liability problems.[23] **[The End]**

[22] One subject for a paper has already been suggested in footnote 8. The chemist might also consider an analysis of the problem of deciding how far back in the chain of production one should go in stating the composition of a product for Food Additives Amendment evaluation purposes. Is a catalyst a component of a resin to be separately evaluated as such, or is it properly embraced in the naming of the resin (for example, "polyethylene," or "polypropylene") since it is not identifiably residual in its original form? What about some impurity from a kettle, or a mill? When do we, or should we draw the line?

At present, to an important extent handling of questions in this area is left to turn on whether or not an inquirer lists something as "a component" in eliciting an FDA opinion about his compound.

The use of properly descriptive chemico-legal language can be vital in asking FDA status questions. A good example is a case where one inquirer might be knowledgeable with regard to the so-called "mixture doctrine," and clearly indicate in a letter that his formulation will constitute a mixture of components believed approved, prior sanctioned, or GRAS. Where this is done FDA will often give satisfactory confirmation letters. Another inquirer might easily neglect to mention the fact that his formulation will be a mixture of the components he lists, thereby implying that there might be some reaction of the components, in which case FDA may well provide an opinion indicating the necessity for filing some type of Food Additive Petition. The FDA letters employed in these situations do not necessarily point out all of the possibilities or distinctions, and this can lead to the filing of unnecessary Food Additive Petitions, with all of the attendant complications.

In the same way, whether or not FDA will advise that a Food Additive Petition might be required can depend on whether or not an inquirer about a material's status unnecessarily includes so-called "reaction control" agents in the description of his formulation. Some truly scientific ground-rules could be helpful with legal problems in these areas.

[23] Two topics for possible papers by lawyers that might help round out this discussion, and otherwise be of assistance, might be:

1. The Constitutionality of the Food Additives Amendment's "Reasonably Expected to Become a Component of Foods" Doctrine in Light of Its Vagueness and the Mode of Its Application by FDA.

2. A Comparative Study of FDA's Rulemaking Activity with That of Other Federal Agencies—Is It Really Rulemaking or a New Type of Group Licensing by Regulation?

Factory Inspection Under the Federal Food, Drug and Cosmetic Act (Section 704)

By JAMES F. HOGE

The Following Article Was Presented at The Proprietary Association's Manufacturing Controls Seminar—Panel on Plant Inspection—in Saddle Brook, N. J., on October 27, 1966. Mr. Hoge Is General Counsel of the Proprietary Association and a Member of the New York Bar.

STATUTORY AUTHORITY FOR FEDERAL INSPECTION of a factory made its first appearance in the Federal Food, Drug and Cosmetic Act of 1938. A provision for it was included in the first draft of the legislation—S. 1944, the so-called "Tugwell Bill."

There was much uneasiness about it, much inquiry as to its constitutionality. The historic fact is that there was then considerable question even in government circles respecting enlargement of federal power. In the framework of present enlargement, that is really hard to believe.

There was, at first, some opposition, even, perhaps, some resentment from industry, because for years manufacturers had voluntarily consented to federal inspection. There was no provision at all for it in the 1906 Pure Food and Drugs Act. But there were inspections and there were inspectors. Walter Campbell and George Larrick, who were to become Commissioners of the Food and Drug Administration (FDA), began their careers as such. Senate Committee Report No. 361, dated March 13, 1935 stated:

> While one of the great weaknesses of the present Food and Drugs Act is the absence of any provision of this kind, *it has been found that most manufacturers welcome inspection by federal officials. Experience has shown that the relatively small minority who refuse permission for inspection, in almost every instance, are undertaking to hide some reprehensible condition.* (Emphasis supplied by author.)

And then House Report No. 2138, dated April 14, 1938—just on the eve of final enactment of the statute—stated:

> Section 704 provides for the inspection of factories doing an interstate business. *While no such provision is in the present law, perhaps more than 95% of food and drug manufacturers have invariably given permission to inspect.* It is only through factory inspection that certain abuses of consumer welfare can be established. A notable illustration of this is unsanitary manufacturing conditions. (Emphasis supplied by author.)

