VOL. 16, NO. 6 JUNE 1961

Food-Drug-Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

June, 1961

Volume 16 • Number 6

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . June, 1961

VOLUME 16 NUMBER 6

Printed in United States of America

REPORTS

TO THE READER

European Food Code.—According to *Edmund Forschbach,* "economic integration of a large part of the European continent is drawing nearer and nearer" since the creation of the European Food Code, a significant step toward the facilitation of "world trade not only by the traditional means of economic policy but also by fostering uniformity of the national laws governing the manufacture and sale of foods."

Mr. Forschbach is presently engaged in a reform of the food law of the Federal Republic of Germany in the European Council for the Creation of a Codex Alimentarius. He discusses the progress made toward the goal of economic integration in the article beginning at page 317.

In Vino Veritas.—In the article at page 335 entitled "A Survey of American Wine Laws," the author, *John D. Garr,* traces the development of national legislation imposing regulations upon American winegrowers, with emphasis upon those aspects of federal law which are comparable to the Food, Drug, and Cosmetic Act in scope. He notes many cases involving adulterated and misbranded wine while expressing a concern for higher standards of production in order to protect the consuming public and inspire confidence abroad.

Mr. Garr is 1957-1958 Food Law Fellow.

Effective Herculean Efforts.—A study of building features most suitable for the maintenance of sanitary conditions in food process buildings is presented in this month's JOURNAL at page 321. The article was regarded as so valuable by members of the food industry that they requested that it be rewritten for JOURNAL publication.

The author is *Hugh H. Walsh,* an engineer for Hercules Powder Company in Wilmington, Delaware.

Additives and the FDA.—*J. Kenneth Kirk's* article at page 361 deals with the response which the Food and Drug Administration has received in relation to their regulations in the area of food additives and requests compliance on the part of industry and a strong enforcement policy.

Labeling Labyrinth.—The basic requirements pertaining to labels and labeling are thoroughly discussed at page 366 by *Robert M. Rubenstein,* an "old hand" at dealing with food law problems.

Mr. Rubenstein is a member of the law firm of Rubenstein & Breger, New York, New York.

Macdonald Bill.—In his address at the seventy-eighth convention of the National Confectioners Association, FDA Deputy Commissioner John L. Harvey briefly discussed H. R. 3548 to amend Section 402(d) of the Federal Food, Drug, and Cosmetic Act.

Section 402(d) now reads as one definition of adulterated food:

"(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except authorized coloring, harmless flavoring,

harmless resinous glaze not in excess of four-tenths of 1 per centum natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non-nutritive masticatory substances."

The proposed amendment would change that to read:

"(d) If it is confectionery, and it bears or contains—

"(1) any alcohol other than not to exceed one-half of 1 per centum by volume derived solely from the use of flavoring extracts; or

"(2) any non-nutritive trinket or object (other than a nonhazardous object which performs a useful purpose) unless such trinket or object is separately wrapped."

Mr. Harvey emphasizes that the Department of Health, Education, and Welfare has not taken a final position on this bill, but gives his views on the bill as follows:

"This would seem to take advantage of modern technology and allow food additives which have been proven safe in sufficient amounts to be added to confectionery for technical reasons. It would seem to preserve the safety feature of precluding or minimizing dangerous trinkets which might be accidentally ingested.

"This Association has gone on record as favoring this proposed legislation. At the risk of being accused of being overly paternalistic and assuming to know more than the experts, I would like to raise a warning flag or two regarding H. R. 3548. First, would passage of this amendment tend to cheapen a product whose long history has been one which emphasized quality? It might well be that under this wording, technological advantages can be taken of processing discoveries through the use of acceptable food additives. The same language would allow, however, the addition of fairly substantial quantities of talc or other products which responsible management would not approve. Because candy is consumed in such quantity by our children, any cheapening would in our opinion have tremendous impact.

"Second, what affect would this amendment have on imported confectionery products? As you know, the rules we lay down would not only apply to domestic confectionery, but to that produced in foreign countries. In this connection we have found it necessary, under the present statute, to deny entry to frequent shipments of confectionery with substantial talc as an ingredient. Under the proposed amendment such merchandise might flow into our domestic market.

"We have suggested, and I do so again, that the addition of a provision at the end of section 402(d) will grant relief and still maintain the unique position of confectionery. We have suggested the addition of 'Provided, however, nothing in this section shall be deemed to prohibit the use of any non-nutritive substance subject to section 409 of this Act if an appropriate regulation has issued under the provisions of that section especially authorizing the use of the food additive in confectionery.'"

Under the broad title 'Confectionery Under the Pure Food Law" Deputy Commissioner Harvey also discussed several other items worthy of note. Referring to the cocoa bean situation, he reported that the Food and Drug Administration had tentatively concluded as a result of their survey that a tolerance of 6 per cent total insect infested and moldy beans, but not more than 3 per cent of either, would be reasonable and proper. He also advised the confectionery industry as to the importance of taking steps to assure that any ingredient used to color candy has been subjected to sufficient pharmacological testing to prove that it is safe for its intended use between now and January 12, 1963, to comply with such provision given in the Color Additive Amendment.

Vol. 16, No. 6 June, 1961

Food·Drug·Cosmetic Law
Journal

The European Food Code "Codex Alimentarius Europaeus"

By EDMUND FORSCHBACH

The Author Is a High Official in the Federal Ministry of the Interior of the Federal Republic of Germany in Bonn, and Chairman of the German National Committee in the European Council for the Codex Alimentarius.

SINCE THE SIGNING of the treaty creating the European Economic Community on March 25, 1957, the economic integration of a large part of the European continent is drawing nearer and nearer. Within the two economic blocs existing at present—the Common Market countries and the European Free Trade Area—a reasonable uniformity of the national food legislation of the various member countries has, therefore, become an urgent need. The exchange of goods must not be hampered by conflicting food laws at a time when all endeavours are directed at pulling down the barriers of economic policies existing in the form of duties and contingents. Furthermore, the necessity of safeguarding the consumer against dangers to his health and against commercial fraud, and of protecting the honest trade in food products against unfair competition likewise requires a reasonable uniformity in the principles which are to govern the establishment of food standards and other rules and regulations concerning the conditions under which food products may be sold on the market. However, inasmuch as unwholesome, spoilt, adulterated or mislabeled food does not stop at the national borders and cannot be contained within the limits of a supranational economic bloc, the assimilation of the above-mentioned economic principles becomes a

For His Outstanding Work Done in Connection with the Creation of the European Food Code, Mr. Forschbach Was Awarded the "Great Medal of Honour for Meritorious Services" by the President of the Republic of Austria.

necessity for the entire European Continent and not only for the member nations of the two presently existing economic blocs.

Foods are by their very nature products of many different varieties which are subject, with respect to their production, transportation and composition, to many different physiological, hygienic and labeling requirements. For that reason it would be an impossible task to try to standardize these requirements by means of inflexible laws, the promulgation and amendment of which always require considerable time. Ordinarily, the food legislation of an individual country consists of a basic law which contains the general principles that are to govern this subject matter and which is implemented by detailed regulations for the different categories of food products. It would prove to be very difficult to harmonize the different national food standards and other detailed regulations by trying to make them uniform through the conclusion of complicated and lengthy international treaties. Such uniform provisions would soon become obsolete due to the fast pace of scientific and technological progress. On the other hand, the task of harmonizing the national food standards of the nearly 20 nations of an entire continent could be achieved much faster and much more effectively if the administrative agencies and the courts of the individual countries would observe and follow the directives and rules compiled in a commonly accepted "Codex Alimentarius" which is based on a systematic compilation of the recommendations and objective opinions of the leading experts in this field.

The satisfactory practical experience with such a compilation which was introduced in Austria under the name of "Codex Alimentarius Austriacus" (Austrian Food Code) and which has been in

constant use for over 80 years, encouraged Dr. Hans Frenzel, a former Austrian Federal Minister and chairman of the Austrian Committee for the Food Code, after discussions with leading experts of other European countries, to propose the idea of a European Food Code at a meeting of the Werder Foundation in Berne in 1954 and again in 1956 at a symposium organized by the CIIA (International Comission of Agricultural Industries). After intensive preparations a commission for the European Food Code was formed in Vienna in 1956 which later adopted the name of "European Council for the Codex Alimentarius." This organization consists of technical experts from 17 European countries—including representatives of the member nations of the European Economic Community, the European Free Trade Area and even some countries from behind the Iron Curtain—and it has started work on formulating the minimum requirements for different varieties of food which would be applicable in all countries. In accordance with an agreement recently concluded with the FAO (Food and Agricultural Organization of the United Nations) and WHO (World Health Organization), the European Council for the Codex Alimentarius will soon be converted into a "Joint Committee" including representatives of both agencies and will thus obtain international status.

Organization of Committees

Several subcommittees have already been organized to deal with the topics "General Principles"; "Taking of Samples"; "Coloring and Preserving"; "Addition of Vitamins, etc."; "Edible Fats and Oils" and "Mushrooms," and to prepare a harmonization of the respective requirements on the European continent. The Federal Republic Germany is actively cooperating in this project as is demonstrated by the fact that its representative is the secretary of the subcommittee on "Basic Principles." This subcommittee has already held three sessions in Freiburg in 1959, 1960 and 1961 in which, in addition to the members of the German National Committee, representatives from Austria, France, Greece, Poland, Spain and Switzerland took part. Already in 1960 the Committee agreed on the definitions of "food" and "harmful to health" and in 1961 it adopted the definitions for "deterioration," "unripeness," "adulteration," "imitation," "mislabeling" and the requirements for correctly stating the place of origin, which is very important in international trade. Thus the chapter on "General Principles" is virtually concluded as its approval by the forthcoming

General Assembly in Vienna (May 30 to June 3, 1961) cannot be doubted. [Written prior to meeting.] This means that the 17 countries which cooperated in the European Council for the Codex Alimentarius for the purpose of facilitating the exchange of foods, will be held to apply these principles to all foods produced in these countries and thus assure the protection of the consumer against dangers to his health and against fraud, and to protect the honest traders in foods against unfair competition. Because of its nature the European Food Code does not constitute supranational law for the trade with food, but is rather meant to be a model code recommended for adoption to the individual countries which are invited to bring their own laws in line therewith so as to obtain a common approach to the basic principles of food law.

Conclusion

All mankind is continuously moving closer together because of the great improvements in the means of transportation, and the exchange of goods between nations is becoming increasingly important. Therefore, it is urgently necessary to facilitate world trade not only by the traditional means of economic policy but also by fostering uniformity of the national laws governing the manufacture and sale of foods. All circles concerned with this subject in the European countries are following with great interest the development of a model food code in the Western Hemisphere. The Latin-American Food Code which was recently completed and published in Buenos Aires under the sponsorship of the Seventh Latin-American Chemical Congress is an important step forward in the direction of uniformity of the food laws in the Latin American republics.

The similar project of a "Pan-American Food Code" which was sponsored by the Pan-American Pharmaceutical and Biochemical Federation was withdrawn in November, 1960 at the Congress at Santiago. It remains to be seen whether the developments in Latin America and in Europe will eventually lead to the creation of a "Codex Alimentarius Internationalis." There is a precedent for it in the international police organization "Interpol" which successfully cooperates in the fight against crime all over the world. An international food code would protect the honest trade in foods against unfair competition and protect the consumer against fraud and dangers to health. The way leading to this goal may be long and difficult but it is certainly worth while. **[The End]**

The Development of Aids to Sanitary Construction

By HUGH H. WALSH

This Article Is Based upon a Speech Which the Author Delivered to the Corn Industries Research Foundation in Chicago, Illinois, on January 26, 1961.

WE AT HERCULES are newcomers to the food industry. In 1956, we purchased the Huron Milling Company in Harbor Beach, Michigan. This company had been processing wheat flour for industrial and food products for three quarters of a century. We currently process flours into protein, monosodium glutamate, starch, starch derivatives and sauce products at these facilities.

Through the purchase of this old plant, we acquired many problems. Some of the process equipment and process design was outdated. Many of the production and storage buildings required renovation. With the acquisition of these facilities, our maintenance and housekeeping costs were very high; therefore, based upon the knowledge of existing plant personnel, we began to solve our problems by a conscientious program of modernization and renovation to produce environmental conditions which would facilitate the maintenance of sanitary conditions. In the past few years, we have spent considerable sums of money for modernization and renovation at Harbor Beach. We are now spending or plan to spend even more in the near future.

Hercules is primarily a chemical firm; however, technological progress in the food industry has opened new markets for a variety of products for the improvement of the qualities of food. This,

Mr. Walsh Is an Engineer in the Engineering Department of Hercules Powder Company in Wilmington, Delaware.

coupled with our operations at Harbor Beach, has made us a part of the food industry.

We are quite familiar with the problems encountered in the construction and maintenance of process buildings for the production of high quality products under stringent quality control; however, in 1956, we were not familiar with the production of food products which are life-supporting, decomposing, bacteria-producing, and hence, self-contaminating in nature.

Development of Knowledge

Based upon our needs and accumulated knowledge at Harbor Beach and our expected needs at other plant facilities, our company through its engineering department initiated a study to determine suitable materials of construction and features of building design adaptable to the construction and renovation of food plant buildings.

Our first step was to evaluate the developed knowledge of our Harbor Beach personnel and the nature of the problems faced by them in the production of high quality food products. Our personnel explained the steps taken in the past to cope with their problems and the remedial measures now being applied in light of their present knowledge.

With an understanding of the difficulties encountered in the renovation of our Harbor Beach plant, we decided to make a thorough investigation into the sanitary problems faced by the food industry as a whole in the processing of products under sanitary conditions.

This study has evolved as a cooperative effort with our operating personnel in the assimilation of knowledge and the development of means for the transfer of this knowledge to plant and design personnel who must practically apply it.

Toward the assimilation of knowledge, our engineers and architects have conducted interviews with engineering personnel and have toured the production facilities of major producers of flour products, dairy products, cereals, soups, beverages, baked goods, and pharmaceuticals to determine how other producers with food handling problems, similar or more adverse than our own, have formerly and are presently constructing their buildings for the maintenance of sanitary conditions.

All available private and government publications are continually being reviewed to broaden our company's understanding of the problems encountered and solved by food manufacturers. Representatives of trade organizations, contractors, architects, and sales personnel have been interviewed to determine their knowledge of materials and methods of construction which may be considered in the solution of our problems.

In the production of food products, environmental conditions are created which are hazardous to personnel, destructive to building components and conducive to the contamination of food products. In light of this knowledge, we realize that we may never have the ideal solution to all our problems; however, we do believe we can eliminate or satisfactorily improve most of them.

Study Observations

Some observations in this study which may interest you are as follows:

The sanitary programs of several visited food producers were reported as becoming more intense in their requirements as the regulatory controls have tightened. In 1956, when our company joined the industry, the appropriation of the FDA was $6 million. In 1961, it is approximately $19 million. We as companies in the industry have a responsibility in a modern advanced society to produce what the consumer expects—clean, wholesome food products. Federal and local governments, through their regulatory agencies, are reflecting the public's expectations by increased laboratory and field activities. Most plants have reported a general increase in inspection frequency.

In the majority of the plants which were visited, renovations were proceeding or had recently been completed. Some plants showed a general program of complete revamping of existing production areas. Most alterations noted were those which improved the sanitary

appearance of building components or reduced the likelihood of product contamination by creating surfaces and conditions that can be more easily cleaned.

It is encouraging to note that we are not the only company in the industry which has recently seriously questioned the adequacy of their buildings for the continued economical production of food products under sanitary conditions.

In the investigation of other food manufacturers' buildings, the following was generally noted:

Warehouses and Storage Buildings.—Few incorporate any special features in the construction of their warehouse facilities for the storage of bagged dry ingredients and package finished products. Most buildings are structural steel frames with 20′ x 20′ to 50′ x 50′ bay sizes. Walls are predominantly masonry; however, some corrugated metal was noted. Sanitary conditions are generally maintained by constant inspection and periodic general housecleaning. Warehouse costs are generally $7 to $10 per square foot for areas between 20,000 and 50,000 square feet. Most warehouse floors were showing signs of rapid deterioration from heavy truck traffic. Few engineers whom I encountered seemed to understand what constituted a heavy-duty concrete wearing surface. Almost all producers have installed, or plan to install, bulk-handling facilities for their dry raw materials.

Process Buildings.—The vast majority of food process buildings which were entered indicated greater initial capital investment than the usual industrial buildings. Perhaps half of the buildings were of reinforced concrete structural frames. Few wood structures were encountered. Where wood roof framing systems existed, engineers indicated that projects had been submitted for their replacement. Many buildings are two-way flat slab construction, a structural system which has inherent advantages since all dead-air spaces and horizontal ledges generally created by structural elements are eliminated.

With the exception of breweries and soup manufacturers, few buildings showed general standardization. Most plants indicated a conglomeration of building types. Few had a program of evaluation of building materials or construction details.

Most manufacturers were having problems with corrosive deterioration and/or traffic wear in areas where concrete slabs were not protected from corrosive wetting. Few companies believed they had

solved their flooring problems, had developed standards of construction or means of evaluating floor service for these problem areas.

All manufacturers were having fenestration problems, except where light panels of glass block were installed with supplemental mechanical ventilation. Many plants are replacing unsatisfactory industrial steel or wood projected sash with architectural aluminum types which provide less ledge area for the accumulation of nutrious dust and corrosive agents. Plant engineers are universally seeking a window design which incorporates a minimum of ledges, crevices and voids, and a maximum of cleaning ease. The need for a cooperative enterprise between the National Window Manufacturers Association and the food industry is indicated for the development of a sanitary sash particularly suited to industrial applications.

Special wall surfacing materials are generally used to facilitate ease of cleaning in wet and dry process areas where mold growth, bacteria-producing wetting, or nutrious dusting is a problem. Structural clay glazed tiles are frequently used; however, ceramic tiles and heavy filmed glazed coatings are rapidly being accepted throughout the industry.

