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Food-Drug-Cosmetic Law JOURNAL

The First Session of the Codex Alimentarius Commission . . . . . FRANKLIN M. DEPEW

The Latin-American Food Code: Chapter XIV—Spirituous Beverages

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

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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

ABA Resolution on S. 387.—At the meeting of the House of Delegates of the American Bar Association which was held on August 15, 1963 in Chicago, the following Resolution was adopted with respect to S. 387, The Packaging and Labeling Controls Act:

"WHEREAS, The American Bar Association believes it to be in the public interest that laws granting regulatory powers to administrative agencies should (1) establish objective standards of proscribed conduct, which may be tested in the courts, and (2) avoid imposition of an undue degree of administrative determination of business policy; therefore be it

"RESOLVED, that the AMERICAN BAR ASSOCIATION disapproves in principle the provisions of S. 387, on the ground that: The enactment of this proposal would delegate administrative power to adopt and enforce arbitrary regulations without adequate standards, and in consequence action may be taken which will unduly restrict freedom of private action for product improvements, variety of consumer choices and purchasing economies.

"Be it FURTHER RESOLVED, that the Section of Corporation, Banking and Business Law be authorized to represent the American Bar Association in opposing S. 387 or any other similar proposal; and in making appearances before Congressional Committees and in taking such other steps as may be necessary and desirable to that end."

Codex Alimentarius Commission Meeting.—Included in this issue, on page 477, is the paper presented by *Franklin M. Depew*, president of the Food Law Institute, Inc., at the initial meeting of the *Codex Alimentarius* Commission at FAO Headquarters in Rome, Italy on June 25, 1963. The paper is entitled, "Suggested Principles for Consideration in Drawing Up International Food Standards," having as its aim the protection of consumers' health and the ensuring of fair practices in the food trade. Mr. Depew considers major obstacles to harmonization by observing, among other things, "Dissimilarity of raw materials now presents a problem where it results in a standard that fails to encompass a substantial portion of the major crop of any country. Moreover, climatic conditions may necessitate the use of preservatives in certain areas, whereas they may not be necessary in other areas." Mr. Depew also gives a full account of the proceedings of the meeting, including election of officers and various important decisions.

Latin-American Food Code.—This JOURNAL contains Chapter XIV of the Latin-American Food Code which was translated from the original Spanish by Ann M. Wolf of New York, pertaining to spirituous beverages.

The translation, which begins on page 491, is based on the 1960 edition of the Code published in Buenos Aires, as subsequently amended by the Latin-American Food Council, up to September, 1962.

Food Labeling and Packaging.—*Shelbey T. Grey,* Director of the Bureau of Program Planning and Appraisal, Food and Drug Administration, presented this paper entitled, "FDA Looks at Food Labeling and Packaging." The author observes that the FDA is stepping up its program to protect consumers with regard to mislabeled and illegally packaged foods. "I can't tell you exactly how many man-years we will put into it next year. The reason is that the requirements of the law with regard to labeling and packaging are given consideration in every food inspection we make, in every sample of food we collect and examine, and I can assure you that we are going to unrelentingly invoke the legal remedies provided by the statute . . ." In this interesting article found at page 505, the author lists the following false conceptions that usually mark the food quack: (1) Disease and poor health are due to faulty diet; (2) Our basic foods are inferior and must be enriched or fortified; (3) The nutritive value of processed foods has been destroyed; (4) Most American consumers suffer from subclinical deficiencies; (5) To reduce or gain weight, special or unusual foods are necessary.

Graduation Address.—*George P. Larrick,* Commissioner of Food and Drugs, delivered this address at the University of Tennessee Medical Units commencement exercises in Memphis, Tennessee on June 9, 1963. Mr. Larrick points out that the present decade, 1960-1970, will see great expansions of medical, dental and pharmaceutical research, and the application of new, more efficient techniques to deal with chronic as well as infectious processes. "It is especially important for all of us concerned with health, to recognize certain factors upon which continuing progress depends." As newer medical products, devices and techniques come into being, it must be possible to utilize them with confidence—confidence that they have been properly manufactured, that they have been properly tested, and that they have been truthfully promoted. The patient must have confidence also, not only that his doctor, dentist, pharmacist and nurse are well-trained, competent individuals, but also that the tools and drugs which they use are safe. In this article, which is found on page 514, the author concludes, "Truly, we share great responsibility on the medical front which changes so rapidly and dramatically today. We pledge to you and other members of our great health professions the full support of the Food and Drug Administration."

A State Drug Control Program.—In an article on page 520, *H. C. McAllister,* secretary-treasurer of the North Carolina Board of Pharmacy, includes specific recommendations in regard to a drug control program for the states. The author is of the opinion that some of these proposals already exist and need only be organized and put into use. He presented this paper at the Fifteenth Annual Conference of the Southern Association of Food and Drug Officials in New Orleans, and was hopeful that organizations such as the Association would interest themselves in the problems of health services and the materials used in connection therewith.

Looking Back.—This month's JOURNAL is pleased to present a talk given by *Erwin P. Snyder* at a testimonial luncheon in his honor. "Judge" Snyder, a founding member of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, of the American Bar Association, is nationally held in great affection and esteem as the "dean" of the food and drug law bar. He looks back on some of the old-time problems he had with the Food and Drug Administration back in the early days of its existence. His interesting remarks appear at page 529.

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Food·Drug·Cosmetic Law
Journal

The First Session of the Codex Alimentarius Commission

By FRANKLIN M. DEPEW

Mr. Depew Is President of the Food Law Institute and Vice President of the Section of Food, Drug and Cosmetic Law of the Inter-American Bar Association. Following Is His Account of the Recent Meeting of the Codex *Alimentarius* Commission, Which He Attended As an Observer.

THE CODEX ALIMENTARIUS COMMISSION, established by the Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Conference on Food Standards, held its first session at FAO Headquarters, Rome, Italy, June 25-July 3, 1963. Some 120 participants, including representatives of 30 countries and observers from 16 international organizations were in attendance. I was invited to attend the meeting as an observer in my capacities as President of The Food Law Institute and as Vice President of the Section of Food, Drug and Cosmetic Law of the Inter-American Bar Association. The United States delegation consisted of John L. Harvey, Associate Commissioner of Food and Drugs, delegate; Nathan Koenig, Special Assistant to the Administrator, Agricultural Marketing Service, United States Department of Agriculture, alternate; and Clinton L. Brooke, Frank C. Elliott, Michael F. Markel, Harry Meisel, Kenneth E. Mulford, Gerald W. Sheldon and Donald R. Thompson, advisors.

Agenda and Election of Officers

The Secretariat had prepared a most comprehensive agenda for the consideration of the delegates, which required their undivided attention at all times in order that all matters should be covered within the allotted time. The skillful handling of many vexing problems by

the Chairman, with the helpful assistance of the Secretariat, enabled the delegates to dispose of all the items on the agenda before adjournment.

Prior to the adoption of its Rules of Procedure the Commission elected as interim officers: John L. Harvey, Chairman, and Dr. M. J. L. Dols (Netherlands) and G. Weill (France) Vice Chairmen. After adoption of its Rules of Procedure (which will not be reviewed here except to mention that they provide that the Commission shall in principle hold one regular session each year at the Headquarters of either FAO or WHO), the Commission elected as its regular officers (to act during the current session and until the end of the next session): John L. Harvey, Chairman, and Dr. M. J. L. Dols (Netherlands), H. Doyle (New Zealand) and Dr. Z. Zaczkiewicz (Poland), Vice Chairmen. In addition the following six countries were elected to the Executive Committee of the Commission: Argentina for the Latin-American area, Australia for Australasia, Canada for North America, India for Asia, Senegal for Africa, and the United Kingdom for Europe. The Chairman and Vice Chairmen are members of the Executive Committee by virtue of their office. Because of Mr. Harvey's election as Chairman, Nathan Koenig acted as the United States delegate throughout the meeting. Mr. Koenig carried out his responsibilities in acting as spokesman for the delegation in a most effective and persuasive manner.

Advisory Group for Europe

The Commission decided to set up an Advisory Group for Europe. After extended discussion, the present European Council of the *Codex Alimentarius* agreed henceforth to serve in this new capacity under the title "Advisory Group for Europe of the Joint FAO/WHO *Codex Alimentarius* Commission." As such this body became an organ of the Commission open to all governments in Europe (including Israel, Turkey and the USSR) and empowered to elect its Vice-Chairman and fix its own working procedures if required, within the general framework of the Commission's Statutes and Rules of Procedure. On the proposal of the European region, Professor Otto Högl (Switzerland), President of European Council of the *Codex Alimentarius*, was unanimously appointed as Coordinator for Europe for a period of two years.

Decision to Establish World-Wide Standards

One of the major issues discussed at the 1962 Joint FAO/WHO Conference on Food Standards had been whether or not the standards

work of the Commission should be on a regional or world-wide basis. This issue was again raised at the meeting of the Commission. As a result of extensive discussion in which the United States, the United Kingdom, Canada, the Netherlands and Denmark were most effective, it was decided that the food standards work of the Commission should be on a world-wide basis, except where unusual conditions required different treatment (such as highly perishable commodities), and then recognition should be given to equivalency for products coming from outside the region.

Guiding Principles for Food Standards Work

The Commission adopted a number of Guiding Principles for use by its Expert Committees and other bodies preparing draft standards and referred these principles for review and completion to its Executive Committee. This Committee reviewed these principles at its first meeting on July 3, 1963, and recommended that they read as follows:

GUIDING PRINCIPLES

(a) Draw up a list of priorities as appropriate among the products involved.

(b) Determine the nature of the standards to be sought, i.e. "minimum platform standards" and/or higher "trading Standards".

(c) Consider the possible need for standards for wholesale trading as well as retail.

(d) Unless clearly necessary, avoid "recipe" standards, i.e. those which exclude the use of other than specified ingredients.

(e) Consider the product involved without reference to possible competing products.

(f) Wherever standards of identity pose special difficulties, minimum requirements should first be laid down in order that a product may bear a group designation (e.g. "cheese" or "groundnut oil"), and sub-categories then be designated by an appropriate term not implying quality preferences where compositional differences alone are involved. Such designations should always accompany any descriptive designation employed under national standards or by the trade. At a later stage, agreement should be sought on descriptive designations of these sub-categories (e.g. "full fat cheese," "skimmed milk cheese," "refined groundnut oil").

(g) In general, subject to appropriate labelling, no product should be required to bear a different designation by reason solely of the presence of permitted food additives.

(h) Product definitions should be no wider than strictly necessary. In particular they should be stated in positive, not negative terms and should not resort to statements of exceptions.

(i) Products similar to standardized products shall be sufficiently designated by a fanciful name accompanied by adequate labelling.

(k) General lay-out recommended for standards of composition:
(1) Definition
(2) Designations and standards
(3) Permitted additions
(4) Marking and labelling.

The Secretariat had requested me, as President of The Food Law Institute, to submit a paper on this subject for the consideration of the delegates at the meeting. It is gratifying to note that the actions taken at the meeting and the Guiding Principles adopted by the Commission basically agree with the recommendations made in this paper. A copy of the paper is annexed as an exhibit.

Consideration of Completed Draft Standards

The Commission considered in first reading the following completed draft standards, drawn up before the Commission was constituted:

(1) General Principles:

(a) European draft prepared by the former European Council of the *Codex Alimentarius*;

(b) Latin-American draft prepared by the Latin American Food Code Committee.

(2) Sampling—draft prepared by the former European Council of the *Codex Alimentarius;*

(3) General Principles for the use of Additives—draft prepared by the Secretariat from Reports of the Joint FAO/WHO Expert Committee on Food Additives.

(4) Permitted lists of Additives—draft prepared by the Secretariat from Reports of the Joint FAO/WHO Expert Committee on Food Additives:

(a) Antimicrobial Preservatives;
(b) Antioxidants;
(c) Emulsifiers and Stabilizers;
(d) Maturing and Bleaching Agents.

(5) Edible Fungi:

(a) European draft;
(b) Latin-American draft.

(6) Fresh Fruits and Vegetables—drafts prepared by the Economic Commission for Europe.

(7) Cocoa Beans—draft to be prepared by the FAO study group.

(8) Olive Oil—text taken from the International Olive Oil Agreement as approved by the United Nations Conference on Olive Oil, April 1963.

The Commission decided to refer these drafts to governments for detailed comment prior to their further consideration in second reading at the next session. Governments have been requested by the Executive Committee to send detailed comments on these draft standards to the Secretariat *not later than February 29, 1964.*

The European draft of General Principles defines foodstuffs, provides for specification of testing methods used, and specifies when a product shall be considered injurious to health, spoiled, unripe, adulterated, or misleadingly packed or labeled. It refers to products imitating a foodstuff without defining "imitation".

The Latin-American draft is Chapter I of the Latin-American Food Code published in the April, 1963 issue of the FOOD DRUG COSMETIC LAW JOURNAL (p. 194). It defines food and deteriorated, contaminated, adulterated and misbranded food, provides that advertising must conform to the requirements of the Code and sets forth tolerances for metals and metalloids. It further provides that household articles, including cigarettes are subject to its provisions.

The draft of General Principles of the use of Food Additives defines a "food additive" to cover nonnutritive substances. It states that the use of a food additive is justified only when it serves the following purposes:

(a) the maintenance of the nutritional quality of a food;

(b) the enhancement of keeping quality or stability with resulting reduction in food wastage;

(c) making foods attractive to the consumer in a manner which does not lead to deception;

(d) providing essential aids in food processing.

The draft standards for fresh fruits and vegetables include a Protocol on Standardization of Fruits and Vegetables (general principles to be followed in determining compliance with standards) and draft standards for apples, pears, peaches, apricots, plums, citrus fruit, cherries, strawberries, table grapes, tomatoes, artichokes, cauliflowers, onions, lettuces and endives, Witloof chicory, spinach, shelling peas, beans, carrots and early potatoes. The Commission endorsed the program of the Economic Commission for Europe as comprehensive and successful in this field and urged interested countries out-

side Europe to participate actively in this work so that their advice could be considered at the Commission's next meeting.

