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Concluding Papers Presented at the Food Standards Symposium of the American Medical Association Council on Foods and Nutrition

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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.

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Journal

The Role of the Technical Services Division

By JACK C. LEIGHTY

This Paper and the Three Following Were Presented at the American Medical Association Council on Foods and Nutrition Symposium on Food Standards in the United States. Dr. Leighty Is Director of the Technical Services Division, Consumer and Marketing Service, U. S. Department of Agriculture.

THE LABELS THAT DESCRIBE MEAT and poultry products for the consumer, the standards that provide definitions for the names of such products, and the containers in which they are packaged, fall under the jurisdiction of the Technical Services Division of the Consumer and Marketing Service, an agency of the United States Department of Agriculture. The system for controlling these products has evolved over the past 60 years. The program is soon to be updated through new regulations to be issued under amendments to the laws.

Each product that a meat or poultry processor wishes to produce under federal inspection must be approved by the Technical Services Division prior to its production. Labels for meat and poultry products may not be printed without prior approval of the product. Possession of unapproved labels bearing the marks of federal inspection is a violation of certain federal laws.

Authority for the mandatory Meat and Poultry Inspection Program is derived from the Federal Meat Inspection Act and the Poultry Products Inspection Act. Limited voluntary programs for

game birds and rabbits are carried out under the authority of the Agricultural Marketing Act.

In addition to controlling approval of these products before production, the department stations inspectors in every federally inspected establishment to give direct supervision to the preparation of the products, their packaging and the application of labels to assure that they are in accordance with the approvals that have been issued.

Product approvals are also required for imported meat and poultry products. Approvals for foreign products are returned to the inspection programs of the exporting countries for supervised production. Specially trained veterinary food hygienists of the Technical Services Division are in continuous travel status reviewing the operations of foreign inspection systems in approved overseas plants to see that they are assuring sanitary processing and proper composition, packaging and labeling. Imported products are inspected again when they arrive at U. S. ports to assure that they are proper in all respects.

Laboratory facilities are maintained to provide assistance to inspectors working with both domestic and imported products. Samples that cannot be adequately examined organoleptically are sent to our laboratories for handling by chemists, microbiologists or pathologists.

The acts upon which meat and poultry inspection programs are based require truthful, informative labeling. A required step in achieving this objective is to determine the true or usual name for each product. The definition of the true name for a specific kind of product constitutes the standard for that product. The product name and definition as proposed by a manufacturer usually include the formula and method of preparation that are unique to the product. Information necessary to evaluate the proposal and establish the true name, and thus the standard for a product, is obtained both from the proponent of the prototype product and through extensive background studies of reference sources and precedents. In the past, standards have been established in this manner and have been available to any interested party upon request. All products of the same kind were required to meet the same standard. A procedure has now been established for publishing in the *Federal Register* each new proposed standard for comment.

Standard definitions of meat and poultry products names assure the consumer of uniform, truthful, informative labeling. To accom-

plish this purpose, systems for establishing standards must not be so unwieldy that they bog down the process. If this should occur, we would be in the indefensible position of allowing the mechanics of the program to defeat its purpose.

Once a standard is established, it may be amended if new information develops that would warrant such action.

In fiscal year 1968, this division processed more than 100,000 labels. When state meat inspection programs are fully functioning, we expect that they will be handling totally approximately 20,000 labels in all or about one-fifth of the total federal program.

Each of these many product labels that we review must bear a true name based either on an established standard for a class of products, a specific standard for the product or a proposed standard. The need for our program to be efficient and uniform in the application of complex policies becomes obvious.

Four Significant Areas

In reviewing a product proposal to see whether it conforms with a standard true name, the following four points are carefully examined:

First, the formula—ingredients and additives that are proposed for use in the product are examined to see that they are acceptable for use in food in the manner proposed. Dyes that would make a product appear to contain more meat than it does are not permitted for use. Preservatives that might make a product appear fresh when deterioration has occurred are also not permitted. In general, additives must be safe as they are proposed for use, must not result in adulteration or deception and must serve some useful purpose in the product. Next, the formula is compared to the proposed name on the label and with the ingredient statement to see that there is an adequate description of the product. The formula is also reviewed to assure that the inspector in the plant will have sufficient information in the copy of the product approval that he receives to assure that only approved quantities of specified ingredients are used.

The second major consideration in reviewing a product proposal is the method of preparation. The processing system for the product is reviewed to assure that it will produce the product described on the label, that it is adequate to produce a safe, wholesome product, and that the inspector will have adequate information in his copy to assure control of the method of preparation.

The third item of significance in product approval is the container. The size, form and composition of the container is examined to assure that it is suitable for the purpose intended. The container must be no larger than necessary to contain the specified quantity of the product intended to be sold in it. Its structure must be adequate to fully protect the product during transportation, handling, storage and presentation to the public. The composition of the container and that of any labeling material that might contact the food must be such that it cannot add any toxic substance to the product. Finally, the container portion of the proposal is reviewed to assure that the inspector will have adequate information to assure that only the specific container approved for the product is used in packaging the product.

The last major consideration in assuring product approval is the label. It is reviewed to assure that it bears certain minimum information for the consumer and that all information on it is truthful and accurate. The basic information that must appear on each label is the true name of the product. This is defined by the product standards. It must bear the word "ingredients" followed by the list of ingredients in the order of predominance. The name, place of business and zip code of the manufacturer, packer or person for whom the product is prepared must be on the label. The number of the plant in which the product is prepared, the official mark of inspection and an accurate statement of quantity must be suitably located on the label. The mark of inspection must appear exactly as published in the regulations. It must be placed on the principal display panel with the name of the product. The new regulations will also bring our program into line with the Fair Packaging Act. Additives will include the requirements for net weight statements and for specifying serving sizes.

The requirement of a carefully defined true name for the product and a list of its ingredients is one of the most significant contributions of our program to the prevention of health hazards and economic fraud.

Great numbers of persons who must avoid certain kinds of foods for the sake of their health must be able to determine from the ingredient statement whether any such food has been included in the product. As more sophisticated methods are developed for maintaining the appearance of quality while reducing the amount of valuable ingredients in products, the consumer becomes increasingly less competent to protect himself from such deceit.

Skilled efforts at reducing production costs or enhancing product appeal can result in health hazards as well as economic deception if not carefully controlled. The division product reviewers, toxicologists, microbiologists, chemists and pathologists all play a part in providing such assurance before the product is produced. This is a service that no individual consumer could provide for himself at the time of purchase.

New products are very common in this area. This makes the problem of arriving at agreement on meaningful descriptive names one of the greatest tasks of our Labels, Standards and Packaging Branch. It is a highly competitive industry. Many of its members are continually involved in efforts to obtain some economic advantage. In most cases these efforts are sound and creative, and they add much to the quality of modern day life. However, those that are directed toward obtaining economic advantage through deception of the consumer must be rejected.

Deception in processing or labeling products may or may not be deliberate. It may occur in any degree and may be obvious or may be very skillfully contrived and very subtly carried out. Maintaining an objective control over proposals having such potentials is a task that requires the talents and dedication of persons who are expert in this subject area and who are supported by scientific specialists.

Under the new system, when a prototype product is submitted, one requiring a new standard, evidence for establishing the standard definition of the new product name must be reviewed and investigated. If our preliminary review finds the proposal to have merit, a temporary approval will be issued to the proponent that will enable him to produce and sell the product in commerce pending final action on the proposed standard. When our review is completed, and has been discussed with the Food and Drug Administration and the National Meat Inspection Advisory Committee, a final decision will be made on whether the proposed standard shall be published for comment in the *Federal Register*.

If the proposal is published, comments are reviewed and a decision is made as to whether the standard should be published in final form or rejected. If published in final form, the prototype product then receives final approval. If important adverse information is received, the proposal for the standard and the temporary approval will either be modified to make it acceptable or terminated.

Consumer Opinion

The Labels, Standards and Packaging Branch receives a high volume of consumer mail on meat and poultry products. Most of it is related to suggestions and demands for the maintenance of a strong program for truthful labeling of meat and poultry products. The branch also conducts statistically based surveys of consumer opinion on labeling matters. Such surveys may be directed to individual consumers or to persons having knowledge of consumer needs, such as consumer organizations, food editors and university home economists.

The most valuable information that we use is obtained through the scientifically conducted consumer surveys. These may either be initiated by us or by private organizations. This kind of data, devoid of special interests, most often reflects the true needs of the consumer.

Our program is characterized by constant change. As products, manufacturing methods and consumer needs change, we do also. We find this is the most effective way of serving the public. The alternative of allowing the program to go through periods without change followed by major overhauls would not be an effective way to run the program. **[The End]**

"LINE AWAY" RULED A DRUG ON APPEAL

Advertising that emphasizes the protein content of "Line Away," a temporary wrinkle smoother, along with repeated statements that the product was prepared and packaged by a pharmaceutical laboratory, is sufficient to bring the product within the definition of a drug, according to a decision of the United States Court of Appeals for the Third Circuit. The Court held that a product will be found to be a drug regardless of its physical effects if the labeling and promotional claims attribute characteristics to the product that would bring it within the Federal Food, Drug, and Cosmetic Act's definition of a drug. (Sec. 201 of the Act provides: "The term 'drug' means * * * (C) articles * * * intended to affect the structure * * * of the body of man * * *.") Because protein is a principal nutrient, the advertising suggests that the product nourishes the skin. Also, denials that the product contains any hormones or dangerous drugs suggest that it is a harmless drug.

The Court stated that promotional material for cosmetic products does not have to explain its limited mechanical operation. However, if the labeling contains strong therapeutic implications, it will be classified as a drug. The fact that an article is a cosmetic does not preclude its also being a drug for purposes of the Act.

The Court did not express any opinion on the views of the District Court that Line Away was a drug because it does in fact affect the structure of the skin.

U. S. v. Line Away, CCH Food Drug Cosmetic Law Reports ¶ 80,257

Food Standards Procedures—A Lawyer's Recommendations

By VINCENT A. KLEINFELD

Mr. Kleinfeld, a Former Food and Drug Law Attorney, Department of Justice, Is a Member of The District of Columbia Bar.

IT BECAME APPARENT, not long after the passage of the first national Food and Drugs Act, that far-reaching as that statute was in 1906, it was not sufficiently comprehensive to cope with a number of consumer protection problems which either had not been met or arose subsequently. Various remedial amendments were enacted by Congress, but one problem which persisted was that posed by the economic adulteration of many foods.

