VOL. 20, NO. 11 NOVEMBER 1965

Food Drug Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

November, 1965
Volume 20 • Number 11

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . November, 1965

VOLUME 20 NUMBER 11

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

"No Residue" and "Zero Tolerance".—This report, prepared by the National Academy of Sciences—National Research Council, Pesticide Residues Committee, for the Department of Health, Education and Welfare and the Department of Agriculture, begins on page 608. It discusses the technical issues involved in the concepts of "no residue" and "zero tolerance" as they relate to the registration of pesticides, the setting of tolerances for pesticide residues, the enforcement provisions of the Food, Drug and Cosmetic Act relating to residues in food, and the recommendations of the federal and state agencies concerning pesticide uses.

More Legislation?—The question of whether or not more legislation is needed in the area of food and drugs is the topic of this article which begins on page 623. The author, *Vincent A. Kleinfeld,* a member of Bernstein, Kleinfeld and Alper, Washington, D. C., begins his article by discussing the Federal Food, Drug and Cosmetic Act and the Drug Amendments of 1962 and their provisions, and the Food and Drug Administration and its authority over food, drugs and cosmetics. Mr. Kleinfeld then states his belief that while more legislation and more amendments for consumer protection are needed, this should not lead to greater cost to the government, to the removal of the small businessman from the market or to higher prices to the consumer.

The Future Relationships of FDA and the Pharmaceutical Industry.—This is the topic of the article commencing on page 632. *W. B. Rankin,* the Assistant Commissioner for Planning, Food and Drug Administration and the author of this paper, traces the development of relationships between the federal government and the drug industry. It is the author's belief that the trend toward increased government control will continue because the public lacks confidence in the drug supply. This lack of public confidence occurred because (1) people think drug prices are too high; (2) industry has convinced the public that the only way to obtain good quality drugs is to buy brand name drugs, and this has lead the public to view a large part of the drug supply with suspicion; and (3) there have been occasions when drugs had to be taken off the market because they were found to be defective. But, in the opinion of Mr. Rankin, this increased government control is desirable since it will lead to better drugs and better protection to the consumer.

Latin-American Food Code.—Chapters I-V, XII and XIII of the *Latin-American Food Code,* translated by *Ann M. Wolf* of New York, appeared in previous issues of this Journal. Beginning on page 638, Chapter XVII is reproduced. Types of food additives and their definitions and regulations concerning packing, labeling and content is discussed in the chapter published in this Journal.

Vol. 20, No. 11 November, 1965

Food·Drug·Cosmetic Law
Journal

"No Residue" and "Zero Tolerance"

This Report Was Prepared by the National Academy of Sciences—National Research Council, Pesticide Residues Committee, for the Department of Health, Education and Welfare and the Department of Agriculture. The Report Was Recently Released for Publication.

I. Statement of Task

IN ACCORDANCE WITH THE RECOMMENDATIONS in the report of the President's Science Advisory Committee on "Use of Pesticides," the Secretary of Agriculture and the Secretary of Health, Education, and Welfare requested the National Academy of Sciences —National Research Council to study the technical issues involved in the concepts of "no residue" and "zero tolerance" as they relate to the registration of pesticides, the setting of tolerances for pesticide residues, the enforcement provisions of the Food, Drug and Cosmetic Act relating to residues in food, and the recommendations of the federal and state agencies concerning pesticide uses.

The Pesticide Residues Committee is cognizant of the advances that have been made through the discovery, manufacture, and application of new chemicals for the control of pests of all types and that their uses are necessary to the health, nutrition, and economy of the nation. Although it is recognized that some pesticide chemicals are more toxic than others to warm-blooded animals, and that their use requires greater restriction to protect the public health, the Committee believes that their valuable properties can be utilized without exposing people, domestic animals, fish, or wildlife to undue risk. By the term "pesti-

cide" the Committee means "pesticide chemical" as defined in Section 201(q) of the Federal Food, Drug and Cosmetic Act.[1]

In an effort to understand and evaluate the problems of "no residue" and "zero tolerance" as they relate to registration and regulation, the Committee ascertained the views of representatives of the U. S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the agricultural-chemical and food industries. Their cooperation and helpful assistance in providing needed information is gratefully acknowledged.

II. Present "No-Residue" Registration Procedure under the Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide and Rodenticide Act carries no specific provisions relating to the contamination of food. However, in administering the act, the USDA has taken the position that directions for use of a pesticide are not adequate to protect the public if any use of it might leave a residual amount of the pesticide on food or feed crops that would make them subject to action by the FDA.

Applications for registration of pesticides for use on food crops must be accompanied by detailed residue data relating to specific uses. If these data show that there is no detectable residue remaining on the crop or other food products as a result of the proposed use, registration may be granted on a no-residue basis. If the data show that a detectable residue may result, registration is withheld until a tolerance, or exemption from the requirement of a tolerance, is established by the FDA for the raw agricultural commodity or until clearance is obtained for processed foods under the Food Additives Amendment. These residue data must be based on the most sensitive analytical method available which must be able to detect residues at a level of 0.1 part per million (ppm) or less.

The recent development of more sensitive analytical methods has made possible the detection of certain residues at levels far below 0.1 ppm. This has resulted in the finding of residues on crops properly treated in accordance with directions for certain products previously registered on a no-residue basis. Under a strict interpretation of the Federal Food, Drug and Cosmetic Act such residues thereby become illegal and the affected crop is subject to seizure even though the amount of residue present may not be a hazard to health.

[1] Food Drug Cosmetic Law Reporter ¶ 54,051.

When the proposed use of a new pesticide does not include direct application on a food crop, registration may be granted on a no-residue basis if it is concluded that no undue hazard to man or domestic animals is associated with the proposed use when applied according to the instructions provided by the manufacturer on the label approved by the USDA.

III. The "Zero-Tolerance" Provision of the Federal Food, Drug and Cosmetic Act

The pesticide-chemicals amendment to the Federal Food, Drug and Cosmetic Act provides for the establishment of safe legal pesticide tolerances, or exemptions from tolerances, under certain conditions. The act provides authority to establish a tolerance "at zero level" if the scientific data do not justify the establishment of a greater tolerance. In practice, the zero tolerance is used under several conditions:

(1) when a pesticide is so highly toxic that no residue can be permitted;

(2) when there are not sufficient data to support a greater tolerance;

(3) when the use of the pesticide on food crops will not result in a detectable residue within the sensitivity of the best available analytical method after a specified interval between application and harvest for a particular chemical and particular crop.

As knowledge, techniques, and methodology have advanced, the lower limit of detection of many pesticide residues has been extended, and where formerly it may have been only 0.1 ppm for a given substance, much lower levels can now be detected. This has resulted in certain uses being found to leave illegal residues although they were once regarded as complying with the provisions of a "zero-tolerance" registration. Even if this small residue may not constitute a health hazard, the recognition of its presence in amounts confidently determined presents an administrative dilemma.