Historically, inspection laws belonged to the states. The United States Constitution, Article I, Section 10, Clause 2, provides:

> No State shall, without the Consent of the Congress, lay any Imposts or Duties on Imports or Exports, except what may be absolutely necessary for executing its inspection Laws:

This section has been interpreted as a reservation to the states of the power to inspect, *Neilson v. Garza* (1876), 17 Fed. Case No. 10,091:

> The right to make inspection laws is not granted to Congress, but is reserved to the states; but it is subject to the paramount right of Congress to regulate commerce with foreign nations, and among the several states.

The Supreme Court said that "inspection laws are not in themselves regulations of commerce. . . ." *Potapsco Guano Co. v. Board of Agriculture,* 171 U. S. 345 (1898). And the great Chief Justice Marshall, in the historic case of *Gibbons v. Ogden,* 22 U. S. 1 (1824) wrote:

> But the inspection laws are said to be regulations of commerce, and they are certainly recognized in the Constitution, as being passed *in the exercise of a power remaining with the states.* (Emphasis supplied by author.)

Chancellor Kent, of New York, one of the great jurists of his day and our country, said in his *First Commentaries,* at page 439:

> Inspection laws are not, strictly speaking, regulations of commerce. Their object is to improve the articles produced by the labor of the country, and to fit them for exportation or for domestic use. . . . *Inspection laws, quarantine laws, and health laws, as well as laws regulating the internal commerce of a state, are component parts of the immense mass of regulatory state legislation over which Congress has no direct power, though it may be controlled when it directly interferes with their acknowledged powers.* (Emphasis supplied by author.)

The authority of the federal government to enact an inspection law per se has never been squarely decided. Other than in the Food and Drug Act, the Congress apparently has not passed a law for what I have referred to as "per se" factory inspection. In other statutes, it is usually the article intended for interstate commerce which is inspected. The Meat Inspection Act applies to the plant, but primarily to the meat. Under revenue laws, articles are examined for determining taxability. In some laws, premises are inspected as a condition to the grant of a license; plants may be inspected in the exercise of the defense power; banks are examined under the

power to regulate and control the currency, etc. The constitutionality of Section 704 was seemingly upheld in *U. S. v. Crescent-Kelvan Co.,* 164 F. 2d 582 (1948) but the language was *dicta,* since the inspection was made with consent and the question of constitutionality under the commerce clause was not in issue. (The case was reversed but on other grounds.)

So—even now—federal inspection is "ancillary." That is, it is *indulged* as an accessory to the exercise of a federal power. That was the way of Section 13(e) of S. 1944 (the "Tugwell Bill"). Inspection was introduced with the words "in order adequately to regulate interstate commerce in food, drugs and cosmetics, and enforce the provisions of this Act."

All Committee reports and Congressional references during the legislative period, 1933-1938, related the authorization to factories doing an interstate business. And, of course, Section 704—as now worded—ties the inspection expressly to factories, warehouses or establishments in which articles *are made or held for introduction into interstate commerce.* But the 1962 Amendments provided as to drugs that every manufacturer, whether in interstate or intrastate commerce, should register yearly with the FDA and be subject to inspection under Section 704 at least once every two years (Section 510(h)). What the courts may ultimately say about this extension is with the future.

This legal and historical background is the rootage for much uncertainty as to the soundness and the scope of federal factory inspection. And it certainly disciplines a lawyer against generalized advice from a public platform as to the rights and duties of individual manufacturers in multifarious states of fact. And that discipline is sharpened by the fact that the provision for factory inspection is contained in a criminal statute whereby refusal to permit the stated inspection is a crime.

So, I should not tell you more than: (1) what the statute says; (2) what the FDA does; (3) what some of the questions are; (4) what the practice of the industry is; and (5) what the law ought to be.