Since there was no provision in the Food and Drugs Act of 1906 authorizing the Food and Drug Administration (FDA) to define and standardize foods, a difficult problem was presented whenever the government sought to proceed against a debased food product. For example, suppose a jam was marketed containing about 25 parts of fruit, the expensive ingredient in jam, instead of the approximately 50 parts traditionally found in that product. The difference between the 25 and 50 parts of fruit was primarily water, which had generously been added by the manufacturer. When the Food and Drug Administration proceeded against the product or its manufacturer, it was required to establish, by either a preponderance of the evidence in a civil action or beyond a reasonable doubt in a criminal prosecution, that the product was adulterated since it did not contain 50 parts of fruit. The government was required to establish what may loosely be called "a common law standard" for jam by the production of witnesses, such as nutritionists, home economists, housewives and chefs, and evidence such as cookbooks and the like, that, traditionally, jam in this country did in fact contain about 50 parts of fruit—that our grandmothers and great grand-

mothers, when they made jam, ended with a product containing that proportion of fruit.

This was not a simple task on the part of the FDA. Another difficult problem was presented by inferior and debased jams which were marketed under a fanciful name such as "Bred Spred." This type of product was defended on the grounds that, since it was not actually labeled as "jam," the public would not be misled into thinking it was jam, and that the debased product was a different commodity. The fact remained, however, that many consumers were misled and purchased the product on the assumption that it was jam, particularly since, organoleptically, "jam" and the debased products were quite similar.

Definitions Are Established

It became clear in the 1930s that further amendments of the Food and Drugs Act of 1906 were not the best or simplest method of closing the gaps in consumer protection which existed, and that a new statute was needed. It took five years of hearings, debates, the introduction of many bills, and the issuance of numerous Congressional Committee reports to pass the Federal Food, Drug, and Cosmetic Act of 1938. One of the major points repeatedly adverted to during those five years was the necessity for providing for the establishment of definitions and standards of identity for foods. The result was the inclusion in the 1938 Act of section 401, which provided that whenever, in the judgment of the Secretary, such action would promote honesty and fair dealing in the interest of consumers, he should promulgate regulations establishing a reasonable definition and standard of identity for a food. Another section of the statute declared that a food would be deemed to be misbranded if it purported to be or was represented as a food for which a definition and standard of identity had been prescribed unless it conformed to the definition and standard and its label bore the name of the standardized product. This appeared to be a real step forward in consumer protection and, in the years that passed, it was accepted by both industry and consumer organization as being a real weapon in the arsenal of the government to be wielded against the sophistication of food products.

The provision for the promulgation of food standards was a long stride forward in enhancing consumer protection by making it much simpler to proceed against adulterated products which not only deceived many consumers but also constituted unfair competi-

tion as far as honest and legitimate food manufacturers were concerned. It was not contemplated, however, that the difficulties which have been encountered during the last few years in the promulgation of food standards would arise, particularly after the enactment of the Food Additives Amendment in 1958.

For example, the problem of alleged toxicity should not now be permitted to be raised in food standards hearings, for this can consume a vast period of time. That issue, however, was permitted to be gone into at the peanut butter hearing, and no determination has as yet been reached as to whether it may be pursued in the current special dietary foods hearing. Yet, it appears clear that although that inquiry was a perfectly proper one before the passage of the Food Additives Amendment, it is not an appropriate issue at this time. One of the specific reasons for the passage of the Food Additives Amendment was to prevent that problem from being raised at food standards hearings, with the resultant unnecessary expenditure of time. Thus, the report of the House of Representatives Select Committee to Investigate the use of Chemicals in Foods and Cosmetics stated, as far back as 1952:

> Section 401 of the Federal Food, Drug, and Cosmetic Act authorizes the [Secretary] to define and standardize foods for the purpose of promoting honesty and fair dealing in the interest of consumers. This empowers him to determine whether a chemical proposed for use in a standardized food has been demonstrated to be safe. Hearings conducted by the Food and Drug Administration leading to the issuance of regulations defining and standardizing foods have been unduly protracted at times, because of the submission and consideration of conflicting testimony on the safety for use of some proposed optional ingredient. It would seem preferable that food standardization hearings should not be devoted to that type of question but rather to the economic factors implicit in the criterion of "honesty and fair dealing in the interest of consumers." A provision in the food chapter of the statute generally similar to the new drug section would help to prevent these burdensome delays in the promulgation of food standards.

At times, it was possible for years to pass before FDA action was taken, particularly where a proposal to amend a food standard was made by an industry member. It was not infrequent for time delays of the same general order to take place, even where the FDA itself initially proposed the standard. One reason for these time delays was the fact that the FDA frequently insisted upon specifying the optional ingredients, which may be used in the standardized food, rather than permitting the use of a generic term, such as "emulsifier." The problem is accentuated, of course, by the increase and prospective increase in new types of foods. The claim is often asserted that

standards can readily be amended. Recent hearings prove that this is rather debatable.

An Unusual Approach

The original pertinent provisions of the Federal Food, Drug, and Cosmetic Act required a hearing upon any proposal initiated by the Secretary to issue or amend any regulation even, apparently, where there was no dispute. Congress chose to adopt, in 1938, an unusual approach by requiring, in rule-making, that the procedures customarily applied in quasi-judicial proceedings be followed. Before this, rule-making had not been surrounded by the safeguards observed in quasi-judicial proceedings such as the proposed revocation of an approved new drug application. In the Act, as passed, the more important requirements applicable to the latter type of proceeding, including the holding of a hearing, were specifically required in connection with food standards.

Experience subsequent to 1938 demonstrated that it was unnecessarily burdensome, time-consuming and costly to require a hearing in every instance, since many proposals were not objected to by anyone. At the suggestion of industry and with the support of the Secretary, therefore, the Act was amended to require a hearing only with regard to those proposed regulations to which industry specifically objected. This amendment has been transmuted by the government, however, into an authorization not to grant a hearing when it decides, in its wisdom, that reasonable grounds have not been shown. This was not the intent of Congress.

The legislative history of the Act reveals in clear and unambiguous language that Congress meant what it said in explicitly requiring a hearing where objection is taken to action instituted by the Food and Drug Administration to issue, modify or repeal an order. In view of this, it is difficult to understand the position taken by some officials of the government that the amendment to the Act which I have described, proposed by industry and recommended by the government for the specific purpose of not requiring hearings where objections are not raised to regulations, removed the right to a hearing even where factual objections are asserted.

Perhaps, like Narcissus, these officials fell in love with their own image, formerly an impressive one in the food standards area. There has been an increasing reluctance to grant a hearing. It may be that this disinclination has caused, in part, the decline of the high regard in which food standards and the procedures for promulgating

and amending them were held for an extended period of time. I believe that the basic reason for the reluctance to grant a hearing is that, more and more as the years go by, what Congress clearly intended to be fact-finding hearings have been transformed into adversary proceedings. The underlying philosophy of some officials appears to be that we have made up our minds and you cannot change it, and there is no sense in wasting time and money in a hearing. The concomitant of that philosophy of these officials is that if the government grants a hearing because in some instances it just has to, there is necessarily something a bit reprehensible with industry, or even with recognized and reputable scientists, if they oppose what the government intends to do. This is true even though the scientists may formerly have been held in high esteem by these officials and may have testified for the government in the past.

Thus, officials, in recent hearings such as the peanut butter hearing, and the current vitamin, special dietary foods hearings which have been going on for more than a year and will presumably continue for another year, if not forever, have acted as if standards proceedings were a criminal prosecution or seizure action. I do not say that industry has not also acted as an adversary. But there are officials who almost immediately disclose their intent, forcefully carried out, to convert what should be a searching inquiry into the facts into a litigious proceeding which must necessarily take an inordinate period of time.

The adversary nature of recent hearings became apparent almost immediately when it was realized by both industry and consumer participants that those in charge of the preparation of the standards and of the government's "case" (I use the term in quotes) were dedicated but inflexible enforcement officials who had spent most of their professional lives with the Food and Drug Administration in enforcement activities. The use of over-zealous rather than zealous officials is, I suggest, offensive to the basic philosophy with which standards hearings should be planned and carried out. The function of preparing rule-making regulations and planning hearings should be performed by mature and qualified administrative officials who are qualified to agree to changes and compromises when they make sense, and are suited to plan and pursue a comprehensive fact-finding hearing and not merely "to win a case." In my opinion, if leading nutritionists from the government and industry had been permitted to get together (and I do not include, in the term "leading nutritionists," attorneys or enforcement officials), more than 80% of the

issues involved in the special dietary foods hearing could have been thrashed out without any appreciable delay. (I might make it clear, here, that the legal profession has taken it upon itself to change the designation of these hearings to the "Attorneys Full Employment Standards Hearings of the Twentieth Century.")

It appears to me that the government should search its soul and attempt to comprehend whether what has happened in the recent years is at least possibly due to the change in its basic approach. I urge that, after this psychiatric self-examination, the government should make it clear to its officials, including examiners, that food standards hearings are not intended to be adversary in nature but are rule-making proceedings designed to bring out all the pertinent facts, whether or not they are in complete accord with the government's positions. I suggest that it is inappropriate for a government agency, for example, not to present at a hearing the leading experts of the land, or the government's own top nutritionists, because they may disagree with the proposed standard in some particulars. Similarly, I submit that the government is not indulging in fact-finding when it presents a leading expert in the field of nutrition, examines him on several sections of the regulations with respect to which he is in accord with the government and then refuses to permit him to be examined by others on portions of the regulations with regard to which he has not specifically testified, on the hypertechnical and legalistic ground that this cannot be done on cross-examination because it was not testified to by the witness on direct examination. Are these attitudes those which should be taken in food standards hearings, the results of which will affect every person in this country?

Reasons for Lower Esteem

There are two other basic reasons for the change in the esteem in which standards are now held—for the opinion of many that food standards have reached the nadir (no pun is intended) in benefiting either the consumer or industry. Some who believed in the past that standards were a vast step forward, not only in the protection of the consumer but also of honest enterprise, have now reached the decision that if things continue to proceed as they have proceeded in the recent past in the promulgation of food standards, perhaps there should be an end to the authority to establish definitions and standards of identity for foods.

One of these two reasons, the focusing of the government on unimportant matters, was present in the late, unlamented peanut

butter hearings. Approximately 4½ months of time and a very considerable amount of money was expended in determining whether peanut butter should be required to contain 90% rather than 87% of peanuts. (The other issues were minor and could have been settled amicably without any real difficulty.) This, indeed, appeared to many to be an egregious waste of time and money, particularly when it is realized that two of the leading nutritionists in the United States testified, without contradiction that, from the viewpoint of nutrition and the consumer, it made no difference at all which percentage was utilized.