Food Additives

The Commission decided to set up a world-wide Expert Committee on this important subject, with the Netherlands serving as Chairman, to consider the draft lists of acceptable food additives together with the reports of the Joint FAO/WHO Expert Committee on Food Additives upon which they are based, and in the light of government comments thereon to (1) draw up a revised list of acceptable additives and (2) survey and designate wherever possible proposed maximum levels of use for these additives in individual foods. The Joint FAO/WHO Expert Committee is essentially a scientific body concerned with safety of use. It draws up standards of identity and purity for food additives together with maximum intake levels. The Commission's Expert Committee, on the other hand, is concerned with the application to individual food standards of the data on additives made available by the Joint FAO/WHO Expert Committee.

Pesticide Residues

The Commission decided to set up a world-wide Expert Committee on Pesticide Residues with the Netherlands serving as Chairman to consider the pesticides for which acceptable daily intakes will have been established by the FAO Working Party on Pesticide Residues meeting jointly with the WHO Expert Committee on Pesticide Residues, in order to survey and propose where possible tolerances for pesticides in individual foods.

General Provisions on Labeling

The Commission requested the Secretariat to draw up for submission to it at its next Session a concise resumé of current food labeling laws, with particular reference to those of countries participating actively in the work of the Commission. This resumé should cover provisions dealing with identity, net contents designations, indication of manufacturer and special requirements on type and style of label declarations. The Commission further requested the Secretariat to include as an appendix to this resumé the chapter on labeling set out in the draft Latin-American Food Code.

Methods of Sampling

The Commission requested the International Standards Organization to develop methods of sampling for physically similar product groups and where necessary, specific methods for important individual products, and to make a progress report to it for consideration at its next session. The International Standards Organization agreed to undertake this work.

Methods of Analysis

The Commission accepted the offer of the Austrian Government to continue its responsibility for organizing an Expert Committee on methods of analysis. This Expert Committee will henceforth work as a world-wide Expert Committee, open to all members of the Commission. The Commission enunciated certain principles for the guidance of this Expert Committee, among them being that the Expert Committee should recommend in each case whether the method of analysis should be published in the *Codex* in full or merely by bibliographic reference. Since the elaboration of methods of analysis will take considerable time, the *Codex* should, as an interim measure, include references to existing practicable methods in each standard of composition pending the elaboration and/or revision of definitive methods.

Food Hygiene

In respect of general questions of food hygiene, the Commission set up a world-wide Expert Committee for the development of standards. The United States was invited to accept the Chairmanship of this Committee. The Commission decided to treat the existing Joint FAO/WHO Expert Panel on meat hygiene as its advisory body on meat hygiene and requested the panel to make recommendations on basic principles of meat hygiene, including microbiological standards. Questions concerning milk hygiene were determined to be within the terms of reference of the Joint FAO/WHO Committee of Government Experts in the Code of Principles concerning Milk and Milk Products.

Milk and Milk Products

The Commission decided to treat the present Joint FAO/WHO Committee of Government Experts as a Committee of the Whole Commission to have exclusive jurisdiction of all questions concerning milk and milk products. The regular FAO budget covers the expense of this committee. The decisions of this Joint Committee will thus

become the decisions of the Commission in this field subject to review by the Commission if requested. All member countries of FAO and WHO are eligible for membership on the Joint Committee. The Joint Committee held its Sixth Session in Rome on June 17-21, 1963 where it adopted a standard for Whey Cheese for resubmission to governments for acceptance in its revised form, and gave preliminary consideration to draft standards for processed cheese products and prepackaged cheese to be submitted to governments for detailed comment. The committee modified the standard for Sweetened Condensed Milk to provide that where sugars other than sucrose are used, their name and percentage by weight shall be declared on the label. It noted that 51 countries have accepted the standard for whole milk powder. The committee considered methods of sampling and analysis, milk hygiene requirements, use of food additives in milk products and suggested those substances be accepted which offer the least likelihood of exceeding the maximum total intake established for unconditional acceptance. Baby foods should be free from all additives except in exceptional situations, when their presence must be declared. The committee suggested governments might wish to propose one or more new generic designations for imitation milks consisting of a combination of milk products with other products. Governments are requested to make their comments available to the Secretariat by *December 15, 1963 at the latest.*

Expert Committees and Preparatory Work for Additional Food Standards

The Commission then made the following allocation of preparatory work in draft food standards:

Oils and fats (excluding margarine and olive oil).—Set up a world-wide Expert Committee, under the Chairmanship of the United Kingdom, to elaborate draft standards for fats and oils of animal, vegetable and marine origin (except margarine and olive oil).

Margarine.—The Commission accepted the offer by the International Federation of Margarine Associations to submit a draft standard for Commission consideration.

Cocoa Products and Chocolate.—Set up a world-wide Expert Committee, chaired by Switzerland, to prepare draft standards for these products for Commission consideration.

Honey.—Set up a world-wide Expert Committee, chaired by Austria, to prepare draft standards for honey for Commission consideration.

Sugars.—Set up a world-wide Expert Committee, chaired by the United Kingdom, to prepare draft standards covering all types of carbohydrate sweetening materials.

Wheat.—The Commission requested the International Standards Organization to survey the work now in hand among several interested organizations engaged in methods of sampling and analysis for wheat and to make the survey available to the Secretariat by the end of the year, in order to allow its submission to governments in good time before the Second Session. This request was accepted. The United States suggested that greater uniformity in methods was needed before grade standards were considered and the Commission action was taken in accordance with this view.

Meat (carcasses and cuts).—Set up a world-wide Expert Committee, chaired by the Federal Republic of Germany, to elaborate proposals for:

(1) Classification and grading of carcasses and cuts of beef, lamb, mutton, pork and veal;

(2) Definitions, labelling and other requirements for such processed meat products as the Expert Committee might feel desirable at this stage.

Fruit Juices.—The Commission warmly welcomed the recommendations by the Working Party on the Standardization of Perishable Foodstuffs of the Economic Commission for Europe, henceforth to carry out jointly with the Commission its recently started work on fruit juice standards covering raw fruit juices, concentrated basic fruit juices, basic fruit juices, fruit juices, concentrated fruit juices, and fruit juice beverages.

The resulting Joint Expert Group is to submit its draft standards for Commission consideration.

Processed Fruit and Vegetables.—Set up a world-wide Expert Committee, chaired by the United States, to prepare draft standards covering all types of processed fruits and vegetables, including dried products and jams and jellies. The Commission requested this committee to make full use of the experience gained by France in earlier work on the subject undertaken on a European basis.

Fresh Fruit and Vegetables.—The Commission endorsed the comprehensive and successful program of the Economic Commission for Europe in this field and urged interested countries outside Europe to participate actively in its work as observers.

Fish and Fish Products.—The Commission adopted a proposal made by the Secretariat that it accept the offer of the FAO Fisheries Division to carry out the preparatory work for such standards in consultation with experts in this field. The Commission at a later session will consider the establishment of an Expert Committee in the light of the progress made in the preparatory work.

Poultry.—The Commission agreed to take up the question of draft standards at its next session. The United States was requested to prepare a study for Commission consideration at that time.

Eggs.—The Commission decided to defer consideration of this subject until the next session, when it hoped to have more information on the program and structure of the International Egg Commission. It requested the Economic Commission for Europe to defer reconsideration of its earlier work until the *Codex* Commission had an opportunity to consider the question at its next session.

Soft Drinks.—The Commission accepted an offer by the United Kingdom to prepare a background paper on soft drinks for consideration and possible further action by the Commission at its next session. It decided not to give further consideration for the time being to standards for beer.

Social Activities

The foregoing reports the principal actions taken by the Commission during its business sessions. The delegates, however, did not only get together to work. The Secretaries General of FAO and WHO invited them and the observers, as well as the Secretariat staff, to a cocktail party on Monday, July 1. The United States held a cocktail party on Tuesday, July 2, in honor of the Chairman. Both parties were greatly enjoyed by those in attendance. They were held on the roof of the EAO Headquarters Building which afforded a delightful panoramic view of Rome, including the Colosseum, the Circus Maximus, and the Arch of Constantine. These occasions afforded those in attendance an opportunity to get better acquainted.

Accomplishments and Future Importance of *Codex* Work

The American food industry owes a debt of gratitude to Nathan Koenig and the other members of the United States delegation who worked diligently toward sound principles of food standardization. John L. Harvey served impartially and effectively and his outstanding service was acclaimed by the delegates. However, it was apparent, from the many and extended discussions held during the meeting that local and national interests have not been forgotten. The program of work adopted by the Commission will require the active participation of the United States in the Expert Committees considering standards for commodities moving in trade to and from the United States. While these standards are only advisory in nature, unless accepted by the United States, they are certain to play an important role in international trade since many countries may be expected to use them in their specifications for international trading purposes. Furthermore, as participating countries may be expected to exert pressure to adopt those standards as legal standards, the American food industry's future interest is not only in the foreign trade aspects of the standards but in their possible effect on domestic food products, if a present standard is revised to conform to the international food standard.

The United States government through its delegation has indicated that it plans to consult with American industry and to seek advice and guidance from industry on these important problems, as well as keeping industry informed in its respective fields of interest.

ANNEX

Suggested Principles for Consideration In Drawing Up International Food Standards

By FRANKLIN M. DEPEW

A Statement for the First Session of the Joint FAO/WHO *Codex Alimentarius* Commission

As stated by the Joint FAO/WHO Conference on Food Standards held in Geneva, October, 1962, the international standards which it is the work of the Commission to draw up "aim at protecting consumers' health and ensuring fair practices in the food trade. Their publication is intended to promote the standardization of standards and in so doing to further the development of the international food trade." While we cannot expect to reach this ultimate goal in the

immediate future, it is desirable to keep it in mind in connection with present efforts. Caution should also be exercised in working toward this long range goal, and toward the more immediate goals, to make certain that the door is not closed to future developments. The spectacular and continuing advance in food technology has made imperative a system of food regulation which will facilitate the movement of existing food products and, importantly, of those yet to be developed. Regulation in this field should be dynamic and capable of adaption to advances in science and changing world conditions.

We may expect to attain this ultimate goal more quickly if we recognize the existing factors which render difficult its early realization. One of the greatest obstacles to the adoption of these standards is the protectionist policies of numerous highly developed countries. Many of these countries are subject to strong pressures to use their food laws as a device for protection of their political and economic interests against foreign competition. Other major obstacles to harmonization are the dissimilarity of food habits in different parts of the world and dissimilarity and varieties of characteristics of the same foods produced in different places. Dissimilarity of raw materials now presents a problem where it results in a standard that fails to encompass a substantial portion of the major crop of any country. Moreover, climatic conditions may necessitate the use of preservatives in certain areas, whereas they may not be necessary in other areas. The harmonization of the differences of opinion in different areas as to what constitutes honesty and fair dealing in the interest of the consumer also presents a difficult problem. Finally, differing interpretations of terminology must be resolved in order to eliminate such deterrents to world-wide standards.

While this ultimate goal cannot completely be realized at this time, we believe it suggests what the immediate program should be and how to approach the task of achieving equal protection to consumers by similarity of regulation to the extent presently possible. We believe the immediate objectives to attain are harmonization of existing food standards and the development of a number of proposals for new standards on both a regional and world-wide basis. In this connection we urge that the public interest will best be served if food regulation is confined to its intended purpose of (1) the protection of the consumer against health hazards and (2) the protection of the consumer against fraudulent or misleading claims. In establishing and harmonizing these food standards they should, thus, be designed to protect the needs of the consumer rather than to protect industry.

Governing Principles

We earnestly believe that the principles that should govern this work are the following:

(1) It is of greater consumer importance to work rapidly toward uniformity of tolerance in pesticide residues, food additives, color additives, and similar substances, such as preservation, antioxidants and emulsifiers, than it is to standardize quality factors for economic purposes. Health is fundamental and should supercede all other considerations. Lack of uniformity of this kind also presently operates as a deterrent to international trade. Where these substances have been scientifically shown to be safe, their general acceptance would appear to be in the public interest. Thus, we urge a general adoption of the principles laid down by FAO and WHO on safety evaluation and specification of food additives. Uniformity of tolerances in this general area could be furthered by a greater use of existing international facilities for standardizing analytical methodology and chemical terminology. There has been a great deal of this type of work done in many countries which might well be recognized and used to advantage on a broader basis.

(2) Food standards should deal with the basic integrity of food products. They should not be rigid recipe or formula standards which specify each and every component. Any ingredient not specifically forbidden by the standard should be allowed as long as the basic integrity of the product is maintained. Past experience has shown that recipe standards will too frequently serve to obstruct the entry of enterprising innovators who offer improved products. Consumer expectation has been used to establish recipe standards in the past which have operated to prevent the use of wholesome substances that the public has never heard of, through ignorance of new developments and new advances in technology. How can the consumer have expectations about anything really new? So long as a product is safe and has the expected characteristics of taste, smell, and so forth, including the essential nutritional value, it would appear to deserve introduction to consumers. Recipe or formula standards do not serve the public interest where they operate as a brake on progress. On the other hand, standards which simply establish basic product integrity will permit the manufacturer to be free to select the type and quantity of ingredients going into his product based on the demands of the market place. Where necessary to protect the consumer in special

situations, appropriate provision may be made for a recipe-type standard which would specifically prohibit the use of certain specified ingredients.

(3) Food standards should aim at the early elimination of trade barriers resulting from differing interpretations of scientific data. Scientific truths are universal and there should be an international acceptance of valid chemical analyses and the results of competent tests. Therefore, food standards should be based upon the best technical advice available in order to assure that the standards are primarily designed to protect the public health.

(4) Where immediate harmonization of food standards is proposed for a particular region, such standards should be promulgated only on the basis of a demonstrated need for such standards, and they should be submitted for review and comment to all participating governments before they are offered for acceptance in the *Codex*.

