VOL. 16, NO. 11 NOVEMBER 1961

Food Drug Cosmetic Law JOURNAL

The Latin American Food Code: Chapter XVI—Correctives and Improving Agents (Additives)

Current Federal Drug Controls For Problems Old and New

. . . . . GEORGE P. LARRICK

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

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

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

November, 1961
Volume 16 • Number 11

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . November, 1961

VOLUME 16 NUMBER 11

Printed in United States of America

REPORTS

TO THE READER

Additives.—One of the most important chapters of the Latin American Food Code is reprinted in this issue beginning at page 641. Chapter XVI of the Code, "Correctives and Improving Agents," deals with the food additive situation currently so widely agitated in the United States due to new federal legislation and regulation. This chapter was translated from the original Spanish by *Ann M. Wolf* of New York.

The October, 1960, issue of the FOOD DRUG COSMETIC LAW JOURNAL published the Introduction to the Code by *Carlos A. Grau* and the Index; the translation of Chapter IV, "Utensils, Receptacles, Containers, Wrappers, Machinery and Accessories" was printed in the February, 1961, issue and the translation of Chapter X, "Sugar and Sugar Products," appeared in the May, 1961, issue.

Dealing with Drugs.—In the Food and Drug Administration there has been a renewed effort to improve the quality and reliability of drugs. The Food, Drug and Cosmetic Act requires adequate labeling and directions for use of a drug. In 1938, there were considerably fewer drugs on the market and physicians were familiar with all of them. Today the scientists and researchers in the medical field are constantly discovering new drugs which are being placed on the market. The Administration discovered that the brochures giving vital information concerning the use of these new drugs did not always reach the physician. Consequently, in July of 1960, the FDA proposed a regulations revision which demanded that any labeling for prescription drugs, including promotional material, must contain full information about the drug.

In the article commencing at page 679, *George P. Larrick* details these new regulations concerning prescription drugs as well as the ever-present problems of drug counterfeiting and the mishandling of physicians' samples. Mr. Larrick concludes by asking the continued cooperation of the members of the Federal Wholesale Druggists Association, before whom he was speaking.

Truth Versus Quackery.—*William W. Goodrich,* in one of the papers delivered before the National Congress on Medical Quackery, suggested that those who were truly interested in destroying the gigantic business of quackery must be willing to do more than just talk about the problem. People must be willing to act and to bring to the public the horrid truth of lives lost and money spent by the unfortunate people who are victims of the quack doctor's unorthodox methods. Only an educated public can protect itself from the smooth talk and the miraculous claims of the exponents of the business of quackery.

Mr. Goodrich discusses three medical problems which the quacks have used to make millions of dollars for them-

selves. These are the problems of proper nutrition, cancer and arthritis. There is no immediate cure for the victims of any of these. The proper medication is long, painful at times and often expensive. The quack offers immediate, painless cures and prices his treatments according to the patient's purse.

The author, who is Assistant General Counsel for Food and Drugs, Department of Health, Education and Welfare, states that unless the problem is exposed to the clear light of truth and the state and local authorities aid in this exposure, the quack doctors will continue to have a billion dollar business at the expense of innocent people who are hoping to be cured. The article appears at page 684.

Hazardous Substances.—The Federal Hazardous Substances Labeling Act was enacted as a result of the efforts of the medical profession, the FDA, and many chemical and manufacturing associations who realized the need for adequate warning labels on many household articles which were not subject to provisions of existing statutes. In the article at page 692, *Irvin Kerlan, M. D.* and *Sam Molinas, Ph.D* discuss this new statute, the criteria used to determine the hazards, and the labeling requirements. Their statement was presented at the annual meeting of the American Association of Poison Control Centers.

Price Conspiracies.—The "Antitrust Division has, in recent months, redoubled its efforts to uncover illegal conspiracies to fix prices, rig bids and divide markets," according to *Lewis Markus,* Chief of the Economic Section. Speaking before the National Institute of Governmental Purchasing, in New York City on October 11, he went on to say that "since last February, twelve cases have been filed charging illegal price-fixing and bid-rigging. Many of these cases affect markets in which a significant volume of public procurement takes place. These cases represent almost a third of all of the cases filed by the Antitrust Division in the same period. Among the products affected by illegal price-fixing are prescription drugs, antibiotics, building materials, bakery and dairy products, electrical equipment and rock salt."

Strommen Receives Award.—*Richard S. Strommen,* Extension Services in Pharmacy, recently received a special citation from the University of Wisconsin School of Pharmacy graduate chapter of Kappa Psi fraternity. He was cited "in recognition of his dedicated and exemplary service as secretary-treasurer," a post he has held since the graduate chapter was organized in 1948. In 1960 he received the national award of the Kappa Psi Pharmaceutical Fraternity.

Mr. Strommen was appointed to the University of Wisconsin School of Pharmacy and Extension Division faculties in 1958 after eight years in community practice. He is presently an assistant professor in charge of the Pharmacy Extension program.

Mr. Strommen is recognized nationally for the development of Secondary Poison Treatment and Information Centers for community hospitals throughout Wisconsin.

Food Science School.—The Department of Food Science of Rutgers, the State University, will hold a series of six day seminars at six month intervals, devoted to the advancement of Food Industry Science, *Dr. C. Olin Ball,* Chairman, announced. The first seminar, designated the Food Science School, will be held January 14 to 20, 1962, at the Empress Motel, Asbury Park, New Jersey. It will be directed by *Dr. Edward A. Nebesky* of the University's Department of Food Science. The deadline for registration for the January seminar is December 31, 1961. Information may be obtained by contacting Dr. C. Olin Ball, Rutgers University, New Brunswick, New Jersey.

Vol. 16, No. 11 November, 1961

Food·Drug·Cosmetic Law
Journal

LATIN AMERICAN FOOD CODE: CHAPTER XVI

Correctives and Improving Agents (Additives)

The Following Chapter XVI of the Latin American Food Code Was Translated From the Original Spanish by Ann M. Wolf, New York. The English Translation of the Introduction to the Code by Carlos A. Grau and the Index Were Published in the October, 1960 Issue of the *Food Drug and Cosmetic Law Journal;* the Translation of Chapter IV (Utensils, Receptacles, Containers, Wrappers, Machinery and Accessories) Appeared in the February, 1961 Issue; and the Translation of Chapter X (Sugar and Sugar Products) Was Published in the May, 1961 Issue.

CHAPTER XVI. — CORRECTIVES AND IMPROVING AGENTS (ADDITIVES)

Thickeners and Stabilizers

Article 561—The following *Thickeners* and *Stabilizers* shall be considered as suitable for use in the preparation of foods: thickeners and stabilizers obtained by the hydrolyzation of skins, tendons and bones of healthy animals; agar-agar or gelose; alginates, isinglass and other fish gelatins, carob gum from seeds of the European carob bean (*Geratonia siliquia*, Linn.), gum from the crown-thistle [1] (*Gleditsia amorphoides*, Griseb.) and similar gums, and starch and cellulose derivatives which meet the requirements of this Code. They shall be purified, dried and odorless, and their sulphur dioxide (SO_2) content shall not exceed 500 parts per million.

[1] Crown-thistle would be the translation of "espina de Corona"—but no reference to a thickener obtained from the crown-thistle has been found.

The use of brominated vegetable oils shall be permitted to stabilize aromatic bases used in the preparation of emulsions and alcoholic or nonalcoholic beverages, inclusive of dietetic drinks.

Article 562—*Edible Gelatin* obtained by the hydrolyzation of skins, ligaments and bones of healthy animals shall contain not more than 3.25 per cent of total ash and not less than 15 per cent of nitrogen. A 1 per cent solution shall have a pH of between 5 and 7.5. A 1 per cent solution in hot water shall, after cooling, form an odorless, flavorless jelly.

Article 563—Solid or liquid *Pectin* preparations intended for the preparation of jams, marmalades, desserts, etc. shall be sold under names indicating their origin: *Citrus pectin* ("Citropectin"), *apple pectin* ("Pomosin"), *beet pectin, currant pectin,* etc. and shall be free from starch, other vegetable gums and foreign matter. Sodium benzoate or sorbic acid may be added to liquid pectins in amounts of up to 1 gram per liter. Up to 40 per cent of sugar (sucrose, glucose, lactose) may be added to solid, dry or powder pectins, in which case the label shall bear a statement to that effect.

The jelly grade of pectins, which means the proportion of sugar which one part of pectin, with the normal amounts of water and acid (pH-3), is capable of turning into a jelly of standard firmness containing 65 per cent of sugar, shall not be less than 80 grade units for solid pectins and 10 grade units for liquid pectins. The jelly obtained after 24 hours at 18-20° C. shall not be viscous or sweating and shall permit cutting into firm geometric solids with distinct edges.

Article 564—Isinglass, a fish gelatin obtained from the air bladder of several fish, especially sturgeon, shall contain not more than 1 per cent of ash and shall melt at 50° C. A solution of 1 part of isinglass in 24 parts of hot water shall, after cooling, form a transparent, odorless, flavorless jelly.

Article 565—The names *"Agar-Agar," "Gelose"* and *"Gelosin"* apply to a product obtained from various species of *Gelidium* and related seaweeds of the family Rhodophyceae. It shall contain not more than 1 per cent of foreign organic substances, 6.5 per cent of total ash and 20 per cent of moisture. A solution of one part of agar-agar in 200 parts of hot water shall, after cooling, form a colorless, odorless, neutral, insipid jelly.

Sodium, ammonium and *calcium Alginates* intended for use in foods are alkaline salts of alginic acid extracted from laminal algae. They

shall have the form of a beige, odorless, tasteless powder with a moistening and agglutinating power. They may contain not more than 25 per cent of water and 1 per cent of insoluble matter (cellulose and lignite) and shall not contain foreign matter. When calcinated, the residue of fixed substances of sodium alginate shall be less than 20 per cent and that of ammonium alginate less than 4 per cent.

Condiments and Spices

Article 566—For the purposes of this Code, the term "condiment" means any substance, with or without a nutritional value, intended to become a component of or to improve foods by giving them a flavor and/or aroma.

Article 567—The generic names *"Spices"* and *"Vegetable Condiments"* apply to certain plants, or parts of plants, which contain aromatic, sapid or stimulating substances and which for this reason are used to season, dress or improve the aroma and flavor of foods and beverages.

Spices must be genuine and harmless, must meet their standard characteristics and be free from foreign matter and from such parts of the plant from which they derive as do not possess the properties of condiments (stems, petioles, etc.). Spices may be sold whole or ground. Spices stored, exhibited, distributed or sold in a poor condition of preservation, spices infested with insects, spices which smell musty and spices prepared under poor or unsatisfactory hygienic conditions shall be confiscated on the spot.

Spice mixtures must be composed of simple, harmless, clean, genuine spices, free from foreign products (sugar, salt, etc.) and may be marketed under a fanciful name, provided that their components are declared on the principal label in the order in which they exist in the mixture.

Article 568—*Spice mills* are the plants at which vegetable condiments are cleaned, selected, ground and packed. Such plants must meet the following requisites in addition to the general rules:

1. The premises on which the raw materials and finished products are stored, prepared and packed must have flat ceilings, waterproof floors and walls waterproofed up to a height of 1.80 m.

2. The machinery and equipment used must at all times be perfectly clean and in good condition.

Article 569—The names *"Summer Savory"* and *"Savory"* apply to the leaves and flowering tops of *Saturcia hortensis*, Linn. Savory shall contain not more than 10 per cent of total ash and not more than 0.5 per cent of ash insoluble in 10 per cent hydrochloric acid.

Article 570—The name *"ground, pressed, triturated or minced Chili"* applies to the coarse powder obtained by the trituration of different kinds of whole, clean red pepper fruits which were crushed without removing their inside part or seeds.

Depending upon its flavor, ground chili is classified into *sweet* and *hot* chili. It shall contain not more than 14 per cent of moisture and 5 per cent of chloride expressed as sodium chloride.

Article 571—The name *"Garlic powder"* applies to the dried and pulverized bulbs of *Allium sativum*, Linn.

Garlic salt is a mixture of salt and garlic powder which must contain not less than 15 per cent of garlic powder.

Article 572—The name "Basil" applies to the whole, clean, fresh or dried leaves of *Ocymum basilicum*, Linn. (large variety) and *Ocymum minimum*, Linn. (small variety); *Average percentage composition* (dried): water 8; proteins 20; fats 5; carbohydrates 45; crude fiber 16; ash 6.

Article 573—The name *"Capers"* applies to the dried closed flower buds of *Capparis spinosa*, Linn., pickled in vinegar and salt, or in salt alone. Capers shall contain not more than 30 per cent of nitrogenated substances and not more than 5 per cent of fatty substances (calculated on a moisture-free basis).

Article 574—The names *"Anise," "common Anise"* and *"green Anise"* apply to the whole, clean, dried fruit of *Pimpinella anisum*, Linn.

Anise shall contain not less than 1.5 per cent of essential oil and not more than 10 per cent of total ash and 2 per cent of ash insoluble in 10 per cent hydrochloric acid. It shall not be blackish in color and shall not smell musty.

Article 575—The names *"Star Anise"* and *"Badiana"* shall apply to the whole, clean, dried fruit of *Illicium verum*, Hook, f. Star anise shall contain not less than 3.5 per cent of essential oil, not more than 5 per cent of total ash and not more than 1 per cent of ash insoluble in 10 per cent hydrochloric acid.

Star anise which contains "shikimi" or false badiana (*Illicium religiosum, Siebold*)[2] shall be confiscated on the spot.

[2] A spurious kind of anise with poisonous properties produced in Japan.

Article 576—The name "*Celery Seed*" applies to the whole, clean, dried fruit of *Apium graveolens*, Linn. It shall contain not more than 10 per cent of total ash and not more than 2 per cent of ash insoluble in 10 per cent hydrochloric acid.

For *Celery Seed Extract*, see Article 618, number 4.

The name "*Celery Salt*" applies to a table salt (sodium chloride), to which between 0.1 per cent and 1 per cent of essential celery oil and 2.5 per cent of sodium glutamate have been added and also to a salt mixture containing at least 15 per cent of ground dried celery seeds. The addition of turmeric or another permitted color shall be declared on the label. *Average percentage composition:* water 5; proteins 5; fats 6; carbohydrates 6; crude fiber 3; ash 75.

Basil, marjoram, bay leaf, etc. salts shall be prepared in a similar manner.

Article 577—The product named "*Saffron*" or "*Crude Saffron*" shall consist of the filiform orange-red dried stigmas of the flower of *Crocus sativus*, Linn., with or without the yellow styles.

Hereinafter the commercial classifications under which Crude Saffron is sold, with the proportions of white parts they must have along their stigmas:

"Coupe": no white part

"Mancha": a white part of up to 25 per cent

"Rio": a white part of between 25 and 32 per cent

"Sierra": a white part of more than 32 per cent.

Crude Saffron shall meet the following requirements:

1. It shall not contain more than 10 per cent of styles and other filaments.

2. Fifty complete filaments, each consisting of the part of the style to which the three stigmas are attached, shall weigh about 337 milligrams.

3. It shall contain not more than 14 per cent of water and volitile matter when dried at 100-150° C. and not less than 60 per cent of aqueous extract; its total ash maximum shall be 6 per cent, and the ash insoluble in 10 per cent hydrochloric acid shall not exceed 1 per cent.

4. The aqueous infusion shall have an alkaline reaction.

5. It shall not be exhausted or mixed with other vegetables (safflower, arnica, turmeric, "rocu," "suncho real"[3] etc.), and shall not contain foreign products (starchy substances, inert matter, honey, glucose, picric acid, coloring agents, mineral salts, etc.).