My concluding observations in this study are that in light of the requirements of law, but more importantly our responsibility to the public, we must store and process food ingredients under conditions whereby the product is not contaminated or may not become contaminated by filth or decomposed substances. These conditions must be economically maintained within our storage or process areas and particularly in the immediate product zone.

Many food processes can be economically operated in ordinary industrial buildings with a minimum of construction features for the maintenance of sanitary conditions. A vast majority of processes could be conducted in the same type of structures if the cost of housecleaning were not considered; however, the maintenance of sanitary conditions is a production cost in food plants. Where processes are such that sanitary conditions are extremely difficult to maintain, then special surfacing materials and building features must be installed. These capital outlays are for the ease of maintenance of sanitary conditions and are a housekeeping cost and must be considered in that light. They are justifiable expenditures when they reduce production cost by lowering housecleaning costs during the expected life of the building feature.

It is the responsibility of the operating personnel of production plants to determine when such features are an economical necessity for the production of wholesome products under constantly maintained sanitary conditions.

The service departments of a company can aid operating departments by assimilating information on these building features and furnishing it to the operating personnel who must make their cost evaluations. This our company is attempting to do in our food plant study. It is a reasonably simple task for an individual in a home office engineering department, surrounded by a concentration of technical data and personnel, to assimilate vast stores of information on materials and methods of construction; however, it is quite another thing to meaningfully transmit it to plant and design personnel who are surrounded by a concentration of specific problems.

Aids to Sanitary Construction

We are developing aids to plant and design personnel in the selection of materials of construction and features of building design suitable for the renovation and construction of process areas which can be economically maintained in a sanitary condition.

Based upon the information gathered in this study, we are developing these specific aids:

(1) We have classified the environmental conditions which exist within food production buildings in the food industry as a whole.

(2) We are classifying building materials, standard details and design recommendations in terms of the environmental condition under which they will economically exist.

(3) We have developed a simple and concise means of assimilating and recording data on material installations within our company and for the circulation of this information to operating personnel who must practically apply it.

(4) We are developing an awareness among designers, project engineers, and operating personnel of the nature of the problems faced in the design, construction, renovation and maintenance of food process buildings. Recognition of the problems of sanitary construction by responsible personnel is a significant step toward their solution.

Building Components (Illustration 1).—In the accumulation of information, a suitable filing system must be maintained in order to

store data for future analysis. The "Building Components" chart has been developed as a graphical representation of the filing system used in the assimilation of knowledge on the elements of buildings which house our food processes. It presents the basic building components being investigated in our food plant study.

Environmental Conditions of Process Areas (Illustration 2).—The first aid is the chart titled "The Environmental Conditions of Process Areas," which has been developed on the premise that for the proper selection of a surfacing material or a building feature, the environmental conditions under which it must economically exist must be known. It is designed to serve a two-fold purpose: First, as a useful vocabulary aid to plant and design personnel for the development of concise and meaningful descriptions of problem areas where special surfacing materials, construction details or design recommendations are needed. Second, it is the basis upon which building materials and construction details are being classified for the development of standards of sanitary construction. By repetitive reference to this chart, a useful aid in the form of a store of meaningful nouns and adjectives can be added to the vocabulary of a person seeking information on materials and construction details for industrial application.

As noted in this chart, process areas are separated into three major categories: Wet Process, Dry Process, or Warehouse.

An area is "wet process" if floors, walls and/or ceilings are generally damp or wet from drips, spills, splashes, washdowns or condensation. An area is wet process if it is generally damp or wet over extended periods of time.

An area is "dry process" if floors, walls and/or ceilings are generally dry and are not subject to frequent drips, spills, splashes or condensation. Occasional washdown of floors or wainscot, say once a day, may be necessary; however, adequate ventilation is available to quickly dry the surfaces. An area which is only occasionally wet for a short period of time is dry process since it is generally dry.

Warehouse areas are predominantly storage buildings for the protection of raw materials, finished products or process equipment.

Environmental Classification (Illustration 3).—The second chart entitled "Environmental Classification" is designed as a practical aid to plant and design personnel for the development of a complete description of the environmental conditions of a process area. The

accurate analysis of any problem is the first and most significant step towards its satisfactory solution. Experience indicates that personnel faced with a specific problem in the selection of a building feature often fail in their objective description of all the factors which effect its proper selection. Any aid to this end is desirable. By use of this organized check list of the general environmental conditions, existing or expected, in a process area, a mental reminder is initiated for the development of a complete analysis of a problem.

With the aid of a "checked" environmental classification chart of the surface conditions of floors, wainscot, walls and/or ceilings—plus supplemental notes—a person unfamiliar with a specific area can develop a fairly clear mental picture of conditions as an aid to the development of recommendations or as an aid to the formulation of questions for further discussion.

If an upper wall surface is exposed to periodic acidic corrosive wetting, then generally any equipment, piping or window attached to that surface is also exposed to acidic corrosive wetting. The building component can be selected in light of this knowledge. If the agents of corrosion are not known, then the uninformed person should determine the exact nature of the corrosion before he selects a material.

Material Classification.—The third group of aids which has been developed is the classification of building materials in terms of the environmental conditions under which their characteristics suit them to economically exist. These materials are being classified in folding chart form. The charts are not reproduced in this publication since their size make it impractical.

One of our charts is entitled "Wet Process: Corrosive Resistant Floor Surfacings." These surfacings are grouped in appropriate headings, descriptive of their physical nature as follows: Bricks and Tiles; Monolithic Cement and Resinous Toppings; Monolithic Bituminous Topings; Heavy Film Coatings; Light Film Coatings. Materials are further classified in terms of their Range of Chemical Resistances; Loading and Traffic Recommendations; Sanitary and Safety Considerations; and General Characteristics and Physical Properties. In all, 27 individual characteristics are listed in a comparative analysis of each floor surfacing material selected for this definitive classification. No attempt is made to list all available surfacing materials; however, those surfacings which have shown continued economical service in

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

BUSINESS REPLY MAIL
NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY—

Food Drug Cosmetic Law Journal

COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

industrial applications are included as recommendations for use by our production plants.

A tabular listing of these materials cannot fully describe all pertinent information necessary for a satisfactory installation; however, it does present to design and project personnel the major characteristics of available materials from which they can make their selection. By summarizing the characteristics of a wide range of materials, a basis of comparison is developed for the analysis of new products which enter the building industry. Each category of the classification serves a two-fold purpose: First, it presents basic information on the material; and second, it serves as a mental reminder to the development of questions which must be considered in the final selection of a material.

Floor surfacings can be classified in terms of the environmental conditions under which they will be called upon to function. Other building features, such as wall surfacings, ceiling coatings, windows and doors, and construction details are similarly being developed and classified. Accompanying each classification will be a detail sheet on each type material summarizing the necessary information for its proper installation.

Product Evaluation Cards (Illustration 4).—The final charts, presented for discussion at this time, which have been developed as aids to our operating personnel, are "Product Evaluation Cards." The chart illustrated here is a reproduction of two 5" x 8" index cards from our files. These cards are multipurpose in intent. First, they serve as a concise means of assimilating and cataloging existing knowledge concerning installations of building materials within our company. With 30 production plants and several thousand technical personnel, vast stores of knowledge are available if accumulated. Second, these cards furnish an easy means of filing information on specific installations in light of the environmental conditions of the area in which they were placed. Third, these cards are a practical and economical means of follow-up to installations. The evaluation of results after prolonged service is essential for the adequate appraisal of any product or construction detail. Finally, these cards can be quickly and economically reproduced and forwarded to plant and/or home office personnel who are seeking information on a particular product.

In conclusion, we realize through experience—as we are sure that you do—that any system of aid which is complicated will soon be discarded. To be permanently useful, it must be easy to understand, simple to carry out, and accurate in its results.

Every dollar spent in the competitive chemical and food industries must be economically justified by either improving the quality of products, reducing their production cost, or creating new and more satisfying products. If these aids to the renovation and construction of food production plants do not meet this challenge, they will be quickly discarded.

Hercules hopes that some of the ideas discussed here will aid other companies in the development of solutions to the complex problems faced in the economical maintenance of sanitary conditions in food production plants. **[The End]**

FDA HALTS DISTRIBUTION OF FREE SAMPLES

The Food and Drug Administration on June 13 announced two seizure actions involving a little known but mushrooming abuse in the distribution of valuable but potentially dangerous prescription drugs—the repackaging for sale of hundreds of thousands of free samples initially prepared for distribution to physicians.

The government charges that the repacked articles included Diuril and Hydrodiuril, used in the treatment of high blood pressure and heart conditions; Chloromycetin, Aureomycin, Terramycin, antibiotics; Equanil and Placidyl, tranquilizers; Permarin, a hormone; and Thorazine, a central nervous system depressant, and numerous other drugs.

It was charged that the repackaged drugs are not labeled as required by the Federal Food, Drug, and Cosmetic Act. The labels do not bear the statement "Caution: Federal law prohibits dispensing without prescription," and do not give the common or usual name of the drugs and their active ingredients, the identifying lot or control number, or the name and address of the manufacturer, packer or distributor.

Commenting on the actions, Commissioner of Food and Drugs George P. Larrick said: "Physicians' samples are not illegal when properly labeled and used as such. However, some of the products involved are new drugs, permitted to be marketed only when prepared and packaged under special controls to assure safety and maintenance of identity, strength and proper labeling. Some are antibiotics requiring certification of every batch for safety and efficacy in FDA laboratories before release.

"The conditions found in repackaging of these physicians' samples short-circuit or nullify the essential safety controls required before marketing.

"Protective labeling required by the law is frequently removed, causing a risk of mixups in the drugs.

BUILDING COMPONENTS

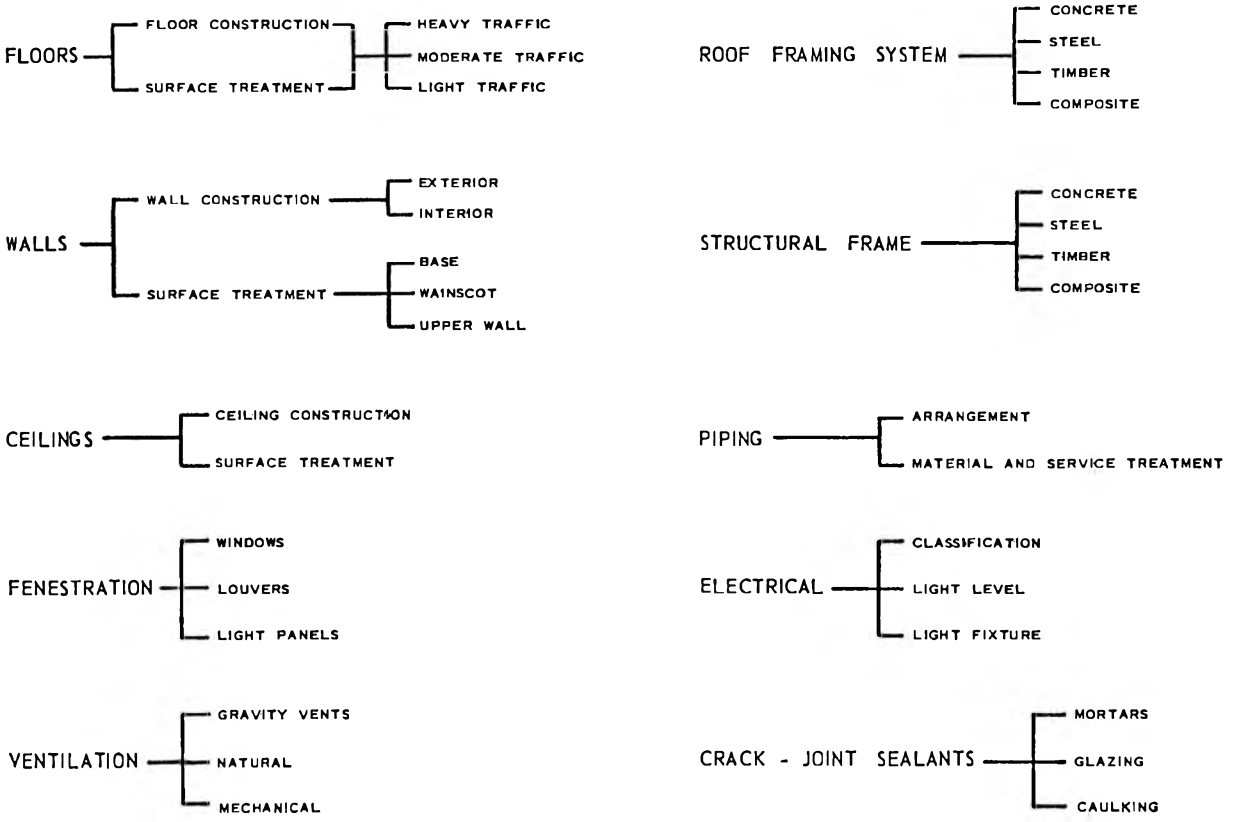


ILLUSTRATION #1

ENVIRONMENTAL CONDITIONS OF PROCESS AREAS

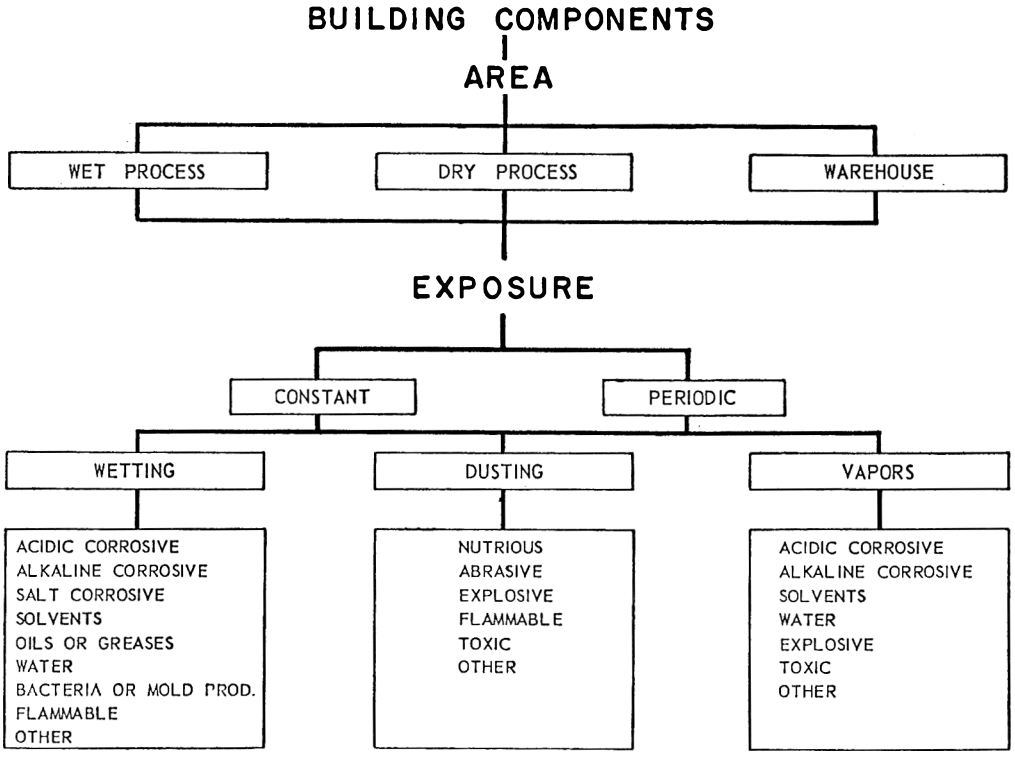


ILLUSTRATION #2

ENVIRONMENTAL CLASSIFICATION

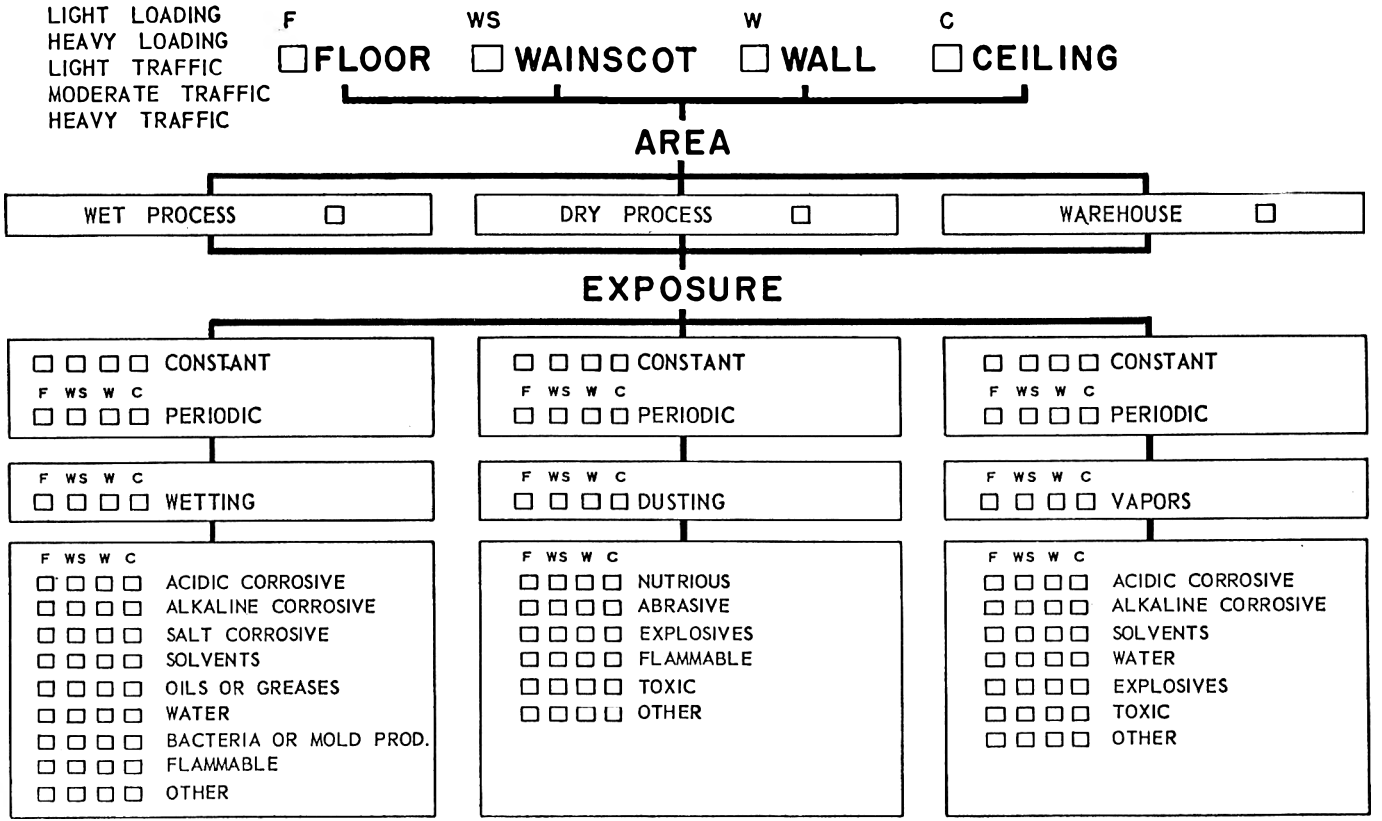


ILLUSTRATION #3

PRODUCT EVALUATION CARDS

PRODUCT:	"Rex-O-Tex", Ajax Products Company
	Neoprene Flooring: 3/16" thickness over new concrete Outside Contractor
APPLICATION:	C. P. Pilot Plant, Research Center, Wilmington, Del.
DATE:	2 February 1960
AREA:	5,760 sf at $.91/sf = $5,230; 150 sf for 71 threads, and 3 landings at $4.07/sf = $610.; 722 lf of 4" rubber cove at $.55/lf = $400.; Avg. Cost - $1.06/sf
ENVIRONMENTAL CONDITIONS:	Dry Process, constant exposure to clean, dust free atmosphere, steel wheeled cart traffic of light frequency
INITIAL RESULTS:	Very good, smooth, non-slip, easy to damp mop, difficult to broom and dust; sanitary appearing surface
EVALUATION AFTER 12 MONTHS	Excellent service, some evaluation as initial

