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Food Drug Cosmetic Law JOURNAL

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

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

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FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . October, 1965

VOLUME 20 NUMBER 10

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Latin-American Food Code. — The first five chapters of the *Latin-American Food Code,* translated by *Ann M. Wolf* of New York, appeared in the September issue of this journal. In this issue, beginning on page 544, Chapters XII and XIII, dealing with aqueous beverages and other refreshing products, respectively, and definitions and regulations concerning them, are published. Other chapters will be published in later issues.

Federalism in Consumer Protection: Conflict or Coordination?—In this article, beginning on page 569, *H. Thomas Austern,* a member of the District of Columbia Bar, discusses the problem of federalism in consumer protection. He analyzes the federal and state roles in consumer protection and divides the areas of needed regulatory activity into the following — environmental sanitation, safety of food and drug composition, and economic regulation. It is the author's belief that the problem of federalism may soon cease to exist, and that although in some areas the federal regulations will be paramount, there will always be an important role for the states.

Developments in the European Economic Community-Food Legislation.— *J. P. K. van der Steur,* a member of the Food Law Advisory Committee, nominated by the Queen (Holland), and an advisor to the Council of Dutch Employers Organizations for Food Law Problems, is the author of this article which begins on page 581. He feels that the reason food legislation in the European Economic Community is developing at a very slow pace is because the countries concerned have divergent interests. This develops from differences in the climate and the habits adapted to it, the development of trade and industry, and the mentality of the population. Also, in some cases the food legislation does not only serve to protect public health and to promote business integrity, but often to realize the economic wishes of a country or of an industry. Mr. van der Steur discusses adopted directives and directives that are being debated.

Consolidating State and Federal Regulatory Power Over Food and Drugs.— Starting on page 587, *David E. Engdahl,* legislative analyst at the Legislative Research Center, University of Michigan Law School, and a member of the Michigan Bar, discusses the need for uniformity in the regulation of the food and drug industries, and for close coordination between enforcement efforts at the federal, state and local levels. In his opinion, a federal-interstate food and drug compact may assure some degree of this uniformity and coordination.

The Mathematical, Legal and Chemical Concepts of Zero.—The concept of zero is the topic of this article which begins on page 597. The author, *Bernard L. Oser,* the JOURNAL's Scientific Editor, discusses the different meanings that are applied to the term "zero" and how these meanings depend upon the context in which the term is used. He also analyzes the practical significance of the "zero level" concept as applied to the prohibition of toxic substances in foods and agricultural commodities.

Vol. 20, No. 10 October, 1965

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Journal

Latin-American Food Code 1964 Edition

In August, 1964, the Latin-American Food Code Council published the Second Edition of the Latin-American Food Code. Information concerning the Code and the Table of Contents of the new edition appeared in the April 1965 issue of the Food Drug Cosmetic Law Journal (Vol. 20, page 238). The first five chapters were published in the September 1965 issue. Chapters XII and XIII follow below. The translation is by Ann M. Wolf of New York City.

Chapter XII: Aqueous Beverages

Waters

Article 435.—The term "potable water" means any water which is suitable for drinking and for domestic uses. Potable water shall be colorless, clear, odorless, pleasant to the taste, and aerated. To classify the water of a certain area, the water naturally occurring in the same shall be taken as a basis. The bacteriological analysis shall not reveal the presence of pathogenic bacteria. The ratio between counts on gelatine plates at 22° C. and on agar plates at 37° C. shall be 10, or more, to 1, and 100 ml. of water may contain a total of 2 bacteria of the B. coli group, but no organisms of the coliform group of fecal origin. The chemical analysis shall not reveal more than 5 p.p.m. of zinc (Zn); 1.2 p.p.m. of fluoride (F); 0.5 p.p.m. of lead (Pb); 0.05 p.p.m. of vanadium (V); 0.3 p.p.m. of iron (Fe); 0.2 p.p.m. of arsenic (As), copper (Cu) and manganese (Mn). Potable water may contain salts in a total amount not exceeding 1½ grams per liter and phosphorus (P_2O_5) in an amount not exceeding 0.5 to 1.0 p.p.m., depending upon the land.

The hardness expressed as calcium carbonate ($CaCO_3$) shall not exceed 300 p.p.m., and the alkalinity, likewise expressed as calcium carbonate ($CaCO_3$), shall not exceed 50 p.p.m.

Running water from public water supply systems shall not only meet the foregoing requirements, but in addition shall have a pH of not less than 6.8. Its active chlorine content may not exceed 0.2 p.p.m.

With regard to the radioelements of the uranium and thorium series that may be found in drinking water, the following limits are permitted expressed as muCi per liter: U^{238}—2; Th^{231}—1; Ra^{226}—0.04; Rn^{222}—0'1; Pb^{210}—.000.

By way of exception, waters with a pronounced salty taste found in certain areas, whose use for domestic purposes has certain drawbacks because of their hardness, shall be permitted to be used as mediocre or average quality potable waters, provided that they do not contain harmful substances, impurities or elements which show that they are contaminated, and provided further that their salt content does not exceed three grams per liter, that their fluoride content does not exceed 1.5 p.p.m. and that they meet all the chemical specifications stated hereinbefore.

Whenever the health authorities consider it advisable they may order drinking water to be purified or treated by such processes as they deem adequate.

Article 436.—In general, surface waters and shallow well waters may not be used as sources of drinking water, except in areas where the deep well water is considered not potable or where pumping is so costly that the expense is out of proportion to the uses for which the water is intended. In such cases the use of surface waters from rivers or lakes may be authorized by the health authorities on conditions which assure their potable properties.

Where it is impossible to obtain naturally occurring water suitable for consumption, the health authorities shall enforce the use of devices that render the water potable; they may also permit potable water to be shipped from other areas, or the consumption of rainwater collected in adequate vessels.

All owners of residential buildings, houses for rent and commercial or industrial establishments shall have to provide enough potable water to satisfy the requirements. The water distribution system shall be installed and operated with the approval of the health authori-

ties. All such owners shall also have to install toilet drainage pipes approved by the health authorities. At locations which have no public sewers, but do have flush water closets, the pipes from the latrines must lead to septic tanks, or another type of installation, for preliminary treatment.

When lots are parcelled for the construction of residential buildings their owners shall, prior to parcelling, secure from the health authorities an official certificate which proves the existence and accessibility of potable water on the land to be parcelled. Said certificate must be filed with the agency which is to approve the parcelling and be mentioned in all advertisements directed to the property.

Article 437.—The terms "mineral table water," "dietetic water," "natural water" (X . . . water) and any other terms that indicate the geographic origin of a drinking water may be used only to designate waters originating from deep or endogenous wells which surface uncontaminated, can be caught and bottled easily at the site at which they surface, contain zinc, arsenic, lead and copper in amounts not exceeding those fixed in Article 435 hereof and at 180° C. have a residue of not more than 1 gram per liter, with the understanding that a residue of 1.5 grams per liter may be tolerated when the sodium bicarbonate content is ½ gram per liter, but not more.

Article 438.—The term "medicinal mineral water" means any oligometallic or mineral water which, surfacing free from bacterial contamination, because of its physical, physicochemical or chemical properties, the gases dissolved in it, or other factors, is suitable for therapeutic uses and has been approved by the competent health authorities.

Article 439.—Mineral table waters and medicinal mineral waters may be treated to remove the iron, manganese, sulfur, arsenic, vanadium or fluoride present in them. They may also be carbonated. The labeling of any waters so treated shall bear a statement to that effect.

Article 440.—To name and classify mineral waters the following criteria and limits shall be used as a basis:

1. *Mineralization:* Depending on the residue per liter at 180° C., waters are classified into the following groups:

Oligometallic waters: Waters with a mineral content of less than 0.10 grams per liter.

Waters of very low mineralization: Waters with a mineral content of between 0.11 and 0.25 grams per liter.

Waters of low mineralization: Waters with a mineral content of between 0.26 and 0.50 grams per liter.

Waters of median mineralization: Waters with a mineral content of between 0.51 and 1.50 grams per liter.

Highly mineralized waters: Waters with a mineral content of more than 1.51 grams.

Waters of marine and supermarine mineralization: Waters with a saline concentration equal to or exceeding that of sea water.

2. *Thermal Classifications:* Depending upon the temperature which the water has upon surfacing, waters are classified into the following groups:

Athermal waters: 0° to 20° C.
Hypothermal waters: 21° to 30° C.
Mesothermal waters: 31° to 40° C.
Hyperthermal waters: Above 40° C.

3. *Isotonic Properties:* Depending upon the osmotic pressure compared with the saline serum of 9.5 o/oo of sodium chloride, waters are classified into:

Hypotonic waters ..... concentration less than 325 millimoles per liter

Isotonic waters ..... concentration at 325 millimoles per liter

Hypertonic waters ..... concentration more than 325 millimoles per liter.

4. *Minimum Values* required for the following classifications:

Acid water: Water the free CO_2 content of which exceeds 0.25 grams per liter, i.e. 125 ml. per liter.

Alkaline water: Water the pure alkali content of which, expressed as H_2SO_4, exceeds 0.12 grams per liter.

Arsenic water: Water the arsenic (As) content of which exceeds 2 p.p.m.

Barium water: Water the barium (Ba") content of which exceeds 5 p.p.m.

Borated water: Water the metaboric acid (HBO_2) content of which exceeds 4 p.p.m.

Bromide water: Water the bromine (Br') content of which exceeds 4 p.p.m.

Strontium water: Water the strontium (Sr") content of which exceeds 10 p.p.m.

Iron water: Water the iron (Fe" or Fe"') content of which exceeds 5 p.p.m.

Fluoridated water: Water the fluoride (F') content of which exceeds 2 p.p.m.

Radioactive water: Water which has a fixed radioactivity, or a radioactivity with an extended half-life of 0'005 muCi/l. or higher, or induced radioactivity, or a radioactivity with a short half-life at 0'1 muCi or higher. Waters are called "highly radioactive" when their radioactivity exceeds 1 muCi/l.

Sulfurous water: Water which contains hydrosulfide, thiosulfide, or free sulfurated hydrogen ions.

Subthermal water: Water the temperature of which is above 14° C. and below 20° C.

Thermal water: Water the temperature of which is above 20° C.

Iodine water: Water the iodine (I') content of which exceeds 1 p.p.m.

The name "mineral water" may be used only for natural (table or medicinal) waters, but may not be used to designate or distinguish artificial saline solutions. The latter shall be named: "artificial mineral waters."

Artificial mineral waters are prohibited from being designated by names referring to natural mineral water springs or localities at which such springs are situated.

Article 441.—When the ephemeral qualities of a water (thermal properties, radioactivity, etc.) are stated on labels, in pamphlets, announcements, business stationery and advertising media, such statements must indicate clearly, and in a manner not capable of causing confusion or deception, that said properties are those of the water as it surfaces from the spring, not as it is sold in bottles.

References to physical, physico-chemical, chemical or bacteriological findings, or to possible physiological and therapeutical appli-

cations may appear in labels, announcements, posters and other advertising matter only if they come from an official scientific agency, the inclusion in labels, announcements and advertisements of findings coming from private sources being prohibited.

Article 442.—Establishments which catch and sell mineral waters are obligated:

1. To assure the protection of the spring;

2. To carry out the filling and other operations only at the site of the spring, unless the spring water is carried through adequate pipes from the spring to the filling and bottling plant.

3. To provide a plant, plumbing, machinery, etc. that meet the requirements of this Code and all other pertinent regulations.

4. To maintain a laboratory equipped to control the physical, chemical and bacteriological properties of the water.

Carbonated Waters and Similar Products

Article 443.—The general term "carbonated water" means any of the following unfermented, nonalcoholic beverages saturated with carbon dioxide that meets the specifications fixed in Article 462 hereof:

1. Chemically and bacteriologically potable water (soda, siphon water, charged water, carbonated water, table water, soda water, seltzer water, aerated water). The addition to the water of sodium chloride (NaCl) and calcium chloride ($CaCl_2$), combined or separately, in amounts of up to 50 p.p.m. and the alkalization with bicarbonate of soda ($NaHCO_3$) in amounts not exceeding 2,000 p.p.m. shall be permitted without a declaration on the label.

In areas where the water is hard, it shall be softened before carbonation, and if it contains an excessive amount of fluoride, this condition shall be corrected.

2. Watery infusions of plants or parts of plants; watery solutions of vegetable juices, milk, whey, natural or artificial fruit extracts, to which the following substances may be added: sugars, honey, molasses, citric, tartaric, lactic, phosphoric, gluconic, and/or ascorbic acid, sodium citrate, essences, bitters and permitted coloring matters, plain and blended wines (lemonades, nonalcoholic beverages, tonic waters, refreshing soft drinks, apéritifs).

3. Nonalcoholic beverages prepared with natural fruit juices or fruit concentrates may contain sodium benzoate or potassium sorbate

in an amount of up to 0.6 grams per liter. Their carbon dioxide pressure may be less than 3 atmospheres.

Article 444.—Any plants which prepare carbonated waters, nonalcoholic beverages and similar products shall comply with the general rules established in this Code and, in addition, shall meet the following requirements:

1. They shall have at least one manufacturing room with a flat ceiling and a waterproof wainscot 1.80 meters in height; a storage room for containers, and next to it, a room in which containers are washed and sanitized; they shall be equipped with sinks made of masonry or a similar material, and with drainage pipes connected with the public sewers or special sewers, the discharge of waste water into public roads being prohibited; a storage room for raw materials, and a room for generators, power engines, steam engines, etc.

2. The driveway shall be paved, but where the street is unpaved, a base of stone or concrete measuring 4 square meters shall be required in front of the landing ramp.

3. On sites without running water, the well which supplies potable water for the preparation of beverages shall be at least 15 meters distant from the cesspool, which in turn shall be connected with a sedimentation chamber provided with a microbial filter.