6. 0.5 grams of the product shall dye 25 liters of distilled water yellow.

The designations *"ground Saffron"* and *"powdered Saffron"* apply to the product obtained by the trituration of saffron in accordance with the definition and standards of this Code. The preparation, distribution, possession and sale of powdered saffron mixed with pimento or cartamo is prohibited, even if its composition is declared on the label.

Ground or powdered saffron shall meet the same requirements as crude saffron, except those listed in Sections 1 and 2 of the article.

Article 578—The designation *"Artificial Food Color"* applies to a color prepared with a base of tartrazine to which new coccin has been added in a proportion of not less than 10 per cent. The word "saffron" is not permitted to be mentioned on the label or in the designation.

Article 579—The names *"Sweet Flag"* and *"Calamus"* apply to the whole, clean, dried rhizome of *Acorus calamis,* Linn. Sweet flag shall contain not more than 6 per cent of total ash and not more than 1 per cent of ash insoluble in 10 per cent hydrochloric acid.

Article 580—The names *"Cinnamon"* and *"Ceylon Cinnamon"* apply to the dried bark of *Cinnamonum zeylanicum,* Nees, from most of which the outer layers have been removed. Any cinnamon that does not meet the macroscopic and microscopic characteristics of Ceylon Cinnamon shall be named *common cinnamon* (China, India, Malabar cinnamon, etc.)

Ceylon Cinnamon and all other kinds of cinnamon (China, India, Malabar, Java, etc.) shall meet the following requirements: They shall contain not more than 14 per cent of moisture, 6 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid, and 22 per cent of starch, and not less than 0.8 per cent of volatile ether extract and 9 per cent of alcohol extract for Ceylon Cinnamon, and 5.5 per cent for the other cinnamon types.

Article 581—The name *"Cardamon"* applies to the whole, clean, dried seeds of *Elettaria cardamomum* White and Maton and similar species.

---

[3] "Rocu" and "suncho real" are names of pharmaceutical plants commonly known in South America, for which no English equivalent seems to exist.

Cardamon shall contain not more than 10 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid and 12 per cent of moisture, and not less than 2 per cent of essential oil.

Article 582—The names *"Indian Curry"* and *"Curry Powder"* apply to a mixture of several sharp-tasting spices such as various kinds of peppers, ginger and turmeric, to which other condiments may have been added.

Although there does not exist an obligation to declare on the label of the mixture the proportions in which the different components were used, their names must be stated in the order in which they are present.

Article 583—The names *"Caraway," "Alcaravea,"* and *"German Cumin"* apply to the whole, clean fruit of *Carum carvi,* Linn. Caraway shall contain not more than 14 per cent of moisture, 3 per cent of total ash and 2 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 3 per cent of essential oil.

Article 584—The names *"Lemon-scented Verbena"* and *"Herb Louisa"* apply to the whole, clean, fresh or dried leaves of *Lippia citriodora,* Kanth.

Dried lemon-scented verbena leaves shall contain not more than 7 per cent of moisture, 6 per cent of total ash and 1 per cent of ash insoluble in 10 per cent hydrochloric acid.

Article 585—The names *"Cloves"* and *"Clavos"* apply to the ripe dried flower buds of *Caryophyllus aromaticus,* Linn.

Cloves must meet the following requirements:

1. They shall contain not more than 5 per cent of clove stems, flower peduncles and clove fruit;

2. They shall contain not more than 15 per cent of moisture, 7 per cent of total ash, 1 per cent of ash insoluble in 10 per cent hydrochloric acid and not more than 10 per cent of crude fiber;

3. They shall contain not less than 15 per cent of volatile ether extract and not less than 12 per cent of quercitannic acid (calculated from the oxygen absorbed by the aqueous extract).

Article 586—The names *"Cumin," "Common Cumin"* or *"Spanish Cumin"* apply to the whole, clean, dried fruit of *Cuminum cyminum,* Linn. Cumin shall meet the following requirements: It shall con-

tain not more than 12 per cent of total ash, not more than 4 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 1.5 per cent of essential oil and 18 per cent of alcohol extract.

Article 587—The name *"Coriander"* applies to the whole, clean, dried fruit of *Coriandrum sativum,* Linn. Coriander shall contain not more than 7 per cent of total ash, not more than 1.5 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 0.6 per cent of essential oil.

Article 588—The name *"Turmeric"* applies to the whole, clean, dried rhizome of *Curcuma longa,* Linn. Turmeric shall meet the following requirements:

1. It shall be free from pathogens, according to tests conducted by the health authority;

2. It shall contain not more than 10 per cent of water, 8 per cent of total ash, 1 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 10 per cent of total ether extract and 7 per cent of fatty matter. The nitrogenated substances shall fluctuate between 5 and 13 per cent;

3. It shall have a positive reaction to sulfurous diphenylamine.

Whenever turmeric is used to color a product, the label of the product shall bear the statement: "Colored with turmeric." No such declaration is required in the special cases in which turmeric is used as a condiment.

Article 589—The name *"Juniper"* applies to the fleshy, whole, clean, dried berries of *Juniperus communis,* Linn.

Juniper berries shall contain not more than 3 per cent of total ash, not more than 30 per cent of moisture and not less than 0.4 per cent of essential oil.

Article 590—The names *"Dill," "Dill Seed," "Dill Fruit"* apply to the whole, clean, dried fruit of *Anethum graveolens,* Linn. Dill shall contain not more than 10 per cent of total ash, 3 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 2.5 per cent of essential oil.

Article 591—The name *"Tarragon"* applies to the whole, clean, dried leaves and flowering tops of *Artemisia dracunculus,* Linn.

The name *Tarragon Extract* applies to the extracts prepared by the maceration or digestion of tarragon with vinegar.

Article 592—The names *"Tonka Bean"* and *"Sarrapia Bean"* apply to the seeds of *Dipteryx odorata,* Willd. and similar species. Tonka beans contain about 25 per cent of fatty matter and more than 1 per cent of coumarin.

The name *"Tonka Bean Extract"* applies to the alcohol extract prepared from the Tonka Bean, with or without the addition of sugar and glycerin. Tonka bean extract shall contain not more than 0.1 per cent of natural coumarin.

Because of their coumarin content, Tonka beans and their derivatives, extracts, etc. may be used only in cosmetics, perfumes and similar products, or as a tobacco aromatic, but may not be added to foods and beverages.

Article 593—The name *"Fennel"* designates the whole, clean, ripe, dried fruit of different varieties of *Foeniculum,* Linn. It shall contain not more than 12 per cent of water, 9 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 3 per cent of essential oil.

Article 594—The name *"Ginger"* applies to the washed dried rhizome of *Zingiber officinale,* Rosc., decorticated (white or peeled ginger) or not (grey ginger). It shall contain not more than 7 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid, 8 per cent of crude fiber, 1 per cent of lime calculated from oxide, not less than 1 per cent of essential oil, 42 per cent of starch and 12 per cent of cold-water extract.

The name *"Bleached" or "Limed" Ginger* applies to whole ginger, coated with calcium compounds for purposes of preservation (slaked calcium, carbonate and sulfate of calcium). In such ginger, total ash and calcium calculated as carbonate of calcium are tolerated in amounts not exceeding 10 per cent and 4 per cent, respectively.

Article 595—The name *"Laurel" ("Bay")* applies to the whole, clean, dried leaves of *Laurus nobilis,* Linn., which shall contain not more than 6 per cent of total ash, not more than 1 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 2 per cent of essential oil.

Article 596—The name *"Mace"* applies to the dried arillus or hull that covers the nutmeg (*Myristica fragrans,* Houtt.). Mace shall meet the following requirements: It shall contain not more than 17 per cent of moisture, 3 per cent of total ash, 0.5 per cent of ash insoluble in 10 per cent hydrochloric acid, and 10 per cent of crude

fiber, and not less than 4 per cent of essential oil. The ether extract shall fall between 20 and 30 per cent and the alcohol extract between 19 and 25 per cent.

Article 597—The names *"Marjoram," "Oregano"* and *"Leaf Marjoram"* apply to the whole, clean, dried leaves and flowering tops of *Origanum majorana,* Linn. and its different varieties.

Marjoram shall contain not more than 16 per cent of total ash, not more than 4.5 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 0.5 per cent of essential oil. Stalks and harmless foreign substances are tolerated in amounts not exceeding 10 per cent.

Article 598—The names *"Balm," "Sweet Balm,"* or *"Lemon Balm"* apply to the fresh or dried leaves of *Melissa officinalis,* Linn.

Article 599—The generic name *"Mint"* (*"Hortela Pimenta"*) distinguishes the leaves and flowering tops of several cultivated or wild plants of the family *Labiatae.* Mint shall contain not more than 12 per cent of water.

The designations *"Mint," "Common Mint," "Garden Mint," "Spearmint,"* and *"Yerba Buena"* or *"Hierba Buena"* apply to the whole, clean, dried leaves and flowering tops of *Mentha viridis,* Linn. and *Mentha rotundifolia,* Linn.

The names *"Menta Peperina"* or *"Menta Peperita"* apply to the leaves and flowering tops of *Bystropogon Mollis,* Koth.

The names *"Peppermint"* (*"Mentha Piperita"*), or *"English Mint"* (*"Menta Inglesa"*) apply to the leaves and flowering tops of *Mentha Piperita,* Linn.

Article 600—The term *"Mustard"* applies to the product obtained by grinding the seeds of *black* mustard (*Brassica Nigra,* Koch.), *brown* mustard (*Brassica Juncea,* Hook.), *white* mustard (*Sinapis alba,* Linn.) or mixtures thereof.

Mustard Flours or *Ground Mustard* are prepared from ground seeds, from which part of the fat has been removed. They shall meet the following specifications: They shall contain not more than 10 per cent of moisture, not more than 6 per cent of ash, not more than 1.5 per cent of ash insoluble in 10 per cent hydrochloric acid and not more than 1.5 per cent of starch. The addition of turmeric is permitted with a declaration to that effect.

The name *"English Mustard"* may only be used for ground mustard which meets the specifications set forth in the preceding paragraph, and the name *"Russian Mustard"* shall be reserved for the powder obtained from *Brassica Juncea* that meets the same characteristics.

Mustards in liquid or paste form, also named *"Table Mustard," "Prepared Mustard," "French Mustard," "Tarragon Mustard," "German Mustard," "Düsseldorf Mustard," "Frankfort Mustard,"* etc. may consist of mustard flour, wine must, wine, vinegar, salt, sugar, citric, lactic or tartaric acid, oils and other condiments. The addition of turmeric is permitted with a declaration to that effect.

They shall contain not more than 24 per cent of carbohydrates calculated as starch, not more than 12 per cent of crude fiber, not less than 5.6 per cent of nitrogen and not less than 0.10 per cent of natural mustard essence, all calculated from the dry product. The addition of sulfurous acid anhydride is permitted in amounts not exceeding 500 parts per million.

The name *"Mostarda"* [1] (*"Cremona Mustard"* and others) applies to a condiment prepared with candied or noncandied fruits or vegetables immersed in a sugar (sucrose, dextrose) syrup which contains mustard flour, flavors and other permitted substances.

If turmeric or another harmless vegetable color is added to a mustard, the label of the product shall bear the statement: "Colored with turmeric" or "Colored with . . . (followed by the name of the substance used)." Any mixture of mustard with flour and other edible products, starchy substances, spices, turmeric etc. shall be designated by the name "Condiment" and any substances used in the composition of such mixtures shall be declared on the label.

The lead and arsenic content of the metal caps used on containers of mustard and vinegar-containing condiments shall not exceed 1 per cent and 0.01 per cent, respectively, unless the cap is completely separated from the container neck and the cork by a sheet of fine tin foil (containing not more than 1 per cent of lead) at least one half tenth of a millimeter thick, a sheet of aluminum foil or a sheet of another material that, after boiling for half an hour, is not affected by a solution of 4 per cent acetic acid to which 5 grams of sodium chloride and 0.25 grams of citric acid have been added.

[1] The Italian word for "Mustard," used to designate an Italian type of mustard.

Article 601—The name *"Nutmeg"* applies to the dried seed of *Myristica fragrans,* Houtt., from which the testa have been removed. It may be given a coating of lime to protect it from insects, provided that the weight of such coating does not exceed 1 per cent. A nutmeg shall weigh about 5 grams; when placed in a glass of water, it shall not sink to the bottom. Nutmeg shall also meet the following specifications: It shall contain not more than 5 per cent of total ash, not more than 0.5 per cent of ash insoluble in 10 per cent hydrochloric acid, not more than 10 per cent of crude fiber and not less than 25 per cent of nonvolatile ether extract, 2 per cent of volatile ether extract and 10 per cent of alcohol extract.

Article 602—The name *"Parsley"* applies to the whole, clean, fresh or dried leaves of *Petroselinum sativus,* Hoffm. Average percentage composition (Fresh): Water 83, proteins 4, fats 1, carbohydrates 7.5, crude fiber 2, ash 2.5.

Article 603—The generic denominations *"Cayenne"* and *"Paprika"* apply to products obtained by grinding selected dried fruits of different red varieties of the genus *Capsicum.*

Cayenne and Paprika shall be sold in containers which indicate their country of origin (Argentina, Spain, Hungary, etc.) and retailers are forbidden to break up containers for retail sales.

Article 604—Cayenne and paprika shall contain not more than 12 per cent of ash insoluble in 10 per cent hydrochloric acid and 20 per cent of nonvolatile ether extract.

First grade cayenne and paprika are not permitted to contain more than 23 per cent of cellulose, and second grade not more than 28 per cent of cellulose.

Article 605—The name *"White Pepper"* applies to the whole or ground, dried, ripe berries of *Piper Nigrum,* Linn., from which the outer coat has been removed by soaking in water.

White pepper, in corns or powder form, shall meet the following standards: It shall contain not more than 3.5 per cent of total ash, 0.6 per cent of ash insoluble in 10 per cent hydrochloric acid and 9 per cent of crude fiber; not less than 40 per cent of starch, 7 per cent of alcohol extract and 7 per cent of nonvolatile ether extract.

The names *"Allspice"* and *"Pimento"* apply to the whole or ground fruit of *Pimenta officinalis,* Berg.

The sale of Allspice under the name of "Clove Pepper" is prohibited.

Allspice, in grains or powder form, shall meet the following requirements: it shall contain not more than 6 per cent of total ash, 0.4 per cent of ash insoluble in 10 per cent hydrochloric acid, 25 per cent of crude fiber and not less than 23 per cent of alcohol extract. 8 per cent of quercitannic acid (calculated from the oxygen absorbed by the aqueous extract) and 3 per cent of essential oil.

The names *"Malagueta Pepper," "Guinea Grains," "Paradise Seeds"* apply to the whole, clean, dried seeds of *Amonun melegueta,* Rosc.

Black Pepper is the dried unripe fruit of *Piper nigrum,* Linn. Black pepper in corns shall contain not more than 5 per cent of peduncles and abortive fruit and shall weigh at least 400 grams a liter.

Black pepper, in corn or powder form, shall meet the following requirements: It shall contain not more than 7 per cent of total ash, 1.5 per cent of ash insoluble in 10 per cent hydrochloric acid, 14 per cent of crude fiber, and not less than 32 per cent of starch, 6.75 per cent of nonvolatile ether extract and 8 per cent of alcohol extract.

Article 606—The name *"Pennyroyal"* applies to the fresh or dried leaves and twigs of *Lippia turbinata,* Griseb. The fresh or dried leaves and twigs of *Lippia integrifolia,* Griseb are known by the same name and the name "Tea of the Inca" (*"Té del Inca"*).