1. *What the statute says:*

Section 704 provides that an inspector must first present appropriate credentials and a written notice of inspection. His entry must be at a "reasonable time" and he must inspect in a "reasonable" manner, and within "reasonable" limits. The repetition of the word "reasonable" is not a matter of redundancy, but of emphasis and

of deference to the Constitutional guaranty against "unreasonable searches and seizures." Inspections are "searches." The statute does not define this word "reasonable" and the factory superintendent must apply it as best he can and at his own risk.

In a plant where non-prescription drugs are made, inspection is limited literally by the Act to the factory and all pertinent equipment, finished and unfinished materials, containers and labeling therein. "Methods" and "processes" were subject to inspection in S. 1944, but not in later editions. In a plant where prescription drugs are made, inspection extends to all things therein (including records, files, papers, processes, controls and facilities) "bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act" have been, or are being, manufactured.

Inspection authorized for prescription drugs does not extend to (a) financial data; (b) sales data other than shipment data; (c) pricing data; (d) personnel data (other than as to qualifications of technical and professional personnel performing functions subject to this act); and (e) research data other than that relating to new drugs and antibiotic drugs subject to reporting and inspection under the regulations.

The scope of inspection applicable to prescription drugs includes records kept to establish good manufacturing practices. Such records, prescribed by regulation, include criteria for buildings, equipment, personnel, components, master formula and batch production records, production and control procedures, packing and labeling, laboratory control, stability, distribution records, and complaint files. Proprietary drug manufacturers should keep similar records but they are not subject to inspection under the literal provisions of Section 704.

2. What the FDA does:

In practice—at least, so I am told—the FDA seeks inspection without limitation. At the Symposium last year, Mr. Philip Brodsky, in his comprehensive statement on "FDA Plant Inspections" said:

> *Whether the establishment does or does not handle prescription items, does not materially affect the inspectional procedure,* since "Current Good Manufacturing Practices" apply equally to both proprietary and non-proprietary establishments in determining whether the processes, facilities and controls employed in the operations conform to the regulations. (Emphasis supplied by author.)

So, apparently, the practice is to inspect everything unless restrained by the factory superintendent. And any restraint by him, as we have seen, is at the peril of violating a criminal statute.

This practice existed before the 1962 Amendments. In the *Cardiff* case (*U. S. v. Cardiff,* 344 U. S. 174 (1952)), the government's brief on its petition for certiorari construed the statute as including observation, photographing and appraisal of formula cards, actual manufacturing work sheets, batch records, qualifications of technical personnel, controls, quarantining, facilities, and complaint files, fifteen factors in all.

Inspectors now frequently ask to see correspondence and interrogate employees; and—on occasion—they have been known to go to the advertising agency; and—on occasion—to make recordings.

So, in a word, we have — or the FDA would have — inspection unlimited, and expanding!

3. *What some of the questions are:*

The first, most frequent, most practical and most important question is "What do we do now?" The telephone rings in the office of the company's counsel. He is told that one or more inspectors are on the premises and making various demands. Rarely can a precise answer be given with confidence. The lawyer knows that if his advice is wrong, the company, and/or its representatives, may be criminally prosecuted; may, on conviction, be fined and imprisoned—three years, if it be a second conviction. You see, it is therefore quite perilous to assert the Fourth Amendment's guarantee of the "right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches. . . ."

The second question relates to inspection in factories "in which prescription drugs are manufactured." In those, the Act says the inspection shall extend to all things which have a bearing on whether prescription drugs which are adulterated or misbranded are being manufactured there. This would seem to confine the unlimited inspection to prescription drugs, but the language is apparently being construed as opening the whole factory to inspection not only with respect to prescription drugs but proprietaries, as well. I'm quite sure that Congress had no such intent in the 1962 Amendments. But who will guarantee the factory superintendent against incarceration if he acts on that assurance?

Now, third, another question which has not been settled is whether evidence developed by an inspector in the absence of any consent—other than mere compliance with the mandate of Section 704—may be used against the inspected party in a criminal case. There have been attempts to exclude evidence on the grounds that

the inspection provided in Section 704 is violative of the Fourth Amendment. In each of these cases, however, it has been held that the defendant had expressly or impliedly waived his rights by failing to assert them. So, if one permits an inspector to go beyond the statutory rights of inspection, the constitutional safeguards are no longer available.

