VOL. 17, NO. 6 JUNE 1962

Food·Drug·Cosmetic Law
JOURNAL

Activities of the Food Protection Committee, National Academy of Sciences, National Research Council

. . . . . BERNARD L. OSER

The Latin American Food Code: Chapter XII—Nonalcoholic Beverages and Refreshing Foods and Drinks

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

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

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

June, 1962
Volume 17 • Number 6

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . June, 1962

	Page
Reports to the Reader	339
Activities of the Food Protection Committee, National Academy of Sciences, National Research Council — Bernard L. Oser	340
Enforcement Highlights in the Milling Industry — M. R. Stephens	348
Latin American Food Code: Chapter XII—Nonalcoholic Beverages and Refreshing Foods and Drinks	355
Waters	355
Carbonated Waters and Similar Products	360
Carbon Dioxide	367
Syrups	367
Vegetables Juices	370
Ice	374
Ice Creams, Sherbets and Cold Beverages	375
The Interstate Ingredient of Section 304(a)—Federal Food Drug, Cosmetic Act — Norman E. Matteoni	380
Washington—Action and News In the Food and Drug Administration	399

VOLUME 17 NUMBER 6

REPORTS

TO THE READER

Food Protection Committee.—"In a true spirit of dedication to public service, the scientists who serve on the FPC and its subsidiary committees (as indeed those on all other committees in the National Academy of Sciences—National Research Council) have, without benefit of financial reward, served diligently, faithfully, and objectively regardless of whether they are employed by the government, by academic institutions or by industry." These words of praise appear in a report, beginning on page 340, which describes the activities of the Food Protection Committee by the Scientific Editor of the FOOD DRUG COSMETIC LAW JOURNAL, *Bernard L. Oser.*

Milling Industry Highlights.—*M. R. Stephens,* Director of the Bureau of Enforcement of the Food and Drug Administration, declares that the goal of the Federal Food, Drug and Cosmetic Act is a safe, wholesome and honestly labeled food supply. Achieving this common goal of both the milling industry and the regulatory official is not an easy job. Mr. Stephens points out the progress which has been made in this field recently. This paper begins at page 348.

Latin American Food Code.—This month's JOURNAL contains Chapter XII, "Nonalcoholic Beverages and Refreshing Foods and Drinks," which is part of the printed 1960 edition of the Code. This chapter was translated from the original Spanish by *Ann M. Wolf* of New York. This translation commences at page 355. Other parts of the Code have appeared in following issues of the JOURNAL: October, 1960; February, 1961; May, 1961; and October, 1961.

Section 304(a).—The broad scope of the interstate ingredient of Section 304 (a) of the of the Food, Drug and Cosmetic Act is thoroughly explored in an article by *Norman E. Matteoni,* which appears on page 380. Mr. Matteoni observes that the decision in the *Pinocchio* case represents an ever broadening interpretation of what constitutes interstate commerce.

Remington Medalist Announced.—The 1962 Remington Honor Medal Presentation Dinner will be held on Tuesday, December 4, 1962 at the Hotel Roosevelt in New York City, *Frank J. Pokorny,* Secretary of the New York Chapter of the American Pharmaceutical Association, recently announced. The Remington Medalist for the year 1962 to be honored on that evening will be *Harry J. Anslinger,* United States Commissioner of Narcotics. Mr. Anslinger will be the thirty-eighth person to be presented with the Remington Medal, the highest award in American Pharmacy since its inception in the year 1919.

Vol. 17, No. 6 June, 1962

Food·Drug·Cosmetic Law
Journal

Activities of the Food Protection Committee, National Academy of Sciences, National Research Council

By BERNARD L. OSER

The President and Director of the Food and Drug Research Laboratories, Inc., Bernard L. Oser, Delivered This Talk Before the Central Atlantic States Association of Food and Drug Officials on May 23, 1962 in New York, New York. Mr. Oser Is the Scientific Editor for the FOOD DRUG COSMETIC LAW JOURNAL.

DURING THESE YEARS OF CELEBRATION of the centenary of the Civil War, it behooves us to remember that it was in Abraham Lincoln's administration that several landmarks were established in the history of American agriculture and science. The World Food Forum held in Washington earlier this month marked the hundredth anniversary of the Department of Agriculture, of the Land Grant Colleges and of the Homestead Act. 1963 will be the centennial of the National Academy of Sciences which was established by Act of Congress to advise the federal government, upon request, on scientific and technical matters. During President Wilson's administration, the Academy organized the National Research Council with the cooperation of the major scientific technical and engineering societies. Its purpose is to facilitate exchange among scientists as a

means of implementing their service to governments. The Division of Biology and Agriculture of the Academy in 1940 appointed the Food and Nutrition Board with authority to act on its own initiative or on request from public or private agencies.

Finally, to come to the subject of the present discussion, the Food Protection Committee was established by the Food and Nutrition Board in 1950 for the purpose of providing scientific guidance and critical evaluation for public agencies and for the industries concerned with the use of chemicals in the production, processing and packaging of food.

Food Protection Committee Activities

The activities of the Food Protection Committee are supported by annual contributions from food, chemical and packaging companies and from independent laboratories. Grants from over 100 industrial organizations exceed $50,000 per year. Representatives of the contributing companies, together with representatives of scientific and technical societies, trade associations and various government agencies comprise a Liaison Panel. However, while the Food Protection Committee welcomes the suggestions of the panel, its judgments and policies are, in the last analysis, arrived at quite independently and are subject to review only by the Food and Nutrition Board. There are at present four subcommittees of the Food Protection Committee which deal respectively with food technology, toxicology, pesticides and carcinogenesis. Their total membership, including the ten on the parent committee, consists of 30 individuals whose affiliations are as follows: universities or medical colleges, 12; government agencies, 9; industrial research institutes and laboratories, 7; medical research institutes, 2.

In addition to supervising the activities of these subcommittees, the Food Protection Committee has assumed the administrative direction of the recently inaugurated Food Chemicals Codex project of which more later.

Scientific Symposium Sponsored by FPC

The Food Protection Committee sponsors an annual meeting to which the representatives on the Liaison Panel are invited. On this occasion business meetings are held both independently and jointly by the Food Protection Committee and the industry panel. However, the "piece de resistance" is a scientific symposium on some special topic

of current interest, the most recent one being devoted to "Problems in Tolerance Setting." In 1960 the topic was "Science and Food, Today and Tomorrow," the proceedings of which have since been published (NAS-NRC Publication 877).

The activities of the Food Protection Committee are best represented by publications resulting from the deliberations of its subcommittees. However not all of its decisions are as widely disseminated as might be desired. For example, when advice is sought by the Food and Drug Administration on a specific subject, the recommendations of the Food Protection Committee or of a specially appointed *ad hoc* committee may be submitted in the form of a statement which is generally available on request but it may not be published as a bulletin.

New Responsibilities for the National Academy of Sciences

An important function of the National Academy of Sciences has been assigned to it by Congressional enactment in the form of recent amendments to the Federal Food, Drug and Cosmetic Act. The amendments regulating the safety of pesticide residues in raw agricultural commodities, and of color additives in foods, drugs and cosmetics provide for referral of certain disputed issues to *ad hoc* advisory committees. On the basis of an "independent study of the data furnished to it by the Secretary of Health, Education and Welfare and other data before it," the committee submits a report and recommendations "together with all underlying data and a statement of the reasons or basis for the recommendations." Since the matters that have thus far, at least, been referred to the National Academy of Sciences under these provisions, concerned toxicological questions within the purview of the Food Protection Committee, its members have played a major role in organizing and serving on these *ad hoc* advisory committees.

It is interesting to note in passing that whereas the Pesticide Chemicals Amendment places no restriction on the nature of the scientific questions submitted for independent review, the Color Additives Amendment limits it to the area of alleged cancer-inducing agents. Strangely enough, the Food Additives Amendment was enacted without provision for independent appraisal of scientific issues by an *ad hoc* committee, this despite the fact that the recommendations of such committees are not binding on the administrative agency and, when necessary, are subject to further judicial review.

Published Reports of Great Interest

As indicated above, the activities of the Food Protection Committee are seen in best perspective through its published reports. Some of these cover areas of advancing knowledge and are of such broad interest as to have justified a second review. Reference will be made here only to the latter reports. Among these is National Academy of Sciences—National Research Council Publication 470 (November, 1956) entitled "Safe Use of Pesticides in Food Production," which discusses the need and use for new pesticides, problems of potential hazard to animals and man, the steps involved in developing, evaluating and marketing new pesticides, and the analytical and toxicological aspects of regulatory control.

Similarly, revision of an earlier report appeared in December, 1959 under the title "Principles and Procedures for Evaluating the Safety of Food Additives" (NAS-NRC Publication 750). Incidentally, a food additives is here defined in simple positive language, in contrast to that employed in the Food, Drug and Cosmetic Act, namely as "a substance or a mixture of substances, other than a basic food stuff, which is present in food as a result of any aspect of production, processing, storage, or packaging." This report outlines in general terms the types of studies employed in evaluating the safety of food additives. The recommendations correspond closely to the procedures described in greater detail in the publication of the Food and Drug Administration Division of Pharmacology, "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics."

Legislation Concerning Carcinogens

As we all know, the fears and doubts engendered in the minds of the public have been reflected in specific legislation outlawing even suspected carcinogens as residues in or additives to food. Hence special consideration has been given by the FPC to this highly controversial topic.

Subcommittee Report on Carcinogenesis

The report on "Problems in the Evaluation of Carcinogenic Hazard from Use of Food Additives" (NAS-NRC Publication 749, December, 1959) represents a major achievement of the Subcommittee on Carcinogenesis, despite the fact that its conclusions, like the knowledge upon which they are based, are somewhat vague and

equivocal. The report considers the problems of benign versus malignant tumors, weak versus strong carcinogens, spontaneous versus induced tumors, and experimental versus epidemiological observations. It also stresses the experimental and interpretative precautions which must be observed in the evaluation of carcinogenity in laboratory animals. The report concludes that a "no-effect" level of carcinogens exists for man as well as for laboratory animals but owing to difficulties of extrapolation between species, "The assignment of a tolerance level, or a safe level of use for man . . . must at present rest largely on the evaluation of alternate risks and values which usually cannot be expressed in quantitative terms." This, it will be noted, does not deny the possibility of assigning tolerance levels for useful, even though carcinogenic, substances.

As a member of the Joint Food and Agriculture Organization/World Health Organization Expert Committee I can say that this report of the Food Protection Committee has provided much valuable guidance and information in the preparation of its document on the same subject, published in 1958.

"Green Book" Served Valuable Purpose

In 1956 the FPC published its famous (though now obsolete) "Green Book" on "The Use of Chemical Additives in Food Processing" (NAS-NRC Publication 398). It included a compilation of the chemical substances generally known to be used in food processing, listed according to functional categories. The tabulation indicated where these uses are permitted by official definitions and standards of identity, and whether or not under limitations as to amount or use. Part I of this two-part report described the technological justification for the use of chemical substances (many of them being of natural origin). Facts developed subsequent to the passage of the Food Additives Amendment of 1958 showed that the "Green Book" listing was hopelessly incomplete. Nevertheless it has served a valuable purpose in encouraging industry to do voluntarily what has since become mandatory, namely, to reveal trade practices with respect to chemical additives to food, which hitherto have been regarded as secret.

The disclosure of a multitude of intentional and nonintentional food additives through the publication of so-called GRAS lists by both the Food and Drug Administration and industry (particularly the Flavoring Extract Manufacturers Association), and the publica-

tion of food additive extensions and regulations, has emphasized the need for a complete revision of the "Green Book" which is now in progress. In view of the frequent changes or extensions in the list of permitted food additives as reported from day to day in the *Federal Register,* it may be quite some time before a "complete" list will be ready for publication. However, in the meantime, the FPC has issued an up-to-date report on "The Use of Chemicals in Food Production, Processing, Storage, and Distribution" (NAS-NRC Publication 887, 1961) which is a substantial expansion of Part I on functional value originally published in the "Green Book."