PRODUCT:	"Acme" Wall Coating -
	3 coat system over new concrete block
APPLICATION:	Wet Starch Area; Bldg. No. 13, Harbor Beach, Mich. By: Plant Personnel
DATE:	15 November 1960
AREA:	2,600 sf at $.24/sf in-place: Material cost = $.18/sf
	Labor cost = $.06/sf - at $2.50/hr.
ENVIRONMENTAL CONDITIONS:	Wet Process, constant exposure to humid corrosive atmosphere in form SO_2 vapor; periodic exposure to corrosive condensation and wetting in the form of sulfurous acid.
INITIAL RESULTS:	Appearance good except for brush marks, special technique needed for base coat - not explained in literature - suitable for easy to clean sanitary surface.
EVALUATION AFTER 12 MONTHS	

ILLUSTRATION #4

A Survey of American Wine Laws

By JOHN D. GARR

1957-1958 Food Law Fellow

THE PURPOSE of this paper is to survey the basic national legislation affecting wines in the United States with special emphasis on the type of product a wine grower is allowed to place upon the market. While this paper attempts to treat briefly those phases of legislation which regulate distribution, and to some extent marketing of wine, laws and regulations that deal with what is called in the trade "alcoholic beverage control" have been de-emphasized. Rather, those aspects of federal law that are comparable to the Food, Drug, and Cosmetic Act [1] in scope are the principal concern of this monograph. Only legislation that is national in scope is included, thus eliminating federal laws of local concern such as laws affecting the District of Columbia, the territories of the United States, sale of wines to Indians, and sale of wines within the boundaries of national parks, monuments, military establishments and other federal enclaves; nor are any of the laws relating to the importation or exportation of wines discussed in this article.

The main agency of the government exercising jurisdiction over the production and distribution of wines and other alcoholic beverages is the Alcohol Tax Unit of the Department of Treasury. It administers the Federal Alcohol Administration Act of 1935 [2] and those provisions relating to wine production in the Internal Revenue Code of 1954.[3] In addition, there is an apparent overlap in jurisdiction with

[1] 52 Stat. (1938), 21 USC Sec. 1 and following (1952).

[2] 49 Stat. 77 (1935), 27 USC Sec. 201 and following (1952).

[3] An elaborate schedule of taxes applicable to wines, both domestic and imported is contained in Section 5041 (26 USCA (IRC, 1954) Sec. 5041) and the section immediately following. See also Part 240 of Title 26 (1954), Code of Federal Regulations for regulations

(Continued on following page)

the Food and Drug Administration and the Federal Trade Commission. Both of the statutes under which the latter two agencies operate contain provisions that include wine and other alcoholic beverages in their scope.

Because of improper labeling, and later, the era of Prohibition, the experience of the United States in relation to wines has been a dark and frightening one. Even before Prohibition, *vignerons* in the United States had gained fame in Europe for two things: one, the American root stocks grafted with European stocks had helped to check the disastrous *phylloxera vastatrix* epidemic that threatened extinction of Europe's vineyards in the nineteenth century. Since the epidemic most likely came originally from American stocks, the help rendered might be said to have just evened the score. Secondly, American growers had gained notoriety for "borrowing" southern European type designations with great liberty—and the use of terms such as champagne, port, madiera and other designations of geographical significance were held in contempt by nations whose laws forbade use of false geographical names.[4]

While Congress had held hearings on wines during the latter part of the nineteenth century,[5] it was not until the enactment of the Food and Drugs Act of 1906[6] that the consumer had some degree of protection against adulterated and misbranded wine. The 1906 act has defined "food" broadly (as does the present Food, Drug, and Cosmetic Act) and there were several cases involving the seizure of wines alleging and condemning the products on the ground that they were misbranded.[7] Typical cases involved carbonated white wine labeled "champagne";[8] wine with starch sugar added labeled "Riesling" and

(Footnote 3 continued)
relating to the production and removal of wine, including special natural wine and effervescent wine, from bonded wine cellars.

[4] For example, Anglo-Portuguese Commercial Treaty Act, 1914 (5 & 6 Geo. 5, c.1) s.1: "The description 'port' or 'madeira' applied to any wine or other liquor, other than wine the product of Portugal and the island of Madeira respectively, shall be deemed to be a false trade description within the meaning of the Merchandise Marks Act, 1887."

[5] U. S. Ways and Means Committee, "Pure Wine" and U. S. Ways and Means Committee, "Wines charged artifically with Carbonic Acid Gas."

[6] 34 Stat. 768 (1906).

[7] Section 10 of the 1906 Act provided for seizure and condemnation of adulterated or misbranded articles while being transported in interstate commerce, or after transportation and while unsold or in original unbroken packages.

[8] *Schraubstader v. U. S.*, 199 F. 568 (CA-9, 1912); *U. S. v. Five Cases of Champagne*, 205 F. 817 (DC N. Y., 1913).

purporting to be genuine Rhine wine;[9] pomace wine misbranded as "Ohio Claret Wine."[10]

The Food and Drug Administration (then an agency of the Department of Agriculture) continued to provide some control over alcoholic beverages until "Prohibition."[11] However, prior to 1919, federal liquor legislation was designed primarily for the collection of revenue. Prohibition came as a rising tide—slowly, and under the guise of a war measure. Congress passed the Webb-Kenyon law[12] which divested intoxicating liquors of their interstate character in certain cases. This was followed by prohibition in Alaska, Puerto Rico and the District of Columbia in 1917. The Eighteenth Amendment[13] to the Constitution was passed in 1919 and provided, after one year from its ratification, for the prohibition of intoxicating liquor for beverage purposes. The amendment gave Congress and the several states concurrent jurisdiction to enforce the article by legislation, and Congress enacted the National Prohibition Act[14] which prohibited the manufacture and sale of intoxicating liquors for beverage purposes. However, two exceptions to the Prohibition laws kept the waning wine industry from annihilation, the use of sacramental wines and the use of wine for medicinal purposes. The Commissioner of Internal Revenue administered the National Prohibition Act until 1927 when Congress created a Bureau of Prohibition in the Department of Treasury. Subsequently, the Prohibition Reorganization Act of 1930[15] created a Bureau of Prohibition in the Department of Justice and converted the Treasury Department's Bureau of Prohibition into the Bureau of Industrial Alcohol with overlapping jurisdiction in the two departments. Thirteen years after the Eighteenth Amendment, Congress adopted a Joint Resolution[16] on February 20, 1933, submitting to the states for ratification the Twenty-first Amendment repealing Prohibition. Meanwhile, the sale of beer was again permitted on April 7, 1933, with the passage of the Cullen-Harrison Act[17] amending the National Prohibition Act to redefine intoxicating beverages as those containing more than 3.2 per cent alcohol by weight. On

[9] *U. S. v. Sweet Valley Wine Company*, 208 F. 85 (DC Ohio, 1913).

[10] *U. S. v. 60 Barrels of Wine*, 225 F. 846 (DC Mo., 1915).

[11] *Duffy-Mott Company v. U. S.*, 285 F. 737 (CA-3, 1923).

[12] 37 Stat. 699 (1913).

[13] The amendment was certified as ratified by the necessary three fourths of the state legislatures on January 29, 1919.

[14] 41 Stat. 305 (1919).

[15] 46 Stat. 428 (1930).

[16] This resolution of Congress specified that it would be valid when ratified by conventions in three fourths of the states.

[17] 48 Stat. 17 (1935).

December 5, 1933, the Twenty-first Amendment was proclaimed adopted by the required 36 states, Utah being the thirty-sixth state to sign. Legal liquor returned.

What happened to the wine industry in the interim period of those 13 years is exemplified by the fate of the vineyards of California. By 1909, production of wine in California was around 50 million gallons, and was increasing steadily until Prohibition. The deadline of the act was January 16, 1920. All wine for export had to be on board ship and out of port on that day, leaving production limited to wines used for sacramental and nonbeverage purposes. California had 700 wineries when Prohibition was effected.[18] Thousands of acres of vines were uprooted and prunes planted in their place. Wines were being made in private homes, often by those with no knowledge of wine-making. Since it is well known in the wine trade that the best grapes are not the most beautiful, the demand for inferior grape types grew, and the truly superior varieties were bypassed. Many fine vineyards were replanted with inferior varieties. As one writer has commented, Prohibition proved merely to be a ban on superior wines.[19] Today, the production of wine is at an all-time high in the United States, with California producing roughly 90 per cent of the wines in the country. The nightmare of Prohibition over, American winegrowers have attempted to take their place among the major producers of the world.[20] How successful they are in this endeavor obviously rests to a large extent upon the devotion of the grower to his art. But to any large volume producer more devoted to immediate profits than to personal pride in a superior product, the quality of the product is more dependent upon the laws regulating wine production.

In a country whose reputation for high standards in foods is world-wide, it is disappointing to be confronted with a European scorn for our wines. Federal regulation of wine producers has been compared to that of the regulation of dope and other undesirable products,[21] and while this is an over-statement of the case, certainly regulation has been extensive. The measure of utility of such regulation must manifest itself in the finished product—the bottle of wine

[18] Wagner, *American Wines and Wine-Making*, (Knopf, 1956) p. 50-53.

[19] Cited at footnote 18, at p. 51.

[20] The United States now produces approximately 90 million gallons of wine a year. The ten leading producers are (respectively): France, Italy, Spain, Algeria, Portugal, Argentina, Greece, United States, Rumania and Hungary. See Marrison, *Wines and Spirits* (Pelican, 1957), p. 23.

[21] Wechsberg, "A Dreamer of Wine," *New Yorker* (May 17, 1958) p. 58.

which the consumer buys. If countries can produce fine wines properly labeled and conforming to health standards with little or no regulation, then perhaps minimal regulation is the solution. On the other hand, if extensive controls over labeling and the amount of production are needed, the laws should perhaps reflect concern with high standards. In any event, it is a basic assumption of this paper that the aim of federal regulation of wines and other alcoholic beverages was to provide the consuming public, not only in the United States but throughout the world, with a sound, healthful product truthfully labeled.

The Twenty-first Amendment

Before discussing the problems of federal jurisdiction that exist in regard to wines and other alcoholic beverages, it is well to consider what, if any, limitations are imposed by the Twenty-first Amendment to the Constitution. This discussion is concerned only with the effect on federal regulation and not with any powers granted to the states by that amendment. The Twenty-first Amendment reads (in part):

"Section 1. The eighteenth article of amendment to the Constitution of the United States is hereby repealed.

"Section 2. The transportation or importation into any State, Territory, or possession of the United States for delivery or use therein of intoxicating liquors, in violation of the laws thereof, is hereby prohibited."

Courts have indicated that Section 2 of the amendment gives effect to any and all state laws prohibiting the transportation or importation of intoxicating liquors into a state in violation of that state's law.[22] But, there is no provision which purports to restrict the power of Congress over commerce in intoxicating liquors when such commerce is carried on absent a violation of state laws, or to deny Congress the power to legislate in aid of the state prohibitions. Thus, it has been held that the amendment did not bar a prosecution under the federal Sherman Antitrust law against producers, wholesalers, and retailers charged with conspiracy to fix and maintain retail prices of alcoholic beverage.[23] However, Justice Frankfurter, in a

[22] *State Board of Equalization v. Young's Market Company*, 299 U. S. 59 (1936); *Indianapolis Brewing Company v. Liquor Commission*, 305 U. S. 391 (1939).

[23] *U. S. v. Frankfort Distilleries*, 324 U. S. 293 (1945).

concurring opinion, cast some doubt on the power of Congress as compared with that of the states. He took the position that if the State of Colorado had in fact authorized the transaction in question, the Sherman Act could not override such exercise of state power, since:[24]

". . . the Sherman law, . . ., can have no greater potency than the Commerce Clause; it must equally yield to state power drawn from the Twenty-first Amendment."

Later efforts, however, to invoke the Twenty-first Amendment as a limitation on the constitutional powers of the national government in cases involving federal price control on retail sales of liquors have been unsuccessful.[25]

In the event of a conflict between a federal statute and a state statute involving intoxicating liquors it would seem that the state statute should prevail by the authority of the amendment. However, some recent cases have cast doubt on the status of a state regulation that conflicts with the Commerce Clause, and the point is not settled.[26]

Congress did not repeal the "Original Packages Act"[27] and re-enacted without change the "Webb-Kenyon Act."[28] The Liquor Law Repeal and Enforcement Act[29] repealed most sections of the National Prohibition Act[30] and subsequent statutes have transferred certain sections to various sections of the United States Code.[31]

Thus, the Federal Alcohol Administration Act and certain sections of the Internal Revenue Code are the statutes which regulate specifically the production and distribution of wines in the United States today.

Federal Jurisdiction of Wines

Three separate agencies of the federal government have exercised jurisdiction over wines since the enactment of the Federal Alcohol

[24] Cited at footnote 23, at pp. 301, 302.

[25] *Jatros v. Bowles*, 143 F. 2d 453 (1944); *Barnett v. Bowles*, 151 F. 2d 77 (1945); *Dowling Brothers Distilling Company v. U. S.*, 153 F. 2d 353, cert. den. (*Gould et al. v. U. S.*), 328 U. S. 848, reh'g den., 329 U. S. 820 (1946).

[26] *Duckworth v. Arkansas*, 314 U. S. 390 (1941); *Carter v. Virginia*, 321 U. S. 131 (1944).

[27] 26 Stat. 313 (1890), 27 USC Sec. 121.

[28] 32 Stat. 699 (1913), which was re-enacted without change by the Act of August 27, 1935, c. 740 Sec. 202(b), 49 Stat. 877 (1935), 27 USC Sec. 122.

[29] 49 Stat. 872 (1935).

[30] 41 Stat. 305 (1919).

[31] See Internal Revenue Code of 1954, Sections 5001 to 5557 relative to Spirits, Wines, and Beer and Part 240 of Title 26 (1954), Code of Federal Regulations.

Administration Act in 1935. In addition to the Alcohol Tax Unit of the Department of Treasury, the Food and Drug Administration of the Department of Health, Education, and Welfare, and the Federal Trade Commission have both dealt at times with wines under the provisions of the Federal Food, Drug, and Cosmetic Act of 1938,[32] and the Federal Trade Commission Act of 1914, as amended.[33] The Food and Drug Administration was concerned with adulteration of wines; the Federal Trade Commission action dealt with advertising of wines. The jurisdiction of both agencies extends into this field under their more general powers. Both agencies have, however, for the most part limited the exercise of this jurisdiction to cases which were not covered by the Federal Alcohol Administration Act, referring cases in which there is concurrent jurisdiction for treatment under the more specific statute.[34] While this apparent overlap in jurisdiction has not been the subject of litigation, the acts do have similar provisions in some respects.

Adulteration

The Federal Alcohol Administration Act does not specifically cover adulteration. However, permits granted under Section 4(d) are conditioned upon compliance "with all other Federal Laws relating to distilled spirits, wine, and malt beverages, including taxes with respect thereto."

It would seem that this provision relates to compliance with the Federal Food, Drug, and Cosmetic Act, and that has been suggested by one writer.[35]

Secondly, the absence of an adulteration provision in the Federal Alcohol Administration Act leaves an inference that Congress at the time of its passage considered the provisions of the 1906 Food and Drug Act to be sufficient to protect the public from adulterated wines and alcoholic beverages.

Section 201(f) defines "food" as "(1) articles used for food or drink for man or other animals . . .".[36] This definition is broad enough to include wines and other alcoholic beverages. The Food and

---

[32] 21 USC Sec. 1 and following.

[33] 15 USC Sec. 1 and following.

[34] Informal collaboration between the Federal Trade Commission and the Federal Alcohol Administrator (now obsolete as an office) is referred to in *Attorney General's Committee on Administrative Procedure*, The Federal Trade Commission (1940), note 22.