Article 607—The names *"Wild Raddish," "Horseradish," "Scurvy Grass," "Cochlearia of Brittany"* apply to the whole, grated or triturated, clean root of *Cochlearia armoracia,* Linn., to which vinegar may have been added. Average percentage composition (fresh): water 74, proteins 3, fats 0.2, carbohydrates 19, crude fiber 2.3, ash 1.3.

Article 608—The name *"Rosemary"* applies to the whole clean leaves of *Rosmarinus officinalis,* Linn.

Article 609—The name *"Red Sage"* applies to the whole clean leaves of *Salvia officinalis,* Linn. Red Sage shall meet the following requirements: It shall contain not more than 10 per cent of total ash, not more than 1 per cent of ash insoluable in 10 per cent hydrochloric acid, not more than 25 per cent of crude fiber, and not less than 1 per cent of ether extract.

Article 610—The name *"Thyme"* applies to the whole, clean, dried leaves and flowering tops of *Thymus vulgaris,* Linn. It shall comply with the following requirements: It shall contain not more than 8 per cent of total ash, not more than 2 per cent of ash soluble in 10 per cent hydrochloric acid and not less than 0.5 per cent of essential oil.

Article 611—The name *"Vanilla"* applies to the unripe fruit of *Vanilla Planifolia*, Andrews and closely related varieties of the orchid family.

Vanilla shall be sold with an indication of its origin: Mexico, Bourbon (Réunion), Tahiti, Java, Brazil, etc. The indications of quality "Superior Grade" and "Fancy Grade" are considered synonymous. The commercial indications of quality, with which they are marketed, shall meet the following requirements:

Commercial Classification	Appearance	Average Length (cm)	Weight (grams)
Fancy Grade	Brown, greasy perfectly smooth	20	6.2 to 6.65
First Grade	Brown, greasy perfectly smooth	19	3.5 to 4.2
Second Grade	Brown, greasy, some ligneous elements	17	4.4 to 4.7
Third Grade	The lignification and dessication more pronounced	17	3.3 to 3.6
Fourth Grade	The lignification and desiccation more pronounced	19	2.9 to 3.8
Common ordinary Grade	Somewhat dry, clearly ligneous and whole	17	2.3 to 2.8

In addition Vanilla shall meet the following requirements:

1. It shall contain not more than 30 per cent of moisture and not more than 6 per cent of total ash, not less than 46 per cent of alcohol extract and not less than 1.5 per cent of natural vanillin and the amount of fatty matter shall fall between 6 and 10 per cent.

2. It shall not be poorly preserved, adulterated, or exhausted and shall not contain balsam of Tolu or Peru, benzoic acid, artificial vanillin, sugar or foreign matter.

The name *"Vanillon"* applies to the fruit of *Vanilla pompona*, Schiede.

The name *"Vanilla Extract"* applies to a vanilla tincture, at least 10 per cent of which shall be 35° to 55° alcohol. It shall contain at least 0.10 per cent of natural vanillin, shall have an acidity of not less than 28 milliliters of normal alkali per 100 grams and contain not less than 0.5 per cent of ash. It shall not contain artificial vanillin, coumarin or acetanilide and shall give a precipitate with a solution of

lead acetate. The artificial product prepared with vanillin and/or ethyl vanillin or *propenyl guaethol,* which may or may not be colored with caramel, shall be designated as *Artificial Vanilla Extract.*

The name *"Vanilla powder"* applies to ground vanilla to which no other substances have been added.

The designation *"Sugared Powder Vanilla"* applies to a mixture consisting of 75 per cent of sugar and 25 per cent of vanilla.

The name *"Vanilla Sugar"* applies to a mixture of sucrose or glucose with dried vanilla, the dried vanilla content of which shall amount to 10 per cent. It shall contain natural vanillin in a proportion of not less than 0.15 per cent and shall be free from artificial vanillin and coumarin.

Article 612—The name *"Vanillin Sugar"* ("azúcar con vainillina") applies to a mixture of sucrose or glucose with at least 0.7 per cent of (natural or synthetic) vanillin or 0.2 per cent of ethyl vanillin or propenyl guaethol. The product shall not contain coumarin.

If instead of natural vanilla, vanillin is used in a product, its labels, pamphlets, advertisements, etc. shall bear the following clearly visible statement: "Preparation flavored with vanillin."

Artificial Sweeteners

Article 613—*Artificial Sweeteners* are the products known under the names of sodium or calcium cyclamate (sodium salt, calcium salt or double sodium and calcium salt of cyclohexanesulfamic acid), saccharin, sorbitol, sucrol, sucrin, dulcin, crystallose, glucin, sucramine and similar harmless chemical substances which, while not carbohydrates, have a sweetening power exceeding that of sucrose without having the nutritive properties of sucrose.

Article 614—Any foods and beverages and any raw materials used in the same, to which artificial sweeteners have been added shall, regardless of the amount of artificial sweetener used, be classified as unsuitable for consumption and be confiscated on the spot, without prejudice to the application of the respective penalties. Exempted herefrom are foods and beverages sold as Dietetic Products, the labels of which shall bear a legend stating that they contain an artificial sweetener. (See Article 678).[5]

[5] Chapter XVII—Dietetic Products.

Emulsifiers

Article 615—*Permitted Emulsifiers* are lecithins, mono-glycerides and di-glycerides, glycerolactopalmitate and any other substance which the health authorities may authorize in the future.

Esters of sorbitol and fatty acids and esters of polyoxyethylene derivatives of sorbitol and fatty acids may be used only if their use has first been authorized by the health authorities.

Glyceryl Monostearate (G. M. S.) may be used as a stabilizer and emulsifier in bakery goods, confectionery, cookies, cakes, ices, creams chocolate icings, condiments and canned meats in proportions ranging from 0.5 per cent in ices to up to 6 per cent in cakes. The commercial product used shall meet the following specifications:

Melting point:	about 56° C.
Glyceryl-alpha-monostearate:	from 30 to 33 per cent
Glyceryl distearate:	from 45 to 47 per cent
Glyceryl tristearate:	from 20 to 23 per cent
Free glycerol:	from 3 to 5 per cent

The use of highly oxidized, polymerized acids with a high viscosity is prohibited.

Flavoring Extracts

Article 616—The names *"Essential Oil," "Essence"* and *"Natural Essence"* apply to solid or liquid products of natural origin, free from foreign matter and solvents, which contain the odorous principles of plants, or plant parts and whose characteristics comply with the requirements of the Pharmacopoeia. Similar products prepared artificially with a base of hydrocarbons, alcohols, acids, aldehydes, ketones and esters used in different combinations shall be distinguished by the name *"Artificial . . . Essence."*

A *Soluble Essential Oil* or *Soluble Essence* is any alcoholic solution which contains not less than 25 per cent of the natural essence. Any product not containing this proportion of essence shall be named *"Extract."*

The designations *"Flavoring Extract"* and *"Food and Beverage Flavor"* apply to any solution of essence in water, ethyl alcohol, glycerin, propylene glycol, combined or not. Extracts shall be designated according to whether they contain natural or artificial essences.

Natural essences and extracts, in the composition of which an artificial essence was used, shall be considered artificial. Exempted herefrom are *natural Flavors* and *Essences* which contain traces of syn-

thetic products added in order to reinforce their odor and flavor or to fix them. In such cases, the products shall be designated: Reinforced natural flavor, or reinforced essential oil.

The name "Extract for the home preparation of . . Liquor (the blank to be filled in with the name of the product used) or Soft "Drink" shall be given to solutions of permitted essences, to which an authorized color may or may not have been added, which are sold for the home preparation of liquors and/or soft drinks. These products may only be marketed in containers holding a quantity of extract not exceeding the amount required for the preparation of one liter of beverage and the label shall bear a large legend "For home use." The sale of this type of extract is prohibited for the preparation of liquors and/or soft drinks which result in a violation of this Code, in beverages with a registered trademark or in distillery products such as: brandy, gin grappa,[6] rum, whiskey, etc.

Brominated vegetable oils may be added as stabilizers to flavoring concentrates intended for the preparation of emulsions and beverages.

Article 617—Flavoring extracts shall be unsuitable for consumption if they contain toxic essences or principles with an active medicinal action, such as: ethyl chloride and bromide, free amyl alcohol, salicylic aldehyde, compounds of the pyridine group, hydrocyanic acid, nitrous ethers, nitrobenzol, and such others as the health authorities may determine.

Article 618—The following generic names shall apply to the products listed hereinafter:

1. *Bitter Almond Flavor or Extract*: This is, from the bromatological point of view, an alcoholic solution containing not less than 1 per cent by volume of essential oil of bitter almonds, free from hydrocyanic acid.

2. *Anise Flavor or Extract*: This name applies to an alcoholic solution containing not less than 3 per cent by volume of essential oil of anise. It shall contain not less than 2.4 per cent of anethole.

3. *Badiana or Star Anise Flavor or Extract*: This name applies to an alcoholic solution of not less than 3 per cent by volume of essential oil of star anise. It shall contain not less than 2.4 per cent of anethole.

4. *Celery Flavor or Extract*: This name applies to an alcoholic solution containing not less than 0.3 per cent by volume of essential oil obtained from celery seeds.

[6] An Italian brandy.

5. *Cinnamon Flavor or Extract*: This name applies to an alcoholic solution containing not less than 2 per cent by volume of essential oil of cinnamon. It shall contain cinnamic aldehyde in an amount of not less than 1.3 per cent.

6. *Coffee Flavor or Extract*: See Article 534.[7]

7. *Clove Flavor or Extract*: This name applies to an alcoholic solution containing not less than 2 per cent by volume of essential oil of cloves. It shall contain eugenol in an amount of not less than 1.6 per cent.

8. *Tarragon Flavor or Extract*: See Article 591.

9. *Ginger Flavor or Extract*: This name applies to the alcoholic ginger extract prepared with not less than 20 per cent of rhizomes.

10. *Ginger Ale Flavor or Extract*: This name applies to the preparation obtained from ginger extract and lemon essence, with or without the addition of other flavoring ingredients and fruit juices.

11. *Guaraná Flavor or Extract*: This is a dark brown, bitter-tasting, astringent liquid prepared by extracting the active principles from the powder of the seeds of *Paulinia cupana*, Kunth, with diluted alcohol (3:1) and concentrating the product at a temperature of below 60° C. until 100 ml. contain 4 grams of guaranine (trimethylxanthine).

12. *Lemon Flavor or Extract* may be prepared with essential oil or peel of lemon, or both. It shall contain not less than 6 per cent of essential oil and not less than 0.3 per cent of citral. *Soluble lemon extract* is the aqueous or alcoholic solution of lemon oil from which all or part of the terpenes have been removed. It shall contain not less than 0.3 per cent of the citral derived from the oil.

13. *Maté Flavor or Extract*: See Article 560, number 3.

14. *Peppermint Flavor or Extract*: This name applies to an alcoholic solution containing not less than 3 per cent by volume of peppermint oil. It shall contain not less than 1.5 per cent of menthol.

15. *Orange Flavor or Extract* may be prepared with oil of Portugal or the peel of sweet oranges, or both. It shall contain not less than 5 per cent by volume of essential oil and not less than 0.45 per cent of limonene. *Soluble orange extract* is a solution in water or alcohol of the essential oil deprived of all or part of its terpenes. It shall contain not less than 0.45 per cent of d-limonene.

---

[7] Chapter XV Stimulating Products —Coffee and Coffee Substitutes.

16. *Nutmeg Flavor or Extract*: This applies to an alcoholic solution containing not less than 2 per cent of oil of nutmeg.

17. *Oregano or Marjoram Flavor or Extract* is an alcoholic solution containing not less than 1 per cent of oil of marjoram.

18. *Licorice Flavor or Extract* is the product obtained by extracting the soluble substances contained in the licorice root.

When treated with an acid it shall give a precipitate of between 6 and 15 per cent.

Licorice extracts shall contain not more than 15 per cent of water, not more than 8 per cent of ash, and not less than 6 per cent of glycyrrhizin, calculated on a moisture-free basis. In addition, the substances insoluble in 10 per cent ammonia water shall not exceed 7 per cent and shall not contain foreign matter, gums, dextrins, starch, sugar, gelatin, etc.

Licorice paste in sticks shall meet the requirements established in the first paragraph of this article. A small amount of sugar, gum, gelatin and permitted essences may be added to it without a declaration to that effect.

The names *"Glycyrrhizin"* and *"Commercial Glycine"* apply to products consisting of mixtures of ammoniated glycyrrhizin and other substances obtained from licorice extract.

19. *Tea Flavor or Extract*: See Article 554.

20. *Thyme Flavor or Extract* is the alcoholic solution of not less than 0.2 per cent by volume of essential oil of thyme.

21. *Tonka Bean Flavor or Extract*: See Article 592.

22. *Vanilla Flavor or Extract*: See Article 611.

23. *Sarsaparilla Flavor or Extract*: This name applies to a solution of 3 per cent by volume of a mixture of essential oils of gaultheria, sassafras, anise and cassis.

Article 619—The designation *"Smoke Oil"* applies to the product derived from the carbonization of nonresinous woods.

Smoke oil shall meet the following requirements:

a. It shall be free from toxic substances, especially menthanol, acetone, formaldehyde, creosote and acetaldehyde;

b. It shall contain not more than 10 per cent of phenolic substances, expressed as ortho-cresol, not more than 12 per cent of acetic acid and not more than 12 per cent of products insoluble in water;

c. It shall at 20° C. be soluble in water in a proportion of not less than 20 per cent;

d. It shall not contain preservatives the use of which is prohibited.

Edible Mushrooms

Article 620—The name *"Mushroom"* applies to the product formed by the fresh or dried cell tissue of acotyledonous plants (basidiomycetes, hymenomycetes and gastromycetes).

Most of the wild growing edible mushrooms belong to one of the following three genera:

1. *the genus Boletus:* Mushrooms with fleshy caps, brown, dark brown or straw-yellow in color, with more or less cylindrical solid stipes. The underside of the pileus has myriads of pores which are the mouths of tubes.

2. *the genus Agaricus:* Mushrooms with fleshy white pilei, with more or less cylindrical white stipes. The underside of the pileus has a number of flat, knife-blade shaped parts which are pink at first and turn dark brown later.

3. *the genus Lactarius:* Mushrooms whose pilei are depressed in the center, with fragile, hollow, orange-yellow stipes.

Article 621—Cultivated mushrooms, also called "champignons" [8] have in general the same characteristics as *Agaricus (Psalliota) campestris*, Fr. ex L.

Canned mushrooms marked "Natural Mushrooms" must be prepared with fresh, whole, clean mushrooms in a good state of preservation and water or mushroom broth; the addition of salt, spices, flavors, citric acid, vinegar and ascorbic acid is optional. The cans must contain as many mushrooms as they can normally hold.

Article 622—None of the genera of poisonous mushrooms listed hereinafter may be used as food, even if they have undergone special treatments to deprive them of their toxic principles:

1. *Amanita:* Mushrooms with fleshy caps colored green (*Green Amanita*), or red with white warts (*Amanita pantera*), or dark (*Fly Agaric* or *Amanita Muscaria*), arranged in concentric circles, with stipes which are at first solid, then hollow, of a generally disagreeable smell, especially on the fully grown specimens.

[8] The French generic word for mushrooms, used in Latin America to designate the well known, edible umbrella-shaped fungus which is grown for the market and in English-speaking countries is generally called "the mushroom."

2. *Coprinus:* Mushrooms with not very fleshy caps and short hollow stipes. They dissolve into a black liquid *(Ink-Mushroom)*.

Article 623—The *fresh Mushrooms* sold on the market shall not be fully ripened, shall possess all the characteristics required to identify them and shall be in a perfect condition of preservation, without larvae, insects or worms; each species shall be sold separately.

