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Food Drug Cosmetic Law JOURNAL

Institute of Food Technologists' Symposium on International Feedback and Good Manufacturing Practices

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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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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

The American Medical Association Council on Foods and Nutrition Symposium on Food Standards in the United States.—Fortunately, the JOURNAL has been able to obtain additional papers presented at the Symposium. The first groups of papers were presented in the August and September issues.

In "Food Standardization Past, Present and Future," which begins on page 464, *William W. Goodrich* contends that past difficulties encountered in standardization give a strong indication of the nature of future problems. The author is Assistant General Counsel for the Food, Drugs, and Environmental Health Division of HEW.

K. G. Weckel, Professor of Food Science at the University of Wisconsin, considers the nature of "Research on Standardized and Nonstandardized Foods in Educational Institutions" in the article beginning on page 474. Professor Weckel notes the difficulty of justifying university research projects in areas of rigid standardization.

Beginning on page 480, *Dr. Bernard L. Oser* presents his "Summary of Symposium Reports," which includes his commentary on the proceedings. Dr. Oser is the Scientific Editor of this magazine and President of Food and Drug Research Laboratories, Inc.

Institute of Food Technologists.—The following papers were presented at a symposium on International Feedback and Good Manufacturing Practices held in Chicago, Illinois on May 13, 1969.

"The Likely Impact of International Standards for Foods and Food Ingredients on 'Hidden Tariffs,'" by *Michael F. Markel,* begins on page 486. The author postulates that the adoption of international food standards involves more than the obvious leveling of requirements.

In "International Food Standards—What Trade Associations Can Do," *Malcolm R. Stephens,* President, Institute of Shortening and Edible Oils, recommends active participation in international programs by an industry-wide organization. His article begins on page 493.

"Codex Alimentarius Feedback," which begins on page 497, is by *J. Bryan Stine,* Director of Quality Standards and Regulatory Compliance, Kraft Foods Division of Kraftco Corporation. The author urges the U. S. Government and industry to air their views at the early planning stages of Codex Alimentarius committee meetings, before standards have been set.

Beginning on page 501, *V. Enggaard* discusses "Problems in Reaching International Agreement on Food Regulations and Standards." Mr. Enggaard is convinced that the most valuable aid to reaching agreement on these regulations is negotiation during committee meetings of the Codex Alimentarius Commission.

Argentina Introduces Mandatory Uniform Food Code.—*Julius G. Zimmerman,* a New York City attorney, reports on the new "Código Alimentario Argentino," beginning on page 506.

Food Product Labeling—The Information Explosion and the Care and Feeding of the American Consumer.—Beginning on page 508, *Peter M. Phillipes* expresses his concern that the wealth of information supplied on food labels can become an unwieldy nuisance. Mr. Phillipes, a member of the New York and District of Columbia Bars, presented this paper at the Fifty-Fifth Annual Conference of the Michigan Association of Weights and Measures Officials at Ann Arbor, Michigan, May 21, 1969.

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Food·Drug·Cosmetic Law
Journal

Food Standardization Past, Present and Future

By WILLIAM W. GOODRICH

This Article and the Two Following Were Presented at the American Council on Foods and Nutrition Symposium on Food Standards in the United States. Mr. Goodrich Is Assistant General Counsel for the Department of Health, Education and Welfare, Washington, D. C.

MY ASSIGNMENT IS TO DISCUSS the past and the future of food standardization from the Government point of view; to explain what food standardization is all about and what we have done and are doing to attain the statutory goals. The importance of the food standardization programs certainly deserves our full attention—and greater efforts from all of us.

Standards for foods—both for man and animal—have been with us for a long time. I could review the history of such standards going back to Biblical times. I could point out that standards historically have related to such things as identity, purity, quality, nutritive characteristics, and economic value, to mention only a few. But I live in the world of today, so I am convinced that a strictly historical discussion would not be helpful.

The earliest food laws of this country and of the countries beyond the seas have addressed themselves to the many sides of food standardization. And the current activities of the Codex Alimentarius Commission tell us that all of the problems implicit in food standardization have not yet been solved.

The Modern Era

The modern era for food standardization in the United States began in 1933 with the first proposals for a comprehensive revision of the Federal Food and Drugs Act of 1906.

Representatives of the Food and Drug Administration (FDA), of the American Medical Association (AMA), and of the food industry all were conscious, from the very first, of the need for mandatory food standards.

FDA's need arose from enforcement difficulties encountered in protecting the public against economic adulteration. AMA joined because of its great concern about the nutritive quality of foods, as well as its continuous interest in a wholesome food supply. And the food manufacturers interest was in fair dealing for its customers and fair competition with other business enterprises.

The road to the passage of the 1938 law was stormy, indeed. But as far as the authority to establish mandatory food standards was concerned, the controversy centered on procedural issues, rather than on the merits or demerits of food standards.

In March 1935, after the revision had been pending for about two years, the President sent a message to the Congress urging enactment of the law. This message featured the need for food standards. The President said:

> Every enterprise in the United States should be able to adhere to the simple principle of honesty without fear of penalty on that account. Honesty ought to be the best policy, not only for one individual or one enterprise but for every individual and every enterprise in the Nation. In one field of endeavor there is an obvious means to this end which has been too long neglected: the setting up and careful enforcement of standards of identity and quality for the foods we eat and the drugs we use, together with the strict exclusion from our markets of harmful or adulterated products.
>
> The honor of the producers in a country ought to be the invariable ingredient of the products produced in it. The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearance with inward integrity. In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently, and producers are handicapped in any attempt to maintain higher standards. Only the scientific and disinterested activity of government can protect this honor of our producers and provide the possibility of discriminating choice to our consumers.

The Federal Food, Drug, and Cosmetic Act was finally enacted in June 1938—and it contained broad provisions to assure the truthful and informative labeling of food products, the sanitary conditions

for food production, and food standardization to promote honesty and fair dealing in the interest of consumers.

The Food Standardization Provision

This latter provision, with which we are especially concerned, directed the Secretary to promulgate standards of identity, quality and fill of container for foods, wherever, in his judgment, such action would promote honesty and fair dealing in the interest of consumers. In promulgating such standards, the Secretary was directed to designate any allowable optional ingredients that should be named on the label. Significantly, grade standards and grade labeling were not authorized. The Secretary's authority with respect to quality standardization was restricted to the establishment of a single standard of quality.

While the food law was being considered, the House Committee Report set out the President's message in full in order to explain these provisions, and pointed to four significant improvements that would offer important protection for the consumer's health and pocket book. These were: 1. Provision to prevent the spread of food contamination with dangerous disease organisms; 2. the elimination of the distinctive name proviso under which debased and cheapened foods were being sold; 3. provision to require reasonable standards of sanitation in the production of foods; and 4. authority to establish definitions and standards of identity under which the integrity of food products could be effectively maintained.

Explaining the bill on the floor of the House, Congressman Chapman said:

> The most important economic provision in this bill is the authorization of standards of identity and quality for foods. Without such a provision the integrity of our food cannot be maintained, nor can purchasers have any definite knowledge of the grade value of the article offered on the grocers' shelves.

That bill passed both Houses of the Congress, but failed of enactment in the final days of the 1936 Session. Finally, in the 75th Congress in 1938, the bill moved to enactment. The final language relevant to food standardization was developed by the House Committee. This was the Committee's explanation:

> Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of

container for food. One great weakness in the present food and drugs law is the absence of authoritative definitions and standards of identity except in the case of butter and some canned foods. The Government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and reputable manufacturers. The housewife makes preserves by using equal parts of fruits and sugar. The fruit is the expensive ingredient, and there has been a tendency on the part of some manufacturers to use less and less fruit and more and more sugar.

The Government has recently lost several cases where such stretching in fruit was involved because the courts held that the well-established standard of the home, followed also by the great bulk of manufacturers, is not legally binding under existing law. By authorizing the establishment of definitions and standards of identity this bill meets the demands of legitimate industry and will effectively prevent the chiseling operations of the small minority of manufacturers, will in many cases expand the market for agricultural products, particularly for fruits, and finally will insure fair dealing in the interest of the consumer.

As a final compromise, the Congress required that food standard regulations, among several other important classes of regulations, be promulgated through formal hearing procedures, subject to judicial review in the United States Courts of Appeals.

Despite a protest in the May 1938 issue of Consumer Reports that called the bill a gross betrayal of consumers' interest, partly because it would put the regulations "at the mercy of the fantastic legal merry-go-round," the bill was enacted and signed into law.

Thus it is clear that the history of the measure in the Congress warned of the difficulties that were to come in its administration.

Establishment of Standards

In the late 30's and early 40's, FDA set to work on the problem of food standardization. Understandably, it first took up standards for jams and jellies, which had been the specific examples noted by the Congress as foods in need of prompt standardization.

About that same time, standard making precipitated the first great economic struggle among ingredient suppliers—a contest between the cane sugar interests and the corn sugar producers. The issue was whether corn sugar should be permitted as an optional ingredient in canned fruits, and whether, if permitted, there should be a requirement that corn sugar be declared on the label.

Secretary Wallace of the United States Department of Agriculture settled the controversy, ruling that the type of sweetener used

need not be specifically named. A court appeal followed in which the Court of Appeals for the Second Circuit sustained the regulations by a holding that the Cane Sugar Refiner's Association was not a person adversely affected. The reasoning was that the regulations did not impose any adverse effect upon the sugar producers—indeed it required the use of sugar in all canned fruits. As the Court put it: "The supposed adverse effect is one which leaves the petitioners' product free of all restriction. The petitioners are adversely affected only in that their competitors are not hampered more."

I note this controversy, and this case, only to illustrate that from the very beginning the standardization program has been a battle ground for competitive interests among ingredient suppliers.

The most significant step in food standardization occurred in the early days—in connection with the standardization of flour and related products. FDA took these products up for standardization because they were basic in man's diet. The standard-making proceeding, in late 1939, began with simple concerns—how much moisture should be allowed, how the fineness of the flour should be fixed, what optional bleaching ingredients should be permitted, how they should be labeled, etc.

But the issue of food enrichment with vitamins and minerals, a practice then in its infancy, entered the hearing. Proposals were made asking the Secretary to permit one or several combinations of vitamins and minerals as optional ingredients in flour and in farina. There was no clear rationale for the proposals—some were based upon the idea that the nutrients lost in milling should be restored; others upon a desire to fulfill nutritive needs of population groups likely to be deficient in one or more of the nutrients.

The late Russell M. Wilder spoke for the Council on Foods and Nutrition of the AMA. After his first appearance, however, Dr. Wilder and others recognized the necessity for a basic examination of the course that food enrichment should follow in the years to come. A recess was arranged, and in the time allowed, the Food and Nutrition Board of the National Research Council was formed. This group then came back to the hearing with further proposals.

When the hearing was completed, FDA established the policy that it was to pursue on this important public health problem. It

decided not to allow the indiscriminate addition of vitamins and minerals as optional ingredients in flour. Instead, it established a standard for flour with no added nutrients and another standard for enriched flour, which was required to contain three vitamins and iron, within established minimum and maximum levels related to public health needs.

Thus, a standard was established for an entirely new food, with an entirely new name, upon the basis of an entirely new rationale that enriched flour should contain the combination of the nutrient additives most likely to be deficient in the diets of large population groups—thus benefitting consumers who were largely uninformed about their needs for vitamins and minerals and unable to make a discriminating choice among a variety of vitamin-mineral fortified flours superficially resembling one another.

