VOL. 23, NO. 3 MARCH 1968

# Food Drug Cosmetic Law JOURNAL

## Concluding Papers Presented at the 1968 Annual Meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law

## Pesticide Laws and Legal Implications of Pesticide Use (Part I)

DOUGLASS F. ROHRMAN

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.

March, 1968
Volume 23 • Number 3

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

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# REPORTS

## TO THE READER

**Twenty-Third Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association.** — The concluding papers presented at the meeting are featured in this issue of the JOURNAL. The previous papers presented at the meeting were published in the February issue.

*Wesley E. Forte,* in his article "The Fair Packaging and Labeling Act—The Problems and Effects of Discretionary Regulations," examines the implications of regulations on package size, cents-off labeling and non-functional slack fill. The article begins on page 109.

In his article, "Product Liability—1967," *William J. Condon* discusses several cases of product liability and compares the decisions of the courts. He concludes that there is increasing espousal by the courts of the strict liability concept. At the end of the article, which begins on page 114, Mr. Condon has compiled a list of product liability cases for 1967.

*J. Kenneth Kirk* in "Developments at FDA," beginning on page 126, discusses recent changes made to insure a higher level of compliance with the Food, Drug and Cosmetic Act.

In the article, "Separation of Functions in FDA Administrative Proceedings," beginning on page 132, *Selma M. Levine* examines the administrative processes employed by the FDA in questions of adjudication and rulemaking and urges that fair standards of procedure be established for both types of cases.

**Pesticide Laws and Legal Implications of Pesticide Use (Part I).**—This article by *Douglass F. Rohrman,* a member of the Illinois Bar, examines the danger of environmental contamination posed by the use of pesticides, and discusses the ways in which the United States has attempted to alleviate this health hazard. He concludes that while pesticide laws are reasonably adequate, there is room for much improvement in the administration of controls.

Part I of Mr. Rohrman's two-part article appears in this issue of the JOURNAL beginning on page 142. Federal and state pesticide laws are discussed in this first part. Part II, which will be published in the April issue of the JOURNAL, examines pesticide use liability.

**Address by His Holiness Paul VI to Representatives of the Food Standards Commission.**—In his address to a group of delegates to the Meeting of the Joint Food Standards Commission of the Food and Agriculture Organization and the World Health Organization held in Rome February 20 to March 1, 1968, *Pope Paul VI* praised the organization's efforts in establishing worldwide food standards. These standards, he believes, will bring about closer communication between the less developed and more highly developed nations of the world. The address begins on page 162. Its French part has been translated by *Ann M. Wolf,* of New York City.

**The Salmonellae—A Current Challenge.**—*Franklin M. Depew,* author of the article beginning on page 164, presented this paper before The American Association of Candy Technologists at a meeting in New York City on February 8, 1968. Mr. Depew, President of the Food and Drug Law Institute, analyzes the nature and increasing incidence of the food-borne infection, Salmonellosis, and discusses the various methods of detecting the organism.


Annual Meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association, January 23, 1968, New York Hilton Hotel. Left to right: William J. Condon, Raymond D. McMurray, Richard Williams, Franklin M. Depew, Bradshaw Mintener, Mrs. Esther Kegan, J. Kenneth Kirk, Wesley E. Forte.

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# The Fair Packaging and Labeling Act— The Problems and Effects of Discretionary Regulations

By WESLEY E. FORTE

This Article and the Following Three Were Presented at the Twenty-Third Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association at the New York Hilton Hotel on Jan. 23, 1968. Mr. Forte Is a Member of the Pennsylvania Bar and Is an Attorney with the Borden Company.

I PLAN TO DISCUSS DISCRETIONARY REGULATIONS under the Fair Packaging and Labeling Act (FPLA). The discretionary regulations are authorized by Section 5(c) of the statute and these regulations will (1) define package size descriptions (as "small," "medium" and "large"), (2) regulate cents-off labeling, and (3) prevent non-functional slack fill. Since it was clear during the legislative hearings that a substantial number of Congressmen believed these regulations were desirable, it may well be "mandatory" for the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) to issue these "discretionary" regulations and we can expect that they will do so soon.

## The Broad Interpretation of Administrative Authority

Despite the fact that the discretionary regulations are unissued yet, we can make one safe generalization concerning them. The discretionary regulations will be based upon a broad interpretation of FDA's and FTC's authority. There is a clear trend in Washington today to view every statute as conferring almost limitless authority on the agency appointed to administer it. Thus, those who insist upon making an early start on their comments on the discretionary regulations can safely begin with a sentence stating, "The regulations promulgated by the Commissioner of Food and Drugs exceed the authority delegated to him by Congress in the following respects . . ." The remainder of that paragraph can be completed after the regulations are issued.

## Characterization of Package Sizes

Under Section 5(c)(1) of the FPLA, regulations can be promulgated governing package size characterizations, for example, "small," "medium" and "large." These regulations will probably have to be issued individually for different product lines. For example, a "medium" tube of toothpaste might contain 2 ozs., while a "small" package of soap powder might contain 10 ozs. In short, what is "small," "medium" or "large" is relative to product identity. It is not clear yet whether the designations, "small," "medium" and "large" will encompass a range of net weights or merely a single net weight. The House Report indicates that either approach can be followed by FDA and FTC.

Regulations defining package size characterizations will often result in a change in the sizes of consumer commodities now packed by many manufacturers. If the regulations prescribe a single size of the commodity as "large," (for example, 8 oz.) the manufacturer will have to pack that quantity to use the designation. If the regulations permit the characterizations to be applied to a range of sizes, they will still have a standardizing effect. Manufacturers will probably want to pack the smallest size in that range so that they can better compete in price. Those manufacturers who resist or are unable to change to the minimum in each weight category will probably omit these characterizations entirely. As Mrs. Peterson indicated in House

Hearings, the Act does not require any manufacturer to use size characterizations (1966 Hearings at 199).

Regulations defining package sizes may also decrease the number of words now used for package size characterizations. Among the words now used for package sizes are "small," "medium," "large," "king-sized," "giant" and "jumbo." FTC and FDA may define only a few of these terms and reason that all other characterizations are misleading. Alternatively, the undefined terms may be considered supplemental statements (that is, another accurate method of stating mandatory information) and be banished from the principal display panel. Either approach will destroy the good-will created in these terms by the manufacturer and may result in a conflict with those manufacturers having an investment in their present terminology.

## Cents-Off Labeling

Section 5(c)(2) of the Act authorizes regulations governing cents-off labeling and "economy size" packages. The new regulations will be intended to prevent "fictitious bargains" and their antecedents are the FTC's Guides Against Deceptive Pricing and its investigation into alleged abuses of cents-off labeling in coffee. FDA and FTC cannot prohibit the use of cents-off labeling; their responsibility is only to insure that these promotions are meaningful.

Intelligent regulations governing cents-off labeling and other promotions will necessarily focus upon the regional rather than the national market. If perpetual use of cents-off labeling is wrong, it would be meaningless to permit a company to sell forever with a cents-off label in Los Angeles merely because it never used such a label in Boston.

The limitations on cents-off promotions can focus either upon time or volume. For example, FDA and FTC could prohibit the sale of over 51% of a product in any market with cents-off labeling in any six-month period. Alternatively, FDA and FTC could simply require that for every three months of promotion, there must be at least three months during which the product is sold without such a promotion. Regulations premised on volume favor the larger seller while regulations premised on time are more favorable to the smaller seller.

Hence, large and small competitors may differ on the substantive content of the regulations.

Questions will also arise concerning the proof of a violation. The most convenient source of information may be the manufacturer who may have a file of announcements of promotions and records of shipment of promotional containers. However, FDA has no clear right of compulsory access to this information.

Twice during the 1965 hearings on the FPLA, FDA officials stated that if cents-off labeling were made discretionary, FDA would need authority to get cost and pricing information to effectively administer the Act (pp. 27 and 8). The statute was not changed to grant FDA access to this information and, as Mr. Goodrich noted in the 1966 hearings, FDA has no subpoena powers to enforce restrictions on cents-off labeling (p. 197). The House Report on the FPLA does state that regulations may require ". . . a showing on the part of the manufacturer that the wholesale price has been reduced in an amount sufficient to enable retailers to pass on the appropriate 'cents-off' to the consumer." However, this probably means only that the regulations may require the manufacturer to prove he has given such price reductions to prevail in a lawsuit based upon alleged misuse of cents-off labeling. Any other interpretation is negated by the fact that Mr. Cohen, Mr. Larrick and Mr. Goodrich all told Congress that FDA had no method of securing such information and that, despite such testimony, Congress did not give FDA the right of compulsory access to this information.

## Non-Functional Slack Fill

The regulations authorized under Section 5(c)(4) of the Act are intended to prevent *non-functional slack fill.* "Non-functional slack fill" is unnecessary slack fill, or slack fill which is not required for the protection of the contents of the package or the requirements of the machines used for closing the package. Regulations governing non-functional slack fill will almost certainly have to be issued on a product by product basis if these regulations are to be more than generalities since the identity of the product affects the extent of settling or the need for protective packaging materials. The formulation of specific regulations will, however, require substantial production expertise. Since FDA apparently had great difficulty in

formulating specific standards of fill under the Food, Drug and Cosmetic Act, it is difficult to understand how it can better formulate specific requirements for fill under the FPLA.

As FDA and FTC approach the slack-fill problem, they will undoubtedly find that there are significant variations in the efficiency of machines and equipment used by industry. Some machines and equipment can fill and close packages with less wasted space than other machines and equipment. I can discern no intention in the FPLA to compel manufacturers to purchase new machinery. Indeed, I discern a contrary intention from the deletion of the compulsory package standardization aspects of the bill.

The FTC and FDA regulations will therefore probably have to recognize a standard of fill which can be used by manufacturers with reasonable but less modern equipment than their competitors. This standard of fill is likely to be lower than the actual fill now packed by many manufacturers. Some companies will probably drop their existing fill to the level of the standards promulgated by the government without making a corresponding price reduction. The slack-fill regulations will therefore be no bargain for industry, government, or consumers.

For those who, however, insist upon seeing some note of cheer in everything, I suggest that a time may come when government will take over one task which we in industry have apparently handled unsuccessfully. For years, many reputable food companies have received occasional letters from irate housewives who refuse to believe that the company cannot fit more product into the package for technological reasons. However, when the FDA puts out its slack-fill regulations, industry will have an answer to that problem. It will then be able to say that the quantity in the package (even if it is reduced) is the quantity set by the government. It may even be possible to send these letters to Washington to have them answered by those in government who have so long believed that they were the real experts in running business. This prospect may provide a little cheer for some of our clients as they face the difficult and complex problems of the discretionary regulations under the FPLA.

**[The End]**

# Product Liability—1967

By WILLIAM J. CONDON

Mr. Condon Is a New York Attorney for Swift and Company.

A YEAR AGO, our report was principally concerned with the spread of strict liability across the nation.[1] Inevitably, this deceptively simple doctrine must give rise to some interesting and, at times, difficult problems. Its rapid acceptance around the country can also be expected to spawn second thoughts among some of our courts. It is with these problems, second thoughts, and some other interesting developments that we will be primarily concerned in this report.

The Court of Appeals of New York handed down a decision in May which can have far reaching consequences. The case is *Rooney v. S. A. Healy Company*, CCH PRODUCTS LIABILITY REPORTS ¶ 5775. Plaintiff's decedent was an engineer employed by the Bureau of Sewage Disposal of the Department of Public Works of New York City. On the day of his death, he entered a sewer to ascertain the cause of an accumulation of water. Before entering the sewer he put on and tested a gas mask, manufactured by one of the defendants. After finding and correcting the trouble in the sewer, Rooney and his companions started out. Rooney collapsed and died of asphyxiation.

The gas mask worn by Rooney was manufactured by one of the defendants and purchased in a used condition, after being in circulation for four years, by the City from the other defendant. In an action based upon strict liability, the complaint alleged defective design. Although there were problems of proof, the Court held that there was enough in the record from which the jury could find a design defect. Accordingly, a verdict for the plaintiff was affirmed.

The significant part of this holding is that it defines an apparently limitless exposure to liability on the part of a manufacturer. One postulate of design defect offered by plaintiff's expert was that

[1] William J. Condon, "Product Liability—1966," 22 FOOD DRUG COSMETIC LAW JOURNAL 125 (February, 1967).

the plunger required to activate the mask protruded and thus was subject to damage. Another was that the plunger might become loose and fall out and therefore not be available to perform its function. The Court never mentioned the four years of life of this mask prior to its acquisition by the City and it is reasonable to assume from the Court's treatment that twenty years would not have made any difference. Inasmuch as the fact of a design defect is a jury question, manufacturers may be permitted a slight shiver in contemplation of this case.

A rather unusual twist in this area was announced by the Florida District Court of Appeal in the case of *Gay v. Kelly*, CCH PRODUCTS LIABILITY REPORTS ¶ 5803. The case arose out of the purchase by plaintiff of a six-pack of a soft drink. As the plaintiff was leaving the retail store, the bottom of the carton broke and one of the bottles fell on her foot and broke it. The issue before this Court was the sufficiency of the complaint to state a cause of action against the bottler wherein plaintiff apparently alleged that the defendant manufactured the carton as well as the contents. On this interpretation of the complaint, the Court of Appeal reversed an order of the lower court dismissing the complaint. The holding was that, in these circumstances, privity of contract was not required to sustain a cause of action. However, in its opinion, the Court made it clear that if plaintiff failed to prove that defendant did in fact manufacture the carton, she must fail. As you might suspect, there was a vigorous dissent to this holding.

Another interesting development occurred in a case of first impression in Maine. In *Kobeckis v. Budzko*, CCH PRODUCTS LIABILITY REPORTS ¶ 5679, plaintiff complained that he contracted trichinosis from fresh pork which he had purchased from the defendant. He claimed that defendant knew that he was purchasing the pork for the purpose of making Polish sausage and that defendant was well aware that, in this process, it is customary to taste the raw sausage from time to time in order to determine whether and when it has been properly flavored. He, therefore, relied upon the skill and judgment of the defendant to provide him with fresh pork suitable for this purpose. Disdaining to decide this case with reference to the rather obvious voluntary exposure by the plaintiff, the Supreme Judicial Court of Maine preferred to rest its decision on a broader ground. Accordingly, the Court held that the warranty accompanying the sale of fresh pork is that it will be wholesome and fit for human consumption if it is properly cooked. It went on to say, "Proper cooking as used

in this case means raising the temperature throughout the meat or meat product to a minimum of 137 degrees Fahrenheit."

## Drug Cases Predominate

Drugs have taken over the position of pre-eminence in product liability. One reason for this is that the drug companies have been exposed to extensive multiple litigation arising out of the side effects of various drug products, which in turn have provided us with numerous reported decisions. Several of these, which came down in 1967, are of more than passing interest. *Yarrow v. Sterling Drug, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5709, and *Krug v. Sterling Drug, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5789, involve the drug manufacturer's duty to warn physicians of the harmful effects from its drug which come to its attention. In *Yarrow*, the United States District Court for the District of South Dakota seemed to feel that defendant had done a fairly good job with respect to literature and letters to physicians as information became available. However, this Court believed that the most effective way to bring information of this kind to the attention of busy physicians is through personal contacts by detail men. This the defendant apparently had not done. Accordingly, the Court held the manufacturer's warning to be inadequate and found for the plaintiff in the sum of $180,000.00.