Consider, for example, two points which will ultimately be thrashed out at the vitamin hearings at a high cost of time and money. A vitamin manufacturer uses an artificial sweetener for technological reasons, particularly in vitamins for children. The regulations, being inexpertly drawn, make no provision at all authorizing the use in a vitamin tablet of an artificial sweetener for technological purposes. What those in charge of the hearings appear to have in mind, however, is to require the manufacturer to get prior clearance after considerable red tape. This is apparently bottomed on the fact that, at one time in the distant past, some manufacturer made the claim that his vitamin pill contained only one calorie. A sensible solution would be to provide that, as long as no claim for weight reduction or calorie reduction is made in either the labeling or advertising of the vitamin supplement, and the only statement on the label with regard to the artificial sweetener is the setting forth of its common or usual name in the statement of ingredients, pursuant to the Act, there will be no objection. But this appears to be too sensible.

And many weeks will be devoted to the status of products which are clearly and obviously special dietary foods; that is, foods specially formulated to be recommended by physicians as part of the dietary regimen of their patients. An example would be a formulated food for consumption by those being treated for ulcers. These products have been treated and labeled in the past as special dietary foods, which indeed they are, and the only reference to ulcers is in literature directed to the medical and paramedical professions. Yet, the FDA is now taking the position that these products will be considered to be drugs, perhaps requiring a prescription. Why? Because some FDA doctors once stated that the products were drugs because the word "ulcers" was used. But the term "drug" in the Act is a term of art—it is not the doctors who should make the determination as to whether a product is a "drug" or "special dietary food." It seems

to be entirely irrational to take the position that the products involved are drugs—they are not drugs and come clearly within the definition of special dietary foods. Nevertheless, as I have pointed out, considerable time will have to be spent, uselessly, in establishing this incontrovertible fact. This, in my opinion, is nonsense.

The second reason for the change in the esteem in which standards were once held is the promulgation of a standard with so many varied and fundamental issues that the hearing must necessarily take years before it is concluded. As I have indicated, the vitamin, special dietary foods hearing has been going on now for more than a year. The regulations (and I may say that attorneys specializing in the food and drug area believe that they are of very dubious legal validity) standardize all vitamin-mineral supplements, all food products which contain artificial sweeteners, all food products which are marketed for consumption by those who are interested in reducing, maintaining or gaining weight, all foods offered for use in the diets of diabetics, all hypoallergenic foods, all foods offered for use as a means of regulating the intake of sodium, and every food in or proposed to be placed in the marketplace of the United States whose manufacturer wishes to fortify it with vitamins or minerals. How could anyone expect that, in one hearing, the manifold and disparate issues and the tremendous number of those vitally interested and affected would not necessarily result in a hearing of inordinate length. It has been stated by an expert in food and drug law that the special dietary foods hearings do not present merely a "big case" where various legal crutches and supports should be supplied in an attempt to shorten the proceeding, but rather an "impossible case" for which there is no rational solution or even a trustworthy crutch or support.

Proper FDA Procedure

I have always believed in the value of foods standards, although I must say that perhaps my own opinion will change if I spend many more months or years at the special dietary foods hearings. In my opinion, a number of steps can be taken with respect to the issuance of regulations and the conduct of hearings which would once again cause the authority to promulgate standards to be considered as one of the more important duties of the Food and Drug Administration. I have adverted to what I believe is by far the most important factor. The government should revert to the former

approach, certainly intended by Congress, that food standards hearings, since they affect all of us, are designed to ferret out all the facts and that they are not and must not be carried on as if they were a magistrate's court proceeding.

Qualified, mature and able personnel should be designated to assist in the preparation of the standard and conduct of the hearings on behalf of the government. These officials should be reminded (and if they are qualified, mature and able they will not really need such direction) that Congress provided for fact-finding hearings. Thus, the leading experts in the United States should be asked to testify, whether or not they are in accord with every provision of the standard and every position of the government.

The FDA should confer informally with all interested parties, including other agencies of the government, consumer groups, scientists, and representatives of the affected industries, before publishing a proposed standard and certainly prior to issuing it as a final regulation. It would also appear appropriate (and wasteful if this is not done) for the FDA to seek and obtain the views of scientific organizations such as the Food and Nutrition Board of the National Research Council, the Council on Foods and Nutrition of the American Medical Association and other prestigious scientific bodies before a proposal to establish a standard is published in the *Federal Register,* and certainly before it is made final. Time will be saved, not lost, by this course of conduct.

In this connection, also, when years have passed after the publication of a proposal to promulgate a food standard regulation, a new proposal should be published after the then contemporary comments and recommendations of the interested parties and scientific bodies such as I have mentioned have been obtained. Four years elapsed between the promulgation of the original proposal to regulate special dietary foods and the issuance of a vastly more far-reaching set of regulations. And this was done despite the fact that contemporaneous inquiries into the problems of hunger and nutrition in the United States were being carried on or contemplated. There is no doubt in my mind that very considerable time could have been saved if the government had taken the simple step of issuing a new proposal before publishing a final order.

I am a firm believer in the value of our system of checks and balances. I think that those of us who have been officials with various establishments of the government know that one who has

spent most of his professional life with a particular agency tends to have his horizons narrowed and his thinking somewhat circumscribed. It would be advantageous to have the Secretary of Health, Education, and Welfare or an assistant secretary, rather than the proponent and initiator of the standard, ultimately promulgate it.

Thus, with the realization of what the facts of life are, consideration should be given to providing that examiners should not be employees of the Food and Drug Administration and should not be attached to the Office of the Commissioner of Food and Drugs. It would be at least a modest step forward to have all examiners for the Department of Health, Education, and Welfare placed in an independent office in that Department and used in rotation for all hearings of the Department, including Food and Drug Administration food standards hearings.

Let us consider, also, whether it is advisable to have only one or two examiners available to conduct the hearings of the FDA. Examiners, too, are human beings with the frailties and predilections which most persons have. An attorney who has spent virtually all his professional life as an attorney for an administrative agency and who is employed by it as an examiner, can hardly be expected to be entirely free from bias. Examiners should not act as if they were senior counsel for the FDA at hearings, should not have *ex parte* meetings, direct or indirect, with attorneys and other officials of the Agency, and should not perform various tasks for it during the periods when they are not acting as examiners. The litany of a food standard hearing should include supplications by participants for prompt and consistent rulings and an affirmative response by the examiners.

I do not believe that the presumed expertise of an examiner in the workings of the Food and Drug Administration, which has been created by years within the Agency, is of sufficient importance to outweigh the disability I have mentioned. A highly qualified attorney who has had experience in administrative law and practice does not necessarily have to be a specialist in the narrow area of food and drug law in order to do a first-rate job. Examiners should be chosen carefully, rather than haphazardly, and have expertise in administrative law. They should have real status and be treated and paid as if they were judges.

A Final Recommendation

I have one last recommendation which, I believe, is also an important one, and which is in line with many of the suggestions I have made. Of course, FDA officials must be designated to aid in the preparation of food standards regulations and in seeking and producing witnesses, to participate actively in the hearings, and perhaps to testify. But it would seem abundantly clear that those officials, who have so acted, should not participate in the decision-making process resulting in the promulgation of a food standard.

In summary, the authority in the Food and Drug Administration to promulgate regulations establishing definitions and standards of identity for foods is a most important function. It can be of real value to industry and, more important, to the consuming public of the United States. If this thesis is accepted, then much of what I have recommended should, it appears to me, be accepted. These regulations, having the force and effect of law, should not be issued lightly and without consultation with all who have a stake in the picture. There should be real preparation and consultation before regulations or proposals to issue regulations are published. There should be no reluctance to grant hearings before a qualified and unbiased examiner, but rather an eager desire to have a fact-finding forum. Comments and testimony from all who are concerned should be sought and not considered a necessary evil. The philosophical approach of the government should be to seek out, produce and have brought out all the facts by the most qualified persons. **[The End]**

TRANSITIONAL PROVISIONS FOR NEW ANIMAL DRUGS

Transitional provisions for carrying out the Animal Drug Amendments, which became effective on August 1, 1969, have been announced in a statement of policy issued by the Food and Drug Administration. Extensive changes in existing regulations to implement the new law will be published at an early date, the FDA said.

Until final regulations are published, current applications (Form FD 356 and Form 5) will be acceptable for approval of new animal drugs and animal feed containing new animal drugs. The applications must include a practical method of analysis for determining the quantity of any substance in or on food resulting from the use of a new animal drug, and any proposed tolerance or withdrawal period to assure that the use of the new animal drug is safe.

Applications for medicated feed (Form FD 1800) for the new animal drug used in the feed must contain a reference to the appropriate food additive regulation instead of the new drug application number. The application must also contain the name and address of the supplier of the new animal drug.

Reg. § 3.517, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 4517

As CPEHS Sees It

By CHARLES C. JOHNSON, JR.

Mr. Johnson Is the Administrator of the Consumer Protection and Environmental Health Service, Public Health Service, U. S. Department of Health, Education, and Welfare in Washington, D. C.

I DON'T KNOW JUST WHAT "AGE" we are living in today. We move so quickly from one to another that one can scarcely remember whether we are now in the "Jet Age" or the "Atomic Age" or the "Moon Probe Age." However, I recall that some years ago, someone defined the "Jet Age" as breakfast in London, lunch in New York, dinner in San Francisco, and baggage in Buenos Aires. It might be appropriate to add "and stomach ache in Honolulu."

The truth is that, today and tomorrow and next year, in this time of rapid technological change, the maintenance of a pure, safe, nutritious food supply is going to continue to be a complicated and difficult matter. I believe it is going to take the combined efforts of government, industry, the medical profession—and the consuming public—to keep pace with the problem.

Since others have given you a rather complete account of the Food and Drug Administration's (FDA's) viewpoint and activities with regard to standards of identity, quality and fill-of-container for food products, it seems to me appropriate that my remarks should be directed toward a broad consideration of food standards. I don't need to tell you, of course, that the responsibility of the Consumer Protection and Environmental Health Service for the purity and safety of the Nation's food supply is a very broad one, and that it encompasses problems that grow more complex with every innovation in food technology and with the changing life-style that marks contemporary life.

Certainly not one of us would be willing to turn our backs on the modern supermarket or trade our pampered life, in which anyone can pass as a Cordon Bleu graduate if he can open a few enticing

packages and follow the simple instructions on the back. We live in a marvelous age of food technology—and yet we must remember that in this, as in other facets of environmental change, our ability to understand and control the hazards of technological progress lags far behind our capacity for environmental manipulation. New food technology has introduced new problems, and has intensified or complicated some of the old familiar hazards of food-borne disease. Let me give you just a few examples.