(5) Uniformity of methodology, affording common yardsticks in different countries, is a most important aspect of food standardization. Food standards should, therefore, prescribe methods of analysis where appropriate, either directly or by reference. Effort should be made to make analytical procedures as quick and simplified as possible so as to make testing as economically available as practicable. Simple and practical methods are important to enforcement officials for effective enforcement. Perhaps qualification of testers should be specified so as to avoid questions of acceptance of tests made in one country by those in another country. **[The End]**

HEARING ON PRESCRIPTION-DRUG ADVERTISEMENTS REGULATIONS SCHEDULED

A public hearing to consider objections to Section 1.105(e)-(j) of the prescription-drug advertisements regulations has been scheduled for October 10, 1963, by the FDA, for the purpose of receiving relevant and material evidence. The effective date of Section 1.105(e)-(j) has been stayed pending the outcome of the hearing. The Department of Health, Education and Welfare believes that there are legal issues of statutory interpretation which must ultimately be settled by the courts, but the hearing will offer the opportunity to present evidence on any factual matters relating to the issues.

William E. Brennan, a duly qualified Hearing Examiner, is designated to conduct the hearing, with full authority to administer oaths, make affirmations, and do all other things appropriate to the conduct of the hearing. FDA Notice, 28 *Federal Register* 9837, CCH Food Drug Cosmetic Law Reports, ¶ 40,057.

The Latin-American Food Code: Chapter XIV

Chapter XIV of the Latin-American Food Code Was Translated from the Original Spanish by Ann M. Wolf of New York. The Translation Is Based on the 1960 Edition of the Code Published in Buenos Aires, as Subsequently Amended by the Latin-American Food Council (Formerly Called the Latin-American Food Code Committee), up to September, 1962. The English Translation of the Introduction to the Code by Dr. Charles A. Grau and the Index Were Published in the October, 1960 Issue of the FOOD DRUG COSMETIC LAW JOURNAL; the Translation of Chapter IV (Utensils, Receptacles, Containers, Wrappers, Machinery and Accessories) Appeared in the February, 1961 Issue; the Translation of Chapter X (Sugar and Sugar Products) Was Published in the May, 1961 Issue; the November, 1961 Issue Contained the Translation of Chapter XVI (Correctives and Improving Agents —Additives); Chapter XII (Nonalcoholic Beverages and Refreshing Foods and Drinks) Appeared in the June, 1962 Issue; and Chapters I, II, III and V (General Provisions; General Requirements for Food Factories and Food Outlets; The Storage, Preservation and Processing of Foods; Labelling) Appeared in the April, 1963 Issue.

CHAPTER XIV—SPIRITUOUS BEVERAGES

Distilled Alcoholic Beverages and Liqueurs

Article 496—Any distilled spirits plant shall comply with the general regulations of this Code and, in addition, meet the following requirements:

1. The name *"Distillery"* (distilled spirits plant) may only be used by plants which own and operate authorized stills and manufacture distilled alcoholic beverages and/or rectified alcohol.

2. The rooms used to manufacture distilled alcoholic beverages, to prepare liqueurs, and to store finished beverages and raw materials shall be separated from each other by fixed partitions and shall have waterproof floors. In addition, the walls of the rooms used for manufacture and maceration shall be wainscotted with a waterproof material up to 1.80 m. This requirement shall not apply to the basements and other rooms used to store wooden casks with products in the process of aging.

3. Distilleries are prohibited from holding any chemicals (dressings, improving agents, anti-fermentation agents, etc.) intended to improve, preserve, artificially age, or imitate distilled alcoholic beverages and liqueurs; from misleading the purchaser or consumer as to the essential qualities, origin, or class of a product; and from attributing to a synthetic product the characteristics of a natural or standard beverage by falsifying analysis results. The presence of the aforesaid prohibited substances on the premises of a distillery, or in distillery annexes, even in sealed containers, shall be subject to penalties, and in addition, the violatory products shall be confiscated forthwith.

4. Manufacturers of alcoholic beverages shall be obliged to exhibit their manufacturing and sales records to the Health Inspectors whenever requested to do so in the course of an official inspection.

Article 497—The terms *"Alcohol," "Neutral Alcohol"* and *"Rectified Alcohol"* mean any alcohol which is obtained through the distillation and rectification of fermented mashes, as well as any alcohol obtained through the rectification of natural brandies. The alcoholic content of the product ready for consumption shall, at 15° C., never be lower than 95 per cent, and its total impurities shall never exceed 0.5 grams per liter of absolute alcohol.

"Wine Alcohol" is rectified alcohol prepared from wine or wine products, from which the methyl alcohol has been removed. All neutral alcohols shall be considered suitable for the preparation of beverages, vinegars and perfumes.

Article 498—The terms *"Genuine Brandies"* and *"Natural Brandies"* mean any brandy obtained from the special distillation of fermented mashes, or from the special distillation of their components or derivatives, provided always that they have not suffered alterations and that no substances extraneous to their nature have been added to them. Their alcoholic content may not in any case be higher than 85 per cent. These products shall be labeled "Suitable for Handling," provided that their furfural content does not exceed 0.08 grams per liter of absolute alcohol and/or that their methyl alcohol content does not exceed 3 milliliters per thousand milliliters of brandy. In natural fruit brandies which are "Suitable for Handling," the presence of methyl alcohol in an amount of up to 5 milliliters per liter of brandy (Kirschwasser, etc.) shall be permitted.

The term *"special distillation"* applies to the distillation performed in a simple pot still, or in a distilling column with partial rectification,

at not more than 85° C., so as to obtain a product with specific characteristics and with the limited amount of impurities permitted.

Article 499—The term *"Distilled alcoholic beverages"* means natural brandies of an alcoholic content of between 35 and 60 per cent, obtained directly, or by redistillation, blending, or the addition of water. During fermentation or distillation, the mash or the brandy may be flavored if this is required to obtain the desired type of alcoholic beverage. In the same manner, sweetening and coloring with authorized substances shall be permitted when the practice makes it advisable or the type of beverage requires it.

In general, if no specific rules have been fixed in this Code, their total volatile impurities or volatile constituents (the term "volatile constituents" meaning the sum total of aldehydes, acids, esters, furfural and higher alcohols) may never amount to more than 1.8 grams or less than 150 mg. per 100 ml. of anhydrous alcohol, and the furfural limit shall be 4 mg., the methyl alcohol limit 0.25 ml. per 100 ml. of anhydrous alcohol. These requirements shall be met by all products listed in Articles 502 and 503 hereof.

Article 500—The names *"Brandy"* and *"Wine Brandy,"* used alone without any other specification, mean a brandy obtained through the *special distillation* of wines or wine brandies.

Article 501—The name *"Cognac"* means the alcoholic beverage obtained from a wine brandy that has been aged in suitable wooden containers for not less than 24 months and has acquired the characteristics peculiar to this beverage. It may be colored with caramel. The dry residue of the finished product may not exceed 2 per cent, and its total volatile constituents shall amount to not less than 280 mg. per 100 ml. of anhydrous alcohol.

Article 502—The name *"Brandy of . . ."* followed* by the name of the fruit used in the beverage designates any alcoholic beverage obtained through the special distillation of mashes of fruit.

The term "Brandy" is prohibited from being used for beverages prepared with alcohol obtained from cereals, molasses or other carbohydrates.

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* Note of the translator: In the English language, the name of the fruit precedes (Apple brandy, etc.).

Natural Fruit Brandies shall be named as follows:

1. *"Plum Brandy," "Slivovitz," "Quetsch"* or *"Mirabelle"*: a brandy distilled from fermented sound fresh plums. Its content in volatile constituents shall exceed 300 mg. per 100 ml. of anhydrous alcohol, inclusive of the hydrocyanic acid content which may not exceed 40 mg. per liter of beverage ready for consumption. Its acidity, expressed as acetic acid, shall be less than 1.8 grams per liter. The hydrocyanic acid in plum brandy must come exclusively from the fermented fruit; the addition, before or after distillation, of vegetable macerations or extracts containing hydrocyanic acid is prohibited.

2. *"Agriot or Cherry Brandy," "Kirsch"* or *"Kirschwasser"*: a brandy distilled from fresh sound agriots or cherries, which have been fermented with or without the stones. Its content in volatile constituents shall exceed 250 mg. per 100 ml. of anhydrous alcohol, inclusive of the hydrocyanic acid which must come exclusively from fermented agriots or cherries and which, at the distillery, may vary between 10 mg. and 100 mg. per liter, but in the beverage ready for consumption is not permitted to exceed 50 mg. per liter.

3. *Apple Brandy*: a brandy distilled from fermented apple juice or apple pulp.

4. *Pear Brandy*: a brandy distilled from fermented pear juice or pear pulp.

5. *"Cider Brandy"* or *"Calvados"* (Applejack): a brandy distilled from genuine ciders, suitable for consumption. Its content in volatile constituents shall exceed 400 mg. per 100 ml. of absolute alcohol, not less than 175 mg. of which shall be esters. It may be colored slightly with caramel.

6. *"Grape Brandy"* or *"Pisco"**: a brandy obtained from the distillation of a fermented grape mash in the presence of grape pulp and waste.

7. *Raki Brandy*: a brandy distilled from a fermented mixture of fruits, such as figs, dates, plums, etc.

Article 503—The brandies named hereinafter, in the preparation of which no fruit juice or fruit pulp is used, shall meet the following specifications:

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* Note of the translator: A higher brandy prepared in Chile and Peru. The name is drawn from the Peruvian port Pisco.

1. *Anise Brandy*: a brandy distilled from a maceration of aniseed (common aniseed, star-anise, or a mixture of the two) in wine brandy, with or without other substances and aromatic extracts.

2. *"Arac," "Arrac," "Arrack,"* or *"Sunchou"*: a brandy distilled from a fermented rice mash, to which palm juice, sugar cane, molasses and flavors derived from pineapple, catechu, or aromatic barks may be added.

3. *"Sugar Cane Brandy," "Aguardiente"* ("Taña," "Cachaza," "Branquina," or "Pinga" *): a brandy distilled from fermented sugar cane syrup or molasses.

4. *"Grain Brandy":* a brandy obtained through the special distillation of a sweetened fermented mash of grain. Its content in volatile constituents may not be lower than 280 mg. per 100 ml. of anhydrous alcohol.

When grain brandy is to be used in the preparation of *Geneva* (Article 507, point 8), the grain mash must be sweetened with barley malt and the brandy obtained (Malt Wine) must be redistilled in whole or in part in the presence of juniper berries, in which case it may be named "Geneva Concentrate" (a product still to be processed).

5. *"Grappa Brandy," "Grapa," "Marc Brandy," "Graspa"* or *"Bagaceira":* a beverage obtained from grape pomace. The use for this beverage of the name *"Grape Brandy,"* or of any statement in advertising which implies that the product is made from grapes, not from pomace, is prohibited. Its content in volatile constituents shall not be less than 300 mg. per 100 ml. of anhydrous alcohol. It may be sweetened and colored.

6. *"Mescal," "Mezcal," "Tequila"* and *"Cocuy Brandy"* **: products obtained through the special distillation of fermented juices of several agave varieties (Amaryllidaceae). (For "Pulque," see Article 495, point 6 ***.)

7. *"Rum"* or *"Rhum":* a brandy derived from the alcoholic fermentation and special distillation of raw or boiled sugar cane juices and other by-products of sugar manufacture. To make it ready for consumption it must be aged in appropriate wooden barrels. It may

* Note of the translator: The last four names, used in Central America and Brazil, are not translatable.

** Note of the translator: Names used in Mexico which are not translatable.

*** Note of the translator: Chapter XIII, "Fermented Beverages, Wines and similar products."

be colored with caramel. Its content in volatile constituents may not be less than 300 mg. per 100 ml. of anhydrous alcohol.

8. *"Malt Brandy"* or *"Malta":* a brandy obtained through the special distillation of a fermented mash of barley malt. It may be named *"Pure Malt Whiskey"* when it has been aged in appropriate wooden containers for more than two years.

Article 504—Distilled alcoholic beverages may contain only one type of brandy, but beverages of the same type may be blended without any statement to that effect on the label.

Neutral spirits may be blended only with others of the same origin, which may be used only in the proportion required to reduce the content in impurities or volatile constituents to the limits specified in Article 499 hereof.

Article 505—Names such as *"Caña* Habana," "Caña de la Habana," "Caña de Habana," "Caña del Paraguay," "Hollands Gin," "French Cognac," "Scotch Whisky," "Jamaica Rum," "Martinique Rum," "Danziger Goldwasser"* and similar or kindred names which define the geographic origin of an alcoholic beverage (brandy or cordial) may be used only when the finished product comes from the country or the locality named in the designation.

Article 506—The terms *"Liqueur," "Elixir"* and *"Cordial"* mean any alcoholic beverage that has been prepared by mixing or redistilling rectified alcohol or brandy with, or over, substances of vegetable origin, or with extracts derived from infusions, percolations or maceration of such materials, and sweetened with sugars or honey. When the amount of sweetener added is less than 10 per cent (by weight/volume), the liqueur may be called *"Dry";* when it is less than 2.5 per cent (by weight/volume) it may be called *"Dry spirit";* when it contains between 10 and 20 per cent (by weight/volume) of sweetener, *"Sweet"* and when the sweetener exceeds 20 per cent (by weight/volume), it may be called *"Fine."* The name *"Cream"* may only be given to liqueurs of a syrupy consistency containing sweetener in a proportion of more than 35 per cent (by weight/volume). The name *"frosted liqueur"* may only be used for products oversaturated with sugar which crystallizes later.

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* Note of the translator: The word "Caña," which translated literally means sugar cane, is used in South America to designate a type of white spirit made from sugar cane.

Liqueurs may be colored with authorized colors without a declaration.

Liqueurs prepared with a base of fruit juices or parts of fruits may be named *"Ratafias."* The words *"Cherry," "Apricot," "Peach"* etc. may be used on liqueurs made from the fruits thus named.

Liqueurs shall have an alcoholic content of not less than 15 per cent and may be designated by distinctive names ("nombres de fantasía") whenever none of the generic names given in this Code fits the product exactly.