IV. Problems in the Use of "No-Residue" and "Zero-Tolerance" Concepts

A. Background Residue

Many pesticides owe their economy and efficiency to a high degree of stability and persistence. The heavy-metal pesticides, with a long history of use are usually regarded as being stable, and diminish

in amount only by mechanical removal. Certain organic chemicals, including many of the chlorinated hydrocarbon insecticides and triazine herbicides, are reported to have considerable stability and to be resistant to chemical and biological degradation, to leaching, or to volatilization, and hence may persist on or in vegetation or in soil for several weeks to many years. On the other hand, some chlorinated hydrocarbon pesticides, as well as some chlorine-containing organophosphorus compounds, are lost, at least in major part, by evaporation or by ready hydrolysis and thus are relatively less persistent.

As a group, the organophosphorus insecticides are usually broken down to water-soluble and usually nontoxic products; for example, one of the most toxic insecticides, tetraethyl pyrophosphate (TEPP) is decomposed 24-72 hours after application. Because in certain situations long-continued protection is advantageous, special formulations have been developed to accomplish this goal by providing slow release of the active ingredient.

The amount of pesticide remaining in the soil after treatment often decreases exponentially with time, whether removed by chemical or biological decomposition or by erosion. Therefore, the concentration may decline to a minute fraction of the initial value, the recognition of which will depend on the sensitivity and specificity of the analytical procedure.

As a consequence of the widespread adoption of improved analytical methods and the development of instruments involving amplification of signals, it has become evident that certain pesticides are pervasive and give rise to persistent residues. After application to a crop they may remain in the soil and appear in measurable amounts in a later subterranean crop, such as carrots or potatoes, even though no new application has been made. Surface contamination of foliage by soil dust or splash may result in the presence of residues on other crops, or if sufficiently soluble in soil water, the residues enter the roots and are translocated throughout the plant tissues. Should these be forage crops or materials used for animal feed, even if the background level of pesticides is quite low, animals may concentrate it into significant amounts in the fatty portion of meats, poultry, or dairy products. Residues in such products cannot readily be reduced in processing as can surface-contaminated produce by washing, peeling, or trimming.

Accumulating evidence suggests that the persistent and pervasive character of some pesticides has to be recognized in relation to products used for human food. For example, human body fat often shows detectable concentrations of DDT-derived materials.

Although these background amounts of pesticides are generally recognized as inconsequential, they may be found in amounts exceeding the legal tolerance, if the tolerance is low or zero.

Presumptive recognition of pesticide residues in check, control, or untreated samples may also arise for a variety of reasons relating to the analytical procedure, such as the presence of compounds causing interference in the specific reaction used in determination, or from spurious electronic signals if instrumentation is involved. Methods are constantly being refined to minimize or compensate for these interferences or uncertainties, but it is desirable to establish from a sufficient number of untreated controls the range of "apparent" values that essentially mean zero. The presence of minute background amounts of pesticide in untreated produce makes it difficult to obtain a true check or control sample, and hence reduces the precision with which small residues can be measured.

The sources of background pesticide residues are varied. In addition to persistence in an area previously treated, there may be downwind drift of dust or spray droplets for considerable distances in dusting or spraying operations. Soil, contaminated by spraying, may be blown in a dust storm. Careless handling and improper use of pesticides, though always a possible factor, should not generally contribute to background. Free water is an unlikely source of significant contamination.

B. Analytical Chemistry

Recent advances in the techniques and instrumentation of chemistry have resulted in the development of analytical methods that can detect some residues and their reaction products at levels in the parts per billion range. These newer methods are far more sensitive than the best procedures available only a few years ago and, thus, have complicated the administration of no-residue and zero-tolerance registration.

In view of these new developments and the extreme shortage of experienced personnel, it is not surprising that there are many problems associated with the present state of the art. Disturbing varia-

tions exist in the reproducibility, reliability, and sensitivity of analyses performed by different operating residue laboratories. The profusion of analytical methods and equipment, as well as the variety of procedures for sampling, concentration, and isolation are matters of real concern. Further, the lack of a uniform terminology has added to the confusion in the interpretation and comparability of results.

It is important that the distribution of dietary intakes of pesticides be monitored on a national scale. This will require full use of modern survey and sampling techniques, of continued standard interlaboratory comparisons, and of competent statistical analysis of results. The statistical and analytical difficulties associated with current efforts along these lines substantially reduce the reliability of the findings.

C. *Comment on the Basis for Pesticide Registration*

It is the considered opinion of the committee that the registration of pesticide chemicals on a "no-residue" or "zero-tolerance" basis is scientifically and administratively untenable. The rapid advances in analytical chemistry have now made it possible to detect minute amounts of residue where previously none had been found. The development of these highly sensitive instrumental methods is necessary in the broad field of analytical chemistry, but it is illogical to associate a tolerance value with the ability of chemists to detect smaller and smaller amounts. The committee considers that the registration of pesticides for uses on foodstuffs should relate more to considerations of safe use than to the limitations of analytical methodology. The small residues that may now be detected in many food products are more likely to be due to uncontrolled factors, such as drift, spills, soil contamination, and residues from previous crop treatments rather than to any recommended use. The possible presence of such inadvertent residues must be considered in registration, setting of tolerances, regulatory enforcement, and recommendations for use. Proposals for registration on the basis of "negligible residue" and "permissible residue" are set forth in this report.

V. Safety Evaluation from Animal Tests

The advances made in toxicological methodology over the past two decades provide a means for obtaining reliable data from animal tests that can be safely and conservatively transposed to man. Although no attempt is made here to detail in full the requirements of

an adequate toxicological assessment of a pesticide chemical, certain important aspects of tests in animals deserve emphasis. Special attention should be paid to the determination of the "no-effect" levels of the substance for the species under study. The term "no effect" is construed to mean no observed adverse effects on growth, function, behavior, reproduction, or on gross histomorphological structure of the test animals. Unless such adverse effects occur, a demonstrable concentration of the pesticide in the tissues or body fluid or an effect on the tissue or blood level of an enzyme should not be considered as a toxic effect per se.

The nature, number, and design of tests required in determining the safety of a pesticide will depend upon the chemical composition of the material, the biological responses observed in acute and subacute tests, and the metabolic disposition of the substance. In addition, the judgment of experts qualified by scientific training and experience to evaluate safety under conditions of intended use is important.

In appraising the toxicity of a chemical, careful consideration must be given to carcinogenicity, since this is another manifestation of toxicity. The statutory ruling against any food additive "found to induce cancer when ingested by man or animal" (the so-called Delaney Clause, Section 409[c]3[A] of the Food, Drug and Cosmetic Act[2]) has focused particular attention on the need for and reliability of animal tests for carcinogenic potential. The principles, practices, and problems involved in these tests have been discussed at length in publications from the Food Protection Committee, National Academy of Sciences—National Research Council, and the Joint Committee on Food Additives of the World Health Organization and the Food and Agriculture Organization of the United Nations. Although it is reasonable to assume that a no-effect level could be demonstrated for a compound with respect to carcinogenic potential, approval of such a compound for use when it might leave a residue on food would require most extraordinary justification.

VI. Safety Evaluation from Tests in Man

A continuing problem faced by the food industry, government, and the public is the evaluation of the safety to man of the chemicals used in production, packaging, transport, and storage of food. The

[2] Food Drug Cosmetic Law Reporter ¶ 55,105.

practical and proven approach is to rely upon the evaluation of experimental data and competent judgment that any hazard associated with the use of a chemical is insignificant in relation to the health and economic benefits derived from its proper use. The primary tool is toxicological experimentation with animals, and subsequent projection of the information thus obtained to large human populations. On balance, the procedures for safety evaluation employed by industry and government in the United States, together with strict enforcement procedures, have contributed to our abundant, healthful, and economic food supply with an extremely low hazard to the consumer from the chemicals used in its production.