Microbiological Infestations

The incidence of food poisoning due to salmonella is perhaps a good place to begin. About 20,000 cases a year are reported to the National Communicable Disease Center in Atlanta, but most health officials and epidemiologists are agreed that this represents only a small fraction of the total cases. Most estimate that about 2,000,000 people every year fall victim to salmonellosis.

During the time I served as Assistant Commissioner of Health in New York City, scarcely a week went by without an episode of food poisoning. For example, on one occasion some four thousand persons gathered in several of the large hotels for a holiday dinner, served by three different catering establishments. Of the 4,000, about 1,400 were made sick from salmonella which was traced to frozen eggs used in a kosher dessert.

Salmonella is, in fact, the "ubiquitous bug" which can become a hazard at almost any stage in the food chain: in production, in the processing or preservation, or in preparation for the table.

In New York City, the Health Department recognized that salmonellosis infection could be greatly reduced if the safety of the frozen eggs so widely used commercially could be assured. The only way to accomplish this is through pasteurization of the "broken out" eggs. It adopted, therefore, a regulation requiring that this technique be used by all processors in the City.

A few years ago, Dr. Ernest Ager of the Washington State Department of Health, speaking at a White House Conference on Health, characterized the salmonellosis problem as "a national disgrace." It is, indeed, shocking to realize that the most advanced nation in the world can tolerate *preventable* food-borne disease as a major public health problem.

A few years ago, Clostridium perfringens was seldom involved in food poisoning episodes. But today it is emerging as a major, recurring problem. This is an organism which multiplies under anaerobic conditions, made possible by methods of packaging. The airtight plastic wrappings, for example, provide perfect conditions for its growth if the best methods of preparation, storage, and handling are not carefully adhered to.

The "heat-and-serve" food, the frozen prepared foods, are especially susceptible to microbiological contamination. And we are actually doing very little in the way of standards to assure their safety. There are growing problems associated with the new infant food formulations—many of them using dried milk, which is so frequently implicated in salmonellosis outbreaks.

It is only in recent years that FDA has had the resources to mount a major surveillance program for microbiological contamination. Since 1966, it has had to recall from the market, because of salmonella contamination, instant non-fat dried milk, chocolate candy, thyroid preparations, animal feeds, ice cream pies, and a variety of other food products.

We are moving ahead steadily in this field. There are now bacteriologists in the laboratories of all FDA district offices. And last year, a national center for microbiological analysis began operating on a pilot basis in Minneapolis.

Samples of food products from around the nation, starting with those foods most susceptible to contamination by harmful bacteria, are being sent to the Minneapolis center for analysis. We believe this research will help pinpoint the hazards and make possible more effective programs of prevention.

I think there is no question that the food industry has made progress during the last few years in curbing contamination through improved plant sanitation and more thorough checks of raw materials. But these problems of microbiological contamination are going to continue to be troublesome until we succeed in establishing and observing effective standards of sanitation at each step in the food process.

Additives and Residues

We must remember too that acute illnesses do not constitute the whole problem. The study of cumulative effects from repeated exposures to small amounts of food contaminants has only begun. The

health effects of various chemical residues and additives make food protection an important consideration in the total environmental health problem. The use of chemical food additives—for flavor, color, or other purposes—has increased 50 percent in the last years, and each of us now consumes about 3 pounds of these every year. Food is the principal source of human intake of pesticide residues, and, as I am sure you are aware, it is estimated that the average American now carries about 12 parts per million of DDT in his fatty tissues.

Of course, the Food and Drug Administration has regulatory authority covering the safety of food additives and is empowered to limit pesticide residues on food products, but we must remember that this authority extends only to foods shipped in interstate commerce. Very few states have laws that provide the same protection for foods marketed only within their own boundaries.

Some years ago, Dr. Jerome Weisner, when he was Special Assistant to the President for Science and Technology pointed out the gravity of the growing chemical contamination of the environment. Contrasting it to the world-wide concern for radiological fall-out, he said:

> As one observes the very rapid increase in the use of all kinds of chemicals, not only the pesticides but . . . the detergents and the atmospheric pollution which originates from many causes, we are led to conclude that potentially this is a much greater hazard to our civilization because it is something which we will be continually exposed to.

As many of you know, I am sure, Secretary Finch of the Department of Health, Education, and Welfare has recently appointed a Special Committee on Pesticides in the Environment, headed by Dr. Mrak, to study this phase of environmental contamination and its impact on human health. It is to make a full report in six months. We will all be most interested in their findings.

Cooperation and Uniformity

One step which we in the Consumer Protection and Environmental Health Service have taken to strengthen our food programs is to bring all of these together, within the Food and Drug Administration. For many years, the Public Health Service (PHS) has conducted a number of very effective food sanitation programs which have set a pattern for voluntary federal-state-industry cooperation in this area. The PHS milk sanitation program, for example, has had a tremendous impact on the sanitary quality of milk in both intrastate and interstate commerce. The "'Recommended Milk Or-

dinance," first published in 1925 and revised many times since then, forms the basis for milk sanitation laws or regulations in most States. Milk was once a major factor in the transmission of typhoid fever and other diseases; today, a single case of any illness attributed to fluid milk is an extremely rare occurrence.

The shellfish sanitation program also involves federal-state-industry cooperation, with the Federal Government certifying state programs and providing training and other assistance.

The PHS recommended standards for food service establishments have also been widely adopted, forming the basis for most State regulations and some 1,400 local jurisdictions. Our changing pattern of life has unquestionably magnified this aspect of food protection—with most working people and most students eating at least one meal a day away from home.

These programs are being shifted to the FDA so that our total effort in food protection can be more closely coordinated and can have the benefit of the strongest possible scientific base.

The transfer of these voluntary, cooperative programs does not, I hasten to add, imply any change in their direction or philosophy. On the contrary, in the matter of food protection—and in all of our environmental programs—effective control requires that we use all the mechanisms available to us. Certainly, a most important one—indeed, an essential one—is close cooperation with industry to foresee and forestall the kind of problems I have been talking about, and the related ones which have been the principal concern of the medical profession.

As Dr. Ley, Commissioner of the Food and Drug Administration, has frequently pointed out, a broader concept of consumer protection has been developing within his Administration for a number of years and, as he puts it, "It came to be recognized that prevention could be more meaningful than prosecution in protecting the public health." This does mean a greater emphasis on pinpointing health hazards or consumer pitfalls at their source and finding the means to eliminate them.

Our view, in essence, is that wherever industry is willing and able to regulate itself to protect the consumer, there can be no need for governmental enforcement. I believe, however, that, where the nation's food supply is concerned, there is great need for *uniform,*

effective standards to assure quality, purity, and integrity. I feel that, in most cases, such standards can best be achieved when they are based on the judgment of competent scientific observers outside the industry affected. In terms of public health, the so-called "consensus" standard seldom provides the kind of protection the public interest requires.

I remember hearing once that if you're ever stuck for conversation, just bring up the subject of food, for everyone likes to talk about that. I'm not at all sure, however, that the food matters I have been talking about would be recommended as luncheon table discourse, however desperate we might be for a conversational gambit. Nevertheless, I have spoken at some length about this aspect of consumer protection because those who are concerned with human health must have equal concern for both the purity and the nutritive value of our food supply.

To turn briefly to the standards relevant to maintaining nutritional quality of foods, the future direction of our standards program will be determined in part by a number of factors which are only now emerging:

One is the need to consider and take necessary action concerning international food standards being developed by Codex Alimentarius committees. Another is the development of new foods such as imitation milk and texturized vegetable protein foods intended as cheaper substitutes for important foods of animal origin. It is our view that the public is entitled to assurance that such "imitations," which have a growing importance, especially to low-income families, at least provide the basic nutritional values of the original.

A third factor which will have a bearing on future actions is the information on nutritional needs which may be revealed through studies that are now being conducted by the Public Health Service. As you know, Secretary Finch has pledged the Department of Health, Education, and Welfare to a broad action program to fight malnutrition. One possibility for meeting this problem is a new National approach to the nutritional enrichment of staple foods.

President Nixon has appointed Dr. Jean Mayer as his special assistant on matters relating to nutrition, and has indicated his intention to call a future White House Conference on Food, Nutrition, and Health.

It appears to me that we are definitely entering a new era in our approach to nutritional standards; as Secretary Finch has said, "The vigor and effectiveness of food enrichment has not kept pace with the changing patterns in our food habits."

Conclusion

In conclusion, let me say again that the combined efforts of government, industry, the medical profession, and the consumer are essential to close the gap. This applies equally to our need for effective standards to maintain nutritive quality and those relating to purity. The importance of consumer participation in this process cannot be overstated, in my opinion. I cannot anticipate a situation, at any time in the foreseeable future, when the regulatory agencies of the United States Government will have the resources to fully police an industry as vast and complex as the food industry. Demand from consumers can, therefore, play a powerful part in assuring compliance with the best food standards.

As for my own Service, I want you to know that we have adopted, as first priority in all our environmental and consumer programs, the enunciation of criteria and standards to help maintain a safe, healthful environment, conducive to the total well-being of the human species. In some instances, such standards will have the force of law; in others, where regulatory authority does not exist, they will be guidelines for voluntary compliance. In all cases, the force of public opinion can help to make them effective.

We believe that industry has a responsibility to comply voluntarily with laws and regulations, and a moral obligation to observe high standards even where these are not legally binding. We are anxious to help them do so through education and information. Where voluntary compliance is not forthcoming, we will apply the sanctions of the law.

There is a little verse that goes something like this: "The good need fear no law, it is his safety, and the bad man's awe."

[The End]

Food Standards: The Balance Between Certainty and Innovation

By H. THOMAS AUSTERN

Mr. Austern Is the General Counsel for the National Canners Association.

HISTORY OFTEN REPEATS ITSELF, Max Beerbohm once observed. Historians repeat each other. History, when it repeats itself, is often interesting. Historians are not.

That aphorism dictates that any historical review be confined to highlights, focus on the original concept of a food standard embodied in the 1938 Food, Drug, and Cosmetic Act,[1] and demonstrate how by legal serendipity over three decades the original formulation has been converted into something different. We may in that way identify the controversies about food standards that may control their future development.

Mandatory food standards,[2] under a Federal law whose violation can result in seizure of the food,[3] in criminal penalties,[4] and in court injunctions against future transgressions,[5] originated in 1930 in the desire of the canning industry to draw a line between acceptable canned fruits and vegetables and those of such poor quality that—even though not adulterated—they should be denigrated in the marketplace.