[35] Lee, "Adulteration and Misbranding of Alcoholic Beverages," 3 FOOD, DRUG, COSMETIC LAW QUARTERLY 85-86 (1948).

[36] 21 USC Sec. 201(f).

Drug Administration has ruled that cordials, liqueurs, wine and whiskey, are subject to the act.[37] In several cases the Food and Drug Administration has filed libels against beer,[38] ale,[39] whiskey,[40] vermouth,[41] and on several occasions against wine.[42] These are uncontested cases in which judgment was for the government and the products were either destroyed or released under bond to the claimant to be brought into compliance with the law under the supervision of the Food and Drug Administration. In the case of *United States v. 4,289 ½-Pint bottles*,[43] whiskey while in transit was submerged in polluted water after being involved in a truck accident. The product was seized as being in violation of Section 402(A)(4) of the Food, Drug, and Cosmetic Act relating to adulteration, and as being misbranded under Section 403(e)(1) and (2) in that the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents. Also, it was alleged that Section 403(i)(1) was violated in that the label failed to bear the common or usual name of the article. Apparently, the labels had become detached from the bottles in the water. The case was disposed of by releasing the whiskey under bond to be brought into compliance with the law by

[37] TC-224: "While we have indicated that cordials, liqueurs, wine and whiskey are subject to the Act, we will continue, as in the past, to leave to the Federal Alcohol Administration the regulation of labeling of these alcoholic beverages under the more specific Federal Alcohol Administration Act.

"While beer is classed as food under the Act and would, therefore, be subject to the adulteration and misbranding provisions of the Act when shipped within its jurisdiction, we expect to continue our policy of not duplicating the work of the Federal Alcohol Administration with respect to the labeling of such products. That Administration, as you know, is charged with the enforcement of specific legislation dealing with alcoholic beverages." (April 11, 1940) I *Kleinfeld & Dunn* 657.

[38] *U. S. v. Minneapolis Brewing Company*, Notices of Judgment under the Food, Drug, and Cosmetic Act, No. 17601 (1951); *U. S. v. 3,862 Cases*, Notice of Judgment No. 18501 (1952); *U. S. v. 1,500 Cases*, Notices of Judgment No. 15051 (1947); *U. S. v. Rubsam & Horrman Brewing*, Notice of Judgment No. 21451 (1953).

[39] *U. S. v. 59 Cases*, Notice of Judgment under Food, Drug, and Cosmetic Act, No. 10351 (misbranding of ale—short—volume, 1946).

[40] *U. S. v. 156 Cases*, Notice of Judgment No. 7710 (distilled spirits—excess of fusel oil—1944); *U. S. v. 1,800.2625 Wine Gallons*, Notice of Judgment No. 21301 (whiskey, etc., Kansas City Flood —1954).

[41] *U. S. v. 14 Cases of Vermouth*, Notice of Judgment No. 7206 (vermouth—splinters of glass—1944).

[42] *U. S. v. Western Wine Corporation*, Notice of Judgment No. 14751 (adulterated wine due to presence of fly pupae, insect fragments, mites and aphids, 1949); *U. S. v. 3 Drums of Raisin Brandy*, Notice of Judgment 6001 (raisin brandy—excessive amount of fusel oil—1944).

[43] Notice of Judgment under the Food, Drug, and Cosmetic Act 19751 (1953).

redistillation under the supervision of the Department of Health, Education, and Welfare, and the Treasury Department. The disposition of the case was a recognition of this concurrent jurisdiction.

Many seizures of wines were effected under the provisions of Section 402(a)(2) when monocholoracetic acid was added to the wine.[44] That section provides that a food shall be deemed adulterated "if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406." Section 406 continues "except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a) . . . ." Such wine that was seized was destroyed.

Thus, from the seizures effected by the Food and Drug Administration it would seem that they have jurisdiction as to adulterated wines. Against this apparent jurisdiction would be an argument of Congressional intent—that the whole of the regulatory scheme, not just particular parts, of the Alcohol Administration Act, must be considered as exception to the later Food, Drug, and Cosmetic Act. This later construction, however, would leave the government powerless to condemn adulterated wine in an *in rem* action against the wine itself. That seems a very unlikely construction of the intent of Congress.

Misbranding

There would appear to be an overlap of jurisdiction in regard to the labeling of wines.

Section 5(c) of the Alcohol Administration Act makes it unlawful for producers of distilled spirits, wine, or malt beverages, and bottlers of distilled spirits to introduce or receive in interstate commerce any distilled spirits, wine or malt beverages unless "bottled, packaged, and labeled in conformity" with regulations issued by the Secretary of the Treasury. This section authorized the issuance of regulations. Section 31 of Regulations No. 4 has defined "Misbranding of Wine in Containers."[45] In addition, Article V of Regulations No. 4 prohibits the bottling or packing of wine without a "Certificate of Label Ap-

[44] The following cases dealt with wine which was adulterated by the presence of monocholoracetic acid: Notices of Judgment under the Food, Drug, and Cosmetic Act: #12411 (1947); #12823 (1947); #12824 (1947); #12825 (1947); #12826 (1947); #12827 (1947); #12828 (1947); #12829 (1947); #13002 (1947); #13207 (1947); #13208 (1947); #13356-13358, incl. (1947); #13502-13504, incl. (1947); #13903 (1948); #13904 (1948); #14301 (1949).

[45] Part 4 of Title 27, CFR, Sec. 4.31.

proval"[46] from the Secretary of the Treasury. Officers of Internal Revenue are authorized and directed to withhold the release of wine from the bottling plant until such certificate has been obtained.

Section 403, subsection (a) through (k), inclusive, are the misbranding provisions of the Food, Drug, and Cosmetic Act. Of particular interest is Section 403(i) which provides that a food for which no standards have been established, shall be deemed to be misbranded unless its label bears (1) the common or usual name of the food, if any, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient. Compliance with the requirements of (2) may be waived by the Secretary where compliance would be "impracticable." If this provision applies to alcoholic beverages it would be in effect a limitation upon the Secretary of Treasury and his authority to prescribe what is sufficient information for the label of such beverages.[47] To comply with the Food, Drug, and Cosmetic Act, all ingredients would have to be listed.

There are authorities to the effect that a later statute is controlling over an earlier conflicting provision.[48] However, that doctrine would seem to have no application here. The standards issued under the Alcohol Administration Act have been upheld where they conflict with the Food, Drug, and Cosmetic Act.[49] It is probable that where the two conflict, that the earlier is controlling. There is nothing in the Food, Drug, and Cosmetic Act or its legislative history to the contrary. The Act does not mention the Federal Alcohol Administration Act. There were two earlier references to the latter act in earlier versions of the bill.[50] The Congressional debates indicate that this was deleted for substantive reasons.

---

[46] This certificate is required unless the wine is not to be sold, offered for sale or otherwise introduced into interstate commerce. In such case a "Certificate of Exemption of Label Approval" must be secured from the Deputy Commissioner.

[47] See last sentence of 27 CFR Sec. 5.34(b)—The Secretary of Treasury has required no listing of ingredients.

[48] 26 *Opinion of Attorney General* 166 (1908). In this opinion the Attorney General stated that the Tea Inspection Act and the Food and Drugs Act did not conflict but that if they did the later Food and Drugs Act would control.

[49] *Gibson Wine v. Snyder*, 194 F. 2d 329 (CA of D. C., 1950); See, also, *W. Jameson & Company v. Morgenthau*, 25 F. Supp. 771 (1939), vac. on other grounds 307 U. S. 171; *Arrow Distillers v. Alexander*, 109 F. 2d 397 (CA-7); *Continental Distilling Company v. Humphrey*, 220 F. 2d 367 (CA of D. C., 1954).

[50] See S. 5, 74th Congress (1936). There were two references to alcoholic beverages in earlier versions of the bill. The first was part of a House version which was not passed. It imposed certain labeling requirements upon alco-

It has been suggested that both acts apply to the misbranding of alcoholic beverages. Mr. Lee suggests that in administering the Food, Drug, and Cosmetic Act, the definitions and standards of identity and the standards of quality and fill of container under the Federal Alcohol Administration Act would presumably be followed by the Food and Drug Administration since no standards have been promulgated by the latter for alcoholic beverages.[51]

Advertising

Section 5(f) of the Federal Alcohol Administrative Act makes it unlawful to advertise distilled spirits, wine, or malt beverages, in most instances, unless such advertisement is in conformity with regulations prescribed by the Secretary of Treasury. Article VI of Regulations No. 4 relating to "Advertising of Wine" contains provisions for both mandatory and prohibitive statements and is a comprehensive scheme for the advertising of wine.[52]

As indicated above, the jurisdiction of the Federal Trade Commission extends into this field under its more general powers. The 1938 Wheeler-Lea Amendment to the Federal Trade Commission Act contains specific provisions with respect to dissemination of false advertisements of foods (the definition of foods is broad enough to include wine and other alcoholic beverages), drugs, devices or cosmetics by mail or in interstate commerce. Such dissemination was made unfair or deceptive practice under Section 5 when it was false or misleading. The Federal Trade Commission has exercised this jurisdiction over wines at various times in spite of the provisions of the Federal Alcohol Administration Act.[53] The procedural remedies of

(Footnote 50 continued)
holic beverages with the provision that these should not apply insofar as they duplicated requirements imposed by the Federal Alcohol Administration Act or regulations thereunder. The second was a provision in the original House version of the bill which became law and would have amended the Federal Alcohol Administration Act, in effect, by making use of the term "whiskey" misbranding for the purposes of that Act if used on any product not distilled from grain. Both provisions were deleted.

[51] See footnote 35, at p. 89.

[52] 27 CFR Sec. 4.60 and following.

[53] The Federal Trade Commission has acted in the following cases:

Artificially carbonated wine and apple juice as "champagne" and "champagne wine" Dkts. 2467 (closed), 2520 (closed); "Champagne" Stips. 1315, 1316, 1396, 1412, 1472; "Sparkling Burgundy" incorrect unless accompanied by "carbonated," "artificially carbonated," or "carbon dioxide added." Stipulation 1398.

Wine as 42 per cent proof when wine makers not permitted to make wines higher than 24 per cent. Stip. 1387.

"Vintage—1928." Stip. 1920.

"Red Wine" without the words "Imitation" and "Artificially flavored" in equally conspicuous type. Stip. 323. See, also, 16 CFR Part 139 (p. 352)—Wine Industry—Trade Practice Conference Rules.

the FTC, however, are limited to a cease and desist order or injunction proceedings.

Federal Alcohol Administration Act

The basic national legislation dealing with wines and other alcoholic beverages is the Federal Alcohol Administration Act.[54] The act itself, unlike the Food, Drug, and Cosmetic Act, is brief, consisting of 11 sections, five of which deal with internal organization, definitions, titles and similar subjects and have little or no effect upon the substantive law applicable to the beverages or their producers. The following summarizes the remaining sections that substantively regulate the wine industry.

Section 3 [55] provides for a basic permit system which extends from the importer and distiller to the wholesaler. The section makes it unlawful, except pursuant to a basic permit issued by the Secretary of Treasury, to: (1) engage in the business of importing into the United States distilled spirits, wine or malt beverages, or for any person engaged in importing such alcoholic beverages to sell directly or indirectly or through an affiliate in interstate or foreign commerce; (2) engage in the business of distilling spirits, producing wine, or rectifying or blending the same or bottling or warehousing and bottling—and likewise for any person so engaged to sell or ship directly or indirectly in interstate or foreign commerce such beverages (it should be noted that no permit is required to engage in the business of producing malt beverages although a permit is required to import them, and to purchase them for resale); (3) to engage in the business of purchasing for resale at wholesale distilled spirits, wine or malt beverages (and the same limitations are imposed on a person so engaged in relation to the sale or offer for sale in interstate or foreign commerce).

The scope of this section is broad in its encompassment of the wine industry—in effect, exempting only the retailer. The preamble to the section expresses the constitutional powers upon which Congress relied: [56]

"In order effectively to regulate interstate and foreign commerce in distilled spirits, wine and malt beverages, to enforce the twenty-first amendment, and to protect the revenue and enforce the postal laws with respect to distilled spirits, wine and malt beverages."

---

[54] 27 USC Sec. 201 and following.
[55] 27 USC Sec. 203.
[56] 27 USC Sec. 203.

The courts have upheld this basic permit system against attacks that it was unconstitutional as beyond the power of Congress under the Commerce Clause.[57] In 1939, the Supreme Court dismissed as being "without substance" a contention that the Twenty-first Amendment restricted the power of Congress in this field,[58] and later lower court cases have continued to reject such arguments.[59]

Section 4[60] deals with the basic permits themselves and the proceedings for application, hearing, conditions, duration, revocation, suspension and annulment and appeal.

There are three bases in the act for refusal of a permit. Basic permits should be denied to (1) any person (or if a corporation, its officers, directors or principal stockholders) who, within five years prior to date of his application has been convicted of a felony under federal or state law or has within three years prior to the date of his application been convicted of a misdemeanor under any federal law relating to liquor, including the taxation thereof; (2) any person who by reason of business experience, financial standing or trade connections is not likely to commence operations within a reasonable time or maintain them in conformity with federal law; and (3) any person whose proposed operations would violate a state law.

The section provides for a hearing where the permit is refused, and upon the denial[61] of an application, suspension or revocation or annulment an appeal may be taken directly to the United States Court of Appeals within 60 days.[62]

Section 4(e) provides that a basic permit shall, after notice and hearing (1) be revoked for a willful violation[63] of any of the conditions

[57] *Arrow Distilleries v. Alexander*, cited at footnote 49, cert. den., 310 U. S. 646, motion granted, 311 U. S. 613.

[58] *W. Jameson & Company v. Morgenthau*, 25 F. Supp. 771 (DC of D. C., 1938), vac. on other grounds, 307 U. S. 171 (1939).

[59] *Hanf v. U. S.*, 235 F. 2d 710 (CA-8, 1956), cert. den., 352 U. S. 880 (1956).

[60] 27 USC Sec. 204.

[61] See *Levers v. Anderson*, 326 U. S. 219 (1945) (a motion for reconsideration is not a prerequisite for appeal to the court of appeals).

[62] See *United Distilleries Products Company v. Heneberry*, 135 F. Supp. 37 (DC Mass., 1955). (A U. S. District Court has no jurisdiction under this section—appeal must go to the court of appeals.)

[63] In *Rex Wine Corp. v. Dunigan*, 224 F. 2d 93 (CA-2, 1955), the court said: "Since § 4(e) of the Federal Alcohol Administration Act requires a finding that the permittee has 'wilfully violated' the conditions of the permit, it is apparent that the proceeding presupposed 'wilfull' violations. The appellant, then, and throughout the proceeding must have become aware that it was being tried for such violations; and indeed it does not show in what way its defense was prejudiced by the omission in the charge."

provided that for a first violation the permit shall be subject to suspension only; (2) may be revoked upon a finding that the permittee has not engaged in the operations for a period of more than two years; or (3) may be annulled if the permit was procured through fraud, misrepresentation or concealment of a material fact.

Section 4(g) provides that the basic permit shall continue until suspended, revoked, annulled or voluntarily surrendered. If there is a transfer by operation of law or if actual or legal control of the permit is acquired, by any other person, then the permit terminates in 30 days —with the provision that if a new permit is applied for within the 30-day period the old one continue until the Secretary acts upon the application.

Section 4(i) relates to limitations applicable to revocation or suspension of the basic permit.[64] The Secretary may not institute proceedings for violation of conditions relating to compliance with federal law more than 18 months after conviction, or if no conviction be had, more than three years after the violation occurred. Also, there can be no revocation or suspension if the alleged violation of federal law has been compromised by an official of the government authorized to compromise such violation.

Section 5[65] relates to unfair competition and unlawful practices. The first four subsections place restrictions on exclusive outlets, tied house, commercial bribery and consignment sales, and these sections are similar in spirit and somewhat in scope to the Sherman Antitrust Act and the later Robinson-Patman Act. However, application of sanctions for violations of these sections is primarily the responsibility of the Alcohol Tax Unit.

Section 5(a) essentially prohibits agreements with retailers to purchase distilled spirits, wine, or malt beverages to the exclusion in whole or in part of other persons where interstate or foreign commerce is affected.

Section 5(b) prohibits the inducement of any retailer to the exclusion of others in whole or in part by (1) having any interest in the license of the premises of the retailer; (2) having any interest in real property used by the retailer in the conduct of his business; (3) subject to exceptions by the Secretary, the giving or furnishing of signs, equipment, fixtures or services to the retailer; (4) paying or crediting

[64] See *Pincourt v. Palmer*, 190 F. 2d 390 (CA-3, 1951); *United Wholesale v. Humphrey*, 203 F. 2d 198 (CA-8, 1953).

[65] 27 USC Sec. 205.

the retailer with any advertising, display or distribution service; (5) guaranteeing loans or repayment of financial obligations of any retailer; (6) extending credit in excess of customary period; or (7) requiring a quota on the part of the retailer.[65]

Section 5(c) prohibits commercial bribery or the offering or giving of any bonus, premium or compensation to any officer, employee, or representative of the trade buyer.

Section 5(d) prohibits consignment sales or conditional sales. It should be noted, however, that this section does not apply to bona fide returns of merchandise.

Labeling

Section 5(e) is one of the most important sections of the act from the standpoint of both the wine producer and the consumer. It requires the packaging, marketing, branding and labeling, and size and fill of container (1) as will prohibit deception to the consumer and it prohibits, irrespective of falsity, such statements relating to age, manufacturing processes, analyses, guarantees and scientific or irrelevant matters as the Secretary of the Treasury finds to be likely to mislead the consumer; (2) as will provide adequate information as to identity and quality and alcoholic content (in the case of wines, statements of alcoholic content shall be required only for wines containing more than 14 per cent alcohol by volume), the net contents and the manufacturer, bottler or importer of the product; (3) as will prohibit statements on the label that are disparaging of a competitor's product or are false, misleading, obscene or indecent; and (4) as will prevent deception of the consumer by use of a trade name or brand name that is the name of any living individual of public prominence or existing private or public organization.