Section 703, which requires carriers to expose shipping records, provides that evidence obtained under it shall not be used in criminal prosecution of the person from whom obtained. There is no such safeguard expressed in Section 704 and until the question is raised in a proper state of fact and adjudicated by an authoritative court, it will be another of the open-end questions pertaining to factory inspection.

The anomaly of this situation is that if one consents to extended inspection, he may be held to have waived his constitutional rights; if he refuses to consent, he may be in violation of Section 301(f) and criminally punished. You can see why—back in the thirties when constitutional questions were taken more seriously—there was disturbing uncertainty about the inclusion of factory inspection in the Act. And we may conjecture whether it would have been included if the present expanded application of it could have been foreseen.

4. *What the practice of the industry is:*

The industry has not stood on technical grounds. Rather, it has been disposed to accommodate the demands of the inspectors; to go with them far beyond what the statute requires. There may be irony in that. Industry may be penalized for its virtue. It may have unwittingly—by acceding to the demands of the inspectors—confirmed the statutory construction asserted by FDA. As I have already said, industry was permitting—even welcoming—inspection back in the days when there was no statutory requirement for it. Industry accepted—with some uneasiness, it is true—the inclusion of Section 704 in the Act. It was moved to do that because of its historic attitude toward inspection; because it was not ashamed of its factories; and because it subscribed to the public health purposes of the law.

5. *What the law ought to be:*

The law ought to be definite. That is an age-old ideal of the law. It is one, however, which in our modern complex society is increasingly more difficult of achievement. But even so, criminal offenses should be defined with certainty. People should be able to know whether they are incurring the risk of criminal punishment.

This is a matter of principle, and it affects more than the public's physical health. It affects the spiritual health of the people, the political health of the nation and the economic health of us all.

The requirement for factory inspection could be made definite. What the industry now readily does could be adopted as the statutory criteria. The law could, and should, specifically require inspection of sanitation methods, analytical reports on unfinished materials, quantitative formula data for active ingredients, qualitative formula data for inactive ingredients, facilities for weighing and measuring, packaging facilities, sterility controls, active ingredient assay controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment, methods for quarantining of drugs until after clearance with control laboratory and file of complaints from licensed medical practitioners and licensed medical institutions.

That is what the industry ought to permit—whether or not required by law. And that is what the law ought to be! And that is what the law could be if we were of the mind and will to make it so!

[The End]

FDA PROPOSES AMENDMENT TO PROCEDURAL NEW-DRUG REGULATIONS

The Food and Drug Administration has proposed an amendment to the procedural new-drug regulations. The amendment would permit the applicant of a supplemental new-drug application to utilize the changes proposed in such an application prior to its approval, after written notification from the FDA that such action is permitted. The National Academy of Sciences—National Research Council is in the process of reviewing the claims of effectiveness for drugs cleared through the new-drug procedure from 1938 through October 10, 1962. Consequently, the FDA has been withholding approval of supplemental new-drug applications. FOOD DRUG COSMETIC LAW REPORTS ¶ 80,156.

The Advantages of, and Need for the Establishment of Uniform Guiding Principles and Model Standards for Food

By DR. PAUL M. KARL

Dr. Karl Is a Member of the German Bar.

THE FIRST EUROPEAN COUNTRIES began to codify their initial food laws at just about the time that Jules Vernes, the well-known French author of classical science fiction and adventure novels, published his famous and thrilling book "Around the World in 80 Days" in 1873.