In addition to these reports on general principles and policy, the Food Protection Committee has issued statements on more specific subjects at the request of either the Industry Liaison Panel or the Food and Drug Administration. For example a statement on "Insignificant Levels of Chemical Additives in Food" (published as an appendix to NAS-NRC Publication 750 cited above) attempts to resolve the dilemma created by the "zero tolerance" concept where the presence of a chemical substance may be analytically demonstrable though toxicologically inconsequential. "In such instances," the statement concludes, "regulatory action is not required." Many segments of the food industry, I am sure, devoutly wish that FDA would more liberally heed this advice.

Pesticide Residues In Milk

Another case in point is the statement of the Food and Nutrition Board circulated in September, 1960 on "Tolerances for Pesticide Residues in Milk." This statement, based on a review by the Food Protection Committee concludes with the opinion "that the present policy that only zero tolerances for pesticide residues in milk can be permitted is not scientifically justified." Among the reasons advanced by the Board in support of this view, the following may be of interest:

> There is no evidence or reasonable basis for presuming that extremely small residues of pesticides in milk are peculiarly hazardous for the infant. In any event, at a few weeks or months of age, the infant is given foods that may contain residues of pesticides. These residues are deemed safe. It is unscientific to insist that, in order to be safe for infants, cow's milk must be absolutely free of residues of pesticides permitted in other foods.

Scope and Intensity of FPC Activity

Further evidence of the scope and intensity of activity of the Food Protection Committee may be seen in reports it has issued on

more narrowly defined subjects, including critical evaluation of data on the safety of specific substances or classes of substances. Emulsifiers have been subjected to careful scrutiny. Its report of 1958 on "The Safety of Polyoxyethylene [8] Stearate for Use in Foods" followed a previous evaluation based on less voluminous data. It concluded that the use of this emulsifier at levels contributing no more than 0.05 per cent to the human diet would be safe. Some time earlier an FPC committee after reviewing the facts concerning the ingestion of surfactants reached the conclusion that surface activity per se could not be assumed to militate against their presence in foods, each such substance having to be assessed on its own merits as revealed in toxicological studies.

This account of the activity of the FPC would be incomplete without reference to what may prove to be its most ambitious undertaking. It has long been felt to be necessary and in fact inevitable, for regulating the safe use of chemicals in food production and processing, to develop specifications for their identity and purity, compatible with their usage. In supporting this view I once had the temerity to propose a name for such a compendium, in analogy with "pharmacopeia" for drugs, namely, "bromatopeia." While this died an early (perhaps well-deserved) death the idea did not; in fact it derived increasing support both domestically and from abroad. Recognizing the need for long-term financial backing for this undertaking, as well as for independent scientific guidance, industrial representatives on the Liaison Panel urged the Food Protection Committee to assume administrative supervision of this project. Upon careful preliminary study, it was estimated to require at least five years of effort and an estimated total budget of $500,000. The project has received a $50,000 per year grant from the United States Public Health Service and expects to obtain an equivalent sum from industry. An organization and staff were established in 1961 under the direction of Dr. Justin L. Powers, together with an advisory panel and a chemistry committee. Thus this long awaited move appears to have gotten off to a good start. A brochure outlining the objectives and program of the Codex project has just been made available.

Tribute to FPC

In conclusion, I should like to point out that it has been my privilege to function in a multiple capacity in relation to the FPC. I am a member of its Subcommittee on Food Technology and represent

my own organization as a contributing member of the Industry Liaison Panel. I also represent the American Public Health Association and the American Council of Independent Laboratories on the Panel. From these vantage points I am pleased to cite the FPC as an example of how much can be accomplished in the public interest by the collaborative effort of well-mentioned scientists concerned with public safety. In a true spirit of dedication to public service, the scientists who serve on the FPC and its subsidiary committees (as indeed those on all other committees in the National Academy of Sciences—National Research Council) have, without benefit of financial reward, served diligently, faithfully, and objectively regardless of whether they are employed by the government, by academic institutions or by industry.

I consider it an honor to have had the opportunity to present this report on the activities of the Food Protection Committee.

[The End]

SEIZURE OF "PEP PILLS" ANNOUNCED

Seizure of some 12,000 amphetamine tablets from a Pennsylvania physician on charges of illegal use was announced on June 15, 1962 by the Food and Drug Administration.

United States marshals seized the "pep pills" in the office of the physician on June 6. FDA said analysis showed they were 10 milligram dl-amphetamine sulfate tablets. The seizure followed an investigation and purchase of 10,000 amphetamine tablets from the physician by an FDA inspector, the agency said.

Amphetamine tablets are in the prescription drug category and can be dangerous because they stimulate continued activity beyond the point of exhaustion, eliminating the protective effects of fatigue and drowsiness, FDA said. The release of inhibitions produced may lead to errors in judgment, dangerous driving and other effects.

Papers filed in the federal district court in Pittsburgh, Pennsylvania charged the tablets are misbranded under the Federal Food, Drug and Cosmetic Act because their labeling fails to bear adequate directions for use. FDA further charged that the prescription tablets are not exempt from bearing adequate directions for use because the agency's investigation showed they were not and will not be used by the practitioner in the course of his professional practice.

Enforcement Highlights in the Milling Industry

By M. R. STEPHENS

This Paper Was Presented at the 1962 Association of Operative Miller's Technical Conference at Denver, Colorado on May 15, 1962. The Author Is Director of the Bureau of Enforcement of the Food and Drug Administration.

IT IS A PLEASURE to be here today to represent the Food and Drug Administration in this joint conference aimed at ensuring the consuming public safe, wholesome and properly labeled milled cereal products.

The great jurist, the late Judge Learned Hand, once said:

> . . . a law couched in general terms, *prima facie* includes all occasions that the words cover, and therefore presupposes a choice on each occasion between some value to be attained and some sacrifice to be accepted.[1]

Clearly from the standpoint of the Federal Food, Drug, and Cosmetic Act the "value to be attained" is a safe, wholesome and honestly labeled food supply. While any regulation is onerous at times we believe your industry subscribes to the proposition that the gain for the public good from legislation of this broad area is such that the burden of compliance is not inordinately great. However, it is no easy task that confronts the milling industry and the regulatory official in achieving this common goal.

There are several facets to it. While your afternoon session today is directed at sanitation problems, with your indulgence I would like to touch on a few of the other areas in the milling business that are also of real concern to consumers and within the realm of our mutual interest and responsibility.

---

[1] Learned Hand, *The Bill of Rights.*

Increased Facilities Insure Greater Protection

As you know, the Food and Drug Administration has been given more enforcement facilities within the past few years. Consequently we have been able to expand our activities into areas which for a number of years had to be pretty much neglected because of the higher priority of other potential violations. I speak specifically of the matter of the accuracy of net weight statements and the manner in which net weight statements and other mandatory information is shown in the labeling.

1958 Survey of Flour Milling Industry

You will recall that following reports from consumer groups and others of short weighting on foods generally and flour specifically, the Food and Drug Administration in late 1958 made a survey of the flour milling industry to gain some firsthand information in order to evaluate the charges. Some 68 mills of different sizes located in 24 states were visited and their products weighed at point of packing. Ninety-four lots of flour were weighed of which 19 lots were slightly below the stated weights and one lot was seriously short weight to the extent of 5 per cent. None of the shortages could be excused on the grounds of moisture losses after packing, since they were all weighed immediately following packing.

The Special Flour Committee of the National Conference on Weights and Measures for 1959 in its report noted that our survey results were consistent with the results of a survey by Weights and Measures officials in 1955, and observed, "The matter of correct weights in packages of flour has been a troublesome problem to weights and measures officials for many years."

Few Cases of Short Weight Flour

Whether as a result of the publicity of those surveys, whether because of increased regulatory attention on various fronts, or whether because of all the general publicity being given to packaging nowadays, of thousands of samples of various foods collected at random in the market place in our most recent survey we have not encountered an actionable lot of short weight flour. As you, of course, know, all our net weight work on flour is based on the philosophy that a bag of flour shall be full weight and meet the moisture requirement of its identity standard when shipped, and that loss in weight following shipment arising out of the drying out of the flour is not a significant

violation in terms of consumer protection. We have been able to devise no better practical approach for checking interstate practices, but at the same time we fully recognize that our approach is not a feasible one for our counterparts at the state and city level. In the interest of uniformity I wish I could offer a ready solution to this troublesome aspect of net weight work, but I am not able to do so.

"Bleached" Flour and Misbranding

On other matters of misbranding such as prominence and conspicuousness of mandatory information, we believe as the result of some activity a few years ago, the word "bleached" has gotten up out of the folds of the bottom of the bag, and that apparently for the most part other mandatory information is being shown satisfactorily. However, we have recently made some seizures of flour on a misbranding charge involving the use of supplies of bags which falsely stated the flour was milled by a known defunct mill.

In the field of identity standards, as you know, there was a recent amendment to the flour standard and a tolerance regulation promulgated under the Food Additives Amendment recognizing the use of acetone peroxides as a bleaching agent.

In the field of enriched flour we continue to run into occasional samples which show the lot to be below the enrichment level required. There have been some seizures and a few prosecutions, including some persistent violators. For example, note this language in a recent request for the filing of a criminal case against a mill and its president and its head miller:

> Their past history of seizures, warnings, and prosecutions reflects a lack of respect for the legal requirements that apply to this basic commodity which is widely used and generally recognized as a prime source of essential vitamins and minerals in the daily diet . . . . It is clear that these violations are not the result of a monetary lapse but are the result of operations conducted in a careless and haphazard manner and with little regard for the consuming public.

The Threat of Adulterated Wheat

Of paramount interest to the consumer is the safety of his food supply. Likewise it has highest priority with the miller and the regulatory official. We are concerned with our continued finding of pink wheat in cars of wheat intended for flour mills. In spite of all the publicity, your rejection of cars, and our regulatory activities, these cars of pink wheat continue to show up. We are seizing several a

year. Over the past six years we have seized approximately 50 car and truck loads. For every car of "pink wheat" we locate and remove from the market how many undetected cars of treated wheat are never spotted because the poisonous seed treatment material is uncolored? We do not know, but are now using some new techniques which we hope will give us more facts in this area. We believe quite strongly that if the public is to be protected against this practice, all poisonous seed treatments intended for application to food seeds for seed purposes should be distinctly colored so that the treatment can be detected with the eye of the ordinary individual rather than having to look for the "needle in the haystack" through the use of slow, laborious, chemical or bacteriological laboratory methods. Through distinct coloring, through alertness of grading officials and milling people, backed up by a stern regulatory attitude, we should be able to break up this very bad practice of blending excess treated seeds back into wheat intended for food. While the actions of necessity have been against adulterated wheat, if we encounter situations where criminal liability of firms and individuals for such violations can be demonstrated we will bring criminal cases.

The milling industry has no food additive problems on direct additives. You do have potential problems arising out of the use of wheat or other grain containing excessive pesticide residues.

I am sure you all are familiar with the food additive tolerances on hydrogen cyanide, inorganic bromide in flour, and the pesticide tolerances for a number of other substances used on wheat as storage fumigants. I shall not enumerate them here. We have seized a few cars of flour over the past years because of the presence of excessive residues of inorganic bromides and I recall a car of wheat seized because of excessive residues of hydrogen cyanide.

Protection From "Hidden Dangers"

How does the mill protect itself from these "hidden dangers"? First of all, through continued alertness on the part of your employees with responsibility in this area; and secondly by remembering that the Food and Drug Administration is just as close to you as your telephone. We will be glad to help you resolve any question of reasonable doubt about the legality of interstate wheat offered you by collecting and examining samples of suspect lots if you will bring such lots to our attention along with the facts that lead you to believe the lots may be violative.

Dangers of Filth and Insanitation

Next in order of priority to all of us come the matters of filth and insanitation—matters which may not necessarily be dangerous but which are repugnant to people generally.

Rodents, birds and insects are still the primary contributors to insanitation in food handling and processing plants. And if you have been following the reports of regulatory actions of late, you have found these predators are no respecters of firms or persons.

While the old Pure Food Law of 1906 had the prohibition against filth and decomposition, it was only after the passage of the 1938 law that we could deal effectively with matters of insanitation. During this quarter century period we have found it necessary to bring into court a pretty representative cross section of the milling industry. And it is interesting to note that one thing many of those who have been in trouble have had in common was an old-fashioned, poorly designed, delapidated mill, and that the firms continued to pour more and more money "down the rat hole" in an effort to correct a fundamentally bad situation. Often there was little demonstrable result other than "paving the road to the court house" through procrastination in cleaning up the bad situation.