Judicial review followed. The Court of Appeals in Chicago struck the standard down as being both unreasonable and unsupported by adequate evidence and by appropriate findings of fact.

The Supreme Court then reversed, holding that the Secretary did indeed have the authority to promulgate a standard of identity that would guard against the probable future effects of the then existing trends in food fortification; a standard which took into account the public demand for vitamin-mineral enriched foods, their increasing sale, their variable composition and dietary value, and the general lack of consumer knowledge about the dietary values. Such standards could and did forbid the sale of an entirely wholesome product. To accomplish the statutory purpose of promoting honesty and fair dealing in the interest of consumers, the Court held that the standard could specify the number, names, and proportions of ingredients, however wholesome other combinations might be.

And so the future of meaningful food standards was firmly established.

Next in our historical review, it should be noted that the war years intervened and the standardization process came to a halt. The War Food Administration required the enrichment of bread—the standardization of which the FDA had begun before the war—and the War Production Board influenced the fill of container for some foods through its control over the allocation of tin-plate.

Continuing the Process

After the war, the standard-making process was picked up again with the bread standard and standards for frozen desserts. Both of these were protracted proceedings, indeed. And, as had been the case with enriched flour, the AMA played a significant role. The major controversy arose out of proposals by the Atlas Powder Company to obtain approval for the optional use of its surface active agents—in bread to make the product softer over a protracted period of time, and in ice cream to serve as a more effective emulsifier. Again competitive companies—interested in selling mono-and diglycerides of fat-forming fatty acids—opposed the Atlas proposals.

The Atlas products also were opposed by the Council on Foods and Nutrition and the National Research Council which offered resolutions viewing the possible toxicity of the surfactants with concern and urging that the emulsifiers should not be approved for use in bread until their safety had been affirmatively established. Upon that advice and other evidence, the Atlas and related products were not permitted. The Court of Appeals sustained their exclusion, which had been based upon a finding that the safety of the products had not been established.

While the promotion of honesty and fair dealing in the interest of consumers was the Secretary's guide in standard making, the Court sustained the decision to exclude the components on the ground that there was no long term experience with the additives, their chemistry was complex and unclear, and their possible toxicity had been viewed with alarm by responsible groups.

These long, drawn-out proceedings gave rise to two important changes in the law—the Food Additive Amendment in 1958 to control in a more direct fashion the use of chemicals of uncertain or unknown toxicity, and the Hale Amendment in the early 50's to simplify the administrative procedures.

The Food Additive Amendment had the effect of removing questions of toxicity and safety from the food standard proceedings. What had been the subject of the most extensive hearings was now regulated under new procedures, emphasizing scientific data review rather than formal, trial type, hearings.

But the Hale Amendment not only failed to solve the critical problem of unduly protracted administrative proceedings, it also

allowed any interested person to initiate the standard-making process. This, in effect, took from the Agency some of the initiative of conducting this important program.

Current Difficulties

The current proceedings to establish regulations to standardize, and to inform purchasers of the value of foods for special dietary use have shown that protracted proceedings will be with us as long as we have controversial proposals, especially where the economic stakes are high. What the FDA is trying to do is make dietary food supplements of vitamins and minerals understandable to consumers by establishing standards of identity for them that will promote honesty and fair dealing, and by requiring labeling on these products that will fully inform purchasers of their value for special dietary use.

Confusing formulations now hamper purchasers in making rational choices, simply because buyers are unable to understand and to evaluate the differences between a multitude of competing supplements, much less to select a product which will reasonably satisfy their own dietary needs. The Supreme Court's opinion in *Federal Security Administrator v. Quaker Oats Co.* sustained the standard of identity for enriched farina on the principles we are attempting to apply to dietary food supplements.

The most controversial issue at the hearing is how to tell the purchaser, on the label of the dietary supplement, what its value is to him.

It is said that there are groups within the population that might benefit from dietary supplementation of vitamins and minerals. Perhaps there are. But the problem is to avoid the exploitation of millions who do not need supplementation, in an attempt to reach the few who might benefit. Vitamins and minerals alone are not the answer to national malnutrition and the problem of malnutrition cannot be extrapolated to support the daily use of vitamin mineral pills and potions.

The simple fact is that the composition of dietary supplements in the marketplace today is so irrational and so confusing that even the most intelligent buyers cannot make a discriminating choice to satisfy any real needs for dietary supplementation. The cost of

these products bears no relationship to their usefulness in dietary supplementation. We have an example of a product priced three times as high as another product of the same manufacturer which differs only in excessive levels of nutrients and in the presence of ingredients which serve no purpose at all in dietary supplementation.

Even multiple vitamin-mineral preparations offered by the largest and most respected pharmaceutical firms have been formulated with little regard to any rational principles of nutrition and dietary supplementation.

There are other examples that might be taken up, but I have talked too long. I might, for example, have discussed with you the issues involved in the labeling of foods with respect to polyunsaturated fats.

But before I close, I must speak briefly on the problems of the present and the future.

Anticipating Problems

Advancing food technology and the increasing sophistication in food fabrication will certainly require standards of identity to promote honesty and fair dealing in the interest of consumers. These entirely new foods and new food processes will be beyond the ordinary consumer's past experience in food selection.

At this very moment, we are in need of standards for diluted orange beverages and substitutes for milk.

Consumers generally are confused about the composition of the dilute beverages that confront them in the marketplace. The orange color and the many additives used to produce these products make it impossible for the purchaser to know exactly what she is buying. There is a need for a better description than "orange drink," or "orange juice drink." A survey among consumers has plainly shown that confusion exists. Dilute beverages sell, in many instances, at about the same price as the 100% orange juice products. But the consumer—and especially the disadvantaged consumer who generally chooses these products on a cost basis—is unable to make a wise buying choice under current marketing conditions.

On June 2, the *Journal of the American Medical Association* printed a statement from the Council on Foods and Nutrition entitled "Sub-

stitutes for Whole Milk." The Council noted that the terminology used in labeling and advertising these products is variable and can be confusing. It said that distinction between the products and dairy products is "blurred because they mimic the organoleptic properties of milk, are packaged in the same type carton, and are found in dairy cases in grocery stores." The statement was issued so that physicians would be aware of these products which can affect both the health and nutritional status of their patients.

An editorial in the same issue states that "the substitution for whole milk represents the dawn of a new day of technological manipulation of foods." And it notes that the speed with which the products will appear in the marketplace will depend largely upon the controls imposed by standards of identity.

Actually, the FDA's initial efforts at control of milk substitutes seem to have drawn the opposition of almost everyone concerned. The producers of the products challenge the "imitation" labeling; the dairy interests oppose the use of the name "milk" in any connection with the products. The important point is that some informative name, other than a fanciful trade name, and some assurance of product composition, are essential if these foods are to satisfy the demands of honesty and fair dealing in the interest of consumers.

Essentials for Consideration

Three essentials clearly emerge for thoughtful consideration. They are:

1. Should the FDA devote a longer percentage of a short budget to food standardization, especially when it is wrestling with major problems of drug promotion.

2. What can and should be done to control the protracted proceedings, the inordinate delays, and the excessive costs of food standardization. There must be a better way of dealing with the scientific and economic issues that standard-making involve.

3. What can and should be done to meet the challenge of the new day in technological manipulation of foods to promote honesty and fair dealing in the interest of consumers.

An effective mechanism must be developed to identify and cope with the new technology before it outruns us all. **[The End]**

Research on Standardized and Nonstandardized Foods in Educational Institutions

By K. G. WECKEL

The Author Is Professor of Food Science at the University of Wisconsin.

IT IS GENERALLY CONCEDED that there is relatively less research interest in food products for which standards of identity have been promulgated than in those for which standards have not been promulgated, either in industry, or in educational institutions, though, of course, this is difficult to establish. There is reason to question whether the system of standards for foods really operates in such a way as to benefit consumers in the use of modern food science. It is proper to evaluate the nature of research in educational institutions on food products to better understand the basis of selection of research programs.

Educational institutions, as organizations, particularly state institutions, have three job assignments: (a) teaching students, (b) undertaking research, and (c) conducting agri-industry extension activities. A well organized college program in food science should be in balance among these activities. Colleges of Agricultural and Life Sciences (as at Wisconsin) are supported in great part by funds derived from state taxes, and thus have allegiance and responsibility to the state taxpayers. In the long pull, the job assignments must be geared to the needs of the state.

Research programs are funded in part by state moneys, and partly by federal and industry sources. The ultimate selection of projects for research study is necessarily determined by a number of factors: (a) pressing needs within the state, (b) availability of student research personnel, and of faculty, with the background training to tackle the research problems, (c) laboratory tools with which to do

the work, (d) availability of funds by which the work can be undertaken, and (e) fortuitous timing in combining the preceding components. In other words, students and professors have capabilities, certain tools are available, or are needed, and funds are necessary. There is an element of timing in bringing these together in initiating the research study. Perhaps fully as important is the stimulation of interest in potential participants to the problem. The affiliation of the institution to the state and its agri-industry problems should be relevant.

Classification of Research

Research may be, and often is, classified as basic or applied, although in the long run it is difficult to distinguish the classifications by arbitrary delineations. There is an inclination to consider food product or food process development or modification as applied science. This tends to delimit the potentials for individuals for such research, since some choose, or have the opportunity, to do research on other types of problems.

It is possible to classify research on food products and food product processes according to the usual designations of classifications within food standards; it is pertinent to note that all foods are regulated in one way or another by community, state and federal authorities. Thus, classifications of development research according to prevailing regulations would be very arbitrary. A suggested categorization would be:

a) Products for which standards of identity have been established.

b) Products for which a standard of identity as a dietary food product have been established.

c) Products for which standards of identity have not been promulgated.

Again, it is pertinent to point out that while many states have adopted the federal food standards, there exist myriads of regulations and laws in various states affecting certain foods, each of which are in effect, standards of identity. There does exist multiplicity in standards, which affects not only decisions on the desirability of undertaking research, but on the potentials of ready adoption of the results of the research.

There is much research done in educational institutions on food products for which standards have been established. Such research generally is for betterment of the products *within the framework* of the standards. Examples are numerous, and a few may illustrate the point: genetic-horticultural development of new shapes and improved

quality of carrots for canning and freezing: uniformity in shape, diameter, length, concentration of carotene of the desired alpha/beta ratio, freedom from green shoulder, deep eyes, or rootlets, thin skin to reduce peeling loss, and uniformly maturing for mechanical harvest; or a new thermal process procedure to better retain flavor and color of canned whole kernel corn; the breeding of disease-resistant varieties of crops; the development of more sophisticated and rapid tools for measuring food quality, development of new slicers, cookers, peelers, toppers, fillers, and so on.

There is, of course, research on food products for which standards have been established, but the objectives, by interpretation, would necessitate change in the standards. Examples which may be cited are: mechanization of certain procedures in the manufacture of cheese (some food standards stipulate not only composition, but also the process); development of new forms of evaporated/concentrated milk; butter and cheese sauces for canned vegetables; modified butter, dairy spreads, powdered dry butter, fortified nonfat dry whole milk; preservative processes for smoked fish; stability of frozen egg products, etc.