Mushrooms may be dried and preserved only under official control. *Dried mushrooms* shall not be divided into pieces so small that their identification becomes difficult or impossible.

Article 624—The *fresh or dried Mushrooms* sold on the market shall be neither suspect nor poisonous and shall be in a perfect condition of preservation, free from worms, insects and mites. Dried mushrooms shall be protected from soil and moisture and shall be stored and sold in closed containers made of waterproof paper, tin plate, glass, cellophane, etc. They shall contain not more than 10 per cent of total ash and not more than 2 per cent of ash insoluble in 10 per cent hydrochloric acid. Alcoholic solutions of dried edible mushrooms take on a color when exposed to ultraviolet light (Wood), whereas as poisonous mushrooms of the *Amanita* genus remain colorless.

The sale of mixtures of several species of mushrooms is prohibited.

Mushrooms intended for consumption may be bleached with pure sulfurous anhydride or pure alkaline bisulfides, using for the purpose not more than the strictly necessary amounts of these substances. The use of tin salts to bleach mushrooms is prohibited, even if the mushrooms are thoroughly washed after bleaching.

Article 625—The name *"Truffles"* applies to the product which consits of the sporogenous apparatus of several kinds of subteranean fungi. They shall be sold thoroughly washed and brushed, and their labels shall state if they are *black (ripe), violaceous black, white* or *grey* (not fully ripened) *truffels*, and the location at which they were gathered.

Yeasts and Fermentation Agents

Article 626—The name *"Yeast"* applies to a product having a base of microscopic fungi (Saccharomyces).

Yeast can be of different origins. It may be obtained from the manufacture of beer, wine, cider, etc., or it may be produced at plants especially intended for the purpose. at which it is cultured on special mashes. It can have various forms: compressed, dry for bread-making, etc.

Article 627—The names *"Compressed Yeast," "Moist Yeast," "Paste Yeast," "Pressed Yeast," "Grain Yeast," "Molasses Yeast"* apply to drained or centrifuged yeast grown on mashes of different origins. It shall be a uniform mass of firm, pasty consistency, with a smell *sui generis,* formed by cells, the majority of which are living. Its water content shall not exceed 75 per cent; it shall contain not more than 2.5 per cent of ash; its maximum acidity shall be equivalent to 5 milliliters of normal alkali per 100 grams and the leavening power (Haydück-Kusserow) of bread yeast shall be one liter of carbon dioxide gas liberated in two hours by the action of a weighed quantity of yeast that contains 10 grams of dry substance. It must be kept under refrigeration. The addition of starch in amounts of up to 10 per cent is permitted.

Article 628—The name *"dry brewer's yeast"* (dead and free from bitter substances) applies to brewer's yeast, from which the bitter substances have been removed and which was dried in drying cylinders by spraying or under vacuum. It is light yellow in color and comes in flake or powder form. The cells appear dead.

Article 629—The designations *"Yeast Tablets"* and *"Granular Yeast"* apply to compressed yeast or brewer's yeast, from which the bitter substances have been removed and which was granulated or pressed into tablets, with the addition of tapioca or corn flour, various starches, and sugars. The quantities and qualities of the substances added shall be declared in the labeling, and their total amount is not permitted to exceed 15 per cent.

Article 630—The name *"Starter Yeast"* or *"Sour or soured Dough"* applies to the sour bread dough obtained from a kneaded dough which has been allowed to stand for some time at a temperature of between 20° and 28° C. (symbiosis of the Saccharomyces minor with Saccharomyces cerevisiae and lactic bacteria).

Article 631—The names *"Yeast Powder," "Artificial Yeast," "Synthetic Yeast"* and *"Baking Powder"* (Backpulver) apply to certain preparations intended for use in specific bakery products which, under the influence of heat, moisture and the mutual action of their ingredients, produce the aeration which lends the dough the necessary fluffiness and sponginess. They have in general a base of sodium bicarbonate mixed with different acid components, potassium bitartrate, tartaric acid, fumaric acid, monocalcium phosphate, sodium pyrophos-

phate, calcium lactate, sodium and aluminum sulfate, with or without 0.1 per cent of egg albumen, starch and flour, calcium sulfate, calcium carbonate and calcium silicate.

Artificial yeasts shall yield not less than 10 per cent of carbon dioxide by weight and are not permitted to contain products considered harmful such as sulfites, bisulfites, copper, tin and zinc salts, etc.

The name *"Yeast Extract"* applies to a product obtained from yeast of any origin through plasmolysis and subsequent autolysis and boiling under pressure, followed by a final vacuum concentration. The origin of the yeast used must be declared. Yeast Extracts must contain not less than 75 per cent of dry residue at 100° C., not less than 9 per cent of total nitrogen and not more than 25 per cent of total ash and 15 per cent of sodium chloride, calculated on the dry product.

Article 632—The following ferments or enzymes may be used provided that the health authorities have first granted their permission:

a. *Carbo-hydrases:* amylases coming from fungi (Aspergillus oryzae) and yeasts (invertase, lactase), except those of a bacterial origin which are prohibited. Used in bakery products and other products with a base of cereals, in beer brewing, in the preparation of syrups, fruit preserves, ice creams, etc.

b. *Pectinases:* pectinesterase and polygalacturonase, used in the wine, coffee and fruit by-products industries. They come from fungi.

c. *Proteases:* proteinases and peptidases coming from fungi, bacteria, animals and plants, used in bakery products, beer, cheeses, meats and meat by-products (pancreatin, trypsin, pepsin, bromelin, ficin and papaine).

d. *Nonhydrolytic enzymes:* glucose-oxidase (glucose dehydrogenase) and catalase used in cheese-making and the preparation of carbonated beverages and fruit juices. The former come from fungi, the latter from fungi, bacteria and animals.

These enzymes shall be free from toxic substances, preservatives and pathogens. Additions are permitted only in the form of substances suitable for nutrition, such as sugars and sodium chloride; other mineral elements are prohibited.

Colors

Article 633—Mineral colors containing antimony, arsenic, barium, cadmium, chromium, copper, tin, mercury, lead, uranium, zinc and hydrocyanic acid compounds are prohibited from being used in foods and beverages and in any papers, boxes and wrappers in contact with

the same, as is also prohibited the use for said purposes of coal-tar or aniline dyes and vegetable colors containing toxic products, harsh resin gums and alkaloids *"Ancoche,"* barberry or unripe grapes, aconite or wolfsbane, *"calafate,"* "goma-gruta" or "Gamboge," "quebradillo," [9] dragon's blood, Canadian bloodroot, etc.

Article 634—Colors which may be used in foods, beverages and other consumers' products, in accordance with the specifications given herein for each case, are the colors of vegetable or animal origin specifically named in Article 635 hereof. These colors may be natural or synthetic and may appear in the form of a powder, solution, paste, extract or as lakes of aluminum, calcium or magnesium of the raw material or pigment or as an artificial derivative of same (aminate, sulfonate, etc.) provided that the health authorities have recognized them as safe, that they do not have the general reaction of prohibited colors, and that the analytical characteristics of the vegetable raw materials from which they derive have not been lost or changed due to the chemical treatment they have undergone.

Article 635—The coloring substances obtained from juices or pulps of edible vegetables and fruits, the dyes named in the table hereinafter and such other colors as the health authorities may approve in the future shall be considered as safe. Synthetic indigotine and alizarine and sulfonated derivatives thereof shall be assimilated to vegetable dyes provided that they meet the purity standards fixed in Article 10.

Coloring Substances of a Natural Origin

No.	Name	Origin of Color	Color Index (1924)	Schultz (1931)
	Red			
1.	Alizarine or Ruby Red	Extracted from Rubia tinctorum, L.	1027	1141
2.	Anchusa or Alkanet (Orcanette)	Extracted from the root of Alcanna tinctoria, L.	1240	1382
3.	Catechu	Extracted from the wood of different acacias: Acacia catechú, Willd.; Acacia Suma, Kurz	1249	1385

[9] The names given in quotes are South American designations and not translatable.

No.	Name	Origin of Color	Color Index (1924)	Schultz (1931)
4.	Campêche	Extracted from the wood of Haematoxylon campechianum, L. (Haematoxylin, Haematein)	1046	1376
5.	Cochineal (carminic acid)	Extracted from dried insects: Coccus Cacti, L.	1239	1381
6.	Orchil	Extracted from lichens of the genus Rocella Ochrolechia	1242	1386
7.	Brazilwood	Extracted from the wood of Caesalpinia brasiliensis, L.	1243	1375
8.	Madder	Extracted from the roots of Rubia tinctorum, L. and Rubia cordifolia, L.	....	1141
	Yellow			
1.	Annatto or Rocou	Extracted from the seeds of Bixa Orellana, L.	1241	1387
2.	Saffron	Extracted from the styles and stigmas of Crocus sativus, L.	....	1388
3.	Beta-carotene	Concentrate obtained from leaves, vegetables, palm oil, etc.	1249A	1403
4.	Curcuma	Extracted from the rhizome of Curcuma longa, L.	1233	1374
5.	Yellow berries, or Persian berries	Extracted from the berries of Rhamnus catharticuse infectorius, L.	1234	1369
	Blue			
1.	Indigotine, or Indigo Carmine	Extracted from indigo and other plants of the genus Indigofera	....	....
	Green			
1.	Chlorophyll	Extracted from the leaves and green parts of plants, as well as their copper compounds containing not more than 0.03% of ionisable copper	....	....
	Brown			
1.	Caramel (See Article 323)	Obtained by heating sugars of vegetable origin above their melting point, but without charring	....	....
	Black			
1.	Vegetable carbon	Prepared from very pure charcoal	1308	1463
	Various Shades			
1.	Anthocyanins	Extracted from vegetables	....	1394
2.	Myrtillin	Extracted from various fruits	....	1400

Article 636—As an exception to Article 634, dessert powders, gelatins, jams, liqueurs, cheese rinds, small bonbons, lozenges and tablets and articles for domestic use are permitted to be colored with the coal-tar (aniline) colors listed hereinafter and such other coal-tar colors as the health authorities may authorize. In cases specifically permitted by the health authorities, beverages and fruit preserves may also be colored when such treatment is required to restore their natural color.

The synthetic colors mentioned herein and such synthetic colors as may be authorized in the future shall be clearly defined and their identity shall be established by a chromatographic and spectrophometric comparison with a standard sample. The labels shall bear full information on their purity, uses, doses and other legal requirements. They shall contain not less than 60 per cent of the genuine dye and may only be mixed with declared nontoxic fillers, such as sugar or starch. They may not contain more than 5 per cent of sodium chloride and/or sodium sulphate. They shall not contain cadmium and mercury salts or derivatives thereof, or elements considered carcinogenic, such as chrome, in the form of chromates, selenium, uranium, polycyclic hydrocarbons or unsulfonated aromatic amines. (Betanaphthylamine, benzidine, xenylamine). Water-soluble colors shall contain not more than 10 per cent of volatile substances (at 135° C.); 0.5 per cent of ether-soluble substances and 0.2 per cent of substances insoluble in water.

Permitted Synthetic Organic Colors

No.	Name	Color Index (1924)	Color Index (1956)	Schultz (1931)	Hecht (1955)
	Red				
1.	Amaranth, Bordeaux Red or Bordeaux S.	184	16,185	212	40
2.	Azorubin or Carmoisine	179	14,720	208	38
3.	Scarlet GN	....	14,815	....	....
4.	Erythrosin J.	773	45,430	887	93
5.	New Coccin, Cochineal Red or Ponceau 4R	185	16,255	213	41
	Orange				
1.	Orange yellow S. or Sunset Yellow FCF	....	15,985	215	29
2.	Orange GCN	....	15,980	....	32

No.	Name	Color Index (1924)	Color Index (1956)	Schultz (1931)	Hecht (1955)
	Yellow				
1.	Quinoline yellow	801	47,005	918	97
2.	Chrysoine S. or Resorcine yellow	148	14,270	186	26
3.	Tartrazine	640	19,140	737	...
	Blue				
1.	Indanthrene Blue or Solanthrene Blue R. S.	1106	69,800	1228	104
2.	Patent Blue V.	712	42,045	826	85
	Black				
1.	Brillian Black BN	...	28,440	...	58

Article 637—Any coloring agents not named in Articles 635 and 636 hereof may be used only after they have first been approved by the health authorities. For this purpose, the interested persons shall file a memorandum [10] which proves their harmlessness, accompanied by conclusive scientific references and physiological test reports. If the health authorities should consider additional tests as necessary, such tests shall be conducted at the expense of the interested parties.

Article 638—Manufacturers of foods and beverages and manufacturers who prepare or mix colors, essences and/or aromatics for use in foods and beverages, shall not be permitted to keep on the premises intended for the preparation of same any products whose use is prohibited; if they do keep such products they will be penalized with confiscation and whatever other penalties are applicable.

Improving or Enriching Agents

Article 639—The admixture of improving or enriching agents to mediocre products, or to products made from inferior raw materials, in order to improve their quality artificially is considered an adulteration. Any product sold to improve a food or beverage, no matter what its designation may be, shall for this reason be considered as intended to adulterate foods and beverages. Exceptions are formed by the chemical and biological improvers of fermentation processes, vitamins, amino-acids and mineral salts in enriched foods and the additives permitted by this Code.

[10] Affidavit or application?

In bread-making, the undeclared use of potassium bromate is permitted to correct and further bread fermentation, and in the preparation of foods and beverages, 99 per cent pure ascorbic acid and isoascorbic acid may be added as antioxidants in a proportion not exceeding 350 mgs. per kilo, while a declaration of its presence or the statement that the product contains vitamins is prohibited.

In the same manner, sorbitol may be used as a stabilizer and homogenizer in bread and confectionery doughs, chocolates, cookies, etc. in a proportion of up to 5 per cent, and in amounts of not more than 1.5 per cent in crown corks intended to be in contact with foods.

Article 640—Meat tenderizers of softeners with a base of protolytic enzymes, as provided for by Article 632, may be sold with the declaration *"for home use exclusively."* They are not permitted to be used at hotels, restaurants, eating places and similar establishments, nor may they be used in the meat industry, except for sausages and canned meat.

Article 641—The manufacture, exhibition, advertising, sale and/or possession of products intended to improve or enrich foods and beverages are prohibited, regardless of whether or not such products are intended to deceive the purchaser or consumer about the essential qualities, origin and class of the product; or to give a product the characteristics of a standard product in violation of this Code, or to give an artificial product the appearance of a natural product or of a quality it does not possess, thus falsifying the results of its analysis; or to neutralize or inhibit the incipience of an alteration. Such products shall be confiscated on the spot, without prejudice to the application of the respective penalties.

Salt

Article 642—The name *"Salt,"* used alone, applies to the commercially pure or purified product, whose chemical designation is "sodium chloride."

It may come from natural sources (crystal salt or rock salt), salt mines, or evaporated salt, and may also be obtained by way of suitable recovery processes used by industrial plants (chemical plants) which have been authorized by the competent authority.

Article 643—The plants engaged in the manufacture of salt for consumption and/or for use by the food industry shall comply with the general regulations and moreover meet the following requirements:

1. They shall make sure that the salt before it is packed be free from pathogens and saprophytes which might change the nutritive properties of the foods.

2. They shall have suitable premises on which to pulverize, grind and pack the salt.

3. They shall use hygienic containers which cannot be re-used.

Article 644—*Common Salt* can come in the form of and be sold as coarse salt, fine salt and superfine salt. The degree of trituration or grinding may vary, depending upon the use for which the salt is intended.