The industry objective was that any low quality food, though wholesome and unadulterated, should still carry what came to be called a crêpe label, reading "Below U. S. Standard . . . Low Quality But Not Illegal."[6] Necessarily, to mark the line between acceptable

[1] 21 U. S. C. §§ 301 and following (1964) (hereafter FD&C Act).

[2] 21 C. F. R. §§ 14-53 (1969).

[3] FD&C Act, § 304, 21 U. S. C. § 334 (1964).

[4] FD&C Act, § 303, 21 U. S. C. § 333 (1964); see *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (D. C. Md. 1944).

[5] FD&C Act, § 302, 21 U. S. C. § 332 (1964).

[6] An early effort to enjoin the enforcement of this legend failed. *F. Clemens Horst Co. v. Hyde* (D. C. Calif. 1931) (unreported).

and crêpe labeled foods, one had first to identify or define the food being regulated. Thus, the concept of a Standard of Identity was born.

The Standard of Identity

That genesis of a mandatory Standard of Identity in the 1930 McNary-Mapes Amendment[7] emphasizes the food industry's basic interest and participation in standard-making. Industry's desire was to preserve the consumer's confidence in the integrity of a food, an interest at least as great as that of the Food and Drug Administration (FDA), because of the long-run economic consequences to industry if public confidence were ever lost.

Standardization, however, inevitably restricts some freedom in food composition.

If an Identity Standard is to draw a recognizable and enforceable line, it must exclude as well as include ingredients in order to achieve certainty for both the manufacturer and the consumer.

The consumer can then be assured, without the necessity for attempting manufacturing judgments she is ill-equipped to make, that the defined food will have recognizable and reproducible characteristics from store to store, from brand to brand, and from week to week.

The manufacturer is in turn afforded certainty that all his competitors, marketing a product identified as the defined food, must meet certain economic baselines, and cannot, with legal impunity, confuse the consumer by falsely simulating or labeling something less than the defined food.

Certainty is not, however, the exclusive goal of either the consumer or the manufacturer. No food is so perfect or inviolable in composition that the consumer has never ventured to experiment, to change it, or to improve its utility.

Nor has any manufacturer long remained in business without endeavoring to make his products more attractive in taste, flavor, appearance, ease of use, keeping qualities, packaging, or a myriad of other ways.

That countervailing pressure for innovation, as against the confining effect implicit in any standard, highlights the three-decade history of food standards.

So long as the balance between certainty and innovation has been a dynamic one—recognizing innovation in optional ingredients, in consumer tastes, in consumer desires, and in new technology—the

[7] 46 Stat. 1019 (1930).

food standards program has effectively, in the statutory language, served honesty and fair dealing in the interest of consumers.[8]

Whenever, because of administrative policy, budget limitations, or official predilections, that balance tipped toward rigidity, standardized foods have become entombed in inflexible regulations. In competing in the marketplace with freely innovating non-standardized products, they have lost favor.

Despite any supposed nostalgia for "home made" foods, like Mother used to make, Americans really do not want a coarse frontier diet.

Against that basic need for a dynamic food standards program, equally of importance to the consumer and the manufacturer, the development of food standards may be examined in the hope of forecasting its future course.

The keystone has been and remains the Standard of Identity. It exclusively appropriates a composition to a label name, and limits the use of that label name to the composition.

Unless the food manufacturer conforms his composition to the standardized label name, he violates the law. His product cannot be sold.

That rule was firmly established in the landmark *Enriched Farina*[9] and *Catsup With Sodium Benzoate*[10] cases. Farina was divided into two foods—farina and enriched farina, the latter having specified vitamins. Boldly labeled "Farina With Vitamin D" was outlawed.

Accordingly, those decisions established that the FDA could exclude from the standardized composition ingredients that were completely wholesome. Unless they were permitted in the standard, they could not be added even though plainly and blatantly labeled. No matter how plainly labeled, the deviation in composition became illegal.

Another consequence that early generated much heat and debate was that an Identity Standard was something more than a yardstick for measuring economic adulteration.

To use a metaphor for legal illumination is always hazardous. But I suggest that simply because the girl is dressed to look like a chorus girl does not necessarily index her morality.

The law provides that one cannot adulterate the food by leaving out a valuable ingredient,[11] or by substituting a very cheap one for

[8] FD&C Act, § 401, 21 U. S. C. § 341 (1964).

[9] *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218, 63 S. Ct. 589 (1943).

[10] *Libby, McNeill & Libby v. United States*, 148 F. 2d 71 (CA-2 1945).

[11] FD&C Act, § 402(b)(1), 21 U. S. C. § 342(b)(1) (1964).

an expensive one.[12] If that is done, the product is deemed adulterated and subject to seizure, but an Identity Standard does not establish that line alone. It may and usually does go further.

For example, the Identity Standards for evaporated milk[13] raised the required butterfat levels over those which measured adulteration.

Absent a standard, no court would hold that peanut butter containing only 88 percent ground peanuts and 12 percent of other ingredients was adulterated in conventional terms. Yet, the promulgated Peanut Butter Standard,[14] now being challenged in court,[15] raised the peanut level to 90 percent.

Obviously, the yardstick of plain adulteration, and the compositional levels to be included in an Identity Standard, should reflect consumer understanding or expectations. Those, as we shall see, are not always easy to determine, and the difficulties compound when one deals with fabricated foods.

A third prickly problem that soon developed was that for many foods there were clearly basic ingredients, and also a wide group of developed geographical and other variations. In 1938 the statute sought to meet that problem by separating necessary mandatory or basic ingredients from so-called optional ingredients. The original concept was that the label name would be standardized and listing of the basic ingredients would not be required. The important optional ingredients would alone have to be disclosed. Underlying that approach was possibly the quaint idea that the American consumer would be able to read the *Federal Register,* or that with well-known simple foods a full ingredient listing would be superfluous.

In any event, in the early days almost a hundred standards were formulated on that predicate that the name of the food adequately conveyed information about the basic ingredients, and only a few optional ones had to be separately labeled.

Today, that idea has been almost completely eroded by circumstances and changing political and administrative attitudes.

The first departure was to fission a food, and to provide that the same food for regulatory purposes could become two foods if it was differently made. As a simple illustration, sliced peaches became one form of food, and peach halves another.[16] The sliced ones in heavy syrup then became a separate food, and the sliced peaches in light

[12] FD&C Act, § 402(b)(2), 21 U. S. C. § 342(b)(2) (1964).

[13] 21 C. F. R. § 18.520 (1969).

[14] 21 C. F. R. § 46.1 (1969).

[15] *Corn Products Co. v. Food and Drug Administration,* Nos. 17,526, 17,689 (3rd Cir. 1968).

[16] 21 C. F. R. § 27.2 (1969).

syrup still another. Each form of the same food became an optional form of ingredient, with a separate standard and a separate label.[17]

Tomato puree could be made from whole tomatoes or portions trimmed in preparing whole tomatoes. Even though the end product was the same, the different methods of manufacture were viewed as so significant as to require label differentiation.[18]

In that process, believe it or not, an egg was refused standardization as an egg, but frozen eggs were separately standardized, as were egg yolks and egg whites.[19]

Bread alone was white bread; milk bread became a separate food.[20] Cocoa was one food; breakfast cocoa another; and low fat cocoa still a third.[21] The genus green beans was fragmented into whole green beans, cut green beans, short cut green beans.[22]

That fragmentation was hardly objectionable, even though the result was to proliferate identity standards. What clearly evolved, however, was that the label name, appropriated to a given basic composition, overtook the original concept. Instead of having a standard built on basic ingredients *not* labeled, and optional ingredients separately labeled, standards were built on *optional forms* of the same basic ingredients.

Where one had a simple food such as a canned fruit or vegetable, that fragmentation was feasible. But when one encountered fabricated foods, essentially collections of optional ingredients, any effort to impound every kind of optional ingredient in a separate standard would be onerous, and also would intensify the objection that innovation was being heavily restricted.

Even more, the developed approach made it more and more difficult to standardize any but the simplest foods. Efforts to do so led to strong dissent, to insistence that the law be amended to permit product development, and thus to limit standardization to basic ingredients and to permit any manufacturer to innovate additionally so long as he plainly labeled his innovation. This was urged as the need for avoiding rigid "recipe" identity standards in favor of a more flexible approach.

The inescapable conflict became more acute with the development of what are called "convenience foods." Early Identity Standards

[17] See footnote 16.

[18] 21 C. F. R. § 53.20 (1969). Detailed history of this early administrative development in food standardization is set forth in Austern, "The Formulation of Mandatory Food Standards," 2 FOOD DRUG COSMETIC LAW QUARTERLY 532, 550 and following (December 1947).

[19] 21 C. F. R. §§ 42.20, 42.40, 42.70 (1969).

[20] 21 C. F. R. §§ 17.1, 17.3 (1969).

[21] 21 C. F. R. §§ 14.3, 14.4, 14.5 (1969).

[22] 21 C. F. R. § 51.10 (1969).

permitted a descriptive approach with a very few limited optional ingredients. Little was needed on the label beyond the name of the food. For tomato juice, a one-paragraph description, and a standard permitting one optional ingredient, was enough.[23]

These early food standards reflected the time when more foods were home-prepared and when home meal preparation started with raw materials which the housewife combined, seasoned, and cooked to her own taste.

Consumer attitudes and preferences have radically changed. Today the homemaker is both willing, and apparently eager, to pay for the convenience provided by prepared dishes, seasoned, garnished and sauced by the maker. Standards that created limited recipe options failed to meet consumer interests, as any tour of a supermarket today will demonstrate. Increasing amounts of shelf space are devoted to fully prepared foods, main courses, and complete dinners in a wide variety of composition.

Of course, some consumers, and for a time the FDA, resisted that trend. Their proposals for Standards of Identity imposed almost aborigine taboos against change. Newly innovated food products were called "economic frauds" or "debased foods." But no administrative King Canute could stem the tide, and rigidity simply had to yield.

One escape from the dilemma of a tight, confining recipe standard and the inability to standardize a complicated fabricated food, might be to loosen the limits of what the standard required. A superb example would be the pending proposed Identity Standard for cherry pie.[24] This simply says that cherry pie is a cherry filling in a pastry shell, wholly or partly covered with pastry or "other suitable topping."

The proposed standard neither defines the filling, nor a pastry shell, nor a suitable topping. A further complication is that a pie smaller than four inches in diameter may also be a cherry tart. Perhaps there is a firm consumer understanding of what constitutes a pie, either as your wife makes it or as you try to tell her how your mother used to make it.