Examples of research on food products for which identity specifications as normally considered not to exist would be: extraction and characterization of plant leaf proteins, fish proteins, aerosol type foods, enzyme-derived flavor components, heat transfer processes, characterization of sugar degradation, pesticide resistance, functional capability of emulsifiers, stabilizers, modified fats and oils, and so on.

Project Selection

There are a number of factors which must be considered in selecting research projects in universities, other than those previously indicated, in which money is to be invested.

(1) The "publish or perish" requirement is a strong motivational factor in selection of projects. Competition for advancement, and income, is no less in academic circles than in industrial. Competition professionally requires production of stimulating findings, or results that have meaningful potentials to industry. Achievement in educational institutions is frequently predicated upon the nature and intensity of scientific publications. Projects of an applied science characterization should have, in such a framework, potentials for adoption of the results. There must be consideration not only as to whether improvements, whatever they may be, are legally feasible, but also as to whether there is feasibility to acceptance or adoption of the results, legally or economically.

(2) The fabrication or processing of many food products is already geared to large-scale established procedures. Any modification of a process or product which involves or requires change in standards may involve expenses and delay in achieving such changes. A modification of a process may require costly investments in new or modified equipment. For example, the development of a continuous process for the manufacture of cottage cheese, which began actually in beaker scale studies, evolved into the design and fabrication of a process unit capable of producing 2500 lbs cheese/hr, and which has a sale tag price over $100,000. The continuous process of butter manufacture involves equipment which produces some 4500 lbs/hr, and which costs about $40,000/unit. One organization operates about 35 units of this type.

(3) There is, of course, no assurance any research project will lead to positively useful or acceptable results. More often, the negative results become stepping stones to further study. Nonetheless, negative as well as positive results are less useful if the results must lie buried until ramifications of standards are unraveled. Thus, it would seem apparent that research time and dollar investments will be more useful if applied to products for which there is less likelihood of administrative delay.

(4) It should be noted that generally there seems to be little professional achievement in the development of a new process, or product, which by administrative fiat must be identified as "imitation."

(5) There must be some premeditated consideration, in research on foods, of the barrier of having to meet standards of a multiplicity of regulations in cities, states and in interstate trade. This is particularly true, for example, for dairy products. It sometimes appears hopeless to attempt development of new dairy products or processes because of the multiplicity of standards, often of labeling, and of multiple inspections by various authorities. For example, one dairy plant producing products for a several-state area must carry over 200 differently-labeled cottage cheese cartons. Another dairy firm developed an improved form of canned evaporated skim milk, and expended some $10,000 in legal fees to unravel diverse regulations of several states in which the product was to be marketed. The firm now carries two different labels to satisfy the various requirements, necessitating double storage, handling and billing overheads. Although there is well-established information that the normal ratio of fat/solids-not-fat in fluid whole milk may be altered to improve its palatability, or nutritional quality, it would be a Herculean legal assignment to introduce such a product over a several-state area.

Similarly, the marketing of an evaporated milk with a ratio of fat/snf differing from the standards would entail much effort and expense. It is interesting to note there is virtually little published information on the nutritionally optimum fat/solids ratio for milk, or for other dairy products, when used in "modern" diets, yet standards of various hues prevail for these products on other than nutritional grounds.

(6) There can be considerable frustration in the meaning or interpretation given standards which must affect selection of research programs. For example, the definition of Cheddar cheese includes ". . . and the curd is drained, and salt is added . . ." In this, salting of the curd is mandatory. Salt, a gras (generally recognized as safe) item, freely served and used by choice in food throughout the land, self-limiting, is perhaps one of the cheapest of ingredients that can be added to cheese. Its withholding cannot decrease the value of the cheese. But being defined in process, the withholding of salt from this cheese is construed to be in violation, and the cheese cannot be made, nor marketed, even if so identified as without added salt. There is considerable medical inquiry for the cheese without added salt. The identity as a dietary food would be costly because of requirements for this class.

The standards for butter, for example, prescribe not only composition, but also process. This would seemingly identify rather precisely the product. Yet there is confusion somehow in the meaning of the term butter, as defined in the standards. Efforts in development of various types of spreads containing butterfat generally have been construed in semblance of butter, although not so characterized, and wholly different in property. Yet a product consisting of half butterfat and half margarine fat must be called margarine. It cannot be called "butterine" unless identified as margarine. Peanut butter and olive butter seem to be acceptable latecomers. A visit to any grocery in the land will reveal instances of food products which have the word "butter," "cream" or "creme" in the identity name, but which contain neither butter nor cream. Cream sauce used in certain foods often is white starch sauce, yet in the dairy trade, regulations abound strictly defining cream. The market stores are full of cream pies, and creme sandwiches, cream of wheat, or rice, all without cream. Airplanes now serve frequently, with complimentary meals, a "creamer" for beverage, which is not cream. Some "imitation" products in semblance of defined dairy products carry rather prominently on the label the expression "use as cream or milk," "not evaporated milk—cream," a "nondairy whitener." What in the world is "nondairy?"

There is, apparently, much irregularity and inconsistency, and may I say prostitution, in interpretation and use of terms. The consumer is little helped by such confusion; research managers can foresee no encouragement in fruition of the results of research, which should be for better understanding and for benefit to the consumer.

(7) There are other aspects affecting decisions on food research project selection. The numbers of new food products generated annually have been reported variously as several thousand. The tenure of those products which survive in the markets is generally but a few years. Thus, competition in the successful application of results of institutional applied research is great; and difficulty in rational interpretation of standards is a real problem in research. The rapid trend to utilization of foods in the institutional trade also alters the meaningfulness of certain aspects of food standards, since much of institutional food is not served in an original form or state. Standards for foods, many developed with the concept of the nation being on a bread, meat, potato diet, are not meaningful in terms of adequacy of nutrition today. While it may have been feasible to standardize and balance the nutrients in the diet when relatively few major foods comprised the diet, it appears no longer true. It is, in fact, extremely difficult to assess the adequacy of possible diets compounded from the thousands of prepared foods now available. It would seem standards do not achieve nutritional balance in the marketplace.

Mandatory Review

Some 10 years ago, I proposed a mandatory periodic review of the standards program: "Perhaps what is needed in the standards of identity program is a mandatory provision for periodic appraisal of the standards, and of the facts by which the original standards were brought into being."[1] It would seem this is even more pertinent today, even though the then Commissioner indicated the "idea was worth consideration." There is need for some means of preclearance or preconsideration by regulatory authorities of potentials in research on foods which are strictly defined to guide those who must decide whether the research is justified in terms of institutional problems, limits in economic and market acceptance, and the better interests of the consumer. It would appear that foods which are rigidly defined can benefit from potentials of research for the benefit of the consumer.

[The End]

[1] K. G. Weckel, "The Pro and Con of Standards of Identity," 13 *Food Technol.* 547, 1959.

Summary of Symposium Reports

By BERNARD L. OSER

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MY PURPOSE IS TO SUMMARIZE the reports presented at the symposium and to touch upon the highlights.

We've had a most interesting and informative program, starting with summaries of the legislative history of our food standards law and regulations, and followed by a discussion of the problems involved in the operation of the law. There is general agreement that the basic purpose of the food standards provisions, which is to promote honesty and fair dealing in the interest of the consumer, is actually being served. The law unquestionably has helped to facilitate enforcement by avoiding the necessity of establishing the identity of genuine or non-adulterated products each time a question of adulteration comes to litigation. There is also general agreement that to a considerable extent, the food standards regulations have served to protect the public health and to protect the consumer's pocketbook against fraud and misrepresentation. I believe, furthermore, that the major companies in the food industry will agree that food standards, as expected, help to prevent unfair competition by fringe operators, some of whom are unfortunately still in our midst.

These discussions of the food standards law and its implementation have pointed up the fact that since the passage of the food additives amendment, considerations of safety need not be an issue in food standards hearings as they have been in the past. Now it is debatable whether standards hearings are the appropriate means by which the nutritional needs should be established. The Food, Drug, and Cosmetic Act is designed mainly to prevent misbranding and adulteration. Many have questioned whether the Food and Drug Administration (FDA) is actually authorized or is properly qualified

to determine the nutritional status of our population. The events of the past year or two would suggest that it is not.

In relation to the effect of food standards regulations on unfair competition, one must consider the fact that the hearings actually provide a forum for perhaps the most violent kind of inter- and intra-industry competition. Looking back at the very first food standard under the Act involving an intra-industry dispute, which I believe was the ketchup standard, we find that the main issue was to decide whether benzoate should or should not be used in ketchup and, as you know, it was no longer permitted. Subsequently, a conflict arose between the fat and oil industry and the synthetic emulsifier manufacturers which prolonged the bread hearings almost interminably, it seemed. More recently, there have been disputes between the sugar (sucrose) industry and the corn sugar industry, and between the sugar industry and users of artificial sweeteners. So there is unquestionably a strong element of industrial competition directly associated with the development of food standards.

Hearing Procedures

As for the hearing procedure, the papers presented here indicate almost universal realization that something is lacking. The atmosphere which prevails, and thus far has seemed unavoidable, has led not only to cumbersome, time-consuming, and expensive hearings, but what is even worse, to reluctance on the part of many qualified scientists to testify. This reluctance has been manifested not only by industrial and academic scientists, but by some of the Government's own scientists. The suggestion has been made that hearings be preceded by open conferences of experts from various fields at which the subject matter would be previewed by specialists in the areas of nutrition, toxicology, food technology, etc., who might then reach some degree of consensus before a proposed standard would be issued. Just as there are arguments among lawyers, there are differences among scientists. At times, scientists, like lawyers, may be wrong but they are never in doubt. When this occurs at public hearings, it is inevitable that they become inordinately prolonged. Disputes often result from failure of one discipline to understand the technical jargon of another.

This reminds me of the story of the legislator who was making a site visit at a university which was seeking a large government grant. In the course of this visit, he was told that the men and the

women matriculated together. Up went his eyebrows. His informant added that men and women shared the same curriculum and his eyebrows rose even higher. Finally, when he learned that the women students had to show their theses to the male professors, he said "By God, I won't give them a cent". And so, the failure to understand technical terminology is not restricted to laymen, but is shared by law makers as well.

The suggestion has been made that "so-called experts"—there always seems to be a tendency to precede the word "experts" with "so-called"—but in any case, groups of experts representing the pertinent disciplines, (for example, the American Medical Association's (AMA's) Council on Foods and Nutrition, the National Academy of Sciences-National Research Council (NAS/NRC) Food and Nutrition Board, the Society of Toxicology, the Institute of Food Technologists, and the Food and Drug Law Institute), ought to take part in symposia and conferences to decide what ought to be included in a proposed standard. Such proposals could then be submitted to consumer groups, to industry groups, and to the Government for consideration prior to holding public hearings, if these should be deemed necessary.

Several of the participants in this conference have discussed the hearing on special dietary foods from the viewpoint of their inordinate length. The question has also been raised of whether the hearing should have continued in the light of the changing policies promulgated by the Food and Nutrition Board of the NAS-NRC and the AMA Council on Foods and Nutrition with respect to food enrichment and fortification. The liberalization of their joint policy is not reflected in the proposals of the FDA. Furthermore, the newly revised recommended dietary allowances, which appear to many nutritionists to have a fundamental bearing on the labeling of foods for special dietary purposes, were also considered by the hearing examiner not to be of sufficient importance to justify postponing the hearings.