Common salt shall always meet the following requisites:

1. It shall have the form of white, odorless, water-soluble crystals with a clearly saline flavor;

2. It shall not contain nitrites, or more than 0.5 per cent of nitrates expressed as KNO_3, or more than 5 per cent of water. The water-insoluble residue (impurities) shall not exceed 0.5 per cent.

3. The dry residue shall contain not more than 1.4 per cent of sulphates, expressed in calcium sulphates, and not more than a total of 1 per cent of chlorides of calcium, magnesium and potassium.

Article 645—The names *"washed and/or purified, coarse, fine* and *superfine salt"* apply to common salt subjected to a process of washing and centrifugation. Such salt shall be perfectly clear and shall contain not more than 2 per cent of water; not more than 0.3 per cent of water-insoluble residue (impurities), and not more than 0.7 per cent of sulphates calculated as calcium sulphate. Maximum turbidity: 25°.

Article 646—The name *"fine running salt"* or *"table salt"* applies to finely ground salt, or to salt produced by evaporation containing crystals which pass through a 420 micron sieve, most of which are caught by a 125 micron sieve, in which not more than 10 per cent of "powdered" salt is tolerated. It shall meet the same standards of quality as common salt, except for its water content which shall not exceed 0.5 per cent and for the water-insoluble residue which shall not exceed 0.3 per cent. In order to prevent the formation of lumps due to moisture, the addition of sodium phosphate, calcium phosphate, magnesium carbonate, calcium saccharate or another authorized product is permitted in amounts not exceeding a total of 2 per cent. The amount of additives used shall be stated on the label.

Article 647—The designation *"Topping Salt"* applies to very pure crystal salt (99.5 per cent of sodium chloride) in the form of transparent crystals.

Impure crystal salt, which is whitish or greyish and contains not less than 96 per cent of sodium chloride and not more than 0.05 per cent of sulphates calculated as calcium sulphate, may be sold only as animal feed, in which case the official veterinary certificate must be attached.

Article 648—The name *"Iodized Table Salt"* or *"Iodized Cooking Salt"* applies to salt to which potassium or sodium iodine or another stable iodized salt has been added in amounts so that 10 grams of salt contain 150 micrograms of iodine.

Article 649—The name *"Fluoridated Table Salt"* distinguishes salt, to which sodium monofluophosphate or other stable, fluoridated salts have been added in a proportion of 50 p.p.m. or higher. The designation *"Mineralized Salt"* or *"Phosphated Salt"* applies to salt to which different mineral salts and/or phosphates have been added. In all cases mentioned in this article, the health authorities shall fix the proper composition when licensing the product.

Celery Salt: See Article 576.

For *Potassium salt, dietetic salt, dietary salt, sodium-free salt,* see Article 679.

Article 650—The name *"Brine"* applies to a solution containing not less than 10 per cent of salt, to which saltpeter (sodium or potassium nitrate) in a proportion not exceeding 50 grams per kilo of salt and commercially pure sodium nitrite in a proportion not exceeding 6 grams per kilo of salt may be added.

Brines with an alkaline reaction or an ammonia odor, brines which show a lactic or butyric fermentation and brines whose microscopic examination reveals the presence of an abundant microbic flora (lactic, butyric, proteus bacteria) are prohibited from being used for the pickling of food products.

Sauces, Dressings and Seasoning Extracts

Article 651—The generic denominations *"Sauce," "Seasoning," "Dressing"* or *"Seasoning Extract"* apply to various preparations made with a base of acid, aromatic and/or pungent, natural or manufactured condiments which are sold to dress salads, soups, roasts and other

dishes; they may be creamy or liquid, clear or cloudy, and may contain constituents in suspension.

Article 652—In general *Sauces* and *Dressings* shall meet the following requirements:

1. All substances used in them shall meet the standards fixed in this Code.

2. Their components shall be named on the label, and if curcuma or another harmless vegetable color is present, the declaration "colored with curcuma" etc. is compulsory.

3. They shall not be adulterated or fermented and shall contain not more than 1 per cent of copper, no preservatives or other foreign products.

4. They shall not contain glycogen.

5. The containers of vinegar-containing sauces shall comply with the requisites fixed in the last paragraph of Article 600 hereof.

Article 653—The designations listed hereinafter shall apply to the following products:

a. The names *"Alioli"* and *"Ajiaceite"* apply to a dressing prepared with a base of crushed garlic, oil and egg.

b. The denomination *"Vegetable Extract"* applies to a preparation of pasty consistency prepared from a vegetable decoction and brewers' yeast which has been concentrated. *Average percentage composition:* water 40; proteins 7; fats 0.8; assimilable carbohydrates 18; ash (sodium chloride 23) 30; acidity in standard alkali 16.

c. The name *"Soup and Sauce Juice"* or *"Flavor"* applies to a product formed by a mixture of amino acids obtained by the acid hydrolisis or of vegetable or animal proteins (wheat and cereal gluten, casein, etc.). *Ketchup:* see Article 410, point 10).

d. The name *"Ketchup"* or *"Nut Catchup"* distinguishes a sauce prepared with a base of vinegar, soya sauce, meat extract, garlic, onions, salt and nuts.

Mushroom Catchup is prepared in a similar manner with mushrooms and various condiments.

e. The name *"Mayonnaise"* applies to a sauce consisting of an emulsion which contains not less than one fresh or frozen egg per liter, with or without the egg-white, in not less than 65 per cent by weight of edible oil and not less than 2 per cent by weight of vinegar, to which lemon or lime juice, citric acid, salt, sugar, honey, mustard,

spices and monosodium glutamate may be added. It may be vacuum-packed in an atmosphere of nitrogen or carbon dioxide. Egg powder, ovalbumen and other emulsifiers are forbidden from being used as substitutes for fresh or frozen eggs. Mayonnaises containing smaller amounts of oil and egg shall be named *"Dressing," "Seasoning"* or *"X Sauce"*.

f. The names *"Pebre," "Chimichurri" and "Criollo"* [11] dressing distinguish the solid or liquid seasonings used to prepare or dress meats before or after cooking. They are made with a base of vinegar, citric acid, salt, laurel, sweet basil, ground garlic and other condiments.

g. The name *"Anchovis sauce"* applies to a sauce prepared from anchovis, beer, vinegar, salt and other condiments.

h. The names *"Soya Sauce," "Japanese Brine"* and *"Choyu"* distinguish a sauce prepared by the fermentation of a decoction of soya beans, cereals, salt and water, with or without the addition of different condiments and molasses.

i. The name *"Lincolnshire Sauce"* applies to a sauce prepared with a base of garlic, red pepper, nut-meg, soya sauce and vinegar.

j. The name *"Worcestershire Sauce"* applies to a sauce prepared with a base of soya sauce, nuts, meat extract, lime juice, cloves, black pepper, curry powders, mustard, brown sugar and cider vinegar.

k. The names *"Tuco,"* [12] *"Gravy"* and *"Seasoning Extract"* distinguish sauces intended to prepare cooked dishes, noodles, ravioli, etc., and made of meat extracts, vegetables and various condiments.

Article 654—99 per cent pure monosodium glutamate (M.S.G., Ajinomoto etc.) may be added to food products in order to accentuate or heighten their flavor.

Acidulants

Article 655—The following acidulants may be used in the preparation of foods, as well as such others as the health authorities may authorize in the future:

1. *Ascorbic acid.* This is technically pure L-ascorbic acid, a white, crystalline, water-soluble powder which is insoluble in fats and oils. Melting point 190-192° C. It is used in foods not so much as an acidulant, as an antioxidant which is to retard color and flavor changes and rancidity. Metals, particularly iron and copper, accelerate its destruction which can be retarded by the addition of citric acid.

[11] These are names of local dressings not translatable into English.

[12] Apparently what in the United States is called "Spaghetti sauce."

2. *Ascorbyl Palmitate.* The product used shall be technically pure. A white crystalline powder used instead of ascorbic acid since it is soluble in fats. 1 mg. of ascorbic acid is equivalent to 2.34 mg. of ascorbyl palmitate, and 1 mg. of ascorbyl palmitate is equivalent to 0.425 mg. of ascorbic acid.

3. *Citric Acid.* The acid used is the anhydrous product and the hydrate with 8.6 per cent of water of crystallization, both technically pure. The anhydrous product melts at 153° C. and decomposes at 175° C.

4. *Phosphoric Acid.* A 25-50 per cent solution of technically pure, triprotic phosporic acid, the density of which varies between 1.15 and 1.35.

5. *Fumaric Acid.* The product used shall be technically pure. Suitable in baking powders and dessert powders (puddings, etc.) since it dissolves and acts in heat. 100 grams of fumaric acid neutralize 134 grams of bicarbonate of soda.

6. *Gluconic Acid.* A solution of 50 per cent technically pure gluconic acid, with a density of about 1.24. With time, it is converted into its gamma and delta lactones which have no acid reaction.

7. *Lactic Acid.* A solution of 75 per cent technically pure lactic acid, with a density of 1.21-1.22.

8. *Succinic Acid.* A crystalline powder which melts at 180° C. The technically pure product shall be used.

9. *Tartaric Acid.* The technically pure product shall be used. A white crystalline powder which melts at 170° C. 100 grams of tartaric acid neutralize 111 grams of bicarbonate of soda.

10. *Potassium Bitartrate* or *Cream of Tartar.* The technically pure product shall be used. 100 grams of cream of tartar neutralize 44 grams of bicarbonate of soda.

11. *Potassium Sodium Tartrate* or *Seignette Salt* or *Rochelle Salt* contains 25.5 per cent of water of crystallization. The technically pure product shall be used, with a melting point of between 70 and 80° C.

12. *Vinegars.* See Article 661.

Bitters

Article 656—The designation *"Bitters"* distinguishes various substances of a safe vegetable origin, i. e. extracts and active principles

of such substances [13] used especially in the preparation of beverages not only because of their bitter flavor, but also in order to lend beverages corroborative properties or properties which stimulate the appetite.

Article 657—The following substances are considered harmful bitters the use of which is prohibited:

1. Bitters containing alkaloids: poppy, belladonna, sneezewort, coca, thorn apple, St. Ignatius bean, nux vomica, etc.

2. Bitters containing irritating, drastic or purgative principles: Aloe, Spanish fly, Eastern coca, colocynth, paradise grains, rue, with the exception of those specifically permitted by Articles 514 and 516 of this Code.

Foaming Agents

Article 658—The name *"Foaming Agents"* applies to substances which have the property of producing persistent foam.

Article 659—*Permitted foaming agents* are foam producing substances of a vegetable origin with a base of licorice root, glycyrrhizin, alfalfa, sarsaparilla and such others as the health authorities may authorize in the future.

Article 660—Foaming agents containing principles used for therapeutic purposes are considered unsafe foaming agents, whose use in foods and beverages is prohibited.

Vinegars

Article 661—*Vinegar* or *Wine Vinegar* is the product made by the acetous fermentation of wine. Vinegars obtained from the fermentation of beer and malt, cider, hydromel, fruit juices, sweetened solutions and diluted alcohol shall be sold under a name denoting their origin.

Article 662—*Vinegar factories* shall meet not only the usual general requirements, but also the following requisites:

1. The storage rooms for raw materials and finished products and the premises on which the product is prepared and packed, shall have flat ceilings, water-proof floors and walls water-proofed up to a height of 1.80 m.

2. The raw materials used, that is, wines, beers, alcohols, etc., shall not contain substances which make them unsuitable for con-

[13] Note of the translator: I wonder if this should be "extracts made from the active principles."

sumption other than the Mycoderma aceti which may develop in them. The preparation of vinegars is prohibited from raw materials (fruits, sweetened solutions, etc.) which are unsuitable for consumption for reasons other than the one stated hereinbefore; from wines which are not genuine, have foreign odors or flavors, are altered by manitic fermentation, have turned sour or are otherwise diseased, or from wines left over at eating establishments, taverns, beverage outlets, etc.

3. Any acetic acid found at a vinegar factory or a vinegar retail outlet is considered as intended to adulterate the genuine product and shall be confiscated on the spot, without prejudice to the application of the respective penalty. All commercial acetic acid in circulation or storage shall have been denatured with technical furfural or another especially authorized substance in a proportion of one per thousand by volume. Pure acetic acid intended for pharmaceutical or scientific uses is exempted from this provision.

4. In the manufacture of vinegars the following operations are permitted: The dilution of the wine in a sweetened or alcoholic solution, made exclusively at the vinegar factory and not permitted to leave it, in the proportion required for normal acetification; the use of permitted wine clarifiers; the decoloration with charcoal; the flavoring with tarragon, laurel and spices.[14]

5. Specific wine-producing regions are prohibited from being named on the labels used on containers of vinegars not manufactured with natural wines coming from said regions; as is also prohibited any statement to the effect that the vinegar was manufactured with aged or selected wine.

Article 663—The following vinegars shall be declared unsuitable for consumption:

1. Vinegars to which free mineral or organic acids have been added;

2. Vinegars which contain toxic metals, unauthorized colors, irritating or toxic acidic substances or other unauthorized substances. As a preservative, only sulfurous anhydride is permitted, of which vinegars, of no matter what origin, are not permitted to contain more than 400 parts per million of total SO_2, and more than 40 parts per million of free SO_2.

[14] Note of the translator: My interpretation of a not too clearly worded text.

3. Vinegars which are altered by a disease, have vinegar eels suspended in them or have a foreign or disagreeable odor or flavor.

4. Artificial vinegars prepared with acetic acid and vinegars which result from a mixture of such artificial vinegars with true vinegar.

5. Artificial vinegars with a base of acetic acid or lactic acid, and solutions of such acids intended for the preparation of same (vinegar essences or extracts) are not permitted to be prepared, held or sold regardless of the name given to them.

6. The mixing of wine vinegar with concentrated or diluted acetic acid or with vinegars of another origin is prohibited.

Article 664—*Wine vinegar* shall comply with the following requisites:

1. It shall be clear and pungent, not acid in flavor, and shall not contain vinegar eels, cryptogamic vegetations or other alterations.

2. It shall contain the elements of the wine from which it was made in the proportion corresponding to its dilution.

3. It shall contain not less than 4 per cent of acetic acid, 1 per cent of free extract of reducing sugar and 0.1 per cent of total ash.

4. It shall contain not more than 0.2 per cent of sodium chloride or sulfates calculated as potassium bisulfate and not more than 1 per cent of alcohol by volume.

Percentage Composition: density at 15° C.: 1.013 to 1.023; total acidity as acetic acid: 4 to 6.5; fixed acidity as tartaric acid: 0.1 to 0.3; dry residue: 1.2 to 3.6; alcohol: 0.1 to 1; ash: 0.1 to 0.4; alkalinity as normal acid of the soluble ash: 2.1 to 5.6 pH = 2.8 to 3.3.

Article 665—Vinegars which are not wine vinegars shall circulate under designations denoting their origin:

Alcohol Vinegar: Produced by the acetous fermentation of rectified or neutral alcohol solutions.

Percentage Composition: density at 15° C.: 1.005 to 1.013; total acidity as acetic acid: 4 to 9; alcohol: 0.2 to 1°; dry residue: 0.06 to 0.30.

Sugar (Glucose, etc.) Vinegar: Obtained by the alcoholic and subsequent acetous fermentation of sugar (glucose, etc.) solutions.

Beer or Malt Vinegar: Obtained from beer with the proper alcohol content or produced by the alcoholic and subsequent acetous fermentation of a mash of malted hops or cereal, whose starch has been saccharified.

Average Percentage Composition: density at 15° C.: 1.017; acidity as acetic acid: 6.6; dry residue 2.5; ash: 0.25.

Fruit Vinegar (dates, grapes, raisins, apples, pears, carob beans, etc.) produced by the alcoholic and subsequent acetous fermentation of infusions, macerations or decoctions of sweetened fruits.

Average Percentage Composition of grape vinegar: density at 15° C.: 1.010; total acidity as acetic acid: 4; alcohol: traces; dry residue: 1.2.

Average Percentage Composition of pear and apple vinegar: density at 15° C.: 1.020; total acidity as acetic acid: 4.9; alcohol: traces; dry residue: 3.7; ash: 0.3.

Honey Vinegar: Obtained by the alcoholic and subsequent acetous fermentation of honey solutions.

Average Percentage Composition: density at 15° C.: 1.047; total acidity as acetic acid: 4: alcohol: traces; dry residue: 10.6.

Cider Vinegar: Originating in acetified ciders.

Percentage Composition: density at 15° C.: 1.015 to 1.020; total acidity as acetic acid: 3 to 4.5; fixed acidity as malic acid: 0.03 to 0.05; dry residue: 1.2 to 1.3; alcohol: 0.04 to 0.05; ash: 0.03; alkalinity of ash soluble in normal acid: 3.3 to 3.5.

Milk Whey Vinegar: Obtained by the alcoholic and subsequent acetous fermentation of sweetened solutions of milk whey.

Lemon Vinegar: Obtained from alcohol, wine or other vinegar, lemon juice and citric acid. The amount of citric acid, calculated as acetic acid, must represent at least 50 per cent of the total acidity.

These names shall be placed on all containers holding these vinegars and shall also be used in the books, invoices, bills of lading and other documents relative to their sale or circulation.

Article 666—The vinegars other than wine vinegars permitted by this Code shall meet the standard composition of their raw materials and shall have an acidity of not less than 4 per cent, with the exception of beer and cider vinegars, whose minimum acetic acid content may be 3 per cent.

Article 667—The metal caps used on bottles and jars containing vinegars, pickles, mustard and other products with a vinegar base are not permitted to contain lead in an amount exceeding 10 per cent, and arsenic in an amount exceeding 0.01 per cent, unless the cap is com-

pletely separated from the neck of the container and the cork by a sheet of fine tin foil (containing not more than 1 per cent of lead) at least one half tenth of a millimeter thick, a sheet of aluminum foil or some other impervious material which is not affected when boiled half an hour in a solution of 4 per cent acetic acid, to which 5 grams of sodium chloride and 0.25 grams of citric acid have been added. [The End]

THE SECRETARY ON MEDICAL QUACKERY

The following is excerpted from an address by Secretary Abraham Ribicoff to the National Congress on Medical Quackery:

"Today, despite our system of education (not as good as we want it to be, but more universal than any other), despite our high standards of living, despite, even, the basic laws in this field and the government agency that enforces them, today quackery is flourishing."

"True, some of the quainter nostrums, detailed in several fascinating books just published, have vanished from our midst. . . . Today, quackery is more sophisticated. The old time hokum has assumed new disguises. The Food and Drug Administration, for instance, is now engaged in legal proceedings against certain vendors of bottled sea water priced up to $20 per gallon which has been offered as a modern preventive and panacea for virtually all human ailments. But for the most part the witch doctor's tom-tom has given way to the illustrated brochure; the medicine show extravaganza to the television commercial; potions, barks and berries to the phony but impressive 'cancer clinic' or 'scientific diet'."

"What is more, the hard working, well equipped physician of today is handicapped in competition with the quack. His enemy—disease—is complex, the quack's is simple. His treatment may be long, painful, uncertain and expensive. The quack's is swift, painless, sure and expense is usually geared to the patient's purse."

"The medical profession itself is trying to deal with literally thousands of quack practitioners. A study made by the Arthritis and Rheumatism Foundation shows that quackery in the treatment of arthritis and rheumatic diseases costs $250 million each year. It has been estimated that quackery in the promotion of special dietary foods and food supplements costs consumers $500 million each year."

Secretary Ribicoff went on to say: "But quackery's costs in dollars only introduces the story. In terms of false hopes raised, in terms of ugly delusions fostered, in terms of tinkering with human life itself, the cost cannot be measured. The quack flirts with disaster. He challenges the sixth Commandment: 'Thou shalt not kill'."

"The *why* of all this and *what* to do about it is the broad assignment of this law enforcement conference. Whatever it's outcome in terms of information, recommendation and present or future action, the results are bound to be salutary. Bringing the representation of the medical profession and of the law enforcement agencies together to discuss their mutual interests is in itself a most valuable undertaking."

"In your deliberations you may find other avenues for effort—if you do, I will give your recommendations my earnest attention, and I promise you that necessary action will be taken speedily. . . . For all of us are determined to stamp out the quack and protect the citizen."

Current Federal Drug Controls For Problems Old and New

By GEORGE P. LARRICK

Mr. Larrick, Commissioner of Food and Drugs, U. S. Department of Health, Education and Welfare, Delivered This Paper Before the Federal Wholesale Druggists' Association Meeting at White Sulphur Springs on September 27, 1961.

FOR SOME TIME we have been considering steps that we in the Food and Drug Administration could take to improve drug reliability and quality. In the past two years we have pursued several courses of action to achieve improvement. I thought it might be of interest to you to outline some of the things we have been doing.

Within the past year we have published revised regulations affecting the labeling of prescription drugs. We expect these regulations to result in substantially improved drug labeling and promotional material supplied to physicians.

The Food, Drug, and Cosmetic Act requires drugs to bear adequate labeling. This includes adequate directions for use and adequate warnings against misuse. When we drafted regulations under the 1938 law, we were advised that physicians because of their extensive training didn't need a great deal of "use" information and ordinarily didn't need warnings in the labeling of drugs that could be sold only on prescription. We were told that doctors already had this knowledge as a result of their training and experience. So the regulations we issued allowed "prescription-only" drugs to be marketed with little information of this type.

At that time, in the early 1940's, there was a sound basis for allowing prescription drugs to be marketed without full directions for use and full warnings. Really new drug discoveries didn't come along very often in those days. But the tremendous expansion of research

during and following World War II and the changes in drug promotion practices that occurred at about the same time, led to a situation in which hundreds of new drugs appeared on the market every year. Obviously it wasn't possible for the busy practitioner to make a careful investigation of each of these products before determining whether to use it in his practice. It was also evident that the doctor who had been out of medical school for a few years had no background of training on which to rely in making use of the new products. Responsible physicians began to question the adequacy of the informational material available to the medical profession with respect to new drugs.

We observed that the material designed to inform the physician about a new drug, specifically the brochure which is an integral part of the new drug application, often failed to reach the physician. Upon occasion the draft material submitted with a new drug application was never printed by the manufacturer. So we endeavored to correct the situation.

We required final labeling, including any brochure that accompanied a new drug application to be submitted in printed form before the application became fully effective. We hoped this would lead to wider distribution of the factual material that had been reviewed by our medical officers. But this was not sufficient. In many instances physicians were not requesting the brochures. They got such a mass of promotional material that they evidently assumed they did not need to ask for further information. The trouble was that the promotional material often failed to include essential information on uses and contraindications.

Revision of Labeling Requirements

Consequently in July 1960 we proposed regulations to revise the labeling requirements of prescription drugs, and most were issued in final form in December of that year. Briefly, these changes provide that *any* labeling for prescription drugs—including promotional material mailed or detailed to practitioners must contain full information about the drug, including relevant hazards, contraindications and precautions. In the case of new drugs, this labeling must be substantially the same as that authorized in the new drug application. It must bear the date of issuance or of its latest revision so the reader will have some indication as to how current the information is.

These and other changes are designed to provide the prescribing physician with the information he needs to use new drugs properly.

In September, 1961, we issued, in final form, a regulation requiring each prescription drug (except those whose uses and contraindications are commonly known to doctors) to bear a package insert giving full directions and warnings. Thus, every physician will have reliable information as close as the nearest retail pharmacy. In addition, if samples are sent direct to the physicians, the package insert with full information will be required to be included. We believe these changes will result in a vast improvement in the quality of information going to physicians.

Drug Counterfeiting

Legal actions have been stepped up during the past year against counterfeit drugs and repacked and outdated physicians' samples.

Counterfeiting has been a recurrent problem through the years and one of varying intensity. We had to bring criminal actions in the early 1950's to break up a counterfeit racket. In the past couple of years we have had to renew our control efforts.

The drugs which are usually selected by the counterfeiters are the well-known, widely-prescribed, large volume products. They are made in such precise imitation of the genuine articles that differences are discernable only by specialized techniques of microscopic, ballistic, or chemical examination. I am sure you recognize that the danger in this situation is that the counterfeits of important medications do not pass through the safety clearances or manufacturing control procedures necessary to assure a safe product that complies with the Food, Drug, and Cosmetic Act.

Early this year, cooperative efforts of the New Jersey State officials, the Department of Justice and the Food and Drug Administration resulted in charging General Pharmacal Company of Hoboken, New Jersey with the manufacture and distribution of counterfeit drugs. All indications are that this firm was the nucleus of the counterfeit drug racket with nationwide distribution made primarily through a drug wholesaler named Tex Palmer. Extensive surveys by FDA during the past two years have linked all of the counterfeits whose origin has thus far been determined with General Pharmacal. We believe that curtailing the operations of this manufacturer and distributor has broken the backbone of the major counterfeit drug racket in the country. But we still recognize the potential hazard and intend to vigorously pursue wiping out this racket whenever it springs up.

Although the center of distribution of counterfeit drugs was a wholesale druggist, we are happy to report that wholesalers generally did not take part in this fraudulent operation. This is certainly a commendable record and you are to be congratulated for your foresight.

Mishandling of Physicians Samples

Another matter to which we have devoted a great deal of time in recent months is the campaign against the mishandling of physicians samples. The abuses which we encountered came to light as an outgrowth of our investigations concerning counterfeit drugs.

You are well aware of the widespread practice of furnishing physicians with drug samples. However you may not be as well aware of the practices which have grown up primarily because physicians do not want many of the drugs they receive. These so-called "waste basket" drugs have been collected by repackers who destroy the essential labeling and then market the repackaged drugs to retail pharmacists. Investigations of these operations have resulted in 34 seizures in recent months and some of them involved many thousands of dollars. We will continue our activities against this illegal practice until we wipe it out.

Just as in the case of counterfeit drugs, we recognize the economic lures involved. We know you can readily recognize the health threat that is inherent in such an operation. If this practice is to be effectively eliminated it is imperative that pharmacists realize the potential hazards involved and confine their drug purchases to established channels which they know are legitimate.

In addition to the foregoing activities we have stepped up our rate of sampling and analysis of drugs to the extent that in the current year we will examine more than twice as many samples as we examined last year.

While we have been able to take all of the actions I have discussed within the framework of our existing authority, there are additional safeguards which should be established by amendment to the Food, Drug, and Cosmetic Act.

We think the law should be amended to require a new drug to be shown effective as well as safe before it may be marketed. Present law requires only a showing of safety and we have been forced to allow some new drug applications to become effective even though we questioned some of the therapeutic claims made in the drug's

labeling. In such situations it is then up to us to prove the drug is *not* effective for one or more of the claims made for it. We should not be required to appear to approve the labeling of a product, in clearing it through the new-drug procedures, when its sale would violate the prohibition against false claims or when it has no significant efficacy for its proposed use. This situation is ridiculous and not consistent with adequate public-health protection.

Complete factory inspection authority will also require amendment of the law. In December, 1960, regulations were adopted to provide that permission to market a new drug may be denied if the manufacturer refuses to allow inspection of his manufacturing methods, facilities, controls, or any records pertaining to them. While this requirement is a positive step toward assuring consumer protection with respect to new drugs, it is limited to firms making new drug applications.

Added authority is needed to permit inspection of formulas, complaint files, personnel records and records of interstate shipment of *all* drug manufacturers and prescription files in drug stores. The inspector needs to examine:

(1) Manufacturing formulas to determine that proper ingredients are being used and that they are being used in the proper amounts;

(2) Complaint files to determine at the earliest possible time any problem arising from the use of the manufacturer's product;

(3) Personnel files to determine that personnel handling potent and sometimes highly toxic chemicals going in to drugs have the training and experience required for such serious responsibilities;

(4) Prescription files in drug stores to trace lots of bad drugs and determine whether dangerous, habit-forming prescription drugs have been diverted illegally to nonmedical use.

When we consider the importance of drugs in our modern day society, I believe there will be no fundamental disagreement with the premise that every reasonable safeguard should be used to assure every drug's reliability and quality. We in the Food and Drug Administration are under no illusions that we can do the job alone. We realize we must have the full cooperation of everyone connected with drugs. Wholesale druggists and manufacturers can be of great assistance and we will look forward to your continued cooperation.

[The End]

Challenging Quackery With Truth

By WILLIAM W. GOODRICH

The Author Is Assistant General Counsel for Food and Drugs, Department of Health, Education and Welfare. He Delivered This Paper at National Congress on Medical Quackery Sponsored by the American Medical Association and the Food and Drug Administration, Washington, D. C., October 6, 1961.

AT THIS STAGE of the morning program, I come before you very mindful of Ben Franklin's sage advice that—

> You may talk too much on
> The best of subjects.

But quackery is considered such a horrid word, embracing some of the very worst of man's meanness to man, that we welcome the opportunity to discuss it with everyone who would join us in an all out effort to contain it, to reduce it and ultimately to destroy it.

Because people dislike the word, quackery is a subject that for much too long has been largely ignored in the hope that it might go away.

It will not.

Until it is exposed in the clear light of truth, it will continue to take the lives of cancer victims who might have been saved, to drain the resources of arthritics while offering them little comfort from their suffering and to offer illusory promises to both patient and physician alike. Nutritional quackery will continue to grow beyond its already gigantic size, costing an estimated 10 million Americans a half-billion dollars each year.

All our talk about quackery is futile, unless we are willing to act in areas of entrenched interest, which surely will involve us in costly and difficult litigation.

All the talk in the world by the Food and Drug Administration and other enforcement agencies will have no effect unless backed by a strong and determined enforcement program.

All the talk by the medical profession, voluntary agencies, or licensing boards will be to no avail if at the first threat of a libel suit talk is intimidated into silence and inaction.

We are deeply concerned about cancer quackery. So long as the cause of cancer is unknown, and its cure so fraught with uncertainty, there will be those who seek a painless and guaranteed remedy. And only the quack can offer this.

We are concerned about the quarter of a million dollars being spent on worthless treatments each year by the victims of arthritis.

No "Anorexiants"

We are distressed by the fact that a variety of remedies are offered with the claim that they will permit fat people to eat what they want, yet miraculously to shed their unwanted pounds. We know, as Dr. Mondell has recently pointed out, that there are no "anorexiants" to fit all disturbances in eating patterns.

We are overwhelmed by litigation involving dietary supplements promoted by four great myths of nutrition—myths that all diseases are due to faulty diet, that soil depletion causes malnutrition and disease, that our foods are worthless because of overprocessing, and that subclinical deficiency diseases abound among our population.

And we are attempting to deal with a growing problem of the misrepresentation of prescription drugs to the busy medical practitioners.

Enforcement action in any of these areas cannot be undertaken lightly. Each case may be very demanding in terms of dollar cost and of required scientific and legal resources. If undertaken without the resources and a real determination to see the matter through, the effort is doomed from the start.

What is it, you may properly ask, that makes it so difficult to prove that a 2 cc injection of triple distilled water or a tonic of potassium iodide and herbs will not cure cancer? What is so hard about proving that a combination of dilute acids, a laxative and a vitamin will not cure rheumatoid arthritis?

Any physician with even a rudimentary knowledge of drug therapy and of cancer and arthritis or diseases could tell us that such

drugs are worthless remedies. But sad experience teaches us much more than the physician's say so is needed for effective legal action.