Article 507—Hereinafter a list of generic names, with the definition of the products distinguished by them:

1. *"Anis"* or *"Anisado":* a liqueur distilled from an aniseed (ordinary aniseed, star-anise, or a mixture of the two) maceration in neutral alcohol, or obtained through the mixing of neutral alcohol with, distilled or undistilled, natural aniseed essence. Other aromatics may be added to it.

An anis to which sugars in an amount exceeding 20 per cent (by weight/volume) have been added shall be named *"Sweet Anis"* or *"Carbanchel Anis,"* and when the amount of sugar added exceeds 35 per cent (by weight/volume) it may be named *"Cream Anis"* or *"Anisette."*

Anise brandy and dry anise liqueur of an alcoholic content of more than 40 per cent may be named *"Arabian Anis"* or *"Turkish Anis."*

2. *"Akuavit," "Akvavit"* or *"Acqua Vitae":* an alcoholic beverage with a base of neutral alcohol, flavored with infusions or distillates of aromatic seeds or herbs.

3. *"Blackberry Liqueur":* a liqueur prepared with the juice or a maceration of blackberries and other fruits.

4. *"Noisette Liqueur":* a cordial obtained from the alcoholic maceration of green walnut hulls and lemon peel.

5. *"Caña"* (Sugar Cane): This term applies not only to the distilled beverage so named (Article 503, point 3), but also to an alcoholic beverage prepared with rectified alcohol, diluted with water, to which authorized essences may be added. The name *"Caña Doble"* may only be used for products whose alcoholic content is higher than 45 per cent.

The name *"Fruit Caña"* (plum, peach, mandarin, kumquat, orange, tangerine, grape, etc. Caña) applies to beverages prepared from the maceration of these fruits in rectified alcohol.

The name *"Burned Caña"* means a liqueur sweetened with sugars or honey in a proportion of more than 10 per cent (by weight/volume) and flavored with authorized essences and/or, distilled or undistilled, infusions or maceration of oranges or other fruits.

6. *"Cassis":* a liqueur prepared with the juice and/or maceration of red currents and raspberries.

7. *"Curaçao":* a liqueur prepared from an alcoholic infusion or maceration of bitter and sweet orange peel, to which permitted aromatics (tangerine, mace, cinnamon, lemon, etc.) may be added and which may be distilled in whole or in part. Strongly flavored "Curaçao" may be named *"Triple Sec"* or *"Extra Dry."*

8. *"Geneva"**: an alcoholic beverage obtained through the mixing of *"Geneva Concentrate"* (Article 503, point 4) with neutral spirits of a suitable alcoholic content. The addition of sugar in amounts not exceeding 2 grams per cent is permitted. Its alcoholic content shall not be lower than 35 per cent.

9. *"Gin":* a beverage obtained through the alcoholic maceration of juniper berries followed by distillation. The addition of other aromatics is permissible. The designation *"Sweet Gin"* ("Old Tom Gin") may be used for gin containing 10-15 grams of sugars per liter, and the name *"Dry Gin"* for gin containing a smaller amount of sugars. These products may not be named *"Geneva," "Dry Geneva"* or *"Sweet Geneva."*

The name *"Sloe Gin"* designates a gin prepared from a maceration of sloe berries, and the name *"Lemon Gin"* a gin prepared from a base of lemon peel or natural lemon essence.

10. *"Cacao Liqueur":* a liqueur prepared from an alcoholic, distilled or undistilled, maceration of de-fatted cacao, to which vanilla and other aromatics have been added.

11. The names *"Cocktail," "Coctél," "Grog"* and *"Punch"* mean mixtures of different alcoholic beverages, to which juices, fruit chunks and syrup may be added. They are usually sold in finished form or are mixed immediately before serving. Cocktails are usually served

* Note of the translator: A Dutch gin, at times referred to as "Schnapps" or "Hollands Gin."

ice-cold or with ice, whereas grogs and punches are prepared with hot water or tea.

12. *"Cherry Brandy":* a liqueur prepared mainly from a maceration or the juice of cherries or agriots and permitted aromatics.

13. *"Coffee Liqueur":* a liqueur prepared from a, distilled or undistilled, coffee tincture to which vanilla and other aromatics have been added.

14. *"Caraway Liqueur"* or *"Kümmel":* a liqueur obtained from an alcoholic maceration of caraway seeds, aniseed, cumin seeds and other aromatics, which may be followed by distillation. The name *"Allash"* distinguishes a "Kümmel" of superior quality, flavored with orris, angelica root, etc.

15. *"Gold Liqueur":* a liqueur prepared from an alcoholic maceration of angelica root, cinnamon, mace, coriander, caraway seeds, cloves, figs, rose water and other aromatics, to which a few gold leaves were added during the bottling process.

16. *Fruit Liqueurs* (banana, plum, peach, orange, tangerine, grape, etc. liqueurs) must be prepared from disintegrated fruits, alcoholic solutions, tinctures or the, distilled or undistilled, alcoholic maceration of the fruit named. The addition of essences with a flavor similar to that of the starter fruit is prohibited.

17. *"Pennyroyal Liqueur"* ("Pulioll"): a liqueur prepared from a distilled or undistilled, alcoholic maceration of pennyroyal (Lippia turbinata, GRISEB), to which other aromatics may be added and which may be colored with chlorophyll or other authorized substances.

18. *"Maraschino"* or *"Marraschino":* a liqueur prepared with cherry or agriot brandy or with a, distilled or undistilled, alcoholic maceration of cherries or agriots, to which other aromatics may be added.

19. *"Mint"* or *"Peppermint Liqueur":* a liqueur prepared with natural peppermint essence and rectified alcohol, or with a distilled or undistilled, alcoholic maceration of mint leaves, which may be colored with chlorophyll or another authorized substance and to which other aromatics may be added.

20. *"Peperine Liqueur":* a liqueur prepared with an alcoholic maceration of peperina (Bystropogon mollis, KOTH)* to which

* Note of the translator: Peperina, or Bystropogon mollis, KOTH, is a mint variety found in Argentina.

other aromatics may be added and which may be colored with chlorophyll or another authorized substance.

21. *"Prunelle":* a liqueur prepared from a maceration of plums in neutral spirits, cognac, or another natural brandy, to which aromatics may be added.

22. *"Vespetro":* a liqueur prepared with alcoholic macerations of angelica root, coriander, aniseed, fennel, badian and other authorized aromatics.

23. *"Vodka"* or *"Wodka"*: an alcoholic beverage obtained from a cereal or tubercle brandy, or from diluted neutral spirits which may, but need not be, flavored and aged.

24. *"Whisky"* or *"Whiskey"*: an alcoholic beverage made from a grain brandy derived from a mash sweetened with malt, stored for not less than two years in barrels of oak or another suitable wood as provided for in Article 511 of this Code. Whiskies may be blended with neutral grain spirits which have been aged for not less than two years.

The alcoholic content of whiskey shall not be lower than 42 per cent; its dry residue, free from sugar, shall not exceed 0.25 grams per cent; its acidity limit shall be equivalent to 1 ml. of normal alkali per 100 milliliters and in the finished product the total volatile impurity content shall not be less than 0.6 grams per liter. It may be colored with caramel and sweetened with sugars in an amount of up to 0.5 grams per cent.

"Blended Whiskey" is a mixture of several whiskies.

"Straight Whiskey" is whiskey not blended with other whiskies.

The various types of whiskey must meet the following characteristics:

a. *"Scotch Type Whiskey"* is made from a Malt Brandy (Pure Malt Whiskey) which may be mixed with a Grain Brandy (Grain Whiskey) derived from a mash sweetened with malt. It may be blended with neutral grain spirits aged in barrels of oak or another suitable wood for not less than two years. The name "Pure Malt Whiskey" may also be given to the *"Malt Brandy"* defined in Article 503, point 8 hereof, when the product has been aged for not less than two years.

Grain Whiskey may be distilled to 95° C.

b. *"Irish Type Whiskey"* is made from a grain brandy derived from a mash sweetened with malt. It does not have the peat flavor characteristic of Scotch Whiskey.

c. *"Bourbon Type Whiskey"* (American Whiskey) is made from a grain brandy derived from a mash containing corn and sweetened with malt. It is aged in charred containers. A dry residue of not more than 0.5 grams per cent is permitted.

d. *"Rye Whiskey"* is made from a grain brandy derived from a mash that contains rye grain and is sweetened with barley and/or rye malt. *Canadian Type Whiskies* belong to this type of whiskey. The total volatile impurity content of Rye Whiskey shall not be less than 0.3 grams per liter of finished product.

On *Bourbon* and *Rye Whiskey* the percentage of the blends must be shown on the label.

25. *"Agriot Liqueur"*: a liqueur prepared with agriot juice or derived from the maceration of agriots in rectified alcohol, sweetened with sucrose, glucose or honey and diluted with water in a proportion of not less than 24 per cent.

Article 508—In the labeling of domestic products which, because of their organoleptic characteristics, are equivalent to products originating in other countries, mention may be made of this fact on the label by placing the word "type" before* the geographic appellation, in a type of letter not larger than the type used for the name of the product. For instance: "Scotch, American or Irish type" Whiskey, "Hollands type" Gin, "French type" Cognac, etc.

Article 509—Any alcoholic beverage not specifically mentioned in this Code and sold with a foreign indication of origin must be equivalent to the original product with regard to raw materials, special manufacturing technique and particular characteristics. Beverages sold as imported from abroad must be accompanied by analysis certificates from the country of origin proving their provenance.

Article 510—The labeling and advertising of spirituous beverages (distilled spirits and liqueurs) are prohibited from containing references to properties or names which may mislead the consumer by causing him to believe that the product has therapeutic properties or qualities, such as: "curative," "tonic," "stomachic" or "digestive." When terms referring to such properties are used, the beverages so designated shall be considered "pharmaceutical specialties"and as such shall require the approval of the competent health authority.

* Note of the translator: In the English, it would read "after."

The consumption of spirituous beverages is prohibited from being recommended in radio, oral, or written advertising on the ground that they provide stimulation, well-being, or good health or have other therapeutic, hygienic or sanitary properties.

Article 511—The time of aging of alcoholic beverages may be mentioned in labeling and advertising only if the aging took place under official control. The storage time is the period during which a beverage has been stored at an appropriate location in suitable wooden containers of a capacity of not more than 1,000 liters. If the beverage was aged in larger containers, the aging is not permitted to be mentioned.

The adjectives "Aged," "Old," or similar terms may be used only on beverages which have been stored or matured for not less than three years, and the adjectives "Extra old," "Extra aged," and similar terms only on beverages more than five years old. The age of blended beverages shall be taken to be the age of the component stored for the shortest time.

Article 512—In the preparation of spirituous beverages (distilled alcoholic beverages and liqueurs), the use of harmless clarifiers shall be permitted. Racking, blending of brandies of the same type, carbon treatment, filtration and washing (alcoholic content) and, under certain conditions, the application of cold or heat to beverages requiring such treatment, shall likewise be permitted. Artificial aging processes may be used only if authorized by the health authority, with the proviso that such aging is not permitted to be mentioned in labeling and advertising the products thus treated.

Article 513—The manufacture, holding and sale of *Absinthe* (an alcoholic beverage prepared from a base of wormwood, peppermint, and fennel) and of *similar beverages* containing or imitating absinthe are prohibited.

This prohibition applies also to beverages whose names resemble the word "absinthe" or similar words in the national or a foreign language, or whose labels, announcements or other advertising matter contain a direct or indirect reference to absinthe, the principles of absinthe, or derivated principles.

The classification *"absinthe-like"* shall apply to alcoholic beverages whose predominant odor and flavor are those of anise and which, when four volumes of distilled water are added to them slowly drop

by drop at 15° C., turn cloudy, which cloudiness does not disappear completely upon the addition at the same temperature of another three volumes of distilled water. It shall apply also to beverages containing an essence with a ketonic effect even if the same do not turn cloudy when subjected to the aforesaid test.

The classification "absinthe-like" shall not apply to alcoholic beverages containing aniseed (anise brandy, anise liqueur, anisette) even when the cloud test is positive, provided that they are colorless or that their only color is that of the brandies or aromatics used; that they do not contain essences with a ketonic effect; and that they do not violate the provisions contained in the second paragraph of this article. Nor shall this classification apply to apéritifs which contain a small amount of Artemisia Absinthium, L. among the vegetable substances used in the infusion or maceration from which the apéritif is prepared.

Article 514—The name "Apéritif" (Fernet, Bitters) applies also to spirituous beverages (see Article 484, 3/e*) containing certain bitter principles which are considered appetizers. They may be derived from the distillation or infusion, maceration or digestion of plants, or parts of plants, in rectified alcohol: bitter oranges, ginger, gentian, quinine, chicory, angostura, absinthe, holy thistle, sweet flag, common erythraea, calumba, quassia, juniper, hops, to which natural essences, sugars, or other authorized substances may be added. Their total dry residue shall not be less than 10 grams per liter.

The name *"Orange Bitters"* designates the bitters prepared from sweet and/or bitter oranges and other authorized aromatics.

The name *"Angostura Bitters"* designates the bitters prepared with angostura bark (*Galipea cusparia,* SAINT HILAIRE) and other authorized aromatics.

Article 515—The preparation, holding, circulation and sale of spirituous beverages which are synthetic imitations of the beverages listed herein or have been prepared in a manner different from the one described in this Code is prohibited.

Article 516—Spirituous beverages (brandies and liqueurs) shall be considered unfit for consumption if they contain:

* Note of the translator: This provision, included in Chapter XIII: "Fermented Beverages," covers apéritif wines.

Free acidity, expressed as acetic acid, of more than 1.5 grams per liter;

Methyl alcohol, higher alcohols, acids and *aldehydes* in amounts exceeding the proportions authorized by Article 499 hereof;

Isopropyl alcohol, benzol, homologous hydrocarbons, pyridine or any other substances officially used as alcohol denaturizers;

Mineral or *organic acids* extraneous to the usual composition of the beverage;

Hydrocyanic acid in amounts exceeding 50 milligrams per liter;

Essences or extracts or *aromatic mixtures* containing toxic constituents which have been prohibited specifically;

Artificial sweeteners;

Coloring matters the use of which is *prohibited;*

Unauthorized preservatives;

Irritating, purgative or *drastic bitters, the use of which has not been authorized or has been forbidden specifically.* Of the authorized substances, black pepper, pimento, mustard, rhubarb, aloe, senna and white agaric may not be used in amounts exceeding 2 grams per liter; if a beverage contains more than one of these drugs,* their aggregate may not exceed 4 grams per liter. [The End]

FOOD PROTECTION—SANITATION

Insanitary storage of foods resulted in a total fine of $2,000 in one case, $200 in another and suspended sentences with one year's probation in two other criminal prosecutions terminated in August.