This section also provides:

"It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label upon distilled spirits, wine, or malt beverages held for sale in interstate or foreign commerce or after shipment therein, except as authorized by Federal Law or except pursuant to regulations of the Secretary of Treasury authorizing relabeling for purposes of compliance with the requirements of this subsection or of State law."

---

[65] See *Black v. Magnolia Liquor Company*, 355 U. S. 24 (1957).

The act further provides for a system of label approval by the issuance of "certificates of label" by the Secretary of the Treasury. These certificates are issued to bottlers of distilled spirits, producers, blenders or wholesalers of wine or proprietors of bonded wine storerooms or brewers or wholesalers of malt beverages. Such certificates are required to remove the above alcoholic beverages from customs custody, in bottles, for sale or other commercial purpose. Exempted from this section are alcoholic beverages not intended to be sold, offered for sale, or shipped or delivered for shipment, or otherwise introduced, interstate or foreign commerce. The act provides that the district courts of the United States have jurisdiction over any final action of the Secretary under this particular subsection. In the case of permits arising under Section 4, appeal is direct to the court of appeals.

Section 5(f) relates to advertising of distilled spirits, wine or malt beverages and in general complements the section of the act relating to labeling of the beverages prohibiting statements that are inconsistent with the labeling. There is a special subsection relating to the advertising of malt beverages only. It provides that the provisions as to advertising shall not apply to malt beverages except to the extent that state law imposes similar requirements.

Section 6[67] entitled "Bulk sales and bottling," relates solely to distilled spirits and not to wine.

Section 8[68] prohibits interlocking directorates unless approved by the Secretary of Treasury and applies only to distilled spirits and not to wine producers.

Classification of Wines

The great variety of grapes used, differences in the environmental conditions under which the grapes are grown, fermentation, and the differences in the cellar treatment have resulted in the production of many kinds of wines in various parts of the world. However, there seems to be agreement that there are at least five basic classes of wine. These are red table wines, white table wines, appetizer wines, dessert wines, and sparkling wines.[69]

Beyond these large groups, wines are segregated according to the country of origin and the type. Wines are of a single type when their

[67] 27 USC Sec. 206.

[68] 27 USC Sec. 208.

[69] This is the classification adopted by the Wine Institute of San Francisco. See *Dictionary of California Wine Types* (Wine Institute-undated). The *Encyclopedia Britannica* uses the same classification. ("Wine," 1947 Ed.)

general and special characteristics show a pronounced similarity. In the case of table wines, for example, a given type may include only wines of a single variety of pronounced character, a principal variety of a pronounced character and several minor supplementary varieties, or several varieties of distinct character that are produced under special environmental conditions.[70]

Each of the countries growing wines has one or more types, and often these are only of local interest. But, many wines have gained recognition throughout the world, and their names become distinctive designations of specific wines. Not only is the particular designation a source of valuable commercial prosperity to the producer or area producing the specific wine, but also consumers through the years are inclined to rely upon type designation as a standard of quality. The most widely used wine type names have geographic origin, from the regions in which the types originated. Others are varietal, representing the principal grape varieties employed. Still others are proprietary, and may be either the name of their producer or a fanciful trademark or trade name used by individual vintners. In this latter instance, the use of the trade name or trademark will be subject to the trademark laws of the particular country or in most instances, the International Convention for the Protection of Industrial Property.[71] These are a matter of private law and the protection of such names is beyond the scope of this discussion.

At various times for the past century, attempts have been made by France and other nations to restrain producers of other countries from using the names of certain generic and semigeneric wine types of European geographical origin. International agreements and many national wine laws reflect these efforts.[72]

In the United States, however, no such agreements have been accomplished. European wine types are used as a designation of American wines when, in some instances, they only vaguely resemble their European counterpart.[73] There has been a great deal of criticism of the use of type names in this manner, domestically as well as abroad.

---

[70] Winkler, "Grapes and Wine," 3 *Economic Botany* 46-70 (1949).

[71] Trademarks are protected by this convention known as the Paris Convention, as revised at Brussels (1900), Washington (1911), the Hague (1925) and London (1934). Most of the countries of the world are members of at least a part of the convention.

[72] See, for example, Anglo-Portuguese Treaty, cited at footnote 4.

[73] Marrison, *Wines and Spirits*, (Pelican, 1957), p. 186.

Amerine and Joslyn, two experts with world-wide reputations, had this to say of the California situation in 1940:[74]

"The nomenclature for California wines has never been standardized. Many of the present type names originated abroad. The advisability of the use of such foreign names as 'Burgundy' and 'sauterne' by California producers, has often been questioned. Undoubtedly, it would be desirable to develop native names for distinctive types. Such a nomenclature would stimulate the production of native wines of more standardized composition and quality. Several type names already widely used—for example, Angelica, Zinfandel, and Riesling—are not derived from any foreign geographical appellation, but originated in California or were derived from names of varieties of grapes. A number of wineries have also developed proprietary names for their wines. These are encouraging developments."

While these may have been encouraging in 1940, eighteen years later it is difficult to repeat such optimism. L. W. Marrison, writing in 1957, groups the United States with Australia, Chile and South Africa as countries using names that are misleading and confusing to those used to European nomenclature.[75]

However, rather than engage in polemics, it is more profitable to examine the federal regulations regarding the labeling of wine. These are found in "Regulations No. 4 relating to Labeling and Advertising of Wine."[76] They govern the labeling, advertising, withdrawal from customs, as well as the promulgation of standards of identity and standards of fill for wines.

Before examining the standards of identity, it is well to consider those provisions of the regulations that relate to grape type designation. Initially, the regulations provide that a name indicative of a variety of grape may be employed as the type designation of a grape wine if the wine derives its predominant taste, aroma and characteristics, and *at least 51 per cent of its volume*, from the variety of grape.[77]

---

[74] Amerine and Joslyn, *Commercial Production of Table Wines*, (University of California, 1940), p. 112.

[75] Work cited at footnote 73, at p. 186-187. But it should be noted that several volume producers have recently adopted arbitrary and fanciful names among their lower priced wines. Gallo now markets "Thunderbird," "Eden Roc," "Ripple," and "Gypsy Rose," while Italian Swiss Colony has adopted the names "Paree," "Arriba," "Hombre" and "Silver Satin." See, also, "Extension of Remarks of Hon. Thomas H. Kuchel" (*Congressional Record* A3415) for comments on a new California wine "Premier Semillon" developed by Cresta Blanca Winery in cooperation with the College of Agriculture of the University of California.

[76] 27 CFR Secs. 4.1-4.80.

[77] 27 CFR Sec. 4.23.

This provision has been another source of concern among many wine growers and authorities in the field.[78] One point of view holds that this encourages, to say the least, the blending of Thompson seedless grapes[79]—a grape that is not suited for production in quality wines—into the finer varietal wines but still allows the use of the type designation.

The regulations establish that a name of geographic significance, which is also the designation of a class or type of wine will be deemed to have become generic only if found to be so by the Deputy Commissioner. If a name has become generic then it may be used without qualifying phrases to indicate the appellation of origin, such as "California" or "New York State." As examples of names which are generic the regulations list Vermouth and Sake.

The regulations further provide for names that have become semigeneric if so found by the Deputy Commissioner. Semigeneric designations may be used to designate wines of an origin other than that indicated by such name only if there appears in direct conjunction an appropriate appellation of origin disclosing the true place of origin of the wine *and* if the wine so designated conforms to the standard of identity. If no standard of identity exists, then it must conform "to the trade understanding of such class or type." The examples given are: Angelica, Burgandy, Claret, Chablis, Champagne,[80] Chianti, Malaga, Marsala, Madeira,[81] Moselle, Port,[82] Rhine wine (syn Hock), Sauterne,[83] Haut Sauterne, Sherry,[84] Tokay.[85] Thus, in order for an American producer to label his wines with these type designations he must qualify them with such terms as "*California* Sherry" or "*New York State* Champagne." Of the above names, only Angelica can

[78] Storm, *An Invitation to Wines* (Simon & Schuster, 1955), p. 47: "Can milk which has been diluted with 49 per cent water honestly be called 'milk'? Why then should a wine be allowed to be labeled Pinot Noir, or Riesling or some other aristocratic name when it has been diluted with 49 per cent inferior juices? Since practically all the fine varieties are especially cared for and have small yields, they should naturally represent the cream of our production. Use of their names should be *rigidly* controlled."

[79] Also named Sultanina. This is the most important grape produced commercially in California.

[80] This wine is *Sekt* or *Schaumwein* in Germany, *spumante* in Italy and even in France itself outside of the Marne area the wine is called *vin mousseax*.

[81] See footnote 4.

[82] See footnote 4.

[83] Note the spelling. In France the variety is "Sauternes" with a final "s."

[84] Work cited at footnote 73, at p. 196: "The wine described as California Sherry is not even sherry-type."

[85] Work cited at footnote 74, at p. 110: "The California wine is an entirely different type from the Hungarian Tokay."

be said to be truly American in origin. It has been used since Mission days in California and has been called the "only contribution of North America to the world's battery of drinks with the exception of the cocktail." [86] This latter statement cannot be taken too seriously since it overlooks the pioneering efforts of certain California producers and the distinct varieties developed in the eastern United States.[87]

A name of geographic significance which has not been found to be generic or semigeneric may be used only to designate wines of the origin indicated by such name but the name shall not be deemed to be the distinctive designation of wine unless the Deputy Commissioner finds that it is known to the consumer and the trade as the designation of a specific wine of a particular place or region, distinguishable from all other wines.[88] Examples of names, not generic or semigeneric, which are not distinctive names of specific wines are American, California, Lake Erie Islands, Napa Valley, New York State, French and Spanish.

A wine is entitled to an appellation of origin if at least 75 per cent of its volume is derived from fruit or other agricultural products both grown and fermented in the place or region indicated by such appellation, and it has been fully finished and manufactured there, and conforms to the laws and regulations of such place or region of wines for home consumption.

The regulations relating to labeling permit a statement of age in the case of domestic vintage wine if bottled or packed by the permittee who crushed the grapes and further processed the wine, provided there is stated the name of the viticultural area in which the grapes were grown and the wine was fermented. Vintage wine means a wine made wholly from grapes gathered in the same calendar year and grown and fermented in the same viticultural area.

---

[86] Work cited at footnote 73, at p. 132.

[87] Grossman, *Guide to Wines, Spirits, and Beers* (Revised Ed., 1955) Chapter 14, "American Wines."

[88] Examples of names, not generic or semigeneric, which are distinctive designations of specific natural table wines, when qualified by the word "wine" or its French or German equivalent: Bordeaux, Medoc, St. Julien, Margaux, Graves, Barsac, Pomerol, St. Emilion, Bourgogne, Grand Chablis or Bourgogne des Environs de Chablis, Cote de Nuits, Gevrey-Chambertin, Morey, Chambolle-Musigny, Flagey-Echezeaux, Vosne-Romance, Nuits or Nuits-St. Georges, Cote de Beaune, Aloxe-Corton, Savigny, Beaune, Pommard, Volnay, Santenay, Meursault, Puligny-Montrachet, Chassagne-Montrachet, Cote Maconnaise or Maconnais, Macon, Cote Beaujolaise, Beaujolaise, Rhone or Cote de Rhone, Cote Rotie, Hermitage, Chateauneuf-du-Pape, Tavel, Loire, Anjou, Coteaux du Layon, Coteaux de la Loire, Saumur, Anjou-Saumur, Touraine, Vouvray, Alsace or Alsatian, Mosel-Saar-Ruwer, Mosel, Swiss or Suisse.

In many countries, the word "wine" can be applied only to the fermented juice of grapes and its use is prohibited on the fermented juice of other fruits and agricultural products such as berries, apples, oranges, etc.[89] In the United States, however, the standards of identity provide that the word wine may be used for several classes of fermented juice and the Internal Revenue Code of 1954 mentions over 15 types of wines from different fruits, including grape wine.[90]

The standards of identity do recognize the five basic types of grape wine, while the Internal Revenue Code classifies wines by the amount of alcohol by volume—except sparkling and carbonated wines which are taxed at the highest rate—and range from 15 cents to two dollars per wine gallon.[91]

Standards of Identity

There are, as promulgated by the Secretary of the Treasury, eight classes of wine. These include three classes of grape wine, citrus wine, fruit wine, wine from other agricultural products, aperitif wines, and imitation and substandard wine. In many instances, each of these classes is subdivided into types and subclasses.

The standards of identity that exist for grape wine are typical of the classification for all of the types of wines as regards alcoholic content, designation of table or dessert wines, and the tolerances for volatile acidity and amelioration.

Class 1—Grape Wine—"Grape Wine" is wine produced by the normal alcoholic fermentation of the juice of sound, ripe grapes (including restored or unrestored pure condensed grape must) with or without the addition, after fermentation, of pure condensed grape must, and with or without added brandy or alcohol, but without other addition or abstraction except as may occur in cellar treatment. The definition continues with tolerances for amelioration. Grape wine deriving its characteristic color or lack of color from the presence or absence of the red coloring matter of the skins, juice, or pulp of grapes may be designated as "red wine," "pink wine" (or rose), "amber wine," or "white wine," as the case may be. Any grape wine contain-

[89] Apparently France, Italy and Germany allow only the use of fresh or slightly dried grapes for the making of "wine." Greece has a definition broad enough to encompass dried grapes. See work cited at footnote 73, at p. 16.

[90] IRC of 1939, Section 3036(c) mentioned peach wine, cherry wine, berry wine, apricot wine, prune wine, plum wine, pear wine, pawpaw wine, papaya wine, pineapple wine, cantaloupe wine and apple wine.

[91] 71 Stat. 9 (1957), 26 USC Sec. 5041.

ing no added grape brandy or alcohol may be further designated as natural.

Grape wine is further classified as "table wine" or "dessert wine," depending upon the alcoholic content by volume. Table wines may not be in excess of 14 per cent alcohol by volume. Dessert wines must have an alcoholic content in excess of 14 per cent but not exceeding 24 per cent. There are provisions for the designation of sherry, angelica, madiera, muscatel, port, and wines "having the taste, aroma and characteristics generally attributable" to those respective wines, and falling within a specified range of alcoholic content. These provisions relating to designation have been questioned by several writers from the standpoint of truthful labeling.[92] Not only is it felt in some instances that the borrowing of European designations is questionable as a trade practice, but further, it may often involve deception of the consuming public.

Class 2—Sparkling Grape Wine—"Sparkling grape wine" is grape wine made effervescent with carbon dioxide resulting solely from the secondary fermentation of wine within a closed container, tank or bottle. "Champagne" [93] is a type of sparkling light white wine which derives its effervescence solely from the secondary fermentation of the wine within glass containers of not greater than one gallon capacity, and which possesses the "taste, aroma and other characteristics attributed to champagne as made in the champagne district of France.[94] Wines produced by a secondary fermentation in large-sized, closed containers (Charmet and other processes) are called "champagne type" or "champagne style" or "American (or New York State, California, etc.) champagne-bulk process" in equally conspicuous lettering.

Class 3—Carbonated Grape Wine—Carbonated grape wine is wine made effervescent with carbon dioxide other than resulting solely from the secondary fermentation of the wine within a closed container, tank or bottle.

Class 4—Citrus Wine—The standards for citrus wine follow the pattern set by the standards for grape wine as to designation as table or dessert wine. Citrus wine derived wholly from one kind of citrus fruit shall be designated by the word "wine" qualified by the name of the citrus fruit, for example, "orange wine," "grapefruit wine." Citrus

[92] See footnote 75.
[93] See footnote 80.
[94] The "champagne district" referred to is presumably the delimited Marne area in France which under French law is the only district entitled to the designation "champagne." The type wine is *vin mousseux* in any other area of France.

wine not derived wholly from one kind of citrus fruit shall be designated as "citrus wine" or "citrus fruit wine" qualified by a truthful and adequate statement of composition appearing in direct conjunction therewith. As with grape wine, any citrus wine containing no added brandy or alcohol may be further designated as "natural."

Class 5—Fruit wine—"Fruit wine" is defined as "wine (other than grape or citrus wine) produced by the normal alcoholic fermentation of the juice of sound, ripe fruit . . . ." The pattern of definition similar to that of grape and citrus wine is followed and fruit wine containing no added brandy or alcohol may be designated as "natural." Fruit wines which are derived wholly (except for sugar, water or added alcohol) from apples or pears may be designated as "cider" or "perry," respectively, and shall be so designated if lacking in vinous taste, aroma and characteristics. Fruit wine derived wholly from one kind of fruit shall be designated by the word "wine" qualified by the name of such fruit, for example, "peach wine," "blackberry wine."

This latter requirement was the subject of litigation in *Gibson Wine Company v. Snyder.*[95] Gibson had in 1948 commenced the production of berry wine from the boysen variety. In 1949, the Deputy Commissioner had issued an interpretative ruling that such wine could be labeled "blackberry wine." Later, the Commissioner after a thorough investigation of trade usages relative to the use of the boysenberry, informed Gibson that the wine could not be labeled "blackberry wine" but rather would have to be labeled "boysenberry wine." After that ruling, Gibson brought a civil action seeking an injunction to restrain official interference with the use of the label "blackberry wine." The district court upheld the action of the district commissioner saying:[96]

"The Federal Alcohol Administration Act and the Regulations relating to labeling and advertising of wine are clearly for the protection of the consumer. Their purpose is to enable purchasers to buy wine for what it really is . . . when a customer buys wine labeled blackberry he expects and is entitled to get blackberry wine. He has a right to proper labeling. It has been held that the consumer is entitled to protection against a substitute product even when it is equally wholesome or even better than the original product."

The principal contention of Gibson was that the boysenberry is a member of the blackberry family and thus such labeling would be

[95] 95 F. Supp. 145 (DC of D. C., 1950), aff'd 194 F. 2d 329 (CA of D. C., 1952).