Considerable Progress In Sanitation

Let me hasten to say, however, that on the whole the sanitation picture in the grain and milling industry is a bright one. Despite the fact that we have had this regular sprinkling of seizures of filthy wheat, and injunctions and prosecutions of mills and responsible officials for bad operating conditions, real progress has been made through the combined efforts of the grain and milling industry, state and federal service and regulatory agencies. If you pause long enough to recall the conditions 25 or 30 years ago you will see what I mean. Also, let me remind you that the situation will not remain static. If you continue your efforts further progress will be made. If you stop, the situation will immediately deteriorate.

There are those who feel that the Food and Drug Administration is today imposing a more rigid rule of sanitation than formerly. We think not. The legislative history of the sanitation requirement of the law clearly shows it was intended that "reasonable standards of cleanliness" be imposed. The impossible was not anticipated then nor expected now in our sanitation program. The conditions outlined by

the inspector in the Form 483 which he gives you at the end of his inspection will reveal those situations he believes do not meet the rule laid down in the law.

Careless Use of Dangerous Pesticides

A serious collateral aspect of sanitation programs is the danger of the careless use of pesticides or rodenticides. This may come about through carelessness of your own staff or it may arise out of the carelessness or ignorance of outside people or firms performing services for you.

I think you will be interested in a recent case involving an exterminator company. A firm engaged in the business of providing exterminator services to warehouses and mills used "1080" as a part if its rodent control program and in our opinion used it carelessly. In considering our request for an injunction the court empaneled a jury to advise him on the matter. Two special issues were raised by the judge with the jury. Both in essence asked whether from the evidence it could be found that, unless prevented by the court, there was a "reasonable possibility" the defendant may contaminate food with "1080." The jury thought so and the court enjoined the firm against further careless use of the highly toxic material. So the court in that language established the rule of conduct to be followed in using poisonous materials around a food supply.

Clean Equipment For Transportation

The collateral issue of the responsibility of the transportation companies as against that of the mills for the cleanliness of equipment furnished for the shipment of food is still with us. We were glad to note that this problem was one of the main considerations of your Association of Operative Miller's Sanitation Committee in its annual report last year. I know from my conversations with the then chairman and others that this problem is still being given a lot of attention. A highly complex factual and legal situation is involved here which makes the question of regulatory action against the transportation company a very difficult one. If and when we have a factual situation that looks satisfactory we are willing to test the law and we intend to do so. In the meantime your technical group must exercise great care to see that the fumigation of infested cars loaded with flour is carefully carried out so there will be no "reasonable possibility" of illegal residues.

From time to time we are asked about the legal responsibility of the mill that instructs the consignee to return a car of insect or rodent infested flour to the point of origin. If this return to the mill involves the interstate shipment of an obviously violative article, we cannot agree to it. Such a shipment could conceivably involve both the consignee who reshipped the car and the mill that ordered or authorized him to do so. It is a question of fact in each case. The federal food law not only prohibits the commission of certain acts, such as the interstate shipment of adulterated and misbranded articles, but also prohibits the *causing* of such prohibited acts. This is obviously a broad sanction which may lend itself to a variety of situations.

The same may be true of the mill that rejects a violative car of grain and then upon instructions of the elevator reships it in interstate commerce. Adulterated foods are contraband and the law intends they be kept out of the channels of commerce irrespective of the motives of those who would introduce them.

In closing I would remind you and caution you that nutritional quackery is on the march in this country. It has become a billion dollar business and I regret to say that it has moved to a considerable extent from the camp of the "fly by night" operator into the pretentious surroundings of what we like to think of as responsible industry. So far as I am aware your industry has not fallen prey to this kind of promotion, and I urge you to be on the look-out to see that you do not permit your products to get on this merry-go-round that gets the consumer no-where and would "gain" for you nothing but trouble.

A few years ago a Committee of the Council of the American Association for Advancement of Science made this cogent observation in one of its reports:

> For nearly two decades scientists have viewed with growing concern the troublesome events that have been evoked by the interaction between scientific progress and public affairs. With each advance in our knowledge of nature, science adds to the already immense power that the social order exerts over human welfare. With each increment of power, the problem of directing its use toward beneficial ends becomes more complex, the consequences of failure more disastrous and the time for decision more brief.

This then is the challenge that confronts you as one of the major food industries of our great country. The realistic and objective approach that has been characteristic of your industry in dealing with problems in the past should serve you well in the days ahead. **[The End]**

LATIN AMERICAN FOOD CODE: CHAPTER XII

Nonalcoholic Beverages and Refreshing Foods and Drinks

The Following Chapter XII of the Latin American Food Code Was Translated from the Original Spanish by Ann M. Wolf of New York. The English Translation of the Introduction to the Code by Carlos A. Grau and the Index Were Published in the October, 1960 Issue of the FOOD DRUG COSMETIC LAW JOURNAL; the Translation of Chapter IV (Utensil, Receptacles, Containers, Wrappers, Machinery and Accessories) Appeared in the February, 1961 Issue, the Translation of Chapter X (Sugar and Sugar Products) Was Published in the May, 1961 Issue; and the November, 1961 Issue Contained the Translation of Chapter XVI (Correctives and Improving Agents—Additives).

CHAPTER XII.—NONALCOHOLIC BEVERAGES AND REFRESHING FOODS AND DRINKS

Waters

Article 413—The term *"potable water"* means any water which is suitable for drinking and domestic purposes. Potable water shall be colorless, clear, odorless, pleasant to the taste, and aerated. To determine the potability of the water of a certain area, the water naturally occurring in the same shall be taken as a basis. The bacteriological examination shall not disclose the presence of pathogenic bacteria. The ratio between the count 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 altogether up to 2 bacteria of the B. coli group, but no coliform bacteria of fecal origin. The chemical analysis shall not disclose 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); 0.5 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 exceed-

ing 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 expressed as calcium carbonate ($CaCO_3$) shall not exceed 50 p.p.m.

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

By way of exception, waters with a pronounced salty flavor found in certain areas, which when used for domestic purposes have 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 414—In general, surface water and water from the first stratum may not be used as sources of drinking water except at locations where water from the deep strata cannot be considered as 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 natural water suitable for consumption, the health authorities shall enforce the use of devices to render the water potable; they may also permit the transportation of potable water from other areas or the consumption of rain water collected in adequate vessels.

All owners of dwelling houses, buildings for rent and commercial or industrial establishments shall be held to provide potable water in quantities sufficient to satisfy the requirements. The water distribution system shall be installed and operated with the approval of the health authorities. In the same fashion, all owners shall be held to install toilet drainage pipes approved by the health authorities. At

locations without public sewers where flush water closets have been provided, 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 dwelling houses, 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 shall be presented to the authority which is to approve the parcelling and shall be mentioned in all advertisements directed to this land.

Article 415—The terms *"Mineral table water," "Dietetic water," "Natural water" (X . . . water)* and any 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 easily be caught and bottled at the location at which they surface, contain zinc, arsenic, lead and copper in amounts not exceeding those fixed in Article 413 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 does not exceed ½ gram per liter.

Article 416—The term *"Medicinal mineral water"* means any oligometallic or mineral water which, surfacing naturally free from bacterial contamination, because of its physical, physicochemical or chemical properties, or the gases dissolved in it or other factors is suitable for therapeutic uses and has been approved by the competent health authorities.

Article 417—Mineral table waters and medicinal mineral waters may be treated to remove the iron, manganese, sulfur, arsenic, vanadium and fluoride present in them. They may also be saturated with carbon dioxide. The labels of any waters so treated shall bear a statement to that effect.

Article 418—To name and classify mineral waters the following criteria and values 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.

Very weakly mineralized waters: Waters with a mineral content of between 0.11 and 0.25 grams per liter.

Weakly mineralized waters: Waters with a mineral content of between 0.26 and 0.50 grams per liter.

Medium mineralized waters: Waters with a mineral content of between 0.51 and 1.50 grams per liter.

Strongly mineralized waters: Waters with a mineral content of more than 1.51 [1] grams.

Waters with 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 50° C.
Hyperthermal waters: Above 51° C.[2]

3. *Isotonic Properties:* Depending on the osmotic pressure compared with the hemoglobin pressure ($\triangle$ = 0° .55), waters are classified into the following groups:

Hypotonic waters = $\triangle$ below 0°.55
Isotonic waters = $\triangle$ 0°.55
Hypertonic waters = $\triangle$ above 0°.55

4. *Minimum values required to use the following definitions:*

Acid Water: Water the free CO_2 content of which exceeds 0.25 grams, 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.

---

[1] Note of the translator: This ought to read "more than 1.50 grams."

[2] Note of the translator: This ought to read above 50° C.

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 1 p.p.m.

Radioactive Water: Water which contains more than 5 Mache Units/ 1 or 2 Emans.

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 only be used for natural (table or medicinal) waters and is not permitted to 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 that refer to natural mineral water springs or localities at which such springs are situated.

Article 419—When the properties or classifications relative to the ephemeral qualities of a water (thermal properties, radioactivity, etc.) are indicated on labels, in pamphlets, announcements, on business stationery and in advertising media, such indications must state 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 of the water sold in bottles.

Any physical, physicochemical and bacteriological determinations as well as any possible physiological and therapeutical uses stated in labels, announcements, posters and other advertising matter used for a water must come from an official scientific authority, the inclusion in labels, announcements and advertisements of any determinations coming from private sources being prohibited.

Article 420—Establishments which catch mineral waters and work them commercially shall be held:

1. To assure the protection of the spring;

2. To carry out the fractionation and other manipulations only at the site of the spring, unless the spring water is carried through adequate pipes from the spring to the fractionation 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 with the equipment required to check the physicochemical and bacteriological properties of the water.

Carbonated Waters and Similar Products

Article 421—The general term *"Carbonated water"* means any of the following nonfermented, nonalcoholic beverages saturated with carbon dioxide that meet the specifications fixed in Article 440 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 may not be saturated with carbon dioxide unless it has first been softened, and if it contains excessive amounts 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 (see Article 655 hereof),[3] essences, bitters and permitted coloring agents (lemonades, nonalcoholic beverages, tonic waters, refreshing soft drinks).

Article 422—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:

[3] Note of the translator: Article 655 fixes the requirements which these acids must meet when used as acidulants.

1. They shall, as a minimum, have a manufacturing room with a flat ceiling and a waterproof socle 1.80 meters in height; a storage room for containers, and next to it, a room in which containers are washed and sterilized; 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, since the discharge of waste water on public roads is 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 loading ramp.[4]

3. On premises 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 only be used in localities at which no plants meeting the conditions of this Code are in existence and at which it is impossible locally to obtain an automatic crowner.

Article 423—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 extraneous bodies, and shall have a normal color, odor and flavor. 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 sediment, but may be opalescent and contain suspended particles coming from the fruit used. The

[4] Note of the translator: Not clearly expressed.

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 extraneous 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 be held to check the condition of the siphons before making delivery to make sure that the glass is not cracked or impaired, that the inside tube is not broken and that the head does not leak.

Article 424—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 the use of which is restricted to medicinal purposes, 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 three grams per liter.

Article 425—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 respective essential oil.

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 426—The names *"Tonic Water," "Soda Tonic," "Indian Tonic"* designate 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 on the label.

Article 427—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 with ginger extract and carbon dioxide, shall be called *"Ginger Beer."* Both types of beverage may be bottled in transparent, dark green glass bottles.

Aricle 428—Any nonalcoholic beverages called *"Guaraná"* shall contain the soluble principles of the seed of *Paullinia cupana, Kunth* and its varieties.

Article 429—Nonalcoholic beverages prepared with various products, such as: catechu, sarsaparilla, kola nut, ginger, oranges and 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 shall be permitted to be prepared and sold without declaring the presence of said ingredients on the label, regardless of whether or not they are identified by distinctive names ("nombres de fantasía"). Nonalcoholic beverages made with guaraná, coffee, cola, maté herb and tea) shall contain caffeine (trimethylxanthine) in a proportion of not less than three milligrams and not more than 20 milligrams per 100 milliliters. When such beverages contain artificial essences or extracts they shall be marked *"artificial."*

Article 430—The term *"Añapa"* means an unfermented mixture of the pulp and seeds of the white carob bean and water, to which milk, jujubes and other authorized products may be added.