4. The syrup and carbonated water pipes shall be made of a material authorized by the health authorities; tin-lined pipes shall not have fixed elbows; the saturators shall have control instruments and safety valves; all machines, utensils, cases, containers, vehicles and other devices used for the manufacture, distribution and transportation of the products shall be cleaned as often as necessary to assure their hygienic condition at all times and shall be kept in a perfect state of repair.

5. For soft drink bottles, the use of pressurized washing and rinsing machines and automatic crowners is compulsory. Foot-operated or hand-operated crowners may be used only in areas where no plants meeting the conditions of this Code are in existence and where it is impossible locally to obtain an automatic crowner.

Article 445.—Carbonated waters, nonalcoholic beverages and similar products which are manufactured, stored, exhibited, or sold shall meet the following specifications:

1. They shall be clear, free from sediments, suspended matter or foreign bodies, and shall have a normal color, odor and taste. Any

products not meeting these standards shall be confiscated immediately. By way of exception, beverages prepared with a base of fruit juices need not be clear and free from sediments, but may be opalescent and contain suspended particles coming from the fruit used. The artificial addition of such particles to products prepared from essences is categorically prohibited, however.

2. They shall contain carbon dioxide at a pressure of not less than three atmospheres.

3. They shall not contain alcohol in a proportion of more than 0.5 per cent by volume, or more than 500 p.p.m. of bromated vegetable oils, the bromine content of which may not exceed 35 per cent.

4. They shall not contain foreign bodies, drugs restricted to medicinal uses, or any substances the use of which is prohibited.

5. Manufacturers of carbonated water siphons and dealers who supply the public with such siphons shall check the condition of the siphons before making delivery to make sure that the glass is not cracked or impaired, the inside tube is not broken and the head does not leak.

Article 446.—Any syrups or extracts to be used in the preparation of lemonades, nonalcoholic beverages and similar products shall meet the following requirements:

1. They shall be prepared with sugar.

2. They shall not contain harmful aromatic extracts or prohibited essences, amyl alcohol, acetic acid, mineral acids (except phosphoric acid), saponins or other prohibited foam-producers, drugs restricted to medicinal uses, prohibited coloring matters and artificial sweeteners.

3. Their alcohol content is not permitted to exceed 5 per cent by volume.

4. They shall not show any traces of alteration and shall not contain fungi or injurious substances.

5. They shall not contain lactic acid in a proportion of more than 3 grams per liter.

Article 447.—The names "orangeade," "natural X . . . orange," "natural orange juice and soda," "soft drink with a base of natural oranges," "lemonade," "natural X . . . lemon," "grapefruit drink," "natural X . . . grapefruit" and similar or derivated names may be used only to designate nonalcoholic beverages the base of which consists of the natural juice of the fruit named (orange,

lemon, grapefruit, etc.), with or without sugar syrup and the essential oil of the fruit.

Artificial products shall be labeled clearly as "artificial." Any beverages prepared artificially by blending several fruit elements (essential oils, dried pulp, etc.) may not be advertised or sold as containing fresh or natural juice of oranges, lemons, grapefruits, etc.

Article 448.—The terms "tonic water," "soda tonic," "Indian tonic" and similar names mean refreshing beverages with a base of extracts or essences of lemons, grapefruits or other citrus fruits and plain carbonated water or carbonated mineral water, with or without the addition of sugars, which contain quinine or quinine salts in amounts of not less than three milligrams and not more than 15 milligrams per 100 ml., calculated as anhydrous quinine. None of their components need be declared in the labeling.

Article 449.—The term "ginger ale" means a refreshing beverage prepared with potable water, acidulated sugar syrup, water-soluble ginger extract, and carbon dioxide. The same product prepared with beer, or the light beer made from ginger extract and carbon dioxide, shall be called "ginger beer." Both types of beverage may be bottled in transparent, dark green glass bottles.

Article 450.—Any nonalcoholic beverages designated by the name "guaraná" shall contain the soluble principles of the seed of Paullinia cupana, Kunth and varieties thereof, and those designated by the names "coffee," "maté herb" and "tea" shall contain the soluble principles of Coffea arabiga, L. and other species of the same genus, of Ilex paraguariensis, Saint Hilaire or of different species of the genus Thea, respectively. These beverages shall contain not less than 3 milligrams and not more than 20 milligrams of caffeine (trimethylxanthine) per 100 milliliters and shall bear the designation "artificial" whenever they contain synthetic essences or extracts.

Article 451.—The preparation and sale of nonalcoholic beverages shall be permitted which have been prepared with products such as: catechu, sarsaparilla, kola nut, ginger, oranges or other citrus fruits, cinnamon, mace and other vegetable extracts, with or without the addition of aromatics permitted under this Code, sucrose, dextrose, invert sugar, caramel, phosphoric, citric, tartaric or gluconic acid and caffeine in a proportion not exceeding 20 milligrams per 100 milliliters, regardless of whether or not such beverages

are identified by distinctive names ("nombres de fantasia"). The presence of these ingredients need not be declared in the labeling. When such beverages contain artificial essences or extracts, they shall be marked "artificial," however.

Article 452.—The term "anapa" means an unfermented mixture of the pulp and seeds of the white carob bean (Prosopis alba, Griseb) and water, to which milk, jujubes (Zizyphus mistol, Griseb) and other authorized products may be added.

Article 453.—Plain carbonated water or soda and soft drinks shall be bottled in transparent glass containers and bear the required labeling which need not be blown into the glass, but may be placed on the crown cork which constitutes the principal label.

Any siphons manufactured after the entrance into effect of this Code on which the labeling is blown into the glass shall also bear the legend: "This container is not negotiable," or: "This container is not for sale," or a similar inscription. Any container used by a person other than its legitimate owner, or found in the possession of another manufacturer, shall be confiscated, except in the cases set forth in Article 458 hereof.

Containers for carbonated beverages shall be sealed in the following manner:

1. With caps of enameled earthenware or porcelain, provided with rings of rubber, cork or another authorized material, which shall be free from toxic impurities.

2. With metal caps of the type named "crown corks" which shall be made of nickel-plated metal or new varnished tin plate and shall have a disk of technically pure tin, good quality cork, or a suitable plastic.

3. With siphon caps (metal head) made of technically pure tin, or a tin alloy containing not more than 10 per cent of antimony and 3 per cent of copper, or another authorized material.

The outside parts of the metal heads shall be perfectly nickel-plated or chromium-plated, and the inside parts as well as the spout, valve and other parts that get into contact with the liquid shall be made of or coated with technically pure tin, or a tin alloy containing not more than 10 per cent of antimony and 3 per cent of copper, or another authorized material.

The coating shall be uniform and continuous, unpunctured, and more than 1 millimeter thick.

4. With heads made of plastic, artificial resin, derivatives of cellulose, casein or a similar authorized material which, when exposed to prolonged (24 hours) contact with carbonated water under a pressure of 10 atmospheres does not yield any substance of any kind.

Article 454.—Automatic siphons which operate on carbon dioxide capsules (sparklets, etc.) for on-the-spot preparation of carbonated waters and soft drinks shall meet the general requirements set forth in Article 453 hereof and, in addition shall have a protective metal grate or mesh. The capsules shall be made of acid-proof steel, the material used for the closing plate shall not contain harmful substances, and the carbon dioxide shall meet the specifications fixed in Article 462 hereof.

Article 455.—Carbonated beverages prepared with natural fruit syrups, fruit extracts, or fruit juices may be labeled with the name of the fruit, preceded or followed by the word "natural." The color of such natural fruit beverages may be reinforced with a permitted coloring matter, the addition of which need not be declared on the label. When such carbonated beverages contain artificial essences or extracts, they shall be considered artificial even if they also contain natural juices or extracts, and shall then be designated by the name of the fruit followed or preceded by the word "artificial."

Article 456.—Nonalcoholic beverages which contain artificial extracts or essences or have been prepared artificially with certain fruit elements are not permitted to be sold or advertised with false indications which may cause the reader to believe that they were prepared entirely from juice or natural fruits and juices. The labels, advertising matter and business papers used in connection with such beverages are not permitted to contain any design or graphic representation of or any reference to fruits or parts of fruits.

Article 457.—The caps of containers in which carbonated waters or nonalcoholic beverages are bottled shall indicate clearly the name of the product, even if, at the discretion of the manufacturer, labels bearing the same indications are affixed to the bottle.

Article 458.—Manufacturers are prohibited from possessing or using containers of other plants, or containers of their own on which their name or trademark is not clearly marked, or containers from which their name or trademark has been effaced by some process.

An exception to the foregoing prohibition may be made for containers, whose owners, having discontinued the preparation of the products originally bottled in the same, have authorized one manufacturer, or several manufacturers to use their containers or have sold the same to such other manufacturers, who shall then identify each container used or owned by them by engraving on the siphons* a serial number issued by the competent authority.

* Note of the Translator: I wonder whether this provision is meant to be limited to "siphons?"

The number of empty bastard siphons existing at plants and delivery vehicles is not permitted to exceed 5 per cent of the total stock of containers extant at the plant or vehicles of the particular manufacturer, and only on condition that the manufacturer is in a position to prove by means of the respective bordereaux that he exchanges them regularly. No limit exists for full bastard containers. Any containers found stored at places which do not belong to the plants owning them, or are being transported on vehicles not connected with said plants, shall be seized to be returned to their legitimate owners, while the penalties provided for by the law shall be imposed on the infringer.

Article 459.—Siphons and containers which are not perfectly safe and hygienic or have cracks or other dangerous defects are prohibited from being filled.

In all plants, warehouses, stores, bars, candy shops, hotels, restaurants and other outlets, the shelves and racks used for carbonated waters, soft drinks and similar products shall be kept perfectly clean and may not be installed at unsanitary or unsuitable places.

Article 460.—Stores, candy shops, bars, hotels, etc. which sell the consumers the kinds of beverages the preparation of which is regulated herein shall refuse acceptance from the manufacturer of any containers which fail to meet the requirements fixed herein or do not belong to the plant which sells them. Failure to do so shall constitute a violation of the law.

Article 461.—The installation of machines for the preparation of limited quantities of carbonated beverages shall require the approval of the competent authorities.

When the machines used to prepare limited quantities of carbonated water are installed in business establishments (stores, candy shops, wine shops, bars, hotels, etc.) not equipped with a gasometer or saturator and are operated in an area less than 32 square meters, but not less than 15 square meters in size, their owner may fill siphons on the premises only for his own consumption. For the sale of siphons and carbonated waters to the public, the provisions contained in Article 445 and related provisions must be complied with and a sufficient stock of containers must be kept. Business establishments which have soda machinery in their business are not permitted to store or use siphons of other manufacturers, regardless of whether the same are full or empty. Any violation of this provision shall be penalized by immediate confiscation of the siphons and a 30-day suspension of the license to prepare carbonated water, without prejudice to the imposition of other penalties.

Carbon Dioxide

Article 462.—The carbon dioxide or carbonic acid gas used in the manufacture of (nonalcoholic, alcoholic or other) carbonated beverages or to be added to beverages (such as beer) at the time of sale, shall meet the following specifications:

1. It shall contain carbon dioxide in a proportion of not less than 99 per cent and air in a proportion of not more than 0.1 per cent. (The sample will be drawn while the cylinder is in horizontal position.)

2. It shall not contain carbon monoxide in a proportion of more than 0.2 per cent.

3. It shall not contain any empyreumatic products or foreign, mineral or organic, substances (nitrogen dioxide, sulfur dioxide, hydrogen sulfide, etc.).

4. The odor and taste of the gas, as the odor and taste of the distilled water saturated with it, shall be agreeable and have the characteristics of the acid.

5. The steel tubes or cylinders used to carry the gas shall be able to withstand a pressure of 250 kilos per square centimeter, be painted on the outside and be labeled in accordance with the law.

Ice

Article 463.—The term "ice," used alone without any other definition, means the product which forms when still potable water freezes. It is opaque when in blocks, and translucent when in thin plates, turbid white or milky in appearance (dull or opaque ice; latent heat of fusion: 80 kilocalories per kilogram).

The term "semi-transparent ice" or "clear ice" means ice prepared from water which is chemically and bacteriologically potable, but has been mechanically agitated during the freezing process. This type of ice is transparent throughout, except in the central nucleus which is opaque.

The terms "crystal ice" and "sterile ice" mean a product prepared exclusively from distilled water from which the air has been removed. It shall be transparent throughout.

No type of ice may be named with the improper designation "chemically pure ice."

Article 464.—Ice factories shall possess separate processing and machine rooms; the two rooms may at times be combined for purposes of ventilation. The premises shall meet the general standards. In population centers where no running water is available, ice factories shall be provided with potable water storage tanks of a capacity sufficient to satisfy the needs of the establishment.

Article 465.—On ice delivery vehicles, and in invoices, announcements, advertisements, business stationery, etc., in which reference is made to ice, the type of ice shall be named clearly according to the manufacturing process used.

Any ice found in circulation or for sale which has been prepared under poor conditions or from contaminated water shall be destroyed forthwith.

Article 466.—The term "dry ice" or "carbonic snow" means solidified carbon dioxide the purity of which meets the standards fixed in Article 462 (Specific gravity: 1.1 to 1.5, depending upon the manufacturing process; temperature: minus 78.4° C.; the latent heat of fusion, including the cooling action of the cold gas produced, shall be equal to 158 calories per kilogram).

Article 467.—The term "eutectic ice" means solutions of sodium chloride or calcium chloride which were frozen at their eutectic point (minus 21° to minus 26° C.).

Chapter XIII: Other Refreshing Products

Syrups

Article 468.—The general term "syrup" means any solution in potable water of sugars, honey or molasses, to which permitted aromatic extracts, alcohol, and citric, tartaric, lactic, phosphoric or gluconic acid may be added. Such syrups, as well as the solid products intended for the preparation of refreshing beverages and consisting of dehydrated vegetable juices or other substances which meet the requirements of this Code, may be called "refrescos."*

* Note of the Translator: "Refresco" is the Spanish term for both "refreshment" and "cold drink."

Article 469.—The name "syrup," combined with the name of the one or several predominant species of fruits used in the preparation, may be applied only to syrups consisting of sugar dissolved in solutions of fruit juices or extracts without the addition of foreign elements.