Because of the obvious difficulties of conducting toxicity studies in man, the conclusions derived from animal experimentation are generally relied upon to provide the ". . . reasonable certainty that no harm will result from the intended use. . ." (Food Additives Regulation, Sec. 121.1[i][3]) of a chemical substance. Nevertheless, valuable information is often obtained from observations in man. For example, exposure of workers engaged in the manufacture and use of pesticides, and well-controlled tests on volunteer subjects, provide information of value in establishing guidelines for safe handling of these substances and safety of trace amounts in food crops. Although several of the pesticides most widely used today may not have been as thoroughly investigated in animals as is now required, considerable information regarding their safety has been gained from controlled investigations in man and extensive experience in use.

Experiments on human volunteers have obvious limitations, particularly with respect to the size or number of dosages of chemicals that may be administered, the relatively short duration of the tests, and the extent to which examination of the tissues may be made. These and many other factors determine the practicability of such studies. In any event, studies of this kind should be made only to answer important questions of safety that cannot be answered in other ways.[4]

---

[3] Food Drug Cosmetic Law Reporter ¶ 55,301.

[4] "Some Considerations in the Use of Human Subjects in Safety Evaluation of Pesticides and Food Chemicals," A Report of the *Ad Hoc* Subcommittee on Use of Human Subjects in Safety Evaluation of the Food Protection Committee. NAS-NRC Publication No. 1270, 1965.

VII. Safe Limits of Pesticide Residues

A. Maximum Acceptable Daily Intake

One of the important steps in establishing the safety of a pesticide chemical for man is the determination of the daily amount that can be administered to test animals without inducing an adverse or toxic effect. The maximum acceptable daily intake in man can then be estimated from the results of appropriate toxicological studies in animals and by the application of such safety factors as may be deemed necessary from the evidence presented to experts in the field.

The maximum acceptable daily intake of a pesticide is the limiting or acceptable daily intake of the substance from all sources and is the weight on the scale of safety which must not be overbalanced by the combined weight of the substance ingested per man per day. This amount should include any background level of residual pesticide that may occur in the foodstuff naturally, by intentional application, or unintentionally through drift, persistence in soil, etc.

It has seemed reasonable to the committee that the use of pesticides be registered on the basis of the concentration of a residue, on or in a foodstuff, that would possibly contribute to its total daily intake from all sources. The legal or maximum concentration of a pesticide is the least concentration required and permitted when used according to good agricultural practice. Such residues might be classified appropriately as "Negligible Residues" or "Permissible Residues" when their contribution to the maximum acceptable daily intake is acceptable but not negligible.

B. Proposed "Negligible-Residue" Registration

Many pesticides that have been registered in the past for use on a "no-residue" or "zero-tolerance" basis, and since found by more sensitive methods to persist on or in foodstuffs, do, in fact, leave negligible residues. It would therefore be prudent to establish a definite relationship between such amounts and the maximum acceptable daily intake established for each pesticide, rather than to set negligible amounts of the residue on the basis of limits of analytical detection alone. In the opinion of the committee, any amount of a pesticide remaining in or on a food or class of foods, which could result in a daily intake below some small fraction of the maximum acceptable daily intake, should be regarded as toxicologically insignificant and therefore negligible, from a regulatory standpoint.

For a pesticide chemical to be registered on a negligible-residue basis for one or more uses on a foodstuff, it would be necessary to demonstrate that the concentration of the pesticide residue on the individual items was such that the total amount consumed per day as a result of all such registrations was no greater than an established negligible daily intake which might, for example, be 5 per cent of the established maximum acceptable daily intake. To relate the negligible residue to the amount of a particular food ingested, reference could be made to the estimated daily intake of the foods as represented by the "high consumption" levels reported by the USDA.[5] To the extent that the negligible-residue registrations would be additive, the daily intake of a pesticide from such sources would be increased by each additional registration to approach the total negligible daily intake established for that pesticide.

C. *Proposed "Permissible-Residue" Registration*

Some pesticides are presently registered for use on the basis of a tolerance,[6] where a determinable residue does in fact remain on a crop when produced according to good agricultural practice. It is to be anticipated that in such instances these concentrations of residue may result in an intake of pesticide from such a source greater than the established negligible daily intake (for example, greater than 5 per cent of the maximum acceptable daily intake).

It is proposed that pesticide uses on or in specific foodstuffs be considered for registration on a permissible-residue basis when their use requires such concentrations that the possible intake from such sources is acceptable but not negligible. In establishing the permissible-residue registration of a pesticide for a given use, cognizance must be taken of its relation to the quantity of food containing the compound that is likely to be contained in the diet, since the total daily intake of the pesticide from all sources must not exceed the maximum acceptable daily intake. Safety for the consumer is assured not only by the conservative estimation of the maximum acceptable daily intake

[5] *High Consumption of Foods,* Household Economics Research Division, Agricultural Research Service, U. S. Department of Agriculture. HHE (Adm.)-214, 11/17/60.

[6] It would seem desirable to abandon the term "tolerance" in this context because it is often erroneously interpreted to indicate the maximum level of intake which can be safely tolerated in a physiological sense, whereas the term, as used in the Food, Drug and Cosmetic Act, defines a legal limit, based on the minimum requirement resulting from technological use, and is actually only a small fraction of the estimated no-effect level in man.

of pesticides but by virtue of the facts that (1) only a minor proportion of the total production of food plant crops is treated with pesticides during a growing season, or more significantly, near the time of harvest, and (2) often the pesticide residue in fruits or vegetables occurs on the outer portions, which may be removed or diminished significantly either by the packer prior to shipment or in the kitchen by washing, trimming, or cooking.

D. Factors to be Considered in the Proposed "Negligible-Residue" and "Permissible-Residue" Registrations

These proposed registrations for establishing safe limits of pesticide residues are based on the determination of a maximum acceptable daily intake of the pesticide derived principally from animal studies. If the maximum acceptable daily intake has not been established, a provisional or tentative maximum acceptable daily intake sufficient for negligible-residue registration of a specific pesticide could be derived from appropriate chronic-feeding studies of at least three months duration and in at least two species of standard laboratory animals. These should be supported by acute toxicity studies, as well as pharmacodynamic, metabolic, and histopathologic investigation. While these studies may indeed meet the requirement for permissible-residue registration, they should be reviewed for adequacy in each instance as the total registrations for use cause the possible daily intake to approach the maximum acceptable daily intake previously established.

Another factor to be considered in relation to the registration of pesticides on the basis of negligible and permissible residues is the necessity for monitoring by the regulatory agencies. Application of such registrations would have to include an analytical method of sufficient sensitivity and reliability to permit the determination of amounts in excess of negligible or permissible residues. However, once such a registration was granted, it should not be jeopardized by subsequent improvements in analytical methodology since the registration would be based on toxicological rather than analytical considerations.