The real thrust of the cherry pie standard proposals is *not* identity, but the quality factor of "too few cherries" or "too shallow" a pie. Those factors of interest to the consumer are treated not as matters of identity, but as provisions in the Standard of Quality.

Yet in my view, to impose drastic legal requirements and sanctions on the elastic parameters of this kind of Identity Standard would not be good government.

[23] 21 C. F. R. § 53.1 (1969).

[24] 32 Fed. Reg. 15116 (1967).

The cherry pie example also illustrates the problem of determining the label name to which a composition, rigid or loose, should be exclusively appropriated. Originally, the law left that wide open. But some people feared giving the FDA complete power to re-baptize foods. They urged that ordinary cows' milk might some day be designated by a zealous bureaucrat as "bovine lacteal fluid." The compromise was to say the FDA had to find and use the "common or usual name" "so far as practicable."

What is considered practicable by one man may have serious economic consequences for another. When cream cheese was standardized, identity was fissioned. High fat cream cheese remained cream cheese.[25] Low fat cream cheese was re-baptized as "Neufchatel."[26] "Lima beans" and "butter beans" became interchangeable names for the same product.[27] It was considered practicable to permit three variations of the spelling of catsup . . . catchup . . . ketchup, perhaps intended for animal lovers, girl chasers, and boating enthusiasts.[28]

But when the search for the common or usual name entered the field of fabricated foods, these problems compounded. Is "cake mix" the common name of some specific composition? What composition should be standardized as "vegetable soup"? Are new substitutes for milk to be permitted only under the common or usual name of "imitation milk"?

Another remaining expedient opened up by the Supreme Court as a legal concept, but questionable in terms of consumer understanding and economics, emerged out of the famous *Imitation Jam* case.[29] There the jam-maker departed from the required composition, put in far less fruit, and boldly labeled his product "Imitation." FDA urged that this was too easy an escape. But the Supreme Court said that the food labeled "Imitation" eluded the standard. It said the word "imitation" was ordinary English. It may have been ordinary English but certainly not ordinary jam.[30]

I doubt that making the price of innovation a commercially dubious label is a good path to follow. Low fat margarine has penetrated the market even though labeled imitation margarine with an accompanying gloss of dietary advantages.

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[25] 21 C. F. R. § 19.515 (1969).
[26] 21 C. F. R. § 19.520 (1969).
[27] 21 C. F. R. § 51.990 (1969).
[28] 21 C. F. R. § 53.10 (1969).
[29] *62 Cases, etc. of Jam v. United States*, 340 U. S. 593 (1951).
[30] For a fuller exposition of the *Imitation Jam* case, see Austern, "Ordinary English But Not Ordinary Jam," 6 FOOD DRUG COSMETIC LAW JOURNAL 909 (December, 1951).

Nutritionally sound milk substitutes deserve better treatment, and there is no need or sound policy basis for relegating the economic strata these products serve to an officially denigrated product label.[31]

In contrast, there is now being considered for an Identity Standard a series of wholesome vegetable protein products. Instead of requiring them to be marketed as imitation meat protein, an Identity Standard, accompanied by a wholly new name, is under consideration.[32]

But any attempt to standardize canned soup on one standard recipe, and to require by law that all others be called "imitation soup," is hardly feasible, or perhaps even sane.

Administrative law is happily flexible. In the middle 1960's, the FDA developed what is now called the "breaded shrimp" approach to Identity Standards. It concluded that the crucial identifying factor to consumers in frozen raw breaded shrimp was the quantity and kind of shrimp, and that there was no consumer need to limit the ingenuity of the manufacturer in developing different kinds of breading material.

The Standard thus specifies a minimum amount of shrimp material as the basic ingredient, characterized according to its shape, and then permits that there can be added any "safe and suitable batter or breading ingredients."[33]

I hestitate to talk about peanut butter because I suffered through almost two of my declining years in administrative hearings on that transcendental and important national problem. Yet what emerged was much the same concept, even though some are now contesting the result in court.[34] The standard deals basically with the level of peanuts, set at 90 percent, and permits any other safe and suitable sweetening or stabilizing ingredient.[35] The choice between the so-called old-fashioned peanut butter—which, however tasty, would separate its oil, cling to the roof of your mouth, and effectively remove your dentures—and developing a smoother and more palatable modern product, seems sensible. But if this new concept of sticking to basics and affording latitude for optional product innovation, within specific limits, is desirable, industry must pay the necessary price. It must list on the label virtually every ingredient in the product. Assuming that we have a truly literate population, who will take

[31] See Imitation Milks and Creams proposal, 33 Fed. Reg. 7456 (1968).

[32] See two proposals for standards for Vegetable Protein Products, 32 Fed. Reg. 14237 (1967).

[33] 21 C. F. R. §§ 36.30-31 (1969).

[34] See footnote 15.

[35] 21 C. F. R. § 46.1 (1969).

the trouble to read labels, that may not be too high a price.[36]

There are, of course, some cost advantages and consumer benefits in simplified labeling practices. For smaller producers who sell for private label distribution, uniformity is often important.

A further refinement may afford both objectives. All types of sweetening ingredients, cane sugar, beet sugar, dextrose or corn syrup, may alike be labeled as added "sweeteners."[37] In short, the optional ingredients may be identified by functional label groups without disadvantage to the consumer.

Fortunately, another administrative aberration has been quietly interred. At one time, some in FDA would insist that before any new optional ingredient, as a product innovation, could be added by amendment to an Identity Standard, it would have to be shown that the new ingredient made a significant nutritional contribution. Indeed, this view was pushed to demanding proof that the new ingredient was vitally needed by significant segments of the population.[38] On that theory, the amino acid, lysine, was never allowed in standardized foods.

That was indeed a difficult roadblock, but it has now been eradicated. Standardized canned vegetables may now include butter as a seasoning ingredient, organoleptically perceived, but probably not nutritionally significant.[39] Lemon flavor is proposed for tuna fish,[40] even though consumers would not become emaciated without it. An anti-sticking agent for macaroni and noodle products[41]—or the decorative coloring of applesauce[42]—will not be barred. Nutritional significance is hardly the test of admission to a modern food.

One would be too sanguine in saying that the argument about nutritional values will not again crop up in standardization. Vitamins were kept out of peanut butter on the theory that it was not viewed by the consumer as a substitute for butter or margarine.[43] On the other hand, nutritional ideas can hardly be important in standardizing carbonated beverages.

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[36] For an extended discussion of FDA paternalism and the label reading public, see Austern, "Section 403(g) Revisited," 6 FOOD DRUG COSMETIC LAW JOURNAL 181, 185-88 (March, 1951).

[37] See, for example, 21 C. F. R. § 27.111 (1969), see also Canned Applesauce proposal, 34 Fed. Reg. 5605 (1969).

[38] This unfortunate FDA policy was detailed in Austern, "The Current Status of the Food-Standards Program —'Eppur Si Muove,'" 14 FOOD DRUG COSMETIC LAW JOURNAL 210, 215-217 (March, 1959).

[39] See, for example, 21 C. F. R. § 51.990(c)(3)(xiii) (1969).

[40] See 34 Fed. Reg. 9996 (1969).

[41] 21 C. F. R. § 16.1(a)(6) (1969).

[42] 21 C. F. R. § 27.80(b)(9) (1969).

[43] See Peanut Butter Standard, Findings of Fact and Conclusions, Finding No. 43, Conclusion No. 4, 33 Fed. Reg. 10506 (1968).

It may sometimes be relevant to inquire into the nutritional significance of an ingredient, but no greater bar to achieve standardization could be found than to urge that every minor optional ingredient must make a significant nutritional contribution. I doubt that maraschino cherries are nutritionally important, rather than what I have called an optical condiment designed to gussy up a fruit salad, a sundae, or, for some, a whiskey sour.

The Standards of Quality and Fill

Turning next to Standards of Quality, they are not intended once again to draw a labeling line between food fit for human consumption and food so adulterated as to be unfit for use. The present crêpe label so indicates in requiring foods that do not meet a quality standard merely to be labeled "Good Food—Not High Grade."[44]

It is also of fundamental importance to understand that a mandatory Quality Standard relates to minimum quality. It is not "A,B,C," or so-called grade labeling.

There are *voluntary* grade labeling standards of the Department of Agriculture,[45] as well as many commercial quality grades above the FDA minimum.

But "grade labeling" involves the two elements of collecting quality factors with arbitrarily assigned values to yield a single collective grade. Within those quality factors are many which are only subjectively determinable. For FDA purposes, only objective criteria yield legally enforceable standards.

Obviously, one must decide whether a given food characteristic relates to identity or to quality. I know of no general rule, but will offer you a few real examples.

For breaded shrimp, the amount of shrimp is an identity factor.[46] For cherry pies, the amount of cherries is made a factor of quality, with too few yielding a crêpe label of "Too Few Cherries."[47] For enriched flour,[48] bread,[49] and macaroni,[50] added vitamins and minerals are included in identity. For proposed imitation milk, vitamins would constitute a quality factor.[51]

Curiously, FDA rules and industry practices are not congruent. Industry urged that the amount of butterfat in cream cheese related

[44] 21 C. F. R. § 10.7(a) (1969).
[45] See, for example, Standards for Grades for Processed Fruits and Vegetables, 7 C. F. R. Part 52 (1969).
[46] 21 C. F. R. § 36.30 (1969).
[47] See Cherry Pie proposal, 32 Fed. Reg. 15116 (1967).
[48] 21 C. F. R. § 15.10 (1969).
[49] 21 C. F. R. § 17.2 (1969).
[50] 21 C. F. R. § 16.9 (1969).
[51] See Imitation Milks and Creams proposal, 33 Fed. Reg. 7456 (1968).

to quality, but the FDA evolved two standards and the two names, cream cheese and neufchatel.[52] For canned fruits, syrup density measures quality for the industry. For the FDA it determines identity and labeling.[53] On artificially colored peas, FDA dug in, accorded them a lawful identity, but ruled their use made a substandard product.[54]

These classification difficulties and the fundamental problem of determining degrees of workmanship, objectively determinable, that meet consumer expectations for use on a national scale, have led to fewer Quality Standards.

Nevertheless, a Quality Standard has one legal advantage. Failure to meet it means merely crêpe labeling, but it still can be sold. Failure to meet an Identity Standard yields an outlawed product that cannot be marketed at all. It is that legal quirk that often converts an ordinary identity factor into a quality factor, and yields an odd Standard of Quality.