Syrups prepared with permitted artificial essences shall be designated as "artificial . . . syrup;" the name of the essence used shall be inserted.

Syrups to which a permitted coloring matter has been added shall be designated by their specific name accompanied by the word "colored."

Article 470.—The names listed hereinafter shall apply to the following products:

1. The name "syrup" alone, without any addition, means a solution of sugars in potable water. At 15° C. it shall have a density of not less than 1.30.

2. Natural fruit syrups (raspberry, strawberry, sweet cherry, pomegranate, red currant, pineapple, grape, etc.) shall be made with syrup and not less than 30 per cent of the natural juice of the fruit named, or an equivalent quantity of concentrated juice. Their natural color may be reinforced with an authorized coloring matter without a statement to that effect in the labeling. Their sodium benzoate or potassium sorbate content must correspond to the proportion of juice contained in the syrup.

3. The name "arrope" means a thick blackish syrup prepared from the juice of prickly pears.† "Arropes" prepared from the juices

† Note of the Translator: In Spain, "arrope" is grape juice boiled to the consistency of a thick syrup. In Latin America, the term when used alone applies to the prickly pear syrup listed here.

of other fruits shall be given the name of the fruit, such as "grape arrope," etc.

4. Coffee or mocha, guaraná, tea and maté syrups shall be prepared with percolations, infusions or extracts of coffee, guaraná, tea, and maté to which sugar has been added.

5. The name "capilé" means a syrup prepared from the juice of a decoction of maidenhair fern (Adiantum capillus veneris, L.) flavored with natural citrus essences, which may be colored with caramel.

6. The term "gum syrup" means a sugar syrup to which gum Arabic has been added in a proportion of not less than 20 grams per liter.

7. The term "grenadine" means a syrup prepared with sugars and permitted acids and colored and flavored with permitted substances.

8. The term "orgeat syrup" means a syrup consisting of sugars and almond milk, to which distilled water or natural essences may be added. If instead of almonds, "chufas" are used, the name shall be changed to "chufa orgeat." The preparation and sale of orgeat syrup made with benzoin and similar substitutes is specifically prohibited.

9. The terms "lime, lemon, grapefruit, cider, tangerine, and orange syrup" mean sugar syrups to which permitted acids and alcoholic extracts or extracts of the fruit named have been added.

10. The concentrated products sold for the preparation of orangeades, lemonades, etc. shall contain the natural juice of the fruit named in a proportion of not less than 80 per cent by volume.

11. The term "sarsaparilla syrup" means a syrup obtained by dissolving not less than 25 grams of sarsaparilla extract in 975 grams of sugar syrup.

12. The term "vanilla syrup" means a sugar syrup to which vanilla extract or tincture has been added.

13. The terms "granolina," "effervescent grains," "refresquina" and similar terms mean granulated mixtures consisting of organic acids and alkaline salts which comply with the requirements of the Pharmacopoeia, sugars and a permitted aromatic, to which a permitted coloring matter may be added.

Article 471.—The distribution, possession or sale of the following syrups shall be prohibited:

1. Syrups which contain essences considered harmful by the health authorities or the present Code; or mineral acids (except

phosphoric acid), resins, prohibited coloring matters, preservatives, prohibited foaming agents, artificial sweeteners or toxic metals.

2. Syrups which contain more than 5 per cent of alcohol by volume; more than 6 per cent of citric acid; 9 per cent of tartaric acid; 3 per cent of lactic acid, or more than 50 parts per million of hydrocyanic acid coming from the fruits or natural juices used in their preparation.

3. Syrups which show traces of spoilage, impurities, mould, or other foreign substances.

Article 472.—Fancy syrups made with sugars, with or without honey and aromatics, and with or without coloring matters, may be called: "artificial honey." Such syrups shall comply with the following requirements:

1. They shall not contain impurities or foreign substances and shall be in a good state of preservation.

2. They shall not contain more than 20 per cent of water, 1 per cent of mineral substances, and 0.5 per cent of acidity calculated as sulfuric acid.

3. They shall not contain unauthorized artificial essences, preservatives, sweeteners or coloring matters, or free sulfur dioxide in an amount exceeding 50 parts per million.

Vegetable Juices

Article 473.—The general term "vegetable juice" (juice of a fruit or vegetable) means the natural juice obtained by the first pressing of fresh whole fruits and vegetables with or without the application of heat. Certain juices may be left to ferment for a short time to improve their organoleptic properties (lemons, apples, grapefruits, etc.). Cloudy fruit juices to which sugar has been added are also called "nectars."

Article 474.—The term "pureed fruits" ("frutas disintegradas") means any product obtained by shredding and homogenizing whole fruits, or fruits from which the peel has been removed in whole or in part.

Article 475.—The premises on which vegetable juices and pureed fruits are prepared and sold to the public require the approval of the health authorities and shall be equipped with the necessary utensils, approved machinery (authorized

comminutors or liquefiers) and the minimum conveniences, a flat ceiling, waterproof floors, a sink with running water in which to wash the materials and a refrigerator in which to preserve fruits and vegetables.

A certain amount of sugar may be added to refrigerated fruit juices sold to ice cream parlors, milk bars and confectionery stores for the preparation or decoration of fancy frozen desserts (sundaes, Melba cups, etc.), provided that the sugar content is declared on the label. Such products shall be kept under refrigeration.

Article 476.—The term "... juice" preceded by the name of the species of fruit or vegetable from which the product was made may be accompanied by the adjective "fresh," provided that the juice has not been subjected to any physical stabilization process other than cold treatment, such as sterilizing filtration, pasteurization, or oligodynamic processes; the term may also be preceded by the adjectives "whole," "natural," or "genuine," provided that the juice has not undergone any alteration and that nothing has been added to or subtracted from it.

Any of the following physical or physico-chemical methods may be used to stabilize or preserve vegetable juices: cold treatment, sterilizing filtration, pasteurization, carbonation followed by sterilizing filtration, tyndallization, sterilization, stabilization by way of permitted oligodynamic processes, ultraviolet rays, the addition of sulfur dioxide, sodium benzoate or potassium sorbate in a proportion not exceeding 1 gram per liter, and any other processes and additions of additives first specially approved by the health authorities.

Fruit and vegetable juices may be mixed and concentrated to a certain degree, with a declaration of the concentration; but under no circumstances may the term "(such or such a fruit or vegetable) juice" be used for products obtained by the later dilution of such concentrated juices or for products obtained by processing the residue from the first pressing.

The color of a fruit juice may be reinforced with the color of another juice in a proportion not exceeding 10 per cent without declaring such addition in the labeling.

The name of a specific fruit or vegetable may not be used to prepare, distribute or sell products to which unauthorized additives or substances extraneous to said fruit have been added.

Article 477.—Bottled or canned vegetable juices (of grapes, apples, pineapples, grapefruits, oranges, limes, tomatoes, etc.) shall be stabilized or sterilized before they are sold. They shall not contain alcohol in a proportion exceeding 1 per cent by volume, and their alcohol content shall be declared on the label. Nor may they be in a state of fermentation (absence of live pathogens). They may contain only the acids, sugars and other elements found in the original product.

They may be carbonated with carbon dioxide, with a declaration to this effect, and may be sulfonated, provided that the amount of free sulfur dioxide retained in the juice does not exceed 50 parts per million and the total amount does not exceed 150 parts per million.

Concentrated juices to be consumed after their dilution in water may contain an amount of sulfur dioxide equivalent to the concentration, but not exceeding 600 parts per million. Formic acid in an amount of up to 1.5 grams per kilogram may be added to all concentrated juices, except grape, apple, pear, grapefruit, orange and other citrus juices. Juices intended for dietetic uses, children less than two years old or invalids shall be free from sulfur dioxide and other preservatives.

Article 478.—The term "pineapple juice" means the juice obtained from the fruit of Ananas sativus L., Ananas comosus L. etc. Average percentage composition: water 87; proteins 0.3; fats 0.1; assimilable carbohydrates (sugars 3) 12; crude fiber 0.02; ash 0.4; acids expressed as citric acid 0.6.

Article 479.—The term "lime juice" means the juice obtained from Citrus Limetta Risso. Average percentage composition: water 91; proteins 0.4; fats 0.1; assimilable carbohydrates 8; crude fiber 0.07; ash 0.4; acids calculated as citric acid 4; density at 15° C.: 1,036.

Article 480.—The term "lemon juice" means the juice obtained by pressing the fruits of Citrus limonia Osbeck. Average percentage composition: water 92; proteins 0.3; fats 0.01; assimilable carbohydrates 7; crude fiber 0.06; ash 0.3; acids calculated as citric acid 5; density at 15° C.: between 1.035 and 1.050.

Lemon juice shall be free from synthetic citric acid and shall contain not less than 4 per cent of natural citric acid and 35 mg. of ascorbic acid (fresh juice), and not less than 7 mg. of nitrogen from free amino acids per 100 ml. of juice, and not more than 2 per cent of ash.

The designation "concentrated lemon juice," or simply "lemon concentrate" means the product obtained by concentrating the juice defined above in a vacuum at low temperature, with or without the addition of sugar. 100 ml. of juice shall contain not less than 14 mg. of nitrogen from free amino acids.

The name "lemon powder" means a product obtained from the evaporation of lemon juice containing between 6 per cent and 8 per cent of pectin or one or two volumes of glucose syrup rich in polysaccharides.

Article 481.—The term "orange juice" means the juice obtained by pressing the fruits of Citrus sinensis L. With time hesperidin precipitates. Orange juice shall contain not less than 40 mg. of ascorbic acid (fresh juice) and not less than 18 mg. of nitrogen from free amino acids per 100 ml. of juice. Average percentage composition: water 86; proteins 0.4; fats 0.1; assimilable carbohydrates 10; crude fiber 0.4; ash 0.4; acid calculated as citric acid 0.8; density at 15° C. between 1.031 and 1.060.

The designation "concentrated orange juice," or simply "orange concentrate," means the product obtained by concentrating the juice defined above in a vacuum at low temperature, with or without the addition of sugars. 100 ml. of juice shall contain not less than 90 mg. of nitrogen from free amino acids.

The term "orange powder" means the product obtained by evaporation of orange juice with 6 per cent to 8 per cent of pectin or one or two volumes of glucose syrup rich in polysaccharides.

Article 482.—The term "grapefruit juice" means the juice obtained from Citrus maxima Osbeck. It shall contain not less than 45 mg. of ascorbic acid (fresh juice) and not less than 5 mg. of nitrogen from free amino acids per 100 ml. of juice. Average percentage composition: water 90; proteins 0.4; fats 0.1; assimilable carbohydrates 8; crude fiber 0.05; ash 0.4; acids calculated as citric acid 0.9.

Article 483.—The lemon, orange and grapefruit juices served as "freshly squeezed juice" at counters, confectionery stores, restaurants, etc. shall never be more than three hours old. Any such juices, the amino nitrogen and ascorbic acid content of which is below the limits indicated in Articles 480, 481, and 482 shall be considered adulterated.

Tomato juice—see Article 432, 2.

Article 484.—The term "grape juice" means the juice obtained by pressing different varieties of grapes, from which the potassium bitartrate may have been removed. Alcohol may be tolerated in an amount not exceeding 1 per cent by volume, and sulfur dioxide in an amount not exceeding 80 mg. per liter. Percentage composition: water 73 to 82; proteins 0.2 to 0.5; fats 0.6 to 1.1; assimilable carbohydrates 17 to 25; ash 0.2 to 0.4.

Article 485.—The term "fermented ... juice" including the name of the fruit from which the product has been obtained, means any natural juice that meets the specifications of this Code, which has been subjected to alcoholic fermentation.

Saturation with carbon dioxide, that must meet the specifications fixed in Article 462 hereof, shall make it necessary to label the product "artificially carbonated."

Fermented vegetable juices prepared in a fashion different from the manner described herein shall be considered artificial and shall be labeled as such in letters of the same size, type, and color as are used to designate the product.

Fermented vegetable juices shall meet the following specifications:

1. No alcohol may be added to them; but to acid fruits, sugars may be added in an amount sufficient to raise the alcohol content by 2 per cent.

2. The percentage volatile acidity may not exceed 4.2 ml. of normal alkali and the sulfur dioxide retained by the product may not exceed 150 p.p.m.

3. They shall not be altered or have extraneous flavors or aromas.

4. They shall not contain foreign matters, regardless of whether or not the same have been added to enhance the natural characteristics of the juice, artificial sweeteners, essences, or prohibited colors.

Article 486.—"Date juice," improperly called "date honey," is the product obtained by pressing ripe muscat dates, which are usually packed in weed baskets.

Ice Creams, Sherbets and Cold Beverages

Article 487.—The generic name "ice cream" (ice, sherbet) means any product which has been prepared by freezing liquid mixtures consisting of milk, condensed milk, evaporated milk, powdered milk, butter, cream, fruit juices or fruit syrups,

fresh, preserved or powdered eggs, egg yolks, cacao, coffee, natural and candied fruits, chocolate, sugars, honey, molasses, grated coconut, walnuts, almonds, filberts, peanuts, authorized colors, aromatics and other permitted substances. These products must be sold in a solidly frozen state.

Sherbets contain less sugar than ice creams. Some kind of alcoholic beverage is usually added to them, and at the time of sale they have the appearance of a frothy cream, for which purpose beaten egg white with sugar or an authorized thickener (see following Article) may be added to them.

Article 488.—The milk and cream used in mixtures composed of milk, cream and eggs and intended for the preparation of ice cream shall first be pasteurized or boiled. Ice cream may contain without a declaration up to 1 per cent of a stabilizer, such as potato starch, cornstarch, edible gelatin, sodium caseinate, pectin, agar-agar, carob bean powder, gum Arabic, gum Karaya, gum Tragacanth, oat gum, methyl cellulose, sodium alginate, edible moss and authorized albumens (see Articles 586 and 587).

The installation of ice cream factories in dwelling houses, garages and basements is prohibited.*

* Note of the Translator: This sentence would seem to belong in Article 489.