Periodic reviews of the combined effects of negligible-residue and permissible-residue registrations on the residual pesticide content of the United States food supply should be continued. If such reviews reveal that the total accumulation of a given pesticide comes close to its maximum acceptable daily intake, enforcement measures, including modification or revocation of existing regulations and registrations, should be undertaken.

VIII. Nonfood Use Registration

The committee recognizes that many pesticides may also be registered for nonfood use, such as in paints, turf management, forest pest control, nurseries, in the home, and elsewhere, and for which the USDA has the responsibility for registration. In registering economic poisons under the Federal Insecticide, Fungicide and Rodenticide Act, the prime consideration of the Department of Agriculture has been and should continue to be safety and effectiveness.

It should be pointed out however, that the widespread use of pesticides by private individuals, municipalities, and local agencies may be a major factor in contributing to pesticides appearing in human tissue and thus increasing the total body burden. It would be impractical to attempt to police the individual user, but the USDA should continually have under review nonfood-use registration of pesticides because such use is a potential source of exposure. There should be a continuous educational program aimed at making the public aware of the hazards involved in the indiscriminate use of pesticides.

IX. Transition Period

About 35,000 pesticide formulations involving some 550 chemical compounds are currently registered with the USDA for use on food crops on a no-residue basis. On some of these a zero tolerance has been set by the FDA. There may not be adequate data on many of these to meet this committee's recommended requirements because pharmacological and toxicological information is lacking or the analytical methods at the time of registration did not detect any residue. To effect a sudden change in the present procedure in registration, regulation, and enforcement could lead to serious difficulties in the economy, for the farmer, and for industry.

If the proposals set forth in this report are accepted, then to permit an orderly transition, the pesticides registered with the USDA on a no-residue basis, whether or not subject to a zero-tolerance regulation, should be authorized for use for a reasonable period of time. During this period, these registrations would be reviewed and industry would be allowed time to furnish such additional data as might be required for registration on a negligible-residue or permissible-residue basis. The task of reviewing these no-residue registrations and the time required to develop additional data are of such

magnitude that a transition period as long as five years may be reasonable. The transition period should not present a significant hazard to public health.

The committee recommends that petitions pending or filed within a reasonable time, which fulfill present requirements, should be registered on the basis of the procedure suggested here for use in the transition period. During the transition period, actionable levels for active ingredients of all no-residue registrations so continued should be published, together with a method of analysis mutually agreed upon by the FDA and the USDA. The method of analysis should be sufficiently sensitive and reliable to detect any amount in excess of the negligible or permissible residue.

X. Registration and Enforcement

In order to accomplish promptly and smoothly the changes recommended in this report, the committee would hope that the Secretary of Agriculture and the Secretary of Health, Education, and Welfare could administer present laws with cognizance and acceptance of the basic principles outlined above and the elimination of untenable concepts. Pesticides are an essential and indispensable part of our modern life and must be used if the public is to have an adequate and wholesome food supply.

Under the Federal Insecticide, Fungicide and Rodenticide Act of 1947, the USDA has the responsibility for approving the registration of economic poisons used on food crops, on agricultural products other than food crops, and for all nonagricultural uses. It has also the responsibility to ensure that all such products are properly labeled with instructions, which if complied with, will be adequate to protect both man and animals. The USDA has been actively engaged in eradication programs and in the development of chemical and biological means of pest control. It would therefore seem appropriate that the registration of pesticides should continue to be the responsibility of the USDA.

In registering a pesticide on the basis of negligible residue, the negligible residue and an analytical method for determining any amount in excess thereof should be published and should have FDA concurrence for enforcement purposes under the Federal Food, Drug and Cosmetic Act. When the pesticide residue is safe but is greater

than the negligible residue, registration by the USDA and regulation of the residue by the FDA on a permissible-residue basis could continue as at present, provided the regulations of the FDA include a practicable analytical method for enforcement purposes. If a pesticide is not established to be safe for a proposed registration, it should not be registered for such use.

Recommendations

1. The concepts of "no residue" and "zero tolerance" as employed in the registration and regulation of pesticides are scientifically and administratively untenable and should be abandoned.

2. A pesticide should be registered on the basis of either "negligible residue" or "permissible residue," depending on whether its use results in the intake of a negligible or permissible fraction of the maximum acceptable daily intake as determined by appropriate safety studies.

3. Where the use of a pesticide may reasonably be expected to result in a residue in or on food, registration by the USDA should not be granted unless (a) it is established that the residue is a negligible residue or (b) such residue is not more than a permissible residue established by the FDA.

4. When a pesticide is registered on a negligible-residue basis, the negligible-residue figure should be published, as well as an analytical method for determining whether or not a food contains a residue in excess of the negligible residue. Both the amount and the analytical method should have the concurrence of the FDA and be controlling for its enforcement purposes.

5. The FDA's regulations on permissible residues should include a published description of the analytical methods used for enforcement purposes and should not be changed without notice and opportunity for comment by interested parties.

6. If a pesticide is known to be too hazardous for a particular use, registration for such use should be refused.

7. Because of the importance that pesticides play in the production of our food supply and the many nonfood uses necessary for protecting the health and economy of the nation, it would seem appropriate that the registration of pesticides should continue to be the responsibility of the USDA.

8. The publication of a reasonable schedule for an orderly transition from the present procedure is necessary, and its duration should be decided by mutual agreement between the USDA and the Department of Health, Education, and Welfare (HEW).

9. Programs should be developed for continuing centralized leadership, free and prompt exchange of information, training activities, and interlaboratory evaluation. A manual of operating instructions for residue methods should be produced by the USDA and HEW and continuously revised according to changing usage, food habits, and new pesticides and mixtures.

10. A formal program for education in residue analysis is urgently needed and the USDA and HEW, and any other agencies concerned should cooperatively sponsor this program with suitable training centers.

11. There should be an expanded research program on the persistence of pesticides in the total environment, and on the toxicology, pharmacology, and biochemistry of pesticides that would improve the reliability and precision of animal studies and their relevance to man.

[The End]

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION (Act of October 23, 1962; Section 4369, Title 39, United States Code)

1. Date of filing: Oct. 1, 1965. 2. Title of publication: Food Drug Cosmetic Law Journal. 3. Frequency of issue: Weekly. 4. Location of known office of publication: 4025 W. Peterson Ave., Chicago, Cook, Illinois 60646. 5. Location of the headquarters or general business offices of the publishers: Chicago, Illinois 60646.

6. Names and addresses of publisher, editor, and managing editor: publisher: Commerce Clearing House, Inc., Chicago, Ill. 60646; editor: Henry L. Stewart, Chicago, Ill. 60646; managing editor: George H. Harris, Chicago, Ill. 60646.