Labeling Requirements

On the matter of labeling, the question has been raised as to whether current labeling requirements are, in fact, informative to the consumer—the ordinary consumer—as distinguished from the "informed" consumer. For example, ingredient statements often are required to go beyond the declaration of the basic food components

and actually to name chemicals whose identity and purpose are rarely understood, even by educated consumers. Labeling should contain what consumers need to know, but merely listing the names of chemicals in an ingredient statement tends to derogate the product and to discourage its use. There are some expert ladies present here on whom I have tried such terms as butylated hydroxianisole, or calcium propionate, or mono- and diglycerides. They don't know what these terms mean and I can't blame them. Even chemists who are not especially knowledgeable in this particular field might not be able to identify such products and the functions they serve.

I believe there is strong sentiment in favor of functional labeling of foods. Mr. Goodrich referred to the fact that this was not provided for under the federal statute.[1] Nevertheless one does see labels stating that a food contains calcium propionate "to prevent mold", or an antioxidant "to protect against rancidity", or mono- and diglycerides "to preserve freshness", and so on. This is functional labeling and would be sufficiently informative even if the name of the chemical substance were omitted. The label could simply state that the food contained a "permitted additive" to perform the declared functional role. Actually, the statute itself has established the precedent for functional labeling since it provides that the presence of artificial flavoring or artificial coloring be declared without actually specifying the identity of these components.

Effect of the Codex Alimentarius

We heard some discussion of the Codex Alimentarius, which had its origin in the effort toward harmonization of the food laws, particularly in the Common Market countries. Variations in the food laws among these countries have operated as trade barriers or "hidden tariffs". Incidentally, the Codex Alimentarius Commission has issued a proposal favoring functional labeling where the identity of the ingredient need not be disclosed for the purpose of informing consumers; in other words, where omission of the chemical name would not misinform consumers.

One important aspect of the Codex Alimentarius that ought to be considered here is that its development in Europe has a very important feedback effect on the U. S. Standards that are proposed or

[1] See Goodrich, William W., "Food Standardization Past, Present and Future," page 464 of this issue.

adopted under the Codex affect trade with these countries. We may, therefore, have to do something about conforming to Codex standards when they differ significantly from our own. Rules concerning the use of food additives can be expected to be even more rigid than in this country. Outside the U. S., food additives are not given the benefit of recognition of safety based, among other things, on long experience in use. In this country, there are hundreds of food additives in use that have been recognized to be safe without having been fed to rats.

Another and perhaps an even more cogent point is that many countries, including particularly the developing countries, do not permit the importation of foods which fail to meet the standards of the exporting countries. We Americans live in a highly industrialized society with almost unlimited resources insofar as refrigeration, freezing, transportation, etc., of foods are concerned. We can afford to adopt strict standards, for example, with respect to microbial content, or the use of preservatives or antibiotics in foods. But in other countries where these resources do not exist, I think there is sound justification on nutritional grounds, if on no other, to permit the use of preservatives or methods of processing that we would not allow. Consequently, international harmonization or uniformity of food laws has certain limitations in the world as it exists today.

A further point to remember about these developing countries is that they adopt food laws more readily than they are able to enforce them. The proper administration of food laws is expensive and many countries cannot afford this luxury. As a result we find that in certain countries, food laws are applied to imported items mainly as a restrictive measure to protect their own industry or agriculture.

The Need for Periodic Review

The need for periodic review of standards has also been discussed. I think that we all agree by now that the applicability of standards and their effectiveness in operation needs to be reviewed from time to time in the light of changing food supplies and manufacturing practices. We now have increasing varieties of prepackaged foods, convenience foods, frozen foods, freeze-dried foods, and methods of producing them that do not comply with present standards. In the coming years we will have entirely unprecedented types of foods, foods not customarily included in human diets, such as microbially produced protein concentrates. It would be unfortunate if our standards become so rigid and the attitude toward the intro-

duction of new foods so conservative that they discourage research and development in these areas. Standards ought to be adapted to consumers' needs and wants and should be modified with changing social and industrial conditions. Not only should standards be reviewed, but the greater need right now is for a reappraisal of the entire standards-making process.

I heartily support the idea that, in the light of its increasing responsibilities, more support is needed for the FDA. Moreover, something should be done to make work in the FDA more attractive to high level scientific personnel. It is not news for me to say that during recent years the image of the FDA has deteriorated considerably and this has been accompanied by numerous resignations and reorganizations. There is still a great deal of uncertainty and confusion within the FDA as to where it is headed. One approach toward remedying this situation would be the review of the entire operation of the Food, Drug, and Cosmetic Act and its administration by a properly constituted Citizen's Committee. This has been done in the past. Bearing in mind that some thirty years have elapsed since the '38 Act was passed, and that in the interim a number of amendments and adjudications have been made, perhaps it is time to consider a more thoroughgoing reassessment of the law and regulations in the light of current needs.

Conclusion

In conclusion, I hope you will not say of me what was said of Bertrand Russell by Whitehead, namely, that he was grateful for the unequalled skill with which he left the darkness of the subject unobscured. **[The End]**

DRUG LABELING REQUIREMENTS PROPOSED

The FDA has issued a proposed statement of policy on the format and sequence of the labeling information required for prescription drugs used in humans. Labeling information would appear in the following order: description, actions, indications, contra-indications, warnings, precautions, adverse reactions, dosage and administration, overdosage (where applicable), and how supplied. Any special warnings which should be called to the attention of a physician for the safety of patients may be required to appear conspicuously at the beginning of the labeling.

CCH Food Drug Cosmetic Law Reports ¶ 40,359

The Likely Impact of International Standards for Foods and Food Ingredients on "Hidden Tariffs"

By MICHAEL F. MARKEL

This Paper and the Following Three Were Presented at the Institute of Food Technologists' Symposium on International Feedback and Good Manufacturing Practices. Mr. Markel Is a Partner in Markel, Hill & Byerley, a Washington, D. C. Law Firm.

MANY OF YOU HAVE had occasion to complain that some of the food laws and regulations of other countries, presumably intended to protect consumers against frauds and health hazards, have really been motivated by domestic trade considerations calculated to protect domestic commodities against competition from imports. Like complaints have also been voiced against some of our own laws and regulations.

Protection of domestic commodities against competition from imports is ordinarily achieved by adoption of tariff laws, often negotiated between the countries directly involved by reciprocal bargaining. On the other hand, food laws and regulations similarly motivated and which have a corresponding impact on international trade are invariably adopted without benefit of bargaining to the countries whose industry is adversely affected by these laws. They are, therefore, "hidden tariffs" in their effect.

Examples of such laws and regulations, which serve to exclude U. S.-approved foods from foreign markets include the banning of: ascorbic acid in moisturized prunes; diphenylamine to prevent mold in apples; antioxidants in fats and oils; sulfites in dried fruits; sulfur

dioxide in bleached raisins; synthetic emulsifiers in dried eggs, baking mixes and other foods; sodium benzoate in fruit cake; certain ingredients in baby foods; potassium citrate and carrageenin gum. These are but a few examples in the area of food additives, the most common source of trade barriers. Many countries also adopt standards of composition of processed foods; that is, standards of identity, similarly motivated and of like impact on international trade in foods.

The adverse impact on foods marketed internationally is readily apparent from the cited examples. Experience has shown that such impact becomes progressively more acute as advances in food technology are made. The enormous strides in advancement of food technology made during the post-war years finally created a situation so serious that many governments recognized that something had to be done about it.

The Codex Alimentarius Commission

On the occasion of the organization of the Codex Alimentarius Commission, the need for such a body was demonstrated dramatically by a compilation of various bodies and groups, including government agencies, quasi-governmental organizations, international trade associations, and others, all engaged in drafting standards and preparing lists of approved food additives and pesticide chemicals. The list of such bodies compiled by one of the members of the U. S. delegation numbers 135. There was no well-coordinated communication between those whose activities overlapped. Therefore, it became evident that some organization which could function on a government-to-government basis was required to deal with the problem. Organization of the Codex Alimentarius Commission in 1962 was the result.

While the purposes of the Commission were stated to be the protection of the public health and protection of the public against frauds, the promotion of international trade in foodstuffs and the need for eliminating trade barriers implicit in existing divergent food laws and regulations were stressed again and again by most delegates to the organizing meeting and at succeeding meetings. The hope was voiced repeatedly that the adoption of standards by this international body would promote greater uniformity in regulatory requirements by various nations and eliminate many of the indicated trade barriers.

Approximately sixty countries are now participating in the work of the Commission. A number of standards have reached the final stages in Commission procedures and will soon be sent out to the various governments for adoption. Lists of approved food additives and pesticide chemicals are also being issued and updated as fast as the respective committees can reach their final conclusions. The lists and the establishment of these standards should go a long way in promoting uniformity among nations in regulating the production and distribution of foods. This, in turn, should eliminate many of the trade barriers which have come to be characterized as "hidden tariffs."

Adoption of Codex Standards

The extent of success in eliminating these trade barriers will necessarily depend on the extent of adoption of the Codex standards by the participating countries. Of necessity, the Commission standards are only advisory because the participating governments are the only ones who can adopt standards for their respective countries which have the force and effect of law in their jurisdictions. It would be too much to expect that all participating countries will readily adopt all of the Commission standards. Indeed, it would be too much to expect that even acceptable provisions will be adopted promptly by many participants because of their specific requirements for adopting such standards.

This certainly will be the case in the United States, since our laws prescribe specific procedures for promulgating regulations of the type adopted by the Commission. Therefore, any Codex Food standard for which a U. S. standard exists cannot be adopted until an amendment of the U. S. standard conforming to Codex standard is in effect. Where we have no regulation, the procedures for promulgating standards, or food additive or pesticide chemicals regulations, will have to be followed. No doubt a similar situation prevails in many of the other participating countries.

Notwithstanding these difficulties and inevitable delays, the adoption of food standards and food additive and pesticide chemical lists by an international body including so many participating countries should go a long way to eliminate many of the hidden tariffs. Any country is bound to find it much more difficult to justify excluding a food from its territory because it contains an antioxidant or emulsifier, for example, which has been found to be suitable and safe for use by the world body of which it is a member.

The Problem of Disparate Requirements

A more difficult problem will be posed by regulations adopted by a country which are not based so much on considerations of protecting domestic foods against imports, but rather on the kind of standard deemed necessary to insure the economic integrity of a food compatible with the standard expected by its consumers. For example, the existence of standards of identity which are higher in their requirement of composition than the Commission standards would make it difficult for a country which has higher standards to lower them in the interest of promoting international uniformity. This is the category in which the United States is likely to find itself in most instances of standards of identity. For example, take our standard for preserves, the commodity which was the prime example before Congress to demonstrate the need for administrative food standards. The specified minimum fruit content for preserves in the standard is forty-five percent. To the best of my knowledge most European preserves contain considerably less fruit. One can readily imagine both consumer and industry reaction should the U. S. Food and Drug Administration come out with a proposal to lower the fruit content with a corresponding increase in the water content of fruit preserves in order to promote international uniformity. It is quite obvious that it will require considerable "give and take" on the part of various participating countries in order to promote substantial international uniformity. Just how much of such give and take participating countries are prepared to proffer in the interest of international uniformity remains to be seen.