Candy containing rodent hairs and insects and manufactured under insanitary conditions resulted in a fine of $300 for the manufacturer. Seizures of corn, corn husks, popcorn, oregano, and dried beans were made during August because of insanitary storage conditions in the warehouses and wholesale grocers inspected. Eight carloads of last year's wheat moving out to make room for the new crop was seized because of contamination by rats and mice during storage. About 35,000 pounds of insect-infested barley were seized at a brewery. Over 110,000 pounds of green coffee and 15,000 pounds of flour were seized because of insect infestation.

Other seizures in the "hygienic" category: butter made from filthy cream, Romano cheese containing maggots, decomposed frozen eggs, decomposed fish fillets, ocean perch infested by parasitic worms, blueberries infested with maggots, decomposed canned green beans and hot peppers contaminated with fly eggs, flies, and maggots.

* Note of the translator: "Substances" would seem more correct.

FDA Looks at Food Labeling and Packaging

By SHELBEY T. GREY

The Director of the Bureau of Program Planning and Appraisal, Food and Drug Administration Presented This Paper on June 4, 1963, at the Annual Convention of the Food Industries Buyers Group of the National Association of Purchasing Agents in Atlantic City, New Jersey.

THERE ARE TODAY an estimated $117 billion worth of foods, drugs, cosmetics and other articles subject to the requirements of the laws enforced by the Food and Drug Administration. We have a budget of $28,658,000 and 3,232 people to do our work. Your chairman has asked me to discuss with you the labeling and packaging requirements of the law applicable to foods.

The basic purpose of the law is to assure American consumers that their foods are clean, wholesome and safe—as well as properly packaged and labeled. In the complex and progressive technology of today's economy, these requirements, in their broadest application, are not always simple.

Deception of man is one of the oldest arts. The British Parliament in 1770 passed an ordinance reading:

> All women of whatever age, rank, profession, or degree, whether virgins, maids, or widows; that shall impose upon, seduce, and betray into matrimony any of his Majesty's subjects by scents, paints, cosmetics, washes, artificial teeth, false hair, Spanish wool, iron staves, hoops, high-heeled shoes, bolstered hips or padded bosoms shall incur the penalty of the law enforced against witchcraft and the like misdemeanors and that marriage, upon conviction, shall stand null and void.

There may be some who believe that a similar law should be in effect in these United States! This type of deception, however, is not subject to any of the requirements of the laws that we enforce. Insofar as the law itself is concerned the shipment, or the introduction for shipment, into interstate commerce of any misbranded food is prohibited. There are a number of defined misbrandings and I won't have the time today to list them all or discuss them with you. I recommend for your reading the Federal Food, Drug and Cosmetic Act, and the Regulations promulgated thereunder, for the details.

Some of the common types of labeling violations are false and misleading labeling, as well as failure of the labeling to bear or contain the information required by law. For instance, I am sure you all know that the label is required to show the name and place of business of the manufacturer, packer, or distributor; an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; and, unless it is a standardized food, the common or usual name of the food and, in case it contains two or more ingredients, the common or usual name of each ingredient. There are some instances in which all of this information could appear on the label and the food still be misbranded because any word, statement, or other information required to appear on the label must be prominently placed thereon, with such conspicuousness, as compared with other words, statements, designs, or devices, in the labeling and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

It is obvious that if a food purports to be or is represented as one for which a definition and standard of identity has been prescribed that it is misbranded unless it conforms to that definition and standard. The law requires, too, that if the product purports to be or is represented for special dietary uses that the label contain information concerning its vitamin, mineral and other dietary properties as necessary to fully inform purchasers of its value for such special uses.

Misleading Packaging

Now I'm going to talk more about labeling, but I want to mention at this point the other requirement of the law involving my subject of today's discussion. The law states that a food shall be misbranded if its container is so made, formed, or filled as to be misleading. The history of our enforcement program involving this requirement of the law is almost that of frustration. The reason is that we haven't won a single contested court case where this was the sole basis for the charge of violation. This doesn't mean, however, that there is no validity to this requirement of the law. Insofar as consumer complaints are concerned, I believe we receive about as many that the way the food container was made, formed, or filled either deceived or misled the purchaser, as any other category.

The dictionary defines the word "deceive" as "to beguile . . . to use or practice deceit . . . to delude . . . ." I suggest that you carefully determine whether the foods you purchase are capable of

causing deception. To do this I suggest further that you assume the role of a purchaser as you make this determination.

We believe that the consumer has a right to expect that a nontransparent container of food is reasonably full; that the size of the container is a reliable index of the amount of food in the package; and that the package must not be filled with excessive padding. The principle of the use of "excessive padding" is, as you will recall, stated in the old 1770 British Parliament ordinance, though perhaps by different application!

Now, for a moment, let's discuss labeling in more detail. I would like to outline for you some of the things that can cause trouble.

President Kennedy's Message

President Kennedy said last year in his Special Consumer Protection Message:

> Consumer choice is influenced by mass advertising utilizing highly developed arts or persuasion. The consumer typically cannot know whether . . . the performance of a product will in fact meet his needs; or whether the "large economy size" is really a bargain. . . .
>
> In our modern society, good packaging meets many consumer needs, among them convenience, freshness, safety, and attractive appearance. But often in recent years these benefits have been accompanied by practices which frustrate the consumer's efforts to get the best value for his dollar. . . .

We believe that most American consumers have learned that they can today rely on the wholesomeness and purity of most of our foods. The fact though that this isn't necessarily true insofar as labeling and packaging are concerned is evidenced by the fact that last year we seized 219 shipments of food due to short weight or improper declaration of net contents; 75 because of inconspicuous labeling, and six because of incomplete labeling. We prosecuted five firms for short-weight practices and enjoined two from continuing the same violation. The food industries involved in these actions are, in descending order of numbers—(1) baking, (2) confectionery, (3) coffee, tea and beverages, (4) fruit products, (5) vegetable products, (6) nuts, (7) grains and flour, and (8) dairy products.

Weight Requirements

You will note that the majority of these violations involved short weight, and you will recall my earlier statement of the legal requirement. We believe that the statement of the quantity of contents of packaged food should reveal the quantity of food in the package exclu-

sive of wrappers and other material packed with the food. The law requires that the statement shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure which are generally used by consumers to express the quantity of food and which give accurate information as to the quantity in the package. We have interpreted the law that in those instances where no general consumer usage in expressing accurate information as to quantity of the 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, semi-solid, viscous, or a mixture of solid and liquid, except that the statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

Insofar as the nomenclature I have used is concerned, a statement of weight must be in terms of the avoirdupois pound and ounce. A statement of liquid measure must be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions, except in the case of frozen food which is so consumed which shall express the volume at 68° Fahrenheit or 20° Centigrade.

A statement of dry measure must be in terms of the United States bushel of 2,150.42 cubic inches and peck, dry quart and dry pint subdivisions or in terms of United States standard barrel and its subdivisions. Statements of this type are meant to inform the purchaser of the net contents of the packaged food and shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

Tolerances As Applied to Legal Weight and Volume Requirements

Your chairman suggested that I discuss tolerances as applied to legal weight and volume requirements. This is a complex area for discussion but I will give you our thinking since that is one of the reasons I'm here today. We believe that the net weight statement should express the minimum quantity or the average quantity of the contents of the food packages. If the statement on the package is not so qualified as to show definitely that the quantity expressed is the minimum quantity the statement is considered to express the average quantity.

Where the statement expresses the minimum quantity, no variation below the stated minimum is permitted except variations below the stated weight or measure 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. We believe that variations above the stated minimum should not be unreasonably large.

Where the statement does not express the minimum quantity, variations from the stated weight or measure are permitted when caused by ordinary and customary exposure under the conditions just expressed. Variations are also permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packaging practices. Under these circumstances, however, variations are not permitted to such an extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated and no unreasonable shortage in any package is permitted even though overages in other packages in the same shipment or delivery compensate for such shortage.

The extent of allowable variations from the stated quantity of the contents is determined by the facts in each case. In other words, there are no specific tolerances that can be expressed in terms of percentages or amounts. I might say here that we are greatly influenced by good commercial practice.

I am sure most of you are familiar with the fact that a number of bills are now pending in Congress dealing with truth in packaging and labeling. I do not believe this is the proper forum for my discussion of the merits or pros and cons of these pending bills. We do feel, however, that new legislation should be considered only where there is a real and compelling need. In our judgment the investigations made by the various Congressional Committees, the experience of the Food and Drug Administration, and the great number of complaints we receive from consumers about labeling and packaging abuses amply demonstrate the need in this case.

Testimony on "Truth in Packaging" Bill

Wilbur J. Cohen, Assistant Secretary for Legislation of the Department, stated on March 21 in testifying on the "Truth in Packaging" bill before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary of the United States Senate:

. . . Mr. Chairman, I endorse your statement, "This bill is not intended as a cure-all to market place confusion, but it establishes an approach and a means

for dealing with the misleading and unfair trade practices affecting the 8,000 items now on an average supermarket shelf. And it has been estimated that in the next decade there will be 20,000 such items from which the consumer must make a choice . . . . It is a reasonable attempt to solve problems that can and should be solved."

Commissioner Larrick in testifying before this same Subcommittee said:

We believe that the "Truth in Packaging" bill represents a better approach in bringing about improvement in the packaging of consumer commodities than a program of enforcement on an individual commodity or case-by-case basis under the present law.

The Commissioner stated further:

The bill would give clear statutory authority to promulgate industry-wide rules and guidelines for the industries to follow. Consumers, industry, and interested Government agencies would participate in this rulemaking. These guidelines would permit the enforcement agencies to concentrate their regulatory activities against those who disregard the rules that have been developed for the industry as a whole. Thus it should decrease litigation and encourage self-regulation and voluntary compliance.

Your chairman requested that I also discuss labeling requirements with respect to deceptive copy, "cents off" promotions, and other such practices. Basically, the requirement of the law involving practices of this type is that they must not be false or misleading in any particular. If a food is alleged to be misbranded because the labeling is misleading then in determining this fact we take into account, among other things, not only representations made or suggested by statements, words, designs, devices, or any combination of these, but also the extent to which the labeling fails to reveal facts material in the light of such representations 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 or under such conditions of use as are customary or usual.

Health-Conscious Consumers

Today many American consumers are more than ever before health conscious, diet or weight conscious, vitamin conscious, mineral conscious, fat conscious, protein conscious, *ad infinitum*, but they have not developed sufficient knowledge to cope with or understand these new "consciousnesses." Consumers today, in making their food purchases, are confronted with all types of "come on" schemes offering special inducements and implied values. Mrs. Housewife is generally familiar with the words vitamins, minerals, proteins, unsaturates,

and so forth, but we doubt if the average consumer really understands what these mean insofar as value as ingredients in food are concerned. We do know that in many instances the consumer feels much happier if he sees several of these ingredients listed on the label of the food he buys, although he may not know why. We know, too, that consumers are constantly being pressured into believing that they must improve their diet with food supplements if they are to enjoy good health.

We now are getting close to the quackery stage of food sales promotion and we find the practices of some promoters are to spread false ideas and half-truths and to undermine consumers' confidence in the nutritional value of staple foods. There is an attempt being made to convince people that all diseases are due to faulty diets, that our basic food supply is nutritionally inferior because our soils have become impoverished through long use and because chemicals necessary in the production of an adequate and nutritious food supply have poisoned the land. All of these claims are false and have been scientifically and legally debunked. Americans today, however, continue to pay hundreds of millions of dollars annually for vitamin pills, food supplements, special formula foods, and other special type foods for what they want to believe will result in better health. You will probably be surprised to know that reputable members of the food industry are making significant contributions to the national problem of nutritional misinformation. I can cite you cases in which the "quacks" attempted in actions we brought to justify their claims by reference to similar claims made by food firms.

The following false conceptions usually mark the food quack:

(1) Disease and poor health are due to faulty diet.

(2) Our basic foods are inferior and must be enriched or fortified.

(3) The nutritive value of processed foods has been destroyed.

(4) Most American consumers suffer from subclinical deficiencies.

(5) To reduce or gain weight, special or unusual foods are necessary.

Need I call to your attention that the advertising and promotional approach used by some of our food manufacturers follows these same techniques? If you don't believe me, what do you think about statements that you can find on many food packages in the supermarkets in this town and in food advertising like "body building," "bone

strengthening," "energy producing," "now enriched" or "now fortified," "provides health," "high nutrition," "less calories per bowlful," "significantly greater in vitamins and minerals," "12 less calories per pat," and "30 per cent more protein per spoonful." These are not all of such phrases that I could list for you but I am sure from them you get my point. Advertising agencies and some food manufacturers and distributors tell us that such claims as these are just "trade puffery." We do not agree because we believe they are definitely false and misleading!

Let me list for you a few examples of some of the other types of foods against which we have taken action because of failure to comply with the labeling requirements of the law.

(1) Fruit cake which had omitted rum and brandy flavors and contained undeclared artificial flavoring and coloring.

(2) Apricot and strawberry bars which had substituted figs and dates in part for other fruit.

(3) Orange juice containing vast quantities of added sugar and water.

(4) Inferior grade Chinook salmon labeled as "pink salmon."

(5) Egg noodles deficient in egg solids.

(6) Standardized food violations, such as canned green beans containing excessive strings, canned mushrooms below the prescribed fill of container, butter containing less than the required 80 per cent butterfat, and so for.

(7) Domestic cheese falsely labeled as imported Romano cheese.

(8) Swiss cheese with artificial "eyes."