For Jules Vernes and his contemporaries a trip around the world in 80 days was an outstanding success and only a few highly gifted people could accomplish an understanding of this kind. For us a trip around the world is now a matter of hours—especially travelling in the right direction—and a quite ordinary affair which is more or less only a question of paying the fares. Technical development since Jules Vernes is outstanding, and what is even more important, it is not limited to a "trip around the world." The production of food, its science and technology, have been progressing in similar or even greater strides. Admittedly, Jules Vernes and his contemporaries already knew processed food and not only artisanal products like bread and sausages, wine and beer, but also "industrial" products such as sucrose. This "stone-age" food production is, however, compared with today's food technology, like travelling with Christopher Columbus to the United States instead of using a modern jet-liner. And yet, the majority of food laws now in force is still tied to basic schemes elaborated in the days of Jules Vernes and merely retouched in haphazard fashion here and there.

Need for Uniformity

Antiquation is not the only problem which we have to face. If we compare the present food laws throughout the world or only in a given region, such as Europe for instance, we will discover numerous and sometimes incredible divergencies not only in their formal systems but also regarding the material contents. Coming back to Jules Vernes for the last time, there was probably not much need for uniform regulations a century ago, because the border crossing trade in food products was relatively unimportant.

With increasing traffic facilities, however, people, or speaking in terms of food laws, consumers, met their neighbor consumers from across the border, became acquainted with them, and often liked their food and way of eating. As a result, the demand for food from other countries grew. Modern transport systems made it possible to ship food from surplus countries into those where there was a lack of food in general or only in certain commodities. And eventually trade barriers created by diverging food laws were discovered, and found to be hurdles even higher than any represented by tariffs or quotas.

Dr. Edmund Forschbach, head of the Division of Food Law and Nutritional Science in the German Federal Ministry of Health and Vice-President of the earlier European Codex Alimentarius Commission, illustrated our food law situation with a few, yet striking lines. In his "Wanted: A Credo for World Food Laws" he stated:

> Food laws applicable not only in Europe but also in the whole world are a hodgepodge of archaic patchwork regulations far behind the times, the technology of food and the needs of consumers.[1]

These obstacles in international food trade should belong to the past. We must realize that the consumer's interest in high quality food has nothing to do with his nationality. If we wish to achieve uniform legislation, we have to give up some of our national legislative power. However, this is a small price to pay for the closer integration of countries that we stand to gain.

Trying to trace the reasons for these legal divergencies, we have to base our considerations on the assumption that scientific insight and knowledge should be the same in any country, regardless of national borders. Furthermore, assuming that food regulations are—to a major extent at least—scientific knowledge expressed in legal terminology, we must conclude that diverging food laws are either evidence of a lack of legislative logic or that the legislation is influenced by interests other than basic food legal principles.

---

[1] Edmund Forschbach, "Wanted: A Credo for World Food Laws," 18 Food Drug Cosmetic Law Journal 93 (February, 1963).

Principles of Health and Honesty

I think we all agree that the principles of health and honesty are —or let me say should be—the sole basis of each developed food law system. Both are ancient and approved legal principles. They are first found in the culture of the Hittites, who had a highly developed social system in the area of today's Anatolia, nearly 3,500 years ago. There is a stone from those days in a Turkish museum with the following inscription (I put it into Shakespearian English to illustrate its venerable age):

THOU SHALT NOT POISON THY NEIGHBOUR'S FAT!
THOU SHALT NOT BEWITCH THY NEIGHBOUR'S FAT!

In his "Credo of World Food Laws" Dr. E. Forschbach has pointed out that this is probably the oldest recorded food law which people have made. THOU SHALT NOT POISON means, You shall put on the market only wholesome and safe food, and THOU SHALT NOT BEWITCH means, in this connection, You shall not mislead the consumer and you shall not outwit him. These two legal principles of health and honesty in the food market can plainly and clearly be realized. Both principles have lasted for thousands of years, and only some years ago they were realized anew on an all-European level in the supreme rule which the Commission for the Codex Alimentarius Europeaus (CAE) took as a basis for its work to establish a European Food Codex.

It reads as follows:

> Supreme law in honest food trade is the well-being of the consumer, his protection against damage to health and his protection against misguidance and fraud. All economic and technical considerations are subordinated to this supreme law.