In *Krug*, the Supreme Court of Missouri reached the same result by finding the same conduct of the same defendant to be wholly inadequate in all respects. In this case, there was an interesting side issue. Plaintiff had sued both the manufacturer and the retail druggist who had filled her prescription. The retailer was found not liable by the jury. He now seeks indemnity from the manufacturer for his attorneys' fees and expenses. The Court found considerable merit in his claim but ultimately disallowed it because the allegations in the complaint against the retailer were of primary negligence. These allegations were that the retailer "failed to inform itself by literature or by any other means of the dangerous qualities of said drugs and of the reasonable likelihood of said drugs causing injury to persons using the same" and that it "failed to inform itself of the injuries being caused by said drugs and failed to warn the medical profession or the public through advertisements or in any other manner of the danger of the further use of said products."

The most proliferated of the multiple litigation drug series has been complicated by claims for punitive damages. Some juries have been moved to honor such claims and appellate decisions resulting

therefrom are beginning to appear. Two very interesting opinions, reaching opposite conclusions, are to be found in *Roginsky v. Richardson-Merrell, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5729, and *Toole v. Richardson-Merrell, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5814. In the trial court *Roginsky* had a verdict of $17,500.00 in compensatory damages and $100,000.00 in punitive damages. *Toole* recovered a verdict of $175,000.00 general damages and $500,000.00 punitive damages. This latter was reduced by the trial court to $250,000.00. On appeal, the United States Court of Appeals for the Second Circuit, speaking through Judge Friendly, affirmed *Roginsky's* award for compensatory damages, but disallowed any recovery for punitive damages. The California Court of Appeal, speaking through Judge Salsman, approved *Mr. Toole's* award, both as to general and punitive damages. Much can be said, and, undoubtedly, much will be said with respect to the propriety and desirability of awarding punitive damages in civil actions of this type. It would be inappropriate, if not impossible, to give proper coverage to the question in this brief report. It is, perhaps, enough to note that the two courts were considering substantially the same evidence in reaching their opposite conclusions. Judge Friendly was obviously concerned with the overall economic effect that punitive damage awards can have in multiple litigation of this type. Judge Salsman, equally obviously, was not.

The *Sterling Drug* cases involved a failure to give adequate warning, whereas the *Richardson-Merrell* cases are principally concerned with a failure to provide adequate information or, in the alternative, with withholding information. The case of *Love v. Wolf*, CCH PRODUCTS LIABILITY REPORTS ¶ 5754, arose out of a somewhat different twist. Liability was imposed on the manufacturer of a drug, in the face of full disclosure and adequate warning, on the ground that its overpromotion of its product tended to cancel out the efficacy of the warning. Here, again, the case is interesting because of two secondary issues. The appeal is from a second trial. An earlier verdict for the plaintiff had been reversed because of extensive misconduct at the trial by plaintiff's counsel. One of the issues on appeal after the second verdict for the plaintiff was misconduct of the trial judge. A recital of a few instances of the alleged misconduct will perhaps explain why defendant complained. First, at the conclusion of plaintiff's testimony, the judge said, "All right, Mrs. Love, then you will be excused. Thank you very much, and I wish you good luck."

During cross-examination of plaintiff's doctor, counsel for defendant asked if plaintiff had had a surgical procedure at that time with-

out any adverse hemorrhaging effects. The Court answered the question by saying, "Yes, with his explanation." Counsel said, "Well, your Honor, may I please continue with this cross-examination?" The Court: "Yes, you may, but I don't want you to try to destroy his testimony." Later, on redirect examination, defendant's counsel objected to a leading question, as putting words in the doctor's mouth. At this point, the Court observed: "You can't put any words in this doctor's mouth. He knows more than all of you attorneys." Later, the Court said, "Thank you very much for the information you were able to impart. He was less disturbed by cross-examination than a good many doctors."

The Appellate Court characterized the judge's remarks as "unfortunate," but found that in the voluminous record considered as a whole they could not have been prejudicial. The Appellate Court was apparently very much impressed by the fact that the judge informed the jury that he did not favor either party and was trying the case fairly and impartially.

On the first trial of this action the jury had returned a verdict against both the manufacturer and the prescribing physician in the sum of $334,000.00. Thereafter, the doctor's insurance carrier paid plaintiff something over $100,000.00 "in partial satisfaction" of the judgment without waiver of its right to appeal. As indicated, that judgment was subsequently reversed and on this trial the jury found for the physician. Now, this Court has reversed again and awarded the plaintiff a new trial as to the doctor. With respect to the partial satisfaction, the Court found, for technical reasons, that the issue had not been fairly presented on appeal and, hence, it was not called upon to make any decision. However, this rather unusual procedure does give rise to some rather interesting questions, particularly if the doctor should eventually prevail.

In two cases decided on the same day, Texas joined the ranks of those states espousing strict liability. In so doing, the Texas Supreme Court exposed another problem area. The two cases are *McKisson v. Sales Affiliates, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5780, and *Shamrock Fuel and Oil Sales Co. v. Tunks*, CCH PRODUCTS LIABILITY REPORTS ¶ 5796. The problem is the effect of the plaintiff's contributory negligence on the liability of the defendant in a strict liability action. The Texas court held that where the negligence of the plaintiff consists of a failure to discover the defect in defendant's product, or to guard against the possibility of its existence, such conduct will not bar his recovery. However, if the conduct of the

plaintiff amounts to a voluntary exposure to a known risk, this will constitute a defense. This latter is commonly referred to as "assumption of risk," but some courts are reluctant to use this phrase, since at common law it was rather narrowly confined to certain specific situations. Thus, in the view of this Court, which finds considerable support among the commentators, failure to discover the defect will not bar recovery, but continuing to use the product after the defect is known, does. The following quotation from the opinion represents the underlying justification for the Court's view:

> Under modern conditions of advertising and marketing, there exists a strong consumer reliance upon the integrity of the manufacturer and vendor of a product. The representation of safety in use is not restricted to those consumers of the reasonably prudent variety. It would be incongruous to hold that one could not recover upon the representation that a product was safe because he had failed to meet the test of the reasonably prudent man in discovering that the representation was not true.

## Causation the Key Issue

We are constantly reminded that causation remains the key issue in product liability. A good example of this is found in the case of *Matthews v. Clairol, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5691. Plaintiff suffered an inflammation of her head and the loss of most of her hair following the use of defendant's hair coloring product. The evidence showed that plaintiff was given a patch test in accordance with defendant's directions and returned after the prescribed 24 hours for her treatment. It was after this treatment that her difficulty developed. Plaintiff's claim was that defendant was negligent in not prescribing a 72 hour waiting period after the patch test, which was based upon the testimony of her expert. However, she failed because the evidence showed that, even after 72 hours, plaintiff exhibited no reaction at the sites of the patch test. Therefore, the failure of defendant to prescribe a 72 hour waiting period was not the cause of plaintiff's injury.

Solomon could not have done better than the Supreme Court of Michigan in balancing the admissibility of circumstantial proof between both parties to an action involving a claim of adulterated mink feed. First of all, in *Savage v. Peterson Distributing Company, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5791, the Court approved the admission by the trial court of evidence on behalf of plaintiff that other mink ranchers had similar trouble with mink food containing products of the defendant, even though there was no evidence that any of them used the same product. The Court said this evidence

was admissible to show a pattern of causally connected carelessness at defendant's plant. On the other hand, it was held that the trial court erred in excluding defendant's offered testimony relative to lack of complaints by users of its product produced at the same plant with the same common ingredients at the same relevant times as the product involved in this case. Further, the Court held that it was prejudicial error to exclude testimony of mandatory Federal Food & Drug Administration inspections of defendant's plant to show the absence of any improper practices during the time relevant to this lawsuit. Thus, if we are going to let the jury speculate, it is appropriate that it be allowed to speculate on both sides.

While we are on this subject, let me call your attention to an opinion written by the United States Court of Appeals for the Fifth Circuit, wherein the Court starts out by asking the question, "How far is the Court willing to let the jury speculate?" This marks the beginning of a most fascinating, in-depth discussion of the proof required to support an action based upon strict liability. The facts in *Helene Curtis Industries, Inc. v. Pruitt,* CCH PRODUCTS LIABILITY REPORTS ¶ 5851, were essentially these: Plaintiff suffered third degree burns on her scalp and right ear resulting from the application to her hair of a mixture of two products designed for bleaching purposes. The products were manufactured by the two defendants involved. They were purchased from a beauty parlor by a friend who applied them to plaintiff's hair at the friend's home. Both products were intended for marketing to beauty shops only, and both carried label instructions which limited their mixture to products manufactured by each defendant separately. After a verdict for the plaintiff against both defendants, the Court of Appeals was faced with the issue as to whether or not plaintiff had proved a cause of action in strict liability.

To paraphrase the opinion will not do it justice. However, we may with profit note a few of its highlights. First of all, not all lawyers or commentators will applaud the court's adaptation of *res ipsa loquitur* to strict liability. This is accomplished by the simple expedient of substituting the word "defect" where the word "negligence" traditionally appeared. One might question whether any useful purpose will be served by cluttering up an already difficult problem with the obfuscatory proclivities of a Latin maxim. This, however, is my last criticism of this very lucid opinion.

## Doctrine of Intended Use

The Court noted that the doctrine of strict liability is not intended to make a manufacturer an absolute insurer and thus liable for any harm that may befall a user of his product. In order to delineate the scope of the manufacturer's liability, it applied what it called the doctrine of intended use. This intended use, according to the Court, is broken down into two facets, the marketing scheme of the maker and the foreseeability of harm. Applying this doctrine to the case at bar, the Court pointed out that the marketing scheme of both defendants here was directed entirely to professional users. All the instructions and all the warnings accompanying both products which were mixed together were beamed at the knowledge and expertise of trained beauticians. Furthermore, both products carried instructions that they should be mixed only with other products of the same manufacturer or with a pure hydrogen peroxide, with which each manufacturer was familiar and thus able to make a judgment. From this, the Court was able to conclude that plaintiff was not an intended user of these products and that the use made of them was not an intended use.

Following this the Court used the same facts and factors to eliminate the injury to the plaintiff as being within the orbit of foreseeability of harm. Based again on the manner in which these products were marketed, the instructions and warnings which accompanied them, and the lack of prior problems, the Court concluded that the injury to plaintiff was not foreseeable. It is interesting and significant that in reaching this conclusion the Court relied heavily upon policy considerations in balancing the interests between the need for adequate recovery and viable enterprises. In making this balance, the Court made two significant statements. First it said, "Furthermore, if the judicial opinions are in conflict on whether the public will be willing to absorb the cost of injuries to innocent bystanders, there can be no doubt that the public will be unwilling to pay higher prices for products when the injured plaintiff is an unforeseen and unauthorized user." Secondly, the Court said, "Alternative ways existed for Mrs. Pruitt to satisfy her desire to be a blonde * * * She could have simply gone to a qualified beautician."

Finally, let me quote one more significant observation: "Confining the maker's responsibility to harm by use of the products in a beauty shop is not a revival of the doctrine of privity of contract. It is simply an attempt to confine the scope of liability to the zone

of danger which could reasonably have been foreseen before these products were sold."

### Concept of Fault

If one conclusion can be drawn from the review of the cases in 1967, it is that the concept of fault is very much alive. While we may have moved away to an appreciable degree from the idea of negligence, one cannot read a large number of modern cases without recognizing that the courts still cling to a fault requirement. Running through all these cases is a common thread. Either the defendant failed to inform or over-represented, or was guilty of some other conduct or failure which can be equated with fault, even though short of negligence. This thought is in the trichinosis case where the court limits the warranty to one that the product will be safe to eat if properly cooked. It even exists in the equipment cases, where the fault may be said to be that the manufacturer's foresight wasn't as good as the jury's hindsight. We are still only at the threshold of strict liability. Based upon our continuing experience, one can only speculate that as time goes on, the differences between strict liability and negligence will be more apparent in proof than in doctrine.

## PRODUCT LIABILITY CASES FOR 1967

The list of cases for 1967, grouped according to classification, is as follows:

### FOREIGN SUBSTANCE AND CONTAMINATED FOOD CASES

*DiOrio v. Hirschheimer,* CCH PRODUCTS LIABILITY REPORTS ¶ 5698 (N. Y. Sup. Ct., Nassau Co.)

*Franks v. National Dairy Products Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5750 (U. S. D. C., W. D., Tex.)

*Rytter v. Parthenides*, CCH PRODUCTS LIABILITY REPORTS ¶ 5752 (Civ. Ct. of City of N. Y.)

*Nugent v. Popular Markets, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5797 (Mass.)

*Deris v. Finest Foods, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5800 (La. Ct. App. 4th Cir.)

*Anderson v. Swift & Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5804 (U. S. C. A.-6)

*Zabner v. Howard Johnson's, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5833 (Dist. Ct. App., Fla., 4th Dist.)

## FOREIGN SUBSTANCE BEVERAGE CASES

*Burns v. Delaware Coca-Cola Bottling Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5670 (Del. Super. Ct., New Castle Co.)

*Tedder v. Pepsi-Cola Bottling Co. of Raleigh,* CCH PRODUCTS LIABILITY REPORTS ¶ 5788 (N. C.)

*Olney v. Beaman Bottling Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5793 (Tenn.)

## BURSTING BEVERAGE BOTTLE CASES

*Ballou v. Blitz-Weinhard Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5723 (Ore.)

*Lafleur v. Coca-Cola Bottling Co. of Lake Charles, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5764 (La. Ct. App. 3rd Dist.). Rehearing ¶ 5802.

## DRUG CASES

*Yarrow v. Sterling Drug, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5709 (U. S. D. C., So. Dakota)

*Community Blood Bank, Inc. v. Russel,* CCH PRODUCTS LIABILITY REPORTS ¶ 5710 (Fla.)

*Hoder v. Sayet,* CCH PRODUCTS LIABILITY REPORTS ¶ 5718 (Dist. Ct. App. Fla.)

*Roginsky v. Richardson-Merrell, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5729 (CA-2); rehearing denied ¶ 5763.

*Chandler v. Anchor Serum Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5734 (Kans.)

*Basko v. Winthrop Laboratories, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5736 (U. S. D. C., Conn.)

*Bristol Myers Co. v. The District Court,* CCH PRODUCTS LIABILITY REPORTS ¶ 5743 (Colo.)

*Love v. Wolf,* CCH PRODUCTS LIABILITY REPORTS ¶ 5754 (Cal. Ct. App. 3rd Dist.)

*Krug v. Sterling Drug, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5789 (Mo.)

*Fritz v. Parke-Davis & Co.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5799 (Minn.)

*O'Hara v. Merck & Co., Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5813 (U. S. C. A.-8); rehearing denied ¶ 5841.

*Toole v. Richardson-Merrell, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5814 (Cal. Ct. App., 1st Dist.)

*Jackson v. Muhlenberg Hospital*, CCH PRODUCTS LIABILITY REPORTS ¶ 5832 (N. J. Super. Ct., Union Co.)

*O. M. Franklin Serum Company v. Hoover*, CCH PRODUCTS LIABILITY REPORTS ¶ 5834 (Tex. Ct. Civ. App.); ¶ 5835 (Tex.)

*Lovett v. Emory University, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5836 (Ga. Ct. App.)

*Blum v. Richardson-Merrell, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5839 (U. S. D. C., Md.)

*Breaux v. Aetna Casualty & Surety Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5864 (U. S. D. C., E. D. La.)

*Jacobs Pharmacy Co., Inc. v. Gipson*, CCH PRODUCTS LIABILITY REPORTS ¶ 5868 (Ga. Ct. App.)

## COSMETIC CASES

*Shahade v. Clairol, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5673 (U. S. D. C., Conn.)