The third type of FDA standard relates to fill of container. By and large, fill standards are designed, where feasible, to afford a more definitive yardstick for condemning slack filling of a container. The law basically condemns as adulterated any product whose container is so filled as to be misleading. That is a fairly elusive concept. Hence, there are a few Standards of Fill.

Administrative Procedures

Food industry attitudes toward standard-making can never be divorced from the complexity and cost of the administrative procedures involved in their formulation, and particularly for their amendment. In the old days, no matter who proposed the standard, it was adopted only after a full trial-type procedure. But with what is called the Hale Amendment in 1954,[55] either the original promulgation or the amendment could be achieved by a simplified procedure.

This was possible only where there was no controversy. If there was, the right to have a trial limited only to what was objectionable was preserved. Of course, where a proposed amendment was objected to by FDA, where administrative resistance or obduracy, or perhaps even fatigue, stood in the way, people became speedily disenchanted with the whole program.

The Hale Amendment has nevertheless enjoyed moderate success. Lately, the welcome mat has been put out for product innovation in

[52] 21 C. F. R. §§ 19.515, 19.520 (1969).
[53] See, for example, 21 C. F. R. §§ 27.2, 27.10, 27.25 (1969).
[54] See 21 C. F. R. §§ 51.1, 51.2 (1969).
[55] Pub. L. No. 83-335 (Apr. 15, 1954). See FD&C Act, §§ 401 and 701(e), as amended by 68 Stat. 54 and 70 Stat. 919 (August 1, 1956).

standardized food. The new procedure also delimits and affords advance notice of what the battlelines will be in the public hearing.

Yet where FDA bites off more than can be reasonably chewed in any one hearing, or where, as in the pending dietary food hearings, it attempts broad-scale standardization of whole classes of foods, prolonged and bitter hearing is sometimes plainly invited. Indeed, in one instance FDA never bothered to issue a proposal for industry, but put out its final order with a full realization of the large-scale hearing it would provoke.[56]

The procedure of forging binding Government Regulation through the process of an evidentiary trial-type hearing may be considered unusual. It was provided by Congress because of the drastic enforcement powers given to FDA, to condemn the goods,[57] to jail the manufacturer,[58] or to close his plant[59] even for an unknowing transgression of a complicated regulation.[60]

I have dubbed that process delegated legislation by litigation. Even though it has been recently criticized,[61] I firmly believe that it is in the public interest. I do so not because it may provide work for food lawyers, or afford judicial review, but because of my abiding conviction that he who regulates ought to appear publicly if there is a challenge, and put on the table, subject to cross-examination, the facts on which he grounds his proposal.

Judicial review is largely a phantom. In my own experience there are few courts that will second-guess the Food and Drug Administration, which has the reputation of protecting the consumer, the aged, the infirm, the ignorant, and the nursing infant.[62]

The vigor of some FDA hearings should not be surprising. An economic judgment remains one no matter how much technical clothing it wears. To measure the quantity of an ingredient is a technical question. But how much of it is needed or should be lawful, or the label name to be given a food, are economic judgments. You do not have to be a chemist or a bacteriologist or a doctor, and could even be a lawyer, to exercise judgment on these questions.

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[56] See Order in Food for Special Dietary Uses, 31 Fed. Reg. 8521 (1966).

[57] See FD&C Act, § 304, 21 U. S. C. § 334 (1964).

[58] See FD&C Act, § 303, 21 U. S. C. § 333 (1964).

[59] See FD&C Act, § 302, 21 U. S. C. § 332 (1964).

[60] See *United States v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134 (1943); *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008 (CA-7 1947), cert. denied, U. S. Supreme Court, 1948.

[61] See Goodrich, "The Food and Drug Administration's View on Procedural Rules," 23 FOOD DRUG COSMETIC LAW JOURNAL 481 (October, 1968).

[62] See report of the oral argument before the Supreme Court of the *Bacto-Unidisk* case (No. 343) in "The Pink Sheet," *FDC Reports*, pp. 11-12 (January 27, 1969).

The basic judgments are economic among competing formulations of what are, up to that point, thought to be the same product.[63] The Identity Standard determines which are to survive and which are to be outlawed.

Understandably, a manufacturer with a significant consumer franchise will denounce a standard proposal that would alter or outlaw the formula on which he is convinced his success was based.[64] That question is vividly posed in the pending appeal in peanut butter,[65] where the standard will outlaw a formula recognized and accepted as peanut butter long before the present statute was even enacted.

Any overview that speculates about the future of food standards can overlook the current criticisms of the present procedure. Without encroaching on others far more expert, I should like briefly to buttress my conviction that the present process is good government, both for manufacturers and the consumer.

First, with safety issues out of the way, as they now are,[66] and with the winnowing capability of the Hale Amendment,[67] the trial-type procedure is mechanically feasible and, for reasons previously given, desirable.

Second, the major cause of protracted hearings is a broad-scale, complicated, badly-drawn order. The hearing reflects the scope of the proposal. If the FDA seeks to bite off in one hearing a whole series of proposals that vitally concern the entire food industry, the hearings will inevitably come to resemble a political convention. Remembering Shakespeare, the FDA perhaps must appreciate that the fault lies not in the legal stars of the opposition but often in themselves.

Third, inadequate and imperceptive preparation contributes heavily to delays and to the building of a record that becomes impenetrable to everyone.

Instead, all should seek effective cooperation between the FDA and the industry segments to be regulated, again assuming focused and ponderable proposals. That cooperation has provided, and can provide, sound economic direction and permit the program to work. Some may add that conventional exploration by pretrial conference is better than the precipitation of complicated hearings on 30 days' notice.

Last, while the Hale Amendment[68] triggers hearings only to resolve contested issues of fact, and not merely to provide a forum

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[63] See generally, Austern, "The Formulation of Mandatory Food Standards," footnote 18.

[64] See *Cream Wipt Food Prod. Co. v. Federal Security Administrator,* 187 F. 2d 789 (CA-3 1951).

[65] See footnote 15.

[66] See FD&C Act, §§ 201(s), 409, 21 U. S. C. §§ 321(s), 348 (1964).

[67] See footnote 55.

[68] See footnote 55.

for FDA employees to offer their particular positions, the Government's role is often too narrowly conceived. FDA counsel ought not merely be an advocate for the Commissioner's final order. He has an obligation constantly to evaluate the progression of the evidence and to consider whether contested issues can be negotiated when it appears that the position originally espoused cannot be supported by significant evidence outside the parochial confines of the agency, or that it is not necessary for consumer protection.

Recommendations

A prophet may not be without honor save in his own country. But anyone who speculates about the future of food standards must nervously recall his earlier predictions. Over the years I have staunchly advocated that the problems that vexed lawyers, consumed endless time, and ran up vast costs, could be surmounted.[69] I still cherish that hope.

For the food industry, the future must necessarily be measured against the food products in the marketplace that remain unstandardized. By and large, these are fabricated foods, composite products in which no ingredient or small groups of ingredients could be isolated as crucial, expensive, or subject to potential dilution. That job is not easy. I leave to you how significant it would be to standardize the symmetry of the crab shell in frozen prepared crabmeat entrees.

Convenience foods today often have no analog in home-produced items. Consumers buy them not on the basis of specific composition or particular ingredients, but for their performance characteristics, often related to flavor and convenience, and consequently not readily susceptible to standardization.

If that view of the marketplace is accurate, it can be turned around and examined from the standpoint of the consumer. Standards do not exist to serve their own ends, but instead to serve honesty and fair dealing in the interest of consumers.

With the trend toward convenience foods fabricated from multiple ingredients, it is not enough simply to identify a preponderant industry ingredient list and assume it will always serve the consumers' interest. That perhaps was feasible when simpler foods were standardized and the consumers' expectations could be measured in terms of composition or methods of manufacture.

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[69] See Austern, "The Current Status of the Food-Standards Program—'Eppur Si Muove,'" 14 FOOD DRUG COSMETIC LAW JOURNAL 210 (March, 1959), Austern, "Current Developments in Food Standard Proceedings," 4 FOOD DRUG COSMETIC LAW QUARTERLY 319 (September, 1949).

Today it is not. Consumer expectations emphasize characteristics that often have no specific correlation with composition. What is perhaps needed, and largely not provided, is a program to isolate for particular foods those characteristics that are crucial to consumers.[70] The real need is to study how these factors of real current importance to consumers can be related to objectively determinable criteria in the composition or quality of the food.

Industry has come to accept and indeed to favor the innovative potential afforded by current FDA approaches. Some manufacturers are reluctant to give up the flexibility of non-standardized food production. They are particularly loath to do so where the agency is willing to spend money to establish standards, but not to enforce them, or where the standards are predicated on criteria that ultimately are not enforceable.

Consumers should be equally unwilling to embrace nonenforceable standards, or paper standards that are really not enforceable. For it is a cruel deception to take the effort needed to formulate a standard that will *not* be enforced, or that cannot be enforced against those marginal yet significant producers whose violations will quickly again prove Gresham's law.

Overall, FDA must, in deploying its enforcement budget, of course give priority to health and sanitation protections. Still, a standard program that in reality carries with it no expected sanctions for non-compliance only sustains the agency, and wholly fails to protect, and indeed deceives, the consumer.

At the outset, I suggested that a standard-making program remained valid only so long as it reflected the dynamic tension between certainty and innovation. Perhaps this might be achieved by limiting the life of each standard, and thus requiring a periodic review to permit consumers, industry, and Government to assess whether it still serves the consumer.

As one who has lived in standard-making, I feel that my attempted overview has perhaps been myopic and narrow. If so, I am reminded of the paper by a famous Boston orthopedist in which he offered five penetrating conclusions. The first four related to the clinical work reported. His fifth conclusion, which I must adopt, could not be challenged. He said, "I have told you far more than I know."

[The End]

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[70] On the possible gap between the FDA's institutional view of consumer desires and those desires as revealed by opinion surveys and other objective methods, see Lambert, *FDA and the Public Interest: Quality Control in Scientific and Economic Regulation*, 18 *Am. U. L. Rev.* 139, 148-155 (1968).

A Critical Look at Good Manufacturing Practices Regulations of the FDA

By LEONARD M. LEVIN

The Following Paper Was Delivered at the Institute of Sanitation Management, Midwest Regional Educational Conference, St. Louis, Missouri, May 27, 1969. Mr. Levin Is an Industry Consultant.

ONE TOPIC IN THE FIELD of Food and Drug regulations which is of interest at this time is the Current Code of Good Manufacturing Practices (Sanitation) in Manufacturing, Processing, Packing, or Holding Human Foods. This is abbreviated as GMP. The Code went into effect on May 26, 1969.