Conclusion

We have also taken action against foods for being short weight, inconspicuously labeled, lacking mandatory labeling information, and so forth. What causes violations like these in the labeling and packaging field? Our experience indicates that they, for the most part, are due to carelessness, inadequate manufacturing controls, overhasty marketing, and excessive promotion. Let me make it plain, however, that not all food manufacturers engage in these practices. The attitude of responsibility on the part of industry is deserving of our highest compliments. I am sure that we are not aware of everything

that industry does to police its own practices and to improve its products and procedures. Our inspectors, however, reported a total of 260 plant improvements last year to prevent future violations of the law at a cost of $9,658,463, up from $8,986,000 the year before. We encourage and promote voluntary compliance. It is significant to note, however, that the development of a philosophy of responsible self-regulation parallels almost exactly the development of a strong and effective law. Our experience indicates that voluntary regulation needs the support of law to make it effective so that the minority violators do not take unfair advantage of the vast majority of companies that are fair, honest and conscientious.

Over the years and through the teamwork of responsible food manufacturers, vigorous enforcement of the law, and a growing consumer knowledge and interest we have today in the United States a supply of foods that is, in the main, safe and reliable. While we have reached this concept of safety and it is firmly embedded both in the law and in the philosophy of consumers, we have not yet fully developed the concept of truth in the packaging, labeling, and distribution of food. With regard to the health and safety of the consumer the old doctrine of "buyer beware" has been, for the most part, replaced with the doctrine of "seller beware," yet in sales promotion and merchandising, the "buyer beware" doctrine still prevails to a substantial degree.

Now, what are we going to do about this? I believe that you will agree with me when I say that it is a problem and if it stands any chance of successful resolvement will require the combined resources and abilities of us all. The responsibility lies first with industry but you as buyers have an important role to play. The Food and Drug Administration is stepping up its program to protect consumers with regard to mislabeled and illegally packaged foods. I can't tell you exactly how many man-years we are putting into this program or how many more man-years we will put into it next year. The reason is that the requirements of the law with regard to labeling and packaging are given consideration in every food inspection we make, in every sample of food we collect and examine, and I can assure you that we are going to unrelentingly invoke the legal remedies provided by the statute to control violative actions by that small proportion of the industry which through negligence, ignorance, or deliberation ignore the requirements of the law to the detriment both of the consumer and the ethical manufacturer. **[The End]**

The Responsibility We Share

By GEORGE P. LARRICK

Mr. Larrick, the Commissioner of Food and Drugs, Presented This Paper at the University of Tennessee Medical Units Commencement Exercises in Memphis, Tennessee on June 9, 1963.

IT IS INDEED A PLEASURE to be with you today on an occasion that is so significant to you who are graduating and to your parents and friends. Your graduation is equally significant to this great State of Tennessee and to the nation which sorely needs your talents for safeguarding the public health.

In the early days of our country we had but few physicians, dentists, pharmacists and nurses. There were no pharmaceutical manufacturers. The physician carried the drugs he used in his bag, and he frequently compounded the patient's medication right at the bedside. Very few of the agents then available to him could be relied upon for a specific or even a predictable effect. We now know, in fact, that many had no therapeutic effect. Some, such as aconite, were not only useless by present standards, but also were toxic.

The pharmacist did his own manufacturing. Occasionally, he gathered botanicals for use in preparation of the extensively used fluid extracts and tinctures. And he rolled out the pills—two at a time. Standardization of potency was empirical.

Some of the more progressive physicians and pharmacists saw the need for central manufacturing facilities which could do a better job of drug manufacturing than the individual pharmacist. They started establishments which have grown to the great pharmaceutical industry of today.

Revolution in Theory and Practice of Drug Therapy

A discovery in 1909 started a revolutionary change in the theory and practice of drug therapy. Paul Ehrlich discovered Salvarsan and the age of chemotherapy was ushered in. The few synthetic drugs employed before then were useful and alleviated the discomfort of the patient, but did not attack the cause of his disease.

You are familiar with the spectacular developments that followed. Insulin came in the 20's, sulfonamides in the 30's, and antibiotics in the 40's. The decade immediately past, 1950-1960, was a period of rapid progress in many areas. Industrial productivity increased, the economy expanded, science and technology flowered, and the material wants of the American people were met to a greater extent than in any prior decade.

In that brief period, science and technology importantly transformed man's concept of the universe, of his place in it, and of his own physiological and psychological systems. Man's mastery over nature was most significantly extended, including his capacity to cope with diseases and other threats to human life and health.

In the fields of medicine and dentistry, the nation developed in the past 20 years an entirely new and more efficient battery of instruments, drugs and techniques. National expenditures for health and medical services have more than tripled in terms of constant dollars. It is commonplace now to have drugs, such as the steroids and the anti-tuberculosis agents, tailored specifically to meet a particular need. But the end is not in sight.

The present decade, 1960-1970, will see even greater expansions of medical, dental, and pharmaceutical research. It will see the application of new, more efficient techniques to deal with chronic as well as infectious processes. It is especially important for all of us concerned with health, to recognize certain factors upon which continuing progress depends.

Medical Profession and FDA Dependent on Each Other

As newer medical products, devices and techniques come into being, we must be able to utilize them with confidence—confidence that they have been properly manufactured, that they have been properly tested, and that they have been truthfully promoted. The patient must have confidence also, not only that his doctor, dentist, pharmacist, and nurse are well-trained, competent individuals, but also that the tools and drugs which they use are safe. It is here that the medical professions and the Food and Drug Administration have their closest relationship. We are dependent upon each other.

You depend upon the Food and Drug Administration through its administration of the national pure food and drug laws to see that the products you use are suitable. Under present law, we can

offer you this assurance with respect to drugs. They must be proved safe and effective before they are shipped from one state to another. We are attempting to get the law strengthened so that we can offer the same assurance with respect to therapeutic devices, ranging all the way from the most complex instruments that you will employ to plastic materials for surgical repair as well as to simple instruments that may be used by the layman in the home.

You also rely upon the Food and Drug Act to insure truthful labeling of these products. Medical quackery has undergone dramatic changes in the past generation. We are confronted today to a decreasing extent with the kind of quackery that used to be peddled from the back of a covered wagon. We are confronted with sophisticated types of misrepresentation which involve subtle, apparently scientific presentations designed to mislead informed consumers as well as members of the medical professions. To the extent possible, the Food and Drug Administration attempts to deal with these problems. But to cope with them successfully, we need continued strong support from the medical professions. Your advice to us about extravagant promotions and about ineffective products will make it possible for us to serve you and the general public more effectively.

When Congress enacted the Kefauver-Harris Drug Amendments to the Federal Food, Drug and Cosmetic Act last October, it placed us in a position to be of greater service to you. These amendments, which were so ably sponsored by the distinguished senior Senator from this state, Estes Kefauver, and by Congressman Oren Harris from across the river in Arkansas, represent the most comprehensive modernization of the national drug laws in a generation. The amendments will without doubt be a model for drug legislation in much of the world.

Objectives Advance by Legislation

Two great and fundamental objectives are advanced by this legislation. First, it is designed to insure the quality and reliability of the drugs you will prescribe or administer. Second, it is designed to improve the communication of necessary information concerning these drugs, their side effects and contraindications, as well as their advantages. Specifically, these two related objectives are advanced by provisions which require:

(1) New drugs to be proved effective before marketing;

(2) All drugs to be manufactured under adequate control;

(3) Government certification of the safety and effectiveness of all antibiotics for human use;

(4) Prompt reporting by manufacturers to the government of adverse reactions attributed to their new drugs and antibiotics; and

(5) Truthful statements in prescription drug advertisements concerning the effectiveness, side effects and contraindications of the advertised drugs.

Further, the new law authorizes the Food and Drug Administration:

(1) To establish official names for drugs in the interest of usefulness and simplicity;

(2) To withdraw approvals of new drugs when substantial doubt arises as to their safety and effectiveness;

(3) To assist the Patent Office, upon request, on technical matters in patent applications for drugs; and

(4) To exercise greater controls over shipment of investigational drugs for testing in man.

In addition to other far-reaching benefits, each of these improvements offers substantial opportunity for mutually beneficial cooperation between the health professions and the Food and Drug Administration. The improved controls over investigational drugs deserve particular mention because of their immediate and far-reaching benefits.

Requirements for a Drug Promoter

Formerly, relatively loose controls were exercised over drugs for testing on man. Thus, some promoters of such drugs could and did stimulate so-called research that was neither well conceived nor controlled. A few firms even promoted commercial use of drugs not yet cleared for safety. The new law and regulations under it now require that before a drug promoter may sponsor a clinical investigation of a new drug, he must be sure tests on man are justified. Among other things, he does this by:

(1) Determining that adequate preclinical tests have been made on animals and in the test tube;

(2) Developing an adequate plan of investigation;

(3) Securing competent investigators to test the product; and

(4) Making a proper report to the government before the drug is administered to humans.

If the reports do not justify use of the new material on man, we may require appropriate improvements or in extreme cases require discontinuance of the tests.

These controls are a desirable safeguard for patients. They also offer protection to those engaged in medical research by assuring them that adequate studies have been made as a prelude to clinical investigation of new drugs. As a result, it may reasonably be predicted that we will have better and more effective drug research in this country.

As you well know, the most careful pre-market testing cannot be expected to reveal as much about a drug as does widespread use of the product in general practice.

Sometimes previously unknown beneficial effects are discovered in general use. Quite often adverse effects or contraindications show up only when a new product reaches wide distribution through the general practitioner. It is to permit early detection of undesirable effects, and their early correction that the Kefauver-Harris Drug Amendments now require manufacturers to advise the government promptly of adverse drug reactions which come to their attention. But manufacturers may not receive reports of very significant observations on a new drug. You doctors, dentists, pharmacists and nurses can render both public service and service to your professions by taking the time to report significant adverse effects or unusual effects of drugs and devices to your professional associations and to the Food and Drug Administration. Your reports will be investigated promptly so that necessary corrections can be effected.

Communication Improvements

As our contribution to better communication, we are developing a system that will increase the flow of information from the Food and Drug Administration to the medical professions. This will be accomplished through your professional journals, through releases which we issue, and upon occasion through letters mailed directly to medical scientists. We expect in the future to advise you more fully than we have in the past of significant developments in our area.

Truly, we share great responsibility on the medical front which changes so rapidly and dramatically today. We pledge to you and

other members of our great health professions the full support of the Food and Drug Administration. And we solicit your advice and support in our efforts to assure the integrity of the drugs and devices you use.

We salute each of you as you enter your professions and carry forward to new horizons their great traditions of service to mankind.

[The End]

STANDARDS SET FOR VANILLA PRODUCTS

Standards setting the amount of vanilla beans in vanilla extract and certain other vanilla products were published on September 14, to become effective in 90 days. The standards were originally scheduled to go into effect October, 1962, but were held up to permit consideration of views and comments presented by the industry.

The purposes of the standards are: to assure the consumer that he gets what he expects when purchasing vanilla products; to put all manufacturers on an equitable basis; and to provide a sound basis on which to proceed against products in which spurious ingredients have been substituted for vanilla beans. Standardized products include:

(1) Vanilla extract and concentrated vanilla extract.

(2) Vanilla flavoring and concentrated vanilla flavoring. ("Extracts" differ from "flavorings" in that extracts contain 35 per cent or more alcohol, and flavorings contain less than that amount, under the standards.)

(3) Vanilla powder (in some cases called vanilla sugar).

(4) Counterparts of these products containing, in addition to vanilla bean extractives, limited amounts of vanillin, an artificial flavor. The amount of flavor contributed by the vanillin must be less than half of the over-all vanilla flavor in the counterpart products.

The new standards prescribe the required content of vanilla beans in terms of a "unit of vanilla constituent." This unit is specified to mean the flavoring equivalent of 13.35 ounces of vanilla beans containing not more than 25 per cent moisture. If beans containing more than 25 per cent moisture are used, the amount used must be increased accordingly. Vanilla extract is required by the standard to have not less than one unit of vanilla constituent per gallon.

At industry's suggestion, FDA made the following modifications:

(1) In the definition of the term "unit of vanilla constituent," an upper limit for the proportion of alcohol in the aqueous alcohol solvent was omitted.

(2) Definitions of concentrated vanilla extract and concentrated vanilla flavoring were revised to make it clear that extracts and flavorings containing two or more units of vanilla constituent and made by using a larger amount of beans per gallon of solvent without evaporation of solvent are not required to be labeled "concentrated." Products so made are simply "vanilla extract" and "vanilla flavoring."

(3) The definition of vanilla powder was revised to make it clear that this product may be made not only from ground vanilla beans or from vanilla oleoresin, but if the manufacturer wishes he may use "both."

A State Drug Control Program

By H. C. McALLISTER

The Following is a Condensation of a Paper Presented at the Fifteenth Annual Conference of the Southern Association of Food and Drug Officials in New Orleans, Louisiana on April 2, 1963. Mr. McAllister Is Secretary-Treasurer of the North Carolina Board of Pharmacy.

WE IN AMERICA PRIDE OURSELVES on our democratic processes. This has indeed been our heritage and the source of much of our strength. Yet democracy, too, has many disadvantages. We in the South have a particularly strong sentiment as to where the authority for the regulation of internal matters should rest. This philosophy has continued to be challenged during the past century—quite strenuously in recent times. This conflict between the federal government and its member states has created many problems in all areas of social interest, including the health services and the materials used in connection therewith.

Speaking before the National Drug Trade Conference in New York in January of this year, John T. Kelly, legislative counsel for the Pharmaceutical Manufacturers Association, complained about the maze of laws, rules and regulations that a pharmaceutical manufacturer must contend with in distributing his products in the several states. He said, in part:

> In the United States we now have hundreds of drug laws, Federal and State. . . . Enforcing and administering these laws are some 190 different State agencies and several Federal ones. Many States and the Federal government have three or more agencies regulating various aspects of the drug industry. Indeed, some States have agencies sharing concurrent, overlapping and even conflicting jurisdiction over drug law enforcement.