7. Owner: Commerce Clearing House, Inc., Chicago, Illinois 60646. Names and addresses of stockholders owning or holding 1 percent or more of total amount of stock: C. T. Corporation System, Wilmington, Delaware; The Corporation Trust Company, (Del.), Wilmington, Delaware; The Corporation Trust Company, (N. J.), Jersey City, New Jersey; The Corporation Trust Company, (N. Y.), New York, New York; Eddy & Company, New York, New York; Gooss & Company, New York, New York; Hurley & Company, New York, New York; The Millbrook Tribute Garden, Inc., Millbrook, New York; Reing & Company, New York, New York; Justus L. Schlichting, Toms River, New Jersey; Stuart & Company, New York, New York; Bertha Palmer Thorne, Bar Harbor, Maine; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York. 8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

9. Paragraphs 7 and 8 include, in cases where the stockholder or security holder appears upon the books of the company as trustee or in any other fiduciary relation, the name of the person or corporation for whom such trustee is acting, also the statements in the two paragraphs show the affiant's full knowledge and belief as to the circumstances and conditions under which stockholders and security holders who do not appear upon the books of the company as trustees, hold stock and securities in a capacity other than that of a bona fide owner. Names and addresses of individuals, who are stockholders of a corporation which itself is a stockholder or holder of bonds, mortgages or other securities of the publishing corporation have been included in paragraphs 7 and 8 when the interests of such individuals are equivalent to 1 percent or more of the total amount of the stock or securities of the publishing corporation.

10.

	Average no. copies each issue during preceding 12 months	Single issue nearest to filing date
A. Total no. copies printed (*Net Press Run*)	1,370	1,500
B. Paid circulation. 1. Sales through dealers and carriers, street vendors and counter sales	0	0
2. Mail subscriptions	983	989
C. Total paid circulation	983	989
D. Free distribution (*including samples*) by mail, carrier or other means	24	24
E. Total distribution (*Sum of C and D*)	1,007	1,011
F. Office use, left-over, unaccounted, spoiled after printing	363	489
G. Total (*Sum of E & F—should equal net press run shown in A*)	1,370	1,500

I certify that the statements made by me above are correct and complete:

(Signed) Henry L. Stewart

More Legislation?

By VINCENT A. KLEINFELD

This Article Was Presented Before the Food, Drug and Cosmetic Law Committee of the Federal Bar Association at the Association's Annual Meeting on September 16, 1965. The Author Is a Member of Bernstein, Kleinfeld and Alper, Washington, D. C.

THE DRUG ERA in which we are now living differs so markedly from that which existed a half-century ago as to bear little resemblance to it. In the earlier era, those who were engaged in the practice of medicine (certainly then, even more so than now, an art rather than a science), had few specifics and could reasonably draw upon an armamentarium of fewer than a dozen drugs.

There is no question but that there has been a virtual revolution in the field of medicine since the enactment of the Federal Food, Drug and Cosmetic Act in 1938, with its strange mosaic of definitions, provisions and sanctions. The discovery and development of the sulfa drugs, antibiotics, tranquilizers, steroids and other remarkably efficacious products vastly extended the vistas of science and medicine, but raised new and difficult problems. Few can disagree, therefore, with the concept that the 1938 act, extensive as its coverage was (due to the diligent and dedicated manner in which it had been administered by the Food and Drug Administration (FDA) and construed by it with the eager assistance of the courts), required strengthening amendments. Early amendments to the act, and the subsequent passage of the Food Additives Amendment, Pesticidal Chemicals Amendment and Color Additive Amendments tremendously increased the scope of the law. The enactment of the Drug Amendments of 1962 can be said to have metamorphosed the drug provisions of the statute.

Coverage of Existing Legislation

Of course, before one may reach a reasonable judgment on whether further legislation is needed in the food and drug area it would appear to be of some relevance to ascertain the present coverage of

the Federal Food, Drug and Cosmetic Act and the authority conferred by it not only by Congress but by the courts.

We are all familiar, of course, with Parkinson's Law, which permits of no exceptions. There are two other immutable laws which are applicable to any governmental agency or establishment, whether it be of this country or any other nation. The first, a rather minor one, is that it is physically impossible to construct a building large enough to house any agency for more than a few years, at most. The other, the more important of the two, is that it is just insuperably difficult to convey enough power to a governmental agency to satisfy it, even if the authority specifically conferred by Congress is aggrandized by regulations extending the coverage of the law to areas which Congress never contemplated.

Position of the FDA

Now it is true that the FDA has traditionally been, and presumably will continue to be, in a most uncomfortable and unenviable position. On one hand, it is faced with the more frantic consumer groups, columnists and publicity-avid Congressmen who seek such legislation as would virtually destroy the regulated industries and put an end to further research and development. On the other hand, it must deal with Neanderthal segments of the affected industries who refuse to face the fact of life that the amendments to the Federal Food, Drug and Cosmetic Act passed during the past few years were inevitable and in the long run will probably redound to industry's benefit (at least to large industry's benefit). There are times, when I read of the going-over given to officials of the FDA by the staff of Congressional committees without any real knowledge of or experience in the field, that the agency appears to me to be in a position comparable to Atlas, Prometheus' brother, who, for sinning against the gods, was condemned:

> To bear on his back forever
> The cruel strength of the crushing world
> And the vault of the sky.
> Upon his shoulders the great pillar
> That holds apart the earth and heaven,
> A load not easy to be borne.

This is particularly regrettable to me, for in my more than twenty years of experience with the FDA, I have found it to be by far one of the more competent and zealous agencies of the federal government. It may be, however, that the horrendous position in which the

agency is traditionally placed is due in part to the apparently insatiable appetite for further legislation, even though the preceding amendments may still be causing digestive upsets. Let us look for a moment at the tremendous scope of the Federal Food, Drug and Cosmetic Act as it stands today. The statutory definitions are broad indeed. Interstate commerce includes imports as well as exports and is gradually being extended to cover intrastate transactions. By the Miller Amendment of 1948, the grasp of the statute was extended so as to include grocery stores, restaurants, hotels, barber shops, beauty parlors, drug stores, in fact, every establishment that may be handling a food, drug, device or cosmetic, or any ingredient in these products, that at one time in the distant past may have moved across a state line. Under the Drug Amendments of 1962, every person owning or operating any establishment engaged in the manufacture, preparation, propagation, compounding or processing of a drug must register with the Secretary of Health, Education, and Welfare even if engaged only in intrastate commerce, and every such establishment is subject to factory inspection at least once every two years. (I believe it is safe to predict that, some time in the near future, the government will advise Congress that it really makes no sense to be compelled to make inspections of intrastate establishments and yet not be empowered to do anything when conditions are found which may present a hazard to the consumer.) The new Drug Abuse Control Amendments of 1965 cover both local and interstate traffic in barbiturates, amphetamines and hallucinogenic drugs, and additional controls are created over the traffic in counterfeit drugs, regardless of their interstate or intrastate origin.

The definitions of food, drug, device, cosmetic, food additive and color additive are such as to cover a myriad of products and substances. These terms have been so construed by the government as to bring a tremendous number of commodities and their ingredients within them. By the ingenious "squeeze play" and the extension of the term "labeling" to cover virtually everything except newspaper and magazine advertising and radio and television commercials, the FDA now has wide, although indirect, jurisdiction of the advertising of nonprescription drugs, and by the Drug Amendments of 1962 it was given direct jurisdiction of the advertising of prescription drugs. Section 201(n), requiring the affirmative disclosure of material facts, may clearly be said to cover a multitude of sins, and is a formidable weapon within the easy reach of the government.