Although all national food law systems of our day are said to be based on these principles of health and honesty, the cultural and social development, the different eating habits, and the repercussions of two world wars and the times of distress connected with them have resulted in food laws which, with regard to their material content, their legal system and formal structure differ from one country to the other to a large extent. Additionally, a good deal of prejudice, misinformation, political interests and other non-relevant considerations has led food law development astray.

I think it becomes obvious from these observations that a continuous modification and renewal of food laws on a nationalistic basis does not bring a solution of the present confusion. On the contrary, such a way would lead into an even more complicated disharmony and into even greater divergencies throughout the world.

Food Law Harmonization

A way out of our present chaos can only be found in supra-national or international harmonization of national food laws. This at the same time would offer an excellent opportunity to remodel and update antiquated provisions. Let us therefore have a look at the various factors which are at present active in the field of food law harmonization regionally and world-wide in at least partly overlapping areas. There are:

(1) Joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Program on Food Standards Codex Alimentarius Commission (based on the earlier work of CAE and extended geographically to a world-wide scope);

(2) Latin American Food Code (including the 20 independent republics of the western hemisphere situated south of the United States of America, and Puerto Rico);

(3) Council of Europe—Partial Agreement—(on an all-European level);

(4) Common Market (European Economic Community (EEC)) for the scope of the "Inner Six."

I have not mentioned the European Free Trade Association (EFTA)—the "Outer Seven"—since the EFTA Treaty provides only for a tariff and customs union and does not aim at a complete economic integration as in the case of the EEC. Due to this fact a food law harmonization for the EFTA countries can at present only be reached on the basis of the activities of FAO/WHO or of the Council of Europe.

The idea of standardizing or harmonizing food regulations on a supra-national or international level is by no means a creation of our days. Since the International Chemical Congress held in Brussels in 1894, European countries have been talking about the necessity of a CAE. Only in 1958 did this project gain shape when by the initiative of Minister Dr. Hans Frenzel of Vienna, A European Council for the Codex Alimentarius was formed to draft such a uniform Food Code. At a conference in Geneva in October 1962, a Joint Commission of FAO and WHO was founded and took over the project on a world-wide basis. Within this set-up the earlier European Council serves as a Coordinating Committee and considerable progress has been made. However, we are still far from a final result.

While the Europeans were still talking, the Latin-American countries went to work. In the late 1920's, a "Codex Alimentarius

Sudamericanus," was drafted. The project, however, petered out. Thirty years later, at the Sixth Latin American Congress held in Caracas in 1955, a Special Commission for the study of a Latin-American Food Code was formed under the chairmanship of Professor Dr. Carlos A. Grau of Argentina. Four years later, at the Seventh Latin-American Congress held in Mexico City in 1959, the first edition of a Latin-American Food Code was approved. This first version was followed by a second revised edition, adopted by the Eighth Latin-American Chemical Congress held in Buenos Aires in 1962 and published two years later.[2] There exists a standing "Latin-American Food Council" which has the task of keeping the Code up to date.

Both the Latin-American Food Code and the Joint FAO/WHO Food Standards Program have only advisory power and thus do not carry much legal weight. For example, experience with the FAO/WHO Code of Principles Concerning Milk and Milk Products has shown a good number of acceptances by national governments. Unfortunately, however, the general acceptances are often accompanied by special reservations. What is even worse is that these reservations do not cover all of the divergencies between the standard and the national laws. The result is a situation almost as confused as the original one.

The Council of Europe undertook to secure harmonization on the basis of international conventions. Up to now, however, they have had little or no success.

The food law harmonization within the Common Market differs clearly from these projects since it is based on an interstate treaty ratified by the national parliaments of the six member states. This treaty contains an obligation for legal harmonization to be effected during the 12 years' transitional period granted for the establishment of the Common Market. It is obvious that this basis—even if we forget the time factor—is an advantage. As a first recommendation, I believe that a similar legal basis for the work of FAO/WHO should be possible.