Article 489.—Ice cream factories shall not only comply with the general regulations, but in addition meet the following specific requirements:

1. They shall have a manufacturing room separated from the rooms intended for other services (kitchen, pantry, dormitory, shed, storage room, etc.). The manufacturing room shall have a flat ceiling; a waterproof floor; a wainscot at least 1.80 m in height made of tiles, marble or a similar material; adequate sinks to wash the appliances and utensils with running hot and cold water and provided with drains that lead to a sewer, a septic tank, or a gutter. Ice cream freezers, scoops and other utensils shall before and after each operation be washed carefully and rinsed with hot potable water. The tables used to prepare and manipulate creams and syrups shall have tops made of marble, tiles, or other adequate materials. In establishments where ice creams, sherbets and similar products are prepared for direct sale to the public, the products may be frozen on premises open to the public provided that the freezing installation meets all the requirements of hygiene and safety.

2. They shall have a room in which to store raw materials, which room shall be well maintained, tidy and clean at all times.

The term "ice cream parlor" ("heladeria") means an outlet at which ice creams are sold and which may or may not be connected with another business. Ice cream parlors may sell only ice creams prepared at officially licensed factories, by personnel who meet the requirements for food handlers fixed in Article 23 of this Code (uniform, and health certificate).

Article 490.—The name "ice mix" means any product composed of milk solids, sugars, salts, authorized aromatics, fruit concentrates, various dehydrated products and up to 2 per cent of stabilizer (gelatin, alginates, etc.). The moisture in such mixes may not exceed 5 per cent. They shall contain milk solids in a proportion of not less than 45 per cent, of which at least 10 per cent shall be milk fat. The name "ice cream mix" means any product of a similar composition, the minimum milk solid content of which shall be 55 per cent, however, of which at least 25 per cent shall be milk fat. The labels used for both products shall give instructions for the preparation of ices and ice creams. Any products which do not contain milk, cream or sugar and are intended for the preparation of ices or ice creams of a specific composition from recipes which were filed with the authorities, shall bear under their name the pertinent indication: (without milk, cream and/or sugar), in letters of the same size, type and color. The resultant ice must comply with the pertinent specification of this Code.

Article 491.—Any ice creams, sherbets and similar products in storage, circulation, or preparation shall be free from pathogenic bacteria, especially Mycobacterium tuberculosis, Brucella sp., Salmonellas and Bacillus coli. Ices prepared from acid fruits may contain nonpathogenic bacteria in amounts not exceeding 10,000 per gram (the count to be made on plates) and those prepared from other fruits (bananas, strawberries, etc.) may contain 50,000 nonpathogenic bacteria, while the bacterial count of ice creams prepared with milk may not exceed 200,000 nonpathogenic bacteria per gram.

Products the names of which indicate or imply that eggs have been used in them shall contain not less than four egg yolks per kilo and not less than 1 per cent of cholesterol.

Products the names of which indicate or imply that they contain milk shall contain whole milk in an amount of not less than 60 per cent.

Products the names of which indicate or imply that they contain fruits, or parts of fruits, shall contain the fruit or fruits named in an amount of not less than 10 per cent.

Products the names of which indicate or imply that they contain dried fruits, nuts, almonds, etc., cacao or chocolate, shall contain these substances in an amount of not less than 2 per cent.

Products which bear the name of a specific food or beverage (fudge, rum, brandy ice, etc.) shall contain the substance named in their denomination.

Essences and coloring matters may be used in ice creams, sherbets and similar products only if the same are named, advertised and sold as "fancy" ("de fantasia"). An exception is made for fruit ices and sherbets the color of which may be reinforced with an authorized coloring matter without a declaration.

Ice creams, sherbets and similar products are prohibited from being prepared:

1. With water that is not potable;

2. With milk the acidity of which, expressed as lactic acid, exceeds 0.18 per cent, or with cream which titrates more than 0.45 per cent of acidity expressed as lactic acid;

3. With raw materials which fail to meet the standards fixed in this Code or which otherwise are not suitable for the use for which they are intended;

4. In containers the lining of which is defective or has disappeared in part or in whole;

5. On inadequate premises, with defective equipment or by personnel that is not in good health or otherwise fails to meet the conditions fixed in Article 23 of this Code.

Article 492.—The names listed hereinafter designate the following products:

1. American-type ice cream—a product with a base of fresh cream, sugar and aromatics, which shall contain milk fat in a proportion of not less than 6 per cent. Strawberry, orange, lemon and other fruit ice creams shall answer to their names and contain the elements of the fruit whose name they bear.

2. Frozen custards, cream ices—of vanilla, chocolate, Portuguese cream, Russian cream, etc. These are products made from whole milk, with or without cream, eggs, sugar, aromatics, to which, depending

upon their name, other authorized substances may be added. They shall contain milk fat in an amount of not less than 2 per cent. The products prepared with milk to which cream has been added are called "French ice creams" ("mantecados") and shall contain milk fat in an amount of not less than 4 per cent.

3. Fruit ices (peach, strawberry, pineapple, etc. ice): The raw materials used for these ices shall include the juice, extract and/or pulp of the fruit named, with or without the addition of milk or cream and sugar.

4. Special-type ices (chocolate, coffee, Russian cream, etc.): The composition of these ices shall comply with the formulae registered with the competent agency.

5. Sundae: A dish prepared with one or several ice creams or frozen custards arranged in a bowl or on a plate and decorated with fruit juices or syrups, whipped cream, fresh or preserved fruit, chocolate, nuts, almonds, etc.

6. Ice cream soda: A cold beverage prepared by combining in a glass a portion of ice cream and carbonated water, to which other ingredients may be added.

7. Milk shake: A cold beverage prepared in the same manner as ice cream soda, in which milk is used instead of carbonated water and the mixture is blended in a mechanical blender.

8. Water ice: A sherbet which looks granulated as the result of the freezing method or because it contains crushed ice.

9. "Leche merengada" ("meringue milk"): A cold beverage prepared with milk, lemon peel, sugar, egg white and ice, all blended in a mechanical blender.

10. "Mazagrán:" A cold beverage with a base of a coffee infusion to which sugar, slices of lemon and crushed ice have been added.

11. Iced tea, iced maté: Cold beverages prepared with infusions of tea or maté, slices of lemon, sugar and ice.

12. Claret cup or "Maitrank:" A cold beverage prepared with wine, carbonated water, crushed ice and slices of fruit.

13. Cocktail: A cold drink prepared by mixing in a shaker several alcoholic beverages and ice to which fruit juices, syrups or chunks of fruits and aromatics may be added. (See Article 528, paragraph 13.)

14. Sangaree: A cold beverage prepared with red wine and water, to which pieces of fruits may be added. **[The End of Chapter XIII.]**

Federalism in Consumer Protection: Conflict or Coordination?

By H. THOMAS AUSTERN

The Following Address Was Presented Before the 69th Annual Conference of the Association of Food and Drug Officials of the United States, July 22, 1965. Mr. Austern Is a Member of the District of Columbia Bar.

IN PREPARING WHAT I MIGHT SAY about what should be the respective roles, in consumer protection, of federal and state officials, I was constantly reminded of the catastrophe that befell the inquisitive sparrow who once flew down to find out how a game of badminton was really being played.

To those concerned with food and drug regulation, the problems of modern-day Federalism are commonplace, complex, and confused.

Federalism, however, is not at all unique to food and drug regulation. In this country, unlike France, England, and many other nations, every question of governmental policy becomes inescapably intermingled with questions deriving from our federal system:

Should Washington or each state decide what is to be done, and who should do it?

Is it the several states or the federal government that constitutionally has the power to decide and to act?

Is the power of one sovereign to be exclusive of any authority or action by the other?

If constitutionally there is scope for both federal and state action, should what one does be limited or qualified or shaped by the power vested in the other?

Background of Ideas on Federalism

More than a century ago, de Tocqueville observed that with us every political issue ultimately becomes a constitutional and a legal question.[1] In large measure, that explains the roving role of public and private attorneys—or what some might call the constant irritating intrusion of lawyers—in every area of American Government. I hope it explains, even though it may not condone, my appearance here this afternoon to talk about Federalism in food and drug regulation.

That there would have to be necessary accommodation between federal and state governments was indeed foreseen by the founding fathers. The Federalist Papers were replete with an amazing perspicacity about the future.

Alexander Hamilton observed that "the establishment of a Constitution founded upon the total or partial incorporation of a number of distinct sovereignties . . . cannot fail to originate questions of intricacy and nicety."[2] Only time, he foresaw, "can mature and perfect so compound a system—can liquidate the meaning of the parts—and can adjust them to each other in harmony and consistent whole."[3]

As Professor Corwin once posed the same basic question: The two governmental centers, state and federal, may be either "Jealous rivals for power," or they may become "mutually supplementing agencies of government."[4]

On that fundamental question—whether the states and federal government should regard themselves as enemies and strangers, or as allies associated in a common enterprise—the Supreme Court has come the full circle.

The early notion that within the same territorial limits the federal and state governments should act separately and independently of each other—and that jurisdiction over a particular subject had to be entirely in either the state or Nation, and not divided between the two[5]—had begun to be replaced as early as 1871 by the view that there were powers of government that could be and should be exercised concurrently by the states and the federal government.[6]

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[1] de Tocqueville, *Democracy in America* 289 (Vintage Books ed. 1945).

[2] The Federalist, No. 82, at 130 (Bourne ed. 1901) (Hamilton).

[3] See footnote 2.

[4] Corwin, "National-State Cooperation—Its Present Possibilities," 46 *Yale L. J.* 599, 601 (1937).

[5] See *Tarble's Case*, 13 Wall. 397, 406-07 (1872); *Matter of Heff*, 197 U. S. 488, 506 (1905).

[6] See *Ex parte McNiel*, 13 Wall. 236, 240 (1872).

In terms of possible constitutional impediment, the *Florida Green Fruit* case made clear forty years ago that in food regulation there could be state action even though it somewhat affected interstate commerce.[7]

Of course, history teaches that not all issues of Federalism can be fully settled by Supreme Court decisions alone. In the long perspective, future historians may conclude that in the Nineteenth Century the basic problems of American Federalism had to be resolved by the bloodiest civil war ever fought, whereas in the Twentieth Century they were worked out by intelligent inquiry, accommodation, and effective coordination.

I do not mean to suggest that today the simmering caldron of controversy about what should be for the federal government and what for the states, has completely cooled off. In the area of civil rights and recent Supreme Court decisions on malapportionment of State legislature,[8] there remain bitter differences and occasional street demonstrations. But the fact is that in wide reaches of Federalism, mutual cooperation for common objectives is today the prevalent and the desirable mode.

The greater financial resources of the federal government and the local and immediate impact of state police power frequently combine for effective action—once the ends and the methods for achieving them are agreed upon.

Apart from the giving, or withholding, of federal financial aid to persuade the states to use their reserve powers to achieve national policy, there are many examples of effective cooperation. These range from the quartering of federal prisoners in state jails,[9] to such monumental experiments as Social Security and unemployment insurance[10] and the Kerr-Mills Act.[11]

Increasingly, federal and state legislation may borrow from each other, incorporating or deferring to standards, language, and policies found in the other. The Uniform State Food, Drug and Cosmetic Bill is a familiar example.[12]

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[7] *Sligh v. Kirkwood,* 237 U. S. 52 (1918).

[8] For example, *Baker v. Carr,* 369 U. S. 186 (1962); *Maryland Committee v. Tawes,* 84 S. Ct. 1429 (1964).

[9] Authorized by Act of June 25, 1948, Ch. 645, 62 Stat. 847, 18 U. S. C. § 4002.

[10] Social Security Act, 49 Stat. 620 (1935), as amended, interspersed throughout 42 U. S. C.

[11] Social Security Act Amendments of 1960, 74 Stat. 924 (1960).

[12] The text of this uniform law may be found in H. R. Rep. No. 445, 88th Cong., 1st Sess. 104 (1963) and CCH

(Footnote continued on next page.)

Another format is found in the Civil Rights Act of 1964 in which the operation of federal law is sometimes to be suspended during the pendency of state or local proceedings, and federal commissions are specifically directed to cooperate with state and local agencies.[13] The Natural Gas Act also authorizes the Federal Power Commission to delegate regulatory authority to boards composed of members of state agencies.[14]

Analysis of Federal and State Roles in Consumer Protection

Against that broad background—and putting to one side all legal arguments about states rights, the limits of preemption, or the ambit of constitutionally possible interference with interstate commerce—I should like to analyze with you the pragmatic problem of coordinating federal and state action in the regulation of food and drugs in the consumer interest.

Two principles, I suggest, should control that inquiry.

The first is that there is a place, indeed an important place, for state activity, and that effective consumer protection requires that there be fully deployed the corps of dedicated state and local regulatory officials who have devoted their careers to that end.

There are still some important local and sectional differences. As Woodrow Wilson once said, no federal enactment can or should obliterate all regional variations in a nation that occupies a continent.

Moreover, there will always be in this area, as in every aspect of good government, a considerable element of discretion as to when to warn, and when to prosecute. Very often that discretion can be more sensitively exercised by the local official who best knows the local situation.

The second controlling principle is that there should be no barriers to the free interstate movement of foods and drugs. As a corollary, the sophistication of modern food and drug production, and the delicacy of present-day techniques for determining pesticide residues, food additives safety, and drug efficacy, require both uniformity and the avoidance of costly duplication of research.

Footnote [12] continued
FOOD DRUG COSMETIC LAW REPORTER ¶ 10102.

[13] For example, Sec. 204(c), 78 Stat. 244 (1964), 42 U. S. C. § 2000a-3(c); Sec. 709(b), 78 Stat. 262, 42 U. S. C. § 2000e-8(b).

[14] Sec. 17, 52 Stat. 830 (1938), 15 U. S. C. § 717p.

The functional application of those two sometimes conflicting principles does not require a full rehearsal of the recently accumulated data concerning the scope, per capita financing, staffing, or relative efficiency of existing state agencies.