Uniformity of Law and Administration Urged

Mr. Kelly continued by outlining the difficulty a manufacturer sometimes experiences in complying with these laws and regulations and made a strong plea for uniformity of law and administration.

Mr. Kelly's responsibility to his client undoubtedly caused him to make the best case that he could for uniformity. At the same time, others have gone much further than Mr. Kelly and charged that state regulation in the area of food and drug control has not only outlived its usefulness, but that it is now hampering progress, and they cite the experiences of the European Common Market as proof of this contention. This poses a basic question—Is society's best interest served by abandoning to the federal government our states' responsibilities for regulating matters of health and safety in order to effect convenience and economies for manufacturers?

If the answer is yes, then what do we do to prevent the eventual development of a federal bureaucratic system of control where growth of products and services, and the right of availability of these, is regulated by an all-powerful central government which has demonstrated its capabilities for failure to appreciate the professional considerations that must obtain in any adequate program of health care. If the answer is no, then what do we do, in a society of growing complexity, to relieve the frustrations that appear to be developing as more and more people allegedly regulate more and more things?

All bureaucracy seems to have a way of transferring emphasis from objectives to mechanics, wherein the system tends to replace the objectives. This is especially apparent in some areas of social control. To some extent this has happened in the field of food and drug regulation, particularly in drug control. This has come about through a failure to fully understand and appreciate the nature of a drug in its environment of use.

Proper Methods of Drug Control Necessary

In most cases, it is a reasonably simple task to take the physical article which we call a drug and to recognize the standards of purity, strength, form, stability, and so forth, that it purports to meet. The enforcement of these standards then becomes largely a matter of routine. But when this article of recognized standards is moved into the area of application and use, where it becomes a drug in fact as opposed to a mere article in commerce, this is something else again. Here consideration of professional practitioners must be taken into account. Such things as diagnosis, treatment plans, agent selection, medication control—including availability, administration, duration, suitability, security, and so forth—all of these things and others

become important considerations. It is because of these considerations that the public interest demands that proper methods of drug control be applied, which are designed to reach objectives that are in the public interest as opposed to procedures that lend themselves primarily to ease and order of enforcement, or to guarantee the smooth and abundant flow of articles in commerce.

To some extent, piecemeal efforts to do all of these things may have led to the purported legal maze of "190 different State agencies and several Federal ones," about which Mr. Kelly complains. This leads us to ask: "Have the mistakes been made, and if so, what is the solution to the problem"? In attempting to answer these questions, to some extent one is operating in the area of philosophical considerations. At the same time, however, we must look to philosophy for our new ideas and concepts which eventually can evolve additional mechanisms of reasonable social and economic control.

As stated earlier, a drug or medicine is more than and different from an ordinary article of commerce. For this reason, it is improper and inadequate to apply ordinary methods of commodity control to its distribution and use; consideration of vocational or professional control over drugs must be taken into account. The three main forces that combine to make up such vocational control over these articles are: (1) competition, (2) law, and (3) profession.

While all vocational pursuits are affected in varying degrees by all of these forces, generally, however, as the requirements for entering the several vocations increase, control tends to migrate from competition, through law, to profession. About the only thing that regulates the vocational activities of a migrant bean picker, for example, is his ability to find work. On the other hand, except for certain basic legal requirements, a brain surgeon's activities are limited almost solely by the bounds of professional ethics as they relate to technical competence and responsibility to patient. The control of the production, distribution and use of drugs falls somewhere in between these two points.

In order to discuss drug control work in a meaningful manner, it is first necessary to examine the nature of the several control mechanisms to determine their usefulness and deficiencies for this purpose and to create a context for their application.

Competition

We all know the reputation of success of a better mouse trap. At the same time, we know the proclivities of human nature toward self-interest. We also know the jungle warfare that is often created by the motivations of excessive self-interest. Except for those who value honor and integrity above profit, society cannot rely upon competition for its protection, and honor and integrity are not always easy to assign with assurance.

Law (Government)

Since man's earliest times he has had what we now call laws to protect the group against its individual members. Down through history these control mechanisms have developed to a high degree of specialization. Early America prided itself on laws that protected the individual against the group. (Unhappily, erosions seem to be occurring, throughout the world, at the foundations of this monument of freedom.) From the beginning, traditions in divisions of authority became established among the several jurisdictions. In the United States the tradition for the regulation of professional practice has always been reserved to the states, and this has been accomplished through the exercise of the police power in the interest of the protection of the health, safety, general welfare, and morals of the citizens.

Broad Interpretation of Powers by the Federal Government

On the other hand, the federal government has felt the necessity to promote economic growth and social development and has attempted to foster these things through its power to tax and to regulate commerce. Through the years, these latter powers have been broadly interpreted (for example, use of the tax power to regulate narcotics) and, in the opinion of some, misapplied (for example, use of the power to regulate commerce in order to pass upon the efficacy of drugs). Whether through default of primary control responsibility, agency ambition, social and economic development, or for whatever reason, this extension of interpretation and application of the federal government's powers to tax and particularly to regulate commerce has caused certain jurisdictional questions to arise which, I believe, have not been adequately settled. More important, they have set a course of control which is already interfering with certain areas of professional practice, and this has been contrary to public interest.

Unless this course is changed through a better informed and more effective program of control on the part of those whose responsibility it is to regulate professional practice, the public's health care in other areas will be further restricted and, in the end, even directed by a federal bureaucracy. This is true because a drug or medicine is not an ordinary commodity of commerce!

Just because, as a part of production and distribution, a drug finds itself (or one of its ingredients) in the channels of commerce at some points, it does not necessarily follow that the usual rules of commerce should be applied to a drug as are applied to other commodities. There are many other considerations that must be taken into account, and these cannot always be adequately or effectively translated into law. Under such circumstances, we find delays in desirable legislative enactment on the one hand, and the hasty enactment of sometimes unnecessarily restrictive legislation, brought about by some isolated but sensational episode, on the other.

We must not deprecate the force of law when attempting to protect the public interest in health matters. We must have good and proper laws. However—and the present state of frustration among many health practitioners bears me out—we cannot rely on law alone to accomplish a full measure of health protection without seriously impinging on certain areas of professional practice, privilege, responsibilities and judgment.

Profession

The final force of vocational control is that of profession. There are three criteria which are generally accepted as precedent to a designation as profession. They are:

(1) An intellectually based technique;

(2) A relationship of responsibility toward client; and

(3) Responsible practitioner organizations which guide the conduct of their members through the enforcement of codes of ethics.

While the benefits which accrue to society as a result of the influence of profession are self-evident, this force has, generally speaking, had greater effect for the public good than that for which it has been credited. Therefore, if we are ever to develop an adequate program of drug control there must be greater responsibility given to and a greater reliance made on profession and those who understand this force.

There is no secret that there exists a certain element of competition between the federal government, on the one hand, and the governments of the several states, on the other, in many areas of social control. The field of food and drug regulation is no exception. Therefore, one of the first orders of business in the development of a state drug control program should be a good understanding of areas of responsibility in this field. Reference was previously made to the propriety of the application of the several powers of government and the impropriety of the use of other than the police power of the states to regulate matters dealing with professional practice and privilege. This will be so as long as the practitioner's judgment must determine his course of action. Considerations of this requirement must not be overlooked in devising any drug control program—federal or state—if the public interest is to come first.

A need exists to explore in depth the attitudes of those who have regulatory responsibilities touching on professional practice, and to clearly identify the dimensions of those responsibilities. In this connection, one cannot help but express wonderment as to why foods and drugs were ever classed together in a program of regulation in the first place. It is to be hoped that the forthcoming study of state regulatory agencies will be sufficiently thorough as to point up the sometimes inefficient nature of this arrangement; and it is especially desirable and essential for the future that an understanding be reached as to who will do what and where and when.

As an official of a state agency concerned with drugs and with professional practice, I am perfectly willing for the federal government to regulate in those areas concerning product integrity and reliability. But I consider it a usurpation of authority when federal regulation goes beyond that point. The procedures, judgments and activities of practitioners of professions should not be subjected to federal control by way of the drugs they use.

While we are in the process of making definitions, we should turn our attention to the very important matter of objectives. Understandably, we must have regulation by law (both civil and moral) and not by men. But drug laws must be adjusted to social necessity and not to convenience of enforcement, or to the implementation of the flow of commerce.

Members of the health professions and the public alike are sometimes bewildered when they observe what appears to be a sledge

hammer of enforcement being used to drive a tack of a prohibition. It is especially disconcerting to pharmacists to know that today they are liable for criminal action and considerable fine if they fail to maintain certain procedures in dispensing a given drug on prescription order, and then, tomorrow, find that the attendant at the filling station on the corner can sell the same drug to anyone with impunity.

Public and Professional Needs and Interests Must Be Kept in Mind

A pressing need exists for a thorough review of our present requirements with the view of aligning them more nearly with public and professional needs and interests. If this can be accomplished, it is my opinion that such things as practitioner educational programs, proper public information releases and efforts, and adequate interagency and professional liaison would do much toward the reduction of the necessity for the use of governmental regulatory procedures.

It is fundamentally unsound for big government to attempt to regulate something as variable and as intimate as professional practice and privilege.

Beginning of Regulation

More than a century ago, when the health profession began to be regulated, the legislatures of the several states recognized their inability to understand and to regulate the technical aspects and ethical considerations which are the body of these vocations. It was for this reason that special agencies and commissions were set up. Membership on these agencies was composed of professionals who had a full understanding of the matters to be regulated. During those early periods, practically all drug control work was carried on by the boards of pharmacy.

As the preparation of most medicinals began to shift from the pharmacist's laboratory to that of the pharmaceutical manufacturer, interest was just naturally focused more on product, to the relative neglect of the services rendered in connection with the dispensing of prescription medication. The early interest in the products was restricted to purity, strength, uniformity, etc. Because of the emphasis on this aspect of control, and the fact that the regulation of drugs was coupled with that of foods, chemists, biologists, and others in the basic sciences began to be attracted to the regulatory process.

Eventually, special agencies were set up—both state and federal—whose special function was food and drug control work.

In the meantime, the boards of pharmacy, being largely voluntary, seemed satisfied to let other agencies assist in the job. Some, perhaps, even experienced transfer of some of their responsibilities to others by default. Under such circumstances, where emphasis was on product, it was natural that considerations of professional practice and privilege failed to exert the influence that they had previously, when they were about the only elements of control in effect. The health professions are just now feeling the full impact of the revolution in industrial pharmacy. In managing this growth, we have seemed to rely largely on law with all of its rigidity and inadequacies. Any system of drug control that is to fully meet the public need must be more than this.

There is no quarrel with the general chemists and other scientific personnel participating in drug control. On the contrary, they are welcome. It would be impossible to discharge any effective program without these highly trained specialists. However, assurance of product integrity is not enough to protect the public interest. More attention must be given to professional control as it relates to product use. Only the health professions are equipped to direct this aspect of control. There is no question but that the scientific personnel who find themselves concerned with certain aspects of drug control work are just as interested and just as devoted to the public's welfare as are the professionals who must be concerned with drug use. But the mechanisms of control are different and are executed in different ways with the two groups. Here again, it is hoped that the proposed study of state agencies will inquire in depth.

Recommendations Proposed

Some problems have arisen simply because many who are charged with regulatory responsibilities in the drug field have not maintained adequate communications and relationships with groups such as this. In regard to a drug control program for the states, were specific recommendations requested, among those to be included would be these:

(1) A conference of all agencies having responsibilities in drug control work, wherein a decision might be reached as to who would do what, when and where, based upon the logical derivation of power and authority.

(2) A continuing interagency mechanism for the exchange of information and assistance.

(3) A cooperative planning project to eliminate duplication of effort and to reduce costs.

(4) A cooperative personnel training facility such as has been set up for the training of government personnel in other areas.

(5) A clearing house for proposed legislation, rules and regulations, standards and other requirements.

Some of these things already exist. They need only to be organized and put into use. Not only do pharmaceutical manufacturers find themselves in a state of frustration; pharmacists and other professionals are equally handicapped. It is hoped that organizations such as this, with its broad base of membership, will interest themselves in these problems. Something must be done to bring greater order out of the chaotic situation that appears to be developing. But, in doing this, we do not want those who must render health services to be exposed to an authoritarian federal government. **[The End]**

FDA REGULATIONS CANNOT BE ATTACKED COLLATERALLY

The validity of a FDA regulation cannot be attacked collaterally as a defense in a criminal action charging violation of the regulation, the United States District Court for the District of Arizona has ruled.

The court action involved a criminal charge that the defendant introduced into interstate commerce lettuce which was adulterated because it contained more than the prescribed limit of DDT established by the pesticide regulations. The defendant attempted to counter the charge by alleging that the regulation was invalid because it was the result of an arbitrary and capricious exercise of discretion on the part of the Secretary of Health, Education and Welfare.

The court refused to entertain the challenge to the regulation's validity. The Food, Drug and Cosmetic Act, the court said, "prescribes a procedure to obtain direct judicial review of the merits of such regulations in a *United States Court of Appeals* by filing a petition within 90 days after the regulations are issued. . . . The judgment of the Court of Appeals is final subject to review by the U. S. Supreme Court. . . ."

"If direct judicial review is not sought within the 90-day period allowed by the statute," the court continued, "the right to such review is lost and the regulations become final in the same way as they would if affirmatively upheld on direct review."

Noting that no statutory appeal on the regulation in question was taken by the defendant or anyone else, the court refused to entertain the defendant's challenge.

The court's decision in *United States v. Bodine Produce Co., Inc.* appears in CCH FOOD DRUG COSMETIC LAW REPORTS, ¶ 40,056.

Looking Back at Food and Drug Law Enforcement

By ERWIN P. SNYDER

This Paper Was Presented at a Meeting of the Division of Food, Drug and Cosmetic Law of the American Bar Association Section of Corporation, Banking and Business Law in Chicago, Illinois on August 15, 1963. Mr. Snyder Is Counsel with the Chicago Law Firm of Chadwell, Keck, Kayser, Ruggles and McLaren.