Apart from commodity standards, however, the inclusion of ingredients such as food additives in such standards and adoption of approved lists of food additives and pesticide residues should go a long way to eliminate many of the hidden tariffs. The approval of specific ingredients for use in a given food for which the Commission has adopted a standard is bound to promote substantial uniformity in the most troublesome area, regardless of the standard of composition for that food. The exclusion of food additives from various foods, including additives allowed in some foods but not others, appears to have been the greatest source of the difficulties. Since substantial uniformity in their use can be achieved by adopting lists of approved additives and including them as optional ingredients in Commission identity standards, we may look for significant easing of the problem as the work of the Commission progresses.

Impact on Administrative Policy

Many people ask, and some have expressed concern, about the likely impact on administrative policy in the administration and enforcement of our own laws, which might be expected from adoption of a give-and-take policy. I am sure the same is true of members of the regulated industry in most participating countries. As I have already indicated, the degree of impact will depend in a large measure on how much the participating governments are prepared to give and take.

I believe the interest of our regulated industry will be best served in the long run if our officials adopt a realistic policy when they consider adopting Codex standards. By a "realistic policy" I do not mean to suggest that required health measures and demonstrated needs for protecting consumers against frauds be compromised in the least on the excuse of promoting international uniformity. It may be that different treatment in certain details will be required in different parts of the world.

I do mean that in balancing considerations of consumer idiosyncrasies, food-faddism, esthetic factors, and economic considerations which do not bear on consumer frauds against the benefits to international trade derived from greater international uniformity, no greater weight be given to the former than they realistically, and not politically, deserve.

Impact on Domestic Laws

The adoption of Codex standards will, by any realistic balancing of pertinent considerations, have a direct impact on domestic laws and regulations, since any meaningful international harmonization of standards is bound to require raising of some standards and lowering of others. However, since any standard adopted by the Commission is bound to include adequate protection against health hazards and fraud, the adjustment in domestic standards will invariably involve a compromise only in revising provisions based largely on quality or esthetic factors. Nothing of any serious consequence will be sacrificed if consumers are left to exercise their preferences in quality by selection.

Some of our existing identity standards, especially those for fabricated foods, do provide opportunities for some relaxation which will, no doubt, become necessary if Codex standards for those foods are to be adopted. Many include provisions which are based more

on quality or esthetic factors than on a demonstrated need for maintaining the basic economic integrity of the standardized food. I shall not cite examples which come to mind. It will suffice to suggest that members of the industry be realistic, should amendments ever be proposed which may make it easier to import the standardized foods. Tariff laws are the remedy where protection against imports is needed.

In the area of food additives and pesticide residues, there will be more occasions to take rather than to give. The reason for this is that many countries, particularly European countries, are much more conservative in their approval of food additives and use of pesticide chemicals, than public health considerations warrant. Many of the food additives approved for general use in the United States are not approved abroad for similar uses. It is hoped that active U. S. participation in the Commission's activities will provide the leadership needed to effect some easing in what appears to be an extremely conservative attitude towards use of food additives and pesticide chemicals.

Leadership Role of the U. S.

It is well understood by our delegates that the one thing not to do is to tell others how we do it in the United States. On the other hand, knowledgeable members of the delegations of other participating countries are well aware of the fact that far more toxicological and functional data are available in the United States than any place else. These delegates say that few food processors in their country could afford to undertake the extensive investigations required to qualify food additives and pesticide chemicals for use under the United States laws. It is because of this recognition by many delegates that the members of the U. S. delegation will have the unique opportunity to provide much-needed leadership to the Commission meetings, but more particularly to meetings of the various committees active in this area. It is also for this reason that the regulated industry should see to it that our government delegates are provided with all available information and data when they go to these meetings.

In all events, adoption of a realistic policy of give and take by the participating governments in a spirit of cooperation is vital to

the success of the Commission's work. If adoption of the standards becomes stalled to a point where only an insignificant number of participants will adopt them, then the whole concept of dealing with the indicated problems on a government-to-government basis through an appropriate international body will fall on its face.

The one point which needs stressing is that it is important that the U. S. Government continue to participate actively in all of the Commission's proceedings. It is also important that members of departments charged with the administration and enforcement of our laws and regulations in this area be the participants. These would be the Department of Agriculture and the Food and Drug Administration of the Department of Health, Education, and Welfare. It should be stressed also that the personnel representing the United States, both at Commission meetings and at committee meetings, be persons who have had extensive background in the administration and enforcement of our laws. We are far advanced over most other countries in the area of regulating production and distribution of foods and should provide the benefit of long-time experience to the work of the Commission.

The Industry's Stake

The U. S. regulated industry has a great stake in the work of the Commission, and it should make it its particular business to see that our Government is represented by the two departments, and that adequate funds are made available to both agencies to enable them to function effectively. Industry should do all it can to see that no cutbacks in this work be made in the name of need for Government economy. The food industry's stake in the Commission's work is even greater than the stake of industry generally in the General Agreement on Tariffs and Trade negotiations since the Codex will affect not only international, but also domestic, trade. It should be pursued with like attention and equal vigor. It is only in this way that hidden tariffs can be minimized to the greatest possible extent. **[The End]**

International Food Standards— What Trade Associations Can Do

By MALCOLM R. STEPHENS

Mr. Stephens Is President of the Institute of Shortening and Edible Oils, Inc., Washington, D. C.

There are many objects of great value to man which cannot be attained by unconnected individuals, but must be attained, if attained at all, by association.

—Daniel Webster

THIS MAXIM IS PARTICULARLY PERTINENT to the role of the food trade association in the establishment of international food standards.

As you all know, the United States is an official member of the Codex Alimentarius Commission. Any international standard which survives the perilous journey through that Commission must therefore be seriously considered by our Government for complete or partial adoption in this country.

Other international organizations are also undertaking attempts at standardizing the regulation of foods. You are all familiar with the Latin American Food Code, and with the work of the Common Market and the Council of Europe. Although standards adopted by these bodies may not directly affect the United States, they will most certainly affect our food industry by controlling exports. These other international standards may also have a significant influence on the Codex work, and therefore eventually on internal United States regulations.

It is thus readily apparent that the United States food industry has a substantial stake in the development of international food standards and regulations. Its foreign markets, and perhaps its own domestic markets, can be vitally affected by these standards. No industry can afford to sit back and ignore these international developments.

It is therefore not a question of whether the food industry should become actively involved in international standard organizations, but simply one of how they should approach these matters.

The likelihood of an unorganized industry participating actively and effectively in an international food standard program is remote, at best. Individual companies obviously do not have the same depth of resources as an entire industry, nor can they purport to speak for the industry as a whole. Only an industry-wide organization—a trade association—can truly represent its industry in a persuasive and convincing manner.

I would break down the responsibilities of a trade association in representing the industry in the establishment of food standards, into three related activities. The first is education and leadership of its own members. The second is the job of gathering together all the technical industry information and the task of formulating a responsible industry position. The third and final responsibility is to pursue the matter with other industry representatives throughout the world, and with the international standard-making organizations, to make certain that reasonable regulation emerges. I shall discuss each of these functions briefly.

Educating the Membership

The importance of international food standards is not always readily apparent to the small United States food manufacturer. The phrase "Codex Alimentarius" sounds foreign anyway, and the fact that most meetings are held in Geneva, Rome or other European cities makes the entire matter seem even more remote. The first job of a trade association, therefore, is to educate its own membership about these matters. Once explained, the enlightened interest of the industry should be sufficient to carry the project forward.

Some industry members may conclude that the official United States representative to these international organizations is sufficient to protect the United States interest. As a former Government official, however, I can testify to the fact that the Government does not always have the detailed technical knowledge available within the industry, and is not always aware of the advances in food technology being planned by individual companies. Thus, there is no adequate substitute for participation of the industry directly through its trade association.

Formulating a Position

Once the industry is properly motivated to participate in the establishment of international food standards, it must begin to gather the technical information available within its membership and to formulate its position on the issues presented by such standards. It is basic that a trade association's work must be in the broad public interest. It cannot otherwise survive. It is therefore apparent that the goal of international standards—to protect the consumer and to promote world trade—are completely consistent with the goals of sound trade associations.

An effective trade association has immediately available to it a reservoir of technical and scientific data. This is made possible through the use of productive association committees made up of top quality scientists and technologists whose pooled knowledge undoubtedly far surpasses anything that could be gathered together by a single firm or Government agency.

Within an industry, however, there may well be differences of approach and opinion. I would be astonished, as well as dismayed, if our food manufacturers all made the identical product in the same way. It is inevitable, therefore, that the establishment of any standards, whether international or national, will result in differences of opinion within the industry. These can most effectively be thrashed out in an effective trade association, where all viewpoints can be accommodated in a single comprehensive industry position.

International Participation

Once this position is determined, it is the responsibility of the trade association to disseminate it throughout the world, and to pursue the industry's interest before the pertinent international organizations. In many instances, liaison can be established with trade associations in other countries, to achieve a common objective.

As you know, the United States official representatives have consistently requested that industry representatives advise and accompany them to subcommittee or full Commission meetings. There is an old axiom that prior planning facilitates all tasks. With good advance coordination and planning between Government and trade association representatives, those subcommittee and full Commission meetings can be approached with considerable confidence. Nevertheless, in spite of all the good planning done in preparation for such meetings, the unanticipated often does occur. Our govern-

ment representatives have consistently demonstrated their expertise in handling unanticipated and perplexing questions from the floor. I think it fair to say that some of this success is attributable to the presence of industry advisors from trade associations, who can immediately supply detailed technical background and judgment on these matters.

The trade association also serves as an efficient communication medium to keep the industry informed about international developments, and to obtain any necessary data from the industry for its governmental representative or the Commission itself. By channeling this information through a trade association, it can be certain that the information will in fact be relayed, and that the job will be done.

Thus, I think it is clear that trade associations make an indispensable contribution toward the development of technically sound and workable international food standards regulations. Indeed, without a coordinated industry-wide participation through trade associations, it is highly doubtful that the basic objectives established for these international standards could ever be achieved.

[The End]

FDA SETS EVIDENCE RULES

The FDA has issued new regulations stating the essential elements of investigations by drug manufacturers required to provide substantial evidence that a new drug or antibiotic is effective. These are: (1) a clear statement of the study objective; (2) a method of selecting patients for drug trials that indicates they have a disease or condition that the test drug is intended to treat; (3) an outline of methods for observing the frequency and kind of responses of patients to drugs tested; (4) a description of how differences among patients have been documented and compared; (5) a description of how differences in patient response have been recorded and analyzed and how investigator bias has been minimized or eliminated; (6) a precise statement of the nature of the control group against which effects of the new drug have been compared; (7) a summary of statistical methods used in analyzing data derived from patients.

The regulations also provide that application for a hearing on a proposal to deny or withdraw approval of a new drug or antibiotic will be denied if the application does not state a full, factual analysis of the data available to support claims of effectiveness.

Reg. §§ 130.12, 130.14, and 146.1, CCH Food Drug Cosmetics Law Reports ¶ 71,312, 71,314, and 74,251.

Codex Alimentarius Feedback

By J. BRYAN STINE

Mr. Stine Is the Director of Quality Standards and Regulatory Compliance, Kraft Foods Division of Kraftco Corporation.