The two 1963 reports on "Consumer Protection Activities of State Governments," developed by the House Committee on Government Operations, afford a readily available, even if occasionally uneven, mass of data.[15]

No one can deny that the reported disparities in state expenditures for food and drug regulation are shocking. No one could today seriously defend the reported median one cent per capita expenditure for state drug regulation, or feel comfortable about the aggregate reported state expenditures now representing only a small fraction of the total federal appropriations.[16]

In whatever one concludes about coordinate activity, there is the obvious and abiding task of persuading state legislatures that only adequate appropriations will permit effective state participation.

Also available to those interested—and every food and drug manufacturer must enlist in that growing army—is the recent study of the Public Administration Service of Chicago, whose summary was made available last February.[17]

While there are some who consider the first part of those findings as novel and revealing as a description of the Pinta, Nina or Santa Maria in Christopher Columbus's fleet, the final generalized recommendations are provocative, and undoubtedly the full report will be even more so.

Regulatory Functions Between State and Federal Agencies

In my approach to the problem of distribution of regulatory functions between state and federal agencies, as well as the desirable coordination and relative emphasis, I divide the area of needed regulatory activity into four parts.

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[15] Comm. on Gov't Operations, *Seventh Report: Consumer Protection Activities of State Governments; The Regulation of Drugs,* H. R. Rep. No. 445, 88th Cong., 1st Sess. (1963); Comm. on Gov't Operations, *Seventeenth Report: Consumer Protection Activities of State Governments, The Regulation of Foods,* H. R. Rep. No. 921, 88th Cong. 1st Sess. (1963).

[16] H. R. Rep. No. 445, *supra* note 15, at 12; *Id.* at 5; H. R. Rep. No. 921, *supra* note 15, at 5.

[17] Public Service Administration, Summary of Findings and Recommendations from a Report to the Commissioner of Food and Drugs, February 1965 (FDA mimeo).

I offer these to you in the progressive order of those in which state activity can be most effective as contrasted with those in which the states ought to yield and to defer to federal action both because of the complexity of the required controls and the compelling need for the freest interstate movement of foods and drugs.

In each area, I hope that it will be clear that there must always be the fullest exchange of information and open-handed consultation between state and federal officials.

First, there is the elementary yet cardinal area of sanitation and contamination. That I call "environmental sanitation." In my view, it is uniquely amenable to local control.

Second, there are the more complex problems of product safety residing in *intrinsic product composition.* These are manifest in the modern use of pesticides, food additives, color additives, in new drug formulations, and in hazardous household substances.

My *third* and *fourth* analytical areas of regulation are *economic* and wholly different from environmental and product composition safety.

They relate instead to *consumer information* and to the control of product composition for economic purposes, as exemplified in food standardization.

It is in these latter two areas that potential conflict between federal and state controls is more acutely present and the danger of creating economic barriers to free trade is most dramatically demonstrated.

Let us briefly examine each area:

Environmental Sanitation

First, as to environmental sanitation. That covers not only food and drug manufacture, but also distribution and retail sale, as well as fundamental sanitation in local restaurants and food stores.

Here the state and local health inspectors and health officials should play the dominant role. They can achieve the greatest degree of protection for the consuming public.

State and local inspectors are available without extensive travel. They are familiar with activities in their own territories. They are usually expert in the basic standards of cleanliness and sanitation that are required in the handling of raw agricultural commodities, in

sanitation control in the manufacture of foods and drugs, and in adequate care in warehousing and conditions of retail sale.

On environmental sanitation the potential for effective state and local enforcement is greatest, and the problems of impeding interstate commerce are minimal. State enforcement of sanitation should precede interstate commerce. State scrutiny of the care and handling of foods and drugs after interstate movement is practicable. I might add that the Federal Olemargarine Act provision for local beanery inspection by the Food and Drug Administration (FDA) is not realistic.[18]

Safety of Food and Drug Composition

Turning to the second area—the *safety* of composition of foods and drugs—the lines of responsibility begin to blend. Present-day sophistication of food manufacture and of drug technology impose too great a burden on the scientific resources of individual State agencies. Detection of pesticide residues, of food and color additives, or of drug contamination requires costly and complicated equipment. Refined and exquisitely sensitive methodology must be developed.

Here the federal government must undertake the development of analytical methods. It must also provide instrumentation and training to permit state agencies to cope with these increasing complexities of chemical and biological determination.

Inescapably, in federal standardization of permissible residue levels, there is considerable potential for conflict. Agricultural states are interested in a closer balance between use levels and residue levels. Dominantly consumer states may lean toward lower residue levels or toward that mysterious concept of a zero tolerance.[19]

In my view, section 408 of the Federal Act provides a workable mechanism for resolving these differences, and in their local enforcement activities the states ought to yield to the federal determinations.[20]

By the same token, determining what is a hazardous substance and its required cautionary labeling falls within this second area of

[18] Federal Food, Drug and Cosmetic Act § 407(c), added by 64 Stat. 20 (1950), 21 U. S. C. § 347(c).

[19] This can be seen in the comments filed on the FDA proposal to reduce the tolerances for aldrin and dieldrin from 0.25 ppm to "zero." 30 Fed. Reg. 7249 (May 29, 1965). California officials sought additional time to permit establishment of a 0.1 ppm tolerance, now under consideration on the basis of a Shell Chemical Co. petition. 30 Fed. Reg. 7258 (May 29, 1965).

[20] See 21 U. S. C. § 346a which provides for comments on proposals, advisory committees, and if necessary, evidentiary hearings on pesticide tolerances.

compositional safety, and again the federal determinations should be the controlling yardstick.[21]

Drug regulation is an even more complicated problem embracing not merely the safety of drugs for the intended use, but also the control of abuse of drugs obtained through illicit channels.

The states of course have an interest in assuring that untested and untried drugs are not indiscriminately circulated to their populations. Yet the FDA regulations governing the interstate shipment of investigational new drugs, and FDA new drug licensing, afford adequate protection.[22] Here again the States might well follow the federal lead. The federal government's particular interest in drug efficacy might well be left wholly within its control.[23]

As to drug abuse, the states have a direct interest centering in their control of local pharmacies. The enactment on July 15, 1965 of the Drug Abuse Control Amendments Act of 1965—restricting the distribution and possession of depressant and stimulant drugs—still affords room for State action. The new federal law requires extensive, though not burdensome, record keeping by manufacturers, distributors, and sellers of these drugs.[24] These records will be available for state use to help control diversion.[25]

It is interesting to observe that this new Depressant and Stimulant Control Act specifically recognizes additional controls by the states beyond those proposed by the federal government.[26] Yet many question whether in this instance, where the main tactic of enforcement is required documentation to control potential diversion, it is either necessary or appropriate to permit additional variegated state controls.

Economic Regulation

When one leaves the area of environmental or compositional safety, and enters the third area of *economic* regulation, the national interest in freedom of the movement of goods usually should stay the hand of the state. The issues here are what should the consumer be told about the product, and what requirements are necessary to control the labeling of that information.

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[21] Federal Hazardous Substances Labeling Act, 74 Stat. 372 (1960), 15 U. S. C. §§ 1261-74; 21 CFR pt. 191 (FDA regulations interpreting the Act's requirements).

[22] 21 CFR § 130.3.

[23] Food, Drug and Cosmetic Act §§ 201(p), 505(b), (d), as amended by the Drug Amendments of 1962, 76 Stat. 781, 21 U. S. C. §§ 321(p), 355(b),(d).

[24] Food, Drug and Cosmetic Act § 511(d), added by 79 Stat. 229 (1965).

[25] See footnote 24.

[26] Drug Abuse Control Amendments of 1965, § 10, 79 Stat. 235 (1965).

As the variety of state regulations increases, so does the potential for conflict between state and federal controls. As a result, those who endeavor to sell in interstate commerce may find themselves burdened with often confused, often obtuse, and too frequently unenforced state statutes, rules, and regulations.

No one can argue that the consumer is not entitled to know what food or drug he is buying, the ingredients from which the food is made, the quantity he is purchasing, and to whom he can turn if he desires to complain.

Yet these four simple requirements are readily comprehended in section 403 of the Federal Act.[27] Moreover, the FDA regulations are not significantly longer, and most of them deal with how to describe units of count, weight, or volume.[28]

Under state law, however, there is nominally a wide variety of regulatory structures. These range from parallel requirements under the Uniform Food, Drug and Cosmetic Act to every type of localized variation and often plain local economic barrier.[29]

Only a Rip Van Winkle who has slept for a hundred years can be unaware of the economic integration and interdependence in what is now often called the common market of the United States.

Interstate dealing, as well as the cost economies of mass production, dictate that there be a uniform package and label for all interstate distribution along with a trademark that can be nationally advertised. The retail package must be readily recognized by the consumer regardless of her location or the mobility of our present-day population.

When a manufacturer is confronted with a variant local law—be it a registration mark for his label, or a regulation requiring particularized information, or specifying elements of label design—he has but two choices: He must either print separate labels for limited local distribution in each area, or he must conform his label to include everything required in every State—assuming that there are not conflicting, different, or impossible local requirements.

That explains why many foods sold in California bear labels with Pennsylvania Department of Agriculture registrations, and why margarine manufactured in Illinois and sold in New York is labeled to comply with specific California requirements.

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[27] 21 U. S. C. § 343.

[28] 21 CFR §§ 1.8-.10.

[29] The variety of state laws is graphically displayed in H. R. Rep. No. 445, *supra* note 15, at 24.

It is at that point, in this area of economic regulation, that the constitutional requirement of not burdening interstate commerce and the doctrine of preemption begin to bite. In my view, they do so properly.

Ultimately, I am persuaded, the Supreme Court will not countenance local administrative regulations by one State which in practical effect impose burdensome labeling requirements on products distributed in all other States.

Even apart from legal impediments, state officials ought to exercise restraint and make realistic obeisance to the need for completely free and interstate movement. If they do not, I am satisfied that we shall see increasing federal controls with explicit preemption that may leave little room for state regulatory activity.

Economic Regulation of Food Composition

Turning, finally, to the economic regulation of food composition by standardization, one finds the most discomforting area of chaos and perhaps plain rivalry. Both the federal government acting through the FDA and the states have moved in mysterious ways.

For example, the federal statutory standard for olemargarine specifically reserves to the individual States the right to regulate the sale, distribution, and use of colored margarine.[30] The political pressures that brought about that result do not excuse state legislation plainly enacted to establish protective interstate barriers.

There is a federal standard for ice cream, developed over many years of arduous administrative effort, that provides a ten percent butterfat level.[31] Nevertheless, Iowa by statute requires twelve percent butterfat. The State of New Hampshire requires even more, and its Attorney General reportedly was told by the FDA that his local law could not prohibit the interstate movement of the ten percent butterfat ice cream.

A federal court has likewise ruled that ice cream labeled in conformity with federal law may not be held misbranded under Iowa law.[32] Whether it may still be deemed adulterated, even if properly labeled, is perhaps still open.[33]

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[30] Act of March 16, 1950, § 6, 64 Stat. 22.

[31] 21 CFR § 20.1(a).

[32] *Borden v. Liddy*, 239 F. Supp. 289 (S. D. Iowa) (three-judge court).

[33] *Id.* at 290 (summary opinion).

There are many who insist that the national interest in freedom of trade dictates that all compositional standards be fully preempted by federal control.

But that does not mean that the interested producing states should play no part in their development. Moreover, a decent comity between state and federal authorities should avoid any race to earliest promulgation.

At the moment, there is a proposed standard for diluted fruit juice beverages drafted by the Association of Food and Drug Officials of the United States (AFDOUS) and accepted by many state officials. There is a slightly different recent enactment for that group of products in one state. There are a variety of pending industry proposals by competing processor groups for the standardization and labeling of these products.[34] At the same time, there has been proposed by the FDA standard and labeling proposals which by no stretch of the imagination are remotely congruent with those developed by AFDOUS or enacted.[35]

As another example of incongruity, the FDA, following court action concerning its standards for orange juice products, has now promulgated an orange juice standard that specifies that it is *not* the intention of the FDA to interfere with or to invalidate any state law fixing higher and more stringent standards for canned frozen orange juice.[36] How the consumer interest is promoted by having standardized frozen concentrated orange juice from Florida mean something different from frozen concentrated orange juice from Arizona or California is difficult to see.

It is not too much to hope that in this area of economic control over composition of food products, the states will yield to federal standardization, and at the same time that the FDA will develop better and more responsive mechanisms for consultation and consideration of the views of state officials. There are few who believe that the currently structured Advisory Committee on Food Standards adequately does that job.[37]

In my view, even though I believe that the federal standards should fully preempt this field, both the industry and state officials

[34] 29 Fed. Reg. 11621 (Aug. 13, 1964); 29 Fed. Reg. 13535-36 (Oct. 1, 1964).

[35] 29 Fed. Reg. 11625 (Aug. 13, 1964).

[36] 21 CFR § 27.109(f).

[37] See FDA, Monthly Report on Enforcement and Compliance, Oct. 1964, p. 4.

ought to be full participants in the development and promulgation of these food standards.

Conclusion

In conclusion, perhaps you will agree that so approached, the coordination of federal and state activity in the regulation of foods and drugs offers for the future a happy and not a dismal prospect. If you share my faith that in this area of Federalism, men of dedication and good will—in which group I include both federal and state officials—can accommodate and coordinate their activities, you may join me in that forecast.

The recent analytical studies have revealed many of the problems. There is a growing awareness both by federal and state officials and by the regulated industries of the necessity for further analysis, evaluation, and division of functions.

Where necessary, federal monetary grants can strengthen the state agencies without exacting the price of their surrendering either their authority or autonomy. There will always remain an important role for the States.

In some areas I have urged that the national interest requires that the federal regulations must be paramount, but that again, I repeat, does not mean that the producing and consuming States ought not to have a greater voice in the formulation of the controlling federal requirements.

Lastly, no one will deny that the vital importance and current complexities of consumer protection require that personalities, jealousies, or Parkinson's Law on either the federal or state level, should play no part.

I am therefore confident that problems of Federalism may soon cease to exist in this area.

From the point of view of the food and drug manufacturer, they must be dissipated. Else confronted with conflicting federal or state requirements, the task of a national distributor of food or drug products may soon come to fit Samuel Johnson's description of a woman preaching. He likened it to a dog walking on its hind legs. The wonder, he said, is not that it is done well, but that it can be done at all.

[The End]

Developments in the European Economic Community—Food Legislation

By J. P. K. VAN DER STEUR

The Following Article Was Written by Dr. van der Steur, a Member of the Food Law Advisory Committee, Nominated by the Queen (Holland), and an Advisor to the Council of Dutch Employers Organizations for Food Law Problems.

FOOD LEGISLATION in the European Economic Community (EEC) is developing at a very slow pace. This is understandable, since there must first be consultation on the subject to be covered by a directive between the relevant EEC—department, which is headed by Dr. H. Steiger, and the government experts of the six countries. This often laborious consultation is to provide the elements of a formal recommendation, which is then discussed with the representatives of the member-states. Moreover, the industries in the six countries, usually combined in a federation, are asked for their opinion.

Problem of Divergent Interests

Clearly, the interests of the various countries are often widely divergent, and so are the requirements of all those industries in the six countries which are active in one particular field. The causes arise from differences in (a) the climate and the habits adapted to it, (b) the development of trade and industry in the various countries, and (c) the mentality of the population. In the South European countries, for instance, the finished products are subject to less rigorous control than in the northern countries. Attempts are being made to compensate for this by means of stricter legislation.

Moreover, in a number of cases the food legislation does not only serve to protect public health and to promote business integrity, but often to realize the economic wishes of a country or of an industry.

The jam industry is an example of how divergent these interests can be. In Italy, where fresh fruit is available nearly all the year round, jam is mostly made directly from the fresh fruit, whereas in the more northern countries of Europe, where the fruit is harvested only once a year and then only within a very short period, the fruit has to be preserved, so that it can be used for making jam later in the year. Preserving can be done in two ways, namely by treatment with sulfur dioxide and/or sulfite, or by cooling to a very low temperature. The first method is used for the bulk of the fruit, since it is cheaper and equally suitable, whilst moreover sufficient freezers are not available. It is therefore in the interests of the Italian jam industry to promote as much as possible the sale of jam from fresh fruit not containing sulfur dioxide. Italy therefore wishes the draft directive for jam to support this.

On the other hand, the industries in the more northern countries wish the general directive to afford them the possibility of preserving their fruit with sulfur dioxide or with sulfite. Overcoming such contrasts often causes great difficulties.

A similar situation exists in the cocoa and chocolate industry. Besides pressed unrefined cocoa butter certain countries use large quantities of extracted refined cocoa butter. Here, too, no problems of public health or business integrity are at issue, but in reality there are advantages which make it desirable for one country to permit and for another to prohibit the use of refined cocoa butter. Such problems are often debated for months and years, until ultimately a compromise is reached.

As a consequence, it has so far been easier to draw up positive lists of permitted food additives for the so-called horizontal directives than to reach agreement on product standards, the vertical directives.

Adopted Directives

When we consider what has so far been achieved in the way of food legislation in the EEC, we see that a directive for the use of colouring agents in foods is already in force. It is now being slightly altered and supplemented, whilst in the future greater changes are likely to be made as a result of the outcome of the discussions on

many synthetic and natural colouring agents by the Joint FAO/WHO Expert Committee on Food Additives in December 1964.

In addition, a directive for food preservatives has been drafted which permits the following preservatives: benzoic acid and its salts; p. hydroxy-benzoic acid, ethyl and propyl esters and their sodium salts; sulfur dioxide and various sulfites; sorbic acid and its salts.

Besides these preservatives a number of substances are permitted which are used mainly for other purposes but at the same time have preserving properties: nitrite, nitrates, acetic acid and acetates, lactic acid, propionic acid and its salts, carbon dioxide.

A directive for antioxygens is very near completion and includes the main antioxygens in use: sulfur dioxide and various sulfites; l-ascorbic acid, its sodium and calcium salts, its acetate and palmitate; natural tocopherol concentrates and DL alpha, gamma and delta tocopherol; octyl gallate; dodecyl gallate; butylhydroxyanisole; lecithin.

A directive laying down the purity requirements for preservatives has been adopted, whilst the purity requirements for antioxygens are in an advanced stage of preparation.

An extensively debated subject at the moment is the emulsifying and stabilizing agents to be permitted in foods. The European Commission has not yet submitted any recommendations, but is preparing these. Dr. Steiger has asked the UNICE, the federation of the European industries in the six countries, for advice. This has already been given for both groups and will be discussed again in October 1965 with the government experts.

Labelling

The same applies to labelling. In the EEC a report on the main lines for a directive has been compiled by one of the German government experts. Here again UNICE has been asked for advice, which has been given to Dr. Steiger and which contains the wishes of industry as far as they have unanimous views.

In general it can be said that the recommendations of the industries on this point, especially as regards the declaration of compositions and food additives, are less comprehensive than in America. In the first place they do not wish declaration of the total composition on the packing of standardized foods to be made compulsory. Only those food additives the use of which might mislead the con-

sumer (e.g. yellow colour instead of egg yolk) should be declared. Further, many countries require the packing to show the name of the manufacturer or the seller of the product. Some countries prefer declaration of both the manufacturer and the firm which sells the product, while here and there, there is a wish to retain the possibility of indicating the manufacturer's name in a code which the authorities can recognize. At this stage it is difficult to see what all this will lead to, but the name of the firm which puts the product on the market or the manufacturer who has ultimately packed the product will probably have to be mentioned on the package in a form suitable for the consumer.

Also being discussed is whether it would be desirable to indicate on the package on what date the product was made and up to what date it is fit for consumption. In general it can be said that particularly the industry is of the opinion that the date of manufacture or the shelf-life should not be declared, unless a perishable product might become detrimental to health in a fairly short time (some months).

At this stage nothing can be said about the ultimate form of an EEC directive on labelling, neither as regards its contents, nor as regards its effect. As far as the latter point is concerned, there is in some circles a certain tendency to restrict the general directive and to lay the emphasis on the regulations per product, the vertical directives.

Packing Material

Further the European Commission wishes to make regulations for the composition of packing material for foods. The Commission has had a preliminary study made, and UNICE is preparing certain proposals to be submitted to Dr. Steiger.

Mainly in view of modern plastic packing material this is an extremely difficult field, and it will take a good deal of time before agreement is reached. Many European countries are working on this, and in some of them regulations already exist, but there are still very wide differences.

Cocoa and Chocolate Directive

Despite the difficulties which are involved in making product directives, a directive for cocoa and chocolate is gradually nearing completion. It is likely that this directive will ultimately permit the use of refined cocoa butter, since in some countries this is a very important product, besides which it enables low quality cocoa-beans

unsuitable for processing as such to be used for making a suitable cocoa butter.

Moreover, in a period when prices of cocoa powder are far too low the fat can be extracted from the beans by expelling, which is a much cheaper process. In this way an economic problem can be solved.

Moreover an ultimate form for the directive on jam has been found and has just been published. It covers a great many varieties of jam and marmalade, and contrary to what is at present usual in many European countries, declaration of colouring agents will be prescribed, whilst raw materials preserved with sulfur dioxide may no longer be used after 1972 in the jam varieties most in demand. From then on only deep-frozen fruit may be used in this type of jam. We have certainly not heard the last about this directive, which we feel implies an unnecessary disqualification of the use of sulfur dioxide. The Italians in particular want jam without sulfur dioxide, but they forget that in view of the large quantities of wine consumed in Italy, 250 times as much SO_2 is consumed in wine than in jam.

Directive on Meat Products

A long-debated point is a directive on the problems concerning the trade in meat products. Although the sanitary regulations recommended may cause great difficulties in view of the high standards which slaughterhouses etc. have to meet, agreement on this point was reached fairly soon. However, these sanitary measures are accompanied by a kind of positive list of permitted additives for meat products. Prescriptions have not at the same time been made for the composition permitted for different types of meat products. This is understandable because in view of the great variety of meat products used in the European countries it is extremely difficult to divide them into groups of comparable composition. On the other hand it is not easy to compile a list of permitted additives without knowing for what product groups they are needed. The latest development in this field is the desire to include in this directive only the veterinary measures and at a later date to make a separate directive for the various types of meat products and the permitted food additives.

Directive on Soups and Bouillon Extracts

Soups and bouillon extracts are important products in Europe. At the time industry as a whole was submitting one proposal, the

European Commission made a recommendation which did not fit in very well with practice thus far. One of the typical features of this recommendation would make it impossible to bring on the market a dried chicken soup, presently a major product in Europe. A short while ago, however, the European Commission and the manufacturers reached a reasonable compromise which takes into account the views of industry as well as the wishes of the authorities, and which is likely to lead to a directive in this field.

The task of harmonizing EEC-food legislation is a difficult one, which will take a very long time. It is fortunate however, that this work is going on steadily and is not hampered by all the crises which are experienced in the EEC. **[The End]**

DRUG EFFICACY IS PROPER ISSUE FOR JURY DETERMINATION

According to the United States Court of Appeals in Chicago, the fact that a jury would be called upon to determine a problem which is not within their normal scope of knowledge or experience, in this case determining the efficacy of a drug charged to be a fake cancer drug, is no reason for taking the issue away from the jury or for conducting a court supervised clinical test. The court thus rejected the contention that a trial prior to an impartial clinical test of the efficacy of Krebiozen in the treatment of cancer would violate constitutional rights to a fair trial and due process of law. *Ivy v. Katzenbach,* U. S. Court of Appeals (CA-7), September 22, 1965, FOOD DRUG COSMETIC LAW REPORTS ¶ 40,201.

KREBIOZEN FACTORY INSPECTION DENIED REVIEW BY SUPREME COURT

The United States Supreme Court has refused to review a decision of the United States Court of Appeals in Chicago which stated that a factory inspection of an establishment in which cancer drugs for investigational use were being prepared, made on a Saturday on which the factory was in operation, was reasonable and authorized under Sec. 704(a) of the Federal Food, Drug and Cosmetic Act. *Durovic v. Palmer,* Sup. Ct. Dkt. 187.

The Court of Appeals decision is reproduced at (CA-7) FOOD DRUG COSMETIC LAW REPORTS ¶ 40,172.

PESTICIDE RESEARCH FUNDING MEASURE SIGNED

The President has signed a bill (S. 1623) raising the ceiling on authorized annual appropriations for pesticide research. The ceiling on appropriations for the continuing study of the effects of pesticides on fish and wildlife will be increased from $2,565,000 to $3.2 million for fiscal year 1966 and to $5 million annually for fiscal years 1967 and 1968. Public Law 89-232.

Consolidating State and Federal Regulatory Power Over Food and Drugs

By DAVID E. ENGDAHL

This Paper Was Prepared for Presentation Before a Conference of District Four, The National Association of Boards of Pharmacy and National Association of Colleges of Pharmacy, at Ann Arbor, Michigan, October 26, 1965. Mr. Engdahl Is Legislative Analyst at the Legislative Research Center, University of Michigan Law School, and a Member of the Michigan Bar.

IN FEBRUARY OF THIS YEAR the Public Administration Service (PAS) of Chicago delivered to the Food and Drug Administration (FDA) its report on a year and a half study of state and local food and drug programs, especially as they relate to federal programs in this field. The report numbers some two hundred sixty pages, and thus is obviously beyond any accurate summarization in so short a time as I have here this morning. Many of you, however, are familiar with this report already; some of you, perhaps, were involved in the processes of the study. Most of you who are not already familiar with it will become so as discussions continue concerning the recommendations made in the report for modifying the respective roles of the federal government and the states in the field of food and drugs. The PAS report is an excellent and fundamental piece of work, and what I have to say this morning on the subject of federal and state food and drug regulation is not to be taken as derogating from that fact. But there are some significant deficiencies in the study and its recommendations which strike me, as a lawyer, as demanding exposition and careful consideration.

Although the PAS study and report covers all aspects of regulation concerning food and drugs—including dairy legislation,

meat and poultry inspection laws, and even weights and measures regulation, as well as general adulteration and misbranding provisions—the present discussion will confine itself generally to those matters which, at the federal level, are within the jurisdiction of FDA. It is laws dealing generally with product adulteration and misbranding which in common parlance are referred to as "food and drug laws."

Need for Uniformity

Among the most important findings of the PAS study is that there is a great need for real uniformity in the regulation of the food and drug industries, and for close coordination between enforcement efforts at all levels—federal, state, and local. Changing trade and production practices, technological advances in the industries, the changing organizational patterns of the industries themselves, have operated to make diversity in regulations imposed at the federal, state, and local levels harmful not only to the industries but even to the consumer. Food and drug products are increasingly prepared by regional or national manufacturers for a regional or national market. A single product must often pass muster under the federal law and the separate laws of several different states before it can lawfully reach the consumer. The interests of the industry and of the consumer—who must bear the costs of enforcement and of industry compliance with these diverse requirements—cry out for uniformity. And yet the PAS report declares:

> The general food and drug laws of the states fail to reveal a basic uniformity among themselves or an adequate correspondence with federal legislation. . . . Differences in laws and regulations are excessive, and many serve no useful purpose; the total body of state and local food and drug laws is a confusing and disjointed mass.

Adequate consumer protection depends upon public vigilance throughout the entire course from production to consumption. Yet, because there is only haphazard coordination (when there is any at all) between the enforcement activities of different governmental agencies, there is wasteful duplication of effort at some points and woeful neglect at others.