[96] 95 F. Supp. 145, 146.

truthful. The court answered that while that was true, there were differences recognized by the growers, by the Food and Drug Administration in prescribing standards of identity for preserves, jams and jellies. The court of appeals upheld the conclusion of the district court with one judge dissenting. The dissenting judge suggested that the wine would be labeled "Blackberry Wine (Boysen variety)." The majority, however, sustained the findings of the Commissioner and the district court, especially in view of the fact that the court below had made detailed findings as to the nature of the berries, their history, and the characteristics of the wine made from them. The decision upheld the scheme of regulations as promulgated by the Secretary in what appears to be the only case testing the validity of Regulations No. 4. A later regulation issued by the Secretary permitted wine made from the olallie berry to be labeled "Blackberry wine of the Olallie variety." [97] From time to time, interpretative rulings are issued further defining type designations.[98]

Class 6—Wine from other agricultural products—Wine of this class is wine (other than grape wine, citrus wine, or fruit wine) made by the normal alcoholic fermentation of sound fermentable agricultural products, either fresh or dried. Raisin wine is wine of this class made from dried grapes. Sake is wine of this class produced from rice in accordance with the commonly accepted method of manufacture of such product. The further standards for this type of wine are similar to those previously noted in the other classes.

Class 7—Aperitif Wine—Aperitif wine is wine having an alcoholic content of not less than 15 per cent by volume compounded from grape wine containing added brandy or alcohol, flavored with herbs and other natural aromatic flavoring materials, with or without the addition of caramel for coloring purposes. It must possess the taste, aroma or characteristics generally attributed to aperitif wine and shall be so designated unless designated as vermouth. Vermouth is in turn defined as a "type of aperitif wine compounded from grape wine, having the taste, aroma and characteristics generally attributed to vermouth." [99]

---

[97] Rev. Rul. 553, CB-1955.

[98] See Rev. Rul. 461, CB-1956, "Pokeberries, because of their toxic properties, are not approved for use in the production of wine. . . ."

[99] See *Treat v. Taylor*, 166 F. 1021 (CA of N. Y., 1908) where the court held that "vermouth" was not wine within either the commercial term or the popular meaning of the term and was not subject to a stamp tax.

Class 8—Imitation and substandard wine—In view of the fact that the definitions in this class are extremely technical and detailed, it seems sufficient to mention that the standards for this class are exactly what the names imply and that very little imitation or substandard wine has found its way to the market.

Standards of Fill for Wine

Article VII of Regulations No. 4 [100] provides for standards of fill for wine and consists of three sections, as follows:

Section 70 exempts (1) sake; (2) wine packed in containers of five gallons or more; (3) imported wine in the original containers in which it entered into customs custody; (4) wine which was domestically bottled or packed prior to the effective date of the article if such container or label bears a conspicuous statement of the net contents, and if the actual capacity of the container is not substantially less than the apparent capacity upon visual examination under ordinary conditions of purchase or use.

Section 71 is entitled "Standard Wine Containers" and concerning this provision there is a statement as to design: "It shall be so made and formed as not to mislead the purchaser." In the wine trade, certain bottles have traditionally been associated with certain types of wines. Many types have bottles which immediately identify the type designation without the necessity of reading the label, either through shape, color or fanciful design. Thus, Germany had protected, until recently, by law the use of the bottle traditionally used for "steinwein." [101] Other German wines can be distinguished by the color of the bottle even though the shape is similar.[102] While there is apparently nothing in the wine regulations as to types of bottles (other than standards of fill and deception of the purchaser as to capacity) the above provision would seem to provide for the rejection of misleading bottling. An example of bottling that would constitute deception of the purchaser would be the bottling of "muscatel" in traditional

[100] 27 CFR Sec. 4.70-4.72.

[101] Originally, only those wines grown on a hill called Steinmantel outside of Wurzberg were entitled to be bottled in the *bocksbeutal* and be called "steinwein." Today, all Franconian growers may use the bottle, but only the wines grown on the Steinmantel may be labeled "Steinwein." See work cited at footnote 78, at p. 51.

[102] All Rhine wines and most white wines are bottled in tall fluted brown bottles. Moselle, Saar and Ruhr wines are bottled in tall fluted green or bluish-green bottles.

Raffia-covered Chianti bottles even though the labeling is proper in all respects.

Several cases arising under Section 10 of the Food and Drugs Act of 1906 involved the shape and appearance of the bottle in the condemnation of champagne. In *United States v. Five Cases of Champagne* [103] a libel was issued against five cases of so-called champagne, each case containing 24 bottles of "very cheap, ordinary, low-grade carbonated white wine." In issuing the judgment of condemnation, the Court said: [104]

"The bottle itself is of the same shape and made in imitation of the ordinary champagne bottle. This bottle is corked and dressed about the neck the same as and in very close imitation in every way of the ordinary genuine champagne bottle, or bottle containing champagne: for instance, Mumm's Extra Dry . . . . In short, the bottles containing the cheap carbonated wine are such a close imitation in form, or shape, dress, corking, and label, that the ordinary observer would and easily does mistake, accept, and use the imitation as a genuine bottle of imported champagne."

Similarly, in *Duffy-Mott Company v. United States* [105] the court weighed heavily the testimony of experts in the champagne trade as to the appearance of the bottles. There, the claimant had put carbonated apple juice, with capsicum added, into bottles which in form and dress resembled champagne and labeled them "Sparkling White Seal." On appeal, the Circuit Court of Appeals quoted from the testimony in the trial court: [106]

"Q. And if you could have read the words, "Duffy-Mott" from your seat upon the witness stand, you would not have answered, would you, that it looked like champagne?

A. On the table there it looks like a champagne package, and I might say it looks like a bottle of champagne, unless I looked at the bottle closely and saw the label, then I would know it was not." (sic)

Thus, even though the labeling was truthful, the general appearance of the packaging and the particular type bottle used were important factors in determining whether or not the product actually misled the purchasing public. **[The End]**

---

[103] 205 F. 817 (DC N. Y., 1913).
[104] See footnote 103, at p. 518.
[105] 285 F. 737 (CA-3, 1923).
[106] See footnote 105, at 738.

Additives and the FDA

By J. KENNETH KIRK

The Author, Assistant Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Presented This Paper at the Chemical Development Association Meeting, Bedford Springs, Pennsylvania, May 25, 1961.

I MUST CONFESS that when I received your program last week, I had definite qualms about making this appearance. It seemed to me that perhaps I would have been better advised to have tried to persuade Dr. Lehman to meet with you in my stead. Starting out, however, on the premise that I am not a pharmacologist, I do have a few thoughts which might be pertinent to the basic subject of the conference.

While there is no question but that current activities have markedly increased the role of the toxicologist in both industry and government, we should perhaps make sure that we disabuse those who seem to believe that the idea of pretesting food ingredients is something new. Admittedly, the fact that this must be done in accordance with law is new, but for many years our pharmacologists have been dealing with those who were genuinely interested in making sure before marketing that the products they contemplated were entirely safe.

Incidentally, there has been noted what might be called a slight attitude of justifiable smugness on the part of those who did the necessary pharmacological investigations even though the law previously did not require that this be done in that now they have prior sanctions for the items involved and need have no concern as far as the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act is involved.

Certainly the requirements of this amendment have called for toxicological investigations of food ingredients on a much larger scale than has even been accomplished in the past. There are those who believe that the law should have called for the Food and Drug Admin-

istration to conduct all of the necessary pharmacological studies on food ingredients and either clear or reject the items on the basis of the results. Obviously, anyone who knows the facts of life recognizes that this would be a practical impossibility. This does not mean that as far as investigations are concerned the Division of Pharmacology of the Food and Drug Administration is out of business. We are conducting studies and expect to continue to do so but with our limited facilities these studies are necessarily on a very selected basis, largely to meet the needs of the regulatory side of the Food and Drug Administration's activities. Dr. Lehman advises me that he constantly has a substantial waiting list of items which he would like to investigate but for which, so far, there have been no facilities available.

It has been said that the requirements for toxicity testing as set forth in the Food Additives Amendment are unfair to the smaller manufacturer who does not have the financial resources which would enable him to do the necessary job. Where this is true, we would, of course, agree that it is unfortunate, but in recognition of the objectives of this law from the standpoint of protection of the public health, we don't see where such economic considerations can be given weight.

We in the Food and Drug Administration and people in industry generally, in our opinion, are in wholehearted agreement that this law is basically a good one which is in the interest of consumer health and well-being. It has already had some very good effects which have not been the subject of widespread publicity or even of *Federal Register* publication. We have learned of a number of instances where, in reviewing their ingredients and operations to see where they stood under the Food Additives Amendment, manufacturers have, on their own initiative, come to the conclusion that certain items should be removed from the food supply forthwith. Without fanfare this has been done.

While there were a number of Congressional hearings on the subject of chemicals in our food supply which took place over a period of several years prior to the enactment of the amendment in 1958, it is, we believe, a good sign that the amendment was enacted without the impetus of some calamity such as the elixir of sulfanilamide tragedy which was in large measure responsible for the inclusion of the new-drug clearance procedures in the 1938 statute.

We have had reports of tragedies involving the food supply of other countries of the world and we have been very happy to be able to reassure our consumers who became concerned about those reports that the Food Additives Amendment was designed squarely to prevent the type of injuries, and even deaths, which had resulted from the use of untested food ingredients in those other parts of the world.

We must all recognize, however, that the existence of the Food Additives Amendment alone is not going to do the job. We must have compliance on the part of industry and a strong enforcement policy to deal with instances where the terms of the amendment are not being met.

A great deal has been published on various methods of procedure to determine the toxicological facts about food ingredients and I am sure that no good purpose would be served by trying to outline these to you today. When you come right down to it, what our scientists need is good evidence of safety, and while nothing in the law requires anyone to discuss with our pharmacologists a program of investigation before it is started, we cannot urge too strongly against a stand-offish attitude in such an operation.

Once a program for investigation of a food additive is tentatively set up, our people will be more than happy to sit down with you and go over it to see whether, in their opinion, the work would be likely to supply the information that they would need in the evaluation of any food additive petition. Some people did not do this perhaps in the belief that the Food and Drug Administration's pharmacologists might be so conservative that they would suggest additional work. Sometimes our people do point out the need for some changes involving additional studies not in the proposed outline of toxicological work, but I know of some instances where the reverse has been the case. People have come to our Division of Pharmacology with a program of study and have been told that the work would, as far as we were concerned, be wholly unnecessary. So it really works both ways.

Perhaps the most controversial item in the Food Additives Amendment is the Delaney or anticancer clause. Say what you will, this clause is in the law. There is no way by which the Food and Drug Administration will take any actions which are in conflict with its prohibitions. We have seen statements and articles over the past two years which indicate the belief on the part of some that the Delaney Clause will result in the discontinuance of research activities

by industry: that with this clause on the books there would be no point in anyone trying to develop new improvements for foods. We strongly believe that this is not the case and that the record of new items since the Food Additives Amendment was enacted clearly disproves any such theories.

We in the Food and Drug Administration see no reason why a firm which wants to improve a food product should not go ahead and do this. If the improvement is found to be a cancer producer, the manufacturer wouldn't and shouldn't want to use it anyway, with or without a Delaney clause.

In making this comment, I am not unmindful of the fact that a special situation may apply in the case of feeds for food-producing animals and consideration is being given to the possibility that the Delaney clause could be amended somewhat in that particular field.

Currently, the food additives staff and the scientific personnel of the Food and Drug Administration are working diligently on pending petitions for food additive regulations. Admittedly, progress in handling these petitions has been slower in some areas than we would like. Where the delays have been caused by the need for additional information to be sure that the product proposed for use is, in fact, safe, we have no apologies to offer. We have, however, in recent months been able to put into effect better procedures for handling food additive petitions which also involve pesticide regulations, new drugs, and food standards matters. We think we are doing better time-wise and we are striving to improve further.

Right now, we have before us a very substantial number of requests for further extension of the effective date pursuant to the authority of the law which was signed by the President early in April. While this law does give us the authority to authorize further extensions up to a cut-off date of June 30, 1964, there is nothing automatic about this. We have issued regulations which outline the type of information which is needed in order to justify consideration of a further extension for such time as is necessary—not to 1964 in every case—and so far, we have had to return quite a few requests for further extension because the necessary information was not included in the request. Very shortly, you will start to see *Federal Register* notices of extensions which have been granted and if we get the necessary information in time, we should have all of these published by July 1, 1961, the date on which all prior extension authorizations finally expire.

Some of you may have already noted a new procedure on the part of the Food and Drug Administration. We have been able to arrange for some of our pharmacologists, chemists, and other scientists who deal with food and drug problems to make brief trips into the field to participate in factory inspections with our inspectors. So far, we have found that this works out very well to the advantage both of the Washington scientists and the field inspector. We anticipate that we will be able to continue this program just as long as it continues to pay dividends.

Another item on the agenda involves the regulations under the 1960 Color Additive Amendments. We published the proposed regulations and received a very substantial amount of comment. This is currently being evaluated and we expect to be able shortly to publish the final regulations.

Less than a month ago, we published the proposed regulations for the new Hazardous Substances Labeling Act. Sixty days were given for comment and from all we have heard to date it looks as though we will get quite a substantial amount.

All of this is extremely welcome to us. We need industry's help to be sure that the regulations we issue are the best that can be formulated.

The hazardous substances legislation opens up a brand new field for the Food and Drug Administration. In the short time that we have been dealing with this law, we have found that there is a great deal which we didn't know about substances which are subject to this law.

In attempting to check on pharmacological data, our pharmacologists have been contacting some manufacturers and have learned that, at least in some areas, there is quite a bit of toxicological information about these chemicals which has been acquired by the manufacturers over the years but which has never been the subject of any publication. We have appreciated greatly the cooperation which has been afforded our people in these inquiries. We expect to be making more of them. In the meantime, however, we are wondering if now that we have the Hazardous Substances Labeling Act there would be any possibility that one or more of the interested industry groups could undertake a project of trying to get together all of this unpublished information about the toxicology of chemicals which may find their way into the household. Our people would be very glad to discuss any such project if the seed of the idea falls on fertile ground. **[The End]**

Your Label, Labeling and the Law

By ROBERT M. RUBENSTEIN

The Author Delivered This Talk at the Forty-fourth Annual Convention of the National Fruit and Syrup Manufacturers Association, in New York City, on April 2, 1961.

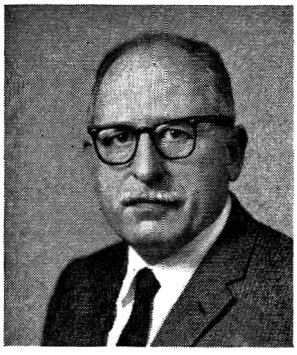
THE NEEDS of our complex society are such as to require laws to govern our conduct in every area. And this is generally recognized as being necessary and desirable in our interests. Concomitant with this need or requirement is the burden which it imposes on the very society it is intended to serve. This, too, is proper and good.

Food being a basic human need, it makes sense that the lawmakers should prescribe appropriate rules of conduct dealing with the production and distribution thereof, to insure the health and safety of the people they serve, and of whom they are a part. Here, again, the subject is not as simple as might appear on the surface. Not only must the consumer be protected, but the producers of the food themselves must also be guarded against dishonest, unscrupulous competitors.

Thus, whereas a very elementary set of rules may have sufficed for a primitive society, a complex code becomes necessary to protect the modern man. In our day, and in this country, the Food, Drug, and Cosmetic Act is the basic law which covers the production, manufacture, distribution and sale of food, drugs and cosmetics, and, as you know, this Act concerns itself with these items in interstate commerce. For intrastate protection, the several states have their own food and drug codes, mostly patterned on the federal statute, and most municipalities, as well, have established sets of rules covering this subject—all of which can tend to give the honest, law-abiding manufacturer of foods or drugs an overwhelming headache!

If a man about to enter the food manufacturing business were to contemplate all the legal restrictions and reservations which are imposed on the business on which he intends to embark, he might well give pause before investing his money, time and effort. A timid man might even give up the idea altogether.

Mr. Rubenstein Is Counsel of The National Fruit and Syrup Manufacturers Association, and a Member of the Law Firm of Rubenstein & Breger, New York, New York.



With all this preliminary, however, I don't want to leave the impression that the laws which govern your business are unconscionable or arbitrary or incapable of being reasonably complied with. On the contrary, they work in favor of the legitimate food or drug manufacturer and distributor.

The Federal Food, Drug, and Cosmetic Act which I shall hereafter refer to as the "Act," specifically spells out what are prohibited acts—and these are divided into two general categories: (1) adulteration and (2) misbranding. My subject concerns itself only with the latter topic. Misbranding, of course, has to do with labels and labeling, which is what I am talking about today.

Incidentally, while the provisions of the Act pertaining to drugs and cosmetics, are, with obvious differences, similar to those covering foods, I shall limit my talk to foods since this audience is made up principally of food people and your interest naturally is in the labeling of foods and not in the other categories covered by the Act.

Judging from the questions I have received beforehand, there are quite a lot of problems pertaining to labels and labeling, to which a simple reading of the Act does not furnish the answers. Being a brave man, I shall attempt to come up with the right answers. I only hope that the food and drug officials, federal and state, who are present here today can accept my answers as correct. If they don't agree, I hope they will challenge them and perhaps I can persuade them that I have correctly interpreted the law. Or, if they will indicate in what particular, I am in error, we will all be grateful to them for setting us straight.

I suppose that in the intelligent discussion of any subject, it is well to define the terms of reference. I shall therefore start by de-

fining "label" and "labeling," or rather, I shall quote the definitions given in the Act.

Section 201(k) of the Act reads, "The term 'label' means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of the Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appear on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

Subdivision (m) of this section states, "The term 'labeling' means all labels and other written, printed or graphic matter (1) upon any article or any of the containers or wrappers, or (2) accompanying such article."

When do we have a case of misbranding? Well, the Act says (Section 201(n)) "If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

These definitions are supplemented by further definitions set out in the regulations promulgated under the Act by the Secretary of Health, Education, and Welfare (originally by the Secretary of Agriculture, when the Food and Drug Administration was under his jurisdiction).