I WAS ASKED TO DISCUSS Codex Alimentarius feedback and what it means to the food industry in the United States.

In general, I think we can classify the feedback that comes from Codex Alimentarius in two ways: first the standards themselves and their effects on the U. S. industry and standards making in this country; and secondly, the reliance on Codex Alimentarius thinking and its effect on future regulations within the United States affecting industry.

At the Sixth session of the Codex Alimentarius Commission which was held in Geneva, Switzerland in March of this year, over 30 provisional standards were passed by the Commission and are to be sent out by the Secretariat to various member countries for acceptance. The United States has been very active in the formulation of most of these standards and of course is very active in all United Nations' work. The world will expect us to take positive action one way or the other on these standards, and since we have been so active in both committee and commission work of Codex Alimentarius, we will be expected to adopt them wherever possible. With the standards coming out for adoption this year, our Government must get set to receive them and consider the true meaning of acceptance.

As you probably know, there are several levels of acceptance and I won't go into the details of each of these levels or their meaning, but I will simply say that a nation can either accept a standard in whole or with minor deviations or reject the standard giving the reasons for rejection. Under our rule-making procedure in the United States, definitions and standards for food products are the prerogative primarily of the Food and Drug Administration (FDA), and they are in no position to accept or reject a standard without

going through the usual procedure of publication, asking for comments, holding a hearing when necessary, and so forth. With 30 standards coming out this year, if our FDA is going to make a positive statement of acceptance or rejection, it will be necessary for them to submit these standards to industry and it hardly seems possible that industry will or could accept wholeheartedly the Codex Alimentarius standards without a great deal of comment.

The Codex and U. S. Standards

Of the standards coming out of the Commission meetings this year, the margarine standard probably comes nearer to being in complete conformance with our own standard than most any other one. Assuming that the Food Additives Committees give their approvals for the food additives requested in margarine, then the margarine standard as passed by the Commission will be generally acceptable by the United States—except for one major difference. It generally meets the U. S. definition and standard; however, this one deviation from our standard requires margarine to have a maximum of 16% moisture. This would almost block the margarine standard in the United States if I am not mistaken. The FDA will be obligated to send out this standard for comment and in light of comments they probably will accept the standard quite generally with the moisture deviation not applying in the United States. The Commission could consider the deletion of this provision in the United States a minor change and allow it or they could consider it unacceptable and a major deviation. In the latter case, all that the United States could do would be to reject the Commission's entire margarine standard.

There are a number of other standards coming through this year and in future years for food products for which we already have a standard and I'm certain the Codex Alimentarius standards will most invariably contain a few points which are different from our own. These will require some sort of change before we can officially accept them, for, when we accept a standard, the FDA automatically takes the position as the enforcement agency for the standard and any product that meets the Codex Alimentarius standard then can move freely in trade within the United States, and domestic production will be required to meet the same standards as imported product.

The Codex Alimentarius Commission is working on standards and a number are coming out for acceptance or rejection this year on products for which we have no standards at all. What are we

going to do about these? Is the FDA going to simply reject the standard because we do not have one and consequently they are in no position to enforce a standard on the product itself, or do they plan to rewrite it in the United States format and send it out to American industry for comments and acceptance or rejection? It almost goes without saying that any Codex Alimentarius standard sent out for comments by the FDA will be objected to in some regard by our industry because we can hardly expect them to agree 100 per cent in all respects with the international standard. If the FDA is to proceed along these lines for the many products for which we have no standard, then industry can expect tremendous activity in the next few years in the Food Standards Division of the FDA, and we can expect standards to be developed on many products for which we have none. As far as I have been able to ascertain, the FDA has not as yet organized themselves to handle this tremendous amount of additional work, if they are going to attempt to do it.

With the 30 plus standards coming out this year, and probably a similar number coming each year in the future, we, as representatives of the food industry, are going to be required to study and evaluate and work to get the government either to accept or reject a tremendous number of standards, some of which we may not even feel we need. Sometimes it may be just as important to see that our government rejects a standard as to see that they accept one.

Food Additives

Besides the standards themselves that will be forthcoming from Codex Alimentarius, I think we can look forward to a great deal of feedback in many regards other than food standards themselves. As an example, the governing bodies of Europe take a much more conservative approach on food additives than we do. I think this is largely because the convenience and pre-prepared foods which are so common in this country are just now coming into their own elsewhere and the industry and the governing bodies of Europe have not been faced with the requirements for additives and preservatives. With this more conservative attitude on food additives, it is absolutely necessary that our industry and government representatives at Codex Alimentarius committees put forward a good story on food additives and preservatives where we know them to be safe, otherwise the sheer weight of numbers of the European countries will outweigh our desires and some of these additives will not be permitted.

Also, we can expect our government to rely upon certain activities of Codex Alimentarius expert committees or the Commission

itself for precedence to be used in formulating our own regulations. A good example of this is the recent proposed cyclamate regulations. You will note that the FDA relied upon the World Health Organization and the Food and Agriculture Organization (WHO/FAO) Committee of Government Experts on Food Additives for the recommended level of cyclamates in food. As you will recall, the WHO/-FAO committee recommended 50 milligrams per kilo of weight for adults, whereas the National Academy of Science, which would have been the normal source of information for the FDA, placed this figure somewhat higher at approximately 70 milligrams per kilo of body weight. The FDA relied upon WHO/FAO and not the National Academy of Science and consequently we have the present set of proposed regulations which permits cyclamates at the substantially lower level. This is simply one example of our government relying upon Codex Alimentarius for information and in this particular case we got a lower level of cyclamates than we would have had we relied upon our own body of experts. I'm not going to take a position on what is the proper level for cyclamates because I don't think this is the point of my discussion, but it does point out the necessity for experts within the United States to be heard in Codex Alimentarius committees and give the committee recommendations as accurate and as complete as possible because you can never tell when one of the Codex committee recommendations might be relied upon as authoritative and be used in our own rule-making by our own rule-making bodies.

Now that we are beginning to get feedback from Codex Alimentarius as a result of the active participation of the United States in Codex Alimentarius committee and commission deliberations, we must get ourselves lined up to take this feedback and utilize it or be prepared to reject it in the best manner. This can only be done by active participation on the part of our government and industry experts in the evaluation of the material coming from Codex Alimentarius before it becomes a part of our regulation. Of course, the best way to get the most favorable feedback is for the food industry to participate actively in drafting the work, at committee levels, of the Commission so that the feedback coming into the United States will be as favorable to our position as possible. I cannot urge the people in this room too strongly to get into Codex Alimentarius committees as far as the products in which they are interested are concerned and be heard at the early stages rather than wait until adverse standards are set up and submitted for acceptance.

[The End]

Problems in Reaching International Agreement on Food Regulations and Standards

By V. ENGGAARD

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BEFORE TRYING TO ANSWER THE QUESTION of how to harmonize food laws, I think it advisable to have a short look at some of the national food laws to discover what the differences are which should be overcome.

If we take two extremes, it will become evident that food laws in older countries very often have their origin in a formerly accepted "national good manufacturing practice" and some of the provisions from that time may still remain, and even be brought into force if found necessary. Most of the law comprises provisions which have been added when necessary, and some may have been appropriate only under certain conditions which no longer exist. The whole content of such a law may be so complex that even a court will have difficulties interpreting it.

Other food laws of more recent date are usually more clear in their composition, but often contain so many extensive provisions that the necessary agencies for enforcement are not available. In such cases one may find that some provisions are enforced at one point of entry and other provisions elsewhere.

In addition to the basic differences which arise from these two types of food laws, differences also exist in the individual food laws

which result in different provisions. This is evident particularly with respect to the provisions concerning food additives such as colors, flavorings, preservatives, emulgators, curing agents, etc., which simply constitute a jungle.

A few years ago Public Analyst Mr. Th. McLachlan of London made a comparison of permitted coloring agents in food of forty-five countries. The result was that no one synthetic food color was accepted universally; all had been condemned by one country or another, although each country had a list of twenty to thirty permitted colors. These circumstances create an embarrassing situation in the international food trade today, mainly for countries depending on export of food, whether raw material or processed food products.

Denmark, for instance, today exports meat products to approximately 150 different countries. This means that we not only have to keep ourselves up-to-date on the food laws in a great number of countries, but further, that products with the same name must be manufactured differently depending upon the intended market.

To give an example of this, luncheon meat for the United States market must not contain any binders, whereas in the United Kingdom, luncheon meat is, in their recent regulations, defined as a meat product where the principal ingredient by weight, other than meat, is cereal. Similar differences in composition force the manufacturers either to produce small lots or to keep big lots in stock pending the next order for that certain composition. Neither of these alternatives facilitate the international trade or make the product cheaper for the consumers.

To assist the manufacturers and the trade with regard to food additives, in 1956 the Food and Agriculture Organization (FAO) undertook to issue a monthly publication, "Current Food Additive Legislation," which summarized different countries' legislation in this respect. Difficulties in getting information from countries in time constituted a severe problem for the FAO, and the information was sometimes history before it was translated and published. Today it seems that this information is more valuable for persons concerned with food legislation than for the trade, where changing lists of food additions often hamper it.

Eliminating Trade Obstacles

Trade obstacles due to varying food laws are not of recent date and efforts to harmonize them go back before this century. Especially

in the 1930's, several international organizations were actively influencing agreements in this respect, but despite the fact that one-fifth of the world trade at that time was in food, the time did not seem ripe for harmonization of the food laws. After the Second World War, a still-increasing international food trade made more nations realize the need for removal of the trade barriers contained in the different food laws.

The International Dairy Federation, founded in 1903, speeded up their work on standards for dairy products, and with support from the FAO the elaboration of the "Code of Principles for Milk and Milk Products" was initiated in 1956. Since then a great number of standards have been issued and accepted by many countries.

Also in 1956, some European countries established the Codex Alimentarius Europaeus on the initiative of Austria. Later this organization was absorbed in the Codex Alimentarius Commission which continued the work on standards already undertaken by the Codex Alimentarius Europaeus, along with the elaboration of standards for other foods.

As the International Dairy Federation, Codex Alimentarius Europaeus and Codex Alimentarius Commission all work on food standards, one could ask whether standards are the best means to harmonize food laws. The answer surely may not be given at this stage, but it should be worthwhile here to consider what the Codex Alimentarius has accomplished until now.

Accomplishments of the Codex Alimentarius

The creation of Codex Alimentarius, the set-up and the standing of the organization, has for the first time in history made it possible to discuss in an international forum of people concerned with food, the requirements applicable to various types of foods. This alone has already had an astonishing effect on countries about to make amendments in their national regulations. Countries often seek information on what has been proposed in the Codex Alimentarius before the final decision is taken, and even in court one can hear quoted discussions from Codex Alimentarius meetings. So far, the mere existence of Codex Alimentarius has added a great deal to an international understanding of the importance of harmonization.

But can the Codex Standards as such add further to this goal? Examining the different activities of the Codex Alimentarius may give the answer.

These activities may be divided into two groups: (1) General principles, codes of practice and the like, which are only of an advisory character. (2) General standards and commodity standards, the provisions of which are mandatory both for imported and domestically produced products when the standard is accepted by a country.

General principles and code of practice, such as general principles for food hygiene, not only serve as a pattern for developing countries setting up food laws, but serve as well as guidance for countries in revising existing food laws.