Public Administration Service Proposals

A sense of the desirability of some degree of uniformity and coordination has exhibited itself among those concerned with food and drug regulation for many years; and some officials insist that within a short time, and without any radical changes in approach, the prob-

lems will be solved. But the PAS study group thought the problem still serious enough as of 1965 to warrant its recommendation of some fundamental changes in the state and federal roles in this field. Stated briefly, at the risk of some oversimplification, the principal PAS proposals are these: The federal role in determining food standards and standards of drug quality, efficacy, safety, and so on, and in determining limitations on dispensing, manufacturing practices, and labelling and advertising, should in practice be exclusive. That is, in these policy-making areas, while the states would nominally retain legal power to exercise their own discretion, they should voluntarily defer to the decisions of the federal agency. As to enforcement, certain matters—such as enforcing standards of drug safety and efficacy and manufacturing practices—should also be left in practice exclusively to the federal authorities; and responsibility for enforcement in other respects should be divided up between federal and state agencies by means of *ad hoc* working agreements, with the states taking as their primary concern enforcement at the retail level. The proposals include a system of financial assistance to the states in the form of selectively undertaken "coordinating projects" designed to encourage state conformity to federal policy and coordination of state and federal enforcement efforts.

Inadequacy of These Proposals

In my opinion, the recommendations made by the PAS are inadequate. No approach based upon the continued existence of legally independent state and federal authority over the same field can assure the real uniformity of regulation which is needed. There will arise numerous occasions when state officials, convinced for example that the availability without prescription of a certain drug not restricted by federal regulations constitutes a significant health hazard, and aware that they retain power under the state law to restrict its sale if they will, may destroy the uniformity of regulation by banning its nonprescription sale in their state. Moreover, uniformity which appears on the face of the statutes or regulations of different states may in practice prove to be illusory. For example, a "uniform" statute in force in several states condemns as adulterated any food which "contains any poisonous or deleterious substance which may render it injurious to health;" but as the history of benzoate of soda as an ingredient in foods aptly illustrates, a given ingredient might be considered deleterious by officials in one state, so that products contain-

ing that ingredient would be outlawed, while officials in another state might consider the same ingredient to be harmless and so approve the product. The statutes or regulations of several states might "uniformly" prohibit "deceptive" labelling; but a label thought satisfactory under this standard by officials in one state might still be barred as "deceptive" in another state. Furthermore, in addition to such differences in administrative interpretation, "uniform" statutes are subject to diverse interpretation by the separate courts of each state; and this is a factor which would remain to disrupt uniformity in spite of any administrative agreements on interpretation which might be made. Finally, as continuing developments in the industries make necessary repeated amendments not only of administrative regulations but of the statutes as well, each new amendment would disrupt the uniformity again, until all the states had taken the necessary, sometimes tardy action necessary to restore it. The most that can be hoped for so long as there remain independent regulatory powers at the two levels—federal and state—is *approximate* uniformity. We have *approximate* uniformity right now, and it is not enough.

The inability of the PAS approach to bring about real uniformity is a shortcoming which should be of major concern to the regulated industries. A shortcoming of greater concern to regulatory officials is its inability to provide the optimum degree of coordination. A system of selective "coordinating projects" and working agreements with the myriad of independent enforcement agencies might reduce the occasions of duplication of effort or neglect of important matters below their present frequency of occurrence; but it cannot reach the level of efficiency and coordination which would be attainable if the whole responsibility for securing compliance were placed in a single enforcement organization. And however willing all agencies might be to divide their enforcement responsibilities according to the practical requirements of the job, under the present legal situation their ability to do so is still impaired by constitutional principles limiting their respective powers. The concepts of interstate and intrastate commerce may be obsolescent as a practical matter in this field; but they remain legally operative however obsolescent they are, and the PAS proposals offer no means to escape their effect.

Furthermore, the role in food and drug regulation left to the states by the PAS proposals is a far smaller one than the states have traditionally thought themselves entitled to play. If they abandoned to the federal government their own discretion with regard to food

and drug policy, the states would be reduced to little more than administrative arms of the federal government in this field. Enforcement of federally determined policy at the level of retail distribution is not an insignificant responsibility; but is a lesser responsibility than the states have generally thought themselves the appropriate agencies to handle.

Problem of Federal Preemption

But there is another shortcoming of the PAS proposals which seems to me, as a lawyer, to be the most critical one. It is the failure to come to grips with the problem of federal preemption.

Federal preemption of state food and drug laws is a subject which arouses the impatience of many state food and drug law administrators; but it continues to occupy the thoughts of food and drug lawyers. Many state officials seem to regard approximate uniformity in food and drug regulation as a sure safeguard against preemption; but this reflects a very inadequate understanding of the doctrine of federal preemption. Opinions among food and drug lawyers on the question of preemption of state food and drug laws are varied. Articles have been published presenting arguments on each side. Decisions rendered by lower courts are not consistent among themselves; and there has been no conclusive decision on the preemption question delivered by the United States Supreme Court. In fact, there has been no decision at all on the question by the Supreme Court since well before the enactment of the present Federal Food, Drug and Cosmetic Act in 1938. Some lawyers rely upon their analysis of the handful of cases which did reach the Supreme Court during the first three decades of this century as settling the question of preemption; but their analysis is mistaken. The question of preemption of state food and drug laws by the federal act of 1938 is still undecided. It is possible only to speak of what the Supreme Court will *probably* do when the question is squarely presented.

I have stated my own understanding of the doctrine of federal preemption and its probable application to state food and drug laws in much greater detail than can be attempted here, in an article which is to appear in the forthcoming issue of the *Journal of Public Law* ("Consolidation by Compact: A Remedy for Preemption of State Food and Drug Laws," 14 J. Pub. L., No. 2, fall 1965). I can only summarize my thinking here. The Constitution establishes conflict between state and federal law as the touchstone of preemption; but

conflict may occur in several forms. In food and drug circles, it seems, the opinion prevails that "conflict" means only direct contradiction. However, the great majority of cases where preemption has been found with respect to food or drug laws or in any other field have involved laws which were apparently compatible—that is, which were not contradictory—but which nevertheless were found to be in conflict. For example, the federal law permitting, but not requiring, a drug such as Primatene to be sold without prescription is not contradictory to a state law prohibiting its nonprescription sale; but this lack of contradiction does not mean that these state and federal laws are not in conflict.

If Congress were to explicitly declare that state food and drug legislation is intended to be excluded, by its very existence any state food and drug law would stand in conflict with that federal law. When Congress makes no such explicit declaration, the Supreme Court might nonetheless interpret an act as implying such an exclusionary congressional intent, with the same preemptive effect. A number of the factors which have induced the Court to make such an inference in cases involving other fields of law are also present in the field of food and drugs, suggesting that the Court might reach the same conclusion when the proper food and drug preemption case arises. For example, as the PAS report points out, the food and drug industries and the problems of regulation they pose transcend state boundaries, so that independent regulatory efforts by the several states not only cannot be effective, but have the effect of unduly complicating interstate commerce in these products and producing confusion for the industries, the public, and the regulatory agencies themselves. The field is one which, as a practical matter, calls for real uniformity—that is, singleness—of regulation. In response to the need, Congress has enacted an exhaustively comprehensive, pervasive, and detailed federal regulatory scheme. In analogous instances, the Supreme Court has reasoned that such action in response to such a need has as its object the provision of a single uniform national regulatory program, and implies that Congress intended state regulatory efforts in the field to be excluded. Again, the state food and drug laws and regulations, though they generally avoid outright contradiction of the federal law, frequently add additional restrictions or more stringent requirements than the federal law alone requires, thus denying the federal government discretion to determine how stringent the standards should be. In other fields, this factor has grounded an inference of exclusionary

intent, leading to preemption. And again, the mere fact that the existence of a state law paralleling a federal law creates the possibility of contradiction between federal law and applications of or regulations made under the state law—even where no such contradiction has in fact yet occurred—has sometimes served as a basis for judicial inference of exclusionary congressional intent, and thus preemption.

There are other kinds of conflict sufficient to work preemption, which are not dependent upon Congress' exclusionary intent. If a state law, for example, or the action of state officials under a state law, in any way interferes with the enforcement of a federal law, there is conflict sufficient to cause preemption. And there are indications that some other factors, such as the yet unactualized possibility of contradiction, or even the fact that as a practical matter a field demands a single uniform scheme of regulation, may now be taken by the Supreme Court as sufficient to show preemptive conflict between state and federal law, regardless of the question of Congress' exclusionary intent.

This very sketchy review of the doctrine of preemption is all that present time and purposes allow, but I think it is sufficient to show that a holding of preemption is a real probability. If it is true that no final answer to the question of preemption can be given until the Supreme Court is actually presented with an appropriate case for decision, it is also true that the probability that the Court will hold for preemption must be taken careful account of by all who are concerned with the development of an effective and efficient program of food and drug regulation.

Compacts

I wish to suggest an approach to the federal-state problems in food and drug regulation which has not heretofore been considered. It is an approach which can assure real uniformity of regulation and coordination in enforcement while preserving to the states a meaningful role in the determination of regulatory policy as well as in enforcement, and at the same time eliminating the risk of federal preemption.

The PAS report contains a brief reference to formal agreements between states—usually called interstate compacts—as a recommended means by which facilities and services of separate states could be made available for the cooperative use of several states. But the

compact device holds more potential than merely this. Compacts may also be made for much broader purposes, and between states and the federal government.

Whether between states or between states and the federal government, a "compact" is comparable to a treaty between independent nations. There is a provision in the United States Constitution which purports to deny the states power to enter into "treaties" and to require congressional consent before they can enter into "compacts or agreements" with one another. This provision has fostered a lot of confused thinking about the kind of modern intergovernmental arrangements with which we are here concerned. There is a distinct class of interstate agreements to which this constitutional provision does apply. The kind of arrangement, however, whereby two or more governments jointly undertake a project or responsibility, or jointly enact legislation intended to bind their respective citizens, simply was not known or conceived of until nearly a generation after the Constitution was drafted. This cooperative kind of arrangement is really not within the original contemplation of the Constitution at all. Confusion over the applicability of the constitutional provision concerning interstate "treaties" and "compacts" to such cooperative arrangements entered into between states in this country has resulted in the basically erroneous but widely accepted use of the term "compact" to refer to them. In international practice they are simply called "treaties," or sometimes "multilateral treaties," or "international legislation." The international treaties regulating production of and traffic in narcotic drugs are examples of the cooperative type of intergovernmental arrangement which I have in mind. The potential of such cooperative arrangements as comprehensive regulatory devices is even more dramatically shown by their successful utilization by our European neighbors in the European Coal and Steel Community, the European Economic Community, and the European Atomic Energy Community. Between states in this country this cooperative type of intergovernmental arrangement has been used, for example, to set up regional water pollution control programs, to regulate mass transportation in interstate metropolitan areas, and in one of the most publicized examples, to regulate and administer the large interstate complex of port and associated facilities shared by New Jersey and New York. Just four years ago, the federal government joined in a comprehensive planning and regulatory compact for the development of the Delaware River Basin. It is this device of joint governmental action, whose

utility has been proved in the international field, in the interstate field, and in the field of federal-interstate relations, that I recommend as the best answer to the federal-state problems we face in food and drug regulation.

Federal-Interstate Compact

A national food and drug regulatory compact could be drafted with essentially the same provisions as are contained in the present Federal Food, Drug and Cosmetic Act. It could place the responsibility for promulgating regulations and for enforcement in a national agency to be composed of representatives of both the federal government and the states. The present FDA could serve initially as the core about which the national compact organization would be built; state agencies involved with food and drug regulation could be integrated into the national organization, or their food and drug responsibilities could be transferred by the respective states to new officers created for the purposes of the compact. Since the national food and drug compact would be based upon the constitutional power both of the states and of the federal government, there would no longer be any application for the constitutional distinction between interstate and intrastate commerce; all would be reached by the single, national law, drafted in terms to reach everything that either the federal government or the states could constitutionally reach.

The compact would require for its creation the legislative action of each of the states and of Congress; but their several acts would result in the creation of only a single law. There would be only one compact, though it would become fully effective for a particular state only upon that state's separate accession to it. There would be a single regulatory agency and a single set of regulations. Moreover, no state would enjoy in its courts any independent or final power to interpret the compact; because the compact would be federal as well as state law, that power would reside only in the United States Supreme Court. For these reasons, regulation by compact would be able to achieve the sought-after goal of real uniformity of regulation.

Instead of scores of independent agencies working at best under agreements purporting to divide responsibilities as well as possible within the limits imposed by constitutional theories of state and federal power, there would be a single national agency organized functionally in the best manner to handle the job. There would be no

problems of duplication of effort in some areas and neglect of others, such as occur today.

Because the essence of a compact is agreement between all the parties, and because each state through its representatives in the national compact agency would contribute directly to the making of regulatory policy, regulation by compact would preserve to the states a very significant and meaningful role. The operations of the compact agency would, of course, be financed in appropriate shares by both the states and the federal government.

Finally, a federal-interstate food and drug compact would preclude all possibility of preemption, because there would not be two or more laws, one federal and the other state, but only one law, which would be at the same time both federal and state law. There could be no conflict of state with federal law, because the state and the federal law would be the same; not merely "uniform," and not even merely separate laws in precisely the same words, but the same, single law.

The concept of a national food and drug compact and some of the more intricate legal aspects of the idea are more fully discussed in Part Two of the article which I mentioned earlier, to be published in the *Journal of Public Law* later this fall. There is no legal barrier to a national food and drug compact. It is strictly a question of its desirability: to the industry, to the states, and to Congress. The purpose of this paper has been to introduce the idea of a national food and drug compact for discussion as to its desirability, in the light of the objectives which seem to be motivating discussions of federal-state relations in this field generally. It is for persons like yourselves, closely involved with this field of the law, to weigh the advantages of this approach against the merits and shortcomings of other proposals before acquiescing in the perpetuation of a less satisfactory scheme of regulation in the important field of food and drugs. **[The End]**

The Mathematical, Legal and Chemical Concepts of Zero

By BERNARD L. OSER

The Following Article Was Presented at the American Industrial Hygiene Association Meeting in Houston, Texas, on May 6, 1965. Dr. Oser Is This Magazine's Scientific Editor.