Section 403 of the Act specifies when a food shall be deemed to be misbranded; in other words, what you must *not* do. Since all of us here want to turn out a legal product, legally labelled, I point out what you must do affirmatively, to comply with the law.

Perhaps this would be a good place to note that while the Federal Food, Drug, and Cosmetic Act deals with the subject of labels and labeling, the Federal Trade Commission Act also concerns itself therewith. This act defines the term "false advertisement" as one "which is misleading in a material respect." Then it goes on to state

that "there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representation or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual."

Of course, there are many instances where both the Food and Drug Administration and the Federal Trade Commission could assume jurisdiction over a particular violation, but generally speaking, the Food and Drug Administration will take over in the case of misbranding through improper labeling, and the Federal Trade Commission will exercise jurisdiction over misleading advertising cases.

In a case where false labeling and misbranding of foods amounted to unfair competition in violation of Section 5 of the Federal Trade Commission Act, the court held that the FTC has jurisdiction to prohibit false labeling and misbranding of food, drugs and cosmetics as well as other products and that the enactment of the Federal Food, Drug, and Cosmetic Act did not nullify this jurisdiction (*Fresh Grown Preserve Corporation et al. v. Federal Trade Commission* (CA-2, 1942) 125 F. 2d 917).

While I know that my listeners need not be concerned by this, perhaps I should mention in passing, the penalties provided for violations under the foregoing acts.

The Federal Food, Drug, and Cosmetic Act provides for certain penalties for violations, as well as other types of action against violators.

Firstly, such a violation is a misdemeanor, punishable by imprisonment of not more than one year or a fine of not more than $1,000 or both, in the case of a first offense, and up to three years imprisonment or a fine of up to $10,000, or both, if the violation was "with intent to defraud or mislead" or if the violator had previously been convicted under this law.

Secondly, the government can apply to the courts for an injunction or restraining order.

And, finally, any misbranded article of food can be seized on a libel of information filed by the government. Usually, when there has been a seizure, it is followed by prosecution, after a pre-prosecution hearing is held under Section 305 of the Act.

The Federal Trade Commission Act provides that for the dissemination of a false advertisement in interstate commerce "for the purpose of inducing, or which is likely to induce directly or indirectly, the purchase of food, drugs, devices or cosmetics . . . ." the penalty shall be a fine of not more than $5,000 or imprisonment for six months or both, "if the use of the commodity advertised may be injurious to health because of results from such use under the conditions prescribed in the advertisement thereof, or under such conditions as are customary or usual, or if such violation is with intent to defraud or mislead."

The FTC may also apply for an injunction against dissemination of a false advertisement.

I think we can now get down to specifics. I shall attempt to spell out from the Act itself, from the Food and Drug Regulations, and from court rulings, trade correspondence, informal department rulings and, with all due modesty, from my own experience, (1) just what your label must show, (2) what it may not contain, and (3) what may optionally appear thereon.

Every food manufacturer and distributor wants to make his label as attractive as possible to the purchaser of his product and this is understandable, and even commendable—but in so doing, the manufacturer or distributor must work within the prescribed rules. I feel that by far the largest number of food processors and manufacturers want to label their product as permitted by law, and it is to those people that I address myself today.

First, let me cover generally, what the label must show. About most of the items in this category, there is little room for argument since between the Act, itself, and the regulations, they are spelled out quite clearly.

(1) It must bear the common or usual name of the food, if any there be.

(2) If the food is made from two or more ingredients, the label must bear the common or usual names of each ingredient, except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings and coloring without naming each.

(3) If the food purports to be or is represented as a food covered by a standard of identity, it must conform to such standard, and the label must bear the name specified in the standard, and if required by the standard, the common names of the optional ingredients (other than spices, flavoring, and coloring) present in such food. Where a

standard does not provide for artificial color or flavor in such food, they may not be used, with or without a declaration on the label.

(4) If it purports to be or is represented as a food for which a standard of quality or a standard of fill of container has been prescribed by regulations under the Act, and its quality or fill of container, as the case may be, falls below the standard, the label must contain a statement that it falls below such standard.

The regulations spell out what the label must say in such cases: "Below Standard in quality—Good Food—not High Grade" or "Below Standard in Fill" printed in two lines of Cheltenham Bold Condensed caps. If the quantity of contents of the containers is less than one pound, the type of the first line is 12-point and of the second line, 8-point. If the quantity is one pound or more, the first line will be 14-point and the second line, 10-point. The statement must be enclosed within lines not less than 6 points in width.

(5) If it is an imitation of another food, the label must bear the word "imitation" and immediately thereafter the name of the food imitated, all in type of uniform size and prominence. For example, the words "Imitation Raspberry Syrup," must be all in type of the same size and prominence.

(6) If it purports to be or is represented for special dietary use, the label must bear information concerning its vitamin, mineral and other dietary properties.

(7) If the food contains any artificial flavoring, artificial coloring or chemical preservative, it must so state on the label. Butter, cheese and ice cream are excluded from the requirement to declare artificial coloring.

(8) If the food is in package form (and this includes any kind of container) the label must bear the name and place of business of the manufacturer, packer or distributor.

(a) If the food is not manufactured by the person or firm whose name appears on the label, the name must be qualified by a phrase which reveals the connection such person has with such food, such as "manufactured for," "packed for," "distributed by," etc., or the word "distributor" may follow the name.

(b) If the place of business is shown in a current city or telephone directory, it is not necessary to include the street address on the label; otherwise the street address must be shown.

(c) A firm which manufactures, packs or distributes a food at a place other than its principal place of business, may state on its label the principal place of business in lieu of the actual place of manufacturing, packing or distributing.

(9) The label must bear an accurate statement of the quantity of the contents of the package in terms of weight, measure or numerical count or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food, and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid; or in terms of weight, if the food is solid, semisolid, viscous, or a mixture of solid and liquid.

(a) Weight shall be declared in terms of the avoirdupois pound and ounce.

(b) A statement of liquid measure shall be in terms of the United States gallon (231 cubic inches) and quart, pint and fluid ounce subdivision thereof, and except for frozen food which is so consumed, shall express the volume at 68 degrees Fahrenheit (20 degrees Centigrade).

(c) A statement of dry measure shall be in terms of the United States bushel (2150.42 cubic inches), and peck, dry quart and dry pint subdivisions thereof; or in terms of the United States Standard barrel and its subdivisions of third-, half- and three-quarter barrel.

(d) In the case of export shipments, the statement of the quantity of the contents may be expressed in terms of a system of weight or measure in common use in the country to which the shipment is exported.

(e) The foregoing requirements are mandatory. The required statement, however, may be supplemented by a statement in terms of the metric system of weight or measure.

(f) Unless a mere statement of numerical count gives accurate information as to the quantity of food in the package, it must be supplemented by such statement of weight, measure or size of the individual units of the food as will give such information.

(g) Where fractions are used, only those generally used in expressing the quantity of the food, shall be declared on the label. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

BUSINESS REPLY MAIL
NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY—

Food Drug Cosmetic Law Journal

COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

(h) The quantity of food in the package must be expressed in terms of the largest unit of weight or measure outlined above. For example, the statement on the label of a package which contains one quart of food shall be "1 quart" and not "2 pints" or "32 fluid ounces." However, where the quantity is made up of a whole number and a fraction, its equivalent in smaller units may be substituted. For example, 1¾ quarts may be expressed as "1 quart, 1½ pints" or "1 quart, 1 pint, 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound, 4 ounces."

The stated number of any unit which is smaller than the largest unit contained in the package shall not equal or exceed the number of such smaller units in the next larger unit. For example, you do not say "1 quart, 16 fluid ounces." The correct statement is "1½ quarts" or "1 quart, 1 pint." Instead of "24 ounces," you state "1½ pounds" or "1 pound, 8 ounces."

Where an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The label statement shall express the minimum quantity, or the average quantity, of the contents. If the statement is not so qualified, it shall be deemed to express the average quantity.

(j) Where minimum quantity is expressed on the label, no variation below the stated minimum will be permitted except variations caused by ordinary and customary exposure (after the food is introduced into interstate commerce) to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where no minimum quantity is expressed, that is, where average quantities are expressed, variations from the stated weight or measure are permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

Variations from the stated weight, measure or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring or counting individual packages which occur in good

packing practice. Variations will not be permitted, however, to such extent that the average of the quantities of the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) Exemption from compliance with the requirements as to statement of contents is granted to foods packed in containers of *less* than ½ ounce, avoirdupois or less than ½ fluid ounce, or where the statement of the contents of the package, together with all other words, statements and information required under the Act, cannot, because of insufficient label space be so placed on the label as to comply with the Act and regulations. This applies to the case where the necessary statements and information cannot be prominently placed on the label with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. This does not obtain where the label is intentionally made smaller when the package or container could conveniently and reasonably take a larger label which could adequately handle the required information.

(m) A food is also exempt from the requirements of a statement on the label of the quantity of contents if said food, having been received in bulk containers at a retail establishment, is accurately weighed, measured or counted, either within the purchaser's view or in compliance with his order.

(10) All words, statements or other information required by the Act must appear on the label prominently and with conspicuousness, and on that part of the label which is presented or displayed under customary conditions of purchase. If the label is made up of two or more parts or panels, each of which has sufficient space therefor and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed, then the necessary statements required by the Act must appear on each such part or panel.

(11) No exemption depending on insufficiency of label space, shall apply if such insufficiency is caused by:

(a) The use of label space for any word, statement, design or device which is not required to appear on the label;

(b) The use of label space to give greater conspicuousness to any word, statement or other information than is required by the Act; or

(c) The use of label space for any representation in a foreign language.

(12) All words and statements required to be placed on the label must appear thereon in the English language. An exception is the case of articles distributed solely in a territory where the predominant language is one other than English, in which case, that language may be substituted for English, but *all* required information shall appear thereon in the foreign language.

(13) The label must contain a statement of ingredients in the order of predominance in the product.

(a) Each ingredient must be listed by its specific, and not collective name. But if an ingredient which itself contains two or more ingredients conforms to a standard of identity, it may be designated on the label by the name of the standardized product. For example, if jelly were used as an ingredient, it would only be necessary to list the word "jelly" instead of all the ingredients of which the jelly was made. If, however, the standardized ingredient so used contains optional ingredients required to be stated on the label of the standardized ingredients, such optional ingredients must be named on the label.

(b) A spice, flavoring or coloring used as an ingredient of a food, other than one sold as such, may be declared on the label as a spice, flavoring or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance. An ingredient which is both a spice and a coloring or both a flavoring and a coloring, shall be designated as "spice and coloring" or "flavoring and coloring," as the case may be, unless such ingredient is listed by its specific name.

(c) Essential oils should be listed by their specific names as ingredients in food.

(d) Artificial flavoring, artificial coloring and chemical preservatives are defined in the regulations as follows:

(i) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(ii) The term "artificial coloring" means a coloring containing any dye or pigment, which was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant.

(iii) The term "chemical preservative" means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties. Benzoate of soda, for example, should be listed on ingredient statement as "Preserved with Benzoate of Soda." It is not necessary to state the quantity.

(e) Artificial flavoring, artificial coloring or chemical preservatives must be declared on the label in such manner as to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food. The exemptions which apply to small units hereinbefore discussed, also include the statements with respect to artificial flavoring, artificial coloring and chemical preservatives.

(14) Provisions are made by the Act and the regulations for exemptions from the labeling requirements of foods shipped or delivered, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantity at an establishment other than where originally processed or packed. Such shipments are exempt if (a) the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled or repacked; or (b) if such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the Act upon the completion of such processing, labeling, or repacking. Copies of such agreement must be kept by both parties until two years after the final shipment or delivery, and copies must be made available for Food and Drug inspection at any reasonable hour.

The exemption shall become void, *ab initio,* if the food comprising the shipment or delivery, is in whole or in part adulterated or misbranded when so received from the shipper's establishment, or upon the refusal of the shipper to make available for inspection a copy of the aforementioned agreement.

(15) In connection with foods for which standards of identity were pending, there existed a so-called "exempt list" which exempted certain foods from label declaration of ingredients. This list included among other items, lemon extract, orange extract, malted milk, unmixed canned fruits in sugar solution of not less than 20 degrees Brix, ice cream, frozen custard, ice milk, milk sherbet, water ice or ice sherbet, nonalcoholic carbonated beverages and vanilla extract. By an order effective September 17, 1959, the exemption was terminated for each food on the exempt list except ice cream, frozen custard, ice milk, milk sherbet, water ice or ice sherbet, nonalcoholic carbonated beverages and vanilla extract.

(16) Foods purporting to be or represented for any special dietary use by man are subject to special labeling requirements.

(a)(i) If a food purports to be or is represented for any special dietary use by man, its label shall bear a statement of the dietary properties upon which such use is based in whole or in part. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent and any other dietary property of such food upon which such use is so based. (Section 125.2a of regulations.)

(ii) If a food purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency in man, its label shall bear, in addition to the information required under paragraph (a) of Section 125.2 of the regulations, adequate directions for such use.

(b) There are special provisions for labeling foods represented for special dietary use by man by reason of their vitamin or mineral properties but these are lengthy and involved, are tied in with minimum daily requirements which are spelled out in the regulations, and would probably be of little practical interest to fruit and syrup manufacturers, so I will not go into them in detail.

(c) Also, special dietary foods for infants are subject to special labeling requirements which, in the interests of conserving time, I shall pass over in this presentation.

(d) Certain foods used in control of body weight or in dietary management with respect to disease, sometimes called dietetic foods, have special label requirements of their own.

If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of

protein, fat, carbohydrates or calories, for the purpose of controlling body weight, or for the purpose of dietary management with respect to disease, the label must bear a statement of:

(i) the per cent by weight of protein, fat and available carbohydrates in such food; and

(ii) the number of available calories supplied by a specified quantity of such food. For example, "Each ounce of this food contains —— calories."

(e) If the food contains any constituent which is not utilized in normal metabolism, such as saccharin, saccharin salt, calcium cyclamate or sodium cyclamate, the label shall bear the statement "Contains —— saccharin (calcium cyclamate, etc., as the case may be) a non-nutritive artificial sweetener which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the per cent by weight of the artificial sweetener in such food.

(f) If a food purports to be or is represented for special dietary use by man by reason of the decrease or absence of any allergenic property, the label must bear (1) the common or usual name and the quantity or proportion of each ingredient, including spices, flavoring and coloring, in case the food is made from two or more ingredients; and (ii) a qualification of the name of the food, or the name of each ingredient thereof to reveal clearly the specific plant or animal which is the source of such food or ingredient, if such ingredient consists in whole or in part of plant or animal matter and the name does not clearly reveal the specific plant or animal which is such source; and (iii) a statement indicating the nature and effect of any treatment or processing of the food or any ingredient thereof, if the changed allergenic property results from such treatment or processing.

(g) If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating intake of sodium or salt (sodium chloride), the label shall bear a statement of the number of milligrams of sodium in 100 grams of the food and a statement of the number of milligrams of sodium in an average serving of the food. This must be expressed in terms of a convenient, readily understood unit, such as in terms of a number of slices, cookies, wafers, etc., or in terms of cupfuls, tablespoonfuls, etc.

(17) Provision is also made in the Act for food, drugs, devices and cosmetics intended for export. The Act states that such articles shall not

be deemed to be adulterated or misbranded if they (a) accord to the specifications of the foreign purchaser, (b) are not in conflict with the laws of the country to which it is intended for export, and (c) is labeled on the outside of the shipping package to show that it is intended for export. But if such articles are sold or offered for sale in domestic commerce, they shall not be exempt from any of the provisions of the Act.

(18) The term "Kosher" may be used only on food products that meet certain dietary requirements of the Jewish religion. In practice, the word "Kosher" is only placed on the label of foods which are manufactured and packed under the supervision of a rabbi or other authorized person of the Jewish faith designated for that purpose.

The term "Kosher style" has sometimes been used on a label to designate a particular food which has been considered as having particular gastronomic appeal to Jewish consumers. An example is a product which has been labeled "Kosher Style Pickles"; another, "Kosher Style Corned Beef."

Since the use of the term may cause the prospective purchaser to believe that the product is in fact "Kosher," FDA discourages the use of the phrase on products that do not actually meet the religious dietary requirements. Many of the state laws or regulations *specifically* ban the use of the term "Kosher Style." The states' regulatory officials take the position that a product is either "Kosher," in which case the label may so state, or "Non-Kosher," in which case *no* language may be used which includes the word "Kosher" and which thus might be misleading.

So far I have been discussing what *should* appear on a food product label. Perhaps, it would be useful to itemize some of the "don'ts" or prohibitions affecting the labeling of foods.

1. The label must not fail to reveal facts material to the representations or suggestions made. For example, the label on nonnutritive sweeteners must reveal their lack of food value.

2. The use of geographic names, such as "English," "French," "Hollywood," "New York," etc., is ordinarily considered false and misleading when the product does not originate from the place named on the label. You can't call a product, "Kentucky Mint" if the mint does not originate in Kentucky. Yet, sometimes, items lose their geographic meaning. For instance, French dressing, English mustard, etc.

3. The label of a food which designates one ingredient in the name, but not all, is misleading even if the other ingredients appear elsewhere on the label. An example of such misbranding would be "Raspberry Jelly," when the fruit ingredients of the jelly are apple and raspberry, even though the word "apple" appeared in the statement of ingredients.

4. You may not use an insignificant quantity of an ingredient simply to enable you to list it in the statement of ingredients on the label. For example, you may not add a tiny percentage of orange juice to an orange-flavored syrup solely to permit you to declare "orange juice" on the label. This is held to be deceptive, and hence prohibited.

5. So too, the statement "98% true, 2% artificial flavor" was held to be misleading because it described merely the percentage of *volume* of each of the ingredients and not the percentage of flavor contributed by each ingredient. The 2 per cent artificial flavor may have contributed more to the flavor of the food than the 98 per cent true flavor.