Each of the general standards cover a certain part of a food law. Under elaboration, for instance, are standards for food additives and pesticide residue, and at the sixth meeting of the Codex Alimentarius Commission, a general standard for labelling was finalized and will soon be sent to governments for acceptance. These general standards contain basic requirements expected to receive a great number of acceptances, and will in consequence thereof, bring some sort of similarity into the food laws of different countries. This is only the first step on a long road which should lead to an extensive harmonization, but nevertheless it may be the most important step, as it will reflect the willingness of the countries concerned to work for a harmonization.

Commodity Standards

Commodity standards are one of the major undertakings in the Codex work and in this context, I should prefer to divide them roughly into two groups: (1) standards for simple foods such as sugars, oils and fat etc., and (2) standards for composite products, where meat products may serve as a good example.

Elaborating standards for "simple foods" should be relatively easy, as these are more or less natural foods which have been refined only, and for some foods given a better keepability by means of safe additives. Standards for such commodities are among the standards at present adopted by the Codex Alimentarius Commission, which to some degree indicate that their elaboration has not been contro-

versial to a high degree. As all countries may be expected to be interested in providing its consumers with products of at least the quality and safety required in these standards, one may also in this respect expect a great number of acceptances of these standards.

The elaboration of standards for composite products is much more difficult, as it usually runs into conflict with national tradition. I mention here only the long and troublesome discussion of a world-wide definition of meat which took place in the Codex Sub-Committee for meat products. It appeared that what is edible meat in some countries is regarded in other countries as strictly prohibited offal.

Similar deviation of opinion appears constantly when the composition of a product is considered. Tradition, religion, state of technology, storage facilities and the like are factors which have to be taken into consideration when commodity standards are elaborated on a world-wide basis. If this is not done the result may easily be either a rather specific standard such as a recipe standard, or a very loose standard without any substance. Neither of these two alternatives will facilitate international trade or serve the harmonization of food laws.

Negotiation—The Key Factor

In the Codex Alimentarius work there are two possibilities for governments to state their views with regard to these factors, either by written comments or by participation in committee meetings. Written comments usually just state a position and seldom give room for deviation. Negotiation during committee meetings seems, therefore, to be a far better instrument in reaching an agreement which can satisfy most countries, and a thorough briefing of the delegate by experts in his homeland together with freedom to negotiate has more than once made a single delegate very valuable.

In saying this, I think that the answer to whether Codex standards can serve as a means to harmonize food laws and facilitate international trade should be affirmative, but I should like to stress that the Codex Alimentarius cannot make miracles. The extent of its work is fully governed by the interest and effort put into it, and by the extent that every country is prepared to give and take.

[The End]

Argentina Introduces Mandatory Uniform Food Code

By JULIUS G. ZIMMERMAN

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THE "BOLETIN OFICIAL" OF THE ARGENTINE REPUBLIC, No. 21.732 of July 28, 1969 published the text of a Law No. 18.284, promulgated by the President of the Republic, and introducing the "Código Alimentario Argentino" (Argentine Food Code) as a mandatory and uniform Food Law for the entire territory of the Argentine Republic, which presently consists of 22 Provinces, one Federal District and one National Territory. Heretofore the Provinces had autonomy in the field of food legislation and had their own Provincial food laws, mostly in Code form, which they will now have to bring in line with the new Argentine Food Code. The Regulations implementing the new Law No. 18.284 are to be issued within 180 days from July 28, 1969.

In 1953 a first step had been taken in the direction of uniform food law in Argentina by way of the so-called "Reglamento Alimentario" promulgated by Presidential Decree No. 141/53. These rules applied immediately only to the Federal District (Municipality of Buenos Aires) and to the National Territories. They also replaced Provincial Food Legislation, but only temporarily, due to Constitutional difficulties. As long as this situation prevailed it was impossible for a food manufacturer in Argentina to distribute a locally approved and registered product in the entire territory of the Republic without also ascertaining compliance with the local Provincial Law.

Throughout the past 16 years, however, the National Government continued to up-date the "Reglamento Alimentario" in cooperation with the Argentine Food Industry, and the text of this "Reglamento," as amended to date, has now been promulgated as

"Código Alimentario Argentino" and will bring about the long overdue uniformity of food law in the Argentine Republic. The publication of the consolidated text of the Argentine Food Code can be expected shortly.

The new Argentine Food Code will be applied and enforced locally by the National, Provincial or Municipal Health Authorities, in their respective jurisdictions (Art. 2). These authorities will cooperate in setting up and maintaining registration records for all products subject to this Code, and in accordance with a uniform system. The National Department of Health will maintain a record of registrations made in all parts of the country (Art. 7).

All products manufactured in compliance with the new Food Code, and which have been properly authorized and registered, may be freely circulated in the entire territory of the Republic, subject only to local check-up and sanitary control (Art. 3). All products which were authorized and registered under Decree 141/53, as amended, may be re-registered upon a simple request by the interested party (Art. 8).

According to Article 4, all imported products must comply with the Code. The same applies to products for export except when:

(a) their manufacture and packaging for export has been specifically authorized by the National Health Department;

(b) they are in compliance with the law of the country of destination; and

(c) they are labelled indicating items (a) and (b) and the name of the country of destination.

According to Article 9 the Penalties for violating the Food Code, this Law and its Regulations are:

a) Fines ranging from Pesos 5,000 to 1 Million (about U. S. $15 to $3,000), which could be increased tenfold in case of repeated offenses.

b) Seizure of the merchandise.

c) Temporary, partial or complete closing of the establishment.

d) Suspension or cancellation of the product registration and permit.

e) Publication of the decision.

In order to help finance the introduction of the new Food Code, a tax of up to ½ of 1% of the wholesale price of locally manufactured products which have been authorized and registered under the new Code, may be levied. The same applies also to imported products, but not to products for export. **[The End]**

Food Product Labeling—The Information Explosion and the Care and Feeding of the American Consumer

By PETER M. PHILLIPES

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UNDOUBTEDLY NO BUYER OF FOODS is better warned, informed and protected by the labeling on the products she selects than is the American housewife. Yet, I dare say that relatively few of these beneficiaries of the recent legislative and administrative overkill in the field of food labeling heed even half of the information provided for their benefit by the much harried manufacturer.

We are truly living in the midst of an information explosion on food product labels. Yet rather than taking advantage of this considerable body of available information in making her buying decision, the American homemaker, spurred on by "Congressmen with a cause," is willing to let the Government, State or Federal, make the buying decision for her.

The scope of this information explosion becomes quite apparent when you consider the current state of regulatory activity—the labeling regulations for foods under the Fair Packaging and Labeling Act (FPLA)[1] have now become fully effective for all food products; the National Conference on Weights and Measures recently met in Washington and adopted further labeling requirements under its Model State Law and Regulation; hearings on the Food and Drug Administration's proposed dietary food labeling regulations continue

[1] 15 U. S. C. §§ 1451-61 (Supp. 1966).

in Washington with no sign of letup; the Food and Drug Administration (FDA) concurrently seeks to establish additional labeling requirements for foods containing artificial sweeteners; and a special Congressional subcommittee has held hearings on proposals to require declarations of drained weight on food labels and unit prices on all consumer commodities.

Each of these labeling developments has its attendant problems, however, and I will touch briefly on each of these problem areas, with the exception of the dietary food marathon.[2]

The FDA Food Regulations

The FPLA Food Regulations[3] have technically passed their first anniversary, having taken effect on July 1 of last year. But although the regulations have, in general, been effective, they have not yet had their full effect on food product labels, since the manufacturers of hundreds of food products whose labels complied with pre-existing requirements under the Food and Drug Act were granted one year extensions which delayed the effective date of the regulations for their products until July 1, 1969. Thus, in many if not most cases, the new food labeling requirements have only recently taken effect.

Many food processors, however, still had noncomplying stocks of packaged goods in their warehouses when their extensions expired on July 1. In most cases these stocks were packed during the extension period without any deliberate attempt to overstock.

Given this fact situation, the FDA took the position that such noncomplying packages could not be shipped after July 1 without the grant of a further extension by FDA; and that few, if any such extensions would be granted.[4] Apparently FDA, sensitive to Congressional impatience with the FPLA, concluded that, regardless of industry or consumer effect, all food packages shipped after July 1 must comply with all FPLA requirements.

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[2] This latest set of hearings on the regulations governing foods for special dietary use has gone on for over a year and has produced a record covering more than 20.000 pages and a room containing 2300 exhibits. The government has not yet completed the presentation of its case; over 100 private parties have not started their presentations; and thus no end is in sight.

[3] The regulations appear in 21 CFR Part 1.

[4] See *Food Chemical News,* June 23, 1969 at 13.

Putting the potential cost to the consumer and industry aside for the moment, there is yet another matter to be considered—that is the FPLA itself.

Section 6(d) of the Act states: "... nor shall any regulation under this Act preclude the orderly disposal of packages in inventory or with the trade as of the effective date of such regulation."

FDA apparently interpreted "orderly disposal" in Section 6(d) to mean only that disposal in connection with an FDA extension. But FDA stated that extensions would not be granted. As a result, on July 1 those packages "with the trade" had no problems, but those awaiting "orderly disposal" from the manufacturer's inventory were left out in the cold.

Fortunately, FDA's questionable interpretation of Section 6(d) did not spread to its sister agency for FPLA purposes, the Federal Trade Commission (FTC). On the contrary, the Trade Commission stated that goods under its jurisdiction, which were placed in non-complying packages prior to the July 1 effective date of its FPLA Regulations, could be shipped for a reasonable time after that date.[5]

The logic of the Trade Commission's position and of the statutory language is clear—nothing would be gained by the consumer were the manufacturer to destroy or repackage quality products merely because the quantity declaration appeared in the wrong thirty percent of the label or because one pound was not also declared to be sixteen ounces. Faced with conflicting interpretations of Section 6(d) within the Federal Government itself, it is highly probable that many manufacturers will accept the FTC view and thus refrain from any wholesale destruction of packages and labels.

Labeling Uniformity and the Model State Packaging and Labeling Regulation

Unfortunately, Section 6(d) of the FPLA was not the only part of that Act to receive potentially troublesome treatment from regulatory authorities during the past year. The Act's provisions relating to federal pre-emption and uniformity among state and federal labeling regulation had rough sledding as well.

[5] However, in the *Federal Register* of July 1, 1969 (34 Fed. Reg. 11089) the FTC announced that the effective date of its FPLA regulations would be postponed "for a short period of time." The postponement resulted from the Commission's desire to resolve legal challenges to its interpretation of the term "consumer commodity" before the regulations became effective.

At the Fifty-Third National Conference on Weights and Measures held in Washington in June, 1968, under Commerce Department auspices, the Conference rejected industry proposals that would have insured full uniformity among state and federal labeling regulations for consumer commodities.

As a consequence, while the Model State Packaging and Labeling Regulation of 1968 adopted by the Conference paralleled most of the FDA-FTC requirements under the Fair Packaging and Labeling Act, there were significant points of departure. Thus, the Model Regulation required a triple quantity declaration for multi-unit packages; that is, number of units, quantity of each and total quantity, while the federal regulations indicated no total quantity requirement. Problems also arose over the fact that the requirements regarding supplementary quantity declarations were different. Even more important, the Model Regulation made no provisions for the automatic adoption of federal product exemptions which establish particular labeling requirements tailored to fit particular products. To date, FDA has adopted eight and two are pending. Instead, the Conference chose to review each federal exemption separately prior to inclusion in the Model Regulation.