The prime difficulty lies at the point at which the professions of medicine and law start their thinking.

In law, a medical claim is presumed to be true until the government is prepared to prove its falsity by a preponderance of the evidence or beyond a reasonable doubt.

In medicine, the claim is presumed to be false until it has been established as true by reliable pharmacological and clinical experiences. When we ask the nation's leading clinical investigators in the field of cancer chemotherapy whether potassium iodide, cascara, buckthorn, prickly ash and related herbs will cure cancer, the answer may well be that they know of no evidence that it will. But this is plainly not enough. There must be proof that it will not.

And the question in any case is not whether the drug sometimes fails; it is whether the drug *ever* works.

Unorthodox Cancer Treatments

And this is where the rub is, particularly in actions against unorthodox cancer remedies.

First, cancer is a capricious disease. It has many forms. It does not always run a predictable course. Second, cancer can be accurately diagnosed only by a biopsy. But this procedure is not always followed. And, thirdly, the recognized treatments—radiation and surgery—do not always yield immediate results on which their ultimate success can be evaluated.

Consequently many people have attributed their apparent recoveries from cancer to the unorthodox treatments, and they are offered as "living proof" against the government's case. There are a few victims who have been given a short time to live, or at least who think they have, but who have survived after taking the unorthodox treatment. A few are mistakenly diagnosed, without a biopsy, as having cancer and are still alive. They, too, sometimes credit the unorthodox treatment. And there are some who had surgery or radiation before seeing the quack, but who attribute their recovery to the unorthodox and painless remedy, wholly discounting any effect from their earlier surgery or radiation.

These claimed cures, accumulated over the years by the unorthodox practitioner, fall into three classes when all the facts are known.

(1) Those who never had cancer in the first place;

(2) Those who had cancer, who still have cancer, or who ultimately died from the disease, though claiming they had been cured; and

(3) Those who had cancer, were cured by surgery or radiation, but who wrongly attribute their cures to the unorthodox treatment.

In court, these "living cures" give the quack strong support. Most, though not all, are entirely honest in their belief that the injection, the pill, or the tonic actually cured them.

Enforcement success requires the most careful investigation into the entire medical history of each claimed cure. Every physician who has seen the patient must be visited and all the relevant medical records obtained. This includes all physicians who saw the patient before, as well as after, the unorthodox remedy was used. Only in this way can the so-called "living proof" be explained, to the jury's satisfaction.

Great care must be exercised not only in the investigation but in reviewing with the prospective witnesses the total medical picture which emerges. A resident in surgery at a charity hospital may be just as vital a witness, as the leading neurosurgeon from the Mayo Clinic. A young surgeon's first, and undoubtedly his only, experience of a lifetime with a neuroblastoma in the abdomen of a six weeks old child may represent a critical point in the case.

But the truth is there; our job is to produce it in terms that a jury of laymen can grasp.

If there is a single message for the medical profession, it is that any cancer patient may go to the unorthodox practitioner. He may do this even after apparently successful surgery or radiation. And this patient may end up as a cure attributed to the unorthodox treatment.

To unfold the true story of this patient's case, accurate records are essential. A careless or incomplete entry at any place may be a major stumbling block to our efforts to prevent the interstate distribution of worthless cancer drugs. Such an entry may enable an unorthodox practitioner to stall enforcement and to exploit cancer victims for years.

Tri-Wonda Arthritis "Remedy"

To take another example, where a little seizure became a big and expensive case, let us consider the Tri-Wonda treatment for arthritis.

The principal ingredients were a combination of acids. These are taken along with a laxative and a vitamin.

Any medical man informed about arthritis would say at once that the treatment could not possibly affect the course of that serious disease. One top notch clinical investigator told us it would be a waste of his time and our money to try such an irrational mixture of medicines in the clinic.

Yet seven full weeks of trial before a federal judge were needed to hear all that had to be said about the drug as an arthritis remedy. More than six years were required to enjoin its distribution. During all those years, the mail-order sale of the drug flourished.

What, one may ask, could possibly have taken such time?

The government presented specialists who testified from expert knowledge, as well as from clinical trials, that the drug is worthless for arthritis. The defendant responded with a medical theory spun for her long after the case was started. When she first consulted expert advisors to formulate some rational basis for her claims, she was told that the problem was "almost hopeless." Nonetheless, a literature search was made by a teacher of pharmacology. It yielded a theory that the acids in the treatment might affect the acid-base ratio of the body, and thus act as a diuretic to draw fluids from the involved joints. The theory was built on work reported in the medical literature by a university investigator. He testified for the government that his research was not in any way applicable to the acids of Tri-Wonda. The pharmacology teacher said that it was. Three general practitioners testified that clinical trials they had conducted on scores of people having miscellaneous joint aches and pains proved the value of the medication for rheumatoid arthritis and osteoarthritis. Eight whole days were required for cross-examination and rebuttal of this testimony to show that these doctors were mistaken. The government won the case.

But had the promoters of Tri-Wonda succeeded, we would have had the anomalous situation in which there was, in the eyes of the law, an adequate treatment for arthritis when, medically, the search for such a treatment is being pursued with great vigor and at tremendous public and private expense.

Jury Lacks Medical Training

We must all agree that a jury is poorly equipped by training and experience to answer medical questions about cancer and arthritis. Any one of many possible trial incidents could well control their decision. The very best of the nation's cancer experts are not necessarily the best court room witnesses. Many doctors fear the witness chair almost as much as lawyers fear the operating table. And the question and answer technique admittedly is a poor device for getting to the truth on these most difficult scientific and medical questions. Good investigation and careful preparation will minimize the risks of failure.

Misrepresentation does not reside wholly in the unorthodox treatment or in modern day patent medicine. Indeed, it touches even the drugs promoted ethically to the medical profession; drugs that are used only on a physician's prescription. Secretary Ribicoff has recently cited a number of examples of such drugs. It is disturbing to learn that 22 per cent of the drugs introduced since 1955 and evaluated since that time by the Council on Drugs of the American Medical Association are being promoted by some claims which the Council considers unproved.

"Clarin" is one example.

The January 14, 1961, issue of the American Medical Association Journal contained an advertisement for the product, which is heparin potassium in a tablet to be taken under the tongue. The advertisement states that the drug has "demonstrated value" in "post coronary management," and that in a significant number of cases it has prevented recurrent heart attacks. Yet in the 1961 edition of *New and Nonofficial Drugs*, a publication of the AMA's own Council on Drugs, the same drug is given the following appraisal: "However, there is as yet no convincing objective evidence that heparin, given sublingually, either prevents or ameliorates any manifestation of cardiovascular disease. Hence, the use of heparin potassium in the hope of ameliorating the progress of atherosclerosis must be considered experimental."

The drug is being prescribed for these unproved conditions. While we cannot estimate its total sales, they exceed $300,000 annually. Local prices are about $8.50 for a bottle of 50 tablets. If three each day were the dose, the patient would be out over $15 a month for what is probably an ineffective drug. The burden of this cost falls

heavily on a post heart attack victim. Physicians prescribing the drug in reliance on claims such as are made in the advertisement are unwittingly experimenting with their heart patients at the patients' expense.

Promotional practices of that kind cannot be squared with the public interest. And the FDA will do all in its power to correct the situation.

We also are concerned with the physician investigator who doesn't investigate or who plans his investigation to yield a predetermined result. No one can justify reporting results for a fee, without taking account of the serious consequences that may attend the interstate distribution of an inadequately studied new drug. There surely will be closer attention to all such practices as we uncover them.

Recent Convictions

In closing, we would like to make a plea to you to be bold in striking at those who practice quackery. We particularly would urge local and state authorities to exercise their enforcement powers. There are some cases that we have prosecuted which might better have been the concern of licensing boards or other appropriate state authority. I refer to the prosecution of Thomas Guy Brown, M. D., Dumas, Texas; Samuel J. DeFreese, M. D., Monroe, Georgia, and Ezra Leroy Callahan, M. D., De Queen, Arkansas. These physicians were supplying amphetamines for sale through truck stops, outside the scope of their medical practice.

The dangers of the unsupervised use of these stimulants by long haul truck drivers as a substitute for rest are obvious. What can happen is illustrated by what is said to have been the worst highway accident in the history of Arizona. This accident occurred when the driver of a cattle truck was speeding down the wrong side of a clear and unobstructed highway at 70 miles per hour and collided head-on with a Greyhound bus, killing nine people, injuring 31, and causing property damage of over $100,000. The truck driver had been on the road for 48 hours without sleep and kept awake by taking amphetamines. A bottle containing 17 tablets of "Amphetamine Sulfate" was found in the demolished cab, and the laboratory found amphetamines in the blood stream of the dead driver.

We were able to place our investigators in these small Texas, Arkansas and Georgia towns to detect the violations. Surely the situations were known to the local authorities, local medical societies

and perhaps even to the state licensing boards. But nothing was done. This is an area that cries out for all our efforts as a life saving measure.

The local attitudes were that nothing could be done; that the local prosecutor would not prosecute and a local jury would not convict. We don't believe it.

We think what is required is motivation. If the local authorities are mindful of the grave dangers, they will be determined to stamp them out. It can be done. We have yet to lose one of these cases when the problem was laid bare before the court and jury. **[The End]**

CONSUMER PROTECTION

The kind of consumer protection which should be provided by the Food and Drug Administration in years immediately ahead will be studied comprehensively by a new Citizens Advisory Committee named recently by Abraham Ribicoff, Secretary of Health, Education and Welfare.

The 16 member committee is headed by Dr. George Y. Harvey, Lecturer in Political Science and Consultant in Community Development at the University of Missouri. From 1948 to 1955, Dr. Harvey was staff director of the House Appropriations Committee of Congress.

Secretary Ribicoff said the committee will make recommendations regarding the steps which the Food and Drug Administration should take to insure adequate protection to citizens in their use of foods, drugs, therapeutic devices, cosmetics and household chemical products, all of which are subject to regulation under laws enforced by the FDA. The retail value of such articles moving in interstate commerce is estimated to exceed $100 billion each year.

The study will be conducted as a new appraisal of problems of consumer protection under the Federal Food, Drug, and Cosmetic Act, rather than as a continuation of a study made by a similar Citizens Advisory Committee in 1955.

The major recommendation of the 1955 committee was a three-to-four fold expansion of the FDA, to be accomplished in five-to-ten years. Since that time the FDA staff has been approximately doubled in size. At the same time a number of important new laws have been enacted, placing additional responsibilities upon the agency.

In announcing the new committee Secretary Ribicoff said:

"Tremendous developments in the fields of science and technology daily present new challenges to those charged with safeguarding the consumer. It is time for another group of responsible citizens to take a new look at what the Federal Government, through the Food and Drug Administration, should do to assure consumers of truly adequate protection. We need a new evaluation of the amount and kind of protection, the changes that may be needed to get it, and the time it will take to reach the desired objectives. This is a difficult assignment, but I am confident that this committee has the necessary experience and ability to carry it out."

Current Status of the Federal Hazardous Substances Labeling Act

By IRVIN KERLAN, M.D. and SAM MOLINAS, Ph.D.

This Paper Was Presented at the Annual Meeting of the American Association of Poison Control Centers, in Chicago, Illinois, October 3, 1961.

THE FEDERAL HAZARDOUS SUBSTANCES LABELING ACT, signed by the President on July 12, 1960, became operative in part in February 1961, and will be fully effective on February 1, 1962.

Regulations implementing the statute were published in the Federal Register of August 12 of this year to go into effect on February 1, 1962.

This law was enacted primarily because of the efforts of the medical profession, the Food and Drug Administration, and various chemical and manufacturing associations who realized the significant need for precautionary labeling on the many potentially dangerous household articles which were not subject to the provisions of existing statutes, such as the Federal Caustic Poisons Act of 1927, the Food Drug and Cosmetic Act of 1938, or the Federal Insecticide, Fungicide and Rodenticide Act of 1947.

The need for this legislation became more and more apparent as many potentially hazardous chemical products, such as silver, floor and furniture cleaners, were introduced into the home through the great advances made in chemical technology, and with the advent of the urge to "do-it-yourself" which occurred after World War II.

Included among such articles are a wide variety of cleaners, floor and furniture polishes, dry cleaning agents, paint solvents and thinners, rust removers and specialty products containing old and

new hazardous chemicals. Many of these hazardous articles did not bear precautionary labeling which is necessary to provide consumer protection, particularly against accidental poisoning in children.

These products though extremely useful in and around the home under ordinary circumstances can, when swallowed or mishandled, result in severe illness, permanent damage or death.

The Federal Hazardous Substances Labeling Act prohibits the interstate shipment of misbranded packages of hazardous substances. The primary purpose of this law is to protect the public health, particularly that of young children, by establishing adequate labeling for hazardous substances which are packaged, distributed and sold in containers that are suitable or intended for household use.

The purposes of the labeling requirements of this Act are to inform the purchaser and user of the hazards which may be encountered, to prescribe adequate precautionary measures, to inform the physician and others of the composition of a hazardous product, and to provide adequate first-aid measures when necessary.

Criteria Employed To Determine Hazard

The criteria which must be employed in determining whether a product is a hazardous substance subject to the provisions of this statute are (1) is it in a container suitable or intended for household use, and (2) is it a substance or mixture of substances which is (a) toxic, (b) corrosive, (c) an irritant, (d) a strong sensitizer, (e) inflammable, or (f) generates pressure through decomposition, heat, or other means, if such substances or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

Substantial personal injury or illness has been interpreted in the regulations as meaning any illness or injury of a significant nature. It need not be severe or serious. What is excluded by this word is the wholly insignificant or negligible injury or illness.

The reasonably foreseeable handling or use mentioned in the statute includes the potential accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household especially children. The criterion which is to be employed in determining whether a container is suitable or intended for household use is whether it may be found in or around a dwelling or any related building. This includes the garage, carport, barn and storage shed.

Articles such as polishes or cleaners that are designed for professional or technical use can be expected to come into the household when because of the do-it-yourself urge they are found in hobby shops and other retail stores for nonprofessional purposes. Such products will be considered as being available for household use and should be appropriately labeled.

Industrial supplies which are labeled and marketed solely for industrial use will not be subject to the provisions of the Act though it is possible that some of these articles, or portions thereof, may find their way from an industrial site or plant into the home.

Although highly toxic, extremely flammable and flammable substances are defined in the Act in terms of specific test procedures, the various classes of hazardous substances are defined only in general terms. Further definitions and specific test methods for these classes of hazardous substances are contained in the regulations which are to become effective on February 1, 1962.

A toxic substance is defined in the Act as any substance which has the capacity to produce personal injury or illness to man through ingestion, inhalation or absorption through any body surfaces.

It is provided in the statutory definition of highly toxic substances that should the Secretary find that the available data on human experience with any substance indicate results different from those obtained on animal, the human data shall take precedence.

A highly toxic substance by ingestion is defined as one which will produce death in half or more than half of a specified number of white rats at a single oral dose of 50 mg/kg.

A toxic substance by ingestion is defined in the Regulations as one which will produce death in half or more than half of a significant number of white rats at a single oral dose of more than 50 mg/kg but not more than 5 gm/kg.

The Regulations also provide that substances 500 mg—5 gm/kg of body weight will be considered for exemption from some or all of the labeling requirements of the Act under Section 191.62, upon a showing that, because of the physical form of the substances (solid, a thick plastic, emulsion, etc.), the size or closure of the container, human experience with the article, or any other relevant factors, such labeling is not needed.

A corrosive is defined in the statute as a substance which when in contact with living tissue will cause destruction by chemical action.