IT HAS BEEN SUGGESTED that I reminisce about some of my connections with the food and drug laws. My early experiences as a lawyer were very general as I was then connected with a firm representing large clients *not* in the food line, but in 1922 I became general counsel for the Kraft Food interests. As such, I was not only busy with acquisitions, mergers and corporate problems but also found myself involved with various food and drug officials, not only the state officials but also the federal officials, who were engaged in enforcing food and drug laws. Mr. Kraft was the inventor of so-called process cheese which was a relatively new food product and this at that time was their principal line. A few comments about some of my experiences with this new product will perhaps bring back to each of you some of your own memories about new food or drug products which you have handled. A new product such as process cheese necessarily raises problems of enforcement and of that very important enforcement tool, a definition and standard of identity.

The Kraft Product

In 1922 and following years, the various state food and drug officials all had curiosity as to how the product was manufactured, as to the ingredients from which the product was manufactured, and as to the legal status of the product, whether it was to be considered as a cheese or a new manufactured product. The Kraft Company

sold it as pasteurized blended loaf cheese, but merely naming it as such did not satisfy the food and drug officials who were being goaded by dealers in many forms of natural cheese to take some action against the Kraft product which was rapidly taking large sections of the market both in the United States and abroad. The Kraft product was prepared by comminuting the original cheese so that it could be heated, blended together and pasteurized. The cheese which was used in the manufacture was high grade cheese and was thoroughly cleaned before it was put in the kettles so that there could hardly be objection to the ingredients. The opposition of the cheese dealers took the form of slandering the Kraft product as something similar to process butter which everyone at that time knew was made from rancid and unmarketable butter which was submitted to various processes to produce a usable butter.

The opposition to Kraft centered in the State of Wisconsin which was and is the leading cheese producing state in the Union. At that time the Wisconsin State Department handling food and drug questions was headed by Dr. Emery, who was a well-trained and reasonable executive. I was able to get along with Dr. Emery very well and Wisconsin investigators and inspectors were welcomed in the Kraft factories. It wasn't long until Kraft had competitors in the field, some of whom added a chemical so-called emulsifier to the cheese to aid in the blending of the cheese components.

Early Standards Fixed by Wisconsin

During these early years when opponents of the Kraft loaf cheese were using every effort to outlaw the product in Wisconsin, the Attorney General of Wisconsin ruled that cheese made in the manner of Kraft loaf cheese could not be called misbranded or adulterated when labeled pasteurized blended loaf cheese. That was in the early part of 1925. Later in 1925, the Wisconsin legislature in connection with a statute fixing the standards for various types of cheese included a definition and standard for process cheese. The standard defined the way it was made and permitted the optional addition of a chemical emulsifier which consisted either of sodium phosphate, sodium citrate or potassium tartrate and set limits on the amount of the emulsifier contained in the product. It also fixed the content of butter fat and moisture for the product. In general, it was a very fair statute. I have always given Dr. Emery credit for having written the definition and standard which became law in July 1925. At that

time Kraft did not use a chemical emulsifier, although its competitors did. So, while there was no doubt but that the law required their product to be named "Process Cheese," Kraft did not feel that it was required to so label its product in view of the opinion of the Attorney General; and nothing was done by Wisconsin about the omission, during those years, of the word "process" from Kraft labels. However, questions continued to arise in the various other states and to secure uniformity of approach it seemed a federal standard would be very helpful. Thus, I learned early in my experience with the enforcement of food and drug laws that the standards are a very helpful and necessary part of the enforcement background. At that time there was no set procedure. It was not easy to secure a federal standard, and there was some question as to how much aid would be secured from such a standard.

Early Federal Food and Drug Laws

At this point, it might be well to review the situation of federal food and drugs laws at that time. You probably are all familiar with what I am going to say, but it won't hurt to repeat it. The earliest federal involvement in food laws was in reference to imports of food into the United States. It was about 1848 when the federal regulation of adulteration in imports of food for human consumption began. It was not until 1869 that Congress turned its attention to the adulteration of food stuffs manufactured domestically for human consumption, and it was not until 1883 that Congress provided funds for the publication of a bulletin by the commissioner of agriculture reporting analyses of various food products. Congress was slow in providing funds to set up chemical laboratories for the analyses of foods to ascertain if they were adulterated, but later, in 1896, Congress authorized the giving of publicity as to the results of such tests. This publicity caused the manufacturers to appear before Congress and secure laws giving them the opportunity of a hearing before the Secretary of Agriculture prior to the publication of adverse findings in reference to foods and drugs. It was not long after this that Congress became interested in the subject of preservatives and colorings in foods and authorized the Secretary of Agriculture to investigate the safety of the same in reference to health. At this time Dr. Harvey W. Wiley came into the picture with his so-called poison squad of 12 young men who volunteered to undergo experimental diets designed to determine the safety of such preservatives and colorings.

1902 and Later Regulations

In 1902 Congress authorized the Department of Agriculture to investigate the chemistry of various food products and adulterants used therein. Finally, in 1906, Congress passed the first comprehensive food and drug law after practically all the states had already passed such legislation. Because of the fast development of packaged food and the growing interstate traffic in food of all types, the federal law quickly became the vehicle used for the prevention of adulteration and misbranding. The law of 1906, however, contained no provision for establishing standards for foods other than canned foods. Provision for the standardization of canned foods was provided in 1930 by the federal McNary-Mapes amendment to the 1906 Act.

In 1902 Congress made an appropriation to enable the Secretary of Agriculture to collaborate with the Association of Official Agricultural Chemists and other experts to establish standards of purity for food products and to determine what constituted adulteration thereof for the guidance of the officials of various states and of courts of justice. It was pursuant to this statute that the Department of Agriculture established so-called "advisory standards" for many food products. These definitions and standards were contained in the Service and Regulatory Announcements issued by the department. These standards did not have the effect of legal pronouncements, but they did have considerable weight in practice and frequently were regarded by the court as expert testimony. While they were of help in the enforcement of food and drug laws, it still was a cumbersome legal job to prove adulteration or misbranding.

"Advisory Standard" for Process Cheese

This was the situation in 1925 when I decided that it would be helpful to secure the adoption of a so-called "advisory standard" for process cheese. I did not advocate that the Kraft product be called process cheese but suggested that it be called pasteurized blended cheese.

My original contact was Dr. Skinner of the Bureau of Chemistry of the Agricultural Department who was then chairman of the Food Standards Committee. At that time the Food Standards Committee was composed of three representatives of the Food and Drug Division of the Bureau of Chemistry of the Department of Agriculture, together with three representatives of the Association of State Food and Drug

officials and three representatives from the Association of Agricultural Chemists. It was a very informal organization and the meetings were informal in nature. I informed Dr. Skinner of the general situation with which he was to some extent familiar. However, procedure called for their own organization to look into the situation which they did. Later a meeting of the committee was held which I attended and to which I presented the situation. Competitors of the Kraft Company were also called in and given an opportunity to present any facts that they desired.

We had several hearings in 1926, at one of which, I recall, Dr. Wiley was present as a guest. He had retired previous to that time. The meetings were open to the public, although there was a very small attendance. We also had several hearings in 1927 before any action was taken. During the latter part of 1927 the committee recommended to the Secretary of Agriculture a standard for process or emulsified cheese and for pasteurized-blended cheese, the latter not containing any emulisfier and having the same moisture content as the original cheese. The process cheese was permitted an additional 1 per cent of moisture to provide for the incorporation of the emulsifier.

I might say there has been very little pasteurized-blended cheese of the cheddar type found on the market since 1927 or 1928 when Kraft decided that because it aided the ease and uniformity of manufacture, the use of an emulsifier was desirable. However, occasional examples have been manufactured by Kraft since that time, such as creamed Old English cheese which was made and sold in the thirties and in which no emulsifier was used and the pasteurized-blended cheese spreads sold at the present time.

While the issuance of the federal standard for process cheese did help very much in securing uniformity of state laws in reference to process cheese and the enforcement of the same, I could not fail to recognize that the enforcement situation would have been greatly improved if federal standards had the force of legal definitions and standards. Accordingly, I was actively interested in subsequent years in persuading Congress to pass the new Federal Food Drug and Cosmetic Act which was passed in 1938 and authorized in Section 401 the establishment of standards of identity and reasonable standards of quality for food products.

Standards Committee

To facilitate standard making operations the Food and Drug Administration at once set up a Standards Committee composed of four experienced state food law enforcement officials and two representatives of the Food and Drug Administration. This committee in cooperation with the administrative officers decided which foods should be standardized and generally pointed out to the field forces the data to be secured for the Administration to present at the standard hearing.

Among the early hearings were hearings on proposed standards for cheddar cheese and cream cheese in 1940. At the hearing on cheddar cheese our distinguished colleague Michael Markel was the government's attorney. Later hearings were held on cream cheese. This hearing became almost bitter and aroused considerable antagonism between various members of the industry.

One of the predecessors of Kraft had originated cream cheese about 1890 and in the last few years before the hearing there had been a trend among competing New York manufacturers of this product to degrade the cream cheese into something approaching a Neufchatel cheese which as such had more or less gone off the market. Neufchatel cheese had been made either from skimmed milk or milk containing small amounts of butter fat.

The government very properly proposed standards which covered the traditional cream cheese made and sold from the year 1890 and Kraft, as would be expected because of its ownership of Philadelphia Brand cream cheese, supported the government's standard. The traditional butter fat standard for cream cheese was adopted as a result of these hearings which were very protracted. Mr. Markel was also the government attorney in the cream cheese hearing. This was all before World War II. During the war the standard making role of the Food and Drug Administration was very much cut down because of the urgency of other problems.

Directors of the Food and Drug Administration

During the years from 1922 to and including the war years, the enforcement activities of the Food and Drug Administration and its predecessor the Bureau of Chemistry of the Department of Agriculture were under the direction of Walter G. Campbell who entered the Department as a lawyer but became chief inspector of the Bureau of

Chemistry very soon after the passage of the 1906 Act. He was put in charge of the enforcement activities in 1922 and became head of all Food and Drug activities in 1928 shortly before the Food and Drug Administration separated from the Bureau of Chemistry. The creation of the Food and Drug Administration independent from the Bureau of Chemistry was in 1930. Mr. Campbell was director of the entire administration from that date, during the Congressional hearings on the 1938 Act which began early in the thirties and during the reorganization of activities under the 1938 Act, until he voluntarily retired in 1944 after 37 years of public service. Whether it was because he was a lawyer or because of his innate sense of right and wrong, he established for the Administration a high code of ethics which continues to this date. Paul Dunbar, Charles Crawford and George Larrick have in turn ably contributed to this tradition. I would be most remiss if I did not publicly acknowledge the outstanding service which Malcolm Stephens has performed as chief of the Bureau of Enforcement. Consumers, government officials and industry representatives all owe Mr. Stephens a respectful vote of appreciation and confidence for carrying on the Campbell tradition.

Developments Since World War II

I have not dealt with the period since the war because you are all more or less familiar with that. During the period immediately after World War II, the Department conducted some very extensive standard hearings in which I participated. Again the importance of standards for uniformity of enforcement was recognized. Sometimes I have doubted the necessity of a standard for a product as a standard may tend to stifle technology and advancements in the product. However, this situation has not gone unnoticed, and means have been devised to permit technological advances within the standardizing concept without creating additional enforcement problems; first, by the introduction of an alternate make procedure clause as was done in the cheese standards. Such a clause permits changes which do not affect the identity of the product. Second, the Hale Amendment now permits standards to be changed more easily and, third, the Administration has helped by providing in its regulations in Section 10.5 for the issuance of temporary permits which permit the companies to try out what appears to be an advance in a standardized product before asking for an actual change in the standard. Perhaps the only remaining action which might be taken by the Administration would be to

add additional personnel to assist Mr. Bellis and the other overworked executives assigned to this division of the Administration.

One of the most important changes made in the 1938 Act has been the much delayed recognition that the provisions of the Act found in Sections 402(a)(1) and 402(a)(2) setting out the poisonous per se rule were a roadblock for present day food technology in reference to chemical substances added to food, and were not adequate without further provision in the Act as to how, when and how much of such additive may be used. This was of great importance to the food industry, and I was greatly concerned to see the statute remedied. After a considerable struggle in Congress the Food Additives Amendment of 1958 was passed which remedies the situation. [The End]

REGULATIONS PERMITTING THE USE OF RADIATION

Two additional regulations permitting the use of radiation in the preservation of food were issued by FDA during August. One of the new regulations authorizes the use of gamma radiation to control insect infestation of wheat and wheat products. The other authorizes the use of electron beam radiation to sterilize canned bacon.

The use of gamma radiation from the radioactive isotope cobalt 60 for the sterilization of canned bacon was authorized by FDA last February in its first action involving the irradiation of food, after the process was shown safe. The gamma radiation, which is an electromagnetic radiation like light but with a shorter wave length, is derived from sealed units of cobalt 60. Electron beam radiation is a stream of minute particles of matter with a positive charge projected from an electronic accelerator.

In the field of radiation, FDA's area of responsibility is the safety of the treated foods. Under the Food Additives Amendment to the Food, Drug and Cosmetic Act, foods that are irradiated must be cleared by FDA for safety before they can be marketed. FDA also evaluates other possible effects of radiation, such as changes in flavor, color, odor, texture or nutritional quality to make sure that the treated product will comply with the law in all other respects.

The new regulation for the irradiation of wheat and wheat products permits the use of gamma radiation at energy levels not exceeding 2.2 million electron volts to provide an absorbed dose of from 20,000 to 50,000 "rads" of radiation. A "rad" is a measure of the total amount of radiation absorbed. Evidence submitted to FDA showed that the treated wheat would not be radioactive, and its nutritive value and other properties would not be adversely affected. Purpose of the radiation is to kill insect eggs and other insect life in the grain.

The source of electron beam radiation to sterilize bacon, under the other new regulation, would be an electron accelerator producing a beam of energy levels up to 5 million volts. FDA scientists are satisfied that bacon irradiated by this process would not be radioactive and would be entirely safe for consumption.

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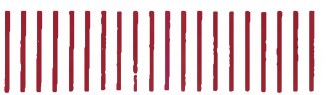

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