These regulations for the control of plant sanitation were first proposed in late 1967 and are intended to meet the over-all sanitation requirements for food establishments. We are promised that specific codes for specific industries will be issued later, specifying such details as temperatures, times. and other technical requirements necessary for the protection of public health. The codes for dry milk, dry yeast, and animal products are said to have already been published, but they may not have been distributed. It has been announced that the additional GMP's covering the following subjects will soon be issued:

smoked fish	natural cheese
frozen eggs	milk and milk-substitute-based infant formulas
dried eggs	breaded shrimp
shelled tree nuts	frozen potato products
filled bakery specialties	

The Good Manufacturing Practices, the umbrella of generalized regulations which we are considering here, did not come out of the

inspiration of any one person, like a bolt out of the blue. It has been an evolutionary process. We could go back to the Kefauver-Harris drug amendments of 1962 which were put into effect in 1963. These included Good Manufacturing Practices for Drugs. The Drug GMP's are much more generalized than the Food GMP's with reference to sanitation. The drug GMP's went into effect without very much discussion. The relative success of the GMP concept in drugs made it inevitable that it would be extended to foods. But the drug industry is vastly different from the food industry.

What is revolutionary about the food GMP's? What is unique about their form and application that bears examination?

Up to May 26, 1969, the Food and Drug Administration (FDA) had no requirements for sanitation in food plants. It is true that if a product being manufactured were contaminated or manufactured under insanitary conditions, whatever that meant or means, its manufacturer or shipper was in trouble. There was also an informal listing on Form 483, if the Inspector took the trouble, for the notation of defects such as lack of hair covering, smoking on the job, etc. But there was no positive listing of sanitation requirements.

Through the years, the Federal Courts have held that the expressions, "filthy" and "insanitary" and "insanitary conditions" were very clear and needed no additional explanation. Those firms who challenged this concept by stating that these terms were vague and indefinite were beaten down in court. Nevertheless, the FDA, on its own initiative and recognizing the increasing complexity of the food industry and sanitation, has gone over to the more positive aspect of GMP's. It may even be a sign of these times of tighter budgets and lack of personnel to enforce the Act. A positive checklist could make enforcement easier, and though denied presently by FDA, enforcement could be done by checklist inspection forms instead of the tedious and time-consuming narrative reporting forms. The U. S. Public Health Service and local health departments have been using checklists for years.

The proposed GMP's are more than a year old and are just now becoming effective. Many changes have been made from the original proposal. For example, establishments engaged solely in the harvesting, storing, or distributing of raw agricultural commodities are now excluded from coverage. The FDA, however, reserves the right to regulate this activity in the future. Another example: when first

proposed, the code prohibited food workers from wearing wrist watches or rings. Now the code merely prohibits workers from wearing jewelry that cannot be adequately sanitized. For several reasons, it would be advisable to study the original proposals, because the Code can be changed without an Act of Congress. Don't throw away your old copies; they are very valuable.

GMP's—Guidelines or Law?

There has been considerable discussion in the legal field as to whether or not the GMP's carry the force of law. In other words, if you don't conform with the GMP's but you do not have an otherwise dirty plant, are you in jeopardy?

Industry lawyers in the main think that these regulations should be regarded as guidelines and not as part of the law itself. The Honorable George Burditt, prominent industry attorney, writes:

> . . . this is a very important question because if the GMP's have the force of law, FDA could bring a suit merely charging violation of one of the many provisions of the GMP's. On the other hand, if the GMP's are merely interpretative regulations, FDA would be required to prove a violation of the Act itself. It seems to me the latter interpretation must be correct; a violation of the GMP's would not necessarily constitute a violation of 402(a)(4) of the Act. . . .
>
> This interpretation of the GMP's appears not only to be correct from a legal point of view, but it also is beneficial from an operating point of view. As guidelines, the GMP's will help to educate plant managers as to the types of conditions which FDA Inspectors will be examining and of which the plant manager should be aware. The GMP's will serve as the standard by which a plant manager can measure his operations without fear that a difference between a particular practice in his plant which may be completely sanitary and a particular provision in the GMP's might result in his going to jail or economic disaster for his company."[1]

The official view of the FDA is that all GMP regulations will have the force of law. They have been, however, hedging their bets in this matter. The final version of the GMP's shows FDA has been trying to remove the regulations from controversy by dividing them into regulations which have the verb *shall* and those which have the word *should*. For example, "you *shall* keep persons with boils or infected wounds from working in a food plant where there is a reasonable possibility of food becoming contaminated." But "you *should* code the products being manufactured to facilitate segregation where necessary if food becomes contaminated or unfit." This is a labeling matter.

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[1] G. M. Burditt, "The Present Status of Current GMP's for Human Food," *AFDOUS Quarterly Bulletin*, Vol. 32, No. 4 (October, 1968), p. 196-200.

Let us now consider the individual GMP's and their impact on the sanitation scene. First, we must mention the regulation which in my opinion is the most important of them all.

This is the requirement, and let me repeat that the FDA requires it as a "must," that the "overall sanitation shall be under the supervision of an individual assigned responsibility for this function." Please note that the function of sanitation supervision must be given over to an individual. Highly organized firms already have this matter under control, but remember that there are food firms consisting of as few as one or two persons. May the individual assigned to sanitation supervision have other duties? Should he have any assignments in production? What guidelines are there for his responsibility? Is the size of the production force a determinant in answering any of these questions?

Plant Sanitarians

The regulations further charge that the sanitation function be "clearly assigned to competent supervisory personnel." What is considered competence in this field? In another section there is described the responsibility of personnel for identifying failures or food contamination and it is specified that these persons "should have a background of sanitation education or experience or combination thereof."

This set of regulations gives official recognition to the role of plant sanitarian. It cannot but be "upbeat" in elevating the importance of our function and inspiring improvements in every aspect of the field.

The regulations suggest that standards of competency could be established. It suggests to the Institute of Sanitation Management (ISM) that schools, seminars, and courses be conducted together with the FDA and universities and colleges for training in Plant Sanitation. The certificate received from ISM could be keyed to a program of continuing education for competence in the field. ISM has a course at Kansas State University in July set up for instruction in identifying failures in bacteriological techniques.

If the GMP's are considered guidelines, I would readily concede that the Code is an excellent document. If the GMP's have the force of law, I would like to look with you at the difficulties apparent in

the regulations, picking out a few examples. No doubt, as you read the regulations, you will be astonished at the use of the words, "excessively, inadequately, suitable, sufficient, adequate, effective, properly, convenient, minimize"—these adjectives and adverbs do not convey precise meaning. If this Code bears the force of law, some way will have to be found to tell us exactly what these words mean.

Let us consider the regulation which states: "Plant buildings shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations." If this is a guideline, fine. If this applies to new construction, O. K. If this is a requirement, and the plant were built decades ago and is still in use, I should lose not a little sleep. Will the FDA make a series of preliminary inspections like the U. S. Department of Agriculture (USDA) meat and poultry inspection program and, in effect, license the plant to operate after approving it?

Let us turn to a large number of regulations where judgment of clean operations is determined, not by economic considerations or by convenience or availability of labor, but by—let me read a regulation:

> All utensils and product contact surface shall be cleaned as frequently as necessary to prevent contamination. Non-product contact surfaces of equipment should be cleaned as frequently as necessary to minimize accumulation of dust.

As a guideline, fine. As a matter of compliance, it scares me to operate without assurances that this will not be enforced unreasonably, uneconomically, or impractically.

Another example of ambiguity and potential complications with ramifications is the regulation which reads, "light fixtures shall be of the safety type or otherwise protected." Does this mean that makeshift means of protection will be permitted or not permitted? Will there be an approved list of methods or a list of disapproved methods? Will there be a certification of equipment such as the USDA supplies in official plants?

Along these same lines, the regulations read, "detergents shall be free of significant contamination and safe and effective for their intended use." Does the FDA intend to certify detergents, handwashing soaps and devices, insecticides and other sanitary products? Will FDA require adherence to handwashing specifications, distance from work site, temperature of water, and other requirements in this area?

These are just a few of the complications we would be faced with if every regulation has the force of law, for make no mistake, the vast majority of citizens, and this includes food processors, want to obey the law.

Fortunately the FDA has been thinking about these matters too. They have invited the various segments of the food industry to have a "dialogue" with them. This will be most welcome by food industry sanitarians. We hope that the ISM will be able to meet the needs of the Industry by a strong and effective program, a real challenge to all of us.

In summary, the promulgation of Good Manufacturing Practices is a landmark on the sanitation scene. It gives status to the practicing sanitarian. It stimulates activity, research, and education in the sanitation field. It has great implications for the manufacturers and distributors of food machinery, detergents, and other sanitary supplies. But if the Code is to be a rigidly enforced legal document, it must be further defined and refined to achieve the confidence of those to whom it applies. **[The End]**

FDA OUTLINES WEAKNESS

An internal study group created by the Commissioner of Food and Drugs, and composed of seven senior FDA scientists and administrators, has concluded that with limited funds, staff, and authority, the Food and Drug Administration cannot assure the public that the consumer products it regulates are safe and effective.

After reviewing the FDA's objectives and programs, the study group stated that it believes the agency is in a critical situation which it is not currently equipped to meet. The study group therefore recommended four separate changes to allow the agency to fulfill its responsibilities. These include: 1) Programs providing for more consumer influence on FDA activities, intensified coverage of imported products, and long-range ecological studies to check chemical and other environmental contamination of our future food supply; 2) Re-evaluation of the food standards program to determine its effectiveness, and whether it should be broadened to include health and nutrition standards; 3) A program of statistical sampling for antibiotics and insulin, and additional industry guidelines for pharmacologic and clinical studies and labeling; 4) For cosmetics, development with the industry of a listing of chemical data on all cosmetic ingredients stating their potential degree of hazard.

The Report from the study group also contains many recommendations which are not new or unique, but which are intended to underscore the importance of meeting needs already recognized.

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Biweekly "GUIDE Reports" follow to keep you right up to date on new developments affecting consumer credit as they break. Oklahoma and Utah have adopted the UCCC, which will replace existing state rules in one clean sweep and may also yield statutory exempt status. New York and other states have made big changes in their consumer credit laws.

A quick-reading "summary" also goes to subscribers at no extra cost, highlighting new items and referring you to where in the "GUIDE Report" each is treated.

CONSUMER CREDIT GUIDE offers welcome help to instalment sellers and lenders, banks, mortgage houses, credit unions, lawyers and other concerned groups. Just your OK and return of the post-free card attached brings all this help to you, starting immediately.

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