This definition is amplified in the Regulations where it is defined as a substance that causes visible destruction or irreversible alteration in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. The Regulations also provide a laboratory procedure for determining corrosive substances on animals.

An irritant is defined in the law as any substance which is not corrosive but which on immediate, prolonged or repeated contact with normal living tissue will induce a local inflammatory reaction. This term by regulation is interpreted as including "primary irritant to the skin" as well as substances irritant to the eye and to mucous membranes.

The Regulations go on to define primary irritant and irritant to the eye mucosa on the basis of available data by human experience and a specific animal test.

A general definition of a "strong sensitizer" is given in the Act. It is further defined in the Regulations as a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Secretary. Before designating any substance as a strong sensitizer, the Secretary, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity. Before a substance is a strong sensitizer within the meaning of the statute, it must be so designated by the Commissioner through regulation. In making his designation the Commissioner must consider the frequency of occurrence and severity of reaction in his finding that a material has a significant potential for producing sensitization. Either the frequent occurrence of a relatively minor sensitization or the occurrence, though relatively infrequent, of a severe reaction is sufficient to provide a basis for classifying an article as a "strong sensitizer."

The following have been declared in the Regulations to be strong sensitizers:

(a) Paraphenylenediamine and products containing it.

(b) Powdered orris root and products containing it.

(c) Epoxy resins systems containing in any concentration ethylenediamine, diethylenetramine, and diglycidyl ethers of molecular weight of less than 200.

(d) Formaldehyde and products containing 1 per cent or more of formaldehyde.

(e) Oil of Bergamot and products containing 2 per cent or more of Oil of Bergamot.

Under the Regulations it is also provided that reliable data on human experience will be taken into account in determining whether an article is a "hazardous substance" within the meaning of the Act. As mentioned earlier, it is further provided that where the human experience data differs from the results with animal data the human experience takes precedence.

Labeling Requirements

Articles subject to provisions of this Act are required to bear a label which states conspicuously (a) the name and place of business of the manufacturer, packer, distributor or seller; (b) the common or usual name, or if none exists, the chemical name of the hazardous substance; (c) the signal word "Danger" on substances which are extremely flammable, corrosive, or highly toxic; (d) the signal word "Warning" or "Caution" on all other hazardous substances; (e) an affirmative statement of the principal hazard or hazards, such as "Flammable," "Vapor Harmful," "Causes Burns," "Absorbed Through Skin" or similar wording descriptive of the hazard; (f) precautionary measures describing the action to be followed or avoided; (g) instruction, when necessary or appropriate, for first aid treatment; (h) the word "Poison" for any hazardous substance which is highly toxic; (i) instructions for handling or storage of packages which require special care in handling or storage; and (j) the statement "Keep Out of the Reach of Children" or its practical equivalent. A highly toxic substance is also required by regulation to exhibit the skull and crossbones symbol.

With one exception, the Federal Caustic Poison Act is to be repealed when this statute becomes effective on February 1, 1962, but those corrosive substances which were covered by this statute and in the concentrations listed in that law will be subject to the provisions of the Federal Hazardous Substances Labeling Act and will, by regulation, bear on their label the word "Poison" instead of a signal word. The Caustic Poison Act still remains in effect in respect to any dangerous caustic or corrosive substance that is subject to the Federal Food, Drug, and Cosmetic Act.

On the basis of human experience as reported in scientific literature by Poison Control Centers, the National Clearing House of Poison Control Centers and upon the advice of medical and scientific experts, the following substances have, by regulation, been declared to be hazardous substances that are required in the interest of the public health to bear conspicuously specific label statements:

(a) Carbon tetrachloride and mixtures containing it. Because of the general systemic poisoning that may result from ingestion or inhalation of the vapors of carbon tetrachloride and mixtures containing it, the labels of such articles are required to bear the signal word "Danger," the word "Poison," and the skull and crossbones. The statement of hazard shall include "May be fatal if inhaled or swallowed," and "Avoid contact with flame or hot surface."

(b) Diethylene glycol including mixtures containing 10 per cent or more of diethylene glycol by weight;

(c) Ethylene glycol including mixtures containing 10 per cent or more of ethylene glycol by weight. The labels on articles containing these glycol substances (including mixtures in the percentages listed above) are required to bear, because they are commonly marketed, stored and used in a manner increasing the possibility of accidental ingestion, the signal word "Warning." For ethylene glycol, the statement of hazard "Harmful or fatal if swallowed" is required, and for diethylene glycol the statement of hazard "Harmful if swallowed."

(d) Methyl alcohol including mixtures containing 4 per cent or more by weight of this substance. Because blindness and death may result from the ingestion of products containing methyl alcohol, the labels of such articles are required to bear the signal word "Danger," the word "Poison," the skull and crossbones symbol; and the statements of hazards "Vapor Harmful," "May be fatal or cause blindness if swallowed," and "Cannot be made nonpoisonous."

(e) Petroleum distillates such as kerosene, mineral seal oil, naphtha, gasoline, benzine, mineral spirits, paint thinner, Stoddard solvent and related petroleum distillates and mixtures containing 10 per cent or more by weight of these distillates.

(f) Turpentine including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine and destructively distilled wood turpentine and mixtures containing 10 per cent or more of these substances. Since turpentine and petroleum distillates (including mixtures) on ingestion result in systemic poison-

ing and are also hazardous because of aspiration into the lungs with resultant chemical pneumonitis, pneumonia and pulmonary edema, articles containing these materials in a concentration of 10 per cent or more are required by regulation to bear the word "Danger" as well as the statement of hazard "Harmful or fatal if swallowed." In addition it is required that the labels for products containing kerosene and related petroleum distillates bear the first aid instruction "Do not induce vomiting."

The Regulations also require that the signal word, the statement of the principal hazard or hazards and instructions to read carefully any cautionary information that may be elsewhere on the label appear together on the *main* panel of the label. The signal word, the statement of hazard shall be in capital letters. In order to be displayed conspicuously the signal word and the word "Poison" are required to be of a size bearing a reasonable relationship to the other type on the main panel, but cannot be less than 18 point type. The statement of hazard cannot be less than 12 point type, unless the label space on the container is too small to accommodate such type size. The other items of label information required by the statute or by regulation may appear on the main panel, but if they do not, they must be placed together in a distinctive place in proximity to the directions for use. The type size required for this additional information can be no smaller than ten point type unless the available space requires reduction, in which event it may be reduced, but no smaller than necessary and in no event smaller than six point type.

Economic poisons, subject to the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, and foods, drugs and cosmetics subject to the Food, Drug and Cosmetic Act are exempt from the provisions of the Federal Hazardous Substances Labeling Act.

The Federal Hazardous Substances Labeling Act and the Regulations authorize exemption of specific substances from full label compliance when because of the size of the package, or the minor degree and hazard presented, public health protection does not require full compliance.

In order to remove offending articles from commerce the law provides for criminal actions against responsible persons, the seizure of misbranded containers of hazardous materials and for injunctions to restrain violations of the Act. It authorizes the Food and Drug Administration to make factory inspections, to secure records of

interstate shipments, to issue publicity concerning actions taken under this law and to regulate imports.

As mentioned earlier, the Act became effective upon date of enactment, July 12, 1960, but six months was allowed before seizure or criminal actions could be instituted. Authority was given to the Commissioner of Food and Drugs to extend this effective date for one year if this was necessary.

The Act became fully effective for highly toxic, extremely flammable and flammable substances (excluding flammable solids) on February 1, 1961. The Act and the final Regulations will be fully effective on February 1, 1962.

With voluntary compliance by purveyors of articles containing hazardous substances, protection of the health of the public will be provided. With the full cooperation of professional health workers great strides will be made in the protection of the public in an area which is controlled for the first time. **[The End]**

STATEMENT REQUIRED BY THE ACT OF AUGUST 24, 1912, AS AMENDED BY THE ACTS OF MARCH 3, 1933, JULY 2, 1946 AND JUNE 11, 1960 (74 STAT. 208) SHOWING THE OWNERSHIP, MANAGEMENT, AND CIRCULATION OF

FOOD DRUG COSMETIC LAW JOURNAL published monthly at Chicago, Illinois, for October 1, 1961.

1. The names and addresses of the publisher, editor, managing editor, and business managers are:

Publisher: Commerce Clearing House, Inc., Chicago 46, Illinois.

Editor: Henry L. Stewart, Chicago 46, Illinois.

Managing Editor: George H. Harris, Chicago 46, Illinois.

Business Manager: James L. Jones, Chicago 46, Illinois.

2. The owner is: (If owned by a corporation, its name and address must be stated and also immediately thereunder the names and addresses of stockholders owning or holding 1 percent or more of total amount of stock. If not owned by a corporation, the names and addresses of the individual owners must be given. If owned by a partnership or other unincorporated firm, its name and address, as well as that of each individual member, must be given.) Commerce Clearing House, Inc., Chicago, Illinois; C. T. Corporation System, Wilmington, Delaware; The Corporation Trust Company, (Del.), Wilmington, Delaware; The Corporation Trust Company, (N. J.), Jersey City, New Jersey; The Corporation Trust Company, (N. Y.), New York, New York; Eddy & Company, New York, New York; The Millbrook Tribute Garden, Inc., Millbrook, New York; Margaret Thorne Parshall, Millbrook, New York; Justus L. Schlichting, Toms River, New Jersey; Bertha Palmer Thorne, Bedford Village, New York; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York.

3. The known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages, or other securities are: (If there are none, so state.) None.

4. Paragraphs 2 and 3 include, in cases where the stockholder or security holder appears upon the books of the company as trustee or in any other fiduciary relation, the name of the person or corporation for whom such trustee is acting; also the statements in the two paragraphs show the affiant's full knowledge and belief as to the circumstances and conditions under which stockholders and security holders who do not appear upon the books of the company as trustees hold stock and securities in a capacity other than that of a bona fide owner.

5. The average number of copies of each issue of this publication sold or distributed, through the mails or otherwise, to paid subscribers during the 12 months preceding the date shown above was: (This information is required by the act of June 11, 1960 to be included in all statements regardless of frequency of issue.) 1,091.

Henry L. Stewart
(Signature of editor, publisher, business manager, or owner)

Sworn to and subscribed before me this 29th day of September, 1961.

[Seal] Seymour Matin
(My commission expires March 10, 1964)

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

October Report of Drug and Device Seizures.—Twenty-six Federal Court actions were taken against drugs and devices in the month of September.

Typical of products involved in eleven seizures charging false and misleading label claims were such products as:

Mavene Wafers "for the treatment of stomach and duodenal ulcers."

Moulinex Electric Grinder Blender to prepare foods "for overcoming tension and anxiety, increasing strength, endurance and energy, and creating a rich, red, powerful bloodstream."

Biotta Lacto-Carrot Juice (and celery and beet juice) for cancer, rheumatism, improper blood pressure, cardiac conditions and many others.

Virilon Hair Follicle Cleanser for growing thick hair and healthy scalp and overcoming male pattern baldness, etc.

"Delamer Minerals in Solution" (sea water) for driving toxins out of the body, delaying aging processes, etc.

Abunda Hydro Massage Bosom Beauty "for awakening and increasing bosom beauty, encouraging bosom perfection," etc.

Audivox Electrostatic Precipitator, for removing germs and protecting the family from peritonitis, broncho-pneumonia, meningitis, scarlet fever, smallpox, measles, tuberculosis and other diseases.

Other seizures involved amphetamine drugs dispensed by a physician and a chiropractor outside their professional practice, a medicated turkey feed containing a dangerous amount of 4-nitrophenyl-arsonic acid, and repackaged physicians' samples offered for sale without the safeguards which the law requires. By the end of September, 37 seizures of physicians' samples had been made of which nine are being contested.

Food Seizures.—Approximately 173 tons of contaminated food were seized in 23 actions.

Filth and decomposition accounted for the bulk of the food seizures (155 tons), and the treatment with pesticide chemicals—captan and heptachlor—caused the seizure of 17 tons of milo maize.

Nonpermitted colors, unsafe for use in foods, were found in cake mix combinations and coconut oil.

Fifty-four tons of seized foods were unfit for human consumption, including bulk wheat containing charred, burned, or scorched kernels; insect infested popcorn, beans, almonds, cashew nuts, flour and rice; decomposed butter, fish, dog food and luncheon meat; and pickles and cereal for sausage filler prepared and packed under insanitary conditions.

Economic cheats included shortweight foods and foods with inaccurate, incomplete or inconspicuous quantity statements. For example, strawberry twists, packed in clear cellophane bags, had the obligatory statements printed in ink similar to the color of the candy in the bag, making the statements almost invisible. Canned mushrooms did not comply with standard regulations for fill of container, and a dietary supplement failed to declare accurately its vitamin and mineral properties.

Ready Now . . . the All New

1962 U. S. MASTER TAX GUIDE

"America's Number One Tax Book"

- *Reflects All New 1961 Federal Tax Law Changes from Cover to Cover*

Anyone who needs a handy desk or brief-case tax aid for quick, ready reference will welcome this brand-new CCH publication.

Not only does the MASTER TAX GUIDE explain the basic rules affecting business or personal income tax questions, it also protects you against overpayments and costly mistakes in year-end tax planning. Here you have clear-cut examples—based on typical tax situations—to illustrate the explanations. Moreover, the GUIDE is eager to assist in the preparation of 1961 income tax returns to be filed in 1962 and in handling everyday federal tax problems all through the months ahead.

Based on the Internal Revenue Code—as amended through 1961—Regulations, controlling Court and Tax Court decisions, the 1962 U. S. MASTER TAX GUIDE is a compact source of tax facts and figures immediately useful in working out sound answers to tax problems.

Leading the field, the GUIDE is the highly polished product of more than forty years' experience in federal tax reporting. Completely dependable, it's produced by the seasoned CCH editorial staff which makes CCH publications the standard for measurement

As a convenient desk tool . . . it can't be beat. So don't let tax 'puzzlers" beat you, when you can have 464 pages of top-flight tax help for only $3 a copy. Fill in and Mail the attached Order Card TODAY! Yours will be one of the first-press copies—for that wanted "head start" on year-end tax planning.

HARD BOUND EDITION

The 1962 U. S. MASTER TAX GUIDE is also available in a handsome, hard bound permanent edition. Contents are identical to the paper-covered edition, but hard bound (two color, gold-stamped covers) for permanent reference. Price, $8.50 a copy.

A COMMERCE CLEARING HOUSE PUBLICATION

BUSINESS REPLY MAIL

NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY–

CCH PRODUCTS COMPANY

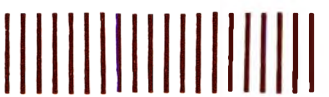
4025 W. PETERSON AVE.

CHICAGO 46, ILL.

ORDER CARD

For Prompt Delivery,
MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.



Card for Ordering Your Copies

1962 U. S. MASTER TAX GUIDE

CCH PRODUCTS COMPANY
4025 W. Peterson Ave., Chicago 46, Ill.

Rush ..... copies of 1962 U. S. MASTER TAX GUIDE (2101) at prices quoted below, plus small charge for postage and packing. (When remittance in full accompanies order, CCH pays postage and packing.)

1-4 copies $3.00 ea. 10-24 copies $2.40 ea.
5-9 copies $2.70 ea. 25-49 copies $2.00 ea.

☐ Quote prices on larger quantities with our imprint

Also send ... copies of U. S. MASTER TAX GUIDE *Hard Bound Edition* at $8.50 per copy.

☐ Remittance herewith ☐ Send bill

Signature & Title .....

Firm .....

Attention .....

Street & Number .....

2101—1071

City, Zone & State .....

Subscribers for CCH's Standard Federal Tax Reports and Current Law Handybooks receive the paper bound edition. They should order only for extra copies.