Criminal Penalties

The existing sanctions for violations are potent and far-reaching. There are provisions for seizures, multiple seizures, injunctions and criminal prosecutions. All of these remedies may be employed if the government so desires. Intent, motive and good faith are no defense to a prosecution, and corporate officials and employees may be found guilty on the basis of their general responsibility in the furtherance of an illegal shipment. A violator is subject to imprisonment for a year or a $1,000 fine, or both, for each violation, and penalties of three years in jail or a fine of $10,000, or both, are provided for a person who has previously been convicted of a violation or who commits an offense with intent to defraud or mislead.

Authority over Food, Drugs and Cosmetics

The FDA is authorized to define and standardize foods—in reality to create unyielding recipes. A food may be contraband not only because of possible danger, filth or decomposition, but also "if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." It is difficult to envision language that is more vague or more indefinite, particularly in a statute with criminal penalties. Foods (as well as drugs and cosmetics) are misbranded if their labeling is false or misleading in any manner, and imitations must be prominently labeled as such. A food is misbranded, notwithstanding a truthful statement of contents, "if its container is so made, formed, or filled as to be misleading." The government is given vast and plenary powers with respect to pesticidal chemicals, colors, hazardous substances and food additives.

The authority of the FDA as far as drugs are concerned is also very extensive, particularly in view of the passage of the Drug Amendments of 1962. Drugs must not be misbranded in any particular; they may not be prepared under insanitary conditions; and they must comply with the standards of the pharmacopeia unless a difference is plainly stated on the label. The labels must bear the generic names prominently and, if the drugs are prescription products, the quantities of the active ingredients must be set forth. Adequate warnings and directions for use are required, and both the labeling and advertising of prescription items must make full and truthful disclosure of the bad as well as good things concerning the product—of side effects and contraindications as well as of effectiveness. No "new drug" may be marketed in interstate commerce unless both its safety and effective-

ness are first approved by the FDA. Reports of any adverse effects due to the utilization of new drugs must be promptly submitted to the FDA. New drugs which are being investigated are tightly and carefully controlled by the government, and it is difficult to conceive of extensive injuries coming to pass as occurred with thalidomide overseas. Every batch of insulin and of every antibiotic is subject to certification by the FDA as to both safety and efficacy. The Factory Inspection Section of the act conveys to the government tremendous authority to inspect the facilities and records of the manufacturers of prescription drugs, and these records are required to be kept by the manufacturers. Another powerful addition to the government's stock of lethal weapons is the requirement that every drug manufacturer operate in accordance with "good manufacturing practice." Under the recently passed Drug Abuse Control Amendments of 1965, the FDA is given far-reaching additional authority with respect to amphetamines, barbiturates, and any drug which the Secretary, after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

Devices and cosmetics are also carefully regulated. Their safety and effectiveness need not be cleared in advance, but the strong sanctions of the act are applicable if they may create a hazard, and their labeling may not be false or misleading in any particular. Cosmetics may not contain any poisonous or deterious substance, and the exception as to coal-tar hair dyes is carefully circumscribed. The Color Additive Amendments (as expanded in the customary way by regulations) provide strict controls of coloring agents. There has been no real factual showing that stronger regulation of cosmetics and devices, at least not the kind and type of regulation proposed by the Government, is required.

More Governmental Weapons

In endeavoring to ascertain whether further legislation is essential, two other factors must be taken into consideration. One is the inevitable governmental tendency, to which I have adverted, to construe what Congress has said is the law so as to broaden it almost beyond recognition. I do not believe one can be accused of exaggerating when one states that many regulations which have been issued tend to go just a little bit beyond what various amendments appear to say. An interesting facet of this is the honest and somewhat in-

genious puzzlement by the government at industry's opposition to such regulations. Industry is admonished that it had better be a good boy and accept what "Big Brother" says is good for it, for otherwise, as recently explained by a government official, there may be adverse public relations consequences. And industry is piously advised that if, by some mischance, the courts do hold that various regulations which have been issued are unauthorized and illegal, "the whole history of Federal drug legislation suggests that the public interest will be served by additional and probably more severe legislation." In other words, do as we tell you, right or wrong, or worse things will happen to you. And if industry attorneys dare object to proposed legislation, they are condemned (as they were recently by a staff member of a Congressional committee) for being advocates, for not offering "constructive criticism," and for being "oblivious" to the purpose of the hearing involved—to secure constructive information. Obviously, industry and its lawyers should follow the same impartial, unbiased, fact-seeking, unemotional and publicity-shy tactics pursued by most Congressional committees and particularly by their counsel and staffs investigating the food and drug areas.

Certainly, also, the act and its amendments, far-reaching as they are, have by no means been whittled down by the judiciary. Contrariwise, there has been the tremendous desire of the courts, when some brave company undertakes the hazards of litigation, to construe the statute so as to accept almost every administrative position, particularly where the case involves an alleged danger to health, direct or indirect. The opinions are explicit and forthright in announcing this. The Supreme Court has said that:

> The purposes of this legislation thus touch the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of the Government and not merely as a collection of English words.

Experts familiar with the fields of criminal law and administrative law feel that the Federal Food, Drug and Cosmetic Act is *sui generis;* that the decisions obtained in this area of law could not possibly have been rendered in any other area. Added to this important basic weapon is another plus the government has, the understandable reluctance of industry in this field of enterprise to face the publicity of litigation—the disinclination to face the knights in shining armor, the Chevalier Bayards, *sans peur* and *sans reproche,* who are protecting the helpless public against the depredations of ruthless entrepreneurs.

Demands for More Legislation

Then why more legislation? The too-ready and glib answer is because, as I have stated, this industry is different from all other industries—that more amendments are required in order to protect the public health and purse. But is any line to be drawn? Consider the vast increase in consumer protection created by the 1938 act, the Miller Amendment, the Durham-Humphrey Act, the Pesticidal Chemicals Amendment, the Food Additives Amendment, the Color Additive Amendments, the Drug Amendments of 1962, and the Drug Abuse Control Amendments of 1965. Now, the demand is for greater inspection authority, and for the preclearance of devices and cosmetics, in reality both as to safety and effectiveness. There must be a "Truth in Packaging" bill, and much greater control of "old drugs" and over-the-counter drugs. Even before the accouchement of the latest additions to the protection of the public weal, there was mention in the trade press of the "next" FDA bill "to impose record-keeping controls over the disposition of MD and pharmacist Rx samples." It is said "that detail men and dispensing MD's would be held accountable to FDA inspectors for recording what happens to Rx samples of drugs covered by the bill." And in the very recent past, a bill has been introduced providing for the continuous inspection of establishments manufacturing prescription drugs "where deviation from declared or professed potency would constitute a significant medical problem" or where the FDA determines that the continuous inspection is necessary in order to assure that a drug is safe or "has the identity and strength and meets the quality and purity characteristics it is supposed to have."

I do not mean to say, by any means, that changes in the act should never be made. The regulated industries are in a dynamic, not static, area. The misuse and abuse of the amphetamines, barbiturates and hallucinogenic drugs apparently could not be controlled by the then existing legislation. The present complicated, burdensome and overlapping control of new animal drugs by means of the Food Additives Amendment, New Drug Section, and Antibiotics Section does not make sense and does not enure to the benefit of either industry or the consuming public. Consequently, there is a real need for H.R. 7655, which would consolidate into one section the various provisions of the act covering the preclearance of those drugs. In most instances, however, there has been no demonstration that grave problems are present requiring more and more legislation.