6. The word "Fresh" is generally understood by a consumer to indicate an article of recent origin. Hence, an article may not be called "Fresh Fruit Salad Topping," if it has been made in whole or part from canned or frozen fruit.

7. The words, "Homemade" or "Homemade Brand" should not be used because they are misleading when the product so labeled is commercially packed.

8. "Vitamin Rich" is out, since it suggests that the product is enriched with added vitamins.

9. The word "Natural" should be reserved for fresh products, such as fresh juice or juice kept without intervention of any process of heat treatment. You may, however, have "Natural Flavors." This will be discussed later.

10. One word which the Food and Drug Administration dislikes seeing on a food product's label is "Pure," because it can mean one of several things: (a) that it complies with a standard of identity; or (b) that it is free from impurities or deleterious ingredients. The Food and Drug Administration discourages its use. However, if it is used on a single food product which is, in fact, pure and complies with the Act, its use would not be false or misleading. The term "100% Pure" is definitely frowned on—a food is either pure or not pure; it cannot be 50 per cent pure or 90 per cent pure!

The words "Pure Food Colors" are objectionable on certified coal-tar color mixtures. The FDA recommends the use of "Artificial Color Added," "Color Added," or an equally informative statement, but it has also accepted "Certified Color" in the ingredient statement on the label.

11. A food is deemed to be misbranded if it is offered for sale under the name of another food. This means you can't use a fanciful misleading name such as "Egg-O-Milk" where substantial amounts of eggs and milk are not used.

12. You may not imitate the appearance of another product because it can mislead the consumer. Bottles of carbonated apple juice which were labeled "Sparkling White Seal" and dressed like champagne, were condemned as misbranded.

13. The container itself must not be misleading. There have been no rulings or standards promulgated by the FDA saying just when a container is misleading. Whether or not a container is misleading within the provisions of Section 403(d) of the Act is a question of fact. Here are some examples of misleading containers: thick glass, indented bottoms, excessive height, false bottoms, over-size cartons, slack-filled.

14. The letters "A," "B," "C," etc., may not be used on the labels of products which fail to meet the standards of the United States Department of Agriculture. If the foods are packed under continuous USDA inspection, however, you may use the designation "U. S. GRADE A," etc.

15. A manufacturer, processor or packer of foods may not use on his label, or in his labeling, advertising or sales promotion, any reference to any report or analysis furnished to him by an FDA officer or employee in connection with his factory inspection and taking of samples for analysis, nor may he use an unfavorable report against a competitor.

16. When you label an "imitation" food, you can't place the word "imitation" on the label in small print not consistent with the size in which the name of the food is set. Nor can it appear in an ink color which blends into the background color of the label so as to make it practically invisible.

17. The phrase "full strength" should not be used on the label—for example, on flavors or flavoring extracts since all such products must be full strength or classified as adulterated, and hence the

expression may be misleading—since it may convey an impression that the flavors as labeled are outstanding in this particular. Likewise, the words "Legal Strength" are also discouraged on a product which is diluted to the minimum strength recognized in an *advisory* standard but which is not one covered by a standard of identity. Vinegar is an example of such a product.

18. You may not use the name or initials of the Food and Drug Administration on your label.

19. A person who merely packages an article may not call himself the "manufacturer" on his label.

20. Manufacturers like to dress up their labels with vignettes or colorful representations. The FDA, however, decries the use, for example, on an artificially flavored strawberry syrup, of a vignette of luscious strawberries calculated to make the consumer's mouth water in anticipation of the true-fruit flavor of strawberries in the syrup. Actually, the Food and Drug Administration frowns on the use of vignettes generally, but will not ban a vignette which actually and truthfully reflects the contents of the package whose label bears same.

21. Your ingredient statement or statement of weight or liquid measure must not be in such small type or in such colored ink, compared to the background of the label, as to render it difficult or impossible for the ordinary consumer to read.

22. Foods which are covered by Food and Drug Standards of Identity must be labeled with the name of the food specified in the standard but they need not carry an ingredient statement. However, optional ingredients present in such food must be declared by their common names where required by the standard.

So far, I have discussed only the first two of the three categories I mentioned earlier, namely, what *must* appear on the label and what you *may not* place thereon. The remaining item can be set down in just a few brief sentences.

So long as the label contains all the required wording and contains no objectionable material such as outlined above, you can place on your label, such other phraseology or artistic embellishments as you wish. You must bear in mind, however, that by so doing, the required label language must not be obscured, nor may the added material render the total label misleading because of any representation or suggestion "by statement, word, design, device or any combination thereof." A general, but sound, bit of advice is to keep your

label as simple and free from clutter as possible, consistent with the requirements of the Act and regulations.

I have received many inquiries from NFSMA members asking about specific labeling on syrups, flavors and extracts. It is difficult to answer these questions with general answers which can be taken as applicable to every other manufacturer who makes the same product. I shall try to explain what I mean.

While it is relatively simple to refer a questioner to the general language of the Act or to the regulations, the answer to his specific question may not be readily available from a mere reading thereof. It gets down to a matter of intent and meaning. To come up with a correct answer, it frequently becomes necessary to know some special facts about the product. For instance, if the question is: "May I label my product 'Butterscotch Topping,'" the one seeking the information cannot turn to the Act or to the regulations promulgated thereunder and find a provision pertaining to Butterscotch Topping, per se. If the question were directed to me, I should have to ask certain pertinent questions about the product—specifically, what are the ingredients, and in what proportions are they contained in the product? Sometimes it becomes necessary to inquire about the method of its manufacture. Only after all the necessary information is available can the answer be given: "You may label the product, 'Butterscotch Topping'" or—"You must call this product, 'Imitation Butterscotch Topping.'"

Incidentally, while discussing the labeling of syrups, flavors, extracts, etc., I shall specifically deal with the question of the labeling of "Butterscotch" toppings and flavors because this is a particular topic about which I have received direct inquiries from several members.

Turning now to syrups, flavors and extracts, I shall first make some general observations applicable to them generally. Then I will deal with specific items about which particular questions have been raised. There is no particular significance to the order in which they appear below. I have simply set them down as they came to my mind or as I came across them in my research in preparation for this presentation.

At the outset, I want to make clear that the requirements as to labels and labeling which I have outlined herein are equally applicable to syrups and flavors. It is just that in dealing with specifics, I have chosen the particular items of special interest to our industry, rather than foods in which we have a less direct concern.

Flavorings may be designated in the ingredient list as "flavorings," without naming each. This simple rule is clear enough, but it brings us to the vexing "W. O. N. F." problem. These initials, as all you syrup people know, stand for "With Other Natural Flavors." Since I have been asked about this item more often than about most other labeling questions, I made quite an exhaustive search with respect to any rulings or directives pertaining to it.

All that appears on record is a so-called "Trade Correspondence" item from the Food and Drug Administration dated April 11, 1940 (TC 221).

This "TC" ruled that the term "Strawberry extract" would be misleading for a flavor made from 45 lbs. of strawberries per gallon, a very small percentage of raspberry extract, and varying quantities of five plant extractives or essential oils, while the amounts of plant extractives and essential oils are small, they contribute materially to the flavor and odor of the article, as shown by an organoleptic examination.

It is not a misbranding to name the product "Strawberry flavor, reinforced with natural flavors," all words being displayed with equal prominence. The names should be followed by an appropriate list of ingredients in the order of their importance as "strawberry flavor, with a small proportion of raspberry flavor, and extract of St. John's Bread, fennel, garlic, and oils of orris and sage." The names of the solvents should also be listed. A name such as "Strawberry flavor reinforced with natural flavors" should not be applied to a flavor unless more than one half of the flavoring strength of such flavor is derived from strawberries.

The foregoing ruling appears to be in conflict with Section 403(i) of the Act which provides, *inter alia*, "except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings and colorings without naming each." The said section also provides, however, that if compliance with the requirements of this provision "results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary."

I might note in this connection, that a label may be deemed to be misleading due to the order in which the names of the ingredients appear, or the failure to reveal the proportions of an ingredient when such proportion is material in the light of the representation that such ingredient was used in manufacturing the food.

The vehicle of a flavoring extract is ethyl alcohol of proper strength. The term "extract" is not synonymous with the term

"flavor." Flavoring products prepared with vehicles other than alcohol should be labeled "flavors."

To justify labeling a product "vanilla extract," it should contain the soluble matter from not less than 13.35 ounces (avoirdupois) of vanilla beans and at least 35 per cent by volume of alcohol.

The FDA has stated (TC 12, Aug. 15, 1939) that the name "Vanilla and vanillin flavor" implies that approximately as much of the total flavor of the product is due to true vanilla as to vanillin. The manufacturer of such product should use ½ gallon of vanilla extract (13.35 ounces of beans per gallon) and ½ gallon of 7/10 of 1 per cent vanillin solution (0.93 ounces of vanillin per gallon).

Flavors made from oils of orange, lime or lemon are not artificial flavors but neither are they "true fruit" flavors since that term is properly applicable to a flavoring concentrate prepared from the whole fruit or fruit juice.

Fixatives added to pure fruit flavors should be declared on the label because the flavoring strength of these artificial fixatives or artificial fixative flavors is enormously greater than the flavoring strength of an equal quantity of flavor derived from fruit. This may be declared as "1/10th of 1% fixatives added."

The use of synthetic flavoring ingredients will usually result in causing the flavor to be classed as an imitation, especially when the flavor is artificially colored.

Caramel may be declared as "colored with caramel" or "caramel color" or "artificially colored." Where caramel color is used in a solution of vanillin and vanilla, it gives the product the appearance of being a true vanilla extract and it should therefore be labeled as "imitation."

In the case of a "cane and maple syrup," if less than about 25 per cent of maple syrup is used, the percentage contained in the product should be declared on the label. If the product contains more than 25 per cent maple syrup, "Cane sugar and maple syrup" satisfactorily takes care of the listing of the ingredients. Where between 10 per cent and 25 per cent of maple syrup is used, the name "cane sugar and maple syrup" must be qualified by the prominent statement, "Contains ——% maple syrup." If the product contains less than 10 per cent maple syrup, the product must not be labeled "Cane sugar and maple syrup" but "Sugar syrup with a trace of maple syrup added."

Spice oils can be designated as flavors. They are not spices and to use "spices" or "spice flavoring" would be misleading.

Butterscotch flavor consists of butter and burnt sugar. If a product contains diacetyl or other artificial or synthetic chemical flavors, it may not properly be labeled "Butterscotch flavor." If the product contains artificial flavor, it should be labeled "Imitation butterscotch flavor." This ruling was made in a letter sent by the FDA to a manufacturer on May 10, 1939. It was, in substance, reaffirmed in a letter from the FDA sent earlier this year to one of our members.

In the light of the fact that over the years, manufacturers of numerous food products, other than syrups and toppings have been using the term "butterscotch flavor" without indicating in the name that artificial or synthetic flavors were used, a question arises as to whether or not the term "butterscotch flavor" has acquired a secondary meaning which should take it out of the ordinary rule regarding "imitations." This will require further exploration and study.

I might point out that, originally, grenadine was prepared from pomegranate juice and sugar, but for many years the name has been loosely applied to syrups and beverages consisting of other fruit juices and sugar syrup. The Food and Drug Administration makes no objections to the use of the name "grenadine" on a syrup containing a mixture of fruit juices which has a characteristic grenadine flavor and color. The characteristic flavor can be obtained from a mixture of black currant juice and other fruit juices and possibly by other combinations of fruit juices with or without a minute amount of spice or similar natural flavoring. The characteristic color of grenadine is red which is derived either from the fruit juices or by the use of an artificial color. (TC 293, May 7, 1940.)

Maraschino cherries have also been the subject of a number of inquiries addressed to me. I understand that the Food and Drug Administration has likewise been requested to rule on the labeling of maraschino cherries.

In one of its "TC" letters, the FDA states that "maraschino cherries may be regarded as the common or usual name of cherries which have been dyed red, impregnated with sugar and packed in a sugar syrup flavored with oil of bitter almonds or a similar flavor."

Since there is no standard of identity promulgated for maraschino cherries, the label will have to carry a complete list of the ingredients, in descending order of their predominance. Artificial color and flavor

must be declared. If a preservative is used, it must be declared on the label in the manner I have already shown. If any sulphur dioxide (which I understand is used to bleach the cherries) remains in the finished product, it too must be declared on the label. In this connection, I call your attention to the fact that any ingredient used in processing any food, which doesn't remain in or on the finished food need not be declared.

A final word of caution: don't copy the existing label of a competitor on the assumption that if it is on his product it must be all right or he would have been stopped from using it. This is poor reasoning. You'd be surprised how many labels are bad, that is, fail to comply with the law and yet appear on the grocer's shelves! This proves nothing, except, perhaps, that the authorities have not yet caught up with them. It certainly is no guarantee that your product, with a label practically identical with the copied one, won't be picked up. Nor is it a defense to a seizure that "The Jones Company's label is identical to mine."

Your best bet is to check all of your proposed labels with your food chemist or your legal counsel. They are best qualified to steer you on the right path in this great maze of laws, regulations, court rulings, advisory letters and the like.

I have tried to cover all the basic requirements pertaining to labels and labeling and have endeavored to answer the principal questions which either have been raised by fruit and syrup manufacturers or which in my experience have caused the most trouble. Naturally, I haven't covered every possible aspect of the subject. That would be an almost impossible task. On the other hand, if I have succeeded in giving you a somewhat better understanding of this whole matter of labeling, I will consider well spent the time I have put into the preparation of this presentation. **[The End]**

AMPHETAMINE SELLERS SENTENCED

Six jail terms, ranging from six months to five years, four three-year probations and three cash fines were handed down by seven Federal District courts in cases involving illegal sale of amphetamine drugs.

The drugs are stay-awake pills variously called "bennies," "goof balls," "co-pilots," and "West Coast turn arounds."

They are commonly bought by truck drivers at truck stops to keep them awake during long cross-country hauls. A brain stimulant, the drug also can bring on a false sense of well-being and a disregard for rules of behavior.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

May report of food seizures.—Over 505 tons of contaminated food were seized in 36 federal court actions during the month of April. Of this total over 16 tons became contaminated in warehouses while being held for sale after shipment in interstate commerce.

Bulk wheat contaminated with rodent filth comprised the largest tonnage involved in seizure actions. Approximately 241 tons were seized in five federal court actions.

Over 143 tons of spices, primarily black pepper, imported from various countries to a warehouse in New York were seized in two court actions. The government alleged that the spices were contaminated with rodent filth and held under insanitary conditions.

Approximately 7.5 tons of food seized in five federal court actions were found to be economic cheats. Of the total, approximately four tons were a vitaminized rice product which the government alleged had false and misleading labeling because it failed to conform to the specifications for enriched rice. Frozen oysters and a seasoned sauce were found to be short weight, and canned peas fell below the standard of quality in that they were broken and not so labeled.

Two licorice candy products were seized on charges of false claims that they were low in calories.

Drug and device seizures.—Seventeen federal court actions were taken on drugs and devices in the month of April. In nine of these the government alleged that the products made false and misleading therapeutic claims, four had inadequate directions for use, three were substandard preparations, and one had inadequate warning on its label statement.

FDA laboratory examination showed that a powdered food supplement varied in actual composition from 50 to 235 per cent of the declared amount of its ingredients. Approximately 476 pounds of the product were seized on charges that it was misbranded by false and misleading statements of its nutritional value, and that it was adulterated because the valuable constituents, protein, fat, calcium, and iron, were in part omitted.

Eighty air purifying, and 70 dehumidifying devices with over 700 accompanying leaflets were seized. FDA charged that the labeling made false and misleading statements which claimed that the devices were effective in preventing colds, sore throats, post nasal drip, muscle spasms, etc., and would provide effective defense against viruses and germs.

Use This Check List to Add to Your Permanent Food and Drug Law Library

Wherever things happen of importance to Food and Drug Men, you'll find CCH there with handy desk helps on food, drug and cosmetic law. Each of these books was written by an outstanding authority in the field and published by Commerce Clearing House, Inc., for The Food Law Institute. They serve as a chronicle of the development of food law, including the associated drug and cosmetic laws; provide an adequate library for everyone concerned.

Some BOOKS IN THE FOOD LAW INSTITUTE SERIES:*

- ✓ General State Food and Drug Laws—Annotated, by David H. Vernon and Franklin M. Depew. Table of contents; 816 pages. Price: $17.50 a copy.
- ✓ Constitutional Questions in Food and Drug Laws, by Thomas W. Christopher. Topical index; 128 pages, 6" x 9", heavy paper covers. Price: $3.50 a copy.
- ✓ Federal Food, Drug, and Cosmetic Act—Judicial and Administrative Record, by Vincent A. Kleinfeld and Charles Wesley Dunn. All these publications include indexes and case tables.

  1953-1957, 1,444 pages. Price: $25.00 a copy.
  1951-1952, 588 pages. Price: $12.00 a copy.
  1949-1950, 543 pages. Price: $10.25 a copy.
  1938-1949, 922 pages. Price: $17.50 a copy.
- ✓ Legislative Record of 1958 Food Additives Amendment to Federal Food, Drug, and Cosmetic Act. Topical index; 160 pages, 6" x 9", heavy paper covers. Price: $3 a copy.
- ✓ Product Liability Cases, by Frank T. Dierson and Charles Wesley Dunn. Table of contents; 1,182 pages. Price: $12 a copy.
- ✓ Canada's Food and Drug Laws, by Robert E. Curran, Q. C. Topical index, case table; 1,138 pages. Price: $19.50 a copy.

** Unless otherwise noted, books come in hard bound covers, red and black with gold stamping, size 6⅝ x 9⅞ inches.*

YOURS—FOR 15 DAYS' FREE EXAMINATION

Any of these authoritative books can be yours for 15 days' free examination. Just fill out the handy tear-off Order Card at the right. If not completely satisfied after looking them over, return the books for full credit.

CCH PRODUCTS COMPANY
4025 W. PETERSON AVE., CHICAGO 46, ILL.

A COMMERCE CLEARING HOUSE PUBLICATION