Article 431—Plain carbonated water or soda and nonalcoholic beverages 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 or be affixed in the form of a 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 wherever it may be, except in the cases set forth in Article 436 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 or good quality cork.

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 432—*Automatic siphons* which operate on carbon dioxide capsules (sparklets, etc.) for on-the-spot preparation of carbonated water and soft drinks shall meet the general requirements set forth in Article 431 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 440 hereof.

Article 433—Carbonated beverages prepared with fruit syrups, fruit extracts, or fruit juices may be labeled with the name of the fruit, preceded or followed by the word "Natural."[5] 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."[6]

Article 434—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 and business papers used in connection with such beverages are not permitted to bear any design or graphic representation of fruits, or portions of fruits, or to make reference to the same.

Article 435—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 436—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 be held to

[5] Note of the translator: In the English language, the words "natural" or "artificial" will always precede the name of the fruit (for instance, "natural orange juice").

[6] See footnote 5.

identify each container used or owned by them by engraving on the siphons [7] a serial number issued by the competent authority.

The number of empty bastard containers 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 the 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 has been fixed 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 in order to be returned to their legitimate owners, while the penalties provided for by the law shall be imposed on the infringer.

Article 437—Siphons and containers which are not perfectly safe and hygienic, have cracks or other dangerous defects are prohibited from being filled.

In all plants, warehouses, stores, bars, candy shops, hotels, restaurants and other business establishments, the shelves and racks holding containers of carbonated waters, soft drinks and similar products shall be kept perfectly clean and may not be installed at unhealthy or inadequate places.

Article 438—Stores, candy shops, bars, hotels, etc. which sell the consumers the kind of beverages the manufacture of which is regulated by the preceding articles shall be held to refuse acceptance from the manufacturer of any containers which fail to meet the conditions fixed herein or do not belong to the plant which sells them. Failure to do so shall constitute a violation of the law.

Article 439—The installation of machines for the small scale preparation of carbonated beverages shall require the approval of the competent authorities.

When the machines used for the small scale preparation 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 a space 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. Business establish-

[7] Note of the translator: It would not seem that this paragraph refers only to siphons.

ments which possess soda machinery attached to their business are not permitted to store or utilize 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 440—The carbon dioxide or carbonic acid gas used in the preparation of (nonalcoholic, alcoholic or other) carbonated beverages, or in connection with their sale, as in the case of beer, shall meet the following specifications:

1. It shall contain carbon dioxide in a proportion of not less than 99 per cent and not more than 0.1 per cent of air. (The sample will be drawn while the cylinder is in a 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 any extraneous, mineral or organic, substances (nitrogen dioxide, sulfur dioxide, hydrogen sulfide, etc.).

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

5. The steel pipes or cylinders used to conduct the gas shall be able to withstand a pressure of 250 kilos per square centimeter, shall be painted on the outside and bear a label with the indications required by law.

Syrups

Article 441—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 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"* ("Refreshment").[8]

Article 442—The name *"Syrup,"* combined with the name of the one or several predominant species of fruits used in the preparation,

[8] Note of the translator: At variance with the English meaning of "refreshments," the Spanish term "refrescos" means particularly a refreshing beverage, or soft drink.

may be used only for syrups consisting of sugar dissolved in solutions of fruit juices or extracts without the addition of extraneous 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 443—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 juice of the fruit named. Their natural color may be reinforced with an authorized coloring matter. Their sodium benzoate 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.[9] "Arropes" prepared from juices 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 the syrup prepared from the juice or a decoction of maidenhair fern (*Adiantum Capillus Veneris, L.*) flavored with natural essential citrus oils. It may be colored with caramel.

6. The term *"Gum Syrup"* means a sugar syrup to which gum acacia 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 composed of sugars and almond milk, to which distilled water or natural essential oils may

[9] Note of the translator: Especially in Argentina. Originally, "arrope" was grape juice boiled to the consistency of syrup.

be added. If instead of almonds, "chufas" [10] 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 of the fruits 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 composed of organic acids and alkaline salts, both of which comply with the requirements of the Pharmacopoeia, sugars and a permitted aromatic, to which a permitted coloring matter may be added.

Article 444—The distribution, possession or sale of the following syrups shall be prohibited:

1. Syrups containing essences which the health authorities or the present Code consider harmful; or mineral acids (except phosphoric acid), resins, prohibited coloring matters, preservatives, prohibited foaming agents, artificial sweeteners and 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 adulteration, impurities, mould, or other extraneous matters.

Article 445—*Fanciful Syrups* made with sugars, with or without honey and aromatics, and with or without coloring matters may be

[10] Note of the translator: Edible tubes of a sedge.

called: *"Artificial Honey."* Such syrups shall comply with the following requirements:

1. They shall not contain impurities or extraneous 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 and coloring matters, or free sulfur dioxide in an amount exceeding 50 parts per million.

Vegetable Juices

Article 446—The general term *"Vegetable Juice"* (juice of a fruit or vegetable) means any natural product 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.).

Article 447—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 448—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 to wash the materials and a refrigerator for the preservation of 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 449—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 oligody-

namic 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 removed from it.

Any of the following physical or physicochemical 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 sulfurous acid, or of sodium benzoate in a proportion not exceeding 1 gram per liter, and any other processes 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 subsequent dilution of such concentrated juices or for products obtained by processing the residue from the first pressing.

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

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

Article 450—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 which are consumed after they have been diluted with 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 451—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 452—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 453—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, 35 mg. of ascorbic acid (fresh juice), 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. It shall contain not less than 14 mg. of nitrogen from free amino acids per 100 ml. of juice.

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 454—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. It shall contain not less than 90 mg. of nitrogen from free amino acids per 100 ml. of juice.

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 455—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 9; proteins 0.4; fats 0.1; assimilable carbohydrates 8; crude fiber 0.05; ash 0.4; acids calculated as citric acid 0.9.

Article 456—The lemon, orange and grapefruit juices served at counters, confectionery stores, restaurants, etc. *as freshly squeezed* juice 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 453, 454, and 455, shall be considered adulterated.

Article 457—The term *"Tomato Juice"* means the juice obtained by pressing the fruits of *Licopersicom esculentum, Mill.* in a hot medium, with or without the addition of salt (1 per cent) which prior to canning may be subjected to homogenization and sterilization. Average percentage composition: water 95; proteins 1; fats 0.2; assimilable carbohydrates 3; crude fiber 0.2; ash 0.2; acids calculated as citric acid 0.6; density at 15°C.: 1.028.

Article 458—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 459—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 425 hereof, shall make it necessary to label the product *"Artificially carbonated."*

Fermented vegetable juices prepared in a fashion different from the manner indicated hereinbefore 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 extraneous 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 460—*"Date Juice,"* improperly called "Date Honey," is the product obtained by pressing ripe muscat date, which are usually packed in weed baskets.

Ice

Article 461—The term *"Ice"* alone, without an additional definition, means the product that 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 its 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 462—*Ice factories* shall possess separate processing and machine rooms, but the two rooms may at times be combined for reasons 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 with a capacity sufficient to satisfy the needs of the establishment.

Article 463—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 with contaminated water shall be destroyed forthwith.

Article 464—The term *"Dry Ice"* or *"Carbonic Snow"* means solidified carbon dioxide the purity of which meets the standards fixed in Article 440 (Specific gravity: 1.1 to 1.5, depending upon the manufacturing process; temperature: minus 78.4° C.; latent heat of fusion, including the chilling action of the cold gas produced shall be equal to 158 calories per kilogram).

Article 465—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.).

Ice Creams, Sherbets and Cold Beverages

Article 466—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 yolk, cocoa, 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 (Article 561) may be added to them.

Article 467—The milk and cream used in mixtures composed of milk, cream and eggs and intended for the preparation of ice creams shall first be pasteurized or boiled. Ice creams 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, sodium alginate, edible moss and authorized albumens.

The installation of ice cream factories in dwelling houses, garages and basements is prohibited.[11]

Article 468—*Ice cream factories* shall not only comply with the general health regulations, but shall also meet the following specific requirements:

1. They shall have a processing room separated from the premises used for other purposes (kitchen, pantry, dormitory, shed, storage room, etc.). The processing room shall have a flat ceiling; a waterproof floor; a socle at least 1.80 m in height made of tiles, marble or a similar material; adequate sinks to wash apparatus 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 for the storage of raw materials that is always well maintained and kept orderly and clean.

The name *Ice Cream Parlor* (*"Heladería"*) designates any establishment 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 13 of the present Code (uniform, and health certificate).

[11] Note of the translator: Logically this sentence belongs in Article 468.

Article 469—The name *Ice Powder* means any product composed of milk solids, sugars, salts, authorized aromatics, and up to 2 per cent of stabilizer (gelatin, alginates, etc.). The moisture in such powders 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 Powder"* means any product of a similar composition, the minimum milk solid content of which shall be 55 per cent, however, of which 25 per cent shall be milk fat.

The labels used for both products shall give instructions for the preparation of ices and ice creams.

Article 470—Any ice creams, sherbets and similar products in storage, circulation, or preparation shall be free from pathogenic bacteria, especially the *Mycobacterium tuberculosis, Brucella* sp., *Salmonella* and *Bacillus coli.* Ice creams 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 they contain eggs 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., cocoa or chocolate, shall contain these substances in an amount of not less than 5 per cent.

Products which bear the name of a specific food or beverage (milk, 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 without a declaration be reinforced with an authorized dye.

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 do not 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 imperfect 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 13 of this Code.

Article 471—The names listed hereinafter shall 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 correspond 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 substances permitted by this Code 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 formula registered with the health department.

5. *Sundae:* This is 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:* This is 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 the carbonated water and which is shaken 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 shaken 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.

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

* The Food Law Institute has a number of copies of the Official Revised Spanish Edition of the Latin-American Food Code as adopted by the Seventh-Latin-American Chemical Congress on April 3, 1959 and published in August 1960.

Anyone interested in securing a copy of this Spanish Edition may do so while the supply lasts by sending a check in the sum of $7.50 to The Food Law Institute, Inc. 205 East 42nd Street, New York 17, New York.

The Interstate Ingredient of Section 304 (a)– Federal Food, Drug, Cosmetic Act

By NORMAN E. MATTEONI *

This Article First Appeared in the March, 1962 Issue of the *Notre Dame Lawyer* and Is Reprinted Here with Permission. Mr. Matteoni Is a Member of the Junior Staff of that Magazine.

IN THE SCIENCE OF MATHEMATICS, there exists the maxim that the whole is equal to the sum of all of its parts. Recently, the United States Court of Appeals, Second Circuit,[1] adopted this principle to expand the scope of the interstate commerce requisite of Section 304(a) of the Federal Food, Drug and Cosmetic Act. This section concerns the grounds and jurisdiction for seizure under the Act. The pertinent part thereof reads:

> Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce *or while held for sale (whether or not the first sale) after shipment in interstate commerce,* or which may not, under the provisions of Section 404 or 505, be introduced into interstate commerce, shall be liable to be prosecuted against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found.[2]

In the case before the Second Circuit, there had been interstate and foreign shipments of various vegetable and olive oils to the A. M. S. Packing Company in Ozone Park, New York. At that point, the oils were blended and packaged under the label, "25 per cent pure olive oil." Upon shipments to Syracuse, the oil was seized by the government and found to contain little or no olive oil. The question

---

* The Author wishes to express his appreciation to John B. Buckley, Associate Legal Counsel, Miles Laboratories, Inc., Elkhart, Indiana, for his time and assistance in this subject matter.

[1] *United States v. 40 Cases, More or Less, of Pinocchio Brand Oil,* 2 FOOD DRUG, COSMETIC LAW REPORTS 7650, 289 F. 2d 343 (CA-2 1961); *cert. den.,* 30 *U. S. Law Week* 3113 (U. S. Oct. 10, 1961).