The question may be asked, nevertheless, why not more and more amendments. One reason is the factor to which I have already adverted, the seemingly inevitable tendency (it may almost be called a reflex action) of every agency to expand the sphere of its authority, no matter how all-embracing and comprehensive existing authority may be. There are some bitter souls who will say, after looking at what has been done under the Food Additives Amendment, Color Additive Amendments, and the Drug Amendments of 1962, that a "New Device Amendment" would soon be construed to include bathtubs, bidets, and other functional bathroom accessories. These same saturnine individuals will predict that, if a "New Cosmetic Amendment" is enacted, the government will recall that in days of yore the interest of the state lay not so much in preventing the adulteration or misbranding of cosmetics, but rather in attempting to protect the male from attack by the female in the eternal war of the sexes. Some earnest officials will recall that, in those days, it was believed that the state should see to it that guileless men should not be lured into the holy state of matrimony by women who, most unfairly in the opinion of the male, used a cosmetic or strategically placed padding to make them (employing phraseology present in the Federal Food, Drug and Cosmetic Act with respect to the economic adulteration of food) "appear better or of greater value" than they really were.

Seriously, however, in my view the question whether there should be more legislation depends on one's concept of the proper scope of government, even in this vital area of food and drugs. Of course, more legislation can be enacted from year to year which, in fact, will convey greater protection to the consumer. (I may say, parenthetically, that this is true in many other areas.) But is the additional protection so necessary, so essential, so advisable, so imperative, that it should be conveyed notwithstanding that there must necessarily be associated with it great cost to the government, seemingly endless delays and frustrations, further inroads in what some still feel is free enterprise, and, most important, the inevitable removal of the small businessman from the marketplace and higher prices to those we are trying to protect?

Since pharmaceutical houses are endeavoring to make a profit (a rather nasty term), and this may sometimes cause a company to do something it should not do or not do something it should do, perhaps all drugs (as well as foods, devices and cosmetics) should be manufactured and distributed by a governmental agency or agencies. In

order to make everyone happy, we could split this between the Federal Trade Commission and the FDA, and perhaps give some of the functions to the Department of Agriculture, Public Health Service and Department of Commerce. If this, some reactionary soul states, is going just a little too far, we could settle by requiring that all research and testing with respect to the safety, efficacy and desirability of new foods, drugs, devices and cosmetics be performed by the government. Or if this simple thing goes beyond what even the doctrinaire zealot (who can see only the colors black and white) desires, I suppose we could abolish all patents or at the very least require that every drug be marketed only by its generic name, perhaps permitting the proprietary name to be placed, in labeling and advertising, inconspicuously and in type size less than half the size of the generic name.

We could do away with the existing definitions of new drug, food additive, and color additive (to a large extent it is being done away with administratively), and require that every drug, food, food additive, color, device, hazardous substance, and cosmetic, as well as their labeling and advertising, be approved by some governmental agency or agencies in advance of marketing. All further promotional material would similarly have to obtain prior governmental clearance. Since practically every drug, and a multitude of other ingredients and commodities, cause some adverse reactions to some persons, these additional grants of power to the government would doubtless result in fewer side effects and adverse reactions, and less slack-fill and deception (as well as fewer products and less profits), and thus increase the protection of the consumer. If this is the only criterion, we ought to do these things. Yet I doubt (perhaps these doubts are invalid) that even the staff of some of our Congressional committees, our dedicated public servants, or our partially color-blind "liberal" friends, would want the possibilities I have mentioned to come to pass. Somewhere along the line, I feel, there must be a balancing of public policy considerations. It seems to me that a careful analysis of the present act, as it has been amended, of the pertinent judicial decisions, and of the regulations and pronouncements of the FDA, will lead to the conclusion that both the public's health and purse are well protected and that the passage of the most recently proposed amendments is not required and would in fact be a disservice to the consumer.

[The End]

The Future Relationships of FDA and the Pharmaceutical Industry

By W. B. RANKIN

This Article Was Delivered at Purdue University, Lafayette, Indiana, on September 24, 1965. Mr. Rankin is the Assistant Commissioner for Planning, Food and Drug Administration.

IN EARLY 1938, there was comparatively little government regulation of drug manufacture. If a manufacturer wanted to put a new drug on the market, he did so. If he wished to test it for safety, he made whatever tests his scientific advisers considered necessary. If he did not choose to make safety tests, he marketed the product without them. There was no law that required safety testing. The manufacturer was sole judge of the therapeutic benefits he should claim for his product. If a claim was fraudulent, and if the government could prove it, the federal government could deal with the problem. But, a false or misleading therapeutic claim was acceptable under the law in the absence of fraud. In other words, the more ignorant the manufacturer, the more sweeping his claims for drug benefit could be.

History of Federal Legislation

These and other shortcomings of the outmoded pure food and drug law of 1906 had been debated in the Congress for five years. But it took a national disaster to provide the final push required for enactment of reforms. When more than 100 people died because a manufacturer marketed sulfanilamide, the wonder drug of the late 1930's, in a poisonous solvent, correction came fast. A section was added to the legislation then being considered by the Congress to require all new drugs to be tested and proved safe before they could be shipped. In 1938, a new statute known as the Federal Food, Drug and Cosmetic Act became law. Though quite inadequate by present day standards, it was a landmark piece of legislation for its day. It did bring great improvements.

Some of the regulated industry considered the 1938 law a disaster almost as great as the Elixir of Sulfanilamide tragedy that brought its enactment; and most gave it less than an enthusiastic reception.

But the industry met the more stringent requirements of the new law. Research staffs were enlarged to make the safety tests required for new drugs, wild claims for therapeutic worth were curbed and public confidence in the drug supply grew. The improvements manufacturers made in their scientific capabilities because of the 1938 law helped place the industry in a position to make the dramatic gains that have come in the past 24 years. And the mutual distrust that marked government-industry relations just after the 1938 law was passed, gradually gave way to more harmonious relationships and even to mutual respect.

In the 1940's, most firms in the industry adopted greatly improved manufacturing and laboratory controls. The Food and Drug Administration (FDA) and the drug industry both supported new legislation requiring government testing of each batch of insulin and five antibiotics before the products could be marketed. Potential problems in producing these drugs and their extreme importance to the user brought general acceptance of the need for the added safeguards. In addition to testing each batch to be sure it met prescribed standards, FDA determined by periodic inspection that production facilities and methods were acceptable, and issued a certificate of safety and effectiveness for each lot produced.

However, in the 1950's, other problems came to the front, some of them new and some of them resulting from inadequacies recognized but not corrected when the 1938 law was passed. For example, manufacturers were not required to prove before marketing that their products would accomplish the benefits claimed for them as they were required to prove safety; the advertising of prescription drugs was essentially not regulated; there were serious problems of drug nomenclature; no mechanism for securing a prompt record of adverse reactions to drugs was in existence; increasingly drugs were having to be recalled from the market after shipment because of errors in manufacture; and, serious abuses developed in the production and distribution of unapproved new drugs for clinical testing. Some firms were commercially marketing unapproved new drugs as investigational drugs. Indeed, large scale quackery was being practiced under the guise of clinical testing.