The maintenance of this condition of federal-state nonuniformity was particularly troublesome in view of the key role of the Federal Commerce Department in administering the National Conference and the clear statutory directives to that Department to seek uniformity in State and Federal weights and measures requirements.[6]

The Commerce Department's position was apparently based upon the Department's questionable interpretation of the somewhat ambiguous language and legislative history of the pre-emption section of the FPLA.[7]

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[6] 15 U. S. C. § 272(d)(5) directs the Department to cooperate with the States "in securing uniformity in weights and measures laws . . . ." Section 9(a) of the FPLA states: "A copy of each regulation promulgated under this Act shall be transmitted promptly to the Secretary of Commerce, who shall (1) transmit copies thereof to all appropriate State officers and agencies, and (2) furnish to such State officers and agencies information and assistance to promote to the greatest practicable extent uniformity in State and Federal regulation of the labeling of consumer commodities." This subject is discussed at length in Dunkelberger, *The Fair Packaging and Labeling Act—Some Unanswered Questions Two Years After Enactment*, 24 FOOD DRUG COSMETIC LAW JOURNAL 17, 18-24 (January, 1969).

[7] Section 12 of the FPLA provides: "It is hereby declared that it is the express intent of Congress to supersede any and all laws of the States or political subdivisions thereof insofar as they may now or hereafter provide for the labeling of the net quantity of contents of the package of any con-

(Continued on following page.)

Under the Commerce Department view, this section's only function is to prevent the States from adopting labeling requirements which are clearly inconsistent with the provisions of the federal act and regulations. But the Supremacy Clause of the Federal Constitution would do that in any case, and it is not to be presumed that the Congress legislated on this subject merely to fill a few more pages of the *Congressional Record.*

Thus, when the Fifty-Fourth National Conference convened, the question of uniformity of federal-state labeling regulation was again a key topic for consideration. Initially, nearly all industry requests for revisions—for purposes of federal-state uniformity—in the proposed Model State Packaging and Labeling Regulation of 1969 were rejected by the Conference's Committee on Laws and Regulations. To the industry representatives at the Conference, it thus appeared that the Conference spokesmen would preach uniformity, while practicing the reverse.

Primarily at issue were those portions of the Model Regulation dealing with the labeling of commodities packaged in multiple units. The Conference reaffirmed its decision of the year before to require a triple quantity declaration (including the *total* quantity) on multi-unit packages. Industry objections (on uniformity grounds) and requests for a reasonable effective date were given short shrift, and the Conference chose instead to petition the FTC and FDA in an effort to have the federal requirements changed to correspond with those of the states.[8]

Of even greater concern to industry representatives, however, was a Conference proposal which would have subjected vast quantities of packaging materials, not covered by the FPLA requirements, to all labeling requirements of the Model Regulation.

Neither the FDA nor the FTC-FPLA Regulations apply to "transparent wrappers or containers which do not bear any written, printed, or graphic matter obscuring the [required] label information . . ."[9] or to "open" containers,[10] such as the soft drink basket-

(Footnote 7 continued)
sumer commodity covered by this Act which are *less stringent than* or require *information different from* the requirements of Section 4 of this Act or regulations promulgated pursuant thereto." (Emphasis supplied.)

[8] In the *Federal Register* of June 26, 1969 (34 Fed. Reg. 9871), FDA published a proposed quantity labeling requirement for multi-unit packages, which would parallel that of the Model Regulation. The FTC has not yet followed suit.

[9] 21 CFR § 1.1b(e). See also 16 CFR § 500.2(d).

[10] 21 CFR § 1.1b. See also 16 CFR § 500.2(d).

type carrier. The original Conference proposal, however, would have limited the non-applicability of the Model Regulation only to those transparent wrappers or carriers for containers which had no written, printed, or graphic matter whatsoever.[11]

The Final Report of the Laws and Regulations Committee, which preserved the controversial proposal regarding transparent wrappers and open carriers, was challenged by concerned State officials on the floor of the Conference. Following heated debate, the Conference recessed to provide the Laws and Regulations Committee with additional time to resolve the dispute.

Reversing its original stand, the Committee[12] recommended that the labeling requirements of the Model Regulation not apply to open carriers and transparent wrappers or carriers for containers which do not bear any matter obscuring required declarations on the individual units.[13] This recommendation was adopted by the Conference by a 2-to-1 vote. As a result, the Model and federal applicability provisions attained a substantial degree of uniformity, and the National Conference, at the same time, indicated at least some realization that consumer care must be balanced with practical reality.[14]

Unit Pricing

The mention of practical reality immediately brings to mind yet another problem area regarding the labeling of food products—pricing.

Several well-publicized studies have been used recently to show that the American consumer is unable, with any sort of precision, to determine whether the large or small package of Brand X cereal is the better buy. Apparently neither the old nor the new math has equipped her to make that highly technical comparison. But no matter, such problems can be solved by still another Federal labeling requirement.

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[11] See "Tentative Report of the Committee on Laws and Regulations, 54th National Conference on Weights and Measures, Model State Packaging and Labeling Regulation" (1969) § 1(f).

[12] R. W. Richards of Pennsylvania dissented.

[13] Section 1 of the Model Regulation of 1969 states: "This regulation . . . shall not apply to: * * * (e) Open carriers and transparent wrappers or carriers for containers when the wrappers or carriers do not bear any written, printed, or graphic matter obscuring the label information required by this regulation."

[14] Industry spokesmen estimated that had the Conference followed the original Committee proposal, the cost of replacement packaging would have been staggering.

Regulations under the Fair Packaging and Labeling Act currently apply only to the commodity as it is labeled when shipped in interstate commerce.[15] Therefore any labeling activity, such as the retailer's placing a price on the product after the goods have completed their journey through commerce, is not within the reach of the Act.

However, lest the retailer feel that he is not being asked to contribute his fair share of label information to the consumer, Senator Nelson has introduced a bill (as have several Congressmen in the House[16]) designed to amend the FPLA and impose a two-pronged pricing requirement on retailers.

The Nelson proposal, S. 1424, would require the retailer to place on the principal display panel of the label of every consumer commodity he sells both the retail price of the entire contents of the package and the unit retail price, that is the price per pound, quart, ounce, etc., as determined by the FDA or FTC for the products under their respective jurisdictions.

Thus, the consumer would not only be told that a 12-ounce can of peas costs 30 cents, but also that it costs 2.5 cents per ounce or perhaps 40 cents per pound.

The practical problems inherent in this attempt to eliminate the need for any consumer calculation are obvious. For the vast majority of items sold in the American supermarket, the price legend appears on the top of the container. This facilitates the mechanical process of rapidly applying the price and avoids confusion with other printed information on the principal display panel.

One need only stop and consider for a moment the additional time and manpower needed to price-stamp a case of canned goods on the principal display panel rather than the top to see the practical effect of the Nelson proposal. The cost to the retailer, and ultimately to the consumer, would no doubt be far greater than any amount saved via the comparison shopping route.

A more reasonable and far more practical approach would be to require that specified price information be conspicuously displayed on the container or label of the product involved. Such a proposal would at least eliminate much of the additional cost that would

[15] FPLA § 3(a).

[16] H. R. 11549, 91st Cong., 1st Sess., introduced by Congressman Rosenthal (N. Y.). H. R. 11757, 91st Cong., 1st Sess., introduced by Congressman Koch (N. Y.). H. R. 9412, 91st Cong., 1st Sess., introduced by Congressman Corman (Calif.).

otherwise be generated by the principal display panel requirement in the Nelson bill.

Ultimately, however, the real gain here will be made by the producers of rubber stamps who must now consider designing products which will enable the poor stockboy, who is no doubt no more of a mathematician than the poor consumer, to grind in total price and total quantity and come up with what Senator Nelson terms "the unit retail price of such contents determined in such manner as such promulgating authority shall prescribe by regulations."[17]

Drained Weight Labeling

The final proposal on which I will comment concerns a possible requirement that drained weight be stated on canned foods, in addition to the present net weight declaration. Although this proposal received considerably less publicity than did the unit pricing bill during the recent hearings before Congressman Rosenthal's Special Consumer Inquiries Subcommittee,[18] its potential for supermarket mischief may be equally great.

It should be noted that this is not the first time the drained weight proposal has been considered. In fact, from the mid-1930's to the present it has been consistently rejected as neither a practical requirement, nor a useful one for the consumer.

The practical problems are obvious. Drained weight will vary tremendously when you are dealing with natural products of varying sizes. But even beyond this, industry has long maintained and consumers have long accepted the fact that the packing medium is a valuable constituent of the total canned food product. In those few cases, such as mushrooms, olives, oysters and shrimp, where the packing medium itself is not considered to be a useful part of the food, the quantity of the product is declared by drained weight alone.

In addition, it is worth stopping to consider what a drained weight requirement would do to the average food label. Instead of merely being told that a particular product has a net weight of 24 ounces (1 pound, 8 ounces), the consumer could be faced with a quadruple quantity declaration which would state "Net Weight 24 ounces (1 pound, 8 ounces), Drained Weight 21 ounces (1 pound,

[17] S. 1424, 91st Cong., 1st Sess. at 2.

[18] The Rosenthal Subcommittee held hearings in Washington, June 3, 4 and 5, 1969.

5 ounces)." Such a declaration can only serve to confuse even the most sophisticated shopper.

Conclusion

This paper has dealt with the information explosion in terms of the ever-burgeoning mass of state and federal labeling requirements allegedly designed to assist the world's best-informed consumer in making the best-informed buying decision.

Unfortunately, the current Congressional fascination with food product labeling tends to overshadow the fact that the American consumer is, and for some time has been, second to none in receiving useful information on the label of the food products she selects. Even before fair packaging and labeling became a newsworthy topic, the average purchaser of canned foods could find the product identity, quantity, ingredients, style, number of servings, and usually some useful recipes or serving suggestions on the label. The FPLA did, of course, provide additional information to the consumer. But one wonders whether the consumer might be less confused if a few of the new declarations were omitted and a few of the recent proposals were dropped from discussion. For example, I doubt whether very many consumers would miss the parenthetical statement of quantity in a dual quantity declaration[19] or the veritable mass of numbers that now confronts the purchaser of paper products.[20] I further doubt whether the cause of consumer care would be well served if the packer of corn on the cob were required to declare the weight as well as the count of his product on the principal label panel. But such a ridiculous requirement was recently suggested.[21]

My point is that even an information explosion can get out of control. The food label serves its constituency best by being a ready reference device offering limited, but extremely useful information, bearing on the purchase and preparation of the food inside. It should not become, by means of ever increasing labeling regulation, a veritable *Information Please Almanac.* **[The End]**

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[19] See 21 CFR §§ 1.8b(j), 1.102d(i)-(n); 16 CFR §§ 500.9-.13.

[20] See 16 CFR §§ 500.12, 500.15.

[21] Fortunately, this proposal has been rejected by FDA. See letter of June 6, 1969 from J. K. Kirk, Associate Commissioner for Compliance, Food and Drug Administration to Herman P. Schmitt, Administrative Assistant to the Executive Vice President, National Canners Association, on file at the National Canners Association, Washington, D. C.

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