[2] Federal Food, Drug and Cosmetic Law, Sec. 304(a), 52 Stat. 1044 (1938), as amended by 62 Stat. 582 (1948), 21 U. S. C. Sec. 334(a) (1958). (Emphasis added to indicate new language of the 1948 amendment.)

before the Court of Appeals was whether Section 304(a) authorized the United States to seize and proceed against misbranded [3] cases of "Pinocchio" blended oils, mixed entirely within the state of New York from components, shipped in interstate commerce under proper labeling. Chief Judge Lumbard, reversing the decision below,[4] answered: "The appellee would have us hold here that the blending of the oils which had been transported in interstate commerce took the final product out from under federal regulation although each of its separate components was being held for sale after shipment in interstate commerce. We do not agree." [5]

This decision represents an ever broadening interpretation of what constitutes interstate commerce,[6] as the Food and Drug Administration seeks to extend the range of the federal Act.

Federal legislation in this area first came at the urgings of muckraking such as that of Upton Sinclair's *The Jungle* and the militant interest that Dr. Harvey W. Wiley, chief chemist of the United States Department of Agriculture from 1883 to 1912, took in the subject of adulteration of food and drink. The Pure Food and Drug Act went into effect on June 30, 1906, and continued in force with the help of various amendments until June 25, 1938.[7] "[P]rofound changes in methods of manufacturing and selling goods and drugs" [8] necessitated the enactment of an entirely new law. The present Federal Food, Drug and Cosmetic Act took a comprehensive look at the subject and notibly expanded coverage to medical devices and cosmetics.[9]

The validity of federal food and drug law rests on the commerce clause of the Constitution, Article I, Section 8.[10] Congress holds the

---

[3] Section 403(a), 52 Stat. 1047 (1938), 21 U. S. C. Sec. 343(a) (1958) states that food shall be deemed misbranded "if its labeling is false or misleading in any particular." For a further discussion of what constitutes misbranding, see 26 *Notre Dame Lawyer* 706 (1951).

[4] 188 F. Supp. 290 (N. D. N. Y. 1960).

[5] Case cited at footnote 1, at p. 345.

[6] Section 201(b), 52 Stat. 1040 (1938), 21 U. S. C. Sec. 321(b) (1958) defines interstate commerce as: "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body."

[7] Arthur, *The Law of Drugs and Druggists,* 286 (4th ed. 1955). For a list of the amendments to the Pure Food and Drug Act of 1906, see Toulmin, *Law of Food, Drugs and Cosmetics* Sec. 3 (1942).

[8] From Senator Copeland's report to the Senate on March 15, 1934, 78 *Congressional Record* 4758 (1934).

[9] See Toulmin, cited at footnote 5, Sec. 7 for a résumé of the primary differences between the Acts of 1906 and 1938. See generally "Developments in the law—The Federal Food, Drug and Cosmetic Act," 67 *Harvard Law Review* 632 (1954).

[10] *McDermott v. Wisconsin,* 228 U. S. 115 (1913); *Hipolite Egg Company. v. United States,* 220 U. S. 45 (1911).

right not only to regulate interstate commerce, but also possesses full power to keep the channels of such commerce free from the transportation of harmful and illicit articles.[11] Since the purpose of the Act is to protect the public health, the courts have consistently declared that it should be given a liberal construction.[12] The decision of *Kordel v. United States*[13] issues a warning against the creation of loopholes at the expense of public protection.

Predecessors of Section 304(a)

Section 10[14] of the original act addressed itself to the problem of federal jurisdiction in seizure of adulterated or misbranded food, drug, or liquor. In the early case of *Hipolite Egg Company v. United States*,[15] it was contended that Section 10 of the 1906 Act did not apply to an article of food which had not been shipped for sale, but which had been shipped solely for use as a raw material in the manufacture of some other product. The Supreme Court refused to sustain such a position:

> The object of the law is to keep adulterated articles out of the channels of interstate commerce, or, if they enter such commerce, to condemn them while being transported or *when they have reached their destination, provided they remain unloaded, unsold or in original unbroken packages.* These situations are clearly separate, and we cannot unite or qualify them by the purpose of the owner to be a sale.[16]

Prima facie, one may think that seizure was valid only where the goods had been adulterated before or while in interstate commerce. This simply was not so.[17] The courts appear to have adopted the position that the element of adulteration of goods, remaining in the original unbroken packages was independent of the interstate transportation factor and that interstate shipment was to be proved as

---

[11] *United States v. Cardiff*, 95 F. Supp. 206 (E. D. Wash. 1951); *United States v. Walsh*, 331 U. S. 432, 434 (1947) states: "The Federal Food, Drugs, and Cosmetic Act rests upon the Constitutional power resident in Congress to regulate interstate commerce. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious, adulterated and misbranded articles of specific types. . . . It is in that interstate context that the various sections of the Act must be viewed."

[12] *United States v. Seven Jugs*, 53 F. Supp. 746 (CA-8 1944).

[13] 335 U. S. 345 (1948).

[14] Pure Food and Drug Act of 1906, 34 Stat. 771.

[15] 220 U. S. 45 (1911).

[16] Case cited at footnote 15, at p. 54. (Emphasis added.)

[17] See statement of Charles W. Crawford, *Hearing Before a Subcommittee of the Committee on Interstate and Foreign Commerce*, House of Representatives on H. R. 3128 and H. R. 3147, 80th Cong., 1st Sess. 2 1947): "The old law authorized seizure of foods and drugs that became adulterated or misbranded after interstate shipment if they remained un-

a condition precedent.[18] Therefore, the government maintained the viewpoint that goods which were in an adulterated condition at the time of seizure were subject to libel regardless of whether they were adulterated when transported, as long as they had remained in the original packages.[19]

When the new law was enacted, the section under consideration was completely revised and the words, "unsold, unloaded or in original unbroken packages," were excluded.[20] The new Section 304(a) [21] contained two phrases worthy of particular note: first, "when introduced into or while in interstate commerce," and second, "while in interstate commerce, or at any time thereafter." [22] These phrases will be examined in inverse order.

It has already been observed that the Act of 1938 expanded the scope of the former law and that it was generally intended to be farther-reaching than its predecessor. The statutory language, "while in interstate commerce, or at any time thereafter" appeared clear. It was believed that these words:

> . . . were at least as inclusive as the language of the old law, "having been transported [from one State to another], remains unloaded, unsold or in original unbroken packages." There is nothing in the extensive legislative history of the new act, including hearings, debates and committee reports, or in the records of hearings before Appropriation Committees where this kind of enforcement work was discussed, that reveals anything but approval by the Congress and the reg-

---

(*Footnote 17 continued.*)
loaded, unsold, or in original unbroken packages. Thousands of shipments of foods and drugs that became filthy, debased, or deteriorated after interstate transportation were seized and condemned under this provision and thereby were prevented from reaching the consuming public. The authority to make seizures in such circumstances was never challenged by court contest."

[18] *United States v. 300 Cans of Frozen Eggs,* 189 Fed. 351, 353 (CA-2 1911): "But the charge was against the goods in the original packages after transportation was over. The applicable words of the Act are 'or having been transported remains unloaded, unsold, or in original unbroken packages.' The allegations as to the carriage of the goods between Nebraska and New York were for the purpose of showing that they were the subject of interstate commerce."

[19] Vincent A. Kleinfield, "Reflections on the Miller Amendment," 4 FOOD DRUG COSMETIC LAW QUARTERLY 43, 45 (1949).

[20] Section 304(a), 52 Stat. 1044 (1938) read in part: "Any article of food, drug, device, or cosmetic that is adulterated or misbranded *when introduced into or while in interstate commerce,* or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or *at any time thereafter,* on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found." (Emphasis added.)

[21] Work cited at footnote 20.

[22] See Vincent A. Kleinfield, "The Seizure Section of the Federal Food, Drug, and Cosmetic Act," 2 FOOD DRUG COSMETIC LAW QUARTERLY 21 (1947).

ulated industries of the long-standing practice of condemning goods which after interstate shipment became adulterated while unsold or in original unbroken packages.[23]

Phelps-Dodge Situation

But when a United States Circuit Court of Appeals declared in *United States v. Phelps-Dodge Mercantile Company* that "the fact that the food was adulterated while held in original packages did not show that it was adulterated when introduced into or while in interstate commerce," [24] the seizure of an interstate shipment of goods "at any time thereafter" was no longer possible.

Briefly, the facts in that case were these: food was shipped from Colorado to Arizona and there held in the original packages for more than two years. But the libel action by the government did not state that the food was adulterated "when introduced into or while in interstate commerce"; to the contrary, it stated, in effect, that the food was contaminated with filth while held in the original packages in the appellee's warehouse. The court held that the terms "interstate commerce" and "original packages" were not synonymous. It went on to say that this "original package" provision of Section 10 of the Wiley Food and Drug Act could not be read into Section 304(a) of 1938 Act, for that section had long since been repealed and the new law made no mention of such words. By his narrow construction of Section 304(a), Circuit Judge Mathews boldly terminated the government's exercise of an authority which had existed (or had been thought to exist) for 40 years,[25] namely, to seize food and drug products that become adulterated or misbranded while held for sale after interstate transportation.

It is interesting to note the decision in *United States v. Olsen* [26] which Judge Mathews handed down eight months subsequent to his *Phelps-Dodge* opinion. He there held that where a therapeutic device was misbranded, although not inherently dangerous, when introduced into and while in interstate commerce, the government was within its rights to seize and condemn it, despite the fact that it was no longer in interstate commerce. In fact, the device was in the hands of an individual purchaser who was satisfied with it.

---

[23] Hearing on H. R. 3128 and H. R. 3147, cited at footnote 17, at p. 3.

[24] 157 F. 2d 453 (CA-9 1946); *cert. den.* 330 U. S. 818 (1946).

[25] Hearing on H. R. 3128 and H. R. 3147, cited at footnote 17, at p. 2. See also 94 *Congressional Record* 134 (1948).

[26] 161 F. 2d 669 (CA-9 1947); *cert. den.* 332 U. S. 768 (1947).

Charles Wesley Dunn theorized from the *Olsen* and *United States v. Sullivan*[27] decisions (the latter of which is considered below) and "the broad concept of 'interstate commerce' in other federal laws and cases, that the Commerce Clause does more or less sanction the incidental application of this act to a food or drug (etc.) which becomes adulterated or misbranded while it is held for intrastate sale after its interstate shipment."[28]

Had the *Phelps-Dodge* fact situation been delayed in presentation to Judge Mathews another year or more, one may speculate that legal reasoning might have spun its fine theories in extending the scope of Section 304(a) to allow an opposite result. Yet, as they stand, there is no inconsistency between the two opinions of Judge Mathews. In the *Phelps-Dodge* case, the point of his concern was that there was neither proof nor allegation that the adulteration had occurred in interstate commerce, while the *Olsen* case, misbranding was shown to have taken place prior to the interstate shipment. It, therefore, followed, by giving effect to the words of the statute, that this device could be seized "at any time thereafter." What the judge balked at in the *Phelps-Dodge* decision is a situation that appeared to be strictly an intrastate matter with no established key in law to permit federal entrance.[29] The Ninth Circuit Court of Appeals had done nothing more than carefully scrutinize the meaning of Section 304(a).

The Miller Amendment of 1948

The Food and Drug Administration's reaction to the *Phelps-Dodge* loophole was immediate, the final result of which was an amendment to the Federal Food, Drug and Cosmetic Act.[30] In recommending the amendment, it was noted that the *Phelps-Dodge* decision revealed:

> . . . a serious defect in the present law. Approximately 20 per cent of the seizures of adulterated and misbranded foods instituted during recent years have involved adulteration clearly resulting from unsanitary conditions and other causes

---

[27] *United States v. Sullivan,* 332 U. S. 689 (1948).

[28] Charles Wesley Dunn, "House of Representatives Bill 4071," 2 FOOD DRUG COSMETIC LAW QUARTERLY 284, 290 (1947). Weight is lent to his argument by the fact that the Supreme Court in the *Sullivan* case, cited at footnote 27, at p. 698, cites the *Olsen* decision to support the validity of the Act's criminal section 301(k).

[29] 157 F. 2d 453, 456 (CA-9 1946): "Whether Congress could have provided in Section 304(a) of the Federal Food, Drug and Cosmetic Act . . . for the condemnation of any article of food that is adulterated while held in original packages after being transported in interstate commerce need not be considered, since Congress did not, in fact, so provide."