*Sales Affiliates, Inc. v. McKisson*, CCH PRODUCTS LIABILITY REPORTS ¶ 5681 (Tex. Civ. App.)

*Matthews v. Clairol, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5691 (C. A. 3)

*Matthias v. Lehn & Fink Products Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5711 (Wash.)

*Davidson v. Wee*, CCH PRODUCTS LIABILITY REPORTS ¶ 5717 (Ct. App. Ariz.)

*McKisson v. Sales Affiliates, Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5780 (Tex.)

*Webb v. The Fuller Brush Company*, CCH PRODUCTS LIABILITY REPORTS ¶ 5822 (U. S. C. A.-3)

*Helene Curtis Industries, Inc. v. Pruitt*, CCH PRODUCTS LIABILITY REPORTS ¶ 5851 (U. S. C. A.-5)

## ANIMAL FEED CASE

*Savage v. Peterson Distributing Co., Inc.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5791 (Mich.)

## DEFECTIVE CONTAINER CASES

*Schutter Candy Co. v. Stein Bros. Paper Box Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5666 (C. A.-2)

*The Kroger Co. v. Bowman*, CCH PRODUCTS LIABILITY REPORTS ¶ 5695 (Ky.)

*Cusumano v. Pepsi-Cola Bottling Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5702 (Ohio Ct. App., Cuyahoga Co.)

*Gay v. Kelly*, CCH PRODUCTS LIABILITY REPORTS ¶ 5803 (Fla. Dist. Ct. App., 1st Dist.)

## DEVICE CASES

*Mocrey v. Superior Artificial Limb Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5668 (N. Y. Sup. Ct., Kings Co.)

*Cheshire v. Southampton Hospital Assn.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5741 (N. Y. Sup. Ct., Nassau Co.)

*Cutler v. General Electric Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5749 (N. Y. Sup. Ct., Kings Co.)

*Texas State Optical, Inc. v. Barbee*, CCH PRODUCTS LIABILITY REPORTS ¶ 5837 (Tex. Civ. App.)

## ECONOMIC POISON CASES

*Skogen v. Dow Chemical Co.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5732 (CA-8)

*Holowka v. York Farm Bureau*, CCH PRODUCTS LIABILITY REPORTS ¶ 5855 (Pa. Ct. of Common Pleas, York Co.)

*Corprew v. Geigy Chemical Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5858 (N.C.)

## FERTILIZER CASE

*Larance v. FMC Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5703 (La. Ct. App. 2nd Cir.)

## TRICHINOSIS CASE

*Kobeckis v. Budzko*, CCH PRODUCTS LIABILITY REPORTS ¶ 5679 (Me.)

## CIGARETTE CANCER CASE

*Zagurski v. The American Tobacco Company*, CCH PRODUCTS LIABILITY REPORTS ¶ 5809 (U. S. D. C., Conn.) **[The End]**

# Developments at FDA

By J. KENNETH KIRK

Mr. Kirk Is Associate Commissioner for Compliance, Food and Drug Administration.

MY COMMENTS ABOUT NEW DEVELOPMENTS in the Food and Drug Administration (FDA) will be, in a sense, an addendum to those of Deputy Commissioner Rankin in the article presented in the JOURNAL for December 1967.[1]

There is no question but that there has been a substantial number of changes in the way FDA is operating, but I hasten to add that these are all designed for the objective which Dr. Goddard has set forth, that is, to insure the greatest level of compliance with the Food, Drug and Cosmetic Act and the other statutes, the administration of which is assigned to FDA.

The decentralization process which started shortly after Dr. Goddard became Commissioner is well on its way and, in our judgment, is working out splendidly. The District Directors are fundamentally responsible for seeing that compliance is achieved in their own areas. Experience has demonstrated that they can do a better job now that we have given them more authority to make decisions as to what should be done and what has to be deferred in the many, many instances where the demands on their inspectional and analytical time far exceed the resources available to them.

The District Directors make their own plans, guided only by the general policies outlined by the Commissioner. They have much greater authority to decide what their particular districts need in the area of inspectional, analytical, clerical and top management people, subject only to the overall budget restrictions of personnel ceilings and available funds. They can try new things as long as they are directed towards the ultimate objective, real compliance.

[1] Winton B. Rankin, "FDA's Organization: The Reasons for Change," 22 FOOD DRUG COSMETIC LAW JOURNAL 660 (December, 1967).

Another innovation which has proven to be desirable is to give the District Director greater latitude in determining what should be done when violations of the statutes are encountered.

I don't have to tell you of the various sanctions in the law: seizure, prosecution, injunction, and, of course, the hearing procedure, which does not result in criminal action or the letter of warning. Additionally, however, we have employed the recall procedures which result, in many cases, in much greater consumer protection than would be achieved had we proceeded only, or at least initially, by trying to remove illegal material from the market under the seizure provisions of the law.

What we have told the District Directors is that in this area we expect them to make a considered evaluation of each such situation as it arises and to give us their recommendation, justified in each case, as to which procedure or combination of procedures should be the action or actions of choice. We are getting excellent recommendations from the District Directors in this category and, by and large, they are being approved just as we get them.

An interesting side observation here is that frequently two situations which initially may appear to be identical can result in the use of different sanctions to achieve protection, with a sound basis for the difference.

## Federal-State Relations

In the field of federal-state relations, there have been many very promising developments. As you know, we have a new Office of Legislative and Governmental Services headed by Mr. Paul Pumpian. Additionally, each of the Health, Education and Welfare Department regions now has an FDA Regional Assistant Commissioner to deal with federal-state matters.

This does not, of course, eliminate the day-to-day cooperation between our District offices and the state people. All concerned are actively working to the end that the consumer gets better protection per dollar whether this is from the Federal Government or the state or local people.

One new development very recently has been the formation of a task force made up of top FDA officials and responsible members of the National Association of State Departments of Agriculture.

## Voluntary Compliance Programs

We have substantially stepped up our voluntary compliance programs, both in Washington and in the field. General Delmore and his group in the just reorganized Bureau of Voluntary Compliance are providing real leadership to this program and we are getting feedback which indicates that the materials we are issuing, the seminars, the workshops, and the like, are more than worthwhile.

We have learned that these kinds of programs aren't worth too much if they are set up so that the FDA people tell industry what needs to be done. Rather, we find the best results come from the kinds of workshops and seminars which are jointly planned and jointly operated with the affected industries, so this is really a two-way street.

There has been a very substantial amount of interest in the so-called self-certification program which we are trying out on limited basis with one of the General Foods Corporation's plants.

The Industry Self-Certification Quality Assurance Program is aimed at producing the highest consumer protection possible with the given resource allotted FDA through increased cooperation between the agency and industry. This involves the sharing of information between FDA and industry, and the establishment of a Quality Assurance Program in the plant which would be a prerequisite for a firm's acceptance into the program. A plant quality assurance program would be based on FDA regulations and standards and consist of three basic elements: good manufacturing practices; self-inspection; and a statistically valid sampling and analysis program.

Initially we have set some basic criteria to be considered in selecting plants for the program, which really boils down to a situation where the plant must either process or repack a "critical" product. This is defined as a product having a significant potential health hazard to the consumer.

We are prepared to discuss this in detail with any firm which desires to participate, but the situation should encompass at least:

(1) a desire by the plant to participate in the program;

(2) a plant already having good manufacturing practices in general and possessing the ability to implement the basic elements of a quality assurance program;

(3) An acceptable past record, that is, number and seriousness of violative inspections and consideration of its legal history: number of recalls, seizures, prosecutions, injunctions;

(4) Such additional factors as the quality of its management, the size of the plant and its "critical product" production.

## Drug Area

In the drug area, you have all heard of the establishment of our National Center for Drug Analysis in St. Louis. This has been particularly valuable to us in several "crash"programs to evaluate the quality of the drugs on the market, but even aside from that the innovation is proving every day that we did not make a mistake in setting up this kind of facility. When the center reaches its full potential, we will be able to do far more in this area of drug analyses than has ever been possible in the past.

Meanwhile, it is no secret that we are not satisfied with the quality of some of the drugs on the market and we are planning additional measures which will enable us to get more basic information looking to compliance.

One important feature here is to find out as precisely as possible why certain deviations have occurred or are occurring, and a plan which we are working on now involves what might be called an intensified drug inspection concept of operations. What this means is that the FDA inspector will be called upon to make a far more comprehensive in-depth review of the manufacturing and quality control practices of the manufacturer of prescription legend drugs with respect to each product produced by that manufacturer.

We hope to be able to identify the practices and procedures which contribute to the marketing of drugs which are either clearly illegal or, shall we say, of uncertain quality.

This is going to mean that in the plants selected by the District Office for this in-depth coverage, our inspector will undoubtedly have to spend far more time than has been the case in the past. We are extremely hopeful, however, that the program as it works out will turn out to be of just as much benefit to the manufacturer as we believe it will be to the consumer.

The reorganization of our Division of Antibiotic and Insulin Certification was announced formally earlier this month. Under the new

reorganization, the laboratory functions will be separate. The medical and veterinary medical operations will be conducted in the Bureaus of Medicine and Veterinary Medicine and the other certification services, including the granting of exemptions and exceptions in the Office of the Associate Commissioner for Compliance.

I have not had direct responsibility for this operation long enough to tell you just exactly how it is going to work out, but I can assure you that we are looking for it to provide the best job possible in seeing to it that the certification service works precisely as contemplated in the statute. I hope to have more to say on this point at a later date.

## Development of Regulations

A very substantial amount of our time has been devoted during the past year to the development of regulations for the Fair Packaging and Labeling Act, which was enacted in 1966.

Following very extensive discussions with manufacturers, label producers, association representatives, and following our study of literally thousands of labels currently on the market, we issued proposals for the food regulations in March of 1967.

We know there were those attorneys who felt we should not have tried to combine the basic Food, Drug and Cosmetic Act regulations with the regulations under the Fair Packaging and Labeling Act, but, as we have explained before, we felt that one set would be better than two, and we went that route.

We were extremely pleased with the comments which we had invited and which we received in response to the original publication. We didn't get very much "I object, period" type of comments. Rather, we got a great deal of thoughtful evaluation of what we had proposed, with suggestions of how we could do a better job. As you know, we came out in July with so-called final regulations which reflected the very substantial comment we received.

Then we received the formal objections, some of which called for a hearing, and in our September publication we explained what we had done as a result of the objections, and concluded that there had not been set up a sound basis for staying the regulations and holding a public hearing.

Personally, I have been told by several attorneys for food firms that they disagree violently with our reasoning in rejecting the hearing request on at least one of the items, but they also added that they did have to agree there was little, if any, hope that an extensive hearing would have produced a different result in the face of the statute.

We were glad to see that the food industry generally recognized that this was a law which would have to be met and the best way to deal with it was to get the regulations settled and to get down to business and comply.

I have seen a good many labels which have been redone to meet the new law and regulations, and they have been excellent jobs.

We do know that with the many labels which have to be changed, the available facilities of the plate manufacturers, lithographers, and other label manufacturers just cannot meet the demands of the effective date of July 1, 1968. In July, Dr. Goddard published a statement of policy under Section 3.57 which recognized this situation and set up a procedure whereby we can consider problems involving those labels which, while not in complete compliance, could not be changed before the effective date.

While we do not have the authority to formally set a new date, we can exercise administrative discretion, as outlined in that policy statement. While it is a little early to be getting them, we already have several dozen letters from firms who feel they will not be able to meet the deadline, but we know that as the spring wears on we will be getting a great many more.

It should be recognized that any such request for administrative discretion should be based on good faith in attempting to comply and should involve labels which were not themselves in conflict with the basic provisions of the Federal Food, Drug and Cosmetic Act, including the conspicuousness feature of Section 403(f).

I have tried to give you a bird's eye view of what we believe to be significant changes in our operations. As Mr. Goodrich has said on many occasions, however, none of these procedures are written on a block of granite with a tongue of fire and we want to continue to make improvements in our operations in any case where it can be shown that they are directed towards the ultimate objective, compliance.

In this respect, we welcome your suggestions always. **[The End]**

# Separation of Functions in FDA Administrative Proceedings

By SELMA M. LEVINE

Selma M. Levine Is with Wald, Harkrader and Rockefeller, Washington, D. C.

IN THE COURSE of administrative proceedings before the Food and Drug Administration (FDA), lawyers have encountered confusion about the applicability both of the procedural requirements of the Administrative Procedure Act (APA) and of the elements of administrative due process.

In an earlier day, this may not have been too significant a problem, as problems go. But recent years have witnessed a dramatic surge of regulatory activity by the agency, and things will get worse, not better. For example, FDA has sharply increased its use of rule-making authority to promulgate food standards,[1] to regulate drug labeling and advertising,[2] and to control the marketing of products catering to the American obsession with slimness and vitality.[3] New statutes have brought FDA into the field of drug abuse control.[4] Just the other day Commissioner Goddard predicted that the Kefauver-Harris Drug Amendments of 1962[5] will be applied to remove from the market a broad spectrum of ineffective drugs which were approved by FDA for safety between 1938 and 1962.[6] It is likely that, in great measure, New Drug Application (NDA) revocation procedures will be followed.

All these regulatory actions have evoked or will soon evoke a contest from adversely affected members of the industry. This would seem to be an appropriate time to evaluate the adequacy of the

[1] For example, 32 Fed. Reg. 15116 (Cherry Pie).
[2] 32 Fed. Reg. 7533.
[3] 31 Fed. Reg. 15730, 15746.
[4] Drug Abuse Control Amendments of 1965, P. L. 89-74, 79 Stat. 227.
[5] P. L. 87-781, 76 Stat. 780.
[6] FDC Reports (The Pink Sheet), January 8, 1968, p. 15.

administrative process employed by FDA to safeguard hearing rights, and thus to ensure that FDA's decisions are fair and well-founded.

I regret to say that, by this standard, at least one aspect of FDA's version of the administrative process can only be regarded as inadequate, and may well be illegal or even unconstitutional. Let us look at the relationship between FDA officials who prosecute or advocate and officials who decide contested issues, not only in adjudication but also in rulemaking actions.

## General Requirements of the Administrative Procedure Act

The Administrative Procedure Act of 1946[7] is the fundamental guide to procedure in formal proceedings before federal administrative agencies. It divides these proceedings into two principal classes: rulemaking and adjudication. "Rulemaking" is "agency process for formulating, amending or repealing a rule,"[8] and a "rule" is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."[9] An "order," on the other hand, is a "final disposition" in any other "matter," including "licensing,"[10] and "adjudication" is "agency process for the formulation of an order."[11]

The fundamental hearing and decision procedure to be followed by administrative agencies is set forth in Sections 7[12] and 8[13] of the APA. (The following description ignores some aspects not relevant to FDA.)

Section 7 requires hearings to be conducted by either the agency itself (or one or more of its members) or by an independent hearing examiner.[14] The proponent in such hearings is assigned the burden of proof, and decisions must be "in accordance with the reliable, probative, and substantial evidence."[15] The "exclusive record for decision" is the transcript, exhibits, and other papers filed.[16]

Section 8 of the APA provides that the officer who presided at the hearing or another qualified hearing officer "shall initially decide the case" unless the procedure established by the agency requires him to certify the record to it for decision. In that case, the hearing officer must "first recommend a decision," except that, in rulemaking or initial licensing (the procedure for first granting a license), "the

[7] 5 U. S. C. § 551 and following.
[8] 5 U. S. C. § 551(5).
[9] 5 U. S. C. § 551(4).
[10] 5 U. S. C. § 551(6).
[11] 5 U. S. C. § 551(7).
[12] 5 U. S. C. § 556.
[13] 5 U. S. C. § 557.
[14] 5 U. S. C. § 556(b).
[15] 5 U. S. C. § 556(d).
[16] 5 U. S. C. § 556(e).

agency may issue a tentative decision" instead.[17] All initial, recommended and tentative decisions "are a part of the record," and parties are entitled to submit proposed findings and conclusions before initial, recommended and tentative decisions, as well as exceptions thereto before final agency decision.[18]

All adjudication (except, in limited respects, initial licensing) must be conducted in accord with these provisions.[19] Sections 7 and 8 are also applicable to rulemaking when the "rules are required by statute to be made on the record after opportunity for agency hearing."[20] As the Attorney General's Manual on the APA points out, the Federal Food, Drug, and Cosmetic Act is "almost unique" in specifically directing, in Section 701,[21] that certain substantive rules may be issued only after notice and hearing—"on the record."[22] Thus, the more formal directions for hearing and decision embodied in the APA's Sections 7 and 8 are applicable to the regulations issued under the Section 701(e) procedure—food standards, special dietary regulations, pesticide tolerances, and the like. Other rules, however, including FDA regulations not governed by Section 701(e), may be made simply after giving "interested persons an opportunity to participate in the rulemaking through submission of written data, views or arguments."[23]

For adjudications "required by statute to be determined on the record after opportunity for an agency hearing,"[24] (again except initial licensing),[25] Section 5 of the APA imposes additional requirements. The officer who conducted the hearing "shall make the recommended decision or initial decision."[26] The presiding officer shall not consult anyone "on a fact in issue" except on notice to the parties with an "opportunity . . . to participate,"[27] nor shall he be a subordinate of any agency employee engaged in "investigative or prosecuting functions."[28] No agency employee who investigates or prosecutes in any case shall, "in that or a factually related case, participate or advise in the decision, recommended decision, or agency review . . . except as witness or counsel in public proceedings."[29]

How does the FDA version of the administrative process stack up against some of the elements of this basic charter?

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[17] 5 U. S. C. § 557(b).
[18] 5 U. S. C. § 557(c).
[19] Section 5(c), 5 U. S. C. § 554(c)(2).
[20] Section 4(b), 5 U. S. C. § 553(c).
[21] 21 U. S. C. § 371(e).
[22] U. S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act*, 32-33 (1947).
[23] Section 4(b), 5 U. S. C. § 553(c).
[24] 5 U. S. C. § 554(a).
[25] 5 U. S. C. § 554(d)(A).
[26] 5 U. S. C. § 554(d).
[27] 5 U. S. C. § 554(d)(1).
[28] 5 U. S. C. § 554(d)(2).
[29] 5 U. S. C. § 554(d).

## Adjudications

In cases of adjudication, the APA's Section 5(c) clearly directs that officials who hear and decide shall be isolated from those officials who investigate or prosecute. The policy behind this separation rule was noted by the Attorney General's Administrative Procedure Committee in 1941:

> A man who has buried himself in one side of an issue is disabled from bringing to its decision that dispassionate judgment which Anglo-American tradition demands of officials who decide questions.[30]

This concept is so basic that it is read into the Due Process Clause of the Constitution as an essential element of administrative due process.[31]

If any FDA proceeding is unquestionably "adjudication," it is a proceeding[32] to *withdraw* approval of a New Drug Application.[33] Yet, in two of the few NDA revocation actions which have gone as far as the formal hearing stage, FDA has attempted to avoid the full implications of the APA.

In 1964, in a proceeding to withdraw NDA's for stilbestrol-treated poultry,[34] the Deputy Commissioner of Food and Drugs copied almost verbatim, and adopted as his final decision, findings of fact proposed to the Hearing Examiner by the FDA staff. On appeal, the District Court, in *Goldhaft v. Larrick*,[35] declared this procedure to violate Section 5(c)'s ban against "participation or advice" by an agency prosecuting staff in an agency decision. FDA asserted that the obvious mingling of functions was sanctioned by the Section 5 exemption from adjudication requirements for proceedings in which "decisions rest solely on inspections, tests, or elections."[36] But, the court held, a "formal, adversary hearing, involving the issue of whether New Drug authorizations should be continued in force or suspended," was not one to which the exemption was intended to apply.[37] The

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[30] Attorney General's Committee on Administrative Procedure, *Administrative Procedure in Government Agencies*, S. Doc. No. 8, 77th Cong. 1st Sess. 56 (1941).

[31] *In re Murchison*, 349 U. S. 133, 137 (1955); *Morgan v. United States*, 304 U. S. 1, 16, 22 (1938).

[32] 21 U. S. C. § 355(e).

[33] See Notes 10 and 11 and accompanying text; Administrative Procedure Act, Section 2(e), 5 U. S. C. §§ 551(8) ("'license' includes the whole or a part of an agency permit, certificate, approval, . . . or other form of permission"), 551(9) ("'licensing' includes agency process respecting the . . . revocation, suspension, annulment, withdrawal . . . of a license").

[34] HEW Docket Nos. FDC-D-49, FDC-D-55.

[35] Civ. No. 122-62, D. N. J., August 20, 1964 (unreported).

[36] 5 U. S. C. § 554(a)(3).

[37] Cited in footnote 35; p. 5.

order of revocation was reversed and remanded for a decision made in complete accord with the APA.

The events of the recent Measurin NDA revocation proceedings[38] against Chesebrough-Pond's, Inc., demonstrate most dramatically FDA's disregard of what seem to be the plain requirements of proper procedure in such an action. There the Assistant General Counsel, Food and Drug Division, Department of Health, Education and Welfare, filed briefs as a prosecutor opposing the manufacturer's motion to dismiss. The Commissioner's covering letter to the company denying the motion to dismiss stated that "*our legal staff* has considered carefully the motion to dismiss" (emphasis added), and that counsel had "been supplied with the memorandum outlining the considerations which led to this decision."[39] Now, the Commissioner has no other legal staff than the FDA Assistant General Counsel;[40] so it was clear that the Assistant General Counsel's office had acted both as prosecutor in opposing the dismissal motion and as advisor to the Commissioner in deciding it.

The Attorney General's Manual on the APA makes perfectly clear that "if the agency's General Counsel . . . engages in the performance . . . of prosecuting functions in a case, he becomes unavailable to the agency for consultation on the decision of that or a factually related case."[41] Chesebrough-Pond's filed a motion to disqualify the Assistant General Counsel from participating in or advising in the formulation of any tentative or final order, or in the decision of any motion in the case, on the ground that the proceeding involved licensing, licensing (other than initial licensing) was adjudication, Section 5 of the APA required separation of prosecuting and deciding functions, and that this principle had been and obviously would be disregarded. But the motion was denied by the Commissioner on the ground that "neither the Assistant General Counsel nor the attorneys in his office participate in the decision-making process that

[38] HEW Docket No. FDC-D-94.

[39] Letter from Commissioner Goddard to Jerome A. Straka, (unreported) January 9, 1967.

[40] The Office of the Department's General Counsel is charged with "furnishing all legal services and advice to . . . all office, branches or units of the Department in connection with the operations and Administration of the Department" (Statement of Organization, Sec. 2-300.30(1), 22 Fed. Reg. 1048), and "legal services in connection with the administration of the Federal Food, Drug, and Cosmetic Act" are performed by the Food and Drug Division (Sec. 2-320.40(2), 30 Fed. Reg. 14225).

[41] *Manual*, cited in footnote 22, at 57.

occurs in drafting these [revocation] orders *after* the evidence and argument have been submitted."[42]

At least implicit in this ruling was the recognition, absent in *Goldhaft,* that the APA requirements for adjudication *do* apply to some degree in NDA revocation proceedings. But it is fair to say that so restrictive a concept of what the separation of functions requires is far out of the mainstream of administrative law. In FDA's view, decisions on interlocutory motions (including motions to dismiss, perhaps?), evidentiary rulings, and all other matters arising prior to final submission of a case after trial are exempt from either statutory or Constitutional prohibitions against making the prosecutor the judge or the judge's legal advisor.

The validity of FDA's position was never judicially determined because the *Measurin* proceeding was resolved short of hearing. But if this is the position FDA seriously intends to adopt in NDA revocation proceedings, then I would predict there will be much litigation and some far-reaching revisions in FDA administrative procedure. The Department may well have to face up to the need to provide legal assistance to the Commissioner independent of that provided by the Assistant General Counsel when he acts as prosecutor.

## Rulemaking

By its own terms, Section 5(c) of the APA requiring separation of functions applies to "adjudication" only. Rulemaking, the other principal type of formal FDA proceeding, is left to Section 4 of the APA or to Sections 7 and 8, as the case may be, and is not subject to the additional procedural standards of Section 5. The teaching of *Willapoint Oysters, Inc. v. Ewing*[43] is that FDA need not separate prosecuting and decision-making functions in proceedings properly characterized as rulemaking.

But that does not end the inquiry. First, it is necessary to decide what is and what is not properly characterized as rulemaking; for, as the court in *Willapoint* itself recognized, the dividing line between rulemaking and adjudication is not always clear. Second, even where the primary nature of a proceeding is rulemaking, the overriding Constitutional imperative of a fair and impartial decision may require FDA to observe the requirements principally applicable to adjudication. Indeed, when the APA was pending in Congress, the Senate

[42] Letter from Commissioner Goddard to Wald, Harkrader & Rockefeller, February 6, 1967 (unreported).

[43] 174 F. 2d 676 (CA-9 1949), Cert. denied, 338 U. S. 860 (U. S. Sup. Ct. 1949).

Judiciary Committee expressed pointed concern about the exemption of rulemaking from Section 5 and warned that "where cases present sharply contested issues of fact, agencies should not as a matter of good practice take advantage of the exemptions."[44]

To recap for a moment, certain substantive FDA regulations—food standards, special dietary regulations, and so forth—are required by Section 701(e) of the Food, Drug and Cosmetic Act to be issued only on the basis of an evidentiary record after notice and hearing. These proceedings look to the issuance of so-called "regulations" and thus at first blush are "rulemaking" matters in which Section 5 of the APA is inapplicable.

The fact that these proceedings involve evidentiary hearings, however, and that the resulting "regulations" must be supported by evidence in the record, makes them in some respects suspiciously like "adjudications." The similarity is strengthened by the highly adversary character of the proceedings, which find not only sharply differing views of industry members, but in most cases an FDA position which many or most industry members violently oppose. The proceedings on the peanut butter standard[45] provide a striking example. FDA strongly advocated a 90% minimum peanut content while the entire industry urged 87% as the proper rule.

Other so-called "rulemaking" matters are of a sort which makes their classification as "rulemaking" even more suspect. Take the Drug Abuse Control Act of 1965.[46] That statute imposes a stringent regulatory scheme on the manufacture, distribution and possession of "depressant and stimulant drugs"[47] designated as such "by regulation" of FDA.[48] "Regulations" listing drugs for this purpose are required to be issued in conformity with the on-the-record rulemaking procedure of Section 701 of the Food, Drug and Cosmetic Act.

The question this scheme presents on its face is whether proceedings to list drugs are truly "rulemaking" or whether they are in fact "adjudications." The principal judicial authority on the distinction between adjudication and rulemaking is *Philadelphia Co. v. SEC.*[49] The Securities and Exchange Commission (SEC) had issued a so-called "rule" purporting to revoke the exemption of a certain class of holding company from certain regulatory requirements. The Phil-

[44] S. Rep. No. 752, 79th Cong. 1st Sess. 30 (1945), reprinted in S. Doc. 248, 79th Cong., 1st Sess. 216 (1946).

[45] HEW Docket No. FDC-76.

[46] See footnote 4.

[47] 21 U. S. C. § 360a.

[48] 21 U. S. C. §§ 321(v)(2)(c),—(3).

[49] 175 F. 2d 808 (D. C. Cir.), vacated on other grounds, 337 U. S. 901 (1949).

adelphia Company was concededly the only holding company in the country to which the exemption, or the revocation, applied.

The Court of Appeals held that the SEC could not revoke the exemption in rulemaking proceedings but was required to follow adjudicative procedures. To differentiate between the proper subjects of rulemaking and adjudication, the Court decided that "the action of an administrative tribunal is adjudicatory in character if it is particular and immediate rather than, as in the case of legislative or rulemaking action, general and future in effect."[50] This would seem to mean much the same thing as the statement in *Willapoint* that "the legislative process, *i.e.*, rulemaking, is normally directed primarily at 'situations,' rather than particular persons."[51]

The well-known analogy (or even identity) between rulemaking and legislation, relied upon by both courts of appeals in *Philadelphia Co.* and *Willapoint*, suggests that more precise guidance in drawing the line between rulemaking and adjudication can be found in the division between Congress' and the Courts' proper function. The principal discussion of that separation of powers has arisen under the Bill of Attainder Clause of the Constitution.[52] The Supreme Court has lately formulated the standard in *United States v. Brown*:[53] "A legislature can provide that persons possessing certain characteristics must abstain from certain activities, but must leave to other tribunals [*i.e.*, the courts] the task of deciding who possesses those characteristics." That is, the legislature cannot "specify the people upon whom the sanction it prescribes is to be levied."[54]

It can forcefully be argued that under *Philadelphia Co.*, *Willapoint*, and *Brown*, drug-abuse listings are properly classifiable as adjudications rather than rules. A listing applies to a particular drug; it affects only those who deal in that particular drug; it applies a set of Congressionally formulated standards to a set of concrete facts and determines whether a particular drug possesses the characteristics selected by Congress to control the applicability of the regulatory scheme. The proceedings are highly adversary in character, moreover, with the FDA staff acting as prosecutor and urging that the drug in question should be listed. The resemblance to adjudication is even more pronounced when only a limited number of companies manufacture the drug in question.

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[50] 175 F. 2d at 816.

[51] *Willapoint Oysters, Inc. v. Ewing*, cited in footnote 43, 174 F. 2d at 693.

[52] Art. I, § 9, line 3.

[53] 381 U. S. 437, 454 n 29 (1965).

[54] 381 U. S. at 451.

Did Congress decide to the contrary in 1965 when it described listings as "regulations" to be promulgated pursuant to Section 701? Put differently, did Congress decide in 1965 that, notwithstanding the enactment of the APA almost twenty years previously, Drug Abuse Control listings were not to follow the procedures of Section 5, even though they might be "adjudications" within the meaning of the APA? A realistic inquiry would lead to the conclusion that Congress had no intent to do any such thing. The Department of Health, Education and Welfare had urged that listings be promulgated in *non-record* rulemaking proceedings under Section 4 of the APA.[55] The House Commerce Committee nevertheless concluded that listings should be promulgated "on a case-by-case basis" and "after opportunity for hearing."[56]

Congress' concern thus seems to have been with strengthening the procedural rights of manufacturers, not cutting them back. It is likely that Congress gave no particular thought either to the additional requirements of Section 5 not found in Section 701, as amplified by Sections 7 and 8 of the APA, or to the possibility that a drug whose listing was proposed might be manufactured by only one company.

Of course, nothing in the Food, Drug and Cosmetic Act or in the APA, as the Senate Judiciary Committee noted in 1945, precludes an agency from giving greater procedural protection to a party than the letter of those statutes requires, even if it were conceded that there is no compulsion to do so. But FDA has not chosen so magnanimous a course. For example, an attack upon off-the-record consultations between the Hearing Examiner and FDA staff in the peanut butter proceeding was denied by the Examiner upon the ground that rulemaking rather than adjudication was involved.[57]

Similarly, the Drug Abuse Control proceeding[58] against Librium and Valium, two drugs made by a single manufacturer only, were conducted strictly in accordance with on-the-record rulemaking procedures. The manufacturer, who was the only party to the proceeding other than the Government, moved for an order disqualifying the prosecuting attorneys and their supervisor from participating or advising in the Commissioner's decision, contending that both Section 5 and basic fairness so required. Invoking *Willapoint*,

[55] Letter from Assistant HEW Secretary Cohen to Hon. Oren Harris, January 27, 1965, reprinted at H. Rep. No. 1430, 89th Cong., 1st Sess. 23 (1965).

[56] H. Rep. No. 1430, cited in footnote 55; at 5.

[57] Transcript of Record of Prehearing Conference (October 20, 1965), pp. 307-308, HEW Docket No. FDC-76.

[58] HEW Docket No. FDC-DAC-2.

the Commissioner denied the motion with the assertion that Section 5 was inapplicable because "these proceedings are rulemaking in character," since a "final order will affect not only the Respondent but wholesalers, distributors, pharmacies, and medical doctors as well as any future or potential producer" of the drugs.[59] In his covering letter to counsel for the manufacturer, the Commissioner made clear his position that "there is no authority or reason to disqualify the Assistant General Counsel or any other attorney from advising me in framing the tentative or final order in this matter."[60]

## Conclusion

Industry and the Bar have become increasingly concerned about FDA's insistence on adhering to a procedural scheme which is ill-suited to an impartial resolution of many FDA rulemaking proceedings which have some of the hallmarks of adjudication.[61] For these proceedings, Congress saw fit to impose a distinctive requirement of an "on-the-record" hearing, and it would seem that an indispensable ingredient to a fair hearing on the record is separation of prosecuting and deciding functions. For the thrust of the separation requirement is to exclude the prejudices, commitments, and one-sided viewpoints of the advocate as factors underlying the decision, to say nothing of the actual expressions of opinion on fact and law which can otherwise be put before the decision-maker without going into the public record —"the exclusive record for decision" even in on-the-record rulemaking, according to Section 7(e) of the Act.

As H. Thomas Austern, one of the deans of the FDA bar, expressed it at the Annual Educational Conference of the Food & Drug Law Institute and FDA last November:

> There is also the desirability that governmental action not only be fair, but that, like Caesar's wife, it always appear to be wholly chaste. Where the same administrative officer conducts the investigation, writes the regulation, appears as the principal opinion witness at the hearing, and then evaluates his own testimony in preparing findings and a final order, both requirements suffer an inescapable credibility gap.[62]

Confidence in FDA, as well as the reliability of its regulatory processes, demand that the credibility gap be closed. **[The End]**

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[59] HEW Docket No. FDC-DAC-2, Order Denying Respondent's Motion to Disqualify, April 28, 1967, p. 2.

[60] Letter from Commissioner Goddard to Thomas D. Finney, Jr., Esq., May 4, 1967.

[61] For example, Earl G. Spiker and P. Gordon Stafford, "A Look at FDA's New Rules of Practice—and Problems Still Unresolved," 21 FOOD DRUG COSMETIC LAW JOURNAL, 448, 455 (September, 1966).

[62] H. Thomas Austern, "Is Government by Exhortation Desirable?," 22 FOOD DRUG COSMETIC LAW JOURNAL, 647, 651 (December, 1967).

# Pesticide Laws and Legal Implications of Pesticide Use—Part I

By DOUGLASS F. ROHRMAN

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MAN'S PRIMARY CONCERNS have always been survival and improvement of his condition. As population increased, he attained greater ability to manipulate and control his environment. In the process, he has inevitably inflicted damage upon himself and his surroundings. Advances in environmental control have always entailed a certain degree of risk which society has been forced to weigh and either accept, alter or reject as the price of material progress. One of civilization's major steps has been the domestication of food plants. Beginning in the early 18th century, new scientific discoveries made possible a more increased agricultural production. Land area for agricultural use increased vastly. Higher crop yields resulted from the discovery of crop rotation principles and better soil management practices. Consequently, growth in food production and supply has contributed significantly to the population explosion of the last 200 years.

A more subtle and far more recent historical development has been the safeguarding of and concern over man's health and safety. In fact, we have come to realize that the future welfare of the human race depends upon vigorous programs to safeguard its health and welfare and maintain a more intensified agricultural output. With the

inception of agricultural organization and the resultant crop abundance, the natural eventuality was the outbreak of pests. Even a casual observation of world history reveals many references to pestilence and plague; indeed, the course of civilization's development has been markedly changed by these problems. As a result of pests, man has had to cope with disease, discomfort and great economic losses.[1] Pest Control has been and will continue to be a very real necessity.[2] This, in turn, makes obvious the great need for pesticides.[3] "Pesticides have made a great impact [on society in the United States] by facilitating the production and protection of food, feed, and fiber in greater quantity and quality; by improving health; and by keeping in check many kinds of nuisance insects and unwanted plants."[4] Pesticides have also made pest control a financially feasible activity, one which does not have to compete with other critical economic demands.[5] Rapid population growth and the resulting decrease in land available for agri-

[1] See especially, Zinsser, *Rats, Lice and History* (1934); Metcalf, "How Many Insects Are There in the World?," 51 *Ent. News* 219-222, Oct. 1940; Sabrosky, "How Many Insects Are There?," *The Yearbook of Agriculture* 161-169, 1952; the "1967 National Communicable Disease Center Report on Public Health Pesticides," *Pest Control* 1-16, March 1967; Horsfall, "A Socio-Economic Evaluation," *Research in Pesticides*, 3-16, 1965; and *Protecting Our Food: The Yearbook of Agriculture*, 1966.

[2] Lylel, "Can Insects Be Eradicated?," *The Yearbook of Agriculture* 197-199, 1952; Bjornson and Wright, "Control of Domestic Rats and Mice," United States Department of Health, Education, and Welfare Training Guide; Mallis, *Handbook of Pest Control*, 1954; and Pratt and Litig, "Insecticides for the Control of Insects of Public Health Importance," United States Department of Health, Education, and Welfare Training Guide, 1967. Only in the past century has there been a scientific approach in the control of pests. In 1888, the U. S. Department of Agriculture imported the ladybird beetle from Australia to control the cottony cushion scale in citrus orchards. Since that time, pest control activities have grown to tremendous capacities. See footnote 12. For an excellent overall view, see *Scientific Aspects of Pest Control*, National Academy of Sciences, 1966.

[3] The dramatic effectiveness of new pesticides has somewhat overshadowed the continuing efforts toward non-chemical pest control. For a short study of insect control by way of other insects see Burks, "Insects, Enemies of Insects," *The Yearbook of Agriculture*, 373-380, 1952 and Clausen, "Parasites and Predators," *The Yearbook of Agriculture*, 380-388, 1952; insect resistant crops: Packard and Martin, "Resistant Crops the Ideal Way," *The Yearbook of Agriculture*, 429-436, 1952; Painter, *Insect Resistance in Crop Plants*, 1951 and Snelling, "Resistance of Plants to Insect Attack," 7 *Bot. Rev.* 543-586, 1941. Research is being conducted presently in the effects of parasites, insect diseases, predators, ecology, and physical force (gamma rays, radiant energy, high frequency sound) on insects. Other studies have included attractants and chemical communication as "bait" for insect traps. See also, Sailer, "Revival in Biological Control," *22 Ag. Chem.* 5, May 1967 and Wilson, "Pheromones," *Scientific American*, May 1963.

[4] "Use of Pesticides," *Report of the President's Science Advisory Committee*, 2, 1963.

[5] See footnote 4, p. 3. See also the charts on pesticide production, footnote 12.

culture necessitate greater crop yield per acre and reduction of losses and spoilage in stored foods. Moreover, many commodities must be protected during the manufacturing process and subsequent distribution.[6]

There is, however, ample evidence of increasing environmental contamination by these compounds. During the two decades of intensive advancement in this field large amounts of pesticides have been dispersed, both intentionally and inadvertently. Pesticides are detectable in man and animals, food and feed, our clothing and natural surroundings. Although these compounds persist usually in only small quantities, their toxicity, variety, and persistence may eventually affect human health. While the consequences of acute exposure are obvious, some of the more subtle and potential risks must still be evaluated.[7] "Precisely because pesticide chemicals are designed to kill or metabolically upset some living target organism, they are potentially dangerous to other living organisms."[8] Some of them are highly toxic in concentrated amounts, and in unfortunate instances they have caused illness and death of people and animals. Although acute human poisoning is a measurable and, ofttimes, a significant hazard, it is relatively easy to identify and control when compared to potential, low-level chronic toxicity which has been observed in the laboratory.[9]

Along with the need for these many and varied compounds, therefore, are the concomitant hazards, both direct and indirect. It thus seems inevitable that, as population increases, so do these hazards.

In 1910 the initial attempt was instituted to control the sale of pesticides in the United States. It was not until thirty-seven years later, however, that technological innovations and expanded industrial capacity presented the necessity for further legislation in this area. The post-World War II availability of new chemicals of all kinds gave rise to an expanding ability to produce dangerous substances which were ideal inhibitors of pests. The necessities and demands of the war effort had led to startling developments in the chemical industry. Compounds and theories developed during and after the 1940's were applied to new uses, and the post war demand for such chemicals became immense.[10] During World War II, a great deal of effort

[6] See footnote 5.
[7] See footnote 5.
[8] See footnote 5.
[9] See footnote 5.
[10] For an analysis of pesticides in the economy, see "Use of Pesticides," *Report of the President's Science Advisory Committee*, 1963. For the popular and controversial source of concern over pesticide use, see Carson, *Silent Spring*, 1963. See also *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides),*

(Continued on next page.)

was expended in producing and perfecting compounds and methods to control pests. In the last twenty years some of the detriments which must be weighed and assessed against the merits of pesticides have been discovered. Some of the detriments, it was found, could be met by way of legislative controls over both the sale and use of these chemicals.

From this, we come to the ways in which society in the United States has attempted to alleviate these potential health and agricultural problems. It has been man's experience that leaving control of dangers to individuals or group self-help, while often beneficial, unfortunately leaves much to be desired. Human failings and weaknesses are largely the subject for which regulatory measures, rules and laws stand as substitutes. The law, philosophically and practically, is and has been the basis of a type of guaranty to keep man from harming, misusing or destroying himself and his property, and often more important, the person and property of others. To support this guaranty, the law has generally developed a system of remedies applicable to a variety of injuries and legal wrongs. Therefore, with this in mind, the justification for enactment of pesticide laws can be based upon the need to provide this guaranty to individuals and society and to make available remedies for injuries due to use, both wrongful and incidental, of these compounds.

Legal control over the use of pesticides can be generally classified into two categories, indirect and direct. Indirect control is maintained by federal and state registration or "labeling" laws. Also, regulations on the federal and more rarely the state level indirectly control pesticides by setting tolerances for residues on agricultural commodities. Direct control is accomplished by means of use and application laws such as applicator's licensing statutes. Often, further direct control may exist by way of specific regulations prohibiting the use of particular pesticides in a particular manner.

## Federal Pesticide Laws

In 1910, in order to protect consumers from substandard or fraudulent products, Congress passed the Federal Insecticide Act.[11]

*(Footnote 10 continued.)*
1963-64, usually called the "Ribicoff Report;" Shepard, *The Chemistry and Action of Pesticides*, 1951; Arrington, *World Survey of Pest Control Products*, 1956 and Headley and Lewis, *The Pesticide Problem: An Economic Approach to Public Policy*, 1967.

[11] Passed on April 26, 1910, the original Federal Insecticide Act, 36 Stat. 335, U. S. C. 121 and following, was repealed by force of 61 Stat. 172 on June 26, 1948. For an example of the administration of the old Act, see *Parke, Davis & Co. v. U. S.*, 225 F. 933 (C. C.
*(Continued on next page.)*

This legislation was the only step the Federal Government took to regulate pesticide sale and use for some 37 years. The reasons for this time lag are made more obvious after an examination of economic history. Neither the domestic demand for new and additional types of potentially harmful pesticides nor technological development had reached a level to merit additional legislation.[12]

During World War II, large scale tests were run in a number of areas to control insect pests. The knowledge gained from this work and new-found industrial capacity led to original and startling developments in the field of synthetic pesticide manufacture.[13] However, until the post World War II era, there was no apparent need for pesticide legislation other than the somewhat limited coverage of the 1910 Act, simply because domestic pesticide development was still on a relatively small scale.

Meanwhile, agricultural development and pesticide technology had reached a level at which legislators realized the need for addi-

*(Footnote 11 continued.)*
A. La. 1919); *U. S. v. Sani-Pine Corp.*, 153 F. 2d 1015 (2 Cir., 1946); *U. S. v. Powers-Weightman-Rosengarten Co.*, 211 F. 169 (1913) and *U. S. v. 681 Cases More or Less of "Kitchen Klenzer,"* 63 F. Supp. 286 (1945). In addition it is well to note that "although in a few states, insecticide laws regulating the sale of paris green and lead arsenate were in effect prior to 1910, a number of other states by 1915 passed laws similar in many respects to the Federal Law," Shepard, *The Chemistry and Action of Insecticides*, 1951, p. 7.

[12] "From 1910 until World War II, the pesticide evolution in the chemical age was a very slow and deliberate process. New means of controlling insects did not appear frequently and even new fungicides were hard for research specialists to find." Ward, "A Dynamic Statute for Pesticides," *The Yearbook of Agriculture* 271, 272, 1966. Prior to World War II, the manufacture of pesticides consisted largely of inorganic products such as calcium arsenate, lead arsenate, paris green, copper sulfate, fluorine compounds, and ground sulfur, along with botanical insecticides: pyrethrum dust and extract, rotenone dust and nicotine sulfate. Since the advent of DDT, there has been a trend toward organic compounds, and each year many new pesticides enter the market. One advantage in the increased manufacture of synthetic organic pesticides lies in the domestic availability of basic materials needed for their production. The United States is dependent to some extent on imports of arsenic and lead (for lead arsenate) and pyrethrum and rotenone are entirely of foreign origin. The Census of Manufacturers valued 1939 production of all pesticides at $76 million. According to the United States Tariff Commission, sales of synthetic organic pesticides alone totaled $150 million in 1951, $133 million in 1952, $118 million in 1953, $124 million in 1954 and reached $302,955,000 in 1961 and $346,441,000 in 1962. These figures do not include other pesticides, which amounted to $160 million in 1953, $175 million in 1954 and over $190 million in 1955. See Arrington, *World Survey of Pest Control Products*, 1956, pp. 1-2. The same work is valuable for coverage of world pesticide production.

[13] See Knipling, "The Control of Insects Affecting Man," *The Yearbook of Agriculture*, 486-496, 1952.

tional protection of the consumer and the general public. The use of pesticides increased not only in volume but also the variety and application of specialized products for specific controls became more general.[14] From this realization, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was passed in 1947.[15]

The FIFRA completely supersedes the 1910 legislation. In short, the Act is designed as a regulatory measure.[16] Any product which can be termed an "economic poison" and classed as an insecticide, fungicide or rodenticide must be registered with the U. S. Department of Agriculture before it may be marketed in interstate commerce.[17] While "economic poison" as used in the Act has been popularly redefined to mean "pesticides," the law defines an "economic poison" as:

[14] For a short, but informative, picture of trends in pesticide production see Frear, *Pesticide Handbook-Entoma*, 19th ed., 1967, pp. 27-29. For a list of pesticide manufacturers and their products see footnote 13, pp. 300-314 and 59-299.

[15] The Federal Insecticide, Fungicide and Rodenticide Act, 61 Stat. 163; U. S. C. 135 and following, or FIFRA as it is popularly known, was passed in 1947 as House Bill 1237. The House Committee on Agriculture concluded before passage of the 1947 Act that "since 1910 great changes have occurred in the field of economic poisons and the present law is now inadequate," 1947 U. S. C. Congressional Service 1200-1206. See also Reed, "The Federal Act of 1947," *The Yearbook of Agriculture*, 310-314, 1952; Anderson, "Official Registration of Pesticides," *Scientific Aspects of Pest Control*, 385-397, 1966; Ward, "The Functions of the Federal Insecticide, Fungicide and Rodenticide Act," 55 *Am. J. Pub. Health* 7, 1965 and Harris and Cummings, "Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act," 6 *Residue Reviews*, 104-135, 1964.

[16] "It should be emphasized that the basic purpose of this law is protection of the general public from personal and economic injury, including not only the purchases of products subject to the Act but all individuals who may come into contact with them or materials which may have been treated with them." Harris and Cummings, "Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act in the United States," 6 *Residue Reviews*, 104-135, 106, 1964.

[17] See 7 U. S. C. 135b; also, registration is good for five years and is renewable, 7 U. S. C. 135b(f); and 7 C. F. R. 362.10, the registration process takes around four to six weeks from the time of original submission, providing supportive data is adequate. 7 U. S. C. 135b states that an economic poison "distributed, sold, or offered for sale in any Territory or the District of Columbia, or which is shipped or delivered for shipment from any State, Territory, or the District of Columbia, or which is received from any foreign country shall be registered with the Secretary . . . ." This clause sets up the relevant commercial transactions to which FIFRA applies, which are, generally speaking, interstate in nature. It should be stressed that exports are not subject to this Act. See 7 U. S. C. 135a (b) and 7 C. F. R. 362.31 ff. While "economic poison" is defined in FIFRA, a more complete definition is found in 7 C. F. R. 362, Int. 3, Rev. 1. It should also be understood that professional applicators, carrying economic poisons across state lines, are not subject to the Act. 7 C. F. R. 362, Int. 1.

(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary shall declare to be a pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.[18]

The Pesticides Regulation Division of the U. S. Department of Agriculture handles all registrations and requires statements from the manufacturer on the composition of the product, the names of the crops on which the product is to be used and the specific conditions under which it is to be applied.[19] Registration, normally reviewed by the Food and Drug Administration (FDA) and the Public Health Service, and the Department of the Interior, is usually granted if these prerequisites are met, if the proposal meets the standards of good agricultural practice and if the use of the product does not constitute a public health hazard. Any manufacturer, seller, shipper, or distributor may register a substance under the Act, but the shipper is primarily responsible for compliance.[20] The shipper, however, may exempt himself from primary compliance requirements by way of specific guaranties found in the Act.[21]

The 1947 Act provides for seizures in cases where pesticides are adulterated, misbranded, unregistered, insufficiently labeled or when devices are misbranded.[22] Other means and consequences of enforce-

[18] 7 U. S. C. 135(a).

[19] Labeling language to be used is set out in 7 C. F. R. 362.5, 362.6 and 7 C. F. R. 362, Int. 4. Labels for large containers are governed by 7 C. F. R. 362, Int. 10, Rev. 1. Ingredient statements must follow the regulations under 7 C. F. R. 362.7 and 7 C. F. R. 362, Int. 5. Advertising policies are found in 7 C. F. R. 362, Int. 9, Rev. 1. More complicated and precise statements are necessary for those pesticides considered highly toxic to man, 7 C. F. R. 362.8. For interpretations concerning statement of net contents, see 7 C. F. R. 362, Int. 6. Warning or caution statements are covered in 7 C. F. R. 362.9 and Int. 18, Rev. 2. Interpretations concerning directions for use are found in 7 C. F. R. 362, Int. 7, Rev. 1. For a case involving improper labeling, see *Wise v. Hayes* 58 Wash. 2d 106, 361 P. 2d 171 (1961). The Pesticide Control Act of 1967 or S. 2057 (1967), now in committee, would require registration of pesticide manufacturers, formulators, etc., coupled with appropriate regulations designed to insure safety in these establishments. 7 C. F. R. 362, Int. 24 is an important section to consider when dealing with safety claims and claims of non-toxicity.

[20] The section on prohibited acts, 7 U. S. C. 135a, deals with the shipping of goods.

[21] See 7 U. S. C. 135e and 7 C. F. R. 362.11.

[22] 7 U. S. C. 135g. This section sanctions seizures for confiscation by a process of libel for condemnation in cases where an economic poison is (a) adulterated or misbranded, (b) not registered pursuant to 7 U. S. C. 135b, (c) improperly labeled under 7 U. S. C. 135-135k, (d) a white powder not properly colored under the same sections, or (e) in situations where a device is misbranded. Precise delineations of "adulteration" and "misbranding" are

*(Continued on next page.)*

ment within the Act are criminal fines and prison terms.[23] The Act also requires all manufacturers, distributors, dealers and carriers who deal in these materials to keep accurate books and records.[24]

Information required on the label constitutes as a practical matter one of the most important considerations for the manufacturer of pesticides. No name or statement on the label of an economic poison may be false or misleading with respect to usefulness, composition

*(Footnote 22 continued.)*

found in 7 C. F. R. 362.13 and 362.14. "Coloration" is covered by 7 C. F. R. 362.12. After analysis of a pesticide and a finding of irregularities, a report is made to the Department of Justice which instructs a Federal marshal to seize the compounds. Thereupon, the substances become the property of the U. S. Government. From this, generally, one of four things happens: (a) the owner of the seized pesticide agrees to condemnation by consent, a decree is issued to that effect and appropriate action subsequently will be arranged (usually destruction); (b) often, when goods are abandoned and no action is taken by the owner, the Government simply destroys them; (c) the owner files a claim and brings an appropriate action in the proper Federal District Court to oppose the libel of condemnation or (d) the pesticides can be reclaimed and reconditioned to meet FIFRA standards by consent to which both parties agree. This often involves a mere word change on the label or, in rarer cases, a complete reprocessing of the chemicals. Procedures under FIFRA are much the same as under the Federal Food, Drug and Cosmetic Act (FDCA), except the latter deals with condemnation of raw agricultural commodities which are contaminated, and rarely can be reconditioned. Under Sec. 408 of the FDCA, when a tolerance is violated, the food is considered "unsafe" within the meaning of Sec. 402(a) dealing with adulterated food. Adulterated food is subject to seizure under Sec. 304 and ultimate destruction under Sec. 304 (d).

[23] 7 U. S. C. 135f. This section, amended in 1964 by P. L. 88-305, deleted certain provisions of FIFRA. As it stands now, any person violating 7 U. S. C. 135(a)(1), which deals with registration and misleading claims, is guilty of a misdemeanor and is subject to a fine of not more than $1,000. Persons violating any provision other than 135(a)(1) (that is, those who violate labeling provisions, special marking provisions, adulteration and misbranding sections, coloring provisions; those who alter, deface, detach or destroy a label; those who refuse to supply the Secretary with certain information or give false guaranty [see 7 C. F. R. 362.11 and 7 C. F. R. 362, Int. 11 for explanation of guaranties]; or those who wrongfully reveal formulas) may be subject to a misdemeanor fine of $500 for the first offense and a fine of not more than $1,000 or one year imprisonment for each subsequent offense. An offense five years after a prior conviction is deemed to be a first offense, however. Enforcement procedures are set out in 7 C. F. R. 362.15.

[24] 7 U. S. C. 135c. Under this section any duly authorized employee of the federal, state or local authorities must have reasonable access to and right to copy the books and records of any person relevantly delineated under this section. The evidence obtained under this section, however, cannot be used in a criminal prosecution. For example and further information, see *U. S. v. Weinreb*, 99 F. Supp. 763 (1951).

and other material factors.[25] Warning and caution statements are set out in detail under Interpretation 18, Rev. 2.[26] Ingredient statements must meet the standards of good manufacturing practice and accuracy.[27] Statements of net contents must appear prominently on the label.[28] Directions for use are essential additions for all containers.[29]

Classification of pesticide toxicity leads to other labeling complications. Four basic classes of economic poisons are delineated under FIFRA. The first is comprised of those considered highly toxic to man; these compounds are subject to special labeling regulations.[30] The second class, which is composed of somewhat less toxic compounds, is subject to lesser requirements because the toxicity is generally one-tenth that of the first class.[31] The third class, which still requires caution on the part of the user, is considered one-tenth as potent as the second class.[32] Finally, the fourth class is considered safe and requires no precautionary statements.[33] All warning statements are required to be concise and easily understood.

In 1959, with industrial production and innovation at a peak, Congress included the Nematocide, Plant Regulator, Defoliant and Desiccant Amendment to the 1947 Act.[34] Coverage of the 1947 Act, therefore, starting in 1960, was extended to those materials named in

[25] 7 U. S. C. 135(2) defines such activity as "misbranding." See 7 C. F. R. 362.14. It is well to note that a name registered with the U. S. Patent Office, if not fraudulent, will generally comply with FIFRA standards. Accepted names are found in *Acceptable Common Names and Chemical Names*, U. S. D. A. (1967). For further information see Harris and Cummings, work cited at footnote 16, pp. 108-111, footnote 13 and 7 C. F. R. 362, Int. 4.

[26] Interpretation of March, 1962, 7 C. F. R. 362, Int. 18, Rev. 2.

[27] 7 C. F. R. 362, Int. 5.

[28] 7 C. F. R. 362, Int. 6. This interpretation, issued in February, 1965, is an obvious precursor of today's fair packaging legislation and the recent attention being given to protection of the consumer in the area of weights and measures. Purity of economic poisons and the violation of such standards (adulteration) are discussed in 7 C. F. R. 362.13.

[29] 7 U. S. C. 135 (z)(2)(c) and 7 C. F. R. 362, Int. 7, Rev. 1.

[30] See 7 U. S. C. 135a(3), 7 C. F. R. 362.8 and 7 C. F. R. 362, Int. 18, Rev. 2(b)(2)(i).

[31] 7 C. F. R. 362, Int. 18, Rev. 2(b)(2)(ii).

[32] 7 C. F. R. 362, Int. 18, Rev. 2(b)(2)(iii).

[33] 7 C. F. R. 362, Int. 18, Rev. 2(b)(2)(iv).

[34] Section 3 of P. L. 86-139, as amended by P. L. 87-10, March 29, 1961, 75 Stat. 18; P. L. 87-19, § 3, April 7, 1961, 75 Stat. 42; and P. L. 88-625, § 3, October 3, 1964, 78 Stat. 1002. Further, in 1962, the regulations were changed to include an expanded definition of "pest" to bring under regulation more materials used in repelling birds, reptiles, predatory animals, certain fish, plant diseases and weeds. This redefinition brought under United States Department of Agriculture (USDA) surveillance about 2,000 more products put out by some 800 firms. Anderson, "Official Registration of Pesticides," *Scientific Aspects of Pest Control*, 385-386, 1966.

the amendment and registration requirements have been applied to them since.

In 1964, Public Law 88-305 was added.[35] This amendment eliminated the controversial "registration under protest" section which allowed the sale of an unregisterable product when a protest was duly filed. The Secretary of Agriculture at the same time was authorized to require pesticide labels to bear a Federal registration number.[36] Simultaneously, the regulations promulgated under the 1947 Act were revised to require precautionary labeling to appear conspicuously on the labels of poisonous pesticides.[37] Manufacturers were also required to remove unwarranted safety claims from the labels.[38]

Besides the 1947 Act and its amendments and regulations, the Federal Food, Drug and Cosmetic Act of 1938[39] is an additional piece of legislation which places some limits on pesticide sale and use. This Act provides that tolerances be established for pesticide residues in foods where these materials are necessary for the production of a food supply. Extensive hearings have been held over a period of years in an attempt to establish such tolerances; however, because of unclear procedural guidelines, divergent points of view and the ever-changing methodology in the pesticide industry, a significant amount of work has never produced a truly complete set of standards.[40]

The so-called Miller Amendment to the Food, Drug and Cosmetic Act was passed in 1954.[41] This amendment provides that any raw agricultural commodity may be condemned as adulterated if it contains a residue of any pesticide chemical the safety of which has

[35] Section 7 of P. L. 88-305, May 12, 1964, deleted the protest section in 7 U. S. C. 135b. See *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, Pt. 1, pp. 96-97, 1963 for list of pesticides that had been registered under protest.

[36] Subsection (z)(2)(b) of P. L. 88-305, May 12, 1964, added to 7 U. S. C. 135 the words: "other than the registration number assigned to the economic poison" which revised the misbranding regulations.

[37] 7 C. F. R. 362.9 (effective October 1, 1966).

[38] 7 C. F. R. 362.122 and 7 C. F. R. 362, Int. 24.

[39] 52 Stat. 1040, 21 U. S. C. 301, and following. For an older article, see Dunbar, "Insecticides and the Pure Food Law," *The Yearbook of Agriculture*, 314-316, 1952

[40] For the tolerances and exemptions from tolerances for pesticides on or in raw agricultural commodities, see 21 C. F. R. § 120 ff. The basis for these regulations is 21 U. S. C. 346 and 21 U. S. C. 346a. See also *U. S. v. Bodine Produce Co.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,056, 206 F. Supp. 201 (1962), (DDT tolerance on lettuce) and *Atlas Powder Co. v. Ewing*, 201 F. 2d 347 (3 Cir., 1952).

[41] 21 U. S. C. 346a; 68 Stat. 411, as amended August 28, 1958, P. L. 85-791, 72 Stat. 947.

not been formally exempted, or which is present in excessive amounts.[42] It gives the Secretary of Health, Education and Welfare the power, previously handled unsuccessfully by hearings, to establish residue tolerances and spells out in detail the procedure to be followed.[43] The manufacturer, for example, must submit information, which is kept confidential, on the chemical identity of the compound, its toxicity to laboratory animals and the amount, frequency, and time of application to the specific crop or crops covered. He must also submit data to indicate the magnitude of residues remaining following the recommended application, and finally, supporting data of the tolerance requested.[44] The Department of Agriculture then must certify that the chemical is useful for the production of the crop or control of the pest in question.[45] The tolerance proposed by the petitioner must reflect the amount of residue likely to result when the pesticide is used in the manner proposed.[46] On the other hand, exemptions from

[42] 21 U. S. C. 346a(a) refers to adulterated food, 21 U. S. C. 342 (a)(2)(B) which refers, in turn, to the prohibited acts section, 21 U. S. C. 331(b) and seizure, 21 U. S. C. 334. See also Porter and Fahey, "Residues on Fruits and Vegetables," *The Yearbook of Agriculture*, 297-301, 1952. Finding 23, Pesticide Chemical Regulations, 20 Federal Register 1473, 1493 explains tolerances on vegetables. Foods, it is generally agreed, may be adulterated regardless of whether they are, in specific cases, injurious to health when a tolerance has been set. If there is no tolerance, then the Government must prove a possibility of injury to human health under the statute. See *U. S. v. Bodine Co.*, case cited at footnote 40. "Raw agricultural commodities" is defined in 21 C. F. R. 120.1 (e).

[43] 21 U. S. C. 346a (b). Such tolerances are subject to the prerequisite of shipment in interstate commerce and the Government, in the case of adulteration of a raw agricultural commodity, has the burden of proof that the goods were adulterated at the threshold of or during interstate commerce. *Pasadena Research Laboratories, Inc. v. U. S.*, 169 F. 2d 375, cert. denied, 335 U. S. 853 (1948). See also the regulations concerning tolerances, 21 C. F. R. 120 ff.

[44] 21 U. S. C. 346a (d). Data submitted in accordance with this section is guaranteed confidentiality as stated in 21 U. S. C. 346a (f). See Roark, "How Insecticides are Developed," *The Yearbook of Agriculture*, 200-202, 1952 and Haller, "How Insecticides are Mixed," *The Yearbook of Agriculture*, 202-204, 1952.

[45] 21 U. S. C. 346a (b) (3), 21 C. F. R. 120.4, and 7 C. F. R. 363. Testing and analysis of economic poisons under FIFRA is governed by 7 C. F. R. 362, Int. 12.

[46] See footnote 45. In some instances, because of the characteristics of the pesticide, the way it is likely to be used or because no studies have been made of the compound, a zero tolerance (no residue allowable) has been set. Zero tolerances have come to be quite controversial and there is an indication that they may be deleted in favor of finite tolerances of a minimal nature, 21 C. F. R. 120.5. See *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, pt. 7, 1319-1334, 1963 for an account of Dow Chemical Company's experiments evaluating the safety of a pesticide chemical. See also Frear, *Pesticide Handbook-Entoma*, 19th ed., 1967, 33-57 for a comprehensive list of tolerances.

tolerances also can be granted when no hazard to human health is exhibited by the use of a certain quantity of pesticide on or in a certain commodity.[47]

The two basic federal statutes, the FIFRA and the Food, Drug and Cosmetic Act, as amended supplement each other and are interrelated by law and in practical operation.[48] It has been the policy of the Department of Agriculture not to register any new pesticide unless either a tolerance has been established under the Miller Amendment or it has been shown adequately that no residues will result from the proposed use of the product. Zero tolerances, however, have given way to outright denial of registration for those pesticides considered highly toxic to man and animals. Conversely, a tolerance will normally not be granted by the Department of Health, Education and Welfare until an application for registration has been filed with the Department of Agriculture. Most manufacturers file an application for registration and at the same time petition for a tolerance or an exemption from tolerance specification, so that the two applications may be processed simultaneously.[49]

An additional Federal Act which has an indirect bearing on this general field of law is the Williams Bill, which was passed in 1958.[50] This part of the Act regulates the additives in processed foods, and covers any material "intentionally" or "incidentally" added to foods. Pesticides added to foods might be covered by this section in only rare cases. Normally, however, an example of the former would be an emulsifier added to ice cream; the latter would include liners or

[47] See 21 C. F. R. 120.6 for exemptions. These exemptions are only for pre-harvest applications.

[48] It is well to note that since 1964 a three-way agreement has existed between the Departments of Agriculture, Health, Education and Welfare, and Interior, providing for coordination in the review of pesticide registration applications. In addition, the Federal Committee on Pest Control (FCPC) coordinates federal pest control activities to see that the total public interest is served in terms of safety and effectiveness. See "FCPC, What It Is, What It Does," *U. S. Government Pamphlet 0-250-459* (30), 1967; *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, app. III & IV to pt. 1, 1963; and Anderson, "The Federal Committee on Pest Control," *Scientific Aspects of Pest Control* 367, 1966. See also 32 *Federal Register* 13202 (Sept. 16, 1967) for outline of FCPC functions and procedures.

[49] Registration is specifically covered in FIFRA under 7 U. S. C. 135b and in the regulation under 7 C. F. R. 362.10; petition for a tolerance or for an exemption is covered in 21 C. F. R. 120.7. Other detailed provisions for review of tolerances is found in 21 C. F. R. 120.8 and following.

[50] See 21 U. S. C. 348 ff.

casing for packages which might dissolve in a food or beverage.[51] Also, as a matter of current interest, the so-called "Delaney Clause" in the FDCA stipulates that no material which is capable of causing cancer under any condition may be permitted in any food.[52] This again only skirts the area of less important, however related, pesticide laws.[53] Such legislation as the ICC Rules and Regulations on transport of dangerous articles, the Federal Caustic Poison Act of 1927, the Post Office Department's rules prohibiting the mailing of injurious materials, and the Federal Hazardous Substances Labeling Act, which specifically does not cover pesticides, are examples of other laws administered by the Federal Government to protect the public from hazards produced by way of dangerous compounds.

From time to time, new regulations and interpretations are promulgated under the authority of the FIFRA to facilitate effective coverage of that area duly delegated for USDA activity.[54] Also, USDA sets up guidelines which, while lacking the force of law, delineate matters of policy.[55]

## State Pesticide Legislation

Generally, there are two types of state pesticide laws. First, there are registration laws, requiring certain controls over the distribution and sale of pesticides in intrastate commerce. In addition, some states have set up pesticide tolerances for agricultural commodities sold within the particular jurisdiction. Secondly, there is a group of laws which are generally considered peculiar to the states: those which regulate the use and application of the substances themselves within the state. The first set of laws has been generally modeled after the FIFRA by way of the Council of State Governments' "Uni-

[51] Frear, *Pesticide Handbook-Entoma*, 19th ed., 1967, 32.

[52] 21 U. S. C. 348 (c)(3)(A).

[53] There is a great diversity of opinion as to carcinogenicity of some pesticides. For a discussion of this problem see *Congressional Hearings: Interagency Coordination in Environmental Hazards (Pesticides)*, Pt. 3, 673-716, 1963.

[54] 7 U. S. C. 135d empowers the Secretary of Agriculture to make rules and regulations. FIFRA regulations can be found in 7 C. F. R. 362 ff and USDA interpretations are found in 7 C. F. R. 362.100—362.122.

[55] Guidelines are often supplements to interpretations and rules and are informational in character, providing recommendations as to the use, sale and shipment of pesticides. See USDA's excellent *Guide for the Use of Insecticides*, 1967, and *Safe Use of Agricultural and Household Pesticides*, 1967.

form State Pesticide Act." The registration laws, dealing with pesticide marketing within state boundaries, have been adopted in more or less similar form by 47 of the 50 states. Only Indiana, Delaware and Alaska are without state labeling regulations.[56]

In actuality, the state registration laws are relatively uniform when compared to the use and application laws. There is a great divergence of coverage, unfortunately mostly inadequate, among the states' use and application legislation. Other than the FAA regulations, no applicable federal counterpart to these laws exists since they regulate activities which are by their nature normally intrastate. Some states have taken significant steps to insure generally ample licensing provisions, specific regulations as to the use of pesticides, inspection of equipment, etc., by way of custom applicators acts, pest control operators laws and aerial application regulations. Other states, however, either have no laws dealing with pesticide use or have what might be considered only partial coverage of the problem. While the lack of uniformity is disturbing, such divergence can be explained in part by the varying needs and desires of the people in different areas. However, certainly the greatest shortcoming in the field of pesticide laws today is the incomplete coverage within the states over the use and application of these potentially harmful substances, which have

[56] Alaska does, however, have an Enabling Act which authorizes the registration of products and the issuance of regulations: ACLA, Sec. 33-1-2, 1949. Also, Indiana does control to some extent the use of pesticides by way of aeronautics regulations. Reg. No. 2, Ind. Aero. Comm. 1951. For a summary of state activities see Petty, "Functions of State Committees on Pest Control," *Scientific Aspects of Pest Control*, 374, 1966. Also, of importance is the federal disclaimer of jurisdiction over pest control operators except in cases of coloring of compounds. This opens for state control the activities of these businesses. 7 C. F. R. 362, Int. No. 1. The Federal Government does in fact exercise some control over the use of pesticides by requiring agricultural aircraft operators to obtain certificates when they are engaged in the spraying of economic poisons. Certification is awarded by the Federal Aviation Agency (FAA) only when certain standards are met by the pilot. No pilot may, under these regulations, dispense an economic poison that is registered under FIFRA (1) for a use other than that for which it is registered, (2) contrary to any safety instructions or use limitations on its label or (3) in violation of any federal law or regulation. See 14 C. F. R. 137 and following. These rules do not relieve the agricultural aircraft operator from more stringent state laws which may be in effect. Assurance in the safety and efficacy of the use of pesticides in agriculture is the primary motive for passage of these rules which went into effect on January 1, 1966. 30 *Federal Register* 8104 (June 24, 1965).

been known to cause injury in a variety of ways. Undoubtedly, this can be overcome by some centralized effort which could be exerted against each individual state problem.[57] However, more practically, a uniform or guideline act, presented to the states as a basis from which they may fill gaps existing in current state codes or adopt as a whole or in part with or without variations to suit particular circumstances, seems to be the most desirable approach to this difficulty. It is noteworthy that uniformity was stressed by the House Committee on Agriculture before the passage of the FIFRA in 1947 so as to minimize conflicts between state laws.[58]

Enforcement of uniform state pesticide use and application acts varies from state to state. Pragmatically, it is difficult from a tactical point of view to enforce licensing, inspections, examinations and technical rules over the use of pesticides. Some states already have adequate means by which surveillance is maintained over custom applicators, pest control operators and the like. Other states have poorly enforced surveillance. Still others have no system through which control over these persons is maintained. A licensing system would, in reality, reduce the apparent threat to public health from pesticide contamination. The problem is, however, how much of this apparent threat will be alleviated by a scheme of more strict control over those who use, handle and apply pesticides? States which now have controls over these persons have met with successes as varied as the laws themselves. However, one point is clear: a program of enforcement is only as effective and vigorous as the agencies who administer it. Having well-written laws is one thing, while adequate enforcement is quite another.

The great number of state statutes, both registration and use and application, are listed below. The list is a compilation of the major pieces of pesticide legislation now in force in the United States.[59]

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[57] See Curran, "The Preparation of State and Local Health Regulations," 49 *American Journal of Public Health* 314, 1959.

[58] 1947 U. S. C. Cong. Serv., 1201.

[59] See also the excellent compilations of laws in full text revised periodically by the Chemical Specialties Manufacturers Association: *Economic Poisons (Pesticides) Laws* (Rev. 1967) and the National Agricultural Chemicals Association: *Law Guide* (Rev. 1967) and *Manual of Pesticide Use and Application Laws* (Rev. 1967).

## State Pesticide Laws

| *STATE* | *REGISTRATION LAWS* | *USE AND APPLICATION LAWS* |
|---|---|---|
| ALABAMA | Insecticide, Fungicide and Rodenticide Act (1951) | 1. Alabama Professional Applicators Law (1953, as amended)<br>2. Regulations concerning Professional Applications (1953) |
| ALASKA | ..... | ..... |
| ARIZONA | Pesticide Act (1956) with rules and regulations | 1. Arizona Pest Control Applicators Act (1953, as amended) |
| ARKANSAS | Economic Poisons Act (1947) with regulations | 1. Regulations on the Control of 2,4-D&2, 4,5-T (1959, as amended) (amended 1966)<br>2. Arkansas Agricultural Application Service Licensing Law (1961) (revised 1966)<br>3. Pest Control License Law (1951)<br>4. Pest Control Law (1965)<br>5. Regulations of State Plant Board |
| CALIFORNIA | 1. Agricultural Code Sections 1061-1079<br>2. California Administrative Code (Economic Poisons)<br>3. Department of Agriculture Regulations: Injurious Materials | 1. California Injurious Materials Law (1949, as amended) with regulations<br>2. Regulations pertaining to Injurious Herbicides (1962)<br>3. Regulations: Agricultural Pest Control Business (1961, as amended with regulations concerning Agricultural Pest Control Operators) |
| COLORADO | Insecticide, Fungicide and Rodenticide Act (1947) | Custom Applicators Law (1961) |

| *STATE* | *REGISTRATION LAWS* | *USE AND APPLICATION LAWS* |
|---|---|---|
| CONNECTICUT | Pesticide Law (1963) | 1. Aerial Application of Insecticides, Fungicides, Herbicides and Fertilizers (1958)<br>2. Connecticut Tree Expert Law (1949)<br>3. Connecticut Law Limiting the Discard of Pesticides (1961)<br>4. Custom Applicators Act (1963) |
| DELAWARE | ..... | ..... |
| FLORIDA | Pesticide Act (1953) (revised, 1966) | 1. Regulations: Commercial Spraying of Lawns and Ornamentals (1959)<br>2. Residential Pesticide Sprayings<br>3. Florida Structural Pest Control Act (1959, as amended)<br>4. Regulations of Board of Health |
| GEORGIA | Economic Poisons Act (1949) | Structural Pest Control Act (1955, as amended) with regulations |
| HAWAII | Economic Poisons Act (1945) (revised. 1966) | Herbicide Sale and Use Act (1949, as amended) with regulations |
| IDAHO | Economic Poison Act (1963) | Idaho Commercial Sprayer's and or Duster's Law (1951, as amended with regulations) |
| ILLINOIS | Economic Poison Law (1962) | 1. Illinois Herbicide Law (1959)<br>2. Custom Application of Pesticides (1965)<br>3. Custom Spray Law (1966) |
| INDIANA | ..... | Regulation No. 2 Aeronautics Commission of Indiana |
| IOWA | Pesticide Act (1963) with regulations | Section 5 and 6 of Pesticide Act (1963) |
| KANSAS | 1. Agricultural Chemical Act (1947)<br>2. Livestock Remedy Law | 1. Kansas Aerial Spraying Law (1953, as amended)<br>2. Kansas Pest Control Act (1953, as amended) with regulations<br>3. Kansas Chemical Spray Law (1963) |

| *STATE* | *REGISTRATION LAWS* | *USE AND APPLICATION LAWS* |
|---|---|---|
| KENTUCKY | 1. Economic Poisons Law (1956)<br>2. Food, Drug and Cosmetic Law | Kentucky Termite and Pest Control Industry Law (1960) (Kentucky Structural Pest Control Act) |
| LOUISIANA | Pesticide Act (1952) | 1. Louisiana Herbicide Law (1954) with regulations<br>2. Custom Applications of Pesticides (1964)<br>3. Ornamental Spraying Law (1965)<br>4. Structural Pest Control Law (1960) |
| MAINE | Economic Poisons Law (1958) | Regulation of Pesticides (1963) |
| MARYLAND | Pesticide Law (1958) | ..... |
| MASSACHUSETTS | 1. Pesticide Law (1961)<br>2. Labeling of DDT Preparations (1947) | 1. Law Licensing Persons Applying Chemicals to Waters (1960)<br>2. Pesticide Board Rules and Regulations (1962) |
| MICHIGAN | Insecticide, Fungicide and Rodenticide Act (1949) | 1. Michigan 2, 4-D Act (1959)<br>2. Michigan Custom Applicators Law (1959)<br>3. Equipment Operator's Act (1959) |
| MINNESOTA | Economic Poisons and Devices Law (1945) | Minnesota Custom Applicators Law (1953, as amended) (revised 1966) |
| MISSISSIPPI | Economic Poisons Act (1950) | 1. Law Regulating Application of Hormone type Herbicides by Aircraft (1952, as amended) with regulations<br>2. Professional Pest Control Operators Law (1938) with regulations |
| MISSOURI | Economic Poisons Act (1955) | ..... |
| MONTANA | Economic Poisons Act (1947, as amended) | ..... |
| NEBRASKA | Economic Poison Law (1961) | ..... |

| *STATE* | *REGISTRATION LAWS* | *USE AND APPLICATION LAWS* |
|---|---|---|
| NEVADA | Economic Poison Law (1955) with regulations | Nevada Custom Pest Control Operators Law (1955) with regulations |
| NEW HAMPSHIRE | Economic Poisons Law (1949) | Pesticide Control Law (1966) |
| NEW JERSEY | Economic Poison Act (1951) | ..... |
| NEW MEXICO | Economic Poisons Act (1951) | Pesticide Applicators Law (1965) |
| NEW YORK | Pesticide Law (1960) | 1. Water Quality Standards Law<br>2. Pesticides in Grape Vineyards Law (1963, as amended) |
| NORTH CAROLINA | Insecticide, Fungicide and Rodenticide Act (1947) | 1. North Carolina Aerial Crop-Dusting Law (1953) with regulations<br>2. North Carolina Structural Pest Control Act (1955) |
| NORTH DAKOTA | 1. Insecticide, Fungicide and Rodenticide Act (1947)<br>2. Livestock Medicine Law (1943) | 1. North Dakota Pesticides Damage Claim Act (1955)<br>2. Aerial Spraying, Dusting, Fertilizing and Insect Control Law (1957)<br>3. Regulations of the Aeronautics Commission (1957) |
| OHIO | 1. Economic Poisons Act (1966)<br>2. Livestock Remedies Law (1949) | Ohio 2, 4-D Law 1961 |
| OKLAHOMA | Pesticides Law (1955) | 1. Oklahoma Pesticide Applicators Law 1961 with regulations<br>2. Ornamental Spraying or Pruning (1965)<br>3. Phenoxy Herbicides (1965)<br>4. Structural Pest and Termite Control Law (1955) with regulations |
| OREGON | Economic Poisons Act (1953) | 1. Control of Application of Agricultural Herbicides and Insecticides Law (1953, as amended)<br>2. Herbicide Tax Law (1961) |
| PENNSYLVANIA | Pesticide Act (1957) | ..... |

| *STATE* | *REGISTRATION LAWS* | *USE AND APPLICATION LAWS* |
|---|---|---|
| RHODE ISLAND | Economic Poisons Law (1951) | Custom Applicators Act (1963) |
| SOUTH CAROLINA | Economic Poison Law (1953) | ..... |
| SOUTH DAKOTA | 1. Insecticide, Fungicide and Rodenticide Act (1947)<br>2. Poison Law (1939) | South Dakota Spraying and Dusting Law (1953) |
| TENNESSEE | Insecticide, Fungicide and Rodenticide Act (1951) | Tennessee Pest Control Act (1955, as amended) with regulations |
| TEXAS | 1. Insecticide, Fungicide and Rodenticide Act (1963)<br>2. Livestock Remedy Act | Texas Herbicide Law (1953, as amended) with regulations |
| UTAH | Insecticide, Fungicide and Rodenticide Act (1951) | Utah Economic Poison Application Act (1951) with regulations |
| VERMONT | Insecticide, Fungicide and Rodenticide Act (1947) | Vermont Aeronautic Commission Regulations (1949) |
| VIRGINIA | Insecticide, Fungicide and Rodenticide Act (1948) | ..... |
| WASHINGTON | Agricultural Pesticide Act (1961) | 1. Pesticide Act (1961)<br>2. Pesticide Application Act (1961) amended, (1967)<br>3. Regulations Relating to Commercial Applicators (1961)<br>4. Regulations: Use of Toxic Insecticides (1952) |
| WEST VIRGINIA | Economic Poison Law (1961) | ..... |
| WISCONSIN | Economic Poison Law (1951) | Pest Control Operator's Law (S. B. 172—Feb. 24, 1967) (Pending) |
| WYOMING | Economic Poison Law (1943, as amended) | Aerial Spraying Registration Regulations (1951) |

**[To be continued in the April issue]**

# Address by His Holiness Paul VI to Representatives of the Food Standards Commission

The Following Remarks Were Addressed by Pope Paul VI to a Group of Delegates to the Meeting of the Joint Food Standards Commission of the Food and Agriculture Organization and the World Health Organization Held in Rome from February 20, 1968 to March 1, 1968. The Article Appeared in the Vatican Newspaper "L'Osservatore Romano" (March 2, 1968), and Its French Part Has Been Translated by Ann M. Wolf, of New York City.

IT GIVES US GREAT PLEASURE to greet you as representatives of the Joint Commission of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), assembled here to perfect the standards of the Codex Alimentarius. We are glad to express to you Our highest esteem, Our sincere encouragement and Our cordial good wishes.

Your difficult work meets in fact the concern which We expressed last year: "Even if considerable, the efforts that are being made to help the developing countries on the financial and technical level would be illusive if part of their results were brought to naught by the interplay of commercial relations between rich countries and poor countries." (Populorum progressio, paragraph 57.)

But, as We realize fully, it is not enough to denounce the evil or, in a general manner, to appeal to the good will: what is necessary is a search for realistic ways capable of leading to effective solutions. This is why We appealed to those who are able to put the proper means into motion: "International conventions whose scope is sufficiently vast would be helpful; they would lay down general rules with a view to regulating certain prices, guarantee certain productions, assist certain new industries." (Populorum progressio, paragraph 61.)

It seems to Us that your efforts fall within these plans since they help the food-exporting countries to present their products in a manner that makes them acceptable to the importing countries. Thus, while the consumers in the latter are given greater satisfaction, the producers in the former find more reliable markets and sources of income that assist them in balancing their economy. May these efforts

towards establishing food standards, made with the collaboration of a growing number of governments, contribute to re-establishing "at least a certain equality of chances among the partners," (Populorum progressio, paragraph 61), as We called it in Our wishes.

This is indeed the goal to be reached: not to strengthen the privileges of nations that are already favored, but to permit all peoples to achieve more decorous living conditions, under which sufferings caused by hunger are no longer a redoubtable spectre, under which "poor Lazarus can sit down at the same table as the rich man." (Populorum progressio, paragraph 47.)

With this goal in mind, it is a pleasure for Us to encourage the joint efforts of FAO and WHO in the service of the world community, and from the bottom of Our heart to invoke the enlightening graces of Almighty God upon you and upon the work of your Commission.*

While bidding you a heartfelt welcome, We wish to assure you of the high importance We attribute to your discussions of alimentary norms in the Mixed Commission of the FAO, and of the WHO.

In fact, by your efforts to establish world-wide standards for food preparation, labelling and grading, you contribute towards closer communications and a more intimate physical communion between the peoples of the world, and particularly between the less developed and the more developed nations.

The consequent wider availability and acceptance of foods will constitute your achievement "to multiply bread so that it suffices for the tables of mankind" (United Nations, Oct. 4, 1965). We referred to such high purposes recently, in Our Encyclical Letter on the Development of Peoples, asserting that "Every nation must produce more and better quality goods to give to all its inhabitants a truly human standard of living, and also to contribute to the common development of the human race" (paragraph 48). And We noted further that "the present situation calls for concerted planning . . . (which) presupposes careful study, the selection of ends and the choice of means, as well as a reorganization of efforts to meet the needs of the present, and the demands of the foreseeable future" (paragraph 50).

It is therefore a pleasure for Us to commend and encourage the work of your Commission which so nobly responds to those requirements; while We invoke upon you, your deliberations, your collaborators and your respective nations, richest divine graces and favours.‡

**[The End]**

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Note of the Translator:
* This part of the address of the Pope was delivered in French.

Note of the Translator:
‡ This part of the address of the Pope was delivered in English.

# The Salmonellae— A Current Challenge

By FRANKLIN M. DEPEW

The Following Article Was Presented Before the American Association of Candy Technologists at The Chemists' Club, New York City, on February 8, 1968. Mr. Depew Is the President of the Food and Drug Law Institute.

PRIOR TO WORLD WAR II, salmonellosis was not recognized as a common food-borne infection. In recent years, due to improved reporting procedures, greater familiarity with the organism and better methodology, the National Communicable Disease Center receives reports of over 20,000 isolations from human sources each year. This compares with reports of 723 human cases of salmonellosis in the United States in 1945. Contemporary eating habits and bulk preparation and mass distribution of human and animal foods on the national and international level help spread any contamination with great efficiency and may thus contribute to this startling increase. Over 1200 different species have been isolated from man and animal, many of which can cause salmonellosis in man. The first species of salmonella was isolated in 1885 by Dr. D. E. Salmon, for whom it was named, then Chief of the Bureau of Animal Industry of the United States Department of Agriculture. The natural habitat of salmonellae is the gastro-intestinal tract of both warm and cold blooded animals as well as man. Salmonellosis is, thus, primarily a disease transmitted by the fecal-oral route. The cycle of infection usually involves the direct and indirect transfer of viable organisms from one host to another and finally to man, with foods and beverages most frequently implicated in outbreaks. Salmonellae can be picked up at any time during the various stages of production, processing, storage or preparation of foods for human or animal consumption. Viable salmonellae may be airborne for considerable distances.

## Sanitation: The Logical Control Measure

With this increased incidence of salmonellosis and the increased knowledge about methods of growth, transmittal and detection of the micro-organism, sanitation becomes more and more important as the logical control measure. The importance and influence of plant environmental conditions, personal hygiene and sanitary practices of employees, separation of raw material and finished goods processing areas and proper maintenance of equipment, including proper design to permit adequate cleaning, have been repeatedly demonstrated. Effective control of food-borne salmonellosis entails a much higher and more rigid level of sanitation than has generally been practiced or required by industry, or by health and regulatory officials.

We in the Institute have always urged that it is important that industry personnel be guided in their actions by the concept that they have accepted a status of public trust. From the time the seed is planted and through all stages of production until the food finally reaches the consumer, every worker should realize that what he does may affect the health of a fellow human being. The present challenge of the salmonellae emphasizes the fact that this is a self-evident truth. Management personnel have a responsibility to train their employees to recognize their duties as well as to maintain an effective bacteriological control program in their plants. As I see it, the best answer to the challenge of the salmonellae is a program of good manufacturing practices for every plant including from time to time a surveillance similar to that of a Food and Drug Administration (FDA) inspector.

As an aid to industry in meeting this problem, FDA has, during the past year, held bacteriological contamination workshops in respect of pecans, breaded and fresh shrimp, frozen eggs, dried milk, smoked fish, Chinese noodles and a number of convenience foods. Additional workshops on bacteriological contamination of convenience foods are scheduled for this month. The National Renderers' Association held nine salmonella workshops throughout the United States to which it invited others interested in the problem. In addition, FDA worked with the Grocery Manufacturers of America (GMA) to develop a series of slides directed at the food plant employee and supervisory levels, setting forth the basic principles of good hygiene and sanitation. It is my understanding that as of about a month ago 173 sets of this color slide presentation with script had been purchased and 23 sets had been borrowed from GMA headquarters for showings. In addition, I understand the GMA Salmonella Education Task Force has recommended, among other things, the establishment of a GMA

Clearing House for Salmonella Prevention. I cite all of the foregoing as splendid examples of the cooperation and manner in which industry and FDA is attacking this problem.

Salmonellae can be destroyed by proper heat treatment. Pasteurization kills the organism in milk. Chemicals used in accordance with FDA regulations are also effective. Salmonella on equipment can be destroyed by using sanitizing compounds after hot water and detergent scrubbing and rinsing. Methods of destruction are reported in some detail in the Report of the Western Experiment Station Collaborators Conference of March 9-11, 1966, ARS 74-37, July 1966. However, I understand the food processor generally needs to know more than is yet available to him as to what he can do to prevent growth of salmonella if it gets into his product.

## Problems of Detection and Control

Another factor complicating the situation is the fact that methods normally used for detecting salmonellae in foods are slow, cumbersome and expensive. At least three days are required even to demonstrate the absence of salmonellae. If there are suspicious colonies their identification requires another three or four days. Often these isolates prove not to be salmonellae. These non-official analytical methods are described in the Bacteriological Analytical Manual, U. S. Food and Drug Administration. These methods are always subject to change and there is currently a great deal of technical work going on on improved methods for the detection of salmonellae and other organisms. As these methods develop they will be published as revisions to the Manual. If you do not have the Manual you may wish to write FDA and ask to be placed on their mailing list. Because of the rapid developments that are being made in this field, if you have any particular problem, I suggest you write the Division of Microbiology of FDA. Revisions in these methods are also published from time to time in the Association of Official Agricultural Chemists' Journal.

A method which is in use by a number of leading industrial laboratories is the fluorescent antibody (F-A) method. This method is reliable for negative results which may be secured within 48 hours. However, as now used, it may give false positive results. In addition to this drawback the method can only be used by a competent microbiologist with special training, using refined laboratory equipment. An FDA-University-Industry meeting of microbiologists having experience with this method was held in June 1967 at the Food Research Institute of the University of Wisconsin. FDA hoped that this meeting

by cooperative exchange of scientific experience would lead to a rapid screening technique which would enable industry to increase its control measures. While this has not happened as yet, it is the hope of FDA that further cooperative research will result in debugging the method to the extent that it can be used as a routine check.

Last July the National Academy of Sciences undertook a broad 18-month study of salmonella and its impact on human health, food technology and animal agriculture. The study will seek to answer such questions as:

(1) At what point in the chain of transmission of the organism can control methods be most effective in preventing outbreaks of disease?

(2) How can the combined resources of government, the academic world and industry be utilized most effectively to reduce the potential salmonella threat to public health?

A review and evaluation of FDA's surveillance and enforcement activities to control salmonella will be part of the study.

In addition, last August the FDA sponsored a 15-month study by the Midwest Research Institute which will analyze the salmonella problem in relation to the total environment, the food and drug industries, and the consumer. The study will attempt to connect the mass of available scientific data and management approaches that may achieve effective control of the salmonella problem.

## Contamination in Candy

As you are aware, during the past year at least three major chocolate candy producers encountered salmonellae contamination in finished products. How this came about is as yet uncertain. I understand the low moisture content of the ingredients, in the processing and in the finished product, would not seem to be sufficient to support proliferation; yet FDA has found finished candy containing a level of contamination that cannot be explained by present day knowledge. The industry has been prompt to show its concern and has shown a determination to remedy the situation. The Chocolate Manufacturers Association has engaged Pennsylvania State University to do research on potential contamination and survival in candy processing and the National Confectioners Association is having research work done by the Food Research Institute. In addition, I understand the candy industry has been active in working for the establishment of minimum sanitation guidelines.

I am sure you will be interested in the results of the FDA tests for salmonella made during the last year on candy ingredients. In giving them to you I stress that they cannot be considered as statistically valid; they are as follows:

| Period | Total Samples | Positive Samples |
|---|---|---|
| | *Candy—Chocolate Candy and Finished Chocolate Coatings* | |
| Apr./Oct. | 182 | 13 |
| Nov./Dec. | 251 | 10 |
| | 433 | 23 |
| | *Cocoa, Raw Press Cake, etc.* | |
| Apr./Oct. | 143 | 2 |
| Nov./Dec. | 33 | 0 |
| | 176 | 2 |
| | *Nuts other than Coconut* | |
| Apr./Oct. | 88 | 2 |
| Nov./Dec. | 47 | 1 |
| | 135 | 3 |
| | | 1 shelled Filbert domestic |
| | | 1 shelled Cashew—import |
| | | 1 shelled Brazil—import |
| | *Coconut & Coconut Products* | |
| Apr./Oct. | 131 | 5 |
| Nov./Dec. | 24 | 1 |
| | 155 | 6 |

As I said, no conclusions can be drawn from these figures. However, we may speculate that the contamination in chocolate candy did not come from the cocoa, raw press cake or other cocoa source.

## Guarantees

Before closing, I would like to comment briefly on salmonella guarantees and certificates. It is my opinion that a salmonella guarantee affords no more legal protection than does the usual food and drug guarantee provided for under the Federal Food, Drug and Cosmetic Act and the regulations thereunder. I understand some buyers are asking for certification that the product has been prepared under strict bacteriological control and that representative tests have been made. Some suppliers feel that these are unnecessarily burdensome and give no positive assurance of freedom from contamination as contamination can occur after the product has left the supplier's hands.

**[The End]**

FOOD DRUG COSMETIC
LAW JOURNAL

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COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
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