WERE IT NOT FOR THE FACT THAT ANOTHER AUTHOR HAD PREEMPTED IT, the title of this discourse might have been "Much Ado About Nothing." It is my purpose to discuss the variety of meanings attached to the term "zero," to show how these meanings depend upon the context in which the term is used, and in particular, to analyze the practical significance of the "zero level" concept as applied to the prohibition of toxic substances in foods and agricultural commodities. Thus this discussion of the mathematical, legal, and chemical interpretations of zero forms the background for a consideration of its toxicological signficance, as implied in the Federal Food, Drug and Cosmetic Act insofar as it is designed to protect public health.

Uses of Zero—Mathematical and Physical

It would appear obvious even to a non-mathematician that a distinction must be drawn between the mathematical uses of zero as a numerical symbol and its use to signify the absence of quantity. It is interesting to note that the ancient Hebrews, Greeks, and Romans did not even have a symbol for zero, and it was not until its introduction as both a cardinal number and an abstract concept by Hindu mathematicians that the science of algebra had its real beginning. The Sanskrit word for cipher or naught was *sunya,* which literally meant void or empty. The invention of zero made possible simplified methods of computation and "liberated the human intellect from the prison bars of the counting-frame." We can say quite literally to the Hindus of old—"Thanks for nothing"!

The Arabic figure "0" was probably intended to symbolize the lack of contents of the circle rather than its circumference. Colloquial synonyms such as "goose-egg," the dismally failing grade for examination papers, or "love" (from the French "l'oeuf") for "no score" in tennis, are descriptive of the shape of the zero symbol. In mathematical usage however zero is both a symbol and a value. Much of its significance depends on how it is used, that is, whether added ($x + 0$), subtracted ($x - 0$), used as a multipiler ($x \times 0$), divisor ($x/0$), power (x^0), etc. The position of 0 determines the magnitude of a number, for example, 0.1 vs. 1.0 or 10, and in the binary system, where 0 and 1 are the only digits, position is everything. In the sequence of integers, 0 marks the transition between positive and negative numbers (for example, 2, 1, 0, -1, -2). When used to mean "none" or "no quantity" in the absolute sense, 0 might be written 0.0 .... 0oc where theoretically an infinite number of zeros follows the decimal point.

Now let us contrast these mathematical uses of zero with the meaning of zero in a physical sense. The absence of any quantity or dimension capable of measurement can be represented by 0.0 .... 0n, where the number of zeros is finite and is determined by the limit of detectability or sensitivity of the instrumentality of measurement. An analytical balance which is sensitive to only 0.0001 gram is not capable of establishing the absence of say, 0.00001 gram; the latter quantity would be regarded as "zero" though, strictly speaking, it should be designated as "less than 0.0001 gram, if any." Similarly, since chemical analytical procedures have definable limits of detectability it is inaccurate to use the expression "none present" when in fact what is meant is "none found."

In deriving a quantitative estimation, the determining factors involve not only the inherent precision of the measuring device or analytical procedure, but the practical purpose of the measurement and the degree of precision required, as well. The decision as to how to round off a measured or calculated value, for example, whether to consider 0.00045 as equivalent to 0.0005 or 0.0000 (or "none") may depend not only upon the precision of the measurement but on the practical needs of the observation. Thanks to improvements in instrumentation and microanalytical techniques, the gravimetric units for measuring so-called trace substances are passing beyond the milligram-microgram stage and entering the nanogram-picogram period. In the area of pesticide residue analysis, it has become more important than ever,

in international dealings, not to confuse "parts per billion" (10^9) as used in the United States with the same expression as understood by our colleagues in Britain where a billion is 10^{12}.

Law and the Zero Concept

A law designed to protect against the hazards of potentially toxic chemicals should of course employ language intended to exclude them from food insofar as this is practicable and achievable.

Recognition of the fact that all chemicals are potentially toxic and that actual hazard to man or animals is determined only by the conditions of administration or exposure, led to the enactment of recent amendments to the Food, Drug and Cosmetic Act. This statute, and the regulations thereunder, determine which chemicals (food additives and pesticide residues) can legally be present in foods, and under what conditions. The law provides that "the Secretary may establish the tolerance . . . applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at *zero level* if the scientific data . . . does not justify the establishment of a greater tolerance." Economic poisons are subject to registration for use by the Department of Agriculture but if, under the conditions of use, an economic poison leaves *"no residue"* in or on food, a tolerance need not be established under the Food, Drug and Cosmetic Act; pesticides which leave residues on foods other than raw agricultural commodities (that is, processed foods) and food additives, unless otherwise exempt, are subject to regulation by the Food and Drug Administration (FDA). In these cases too, tolerances may be set at zero level.

The law also provides that no regulation shall be issued if the proposed use will be unsafe. Under this clause any substance which is found to induce cancer upon ingestion by man or animal is denied a regulation permitting its use (except in animal feed under certain conditions). The reasons given for establishing a zero tolerance for pesticide chemicals in or on a raw agricultural commodity are:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reasonably determined.

(b) The chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals.

(c) The pesticide chemical is toxic, but is normally used at times when, or in such manner that fruit, vegetables, or other raw agricultural commodities will not bear or contain it.

(d) All residue of the pesticide chemical is normally removed through good agricultural practice such as washing or brushing or through weathering or other changes in the chemical itself, prior to introduction of the raw agricultural commodity into interstate commerce.[1]

Inasmuch as the enforcement of regulations on a "no residue" or "zero level" basis requires analytical control by methods of adequate sensitivity, and the sensitivity of any such method can be expressed in finite terms, it follows that the absolute mathematical significance of "zero" or "none" cannot be applied in this context. The only way of excluding completely the possible presence of a residue level of a pesticide is to disallow its use for any purpose whatever. This is tantamount to prohibiting its manufacture, an extreme measure which would rarely be necessary for the protection of public health, though it has been invoked in at least one instance. However, it is clearly the intent of pesticide and food additive legislation to provide for the safe use of chemical substances which perform agriculturally and technologically useful functions. Prohibition of their use would, therefore, defeat this purpose.

Analytical Methods

Analytical methodology has improved tremendously over the years, leading to unprecedented degrees of accuracy, precision, and sensitivity. Minute but nonetheless finite amounts of substances can now be detected in air and water, as well as in food, which by earlier methods escaped detection. The estimation of residue levels involves many other considerations, for example, errors of sampling, the size of samples, background "noise," variations in "clean-up" procedures, etc. As indicated above, the expression "none found" in an analytical report in no wise excludes the possibility that a more sensitive method might reveal the presence of a finite level of the substance in question. Concomitant with the increased use of pesticides in agriculture, chemists have continually been pressed to develop analytical methods of increasing sensitivity. A DDT level of one part per billion is barely detectable in milk. At this concentration a liter of

[1] Food, Drug and Cosmetic Act, Pesticide Regulations 120.5, Zero Tolerances, FOOD DRUG COSMETIC LAW REPORTER ¶ 54,305.

milk would contain about 1.7×10^{15} molecules of the pesticide; if the analytical detectability were improved even 1000-fold, as many as 1.7×10^{12} molecules of the pesticide could escape detection. Thus, it is not only "vexatious in either logic or science," as a spokesman for the FDA has put it, but futile to the point of absurdity to tax the ingenuity of the analyst by requiring proof of the absence of a substance, unless it can be established that its presence in any amount, however small, poses a genuine rather than hypothetical hazard.

"No Effect Dose"

There is another negative term which is perhaps of even greater concern to the toxicologist whose duty it is to estimate safe levels of administration of or exposure to chemical substances. Here reference is made to the use of the term "no effect dose" as though it had a literal, absolute significance.

In animal studies designed for safety evaluation, a major aim is to determine the "no effect" dose. This goal may be approached to a degree sufficient to provide virtual certainty of safety (particularly after the application of a safety factor) but it can never be attained on an absolute basis. Among the many reasons are the facts that (1) the size of test groups of animals is small relative to the particular species and to the millions of population to which the data are to be applied; (2) a certain degree of risk (probability factor) is inherent in any findings dependent on a finite number of animals; (3) no effect levels vary with the species, strain, age, sex, etc. of test animals and hence the failure to observe an effect under one set of experimental conditions does not preclude the possibility of an effect under other conditions; (4) however many parameters of response may be measured in toxicological studies, it is always conceivable that one or more tests not employed in a particular study, or not yet devised, might reveal an effect where none was previously observed; (5) "no effect" implies no toxic effect, but it is difficult sometimes to decide whether an aberration, that is, a difference from a "normal" or control response, is indeed an adverse effect. For example, an elevated level of a normal constituent in blood or tissue, or a so-called nonspecific histomorphologic alteration, unaccompanied by dysfunction, may not be indicative of disease or injury.

For these and other reasons the subjective element of judgment enters into the estimation of "no effect" dose levels. Because of the

inherent uncertainties in applying the conclusions derived from one species to another species, to wit man, it has become conventional to introduce a safety factor in this transition.

The multiplicity and complexity of factors involved in safety evaluation, many of which are not subject to quantitation, make it impossible to establish the risk of transferring animal toxicity data to man with a finite degree of statistical probability. In any case, the pragmatic approach in current use of estimating maximum acceptable daily intakes of potentially toxic substances from toxicological studies in more than one species of test animal, by applying a safety factor to the observed (rather than extrapolated) no effect level, has seemed reasonable and sound in practice, notwithstanding the more or less arbitrary magnitude of the safety factor. Thus, it is possible to arrive at a "toxicological zero" as distinguished from a mathematical or analytical zero.

The maximum acceptable daily intake for any substance is in effect the limiting amount which should not be exceeded by the total of all permissible use levels. It is, in fact, the maximum "no-effect level for man." This acceptable limit must be clearly distinguished from tolerance levels in the regulatory sense, inasmuch as legal tolerances are maximum permissible levels determined by good agricultural or manufacturing practice and are set no higher than are actually needed in practice. Legal tolerances should not be construed as maximum safe levels, since there is always a considerable margin between such tolerances and the maximum acceptable daily intake.

Reports on the Chemical Concept of Zero

Shortly after enactment of the Pesticide Residue Amendment of 1954, it was stated by a spokesman for the FDA[2] that "To the analytical chemist zero is an unrealistic figure and, in practice, zero becomes the limit of sensitivity of the analytical method." In 1957 an *ad hoc* Committee of the National Research Council[3] reviewed this subject and concluded that "The term 'practical equivalent of zero' has no rigorous scientific basis, and that to designate a finite concentration

[2] W. I. Paterson, "Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs and Cosmetics," 1 CHEMICAL, FOOD DRUG COSMETIC LAW JOURNAL, 10, 681 (1955).

[3] Report of *ad hoc* committee on the Practical Equivalent of Zero, Food Protection Committee, National Research Council, 1957.

as zero cannot be justified on a scientific basis (although it may be expedient legally to do so)."

The report went on to recommend that consideration be directed toward relating a minimum deleterious level to a harmless level, suggesting that:

> Perhaps such consideration by a group of pharmacologists and toxicologists could result in the development of a workable formula for deriving from the minimum level of observed toxicity a level at which the probability of damage would be so incredibly low as to approximate zero. The committee has in mind here a mathematical or statistical derivation rather than the present rule-of-thumb factor of safety.

No practical solution to the problem was invoked, however, and in 1963 the President's Scientific Advisory Committee Panel on the use of pesticides again reviewed the situation.[4] This Committee's report stressed the need for further study and recommended that "The National Academy of Sciences—National Research Council be requested to study the technical issues involved in the concepts of 'zero tolerance' and 'no residue' with the purpose of suggesting legislative changes."

The Committee's recommendation was adopted by the Secretaries of Health, Education, and Welfare and Agriculture, following which a special *ad hoc* committee was appointed to handle the assignment. Whereas the Committee has not yet reported[5] and it would be presumptive to anticipate its recommendations, it is nevertheless useful to speculate on several possible administrative alternatives to construing a "no residue" or "zero level" in an absolute mathematical sense.

1. The finite level corresponding to the limit of detection of the initial analytical method could be adopted. This might be the method in use when the tolerance was first established, or any other specified method.
2. Instead of defining the level as in[1], the method itself could be specified by regulation. For example, the Delaney clause was recently amended to permit the use of a carcinogenic additive to animal feed provided no residue remained in any edible portion of the animal or in any food derived from the animal,

[4] "Use of Pesticides," a Report of the President's Scientific Advisory Committee, May 15, 1963.

[5] On July 19, 1965 (subsequent to the presentation of this paper), the report of the Pesticide Residues Committee was released for publication.

as determined by methods of examination prescribed in regulations (which methods, incidentally are not subject to review).

3. A finite level, uniformly applicable to any and all pesticide residues, could be set arbitrarily at a point low enough to be beyond the range of probable risk, but analytically detectable for the purpose of regulatory control. This approach would not take into account potential differences in toxicity among pesticides.
4. An inconsequential, and hence negligible, level could be established for each pesticide as the practical equivalent of zero or no residue, by increasing the safety factor employed in the transition of the no effect dose from test animals to man. For example, the commonly used safety factor of 100 could be increased by an order of magnitude, thus establishing a "maximum *negligible* daily intake" at, say, one-tenth the "maximum *acceptable* daily intake."

In any event, it is clear that the very use of a food additive or pesticide is bound to result in some residue which may escape detection by the best methods available today. Hence, the concept of zero in an uncompromising absolute sense is illusory and indefensible. It is hoped that a reasonable scientific solution will be found to this perplexing, legalistic problem. **[The End]**

DELETION OF CERTIFICATION PROVISIONS FOR UNMARKETED DRUGS PROPOSED

The Food and Drug Administration has proposed to delete the certification provisions for drugs which no longer are being certified, and to clarify the nomenclature of crystalline penicillin and procaine penicillin. Views and comments may be filed by December 5, 1965. FOOD DRUG COSMETIC LAW REPORTS ¶ 80,108.

DEPRESSANT AND STIMULANT DRUG REGULATIONS ISSUED

Regulations prescribing the registration procedure for domestic and foreign producers and distributors of depressant and stimulant drugs have been issued. Initial registration may begin on November 15, 1965, and must be effected by February 1, 1966. FOOD DRUG COSMETIC LAW REPORTS ¶ 72,000—72,051.

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