Food law harmonization obviously became a favorite endeavor on the part of many of today's organizations and this is a danger in

[2] Information concerning the Code and the Table of Contents of the new edition appeared in the April 1965 issue of Food Drug Cosmetic Law Journal (Vol. 20, page 238). The first five chapters were published in the September 1965 issue (Vol. 20, page 505), Chapters XII and XIII in the October 1965 issue (Vol. 20, page 544), Chapter XVII in the November 1965 issue (Vol. 20, page 638), Chapter X in the December 1965 issue (Vol. 20, page 695), Chapter VII in the June 1966 issue (Vol. 21, page 312), and Chapter XVIII in the August 1966 issue (Vol. 21, page 404). CCH.

itself. When FAO and WHO started their joint program for international food standardization, a survey on international organizations and their efforts in food law harmonization was compiled. This list, even in condensed form, occupies some 30 pages of the official report of the initial 1962 Session of the FAO/WHO Food Standards Program and, presumably, even more organizations have become involved in these matters by now. Admittedly, the majority of organizations will only work on a very limited sector and geographical and substantive overlappings and divergencies will be inevitable. It sometimes appears to me that the confusion in harmonization activities is even greater than in the food law itself. If we are not able to coordinate all these activities, we run the risk of "harmonizing" our food laws into disharmony. I would therefore suggest that only one world-wide body deal with harmonization of food laws and that this body be assisted by integrated regional subgroups. The Latin-American Food Code Council might wish to serve within the Joint FAO/WHO Food Standards Program as the Coordinating Committee for Latin-America just as the former European Codex Alimentarius Commission became the Coordinating Committee for Europe. This suggestion may have one weak point: the Common Market has to harmonize its food laws within the time limit provided in the Rome Treaty, and this creates the danger of a dualism between FAO/WHO and EEC.

Please allow me a third and final recommendation. As I have already stressed, the principles of health and honesty should be the sole basis of each food law system and constitute exclusively its legislative target.

Such a "Magna Charta" for food law should always be left intact and invariable in its essence. It should be a kind of constitution covering the development of specific food regulations. Decrees or regulations which deal with the production, composition, quality and labeling of individual foodstuffs or special food groups must be a mere interpretation referring to products and branches and a specification of the basic principles. Contrary to the established framework of the basic rules, the interpreting provisions must be flexible in their shaping and must have the possibility of amendment so that they may be adapted to technological and scientific progress in a quick and smooth manner, as well as to all changes in the needs of the consumers and their eating habits.

If you agree with me on this philosophy, any food law codification, and likewise any harmonization, has to start with a framework consisting of a basic food act, which sets the fundamental principles, the general definitions and the legal system. Only this basic framework plus perhaps general regulations regarding the use of chemical additives in food are worthy of legislative action. The elaboration of interpreting rules can and should be entrusted to one or several committees of food experts as has been the case in Austria for over half a century.

Summary

The following summary is my personal opinion regarding world food laws:

(1) The national food laws throughout the world differ from each other radically and are in many cases to varying degrees outdated.

(2) Harmonization of these laws on a regional and, finally, a world-wide basis has become a necessity of our day. It is an instrument essential to mutual understanding and a piece in the mosaic of international integration.

(3) A legal basis in the form of an interstate treaty or a similar agreement would facilitate harmonization and yield broader results.

(4) Harmonization activities should be carried out by one international body, such as the Joint FAO/WHO Food Standards Program. This body may and should have subsidiary regional groups. A close coordination with EEC harmonization should be established and maintained to avoid changing harmonization into disharmony.

(5) The first step of food law harmonization is a framework consisting of a food act based exclusively on the principles of health and honesty. The elaboration of interpreting rules relating to specific commodities does not require legislative action. It should be entrusted to competent expert groups.

Food law is, as the word indicates, first of all a legal matter, and therefore a lawyer's job. Secondly it is a result of teamwork between lawyers and scientists of different disciplines, the latter having to supply scientific facts only. I hope that the time when food law is treated as a sort of stepson by the legal profession has come to an end.

[The End]

INDEX

VOLUME 21 1966

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS OF TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION