VOL. 24, NO. 1 JANUARY 1969

Food Drug Cosmetic Law JOURNAL

Additional Papers Presented at the Twelfth Annual Educational Conference of The Food and Drug Law Institute, Inc., and The Food and Drug Administration

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.

January, 1969
Volume 24 • Number 1

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

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REPORTS

TO THE READER

1968 FDLI-FDA Conference—Additional papers presented at the Twelfth Annual Joint Educational Conference of the Food and Drug Law Institute, Inc. and the Food and Drug Administration are included in this issue of the JOURNAL. Some of the papers presented at the Conference were published in the December, 1968 issue, and others will appear in the February issue.

Nathaniel L. Geary, in "Self-Certification of Foods," beginning on page 4, evaluates, from the Agency point of view, the pilot programs for self-certification through which the FDA has worked with the General Foods Corporation and the Green Giant Company. Mr. Geary is Special Assistant to the Director for Quality Assurance, Bureau of Voluntary Compliance of the FDA.

New Jersey's Commissioner of the Department of Health, *Roscoe P. Kandle,* describes that State's Single Service System for advancing GMPs in his article, "Application of Current Good Manufacturing Practices," beginning on page 9. Under this system federal and state agents have been given, by reciprocal commissioning, roles allowing immediacy in action not possible in areas where independent surveillance is the rule.

In his article "GMPs—An Industry Point of View," beginning on page 14, *Irwin S. Shupe* questions whether a single definition of Good Manufacturing Practices can be meaningfully applied to industry's multifarious productive system. Mr. Shupe is the Director of Quality Control for the Winthrop Laboratories.

"The Fair Packaging and Labeling Act—Some Unanswered Questions Two Years After Enactment," is an examination of the weaknesses of the mandatory and voluntary rules of a program designed to "enable consumers to make rational comparisons of competing products" in a fair market. *Edward H. Dunkelberger, Jr.,* the author, is associated with Covington and Burling, Washington, D. C. attorneys. The article begins on page 17.

An optimistic view of industry-government-consumer rapport, based on industry-fostered "Consumer Dialogue" and government-fostered self-certification program is reflected in *Theodore R. Gamble's* article, "Teamwork for Consumer Protection," beginning on page 37. Mr. Gamble is Chairman of the Board of Pet Incorporated.

Milan D. Smith, Executive Vice President of the National Canners Association, confines his review of self-regulatory advances toward quality assurance to the canning industry, in "Quality Assurance Through Self-Certification," beginning on page 46.

Harold A. Golle, in "Status, Self-Certification Program," which begins on page 53, analyzes the achievements of the pilot self-certification program known as the Dover Agreement, entered into by the FDA and GFC in September, 1967. Mr. Golle is the Director of Quality Assurance of the General Foods Corporation.

Theodore E. Byers, author of "Fair Packaging and Labeling Act," which begins on page 60, states that the very heart of the FPLA is "the declaration of contents." Mr. Byers, who is the Director of the Division of Case Guidance, Bureau of Regulatory Compliance of the Food and Drug Administration, re-emphasizes the stipulations of the declaration.

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Self-Certification of Foods

By NATHANIEL L. GEARY

The Following Report Was Presented at the Food and Drug Law Institute, Inc.—Food and Drug Administration's Twelfth Annual Educational Conference at Washington, D. C. on December 3, 1968. Mr. Geary Is Special Assistant to the Director for Quality Assurance, Bureau of Voluntary Compliance of the Food and Drug Administration. Succeeding Articles in This Issue Were Presented at the Same Conference.

MUCH HAS BEEN SAID ABOUT SELF-CERTIFICATION, but little has been communicated about what we are trying to do. Our primary objective is to achieve quality assurance (that is, consumer protection) in foods more efficiently. One of our main assumptions is that quality assurance is the responsibility of industry which daily lives with the problems of satisfactory raw material supplies, adequate equipment and process design, and appropriate control measures. The Food and Drug Administration (FDA) cannot do industry's job. Moreover, FDA, with its limited resources and extensive responsibilities, could not be expected to provide this assurance by periodic inspections and sample collections or by continuous inspection for about 50,000 establishments doing more than one hundred billion dollars' business per year. That this nation's food supply is the best in the world is due in large part to your efforts, the efforts of a responsible and responsive industry.

Members of industry have expressed interest in more self-regulation and less governmental regulation. In other words, industry says it is willing to regulate itself. Our experience with both General Foods and Green Giant has shown that these two companies have the attitude, resources, ability and desire to assume their full and rightful responsibility for quality assurance. We believe that responsible members of the food industry share this attitude.

FDA proposes legislation, when necessary, to control or effect correction of problem situations. As the intent of legislation must be recognized, so must our intent in self-certification. That is, the law, regulations, and specifications must be generally recognized and accepted as practical and enforceable rules and operating procedures which, if followed conscientiously, will result in compliance. The Congress has charged FDA to enforce the Food, Drug and Cosmetic Act and other consumer protection laws. It is essential for us to remember that FDA cannot delegate its responsibilities. Nor would we want to—any more than would a member of industry. We have had to examine our inter-relationships with Green Giant and General Foods very carefully to assure that we retain a proper posture relative to our position as a public regulatory agency.

Our laws do not prescribe specific methods for attaining compliance except through legal actions. Our traditional methods of inspections and sample collections, legal actions, workshops, and national conferences such as this are well known to you. Yet self-certification, too, is a method or tool which is being tested and scrutinized without too much fanfare. This method has several values worth describing which were discovered during our pilot studies. But first a little background.

A little more than a year ago FDA and the General Foods Corporation signed an agreement to participate in a pilot self-certification program. This agreement defined the "ball park" and the "ground rules" for the participants. The agreement did not evolve easily. It required many hours of hard work by administrative, technical, and other personnel at General Foods and FDA to hammer out mutually agreeable specifications for Golden Egg Custard and Jell-O Gelatin Dessert. We had to define acceptable quality limits for raw materials, production processes, and finished products. We had to assess and agree upon specifications which included inspection, sanitation, sampling, and analytical protocols. Differences were resolved laboriously. As time passed, we found that communications improved. Semantic problems began to disappear. For example, what FDA had called a "subsample," General Foods termed a "sample" and what FDA called "sample" would be a number of "subsamples." Meetings between us were frank, constructive, and informative. Explanation of the differences between us resulted in better understanding and appreciation of the other's problems.

About six months ago we entered into an agreement with the Green Giant Company and the State of Minnesota Department of

Agriculture. Our experience with General Foods was used to good advantage but it was immediately obvious that we did not communicate very well. As we worked together to develop specifications, communications improved as they had with General Foods.

The Value of the Pilot Programs

The self-certification program as presently conceived is not a panacea for our mutual problems but may be a constructive adjunct to our present quality assurance programs. For example: You cannot discard your present quality control systems, but you may improve them. We cannot eliminate inspections, but we may do them more efficiently. Our work with General Foods and Green Giant proved to be a learning process for FDA:

(1) *FDA found that industry needs to know the FDA requirements for quality.* This problem was met head-on, and we produced mutually agreeable specifications to cover the two General Foods' products as well as canned peas and whole kernel corn at Green Giant. Incorporated in these specifications are objective quality requirements which reflect both the FDA and the companies' policies and operating guidelines. This worked very well for four products in two plants. But what about specifications for the same or similar products produced in various plants throughout the industry? Studies are in progress to determine who should have input to the specifications and the process by which specifications could be established, implemented, and amended.

(2) *Our pilot studies showed that routine feedback through "monthly exception reports" was too complicated.* The reporting requirements are being reduced in frequency and content. The Bureau of Voluntary Compliance has almost completed a study of the information requirements for self-certification and will soon ask General Foods, Green Giant, and FDA units for their advice.

(3) *The General Foods study caused us to re-evaluate our thinking about products and problems.* Our initial approach was to control potential bacterial contamination through raw material and process controls as much as good sanitation practices. The test of the efficiency of these measures was in statistical sampling and analysis of the finished product. Re-evaluation of this approach resulted in a revision which placed increased emphasis on raw materials and the environment and decreased emphasis on finished products.

(4) *We began to ask whether more emphasis should be placed upon self-certifying manufacturers of raw materials subject to microbiologic contamination or upon users of these raw materials.* Certain economics of sampling would benefit users of uncontaminated raw materials—analyses would not have to be duplicated by the user. But more importantly, there would be a larger umbrella effect for quality assurance if the source of the raw material could effect control of the problem.

(5) Having spent more than a year with General Foods and six months with Green Giant *we have developed excellent rapport and confidence in the ability of each company to meet the specifications.* Incidentally, this rapport has spilled over into communications about other phases of quality assurance, not connected with the pilot program.

(6) *The approach to quality assurance is one of problem solving.* FDA and industry working together command complementary groups of resources which, when effectively directed toward a problem, may produce a satisfactory solution—a solution unattainable by a single group. The State of Minnesota Department of Agriculture has contributed significantly to the Green Giant pilot program through certain microbiologic sample analyses, inspections, and consultations. Perhaps resources from other groups can be used to better solve problems of quality assurance, as for example, the Canned Salmon Control Plan of the National Canners Association and the Food and Drug Administration. A thorough study of possible inter-relationships of various groups from industry, governments, professional associations, and the academic community should give us valuable knowledge about available resources and how they can help improve quality assurance.

(7) *It became clear very early that the mechanics of the program must be streamlined.* Agreements must be negotiated expeditiously. Criteria for evaluating quality control programs must be developed. We must prepare explanatory materials, decide upon operating procedures, and begin to train our personnel. Systems work in these areas is in progress.

Conclusion

These are some of the experiences and problems FDA has encountered in its brief experiments with General Foods, Green Giant, and the State of Minnesota. FDA must still evaluate the self-certification program in terms of the pilot programs and their overall

effect. Today we cannot tell you how the program will proceed. But by this time next year, we hope to be able to give you the whole story.

Much of the value of this approach to compliance results from improved, effective communications between FDA and industry and a scientific, systematic approach to problem-solving. Both of us must exert every effort to develop the necessary ground rules to assure quality in the food supply. This task will not be easy but the rewards will be well worth our efforts.

Self-Certification is a compliance tool which has the potential to promote, between FDA and industry, meaningful communication about objective requirements for quality, and cooperation and collaboration in defining mutual problems and methods for reducing or eliminating these problems. By working together effectively, FDA and industry can provide high confidence that products for the consumer are in compliance. **[The End]**

FEDERAL COURT UPHOLDS FDA's DISCRETIONARY POWER

A decision of the U. S. District Court in San Francisco excluding certain damaged coffee beans from import as adulterated will stand, the U. S. Court of Appeals for the Ninth Circuit has ruled. The FDA has the discretionary power to make the final determination as to the admissibility of imported food and the FDA's determination that certain coffee beans were adulterated is not reviewable under the Administrative Procedure Act because such agency action was committed to agency discretion by law. *Sugarman v. Forbragd,* CCH Food Drug and Cosmetic Law Reports ¶ 40,335, CA-9, Dec. 31, 1968.

Application of Current Good Manufacturing Practices

By ROSCOE P. KANDLE

Dr. Kandle Is Commissioner of the New Jersey Department of Health.

FEDERAL REGULATIONS GOVERNING Good Manufacturing Practices (GMPs), supported by uniform state regulations, are now enforced in New Jersey by means of a new single service system combining federal and state forces. This combination is making improvements and solid advances in the drug industry.

The regulations, based on decades of experience, are a strong support in the protection of public health. They spell out for companies, large and small alike, what procedures are required in terms of current good practices. They impose no undue burden upon legitimate business, but they deter substandard operators who cut corners and gamble with careless operations which pose serious hazards to public health. The federal regulations, first promulgated in 1962, have aided enforcement agents to close down unfit operations, and to help bring substandard companies up to par.

A Positive View of GMPs

In a broad sense, the regulations, commonly called GMPs, detail what one would simply refer to as "good business." If for no other reason, both the entrepreneur and the investor in the drug industry should favor such good drug manufacturing practices. Certainly, neither would, with prudence and good will, involve himself with an unsanitary, unsafe, inadequately equipped drug manufacturing facility. By efficient use of modern GMPs, it should be possible for industry to reduce costs and forestall a rise in the prices of drugs.

These regulations are not intended to hinder progress. The pharmaceutical industry is progressing and becoming more and more automated. Professional plant managers, chemical engineers, and scientists as well as drug inspectors appreciate the value of GMPs. Drug inspectors have learned much from pharmaceutical experts in

well-operated establishments, and in turn inspectors have provided sound advice to producers who needed it. These regulations, adjusted to the times, impose a floor, but no ceiling, on GMPs and aid federal and state inspectors to increase their efficiency and to reduce costs. But first and most important, the regulations provide added protection of the public's health.

Laymen have no real means of self-defense against unscrupulous drug operators. With the number of drugs and the many brands of each multiplying each year, even the trained physician has trouble in keeping abreast of the ever thickening Physician's Desk Reference. The expert pharmacist is, in some respects, worse off. He has no way of differentiating the real drug from the slick counterfeit or the repackaged physician's sample. If professionals are having difficulties, there can be no reasonable doubt that the layman needs protection. Properly enforced, the GMP regulations can be used as a sound basis for protecting the public by assuring the integrity of drug products.

Compliance in a Key State

In New Jersey, pertinent sections of the federal regulations were promulgated by the State verbatim. These regulations are necessary norms. No state should permit the manufacture or sale of drugs produced in factories which do not comply with such widely accepted regulations governing GMPs. In order, properly, to implement the GMP regulations, it is necessary that uniform food and drug laws be achieved as soon as possible in all states.

New Jersey has consistently brought its laws promptly and as closely as possible into compliance with federal law since enactment of the Federal Act of 1938, three decades ago. It is recognized that some states and some communities have special problems requiring special legislation, but these variations are usually minor. If drug companies were obliged to comply with 30 or 40 different state laws, drug costs would increase and the increases would be passed on to the consumer. Looking forward, it is reasonable to expect that a sufficient uniformity across the land will permit companies to operate at reduced costs and to bring an increased efficiency in inspection and enforcement efforts.

It may be recalled that much of the old colonial road from Boston to Washington runs through New Jersey. By a fact of geography, New Jersey covers a large central portion of the megalopolis extending from Boston to Washington and beyond. Factories, plants, and facilities of practically every major pharmaceutical company repre-

sented in the United States are within the boundaries of New Jersey. Trite but true, it has been said that "New Jersey is the medicine chest of the nation."

This concentration of industries has brought great advantages to the people of New Jersey. The high ethical standards and the genuine spirit of cooperation maintained by leaders of drug companies have eased the workload of New Jersey State Department of Health inspectors. In many instances, members of the drug industry have assisted in rooting out counterfeiters, bootleggers, drug diverters, and other illegal operators who cling to the industry in New Jersey worse than barnacles on a ship.

Development of a Single Service System

One cannot view the application of good drug manufacturing practices in proper perspective without looking at the relatively new single service system. The development of this system, which has the potential to increase greatly the striking force of existing and future personnel, may be outlined as follows:

(1) To combat organized crime, and organized crime it is, New Jersey has for decades extended its hands across state lines to shore up mutual defenses. Counties and municipalities within New Jersey have been supported by the State in their efforts, and close cooperation has been extended to all related federal agencies.

(2) New Jersey has always enjoyed good relations with the Food and Drug Administration (FDA), but cooperation and coordination of efforts were not always the most efficient. Some time ago, in conversations with former Commissioner James L. Goddard, it was agreed that improvement was needed. After considerable thought, emissaries were sent to Washington with an idea which fired Doctor Goddard's enthusiasm. He promptly set the machinery in motion. His associates arrived in Trenton to develop a crash program which was later to become known as the Single Service System.

(3) It is well known that jurisdiction of state departments of health has been restricted to intrastate traffic. On the other side of the coin, the FDA has been, in general, limited in its enforcement efforts to interstate violations. These limitations made it possible for a scoundrel operating within a state to skip across a border just before apprehension to carry on his illicit operations in another state. It was necessary to find a way to plug this loophole.

(4) It was finally decided that this loophole could be closed by means of cross-commissioning of state and federal agents. After proper clearance and training in New Jersey statutes, 23 FDA inspectors and two administrators were commissioned as special agents of the state. This action made New Jersey the first state in which federal agents have the power to embargo suspect food or drugs. Prior to this action by the State, federal agents depended upon the slower process of seizure authorized by the courts. These commissions also empower federal agents to make inspections, review records, take samples, and so on, as special agents of the State. When an illicit company operates solely within New Jersey, federal agents thus help provide the necessary evidence for the State to take legal action within the framework of New Jersey laws.

(5) Gaining federal commissions for New Jersey inspectors was more informative. State personnel, comprised in the main of licensed pharmacists trained as drug inspectors, did a remarkably good job for the State Department of Health, and were aware of the sophistication and the sleight-of-hand practiced by interstate computer age gangsters. Available to the inspectors was the FDA laboratory and analysts who were expert in classical laboratory equipment, including ultra-violet, visible, and infra-red spectrophotometers, paper, thin-layer and gas chromatography, supplemented by the more esoteric nuclear magnetic resonance, neutron activation equipment, and so on. To teach and to make New Jersey personnel familiar with equipment and the federal program, each inspector was given a tough two-week laboratory course. It is necessary for inspectors to be familiar with the uses and the limitations of latest laboratory equipment in order to know what data can be obtained in a modern up-to-the-minute laboratory. Each was coached in federal laws and regulations, was trained in federal approaches to food and drug recalls, and made joint plant inspections in the presence of a well-trained federal agent. Only then was the individual, based on his ability, commissioned as a special agent of the federal government. The time and effort devoted to State personnel by federal agents were of great value. For this help, thanks are due Dr. Herbert L. Ley, Jr., Commissioner of the FDA, under whom this program was developed and carried forward.

The key to the Single Service System is cooperation, not assimilation; partnership, not rivalry. Cooperation has been advanced by

means of modern technology. Uniform reports are now fed into computers which have implacable memories. Telecommunications place the nearest man at the necessary spot in the shortest time. No longer is it necessary to wait days or longer to attack threats to public health. No longer do inspectors from two or even three different governmental agencies arrive unknown to each other at different hours of the same day to inspect the same factory. The savings to industry and government are great, and the striking force of governing agencies is increased enormously. The savings to government in terms of man-hours have not yet been calculated. When efficiency experts have completed their evaluation, their results will no doubt be expressed in man-years, not man-hours. The potential built into this Single Service System is great. The benefits to public health are far from completely realized. As this network of cooperation spreads through all levels of government, public health problems will be attacked more swiftly and more effectively.

Potential Benefits

The effectiveness in New Jersey of the Single Service System, reinforced by GMP regulations, can best be illustrated by concrete actions already taken. Shortly after the inception of this cooperative plan of attack, in rapid succession, a company that produced mineral oil for the Veteran's Administration was closed, a food firm was closed and 400,000 pounds of food items were destroyed, ten tons of substandard chloramphenicol were seized and destroyed, and 1,350 misbranded devices were embargoed. More recently three submarginal plants were brought into compliance with GMP regulations, and an order to comply was issued to a New Jersey pharmaceutical company. This action was taken by the State jointly with the FDA. If the company does not come into compliance within the thirty-day period of grace, the company will be closed. The list could be lengthened, but the message would not be strengthened.

Conclusion

Current GMPs, a forward-looking set of federal regulations, have been reviewed in broad perspective. Their application in the State of New Jersey has reinforced the view that uniform food and drug laws are needed throughout the United States. Their application is of fundamental value to the Single Service System, a plan of attack based upon the cooperation of the FDA and state health departments. This Single Service System will expand and bring with it increased enforcement effectiveness and greater protection of public health. **[The End]**

GMPs—
An Industry Point of View

By IRWIN S. SHUPE

Mr. Shupe Is Director of Quality Control of the Winthrop Laboratories.

GOOD MANUFACTURING PRACTICES (GMPs), or the application of them, may mean different things to different people. For example, to some it may mean the Food and Drug Administration (FDA) current Good Manufacturing Practice regulations. To others it may mean Quality Control. To still others it may signify an organized plant-wide program where an entire establishment is considered to be involved in a total control of quality objective. This broader concept is expressed in the "General Principles of Total Control of Quality in The Drug Industry" as approved by the Pharmaceutical Manufacturers Association (PMA) in 1967.

When we speak of quality, just what is meant? Or in the case of control of quality, just what do we mean? In this PMA statement there are some valuable definitions for these and related expressions. These are as follows:

> The quality of a product is its degree of possession of those characteristics designed and manufactured into it which contribute to the performance of an intended function when the product is used as directed. The quality of medicinal and related products is the sum of all factors which contribute directly or indirectly to the safety, effectiveness, and acceptability of the product . . .
>
> Total control of quality as it applies to the drug industry is the organized effort within an entire establishment to design, produce, maintain and assure the specified quality in each unit of product distributed . . .
>
> The ultimate objective of a program for the total control of quality in a drug company is the attainment of perfection in meeting specifications for a product of high quality. It is a program designed to assure the professional user, or ultimate consumer, that every lot of a product conforms to specifications and that each dose distributed will fulfill the representations made in the labeling and will meet all legal requirements and such additional standards as the management of a firm may adopt.

Industry's Definition

One might say, therefore, that GMPs from an industry point of view is this program of total control of quality. It is important to emphasize basic principles and basic considerations in setting forth guidelines in this area of GMPs, or control of quality. For one thing, it is considered impossible to design *in detail* a single universally applicable system because of the many differences in products produced and in industry organizations. An important basic policy in many companies is that there shall be no significant changes made in manufacture or quality control until there has been a careful and complete review, and after formal approval and authorization by the appropriate company officers. This policy of no changes without comprehensive review and authorization might at first appear to favor a static situation. However, this is not the case at all. In fact this whole area is dynamic and changing, rather than static. New buildings are being constructed, manufacturing and packaging methods and equipment are constantly being improved. New laboratory testing instruments and procedures are being developed regularly. The end result is that quality controls and quality are being constantly upgraded. There are consistently higher quality standards being achieved over the years, in fact every day.

Again referring to the PMA statement of principles, these are some areas mentioned for basic considerations: personnel; product design; specifications and procedures; facilities and equipment; materials and records. I would like to comment especially on two of these items—personnel and records.

Intra-Plant Cooperation Essential to Compliance

Personnel must, of course, be competent and well qualified to carry out their respective duties. In considering the control of quality one might think primarily of the personnel in the manufacturing department, the packaging department and the control department. This does not mean, however, that other departments such as accounting, purchasing and engineering are excluded. For comprehensive control of quality, all of these groups, in fact all of the people in the plant, must work together toward the accomplishment of quality objectives. If every employee truly has a feeling of sincere responsibility to do his own job carefully and right, he will automatically have a feeling of pride and accomplishment in his good workmanship. We try very hard to promote this attitude in all of our people because we believe it is of greatest importance in the

prevention of errors and in the building of confidence in the quality of our products.

Significance of Control Number

When records are mentioned, one thing that is frequently emphasized is the control number. This is because the control number has such great importance and significance. It is through the control number that the history of a product can be traced. This history includes information about the starting materials, the manufacture, the packaging, the control testing, the distribution and the people who may have been responsible for these various operations. In support of this control number are the documents and records which precede, accompany and follow a manufactured product. Among such basic documents are the master manufacturing formula and procedure, the production record, the master packaging specification, the packaging record, the quality control monograph and the quality control test record. An evaluation of a quality control system may therefore be made by an examination of the completeness of this written history.

Conclusion

Any trend in the FDA current GMP regulations toward more and more restrictive details in guide lines, rather than emphasis on basic principles, might be questioned. This is because the mechanical conformance to minor details which do not affect the quality, efficacy or safety of a product could lead to mediocrity and stifle progress

The emphasis on basic principles, and the recognition of and appreciation for the fundamental objectives in a total quality control system, is of great importance. It will permit adequate flexibility and freedom for individual companies to continue in the direction of progress and upgrading of quality standards. **[The End]**

NEW REPORT FORMS

A new form has been authorized for making periodic reports concerning experience on drugs. Another form was also authorized for use in submitting advertising and promotional material for drugs. Finally, the new drug regulations were amended to specify that advertisements are to be submitted at the time of initial publication. The amendments authorizing these changes become effective January 21, 1969. Reg. §§ 130.13 and 146.14, CCH Food Drug and Cosmetic Law Reports ¶ 71,313 and 74,264.

The Fair Packaging and Labeling Act— Some Unanswered Questions Two Years After Enactment

By H. E. DUNKELBERGER, JR.

Mr. Dunkelberger Is an Attorney Associated with the Washington, D. C. Law Firm of Covington and Burling.

AS ALL OF YOU WELL KNOW, the three major aspects of the Fair Packaging and Labeling Act (FPLA) are the industry-wide mandatory labeling regulations promulgated by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), the commodity-line discretionary regulations to be issued by these same two agencies, and the encouragement of voluntary package size standards by the Department of Commerce.

The Mandatory Regulations

Turning first to the mandatory regulations, the food regulations have of course been adopted in final form and most manufacturers are well on their way toward bringing all of their labels into compliance. The FDA regulations for drugs and cosmetics were published in final form in June of this year to become fully effective on July 1 of next year, but as of this date the FDA has not announced whether objections were filed that will necessitate the holding of a hearing on some aspects of these regulations.

It is by now almost ancient history that the FDA virtually stared down the industry when it refused to schedule a hearing on any of the numerous objections that food companies had filed to the final food regulations. Many food industry lawyers, and indeed a number of trade associations and companies, felt that the FDA was not acting in accordance with the procedural requirements of Section 701(e), (f) and (g) of the Federal Food, Drug and Cosmetic Act, which are

incorporated by reference in the FPLA.[1] But that question has now become academic, for none was sufficiently outraged or concerned to take the FDA to court to test its right to refuse to hold a hearing on what many industry representatives considered to be valid objections to the regulations raising substantial issues of fact.

Presumably, the FDA is now facing a similar decision under the drug and cosmetic regulations, and almost certainly the agency will be criticized for whatever course it takes. If it grants a hearing to objections on some of the drug and cosmetic regulations, then undoubtedly many people in the food industry will feel they have been discriminated against and that there is no rational basis for denying procedural regularity for one segment of industry and observing it for another. If no hearing is granted, then many may conclude that this merely confirms their belief that the FDA has sought to rewrite the requirements of Section 701 without the inconvenience of Congressional action.

The FTC published its final regulations for other consumer commodities three months before the drug and cosmetic regulations were published in final form, and it too has yet to indicate publicly whether it will further modify its regulations, hold a public hearing on some of its provisions, or merely decide that the March 19 regulations will go into effect as published.

The question common to all consumer commodity manufacturers with respect to the mandatory regulations is whether state authorities will follow the letter and spirit of the federal FPLA regulations, and give substance to the universally stated goal of uniformity of regulation among federal and state jurisdictions. At the June meeting of the National Conference on Weights and Measures, sponsored by the United States Department of Commerce, the Conference rejected industry's proposals (1) that the Model State Packaging and Labeling Regulation reflect without variation the FPLA Regulations and interpretations of the FDA and the FTC, and (2) that the exemptions under the Federal Act and Regulations be automatically incorporated by reference in the Model Law or Regulation.

Although most of the revisions that the Conference adopted for the Model Regulation faithfully follow the requirements under the Federal Act, there are a few notable departures. For example, Section 5.3.3 of the Model Regulation would require that multi-unit packages of the same commodity declare not only the number of individual units and the quantity of each individual unit, but also the

[1] *See,* for example, Forte, *Fair Hearing in Administrative Rule-Making,* 1968 Duke L. J. 1 (1968). 23 Food Drug Cosmetic Law Journal 366 (July 1968).

total quantity of the contents of the multi-unit package. The FDA regulations are not explicit on this point, but they have generally been interpreted not to require declaration of the total quantity of all the packages in the multi-unit container. Indeed, the FTC regulations contain an example in Section 500.7 that makes it clear that total quantity is not required:

> The net quantity of contents shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight, size, or measure (for example numerical count and sheet dimensions of writing paper, *numerical count and net weight per bar of multiunit packages of bar soap, etc.)* . . . . (Emphasis added.)

A second difference between the federal requirements and the Model Regulation is that Section 5.8.1 of the latter purports to prohibit a supplemental or combination declaration in larger type than the required declaration. The federal regulations contain no such prohibition (see, for example, Section 1.8(o) of the FDA Food Regulations).

Of even greater significance is the refusal of the Conference to provide for automatic adoption of federal exemptions, which prescribe particularized labeling requirements for a large number of products. Instead, the Conference or its Executive Committee will review each federal exemption and decide whether it should be added to the Model Regulation. It is not at all clear how each state will so conveniently consider and adopt—or reject—each exemption promulgated by the FDA and the FTC.

This disparity between federal and state regulation is particularly disappointing—and puzzling—in view of the major role of the Department of Commerce in providing administration and leadership for the National Conference, and the directives of Congress to the Secretary of Commerce that he work to achieve uniformity in federal and state weights and measures regulations.[2] At the Conference Department officials maintained that states were permitted under the FPLA to adopt labeling regulations imposing more stringent requirements, and supported this conclusion with an opinion from the Department's General Counsel's office. There can be no doubt

[2] There can be no doubt that the activities of the Department of Commerce, through the National Bureau of Standards and the National Conference on Weights and Measures—augmented by such industry efforts as the Industry Committee on Packaging and Labeling—have been the major factor in bringing about uniformity in Federal and State labeling regulation. Indeed, it is precisely because of the excellent past record of the Department in this regard that the few disparities between the FPLA regulations and the Model Regulation, and the Department's interpretation of section 12 of the FPLA that is discussed below in the text, stand out as such glaring exceptions.

that the expression of these views and the announcement of this opinion were major factors in persuading the states to reject industry's arguments in favor of complete federal-state uniformity.

Very frankly, I do not see how these events at the National Conference can be squared with Congress's directives to the Secretary of Commerce. The basic statutory authority for the Department of Commerce's sponsorship of the National Conference is found in Section 272 of Title 15 of the United States Code. That section authorizes the Secretary of Commerce to undertake a number of specific functions, one of which is: "(d) Cooperation with other governmental agencies and with private organizations in the establishment of standard practices, incorporated in codes and specifications."

In carrying out these functions the Secretary is authorized to undertake certain listed activities "and similar ones for which need may arise in the operations of government agencies, scientific institutions, and industrial enterprises . . ." One of the listed activities is: "(5) cooperation with the states in securing uniformity in weights and measures laws and methods of inspection . . ."

Congress has thus made it clear that the Secretary is to cooperate with the states in securing uniformity in weights and measures laws. One of the stated goals of the National Conference has been to work for the achievement of such uniformity, and the development of the Model Law and Regulation has been consistent with that goal.

In addition to this general directive to the Secretary of Commerce to work for uniformity in federal and state weights and measures regulation, the FPLA contains an even more explicit directive:

> Section 9(a). A copy of each regulation promulgated under this Act shall be transmitted promptly to the Secretary of Commerce, who shall (1) transmit copies thereof to all appropriate State officers and agencies, and (2) furnish to such State officers and agencies information and assistance to promote to the greatest practicable extent uniformity in State and Federal regulation of the labeling of consumer commodities.

The Congressional purpose could hardly have been more clear. What is not clear is why the General Counsel's office of the Department of Commerce should announce an interpretation of the preemption clause in the FPLA that could only have the effect of discouraging, rather than encouraging, uniformity in federal and state regulation.

The federal preemption clause of the FPLA varied in content during the five years of Congressional consideration of the bill. During the first few years the bill made clear Congress's intent *not* to supersede or preempt any state law unless absolutely necessary because of a direct and positive conflict. The provision read in relevant part:

Nothing contained in this Act shall be construed to repeal, invalidate, supersede, or otherwise adversely affect . . .

(d) any provision of State law which would be valid in the absence of this Act unless there is a direct and positive conflict between this Act in its application to interstate or foreign commerce and such provision of State law.

Clearly what the sponsors had in mind at this stage was to give the states a completely free hand in adopting their own labeling requirements, except in those instances when compliance with a state regulation would require violation of a federal regulation.

When the bill was under consideration by the Senate Commerce Committee in the spring of 1966, this approach was turned completely around, and a new preemption section was added, which read:

Section 12. It is hereby expressly declared that it is the intent of the Congress to supersede any and all laws of the States and political subdivisions thereof insofar as they may now or hereafter provide for the labeling of the net quantity of contents of the package of any consumer commodity covered by this Act which differs from the requirements of section 4 of this Act or regulations promulgated pursuant thereto.

The Senate Report made no effort to explain the significance of this about-face except to state that the regulations under the Act "shall supersede state law only to the extent that the states impose net quantity of contents labeling requirements which differ from requirements imposed under the terms of the Act." The Report went on to make clear that it was not intended to affect the regulation of intrastate commerce, as distinguished from interstate commerce, saying that the "bill is not intended to limit the authority of the states to establish such packaging and labeling standards as they deem necessary in response to state and local needs."

Apparently the Senate Committee, and in turn the Senate, felt that its intent was clear. If a state regulation imposed a labeling requirement for a consumer commodity that was different from a requirement that was imposed under the federal requirement, then the federal provision would take precedence, and the state provision would be inapplicable to commodities covered by the Federal Act.

This interpretation of Section 12 is supported by the House Commerce Committee's explanation of virtually identical language in the Child Protection Act of 1966, adopting amendments to the Federal Hazardous Substances Labeling Act,[3] which explained the "differs from" language as:

[3] The provision in the 1966 amendments to the HSLA reads: "It is hereby expressly declared that it is the intent of the Congress to supersede any and all laws of the States and political subdivisions thereof insofar as they may now or hereafter provide for the precautionary labeling of any substance or article intended or suitable for

(Continued on next page.)

a limited preemption amendment which would encourage and permit States to adopt requirements identical to the Federal requirements for substances subject to the Federal Act, and to enforce them to complement Federal enforcement, but at the same time would free marketers of products sold interstate from varying or added labeling requirements for such substances now existing or which States and cities might otherwise adopt in the future.

There was thus no doubt that the "differs from" language was intended to prevent the adoption of "varying or added" requirements by the states. This Congressional interpretation of language in one bill under consideration in 1966 can fairly be applied to the virtually identical language in another labeling bill under consideration at the same time.

When the FPLA was considered by the House of Representatives, the House Commerce Committee accepted the Senate language verbatim, except to change "which differs from" to "which are less stringent or require information different from." The "different from" language was retained, and the "less stringent" language was added. The logical interpretation of this change is that the Senate's understanding of the "different from" language would remain—that is, that a state could not oppose *varying* or *added* labeling requirements. But the House Committee wished to make it clear that if a state proposed to require *less* information than the federal regulations, the federal regulations would still take precedence. In other words, compliance with less stringent state regulations could not be claimed as a justification for ignoring more stringent federal regulations.

The House Commerce Committee Report stated that preemption was intended for state laws that "impose inconsistent or less stringent" net quantity labeling requirements. No explanation was given for the use of the word "inconsistent" in the Report, when the Act contained the words "different from." The Conference Report makes it clear that it was the House version that was accepted by the Conferees, but sheds no further light on the meaning of either the statutory or Report language.

On the basis of this somewhat ambiguous legislative history, a representative of the General Counsel's office of the Department of Commerce stated publicly at the 1968 National Conference of Weights and Measures that the effect of Section 12 was to permit states to impose labeling requirements going beyond those imposed under

(Footnote 3 continued.)
household use . . . which differs from the requirements or exemptions of this Act or the regulations or interpretations promulgated pursuant thereto. Any law, regulation, or ordinance purporting to exempt such a labeling requirement shall be null and void." 15 U. S. C. § 1261, note.

the federal regulations. Apparently he relied on the "inconsistent" wording of the House and Conference Reports, and totally ignored the clear language of the Act itself and the Senate's understanding of that language.

If a federal regulation imposes labeling requirements A and B, and a state regulation requires A, B and C, then it seems clear that the state requires information that is "different from" the federal requirement. And the added state requirement C can be said to be inconsistent with the more limited federal requirements.

But the Commerce Department attorney apparently concluded that the House Committee Report use of "inconsistent" transformed the statutory language of "different from" into nothing more than an intent to preempt only state requirements that were in direct and positive conflict with federal requirements.[4] This approach had, of course, been totally repudiated by the sponsors of the bill when they discarded the original language of the preemption section. Such an interpretation makes the "different from" language totally unnecessary, for the supremacy clause of the Constitution has repeatedly been held to invalidate state law that directly conflicts with federal law.

My purpose in going into the detail of this preemption quagmire is two-fold:

(1) If uniformity between federal and state requirements is to be achieved, then a proper understanding of Section 12 of the FPLA can contribute significantly to this goal; and

(2) The Department of Commerce has failed to carry out its statutory directive of encouraging uniformity in weights and measures laws, and uniformity in state and federal regulation of the labeling of consumer commodities, by adopting a questionable interpretation of Section 12.

I personally feel that the language of Section 12 is clear on its face. States may not impose *additional* or *varying* or *less stringent* requirements than those imposed by the federal regulations. A federal exemption excusing a commodity from a particular labeling requirement cannot be nullified by a state regulation. That understanding is reflected in the explanation of the similar preemption provision in the Child Protection Act of 1966.

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[4] This preference of the General Counsel's office for the legislative history over the language of the Act brings to mind the statement by Mr. Justice Frankfurter that "Spurious use of legislative history must not swallow the legislation so as to give point to the quip that only when legislative history is doubtful do you go to the statute." Frankfurter, "Some Reflections on the Reading of Statutes," 47 *Columbia Law Review* 527 (1947).

At the very least, this is a logical and reasonable interpretation of the Act and the legislative history. Why, then, did the Department of Commerce feel obliged to reject an interpretation that would most effectively carry out Congress's directive to achieve uniformity, and instead publicly to espouse an interpretation that could only encourage states to adopt requirements in addition to those imposed under the federal regulations?

It is my hope that the Department of Commerce will recognize its clear statutory responsibility to encourage uniformity, not diversity, in labeling requirements, and will emphasize the overwhelming need for one set of labeling requirements for products shipped in interstate commerce.

Discretionary Regulations Under Section 5(c)

In recent months there have been a number of indications that the FDA and FTC are considering the promulgation of regulations under Section 5(c) of the Act, although nothing has yet appeared in the *Federal Register*. These so-called discretionary regulations differ from the mandatory regulations in several respects.

The mandatory regulations are based on a Congressional finding of general need for prominent disclosure of certain information on all labels, and the only question at issue in their promulgation was the appropriateness of the detail of the regulations to carry out the Congressional directive. Under Section 5(c), however, the agencies have the burden of establishing that additional regulations are necessary for particular commodities in order to prevent deception or to facilitate value comparisons.

The Section 4(a) regulations apply across-the-board to whole categories of consumer commodities: all foods, all cosmetics, all proprietary drugs, and all other covered commodities. But Section 5(c) is worded differently. It refers to deception or value comparisons "as to any commodity," and the promulgation of regulations "with respect to that commodity." Apparently Congress intended that these regulations would not apply across-the-board to all or many different commodities, but instead would be applicable on a product-by-product or commodity-line basis.

The legislative history supports this clear meaning of the statutory language. The Antitrust and Monopoly Subcommittee, for example, stated in its Report on one of the first revisions of the bill that these regulations would be adopted on a "product-by-product

basis" and "only on a product-line basis."[5] Similarly, the Senate Commerce Committee Report on S. 985 stated that regulations under Section 5(c) would be adopted "on a commodity line basis," and that this section "authorizes the promulgating authority to issue commodity-by-commodity regulations."[6] And the House Commerce Committee Report stated that this section authorized the agencies "to promulgate regulations with regard to particular consumer commodities."[7]

There is nothing in the Act or Reports, however, that authoritatively spells out what would constitute a "product," a "product-line," or a "commodity-line." The most logical explanation is that a Section 5(c) regulation can be made applicable only to those commodities for which a finding is made—and can be justified on the facts—that deception has been fostered or value comparisons have been rendered difficult by existing industry practices that will be corrected by the regulation. A finding that manufacturers and distributors of commodities A and B have fostered deception of consumers by their misuse of "cents-off" labeling could thus be relied upon as a basis for promulgating a regulation regulating that practice for commodities A and B, but it could not be used to justify a regulation of broader applicability—to products C, D and E, or to all foods. This interpretation squares both with the "product-by-product" language, and with the explicit requirement of a finding of deception or difficulty of value comparisons.

A related question under Section 5(c) is what type of showing will have to be made by the FDA or the FTC to support a finding that a regulation is "necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity." There was some discussion of the term "deception of consumers" during the course of the House hearings, but it was at best inconclusive, and the legislative history in total provides no clear picture of Congress' intent as to the content of this term.

It may be expected that the FTC will seek to rely on its experience and precedents under Section 5 of the Federal Trade Commission Act, which declares unlawful "unfair or deceptive acts or practices in commerce," and that the FDA will look to its practice under Section 403(a) of the Federal Food, Drug and Cosmetic Act, which defines misbranding to include "false or misleading" labeling. But

[5] Report on Truth in Packaging of the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 88th Cong., 2d Sess. 5, 19 (1964).

[6] S. Rep. No. 1186, 89th Cong., 2d Sess. 2, 6 (1966).

[7] H. Rep. No. 2076, 89th Cong., 2d Sess. 11 (1966).

there may be a significant difference between a determination of deception in an adjudicatory proceeding and a determination of whether a particular regulation is necessary to prevent deception under Section 5(c) of the new Act.

The question of what constitutes deception under section 5(c) may well become academic, however, if the agencies decide to rely on the determination that a regulation is necessary "to facilitate value comparisons as to any consumer commodity." The first version of Senator Hart's bill—S. 3745 in the Eighty-Seventh Congress—authorized additional regulations for particular commodities upon a determination that they were necessary "to establish or preserve fair competition between or among competing products by enabling consumers to make rational comparisons with respect to price and other qualities, or to prevent the deception of consumers as to such products." This language was retained in S. 387 in the Eighty-Eighth Congress, except that the Antitrust and Monopoly Subcommittee changed the word "qualities" to "factors." The Subcommittee Report does not explain this change, nor does it throw any light on meaning of the "comparison" and "deception" criteria.

S. 985 as introduced in the Eighty-Ninth Congress repeated the language as revised by the Antitrust and Monopoly Subcommittee. The Senate Commerce Committee further changed this language to provide for additional regulations when the agencies determine they are necessary "to prevent the deception of consumers or to facilitate price comparisons as to any consumer commodity." The Committee Report contains no explanation of this language or the reasons for the change from previous versions.

The House Commerce Committee substituted the word "value" for the word "price" and reported out the bill in that form, again with no explanation of the change, or of the language. The House passed the bill as reported, and the Conferees recommended the House version. The Statement of the Managers on the part of the House in the House Conference Report explained the change by saying that "'value comparison' is broader than the concept of 'price comparison,' "[8] but did not otherwise throw light on the intended meaning.

Senator Hart sought to explain this change of wording on the floor of the Senate prior to the Senate adoption of the Conference Report:

[8] "The conferees wish to make it clear that the concept of 'value comparison' is broader than the concept of 'price comparison' and includes the latter within the former as a very important factor in making a value comparison." H. R. Rep. No. 2286, 89th Cong., 2d Sess., Conference Report to Accompany S. 985 on the Fair Packaging and Labeling Act 9 (1966).

What this means is that the U. S. Congress has now assumed responsibility for assisting consumers by facilitating "value comparisons." This declaration is significant because it enlarges Congressional policy to include quality comparison—a component of value. This quality element has vastly greater implications than the more limited concept of price. For instance, it opens the door to consideration of legislation such as grade labeling and Government testing of consumer products.[9]

Congressman Gilligan, a member of the House Commerce Committee, took exception to Senator Hart's interpretation of the Committee's change from "price" to "value." He stated that he was responsible for proposing the change, and that the Committee intended only to emphasize that price is just one aspect of value.[10]

In practice, the term "value comparison" may become equated with "price comparison," for it is difficult to see how most of the Section 5(c) regulations could bear upon other factors of "value," whatever that may be understood to mean. The trouble may come when an attempt is made to specify which commodities are subject to a particular 5(c) regulation—similar products differing significantly in quality or "value" should perhaps not be subject to the same regulation.

At any rate, the agencies will be obliged to justify a regulation under this provision on the basis of one of the two criteria. The burden of establishing the justification will be on the agency, for until it makes the necessary determination—on the basis of the evidence before it—no regulation may be promulgated.

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[9] 112 Cong. Rec. 26564 (Daily ed. Oct. 19, 1966).

[10] "I am the author of this amendment in the House Committee on Interstate and Foreign Commerce. It is designed to insure that the government agencies and officials charged with enforcing the law and issuing regulations thereunder do not exercise the powers conferred upon them, particularly by section 5, for the sole purpose of facilitating a mathematical computation; that is, a price comparison, in the supermarket aisle. Price is only one element in a consumer value decision; other factors of equal or greater importance are product performance, the convenience of the package, and the suitability of the size or quantity of the product in satisfying a consumer's personal desire or need. Obviously what constitutes value is highly subjective.

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

In short, the amendment was conceived to avoid having this new statute mislead consumers by over accentuating price at the expense of other and often more important elements of true value, rather than opening broad new areas of regulatory control or experimentation. I am sure I can fairly say that all members of the House Committee had this understanding when I offered the amendment and obtained its approval." 112 Cong. Rec. 27536 (Daily ed. Oct. 21, 1966).

Four different types of regulations may be adopted under Section 5(c), and the legislative history throws at least a little helpful light on each.

Package Size Descriptions

The first type of regulation authorized by section 5(c) is that described in section 5(c)(1), under which the regulation would:

> establish and define standards for characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity, but this paragraph shall not be construed as authorizing any limitation on the size, shape, weight, dimensions, or number of packages which may be used to enclose any commodity.

This provision was retained virtually without change throughout the entire history of the bill, from S. 3745 as introduced in the Eighty-Seventh Congress, through final enactment, except that the Senate Commerce Committee added to S. 985 the proviso to make it clear that regulations under this provision could not authorize any limitation on the packages themselves.

The Antitrust and Monopoly Subcommittee Report explained:

> [Subsection] (e)(3) provides for the defining of size nomenclature relating to quantity such as "small," "medium" and "large." . . .
>
> The purpose of this section is to make size nomenclature meaningful as between competing products in the same product line so that one manufacturer's "king size" does not represent less product than another manufacturer's "large." Should such standards be established on a product line basis, there is no compulsion for the manufacturer to use them if he chooses to use no size designation whatsoever. If, however, he wishes to use size designations, they would have to be those established for the range of quantity into which the amount within his package falls.[11]

The House Commerce Committee in its Report stated that regulations under this provision may establish "specific weights and measures, or ranges of weights or measures, for such designations." A regulation under 5(c)(1) might thus specify that the term "small" may be used only on packages of a particular consumer commodity ranging from two to four ounces. Or it might specify that the term "small" may be used only for packages containing three ounces.

The statement in the Subcommittee Report quoted above suggests that once a regulation was adopted specifying size designations for a particular commodity, packages of that commodity could not use any size designations unless they were those specified in the regulation. Thus, if the regulation specified "small," "medium" and

[11] Report on Truth in Packaging of the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 88th Cong., 2d Sess. 24 (1964).

"large" for certain sizes, but no others, apparently no other terms could be used to describe the size of any package containing that commodity.

In the case of Section 5(c)(1), as in the case of all 5(c) regulations, the burden will be on the agency to establish that the specific regulation proposed is necessary either to prevent deception or to facilitate value comparisons. If manufacturers during the course of the hearing can establish that there is in fact no consumer deception with respect to the use of size designations for the commodity in question, or that no such standardized terms would facilitate value comparison, then no regulation could be adopted.

Cents-Off and Economy Size

Under Section 5(c)(2) regulations would be adopted by the promulgating agency with respect to a particular consumer commodity to

> regulate the placement upon any package containing any commodity, or upon any label affixed to such commodity, of any printed matter stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents.

In the earlier versions of the packaging and labeling bill introduced by Senator Hart the agencies were directed to adopt regulations to *prohibit* "cents-off" and "economy size" label statement practices for *all* consumer commodities.[12] In response to strong objections by industry witnesses that the "cents-off" promotion practice was highly regarded by consumers and afforded them substantial savings, Senator Hart himself proposed an amendment to the bill in March 1966 (see Committee Print, March 15, 1966) to transfer this provision from Section 4(a) to Section 5(c), so that such a regulation could be adopted only on a commodity-by-commodity basis, and only upon the finding required by Section 5(c).

This provision was modified further by the Senate Commerce Committee, which substituted the word "regulate" for the word "prohibit" at the beginning of the subsection. The provision as thus changed was explained in the Senate Committee Report as follows:

> This provision is primarily directed at "cents off" label representations placed on the package by the manufacturer and at such label designations as "economy" size. While the committee was of the opinion that these practices should be prohibited where abused, the agencies are granted a measure of

[12] See § 3(A)(b)(4) of S. 3745 in the Eighty-Seventh Congress; § 3(A)-(c)(4) of S. 387 in the Eighty-Eighth Congress; and § 3(a)(5) of S. 985 as introduced in the Eighty-Ninth Congress.

flexibility in establishing regulations for the utilization of such promotional techniques in a nondeceptive manner. Nothing in this subsection would inhibit the retailer's right to set retail prices or to make sale offers.[13]

The House Commerce Committee considered a further modification of this provision, to add the words "but not prohibit" after the word "regulate" at the beginning of the subsection. (See H. R. 15440, Committee Print of September 13, 1966.) But as reported by the House Committee the provision was left unchanged, and these words were not added. Nevertheless, the Committee sought to achieve the same effect by indicating in its Report that this provision was intended to authorize regulations "to regulate (but not prohibit) the use of such promotions as 'cents off' or 'economy size' on any package."[14]

The Committee's intent was further expressed when it stated that regulations under Section 5(c)(2) would be for the purpose:

> To regulate, but not prohibit, the use of such promotions as "cents off" or "economy size" on any packages in order to assure that insofar as practicable any price reductions claimed on the package will be passed on to the consumer. Such regulations, for example, may require a showing on the part of manufacturers that the wholesale price has been reduced in an amount sufficient to enable retailers to pass on the appropriate "cents off" to the consumer; or they may limit the duration of, and the intervals between such promotions; or the percentage of the output annually which may be marketed under "cents off" promotion.[15]

The Senate and House Committee Reports thus reflect a slightly different interpretation of this provision. The Senate Committee felt "that these practices should be prohibited where abused," whereas the House Committee felt that regulations under this provision should regulate "but not prohibit" the practice. In view of the fact that the Senate and House Conferees recommended enactment of the House bill, with only two changes, and the Senate acquiesced in this recommendation, it may reasonably be concluded that the House interpretation of Section 5(c)(2) should prevail over that stated in the earlier Senate Committee Report and that cents-off labeling may not be prohibited altogether for any commodity.

Another question that comes up in connection with a cents-off regulation is whether the FDA or the FTC could require a retailer to reduce the retail price by the amount of the stated cents-off reduction on the label. For example, if a product labeled to be sold at five cents off the regular price in fact was regularly sold by a retailer at $.40, could the FDA require in a regulation that the retailer sell the product for $.35?

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[13] S. Rep. No. 1186, 89th Cong., 2d Sess. 6 (1966).

[14] House Report at 7.

[15] See footnote 12.

Several provisions in the FPLA are relevant to the resolution of this question. Section 3(b) provides that regulations under the Act shall not apply to wholesale or retail distributors except to the extent that they are engaged in the packaging or labeling of a commodity, or prescribe or specify the manner in which the product is packaged or labeled. Since a manufacturer's cents-off label statement is not prescribed by the retailer (except for private labeled products), it might be argued that this exemption wholly protects the retailer from coverage under a cents-off regulation.

But a label is defined in Section 10(c) to mean any written, printed or graphic matter appearing on a package containing a consumer commodity. Because the retailer marks the package with the selling price of the commodity, that marking would appear to constitute labeling under the Act. If so, the retailer has engaged in the labeling of the commodity and would thus not be covered by the exemption contained in Section 3(b).

There is another limitation in the Act, however, that would appear to prevent the application of any FPLA regulation to the marking or labeling of a commodity after it has reached the retail store. Section 3(a) makes it unlawful for any person to distribute or to cause to be distributed in commerce any packaged commodity which does not conform to the provisions of the Act and regulations. Thus, regulations adopted under the Act apply only to the commodity as it is labeled when shipped in interstate commerce. If the product is lawful when shipped in interstate commerce, then any labeling that takes place after it has come to rest within a state is not subject to the reach of the Act.

This conclusion is supported by a letter from the Department of Health, Education and Welfare (HEW) to Senator Magnuson, reprinted in the Senate Commerce Committee Report at pages 14-18. HEW suggested that the bill should be amended to make it clear that the Act was coextensive with the Federal Food, Drug and Cosmetic Act "including violations that occur after an article has been shipped in interstate commerce, for example, by alteration of the label while the article is held for sale after such shipment." No such amendment was adopted, and it thus seems clear that unlike the Food, Drug and Cosmetic Act the FPLA does not apply to labeling that takes place after shipment in interstate commerce.

It is entirely conceivable, however, that the FDA may take the position that the failure of a retailer to pass along the savings promised on the label would constitute false or misleading labeling under

Section 403(a) of the Federal Food, Drug and Cosmetic Act. Many provisions of the FDA's mandatory labeling regulations are based on both the FPLA and the Food, Drug and Cosmetic Act. If this same approach is taken, then conceivably the FDA could regulate retailer practices in a cents-off regulation.

Ingredient Information

Regulations under Section 5(c)(3) would:

> require that the label on each package of a consumer commodity (other than one which is a food within the meaning of section 201(f) of the Federal Food, Drug and Cosmetic Act) bear (A) the common or usual name of such consumer commodity, if any, and (B) in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be divulged.

This wording was added by the House Committee as a substitute for a provision in the Senate bill that would have authorized the adoption of regulations to require that "information with respect to the ingredients and composition of any consumer commodity . . . be placed upon packages."

Nothing can be found in the legislative history to explain the significance of subparagraph (A), which would require that the common or usual name of the commodity be included on the label. The mandatory regulations under Section 4(a)(1) now require that all commodities bear a label specifying the identity of the commodity, which in most cases is the same as the "common or usual name" of the commodity.

A regulation under subparagraph (B) would require the listing of ingredients in decreasing order of predominance. The exclusion for foods is explained in the House Committee Report on the ground that the Food, Drug and Cosmetic Act requires that all nonstandardized food labels include a list of ingredients.

The only legislative history which throws any further light on the meaning of this provision occurred during the floor debate in the House. In an exchange between Congressman Kornegay and Chairman Staggers, the former pointed out that many drugs and cosmetics contain literally dozens and dozens of nonactive ingredients, and asked whether these ingredients which have no value so far as price comparison is concerned need be declared on the label under such a regulation. Chairman Staggers answered, "Not unless the listing is necessary in order to make the value comparison possible."[16]

[16] 112 Cong. Rec. 23865 (Daily ed. Oct. 3, 1966).

Thus, although the language of this section might conceivably be read to provide that a regulation under Section 5(c)(3) must require that every ingredient in a commodity be declared on the label, it can very well be argued that in the light of the legislative history, the intent of Section 5(c), and the statutory purposes, ingredients need not be declared if they are not relevant to a value comparison or to the prevention of deception. Such a conclusion can be justified further on the ground that the discretionary authority in Section 5(c)(3) to require the listing of every ingredient must include the lesser authority to require the listing of only those ingredients relevant to the question of value comparison and deception. Quite obviously a narrow interpretation of the language to require the listing of fifty or a hundred ingredients on the label would tend to defeat one of the basic purposes of the Act to enable consumers readily to obtain accurate information as to consumer commodities.

Nonfunctional Slack-Fill

Section 5(c)(4) authorizes regulations effective to "prevent the nonfunctional slack-fill of packages containing consumer commodities." The final sentence in Section 5(c) provides that "a package shall be deemed to be nonfunctionally slack-filled if it is filled to substantially less than its capacity for reasons other than (A) protection of the contents of such package or (b) the requirements of machines used for enclosing the contents in such package."

This provision was added to the bill by the House Commerce Committee. The only explanation found in the legislative history is in the House Committee Report, which states:

> When a consumer buys a nontransparent package containing a consumer commodity, he expects it to be as full as can be reasonably expected. He makes his purchase in many instances on the basis of the size of the box. There are practical justifications for less than a complete fill in many instances. A container has to be large enough to protect the contents and it is necessary to recognize that many consumer packages are prepared by machine operations. Therefore, to the extent that the safety of the product requires additional wrapping and a somewhat larger box and to the extent that machine packaging requires that the box be somewhat larger to accommodate the machine closing, slack-fill is necessary and justifiable. However, nonfunctional slack-fill which involves, for example, the use of false bottoms and/or unnecessary bulky packaging is not justified. The bill would allow the Department of Health, Education and Welfare and the Federal Trade Commission to prevent abuses of that kind.[17]

The definition of nonfunctional slack-fill in Section 5(c)—a package filled to substantially less than its capacity for reasons other than

[17] House Committee Report at 8.

protection of the contents or the requirements of machines used for enclosing the contents in the package—was thus apparently intended to include all legitimate technological reasons for less than a complete fill.[18]

As for the content of these regulations, a logical approach would be for the agencies to adopt standards of fill similar to those that have been adopted by the FDA under Section 401 of the Food, Drug and Cosmetic Act, which authorizes regulations to establish for any food a reasonable standard of fill of container. The FDA has adopted standards of fill under Section 401 based on at least four standards of measurement:

(1) A percentage of the total capacity of the container (*for example,* the standard of fill of container for canned tomatoes is a fill of not less than 90% of the total capacity of the container);

(2) Volumetric determinations (*for example,* the standard of fill of container for canned peas is a fill such that, when the peas and liquid are removed from the container and returned thereto the level peas, irrespective of the quantity of the liquid, 15 seconds after they are so returned completely fill the container);

(3) The drained weight of the food product measured against the water capacity of the can by weight (*for example,* the total weight of drained fruit cocktail must be not less than 65% of the water capacity of the container); and

(4) The maximum quantity which can be sealed in the container and processed without crushing or breaking (*for example,* canned fruits).

Voluntary Packaging Standards

The third major area of coverage in the FPLA concerns the encouragement of voluntary packaging standards designed to reduce the number of weights or quantities in which a particular commodity is packed. I will not try to rehearse here the legislative history that most of you are familiar with during which the compulsory standard provisions of the earlier versions of the bill were finally converted to voluntary standards provisions by the House Commerce Committee. It is enough for present purposes to emphasize that the House Committee—and subsequently Congress—concluded that there were indeed some significant drawbacks to compulsory packaging standards, and that industry should be given an opportunity to work through

[18] For discussions of the technological reasons for less than a complete fill, see 72 Yale Law Journal 788, 794-95 (1963); Forte, "The FDA, the FTC and the Deceptive Packaging of Foods," 40 New York University Law Review 860, 874-75 (1965). 21 Food Drug Cosmetic Law Journal 205 (April 1966).

voluntary means to reduce the number of package sizes in those instances where "undue proliferation" exists.

There have been a number of developments in this area in the two years since enactment, but many questions remain. Let us look briefly at what has happened and at some of the most obvious questions that most companies and associations in the consumer commodity industries are now facing.

Many of your companies and associations are working on or have completed a program to reduce or stabilize the number of package sizes. The Department of Commerce has on several occasions announced those products for which standards have been developed or are in process. Some industries have been working through the voluntary standards procedure of the Department of Commerce, but most have chosen to work through their industry trade associations.

To date, there have been no formal proposed determinations by the Department of Commerce that undue proliferation exists in the package sizes for any commodity. Apparently the Department has decided that the best approach for all concerned is to encourage industry segments to move voluntarily to reduce or stabilize package sizes without the necessity of a formal finding of undue proliferation.

The Department's regulations do not define "undue proliferation" and do not spell out what constitutes the impairment of the reasonable ability of consumers to make value comparisons with respect to a consumer commodity or commodities. The substantive content of these terms will remain to be determined on a case-by-case basis. Until that time, industries will have no clear guidance in trying to decide whether a voluntary reduction in package sizes is desirable, or necessary, in order to preclude a charge of undue proliferation.

A second question concerns the degree of industry adherence to a voluntary standard. Obviously, if the bulk of the industry disregards a voluntary standard, then its existence would have little or no relevance for purposes of an undue proliferation inquiry. But is a finding of undue proliferation justified if there are only regional aberrations, or if a single manufacturer feels he must market a size that is not included in the standard?

The Department's voluntary standards procedures contain the proviso that:

> A standard published by the Department under these procedures is a voluntary standard and thus by itself has no mandatory or legally-binding effect. Any person may choose to use or not to use such a standard.

Although I have not seen the documentation of most of the industry voluntary standards that have been developed over the past year or so, I assume that this same noncompulsory concept is included in most of them. Nevertheless, failure of an industry to observe a standard might well raise the question of undue proliferation and trigger the Section 5(d) and 5(e) procedures of the FPLA.

Under those procedures, if the Department finds undue proliferation, it must then request the industry to cooperate in the development of a voluntary packaging standard under the Department's procedures. Subsequent failure to develop such a standard or to observe a standard that is developed must be reported by the Secretary of Commerce to Congress, with his recommendation as to whether Congress should enact legislation providing regulatory authority to deal with the situation in question.

Thus, the third major unanswered question in this area is whether conditions will arise in 1969 or thereafter that would lead the Secretary of Commerce, or others, to propose once again that compulsory packaging standards be authorized by Congress. Undoubtedly it is this possibility that has prompted many segments of industry to make the voluntary approach an effective and workable one.

Conclusion

Finally, a brooding specter over all voluntary standard efforts is the question of compliance with the federal antitrust laws. Some of you may have seen reports in the trade press that the Department of Justice has been in communication with the Department of Commerce concerning the procedures that should be observed by an industry that is developing a voluntary standard. I am confident that many industry groups will be very interested in seeing the outcome of these inter-Departmental discussions.

I have talked to more than a few industry representatives who believe they are caught between the pressure of the FPLA toward voluntary package size reduction on the one hand, and the threat of antitrust prosecution on the other. In the meantime they must continue to compete effectively, and meet the changing tastes and demands of customers and ultimate consumers.

I doubt whether any of these questions will be finally resolved in 1969. Indeed, the prospect is that at least some of these questions will become rather acute for many segments of industry over the next few years. **[The End]**

Teamwork for Consumer Protection

By THEODORE R. GAMBLE

Mr. Gamble Is Chairman and President of Pet Incorporated, St. Louis, Missouri.

IN TALKING WITH YOU TODAY I hope all of you understand that it is impossible for me, or for anyone for that matter, to speak for the entire food industry. It is this country's largest business and it is obvious that no one can speak collectively for all of it. However, as immediate past chairman of the Grocery Manufacturers of America (GMA) and as one who has headed a major American food processing company for a number of years, I believe I can speak with some reasonable background on the matter of teamwork for consumer protection.

Before getting into the substance of my remarks, I think it is important to reiterate a point I tried to make three years ago at the Ninth Annual Joint Educational Conference. That is, the food industry endorses vigorous enforcement of all existing laws. In addition, our industry has committed itself to a continuing policy of voluntary compliance and self-regulation in the interest of the consuming public. I believe our actions in this regard speak as loudly as anything I might say.

A man who just a month ago lost an election but who won millions of friends in the process, Senator Edmund Muskie of Maine, has a favorite story about an out-of-state motorist who crossed the New Hampshire border into Maine. A few hundred yards later he arrived at an intersection with two roads pointing north—U. S. Route 1 and the Maine Turnpike, with two signs—both pointing to Portland. Puzzled, the motorist stopped and asked a native, "Does it make any difference which road I take to get to Portland?"

The native's reply was, "Not to me, it don't."

As appealing as that picture of Maine independence is, I think we've all learned in recent years that what happens to each of us *does* make a difference to the rest of us.

Common Objectives

Business and government today share many common objectives. Each desires to contribute to the development of a society which offers maximum opportunities for individual initiative and enterprise and which also places a premium on a person's worth and merit. And yet, business and government each knows that it makes a difference to others, and to the achievement of common objectives, if the routes traveled toward those objectives are not compatible.

Should business and government be antagonists or cooperative partners? I suspect that the ideal lies somewhere in between. There will always be situations in which government must be on the opposite side of the table from business. Arm's-length dealings are absolutely essential in many such areas of regulation and supervision.

But there are even more areas where business and government can and should work together cooperatively as partners. That we are beginning to do so successfully is, I believe, a measure of how far we have come in recent years. To be sure, we still have a long way to go but any person whose eyes are open can plainly see that we are headed in the right direction and that we have already traveled down the road some distance.

This progress has been made possible in great part by the ever-increasing attention which has been devoted to the "four c's" which provide the theme of your conference—communication, collaboration, cooperation and compliance. Speaking from the standpoint of the food processing industry, I'd like to share with you some thoughts on these basic foundation stones of consumer protection.

Rapport with the Consumer

It has become a cliché these days to talk about communication gaps but there is so much conversation about them simply because they do exist. As Robert McNamara has said, "The only real trouble about clichés is that they are too terribly true."

We in the food industry believe we are in the process of closing at least some of these communication gaps. In the past two to three years our industry has faced a situation for which we were not completely prepared and we've had to start communicating more effectively as a matter of sheer survival. As never before we have had to

defend ourselves against vigorous activists in government as well as against militant consumer groups. The former were typified by those who were fighting aggressively for the so-called truth-in-packaging bill and the latter, of course, by picketing housewives who started the supermarket boycotts.

Looking back now, I think it is safe to say that the food industry did not have the contact or rapport with the buying public we thought we had. An industry which excelled in the use of advertising, marketing and marketing research to bring consumers into supermarkets to buy its products failed to understand sufficiently any number of basic consumer wants, needs and desires.

We were communicating in those days but our communication was mostly one-way—from us to consumers. Because there was so little communication in the other direction, a real communications gap developed.

A time of adversity is a time for soul searching and I can assure you that the entire food industry has done much of this during the past several years. We concluded we had been doing too much talking and not enough listening. We came to realize that two-way communication was more than a phrase; that it had to become a way of life for us. Our rather complete change of philosophy throughout much of the food industry has been in the spirit and tradition of the prayer by St. Francis, "Oh, Divine Master, grant that I may not so much seek to be understood as to understand." I believe we are more and more beginning to understand our obligations and responsibilities in this regard and are fulfilling them. Let me give you just a few specifics from the many examples I could cite.

The GMA has initiated an effort which many of us believe will bear healthy fruit in the years ahead. The Consumer Research Institute is less than a year old now, but it has begun operations on a modest scale. It is successfully funded and a small nucleus staff has been assembled. This research organization will look into areas of concern to consumers and explore them in depth. Again, it will do a great deal of listening and searching in a continuing effort to determine what consumers really think. We regard the formation of this research organization as a major step in the right direction for our industry.

An important communication undertaking in the consumer area is the "Consumer Dialogue" program which has been carried on in major cities throughout the United States by the National Association of Food Chains (NAFC). Although many other organizations

and even individual companies in segments of the food industry have since created their own consumer panels, I believe the NAFC program was the first. Its purpose has been to open new and continuing channels of communication between homemakers and food distributors. Another basic purpose has been to demonstrate publicly the interest the food industry has in discovering *changing* consumer wants and needs so they can be adequately met.

The give-and-take exchange of pointed questions and candid answers in the highly intimate and believable atmosphere of these unrehearsed panel discussions has had a refreshing effect wherever they have been held. National and local news media have been highly laudatory in their praise of this effort.

These are but a few of the many indications that two-way communication is steadily improving between food processors and manufacturers, wholesalers, retailers, consumers and government personnel as well as the news media.

As good as this is, it is still not good enough because we must do so much more. Last year, the well-known syndicated columnist Jimmy Breslin reviewed the evolution of civil rights protests from the peaceful March on Washington in 1963 to the violence that erupted in Newark and Detroit and had this observation:

> In a country that can do anything as long as there is a machine involved, we have come from the March on Washington to sniping in Detroit because nobody knows how to perform the simple art of talking and listening to somebody else.

Industry-Government Cooperation

One of the most fruitful and productive improvements in communications between the food manufacturing industry and the Food and Drug Administration (FDA) has been the formation of the GMA-FDA Council. On the industry side of this group, the chief executive officers of major food companies meet regularly with top FDA officials for mutual exchanges of ideas across the conference table. I know from personal experience that these meetings have greatly increased the understanding we have of FDA and I am confident the FDA personnel involved feel they have a far better understanding of us.

The basic purpose of these regular meetings has been to establish a continuing dialogue which in turn has provided a forum for consideration of mutual problems. The environment in these meetings is such that a free exchange of ideas is not only possible but expected. A better common understanding of government and indus-

try responsibilities has resulted. Two-way communication between government and business was not only planned in this instance, but it is being implemented with a high degree of success.

One notable result, among many others, which has come of these GMA-FDA Council meetings was the agreement reached on the definition of product withdrawal. When a food product is still under the control of the manufacturer, taking it off the market voluntarily now does not constitute an FDA withdrawal. This change is of great benefit to the manufacturer while fully protecting the consuming public in precisely the way FDA and the food industry both desire. This new approach to an admittedly difficult problem avoids misleading publicity which in the past has seriously damaged some companies and contributed greatly to the failure of at least one business. FDA's prior product recall and seizure approach created tremendous problems at all levels of the industry and frequently resulted in irreparable damage out of all proportion to the possible danger involved.

If I had to pinpoint one area in particular where I think we must do a better job in the months and years ahead it would be in improving our communications at the state and local level. Relatively, a much better job has been done at the federal level than with other echelons of government. But great confusion, wheel-spinning and needless expense will result unless equally effective two-way communication is developed with state and municipal officials. This is a challenge to those in the federal government as well as to those of us in industry.

As far as industry-government cooperation is concerned in food regulation, I suggest we take Al Smith's famous advice—"let's look at the record." The then-infant food processing industry itself played an important and helpful role in the passage of the initial federal food regulation act of 1906. In the 1930's our industry, then acting through the GMA, Inc., played a similar and perhaps even more helpful role in suggesting many provisions of the Federal Food, Drug and Cosmetic Act of 1938 and strongly urged its approval in Congress.

The food industry, in my judgment, has continuously acted in a responsible manner in connection with such legislation because we ourselves have known that such laws at the federal level would strengthen the food industry as a whole rather than weaken or hinder it. Integrity and safety have been as essential to our own well-being as they have been to the government and to the consumer. Through the years, there has been a high degree of successful teamwork between government and industry toward a common objective—that of

providing consumers with the most useful, wholesome and nutritious food products at the fairest possible prices. Virtually all food manufacturers recognize that this teamwork has been one of the factors in their own growth and success.

One of the most recent and perhaps even revolutionary instances of this cooperation between the food industry and FDA is in the self-certification program. Although to the best of my knowledge this presently involves only two companies—General Foods and Green Giant—it is a program which virtually every food executive is watching closely and carefully because it has great implications for the future. Although this pilot program is admittedly limited in scope at this time, I think it represents a sincere mutual effort to find out how such a plan on a much wider and broader basis could and should work. Although the program has been under way for a little over a year, I have been told by representatives of both the manufacturers and government that much has been accomplished and that a far deeper understanding of each other's problems has already been achieved.

Because this self-certification approach is such a different one from any used in the past we—like FDA officials themselves, including Dr. Ley—believe it is wise to move slowly and carefully. There is too much to be gained by doing this properly to risk doing it hastily and poorly. All of us, including the consumer, will benefit if effective and proven guidelines can be developed prior to the broad-scale adoption of a self-certification program.

The thrust of FDA-industry cooperation has not been restricted to any one company or any one trade association. On the contrary, it has been widespread throughout all areas of the industry. Direct cooperative programs have been underway with too many companies to enumerate. And it would be almost impossible to list all the food trade associations with which FDA has worked so effectively. Some that I'm aware of, in addition to GMA, are the National Dairy Council, the Milk Industry Foundation, the National Association of Frozen Food Packers, the Food Research Institute, the National Canners' Association, the American Bakers' Association, the Millers' National Federation, the Corn Industries' Research Foundation and the National Association of Ice Cream Manufacturers. These examples multiplied many times over indicate that business and government *are* communicating and *are* cooperating in implementing the food laws of this country.

It is important that this successful partnership continue because the coming demands for more and better food in this country and throughout the world require rapid acceleration of technological development within the food industry. Literally, if we are to avoid massive starvation in many areas of the world all of us connected in any way with the food industry will have to improve our performance steadily. With world population expected to increase from the present 3 billion to more than 6 billion by the year 2000—just 32 years from now—the problem is one which will require the best efforts of each of us.

FDA's New Approach

The stated mission of the FDA is that of total consumer protection. Law enforcement is set forth as just one method by which this protection is to be assured. Although in the past there has been great reliance on enforcement through FDA's inspection and laboratory staffs, we in industry are pleased to see that there are many other avenues being adopted today as we approach a more meaningful partnership. Although traditional law enforcement through punitive action is always a clear and present possibility even today, it appears to us that FDA is beginning to understand that it can just as often rely on voluntary compliance to accomplish specific objectives.

Food processors themselves have progressed far beyond the old limited concepts of quality control, as I tried to point out in my remarks here three years ago. Even a change in title has been made in most companies to reflect the different job responsibilities. The person in charge today is frequently called the quality assurance director and he invariably reports directly to top management in his company. His work cuts across all facets of a company's manufacturing and supply operations, as it must if he is to succeed. This is especially important as so many of our companies grow and diversify. Quality assurance is a high-level concern for every responsible food manufacturer and none of us takes lightly our responsibilities in this area.

One rather recent FDA action which industry welcomes and applauds because it has led to substantial mutual benefits is the new district office approach to compliance procedures. Rather than seeking more and more inspection, we are pleased to see that the FDA district offices are now relying to a greater degree on the workshop and seminar approach as well as the training of more industry personnel in meeting compliance requirements. According to FDA's figures, almost 3,000 different firms have sent men and women to

these recent district workshops and seminars. This, we submit, is real progress—for everyone. FDA is to be commended for its efforts.

As the years have gone by, there has been a change in the nature of the problems we all face. For example, when food adulteration involved primarily filth contamination and insanitary plant conditions, legal sanctions were in order and it was relatively easy to stop offenders. But today the problem goes far beyond this. Pesticide residues are a case in point. Where the previous situation was one of trying to assess the blame and punishing the guilty, the problem today is of trying jointly to find solutions where they may be well-nigh unattainable—even when we *do* work together. Industry found it could not do this job alone and even industry trade associations, with a wider base, were unequal to the task. For that matter, the FDA itself found it had to call upon such other government agencies as the Department of Agriculture in its efforts to *approach* these problems, much less solve them.

Another area where traditional concepts of enforcement have had to be restructured relates to salmonella. Most knowledgeable persons recognize that complete eradication of salmonella is virtually impossible. Because it is, there is growing realization that—in the language of the sports world—all we can hope to do is "hold down the score." What we must do together is to determine where the greatest dangers are from salmonella and concentrate our attention in those areas, all the while educating the public more fully regarding the seriousness of the problem. It is in this area that I believe much more can and should be done in the near future. One of the most likely areas of salmonella contamination is in the home itself. Far more must be done to educate and inform the housewife about *her* responsibilities in salmonella control. Similarly, the growing trend to eating out has created huge new problem areas in salmonella control at the restaurant, snack bar, hotel and institutional level. Every effort should be made to improve salmonella control in these places of business.

Another change in emphasis I would like to suggest to the FDA would be a more meaningful selection of salmonella control targets. There has been a great deal of activity in areas and with products where the incidence of salmonella is relatively negligible and where illness and death have been minor or non-existent. At the same time, perhaps insufficient force has been mustered where the problem is far more dangerous or potentially so.

The food industry welcomed in 1964 the establishment of FDA's Bureau of Education and Voluntary Compliance and welcomed equally the restructuring of this operation earlier this year when the important consumer education function was transferred elsewhere within FDA. The Bureau's program of working with industry in developing specific programs for voluntary compliance with FDA regulations and in providing technical assistance in quality assurance has done and will do much to achieve positive results. By thus shifting part of the burden of responsibility for inspection and regulation, FDA can free its limited forces to police traditionally troublesome situations and at the same time know that product quality and safety are still being checked continuously.

This effort also has two other major advantages. Consumer protection is actually enhanced while government costs are not being materially increased. The arrangement gives the FDA access to industry information which has previously been withheld from it and it also frees the food processor from periodic inspections.

Conclusion

In conclusion, let me say that while I'm pleased with the progress we've made together in the past three years, I'm not satisfied with it nor complacent about it. While they represent a smaller and smaller minority, there are still some industry people who regard every FDA action a bureaucratic harassment. And, regrettably, a few FDA personnel still view each industry move as an effort to increase profits without consideration for the public interest. Happily, these "hard-core inconvincibles" grow fewer and fewer by the day. More and more, industry and government are communicating and cooperating for the common good.

By working together in this fashion, this nation has made possible the development of an industry which provides our citizens with the safest, most nutritious and most abundant food supply in the history of mankind. This food is both conveniently and attractively packaged and is sold at a more advanced stage of preparation than in any other country in the world at prices that are the envy of every other country.

Together, we are obviously doing something right. Let's keep on doing more of the same! **[The End]**

Quality Assurance Through Self-Regulation

By MILAN D. SMITH

Mr. Smith Is the Executive Vice President of the National Canners Association.

THOUGH THERE IS A TEMPTATION TO SPEAK on quality assurance in the total food processing industry, it seems appropriate that I confine my remarks to that segment I represent and know best, the canning industry. Certainly this is a highly significant segment, with approximately 1,800 canning plants producing about 27 billion containers of food yearly, with a wholesale value approaching $6 billion.

Assurance of the quality and safety of canned foods through self-regulation has been the aim of the National Canners Association (NCA) since its formation in 1907, and this concern goes back well before that date to the period of its two predecessor organizations. Many of the problems involved are common to all canners and require solutions based on information, research, study, and interpretation which could not be achieved as well, if indeed at all, by any individual canner. In these instances NCA can most appropriately become the catalyst or motivating force.

The name of the game is *education*. It is equally important that the canner *and* his operating personnel have broad knowledge about the industry and what makes it function. Self-regulation is a team effort, and it is achieved effectively only by working together. It is effective two-way communication. NCA has been fortunate in receiving vital cooperative guidance from its canner members.

I will briefly describe some of our educational programs which are successfully designed to assist canners in supplying the consumer with food of dependable quality and wholesomeness. In the interest of time it will, of course, be necessary to restrict the number of examples.

Pesticide Residues

Much has been said in recent years about pesticides, their safety, their application to raw products, etc. Pesticides must be used to obtain a high quality raw product, and their residues must be removed to assure safety.

Shortly after organic pesticides came into the picture, the NCA established its "protective screen" program. The program includes furnishing growers with pesticide information for effective and safe application. This also supplies canners with a list of registered pesticides; outlining to them the precautions which must be taken for proper pesticide use; and obtaining from growers certification as to the pesticides used as well as records of the time and rate of application and all other pertinent information. We have also published a special 18-page bulletin entitled, "Pesticide Safety." This organized program has become an effective tool to aid the field staffs of the canners in doing a thorough policing job with their growers. With this field staff cooperation it has been necessary to reject only a relatively few deliveries of raw products because residues were in excess of levels enforced by the Food and Drug Administration (FDA).

In 1963, a comprehensive survey was taken to determine if this "protective screen" was being strictly followed and if each canner had developed a program of his own. In the reports filed by 90 percent of the canners participating, each was following a specific program based primarily on NCA recommendations but with contributions being made by each company in cooperation with growers and often with state agricultural colleges. More than 30 percent of the processors were either applying pesticides with their own trained crews or were supervising their application through contracted applicators. A fairly high percentage of canners also was pre-sampling raw products for determination of residue level before accepting delivery at the receiving dock.

To supplement the program, NCA has conducted much research on analytical methods for detection of pesticide residues on the raw products as they come to the canneries. Such quality control checks are designed to detect abnormal conditions. Analytical methods, checked with those used by regulatory agencies of government, are now of sufficient sensitivity to detect fractions of a part per million.

In 1964, an NCA Committee of Canning Industry Residue Analysts was organized to facilitate cooperation among industry analysts in resolving difficult analytical problems. One of the most important functions of this committee is maintenance of a collaborative test

sample program. Food samples containing known amounts of specific pesticides are prepared and distributed by NCA for analysis by the committee members in their respective company laboratories. Meetings are held periodically to review results and pinpoint particular difficulties. These cooperative efforts are continuing today and have been effective in eliminating many analytical problems.

Canners who do not have facilities for testing their own products are urged to have this done by a reliable commercial laboratory. The NCA assists them in making contact with such organizations and advises on the sampling and testing procedures if desired.

Associated with the safety assurance program in pesticide usage has been the development of product washing and preparation procedures which remove all harmful pesticides before the product goes into glass or metal containers. We recently completed a research study, supported by the U. S. Department of Agriculture, wherein the canning preparation procedures were compared with actual home preparation of foods. The results indicated that the washing procedures for removing traces of pesticides, as developed by NCA and used in canneries, are equal to, or better than those employed by the homemaker.

To summarize, self-regulation in the area of pesticides has been effective in assuring the consumer that canned foods are free of harmful residues.

Thermal Processing

In the canning of most foods, the product is hermetically sealed and preserved by heat. The time and temperature of heating for such preservation is referred to as the process. The primary purpose of processing is to assure a wholesome, commercially sterile, shelf-stable canned product.

To prevent potential hazards to health and to eliminate possible spoilage outbreaks, the NCA laboratories, beginning in 1918, determined the fundamental principles involved in proper processing procedures. The research on heat resistance of spoilage bacteria, rate of heat penetration into canned foods, and heat distribution in the steam pressure retorts put processing on a scientific basis and permitted the calculation of safe processes.

Beginning in 1923, the results of processing research were released in NCA Laboratory Circulars. In January, 1930, the sterilizing processes to be used for various non-acid foods were collected and published as Bulletin 26-L "Processes for Non-Acid Canned Foods." A pattern of revision and supplementation has been followed

ever since. The tenth edition of Bulletin 26-L "Processes for Low-Acid Canned Foods in Metal Containers," was published in September, 1966, and the third edition of Bulletin 30-L covering processes for many foods in glass containers was published in June, 1963. These editions are the result of continuing processing research directed by the NCA Processing Committees, consisting of representatives of NCA and of the container manufacturers. Significantly, FDA recognizes and makes use of these Bulletins as a "bible" for reliable processes.

Consumer acceptance of canned foods rests on confidence in their wholesomeness, tastiness and nutritional properties. More than any other single factor, wholesomeness depends on proper processing; thus NCA, in cooperation with the container manufacturers, promotes adequate processing methods in every available way: by published bulletins, retort surveys, and educational conferences.

In a letter of July 8, 1965, the late Commissioner Larrick informed me that the FDA appreciated the interest of the NCA in disseminating the information needed to prepare foods which are free from decomposition and substances which might render such foods injurious to health. While the Commissioner's letter referred specifically to our processing program, his comment is applicable to the NCA efforts in other areas.

Sanitation

The observance of good sanitation practices in the packing of canned foods has been a major goal of NCA programs for more than 50 years. The NCA Laboratories have worked continuously and closely with every element of the canning industry to develop and recommend procedures to assure that sanitation in canning plants is maintained at a high level. These efforts are supported in the laboratory and the field through development of sanitation guidelines, by practical advice to individual canners, and from periodic inspections of members' plants.

Initial training courses in sanitation in 1945 were followed by publication of the textbook, *Sanitation for the Food-Preservation Industries,* prepared by the NCA in cooperation with the Association of Food Industry Sanitarians, Inc.

During the ten-year period of 1956 to 1966, the NCA laboratories staged 123 sanitation and processing conferences for 5,500 cannery supervisory and operating personnel. This is a continuing educational program. Sanitation practices are reviewed and emphasis is placed on the imperative nature of adequate processing equipment

and operation by well-trained personnel. Official inspection activities, product standards, bacteriology of canning, and post-processing can handling are also covered; and of course, the prevention of product contamination with extraneous materials is emphasized. NCA arranges for these conferences to be jointly sponsored by state or regional canners associations and NCA. They are geared toward the supervisory personnel including superintendents, foremen, and foreladies, as well as to retort operators and clean-up crews, because these people have the most direct control over product quality.

Recently, NCA further expanded its educational efforts on this subject by preparing and distributing audio-visual presentations consisting of colored slides, printed commentary, tape recording of the commentary and reference material. These are intended for in-plant use and as an aid to discussions with cannery supervisory personnel. One of these presentations, "Planned Sanitation," covers the scope, importance, and objectives of a good sanitation program.

We recognize that good sanitation practices are not only absolutely essential to meet the public's demand for a wholesome food supply, but are also a basic element of a successful canning operation. There can be no doubt that the interests of the consuming public, federal and state regulatory agencies, and the industry are identical in this regard.

Other audio-visual training aids now in circulation include "For the Retort Operator," "Using Statistical Quality Control," and "Can Handling." Presentations on the bacteriology of food plant sanitation, and on the chemistry of food plant cleaning are now being produced.

Design of sanitary canning equipment is fundamental to cleaning and maintenance. NCA has a Committee on Sanitation of Canning Equipment; it consists of NCA staff, NCA member representatives, and a liaison member representing the Food Processing Machinery and Suppliers Association. The committee has developed and distributed recommendations on the sanitary design and operation of drum-type blanchers, belt conveyors, tomato washers, piping valves and pumps, and post-processing can handling equipment. Other equipment is under consideration and work in this area will be continued.

Last month the NCA published a new booklet, "The ABC's of GMPs" (Good Manufacturing Practices), prepared by the Research Laboratories. Over 5,000 copies are already being used to furnish the cannery worker, in simple language, the important facts about the relevance of sanitation to a good finished product. It points out

that the GMPs, on which hearings were held have, in a somewhat similar form, served as the basis for NCA's sanitation program for many years and have contributed in large measure to the production of clean, wholesome food, regardless of any regulatory authority which may exist in this area. It is of interest to us that a high-ranking official of the FDA, only last week, said that NCA deserved a pat on the back for the fine ideas expressed in this recent publication. He added, "It has a definite meaning for the people for which it is intended." The booklet definitely carries helpful ideas for the line worker, and it demonstrates what an association can do for its members. FDA, of course, is encouraging all associations in the area of self-regulation.

Nutrition

Our industry is proud of the part canned foods have played in the task of providing America, and in fact a large part of the world, with a continuous supply of high-quality nutritious foods not only in the normal daily diet, but also in times of war and national emergency. We are not Johnny-come-latelys in the field of nutrition research. Since 1922, when food science was in its infancy, the NCA has been gathering facts, conducting and sponsoring research, and making the results known to its members, and frequently, in addition, to other interested parties. As knowledge of vitamin chemistry and methods of assay improved, the pace of this effort was stepped up.

In a major project, beginning in the 1940's and jointly conducted by NCA and the Can Manufacturers Institute, some fifty thousand samples representing over forty important products from 526 canneries were tested for the full gamut of significant nutrients. On the whole, canned foods were shown to be good sources of vitamins with little or only moderate loss during canning. As sources of mineral nutrients, canned foods were found comparable to the same products in the raw state. Also, allowing for preparation steps, there was little difference in the raw or canned foods with respect to calories, protein, carbohydrate and fat content.

Running tests on finished products to check their food values represents only one phase of the industry nutrition program. Many canners conduct extensive research on breeding of varieties especially suitable for retention of their desirable characteristics during the canning process; and harvesting and handling are timed for greatest retention of quality. In addition, the technological skills available in the canning industry are often teamed with those of specialists at state

experiment stations for the production of the best possible raw produce.

The industry nutrition program included a study of specific effects of different canning processes on the retention of nutrients. In several instances it has been found that changes could be made in the product handling and processing procedures to increase retention of certain vitamins to even higher levels.

As indicated, time makes possible a mention of only a relatively few examples of our broad programs in our fourteen Divisions. We have been pleased to have taken the initiative more than 30 years ago in working out a Simplification of Containers Program; over the years we have worked with the appropriate Government agencies in developing Standards of Identity and Fill of Container, etc., on a significant number of canned food products. Our Annual Convention also affords NCA members further education and clarification of our programs. Within the past two years, NCA opened up a new channel of two-way communication for its canner members by conducting Industry Forums in various parts of the United States. These forums have made it possible for management and operating personnel to be fully versed on NCA policies and programs such as those outlined to you today. Also we have held successful dialogues with consumer groups, being one of the first, if not the first national trade association to launch a very important project which we named IMPACT, short for Industry Mobilization for Positive Action on Consumer Topics.

In conclusion, I know that all canners recognize that the ultimate end of its product is *the consumer*. He or she must be satisfied if the canner is to retain consumer loyalty. If a company loses its consumer following it will not long remain in business.

We of the canning industry are pleased to report that long before the present public attention to the matter of consumer protection, we were working on many fronts through voluntary programs to assure such protection. The educational approach in reaching the present high level of achievement has involved in large measure our recognition of the need for effective communication, for constructive collaboration, for mutual cooperation and for compliance with pertinent laws and regulations. We hope to make further progress in the four areas of consumer protection which are dramatized at this Twelfth Joint Educational Conference of FDLI-FDA. To each goes our salute for furnishing this impressive conference and for your many other respective contributions to make the theme of this conference a reality. **[The End]**

Status, Self-Certification Program

By HAROLD A. GOLLE

Mr. Golle Is the Director of Corporate Quality Assurance of the General Foods Corporation.

LET ME BEGIN by bringing you up to date on the progress of the self-certification pilot study we have been conducting at the General Foods plant in Dover, Delaware. As some of you may recall, the study was begun under a one-year agreement, and was signed on September 1st of last year. Both parties—FDA (The Food and Drug Administration) and General Foods Corporation (GFC)—have now seen fit to extend the original agreement to April 1, 1969. A second agreement, called Phase II, had been in preparation for some time, but an extension of Phase I was seen as desirable to allow an in-depth appraisal of what has been accomplished during the first year, before proceeding into a new, more sophisticated phase. Important questions are being asked that need to be answered, and I will get to those a little later. Suffice it to say at this point that a delay for careful assessment seemed prudent before a commitment was made to broaden the scope of the program.

We have come a long way since self-certification was discussed at this same conference last year by our [General Foods Corporation's] Dr. Barnie Daubert. At that time, we were just getting started at Dover, and many in the industry were expressing grave doubts about the wisdom of our working so closely with a regulatory agency which at times in the past had ruffled a few feathers and caused a certain amount of discomfort. They were convinced that we were about to give away the keys to the vault.

Let me reassure you that the agreement we have been working under does not compromise any legitimate rights which now belong to industry. Our pilot study at Dover has concerned itself almost exclusively with product safety—not product elegance or consumer satisfaction attributes or formulae. We have opened no doors to such

economic areas as raw material costs, production costs, administrative costs, profits, market shares, or the like. Our communications, both verbal and written, have concerned themselves with quality control standards and practices necessary to product safety, and, to a lesser degree, net weight performance.

Within this limited area of product safety, we have been completely candid with all FDA personnel involved in the program, revealing anything they wished to know about our quality assurance practices at Dover—where it concerned itself with those products under study. In return for such openness, and as part of the agreement, FDA has agreed to keep all such information confidential, and there has been no indication of even the slightest compromise of this trust.

As I said a moment ago, we have come a long way. We have learned a great deal and, in my view, made progress. Our continuous dialogue, at both the administrative and production level, has led to valuable, increased understanding on both sides. This already has led to two rather important changes.

Modifications in FDA's Policies

First, and we feel as a direct result of our self-certification project, FDA has modified its policy on the publicizing of certain recalls —those made voluntarily by the manufacturer for products under his control, and the change applies to *all* manufacturers. This, to us, is a forward step, not only because it gives us greater protection in a vital area—right now—but because it very well could lead to further policy modifications. If and when a sanitation lapse occurs in manufacturing, I am sure all of us would like to see FDA first consider how a product is prepared and used by the consumer, and then base the scope of its national or regional publicity on the extent of possible danger to the public.

A second important change, I believe, is a recognition that zero tolerances, whether for Aflotoxin or Salmonella, are neither reasonable, practical, nor technically sound for many food products, particularly those we are still unable to safeguard by terminal purification or sterilization. The issue is a sensitive one because safety is our principal concern. So we are jointly developing new methods, new approaches involving sampling plans, frequency of sampling—and even total quality systems that will provide adequate, affordable consumer protection.

Possibly the key word in our entire project is "agreement." And this always begins with questions such as: "What is adequate raw material inspection?" or "What constitutes adequate in-process, environmental and finished goods sampling?" or "What are practical, affordable limits against which a food process should be controlled?"

To find answers to these and other questions, we have used the best combined knowledge available and developed approaches satisfactory to both parties. This takes time, effort, mutual trust and respect, plus a willingness to explore issues in depth. I think both of us have been a little surprised, and certainly gratified, by the extent of desire on both sides to reach workable solutions.

Our most significant progress on the present agreement, I believe, has come in four main areas:

(1) We have developed a simplified approach to writing specifications covering areas of FDA concern—microbiology, food additives and weights. In fact, we are considering batching sheets with perforated sections so we can separate our records into those things in which FDA has a legitimate interest and those things in which they assure us they have no interest at all—mainly factors relating to product formula and product elegance.

(2) Our reporting system has been streamlined to the point where we are now reporting only exceptions to specifications; exceptions to the program; weight performance, in terms of average weights; and complaint rates per million packages involving only health, foreign matter and weights.

Let me pause here to mention some of the concerns we and others have had regarding specifications and reports. Basically, the issue is how information we share with FDA will be used by FDA. We have been assured by FDA that such material as microbiological specifications which we submit to them *will not* be used to develop industry standards. Internal controls show action limits for response to "out of control" situations, both process and product actions, plus reject limits which *we* impose on our processes or products. Obviously, if FDA has information that suggests a potential, serious health hazard, their limits will be controlling. We do not consider this unreasonable. Now to get back to other progress we feel we have made.

(3) In the case of reports from a company to the agency, our experience suggests the real possibility of changing the frequency from monthly to quarterly. Eventually, it might be stretched

to semi-annually, with the provision that there would be immediate posting on significant items whenever necessary.

Perhaps another way of looking at the project will help. Self-certification is a little like the posting of speed limit signs on a specific road of food manufacturing—but with minimal police patrolling of the road. The manufacturer patrols himself through a planned inspection and control system and reports to the authorities any violations of the speed limits or any detours off the road which he might take. As confidence in the system increases, the need for frequent reporting diminishes. Of course, an immediate alert is sounded if and when an accident occurs.

(4) Our joint study indicates that, in the past, we did not always make the wisest choice in the area of what constitutes the best approach to process and product surveillance, nor did we always use our limited resources most effectively. It *is* possible, we have learned, to get a better return on our investment of time and money by examining our processes from an "exposure" approach and applying our efforts where it will count most. In this way, we believe that more assured protection is possible, and at lower cost to us.

Let me add here that when we began this joint pilot study over a year ago, we concentrated most of our testing effort on the examination of finished products, with some raw material sampling and very little sampling of the process and environment inside our plant. We now believe, both of us, that we will get more positive control and more meaningful results through increased examination of raw materials and environment, anything which comes in contact with the product during manufacture. Finished product testing will then play a lesser role without undue sacrifice of product safety. This approach is at the heart of the Phase II study being developed.

In fact, we began to discover some time ago that certain raw materials constitute our prime source of contamination in many of our products—microbiologically sensitive ingredients such as dried eggs and dried milk. Many vendors of these materials already function under a USDA (United States Department of Agriculture) program, which in itself has suggested the possibility to us of combining all regulatory efforts under self-certification—FDA, state and local agencies, and USDA—something much easier said than done, but it posts a beacon to guide future efforts. The probing of such a possibility seems appropriate not only to see if it would raise the level

of confidence in these raw materials, but also reduce the total cost of government surveillance.

Another sign of the progress being made are the *types* of questions we are asking. We are no longer concerned with whether or not a workable program can be developed. Our experience convinces us that *it can!* Rather, we now ask questions such as: Where should self-certification be applied? How should it operate from an agency standpoint? What tangible incentives can an agency offer food companies to attract the broadest possible participation?

It seems to us that self-certification would have the greatest value with vendors of sensitive raw materials, as compared with the processors of those materials. This does not mean that self-certification is inappropriate for certain types of manufacture. It simply suggests a direction and a priority of effort.

As to how the program should operate from an agency standpoint, I think it appropriate to highlight the fact that *we* have worked with FDA exclusively, whereas the Green Giant project added a third party—the State of Minnesota. Considering the significant number and variety of regulatory agencies that have jurisdiction over food businesses in the area of sanitation—FDA, USDA, state and local agencies and, in some cases, even the Bureau of Fisheries—we are beginning to ask ourselves about the possibility of combining some of this effort and still satisfying all parties—including the public. It seems to make sense, for the sake of uniformity across widely separated geographical areas of our country, that a federal agency should be importantly involved in setting up a program, with subsequent administration by state agencies perhaps. The need for effective communications between all parties, however, strikes an important challenge to government.

As to incentives that might be offered to attract food companies into a self-certification program, quite frankly we have found very few. The most obvious—an FDA self-certification seal as an advertising and merchandising device for grocery products seems to us to possess little merit. In fact, the seal idea could prove far more attractive to vendors of raw materials than to processors, and we hope to test such an idea with one of our industrial products during Phase II of our pilot study at Dover. The government, of course, might attract companies by offering more careful or limited publicity treatment to participants in those cases where sanitation lapses occur but no serious health hazard exists.

In total, we have gone a fair distance down the path, but we now realize that the course is longer and more complicated than any of us originally anticipated. This is in the nature of learning and the nature of pioneering new approaches to involved problems. We feel the effort should be continued.

The Effects of the Dover Agreement

Now, just a few words on joint government/industry efforts. On balance, we think the program so far has produced more pluses than minuses. It has supplied a useful and most unusual opportunity for us to engage in intelligent and meaningful dialogue with government on a regular and fairly informal basis. It is a little like the United Nations, perhaps—better to talk than fight.

The principal product of this consistent dialogue is the increased understanding by both parties of the other side's problems and approaches. I believe FDA will agree that they have learned more about what it takes to operate a food business—an opportunity not available to them under normal surveillance inspection procedures. Concurrently, GFC has learned more about some of the genuine and legitimate concerns that influence FDA decisions and actions.

As contacts have increased in number, trust has replaced fear and the realization that our goals are not dissimilar has increased. This, in turn, has dispelled the notion that members of FDA are the "cops" and representatives of industry are "trying to get away with something."

Consumer safety is an area where consumers look to the government for protection—as the court of last resort. Because of this, industry's failure to meet its responsibilities is inevitably followed by regulations. It is here that the self-certification pilot study provides an opportunity to replace sometimes theoretical and arbitrary regulations with realistic and more practical approaches. The results of this effort could bring genuine benefits to everyone—FDA, industry and the American public.

Finally, the project literally has forced quality assurance at General Foods to "come of age." The Dover Agreement and our work at Dover have given considerable impetus to our entire company-wide quality assurance program—from package-line workers and

laboratory technicians in plants throughout the country all the way up to top management.

Convincing plant personnel performing routine tasks to build quality into products from the very beginning is a difficult, day-in-day-out job, as many of you know. To our surprise and delight, the Dover project has turned out to be a strong tool—and not just at Dover. In addition, we have been able to fortify the conviction of management at both the headquarters and plant level that consumer protection goes hand-in-hand with consumer satisfaction.

I personally believe that even if we stopped self-certification today, it will have achieved one major breakthrough for us. We are learning more about what constitutes adequate control for consumer protection that is both effective and economically feasible. We already know that more and more controls do not necessarily result in more and more safety.

Self-Responsibility Imperative

Self-responsibility *is* possible. And self-certification, as an exercise in self-responsibility, is one approach, one method, one attempt to find a better way to do a job. It seems to us, thus far, to be infinitely more desirable than secrecy and inspection badges and big sticks and the constant flow of new legislation and new, more stringent regulations.

This is the consumer era. Just since 1960, more than 20 nations throughout the world have passed legislation providing basic protection for the consumer. Concurrently, private consumer-protection organizations have increased from 16 to 80.

This leaves industry with but one option—self-responsibility. Unless we desire to be legislated and regulated out of business, something like self-certification seems almost essential. Unless we prefer to sit back and be nibbled at by more and more controls and more and more surveillance, we are going to have to—through our own actions—reduce the *need* for controls and surveillance. No one is going to do it for us, not the government and certainly not the public. The public in this country prefers self-responsibility—and, oddly enough, so does the government. At least that has been our feeling during the past 15 months. **[The End]**

Fair Packaging and Labeling Act

By THEODORE E. BYERS

Mr. Byers Is the Director of the Division of Case Guidance, Bureau of Regulatory Compliance of the Food and Drug Administration

WE WELCOME THE OPPORTUNITY to discuss with you this morning the Fair Packaging and Labeling Act (FPLA) and regulations. We in the Division of Case Guidance, Bureau of Regulatory Compliance, have been charged with the responsibility for practically every phase of writing regulations, exemption petitions, and granting extensions of time in which to utilize stocks of labels and/or packages which are not in compliance with the Act. The advent of FPLA has afforded the Food and Drug Administration (FDA) the opportunity to re-examine regulations regarding labeling which have stood for nearly 30 years and to modify them to more realistically deal with current trends in industry and the needs of today's consumer.

The FPLA provides that the FDA, through the issuance of regulations, require the following on labels or specific categories of consumer products:

(1) The identity or name of the product and the name and place of business of the manufacturer, packer, or distributor.

(2) An accurate and separate statement of the net quantity of contents at a uniform location on the principal display panel.

(3) A statement describing the contents of a serving, if a declaration of the number of servings is given.

Mandatory Regulations

One of the outstanding features of the FPLA is that it affords us the opportunity to amplify, and render more meaningful, some of the previous labeling requirements which were provided for by the Federal Food, Drug and Cosmetic Act. The previous requirement most affected is the very heart of FPLA—the declaration of the quantity of contents. It is compliance with this provision which will require revision of the greater majority of the labels and packages of consumer products. The regulations provide that this declaration generally must:

(1) Be located on the principal display panel and positioned within the lower 30 percent of the label in lines generally parallel to the base upon which the package rests. (This placement in the lower 30 percent does not apply to containers with a principal display panel of 5 square inches or less.)

(2) The declaration must be conspicuous in easily legible bold face type, in distinct contrast, and in a specific type size in relation to the area of the principal display panel of the package. This requirement means that consumer packages of substantially the same size will state the quantity of contents with corresponding uniformity.

(3) On consumer packages of one pound, one pint, or more, but less than four pounds or one gallon, the declaration of net contents must be of a dual nature with the first expression in total ounces (avoirdupois) or fluid measure, followed by a parenthetical quantity of contents declaration in the largest whole unit of drug or liquid measure and subdivisions thereof.

This concept of weight and volume declaration is set forth in the food regulations, and the clarifying amendments, published in the *Federal Register* on July 21, 1967 and September 20, 1967, respectively.

In order to provide for an orderly and reasonable transition from labels designed prior to the passage of FPLA and issuance of regulations under that Act, a Statement of Policy 3.57 was published in the *Federal Register* on July 21, 1967, and revised and republished in the *Federal Register* of February 28, 1968. This policy statement set forth guidelines applying to the request for extensions of time for utilization of stocks of labels not in compliance with the FPLA beyond July 1, 1968. The Statement of Policy provides for extension consideration on an individual case basis when good cause is shown. We anticipate that these guides will be equally applicable to drugs, devices and cosmetics when their regulations become fully effective. Good cause is interpreted to include the following points:

(1) That stocks of labels and packages on hand be in compliance with the existing Food, Drug, and Cosmetic Act.

(2) That due diligence was expended in an effort to devise and obtain new labels insofar as the facilities of the label and package manufacturers would permit.

(3) That existing stocks of labels and packages, for which the extension is being requested, did not result from a deliberate attempt to overstock.

The Statement of Policy was revised February 28, 1968, to include the following requirements:

(1) A statement of the total number (not quantity) of labels or packages for which the extension is requested.

(2) Approximate dates revisions will be completed.

(3) The number of labels or packages which have been revised to comply with the Fair Packaging and Labeling Act.

(4) The number of labels or packages scheduled for revision by July 1, 1968.

(5) A duplicate set of representative product labels or packages for which extension is requested. The number to be submitted should be determined as follows:

(a) Ten products or less: Submit all

(b) More than 10 products: Submit sufficient labels, but not less than 10, to be fully representative.

Under the criteria previously mentioned, approximately 3,300 food firms were granted extensions of time for use of stocks of labels, but not beyond June 30, 1969. In addition, approximately 200 firms requested extensions of time for use of labels on products which were the subject of pending exemption requests as provided by Section 5(b) of FPLA. Since such firms were unable to complete label revisions during pendency of these exemption petitions they were also afforded additional time to June 30, 1969, to complete any changes made necessary by the new regulations.

Our review of labels submitted by the large part of the food industry indicated two things which were very gratifying: (1) The great majority of the labels submitted (over 95%) were found to be in compliance with provisions of the then existing Food, Drug, and Cosmetic Act and (2) the great majority of the firms had made excellent progress toward revision of their labels to comply with the new Act. From information furnished us by these firms, it was estimated that labels had been revised at the time of their request for extensions for approximately 165,000 products and revision had been scheduled on an additional 250,000 products prior to July 1, 1968. In addition, it is encouraging to know that some of the firms and industry groups that most vigorously opposed passage of this legislation are now just as vigorously attempting to comply with the law and are revising their labels as rapidly as possible.

In keeping with the directive of Section 5(b) of FPLA, that the Secretary shall promulgate exempting regulations when it is shown that compliance with Section 4 of FPLA is either impractical

or is not necessary for the adequate protection of consumers, 10 exemptions were published in the *Federal Register* or were initiated during the preceding fiscal year.

(1) Soft Drinks, proposed December 19, 1967 (32 FR 244). An order ruling on this proposal was published May 7, 1968 (33 FR 6861).

(2) Frozen Desserts, proposed January 26, 1968 (33 FR 1020). An order ruling on this proposal was published July 16, 1968 (33 FR 10140).

(3) Milk Products, proposed February 14, 1968 (33 FR 2947). An order ruling on the proposal was published July 20, 1968 (33 FR 141).

(4) Flour Products, proposed February 17, 1968 (33 FR 3139). An order ruling on the proposal was published July 17, 1968 (33 FR 10206).

(5) Fresh Apples, proposed March 12, 1968 (33 FR 4420). This proposal was terminated July 16, 1968 (33 FR 137).

(6) Coffee, proposed April 2, 1968 (33 FR 5268). This proposal was terminated August 24, 1968 (33 FR 12054).

(7) Butter, proposed April 17, 1968 (33 FR 5883). An order ruling was published August 24, 1968 (33 FR 12039).

(8) Eggs, proposed April 17, 1968 (33 FR 5883). An order ruling on the proposal was published August 22, 1968 (33 FR 11902).

(9) Margarine, proposed May 25, 1968 (33 FR 7726).

(10) Corn Products, proposed July 11, 1968 (33 FR 134).

In contrast to the foregoing exemption requests, which warranted publication, approximately 26 exemption petitions were denied due to insufficient grounds.

The implementation of the Section 4 requirements, as they pertain to OTC (over-the-counter) drugs, devices and cosmetics, began with publication of the proposed regulations in the *Federal Register* of August 22, 1967. Over 50 comments were received. After a careful evaluation of the comments, an order ruling on the proposal was published in the *Federal Register,* January 11, 1968.

Objections and comments were received from 25 firms and trade associations in response to the order ruling on the proposed OTC drug, device and cosmetic regulations. Many of the objections were accompanied by requests for public hearings on the issues involved. After a study of the objections, the Commissioner concluded that the major issues might best be resolved by a re-issuance of the order

ruling on the proposed regulations, revised to reflect consideration of all valid objections. The revised order was published June 28, 1968, in the *Federal Register*. Two objections to the re-issued order have been received and a ruling on their validity and the advisability of public hearings will be reached shortly.

Discretionary Regulations

After the drug, cosmetic and device regulations have been finally dealt with, we are still faced with the promulgation of discretionary regulations provided for in Section 5 of the Act. These areas include:

(1) The establishment and definition of standards of package sizes such as large, small, economy, etc.

(2) Regulating, but not prohibiting cents-off or other such promotions.

(3) Preventing non-functional slack-fill of consumer packages.

When we deal in this area we find that our problems with the mandatory requirements (Section 4) of the Act were insignificant in comparison. At the present time we are wrestling with the writing of meaningful cents-off regulations. We are facing such problems as writing regulations (1) which will not be in conflict with other statutes prohibiting restraint of trade, (2) that will assure reduction in cost by the supplier being passed on to the consumer, and (3) which will provide for means of assuring the above.

A brief visit to the supermarket allows one to see that the average shopper is bombarded by a multitude of package sizes, weights and descriptive superlatives such as "giant," "super," "king," "family," "extra large," "large," "economy," etc. The consumer finds it all but impossible to determine the best value for the money. While the price of a product has been relatively stable, its size has diminished while its description remains the same.

Many of you are aware of previous experiences under the Food, Drug and Cosmetic Act insofar as deceptive packaging was concerned and can recognize the problems we face in writing meaningful regulations to define non-functional slack-fill of consumer packages. The problems are staggering to us, especially in light of the extremely limited staff available. However, we are encouraged by industry's voluntary compliance and cooperation in the area of the mandatory requirements of the Act and are hopeful of the same cooperation in the discretionary area, namely, Section 5. We look forward to the evolution of this Act. Fair labeling of consumer products requires the active involvement and cooperation of state and local officials in implementing the provisions of this Act and its regulations. **[The End]**

FOOD DRUG COSMETIC
LAW JOURNAL

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

SECOND CLASS POSTAGE PAID
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