[30] 62 Stat. 582 (1948).

during storage after interstate shipment. Many other cases were such that it would have been impossible to prove that contamination or deterioration occurred before transportation ended. Even where that fact could have been established through investigations, the time required to make them frequently would have been such that unfit material would have reached the consuming public.[31]

Further, this same report comments upon a serious enforcement problem in the 1938 law:

> Many articles which actually were offensive at the time they were introduced into interstate commerce will escape seizure because of the impossibility of obtaining proof prior to distribution to customers to show that the condition did not develop after interstate transportation. Scientific methods have not advanced to the point where they will show infallibly when a particular product became debased. . . .
>
> The practical reasons for the assertion by Congress of its power to the extent recommended by the committee become apparent in viewing the problems of enforcement. More than 25 billions of dollars' worth of these commodities annually flows through the channels of interstate commerce. The Food and Drug Administration has approximately 200 food and drug inspectors on its rolls. The opportunity for inspection while the goods are in transit is quite inadequate. It is inevitable—at least in the absence of an increase in inspection personnel beyond anything that might be considered practicable—that the bulk of Federal inspection activities takes place after merchandise has been transported in interstate commerce and while it is stored pending further processing or disposition to consumers.[32]

The amendment sought to clarify the phrase, "when introduced into or while in interstate commerce," by inserting immediately after these words the following: "or while held for sale (whether or not the first sale) after shipment in interstate commerce." These added words, minus the parenthetical phrase, are identical to those appearing in the 1938 criminal Section 301(k)[33] of the act. Moreover, the Miller Amendment effects changes in this latter section [34] to make it coextensive with the new language of Section 304(a), by including acts which result in adulteration as well as misbranding. Further, it adds the parenthetical phrase, "(whether or not the first sale)," making express what had previously been left to implication.[35]

---

[31] Senate Report No. 1221, *United States Code Congressional and Administrative News,* 80th Cong., 2d Sess., p. 2120 (1948).

[32] Work cited at footnote 31, at p. 2121.

[33] Section 301(k), 52 Stat. 1042 (1938).

[34] Section 301(k) as amended, 62 Stat. 582 (1948), 21 U. S. C. Sec. 331(k) (1958) prohibits: "The adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale (*whether or not the first sale*) after shipment in interstate commerce and results in such article being *adulterated or* misbranded." (Emphasis added to indicate the amended portions.)

[35] See footnote 31, at p. 2121.

Sullivan Discussed

The Miller Amendment was approved and signed into law by the President on June 24, 1948.[36] Earlier that same year, the *Sullivan*[37] case was decided under the yet-to-be amended Section 301(k). In that criminal proceeding, a retail druggist in Columbus, Georgia had purchased sulfathiazole tablets from a distributor in Atlanta, Georgia who had in turn received them from Chicago, Illinois. It was suspected that he had been selling this drug without a prescription to men stationed at nearby Fort Benning for treatment of venereal disease. Investigators moved in and on two separate occasions found that the druggist removed tablets from their properly labeled bulk container in which they had been transported in interstate commerce and in which they were than being held for resale. He then placed them in a pill box, labeled simply "sulfathiazole" and not containing the statutory required directions for use or warnings of danger, and sold them locally to customers. The Court held that Sullivan's conduct fell within the language of Section 301(k) and that a literal interpretation of this section was consistent with the general purpose of the Federal Food, Drug and Cosmetic Act. "Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their delivery to the ultimate consumer."[38] In the concluding paragraph of the majority opinion, Justice Black quickly disposed of the constitutional objection to the above interpretation by relying primarily on *McDermott v. Wisconsin*,[39] a 1913 decision which upheld the constitutional power of Congress to regulate the branding of articles that have completed their interstate journey and are being held for local sale. He then offered a brief barrage of recent cases as auxiliary support.[40]

Since the Miller Amendment made Sections 304(a) and 301(k) coextensive, the *Sullivan* opinion is often[41] cited in support of Section 304(a)'s constitutional validity.

---

[36] 94 *Congressional Record* 9366 (1948).

[37] *United States v. Sullivan*, 332 U. S. 689 (1948). See Recent Decision, 23 *Notre Dame Lawyer* 392 (1948).

[38] Case cited at footnote 37, at p. 696.

[39] 228 U. S. 115 (1913).

[40] *United States v. Walsh*, 331 U. S. 432 (1947); *Wickard v. Filburn*, 317 U. S. 111 (1942); *United States v. Wrightwood Dairy Company*, 315 U. S. 110 (1942); *United States v. Darby*, 312 U. S. 100 (1941); *United States v. Olsen*, 161 F. 2d 669 (CA-9 1947).

[41] For example, *United States v. 4 Devices, Labeled in Part "Color-Therm,"* 176 F. 2d 652 (CA-10 1949.)

The Expanding Interpretation of Section 304(a) of the Miller Amendment

Although the Miller Amendment was precipitated by the *Phelps-Dodge* decision, it went much further than merely filing this breach in the administration of the Act. It is to be observed that a proscribed article remains under the ambit of the 1948 Section 304(a), despite the number of sales that occur in intrastate commerce. As long as the interstate origin of the article can be traced in its travels of sale and resale within a state, it appears that the government may extend its reach over that article.

The tremendous authority intended to be granted to the Food and Drug Administration is made evident by the following inquiry during a hearing before a subcommittee of the House Committee on Interstate and Foreign Commerce:

> Mr. Hale. Under this language as drawn there is no limitation at all as to Federal jurisdiction until the goods reach the ultimate purchaser, is there?
>
> Mr. Crawford. That is right, and that was on the assumption that the happening of evil things to these goods which originate in interstate commerce reacts unfavorably upon the interstate demand for those goods.[42]

Mr. Crawford, later in this same interrogation, added:

> Congress unquestionably has the authority to maintain these goods in a state of lily-white purity up to the time the interstate vehicle stops rolling; but if that is all the authority Congress has it may be futile to exercise that authority because it cannot protect the consequences of the regulation by preventing the evil things happening to the goods after the interstate journey has ended. It seems to us to be a kind of negation of the beneficent effect of that authority while interstate transportation is in course, to say that nothing could be done to carry out the purpose of Congress and to bring it to fruition, the purpose being the protection of the ultimate consumer of goods from interstate sources.[43]

Before examining the case history subsequent to the Miller Amendment, a moment should be taken to pick up an early thread in the pattern of expanding interpretation. In October of 1948, the Supreme Court declared that the separate shipment of machines and leaflets did not prevent the machines, when the leaflets, containing false and misleading statements, were attached thereto, from being subject to condemnation under the 1938 version of Section 304(a).[44] This reversed the decision of the court below.[45] It appears that the Court, well aware of the scope of the 1948-designed Section 304(a),

---

[42] Hearing on H. R. 3128 and H. R. 3147, cited at footnote 17 at p. 19.

[43] See footnote 42.

[44] *United States v. Urbeteit*, 335 U. S. 355 (1948).

[45] *Urbeteit v. United States*, 164 F. 2d 245 (CA-5 1947).

offered a liberal interpretation of the former language to maintain consistency.

This same question, under the new section, was given further study in *United States v. 4 Devices, Labeled in Part "Color-Therm"* [46] and *Lee v. United States.*[47] In the former case, one Lee was a district salesman in Oklahoma of therapeutic devices, which had been shipped to him from a Dr. Gerkey of Mission, Kansas. The device itself was a wooden cabinet, with various tubes on the top and electrical connections needed to operate it. When a person, seeking relief through the machine, properly positioned his bare feet on the cabinet tubes and elevated his head to the right level, he could see neon lights flashing in pinball machine-like fashion, as he massaged with the applicator. Copies of instructions concerning the device were typed in Oklahoma from a master circular furnished to Lee by the Kansas doctor. These papers contained false and misleading statements as to the efficacy of the device. Consequently, it was here that the government had to find a nexus to establish misbranding of the machine. Section 201(m) of the statute stated clearly: "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." [48] But the instructions neither accompanied the devices in interstate commerce from Kansas nor were they affixed to the devices while in Lee's possession. The evidence simply showed that when Lee made a sale, he would fold a copy of the instructions under the tubes before delivery to the customer. Nevertheless, the court found that "textual" rather than physical attachment was significant; it was sufficient that the instruction supplemented or explained the devices. With little ado it was then declared: "The devices were misbranded while held for sale after shipment in interstate commerce." [49] The same court further expanded its view in the *Lee* case (after *Color-Therm* was remanded and the district court sustained a motion by the United States for summary judgment, this appeal was prosecuted) by finding that the article "is subject to seizure at any time, the fact that at the time of seizure the false label is not upon the device or does not accompany the device does not purge the device of its prior false labeling or render it immune from seizure and condemnation." [50]

---

[46] 176 F. 2d 652 (CA-10 1949).
[47] 187 F. 2d 1005 (CA-10 1951).
[48] Section 201(m), 52 Stat. 1041 (1938), 21 U. S. C. Sec. 321(m) (1958).
[49] *United States v. Color-Therm,* 176 F. 2d 652, 654 (CA-10 1949).
[50] *Lee v. United States,* 187 F. 2d 1005, 1007 (CA-10 1951).

The case of *United States v. Allbrook Freezing & Cold Storage*,[51] decided in 1952, bears a strong similarity to the *Pinocchio* case. Here, though, the articles in question, raw strawberries, were alleged to be adulterated before interstate shipment and later processed and packaged in this condition. But, the point to grasp is that the court refused to recognize that processing and packaging of the strawberries created a new product "which cannot be seized unless and until it moves in interstate commerce in its changed form. If this were a sound view, and adulterated constituents of processed products could be seized only when in their unprocessed form, the enforcement of the act would be easily defeated." [52] Seizure was not premature; it was enough that the ingredients of raw strawberries were adulterated while in interstate commerce.

Aftermath of Flood Produces Interesting Case

The devastation of the 1951 Missouri flood produced an interesting food and drug case,[53] the concern of which was the meaning of "while held for sale." Claimant to the ensuing libel action was the owner of a large quantity of distilled spirits which was stored and held for sale in the Last Chance Tavern and Shawnee Club. At the advance of the rising waters, the tavern and club were closed; and while closed they were engulfed by the deluge, which covered the stored bottles with filth and mutilated their labels. Several days after the waters had subsided, claimant washed the bottles and removed them to two residences in Kansas City, Missouri, where they were later seized. The issue presented was whether the intoxicating beverages were adulterated and misbranded by the flood waters while "held for sale" and therefore subject to forfeiture under Section 304(a), inasmuch as the imminence of the flood forced a closing of the tavern and club. The district court found that there was no contention by the claimant that he intended to cease business or abandon the goods in question. Therefore,

> . . . the only conclusion to be reached is that from the time the floodwaters descended until the liquor was removed from the above premises they became and were adulterated and misbranded within the meaning of the Federal Food, Drug and Cosmetic Act . . ., while being "held for sale." The removal of such liquor from the premises where it was so held, after its adulteration and misbranding, did not withdraw such liquor from the ambit of the Act.[54]

---

[51] 194 F. 2d 937 (CA-5 1952).

[52] Case cited at footnote 51, at p. 939.

[53] *United States v. 1,800.2625 Wine Gallons of Distilled Spirits*, 121 F. Supp. 735 (W. D. Mo. 1954).

[54] Case cited at footnote 53, at p. 738.

It is not the holding for sale after adulteration but the adulteration or misbranding of the article "while held for sale (whether or not the first sale)" after interstate transportation that subjects the goods to immediate forfeiture.

A few years later a United States district court in Pennsylvania [55] concerned itself with this same problem of when an article is held for sale, and it cited *United States v. 1,800.2625 Wine Gallons* [56] as controlling. The Food and Drug Administration had charged that the pills dispensed by the Hoxsey Cancer Clinic in Portage, Pennsylvania were misbranded by leaflets and printed matter which explained the drug's usefulness. The medications, located in the drug and sterilization rooms, were seized while in their original containers from which they were eventually to be transferred to small envelopes for distribution to patients. At the same time, the literature in question, found in the entrance hall of the clinic, was seized. The court determined that where printed or graphic matter is used in the distribution or sale of the drug to explain its use and effectiveness, it may be considered labeling within the act, even though there is a separation between the article and the printing.[57] But the claimants urged that the drugs were not intended for sale in the statutory sense, but for prescription by physicians in pursuit of a local practice of medicine. The argument was lost upon the court:

> It may be that physicians are not understood as holding for sale the drugs which they may administer or prescribe in connection with their treatment of patients. But potentiality of harm to the public from misbranded drugs is not less because the intervening agency of distribution may be a physician rather than a layman. The terms "while held for sale" have been given an expansive rather than a technical construction. . . . It is not the holding for sale in a technical sense which gives rise to the federal jurisdiction in cases arising under Section 304(a) but the fact that the channels of commerce have been used.[58]

The above selection of cases manifests a persistent forward push by the Food and Drug Administration. The act has been extended to an ever greater control of goods which have been shipped in interstate commerce, but which at the time of the government's seizure have ended their trans-states travel. However, there are limits to how far the government may reach into a state in order to keep its finger on the articles which have their origin from without that state.

---

[55] *United States v. 10 Cartons, Labeled in Part "Hoxsey,"* 152 F. Supp. 360 (W. D. Pa. 1957).

[56] 121 F. Supp. 735 (W. D. Mo. 1954).

[57] *United States v. Urbeteit,* 335 U. S. 355 (1948) was cited in support of this position.

[58] *United States v. 10 Cartons, Labeled in Part "Hoxsey,"* 152 F. Supp. 360, 364-365 (W. D. Pa. 1957).

This line was sharply drawn in the *Phelps-Dodge* decision under the 1939 version of Section 304(a). The same reluctance was demonstrated under the amended section in *United States v. An Article or Device Consisting of 31 Units (Gonsertron)*,[59] a 1959 case over which Chief Judge Levin presided. The federal district court, in an almost matter-of-fact opinion, refused to allow libel against a device,[60] constructed entirely within the state of Michigan, partly from nine components which were received from various other states, where the device was neither sold nor held for sale outside the state. These components were ordinary electrical fixtures "in common use in industry. None of them were made to the specifications of the manufacturer of the device." [61]

However, in March, 1961, the *United States v. An Article of Drug Consisting of 39 Cases (Korleen)*[62] case arose on this same point before the same judicial representative of the United States. Here, the government alleged a misbranding of drug tablets under Section 304(a). Judge Levin held that tablets which were composed of drugs shipped in interstate commerce were subject to the act, although they were manufactured in Michigan for distribution there. In contrast to *Gonsertron,* "in the case at bar, the 'drugs' comprising the Korleen Tablets are the very heart of the manufactured and tableted 'drug' and were proclaimed as such to the public." [63] The advertisements laid stress on the alleged therapeutic value of the active ingredients of Korleen Tablets. Further, the court declared:

---

[59] 180 F. Supp. 52 (E. D. Mich. 1959).

[60] Section 201(h), 52 Stat. 1041 (1938), 21 U. S. C. Sec. 321(h) (1958) states: "The term 'device' (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602 (c) of this title) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

Compare the above to the parts (2) and (3) of the definition of "drug" which is the subject matter of the case immediately following *Gonsertron* in the text. Section 201(g), 52 Stat. 1041 (1938), 21 U. S. C. Sec. 321(g) (1958) states: "The term 'drug' means (1) articles recognized in the official United States Pharmacopœia, official Momœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for uses as a component of any article specified in clause (1), (2), or (3) of this paragraph; but does not include devices or their components, parts, or accessories."

[61] *United States v. Gonsertron,* 180 F. Supp. 52, 53 (E. D. Mich. 1959).

[62] 192 F. Supp. 51 (E. D. Mich. 1961).

[63] Case cited at footnote 62, at p. 52.

It would be a strained interpretation to say that each "drug" component falls within the jurisdiction of the Act, being shipped in interstate commerce, but, when compounded together to form another "drug," the finished product is not being held for sale after shipment in interstate commerce.[64]

It appears that the Food and Drug Administration has carefully chosen fact situations from which its attorneys can fashion fuller federal control of food, drugs and cosmetics, under the banner of protecting the public health and purse. One of the latest of these chosen cases has yet to be examined.

United States v. 40 Cases, More or Less, of Pinocchio Brand Oil [65]

It will be recalled that here the government brought a libel action against a food [66] product, known as "Pinocchio" oil, which had been manufactured and misbranded in New York State from components received by interstate shipment. Although the blended oil product was not held for sale outside of New York, the Food and Drug Administration pressed its case on the ground that all of the components had been shipped in interstate commerce and that the sum of these separate components was misbranded after their shipment and while held for sale in their blended form.

When a federal district court ruled that this constituted "a new product or complete article of intrastate manufacture" [67] which was beyond the reach of Section 304(a), the government quickly sought an appeal. *The Wall Street Journal* noted that the administration feared this decision, "if upheld, would significantly curb [its] power to seize misbranded foods." [68] The news article further stated:

Agency lawyers regard the new ruling as a "test case" of the agency's jurisdiction over the misbranding of similar foods. This type of violation makes up 3% to 5% of the agency's 100 to 150 monthly enforcement cases. If the District Court is upheld, an agency spokesman said a "significant number" of cases will be removed from the agency's reach. The Supreme Court never has interpreted the scope of the agency's power under the 1948 amendment.[69]

On appeal before the Second Circuit, appellee, A. M. S. Packing Company, contended that "the libel alleges that Pinocchio the product

---

[64] Case cited at footnote 62.

[65] 289 F. 2d 343 (CA-2 1961); *cert. den.*, 30 *U. S. Law Week* 3113 (U. S. Oct. 10, 1961).

[66] Section 201(f), 52 Stat. 1040 (1938); 21 U. S. C. Sec. 321(f) (1958) states: "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."

[67] 188 F. Supp. 290, 291 (N. D. N. Y. 1960).

[68] *The Wall Street Journal*, Nov. 25, 1960, p. 3.

[69] See footnote 68.

manufactured in New York was misbranded and adulterated; not the original oils (ingredients) received from out of state."[70] In addition it was stated that the product was first created in New York and never left that jurisdiction.[71] Appellant attacked both this contention and the holding below that Pinocchio was a "new product":

> The article is "new" only in the sense that the interstate components have been blended together, a mixture almost wholly vegetable oil substituted for a blend containing a substantial amount of olive oil, and a false label affixed. The very same interstate oils are in the cans, and the Government is attempting to bring to bear the Congressional protection against their sale to the consumer in their now adulterated and misbranded form.[72]

The agency attorneys argued further:

> As in *Sullivan,* articles were shipped legally in interstate commerce; mixed together so as to alter their form as in *Allbrook;* and, subsequently, misbranded as in *Color-Therm* and *Lee.* In addition, in this case, the articles were also adulterated. The important fact on which federal jurisdiction rests is that the components of the misbranded and adulterated oil had once moved interstate. A. M. S. as the consignee received the advantages of federal regulation which assured it honest labeling and unadulterated components. It now would deny the same protection to the ultimate consumer on the technicality that the honestly labeled oils it received have been mixed together.[73]

The force of these arguments obviously left their mark on the mind of the court. It declared that the completed mixture which was being held for sale as "oil" was "the very same type of food which had traveled across the state line."[74] Judge Lumbard easily distinguished the *Gonsertron* case with the aid of the *Korleen* limitation. Yet he reasoned with strain that it was the end result of the labor expended in assembling the component parts which was misrepresented. However, in the case before him, the "misbranding related directly to the percentage content of the olive oil shipped in interstate commerce."[75] It is in this no doubt subtle distinction that the essence of the opinion lies. This is a point which will again be examined in appraising the scope of the decision.

A. M. S. Packing Company petitioned the Supreme Court for certiorari. This was denied in October, 1961.[76] The petition, however, offered the government an opportunity to sharpen its argument.

---

[70] Brief for Appellee, p. 8.

[71] See footnote 70, pp. 4-5: "Pinocchio was created in this state and moved solely intrastate. The wrong, if any, occurred in connection with such newly manufactured article by reason of acts committed *wholly* within the State of New York, and hence this transaction falls within the orbit of intrastate—not interstate commerce, and the libel was wrongfully filed."

[72] Brief for Appellant, pp. 7-8.

[73] See footnote 72, p. 13.

[74] *United States v. Pinocchio,* 289 F. 2d 343, 345 (CA-2 1961).

[75] See footnote 74, at p. 346.

[76] 30 *U. S. Law Week* 3113 (U. S. Oct. 10, 1961).

In its brief in opposition to certiorari, the policy issue is brought into clear focus:

> If the petitioners are right in their contention that misbranding or adulteration of food "while held for sale . . . after shipment in interstate commerce" can be removed from the reach of the Act by any change, however slight, in the form of the product, there would be a significant loophole for evasion. For example, many misbranders and adulterators of food and drugs that move in interstate commerce could get around the Act simply by "decentralizing" certain phases of their operations. A nationwide operator who, before the 1948 amendment, could get away with mixing or processing his product at one central location and then shipping it interstate for misbranding or adulteration in the state of sale, could now escape the effect of the amendment by varying his operation solely to the extent of doing the mixing or processing at the same place he does the misbranding or adulteration. And if the simple mixing involved in the instant case is a sufficient "change in form" to achieve this result, presumably almost anything, such as addition of a coloring agent, would do. It is not reasonable to suppose that Congress intended to permit such artificial distinctions to defeat its purpose.[77]

The Law of *Gonsertron, Korleen* and *Pinocchio*

The *Pinocchio* case and its two immediate predecessors, *Gonsertron* and *Korleen,* represent the law of what constitutes the necessary interstate ingredient for the Federal Food and Drug Law to attach to an article which has received a new form after it has come to rest within a state. The *Gonsertron* decision makes it difficult to harmonize the three cases. Both the court of *Korleen* and that of *Pinocchio* recognize this dissonance, in drawing distinctions to the *Gonsertron* fact situation.[78] These have been examined. Yet, some difficulty with these distinctions may still persist.

One is inclined to wonder why the government ever initiated the *Gonsertron* case. The libel was tersely dismissed in the United States District Court of Michigan's Eastern Division; there was no appeal. Mr. William W. Goodrich, Assistant General Counsel of the Department of Health, Education and Welfare, Food and Drug Division, answers: "The case came to us because this worthless device was being used locally in the treatment of serious diseases and could not

---

[77] Brief for the United States in Opposition to Petition for a Writ of Certiorari, pp. 9-10.

[78] It is interesting to note that Judge Levin in *United States v. Korleen,* 192 F. Supp. 51, 52 (E. D. Mich. 1961) distinguished the situation before him from both the district court's decision of *Pinocchio* as well as the *Gonsertron* decision: "In both cases, the Courts held that an article or device is not subject to the jurisdiction of the Act where only components shipped in interstate commerce were either a minor ingredient of the final product or several commonly used components which lost their identity within the newly manufactured device." The *Korleen* case was decided in March, while the appellate court's decision of *Pinocchio* was not issued until April, 1961.

be controlled by the state medical authorities. We thought we had a good case. We recommended an appeal. The Solicitor General declined." [79]

Probably, the most lucid distinction between the *Pinocchio* and *Gonsertron* decisions was set forth in the government's brief in opposition to petition for certiorari:

> Petitioners' reliance upon [*Gonsertron*] is misplaced. There the components that had been shipped interstate were ordinary electrical fixtures, shipped with no intention that they be used in assembling a therapeutic device. They were purchased on the open market by the claimant, who originated the idea that the assembled machine had a therapeutic and diagnostic merit. Thus, unlike the situation here where all the component oils had been received in interstate commerce, no "device"—defined by the Act as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (21 U. S. C. 321(h)) —had moved interstate.[80]

This, Mr. Goodrich indicates, was the point the Solicitor General's office stressed in declining appeal to the district court's determination in *Gonsertron.* "They considered the record inadequate to show that the components met the statutory definition of 'device' when they were in interstate commerce or at any time prior to their purchase on the open market in Michigan and their assembly into a therapeutic device." [81] However, in *Korleen* and *Pinocchio,* it is to be noted that the drug components and oils which went into their respective blends were *already drug and food when they were transported in interstate commerce.*

No distinction among the cases can be based on the number or percentage of ingredients received from out of state as the criterion for determining whether the completed article of food, drug or device was sold or held for sale after shipment in interstate commerce. One will recall that only some of the components which made up the *Gonsertron* device were of foreign origin, whereas in *Korleen* and *Pinocchio* all the ingredients of the articles involved came from without the state. Particular significance is not attached to this. Neither court in the latter decisions made an argument of it, although each distinguishd the case before it from *Gonsertron.*

Perhaps the point to grasp is the degree of change which takes place in the articles from their condition "while in interstate com-

[79] Letter of Nov. 29, 1961, from William W. Goodrich, Assistant General Counsel of the Department of Health, Education and Welfare, Food and Drug Division, on file at Notre Dame Law Library.

[80] Brief for the United States in Opposition to Petition for a Writ of Certiorari, p. 8.

[81] See footnote 79.

merce." Must the components remain basically the same, differing only in form; or must the intrastate product be primarily composed of the ingredients which have been shipped interstate? Mr. Goodrich is again informative:

> When you ask how great a change must be made in the component, I must answer that I do not consider that the critical problem, although it was quite significant in the *Pinocchio* and *Korleen* cases. Assume that there was shipped in interstate commerce a food additive which is permitted for use in potato chips at a level of 50 ppm. This tolerance has been established to assure the safe use of the additive. If we found potato chips, prepared locally, with the food additive of interstate distribution present at a level higher than the established tolerance, we would attempt to enforce the tolerance and to condemn the potato chips in the interest of protecting the public health.[82]

Limits of Federal Jurisdiction

What then are the limits of federal jurisdiction? The petition for a writ of certiorari in the *Pinocchio* case points up this problem:

> If the present attempt at power by the Food & Drug is upheld it means that the Act will affect every food product manufactured locally from wholesome ingredients obtained from out of state—even though the manufactured product is sold intrastate—a revolutionary concept in the enforcement of the law and recasting with strange meaning the definition of interstate commerce and the term "while held for sale after shipment in interstate commerce." [83]

The petitioner appears to be indulging in invective. The Supreme Court answered just such a contention in the *Sullivan* decision, when it said:

> The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different misbranding provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise.[84]

Each case must be judged on its merits. The author does not presume to draw the line. "An accurate, all-inclusive definition of interstate commerce has never been formulated by the courts. . . . [I]ts facets are far too numerous and diverse." [85]

Conclusion

The difficulty in interpreting the commerce clause, as the basis for federal jurisdiction, is often one of determining whether local goods

---

[82] See footnote 79.

[83] Petition for a Writ of Certiorari, pp. 7-8.

[84] *United States v. Sullivan,* 332 U. S. 689, 694 (1948).

[85] *United States v. Sanders,* 99 F. Supp. 113, 115 (W. D. Okla. 1951).

or transactions have a sufficient effect on interstate commerce.[86] However, recent interpretation of the Federal Food, Drug and Cosmetic Act's Section 304(a) has given consideration to the other side of the coin. *Gonsertron, Korleen* and *Pinocchio* all face the question of how far into local commerce the Food and Drug Administration can reach after interstate transportation has come to a halt. No doubt the best insight to the problem lies in the words of the Assistant General Counsel of the Department of Health, Education and Welfare: "To my mind the problem is whether the misuse or misbranding of the interstate component has some consumer significance in the end product. If it does, we would try to apply the statute to it." [87] The government will seek to extend its jurisdiction as far as possible. Moreover, the *Gonsertron* limitation cannot be generalized. The same judge who decided that case, narrowly limited it to its facts in the subsequent *Korleen* decision.

The scope of Section 304(a) appears in the words of the Second Circuit Court of Appeals: "Congress surely intended the provisions of the Food, Drug, and Cosmetic Act to apply to foods processed within a state, after shipment in interstate commerce, as was the case here. The statute must be read and applied broadly in order to effectuate its remedial purpose." [88] **[The End]**

CARBON TETRACHLORIDE SEIZURE

The Food and Drug Administration announced on June 6, 1962 seizure of a quantity of carbon tetrachloride—one of the most dangerous chemicals to be found in the household—on charges that the home-size containers failed to bear required warnings under the Federal Hazardous Substances Labeling Act.

United States marshals seized 33 gallon bottles and seven pint bottles at a company in Colorado on May 31. Papers filed in the federal District Court in Denver said the company repacked the product into the bottles from bulk drums shipped by the manufacturer. FDA said that carbon tetrachloride has been found to present a special hazard and charged the containers failed to bear labels stating conspicuously the following: the signal word "Danger"; the affirmative statement "May be fatal if inhaled or swallowed"; the statement "Avoid contact with flame or hot surface"; instructions for first-aid treatment; the statement "Keep out of the reach of children" or its equivalent; the word "poison" and the required skull and crossbones symbol.

---

[86] For example, *Wickard v. Filburn*, 317 U. S. 111 (1942).

[87] See footnote 79.

[88] *United States v. Pinocchio*, 289 F. 2d 343, 346 (CA-2 1961).

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

Exemption from certain drug-labeling requirements.—Section 3.515 (a) Section 1.106(b)(3) of this chapter provides that in the case of certain drugs for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law, such information may be omitted from the dispensing package. Under this proviso, the Commissioner of Food and Drugs will offer an opinion, upon written request, stating reasonable grounds therefor, on a proposal to omit such information from the dispensing package.

(b) The Commissioner of Food and Drugs has considered submitted material covering a number of drug products and has offered the opinion that the following drugs, when intended for those human uses for which they are now generally employed by the medical profession, should be exempt from the requirements of Section 1.106(b)(3) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

Aminophylline. For oral use, not in excess of 200 milligrams per dosage unit, with or without not in excess of 33 milligrams of phenobarbital.

Atropine methyl nitrate. For oral use, not in excess of 1.0 milligram per dosage unit.

Atropine sulfate. For oral use, not in excess of 0.54 milligram per dosage unit; for injection, not in excess of 0.54 milligram (1/120-grain) per dosage unit.

Barbiturates. For oral use, not in excess of 100 milligrams per dosage unit; for use as suppositories, not in excess of 130 milligrams per suppository.

Chloral hydrate. For oral use, not in excess of 500 milligrams per dosage unit; for use as suppositories, not in excess of 1.0 gram per suppository.

Codeine phosphate. For oral use, not in excess of 65 milligrams per dosage unit; for injection, not in excess of 65 milligrams per dosage unit.

Codeine sulfate. For oral use, not in excess of 65 milligrams per dosage unit; for injection, not in excess of 65 milligrams per dosage unit.

Digitalis. Preparations of whole leaf digitalis including forms such as digitalis tincture. For oral use, containing the equivalent of not more than 1 U. S. P. digitalis unit per dosage unit.

Dihydrocodeinone bitartrate. For oral use, not in excess of 10 milligrams per dosage unit.

Dihydromorphinone hydrochloride. For oral use, not in excess of 4 milligrams per dosage unit.

Epinephrine injection, 1:1,000.

Erythrityl tetranitrate. For oral use, not in excess of 30 milligrams per dosage unit.

Homatropine methylbromide. For oral use, not in excess of 5 milligrams per dosage unit.

Hyoscyamine hydrobromide. For oral use, not in excess of 1 milligram per dosage unit.

Hyoscyamine sulfate. For oral use, not in excess of 1 milligram per dosage unit.

Hyoscyamus tincture. For oral use, not in excess of 2 milliliters per dosage unit.

Mannitol hexanitrate. For oral use, not in excess of 32 milligrams per dosage unit.

Methenamine. For oral use, not in excess of 1 gram per dosage unit.

Morphine phosphate. For oral use, not in excess of 33 milligrams per dosage unit; for injection, not in excess of 33 milligrams per dosage unit.

Morphine sulfate. For oral use, not in excess of 33 milligrams per dosage unit; for injection, not in excess of 33 milligrams per dosage unit.

Nitroglycerin. For oral use, not in excess of 0.65 milligram per dosage unit.

Pentaerythritol tetranitrate. For oral use, not in excess of 20 milligrams per dosage unit.

Pentaerythritol tetranitrate with phenobarbital. For oral use, not in excess of 20 milligrams of pentaerythritol tetranitrate and 35 milligrams of phenobarbital.

Quinidine sulfate. For oral use, not in excess of 325 milligrams per dosage unit.

Scopolamine methylbromide. For oral use, not in excess of 2.5 milligrams per dosage unit.

Sodium chloride injection.

Sodium nitrite. For oral use, not in excess of 60 milligrams per dosage unit.

Theobromine. For oral use, not in excess of 325 milligrams per dosage unit.

Thyroid. For oral use, not in excess of 220 milligrams per dosage unit.

Water for injection, sterile.

(c) The Commissioner of Food and Drugs has considered submitted material covering a number of drug products and has offered the opinion that the following drugs, when intended for those veterinary uses for which they are now generally employed by the veterinary medical profession, should be exempt from the requirements of Section 1.106 (c)(3) of this chapter, provided that they meet the conditions prescribed in this paragraph. Preparations that are not in dosage unit form (for example, solutions) will be regarded as meeting the conditions with respect to the maximum quantity of drug per dosage unit if they are prepared in a manner that enables accurate and ready administration of a quantity of drug not in excess of the stated maximum per dosage unit:

Atropine sulfate. As an injectable for cattle, goats, horses, pigs and sheep, not in excess of 15 milligrams per dosage unit; as an injectable for cats and dogs, not in excess of 0.6 milligram per dosage unit.

Barbital sodium. For oral use in cats and dogs, not in excess of 300 milligrams per dosage unit.

Epinephrine injection, 1:1,000. For cats, dogs, cattle, goats, horses, pigs and sheep.

Morphine sulfate. As an injectable for dogs, not in excess of 15 milligrams per dosage unit.

Pentobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Phenobarbital sodium. For oral use in cats and dogs, not in excess of 100 milligrams per dosage unit.

Procaine hydrochloride injection. Containing not in excess of 2 per cent procaine hydrochloride, with or without epinephrine up to a concentration of 1:50,000. For use in cats, dogs, cattle, goats, horses, pigs and sheep.

Thyroid. For oral use in dogs, not in excess of 60 milligrams per dosage unit.

(Sec. 701(a), 52 Stat. 1055; 21 U. S. C. 371(a))

[*As added, 26 F. R. 12563, effective December 20, 1961; amended, 27 F. R. 5428, effective* May 31, 1962.] FOOD DRUG COSMETIC LAW REPORTS.—¶ 1275.15.

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

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

Some BOOKS IN THE FOOD LAW INSTITUTE SERIES:*

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

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

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

YOURS—FOR 15 DAYS' FREE EXAMINATION

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

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

A COMMERCE CLEARING HOUSE PUBLICATION

BUSINESS REPLY MAIL

NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY–

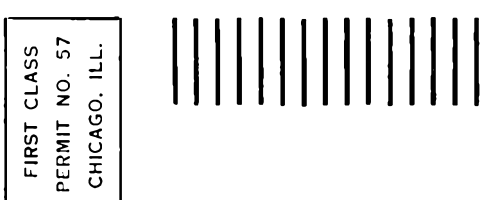
CCH PRODUCTS COMPANY

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

FOOD LAW

INSTITUTE SERIES



ORDER CARD

Detach and Mail This Card Today
To Order Additional Books
For Your Food and Drug Law Library

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

Send the copies of CCH books indicated below at prices quoted. (Remittance with order saves postage and packing charge.)

Fill in Amt.

1. ....General State Food and Drug Laws —Annotated (4436). Price: $17.50 a copy.
2. ....Constitutional Questions in Food and Drug Laws (0226). Prices: 1-4 copies, $3.50 ea.; 5-9, $3.20 ea.; 10-24, $3.00 ea.; 25-49, $2.80 ea.
3. Federal Food, Drug, and Cosmetic Act—Judicial and Administrative Record:
   ....1938-1949 Edition (1446). Price: $17.50 a copy.
   ....1949-1950 Edition (1329). Price: $10.25 a copy.
   ....1951-1952 Edition (3228). Price: $12.00 a copy.
   ....1953-1957 Edition (8224). Price: $25.00 a copy.
4. ....Legislative Record of 1958 Food Additives Amendment (8445). Prices: 1-4 copies, $3 ea.; 5-9, $2.70 ea.; 10-24, $2.40 ea.; 25-49, $2 ea.
5. ....Product Liability Cases (4118). Price: $12 a copy.
6. ....Canada's Food and Drug Laws (3334). Price: $19.50 a copy.

☐ Remittance herewith ☐ Send bill

Signature & Title .....

Firm .....

Attention .....

Number & Street .....

City, Zone & State .....

(If ordering by letter or purchase order, please attach this card for our records.)

4436—519