These and other developments led to the enactment in 1962 of the Kefauver-Harris Drug Amendments which were designed to correct a number of the problems just listed as well as others. The 1962 Amendments were supported in part by the drug industry, and were opposed in some respects. For example, industry did not support the idea that the effectiveness of drugs for their intended uses should be established before they could be marketed. Since 1962, we have seen in some areas a recurrence, though fortunately on a smaller scale, of distrust and arms-length relationships between government and industry. We are still involved in litigation to determine the scope of the effectiveness provisions of the 1962 Law. As we see it, the issue is whether the industry and the FDA, together, will be able to assure the public that all the drugs that have been approved by FDA are effective as well as safe. In other areas, fortunately, it has been possible to achieve very rapidly a meeting of the minds as to what the law requires from each of us. Within about three years we hope to have the amendments fully operative.

And this brings us now to the risky part of the speech—the forecast. There is little doubt that the trend toward increased government control will continue.

Lack of Public Confidence

This will occur, not because the FDA or industry does or does not want it, but rather because the public generally does not yet have the confidence in the drug supply of the United States that it wishes and that it deserves.

Public confidence is important to all of us. Whether or not it is justified, if the public generally has reservations about the adequacy of the drug supply, the FDA and the industry are in trouble. The public does have such reservations today.

Let us look at a few reasons. Some people think drug prices are too high. Whether this is or is not true, it has an important bearing on all of us. If those who buy drugs think they are being overcharged, they think something is wrong with the manufacturer and the government.

This past summer, the price of quinidine sulfate more than doubled almost overnight. Most consumers did not see the reports in the trade press stating reasons for the short supply of quinidine. If the price increase was justified, the reason was not adequately explained to the people who must have maintenance supplies of the drug. The FDA

has received scores of protests from irate consumers about the price of quinidine sulfate. And even though we do not determine the price at which a drug will be sold, we have been given credit, along with the entire drug industry, for permitting what the consumer regards as an unsavory situation to develop and continue. There are other drugs the public considers overpriced.

Another factor leading to a lack of public confidence is an "educational" program that has been conducted for months by some parts of the industry to convince prescribing physicians and others that the only way that they can get good quality drugs is to buy trade marked or brand name drugs.

If this were true, and I do not believe it is, then the other side of the picture is that there must necessarily be large quantities of questionable drugs on the market. The history of drug controls in our generation shows clearly that the public and the government intend for all the drug supply of the United States to be of top quality. If the 1962 Amendments do not insure this result, then whether you or I want it or not, there will be more, stronger legislation designed to guarantee the quality of the drug supply. Any "educational" program which convinces the public that a large portion of the drug supply must be viewed with suspicion surely will hasten this result.

Further, there have been too many occasions in recent years, when drugs had to be taken off the market because they were found defective after shipment. This necessarily raises questions as to the adequacy of the drug supply. It is our hope that the "current good manufacturing practice" requirements of the 1962 law, when fully applied by industry and government, will essentially eliminate the occasions on which drug recalls are necessary because of errors in the manufacturing plant.

Trend Towards Better Drugs

Last August, the FDA, the Pharmaceutical Manufacturers Association, and the University of Wisconsin School of Pharmacy jointly sponsored a seminar on good manufacturing practices. This was attended by representatives of about 100 drug producing establishments. At the seminar, there was discussion and general acceptance of the concept of "zero defects" in drug manufacturing. Successful application of this idea would mean that every dose of drugs produced by our manufacturers would be of acceptable quality. The concept has been applied quite successfully to the production of equipment and

parts used in our defense and space programs. There is every reason to believe that its determined application by the pharmaceutical industry will bring dramatic improvement in drug quality.

Several manufacturers have contacted our Bureau of Education and Voluntary Compliance since the Wisconsin Seminar closed and have solicited our assistance in their efforts to achieve "zero defects" in their production. We are pleased to offer assistance wherever we can.

We hope also that studies of good manufacturing practice will become a standard part of formal instruction in pharmacy.

The attention which manufacturers are giving to recruiting highly trained and skilled individuals to operate their plants, unquestionably will place increased demands upon the pharmaceutical skills of the nation. Industry and government need people with the training the pharmacy schools can give. All of us can take pride in the steps the schools are taking to meet these needs.

We should see the development in coming years, of better protocols for drug testing—plans carefully worked out to meet the needs for safety and effectiveness data about a new product with the minimum expenditure of time and money. Such protocols should shorten the average time needed to get a worthwhile new discovery to doctors and patients. Scientists in government and industry are cooperating to develop more effective test procedures.

We look forward to the time that responsible scientists outside of government will submit summaries of the test results on new drugs together with their certification that the summaries are complete and accurate. These certified summaries should decrease the time needed for new drug approval by FDA.

There should be some method of making the total information that is developed about a new drug during the premarket testing program freely available to physicians and other responsible scientists when the product is placed upon the market. Presently, the package insert accompanying a new product must contain directions for its safe use; warnings about conditions in which it should not be used; and other information needed by the prescribing physician. But some research physicians tell us that this is not enough to permit them to do the best job of picking up and advancing the studies already performed. They hope some method can be devised to reduce the time lag that now occurs between development of basic research data and its publication in the scientific literature. We share this hope.

There will no doubt be greatly increased use of automatic data processing to handle the increasing mass of medical information that must be utilized by physicians and other scientists. Scientific and medical information is doubling in quantity approximately every 15 years. Our nation will have to improve methods of retrieving facts from this mass of accumulating knowledge. Reports of adverse effects accompanying the use of drugs in medical practice, now being received by FDA should be refined to yield information, also, on the incidence of the reactions.

Perhaps the most important trend is a continuing intensive effort by government and industry to bring about the production of better drugs through voluntary improvements in manufacturing. There will be occasions, of course, when the government will still find it necessary to apply court actions. But the increased emphasis upon voluntary compliance which has full support of responsible people in and out of government should make resort to formal legal actions only occasionally necessary. Working together in a spirit of mutual respect and confidence, we can accomplish far more than through conflict. We welcome the earnest cooperation evidenced by the drug industry and we pledge the FDA to make every proper effort to assist the industry as it carries forward the important task of supplying our nation and many other parts of the world with good, health-giving, and life-saving drugs. **[The End]**

TIME TO COMMENT ON PROPOSED VITAMIN D RESTRICTIONS ON DRUGS EXTENDED

The time in which interested persons may comment on the proposal made by the Food and Drug Administration to place a limit on the amount of vitamin D which may be added to foods and drugs sold over-the-counter has been extended to January 1, 1966. The proposed amendment to Title 21, Chapter I, of the Code of Federal Regulations would provide that vitamin D may be added to foods such as milk, milk products and infant formulas at 400 U.S.P. units per quart. Preparations containing more than 400 U.S.P. units in a suggested daily dosage would be available only by prescription. Any drug containing vitamin D whose labeling bears direction for use in self-medication of vitamin D deficiency in recommended dosages greater than 400 U.S.P. units per day would be misbranded. Also, any drug supplying 400 or less U.S.P. units of vitamin D intended for use in the treatment of vitamin D deficiency by the lay public would be misbranded. FOOD DRUG COSMETIC LAW REPORTS ¶ 60,121.

Latin-American Food Code 1964 Edition

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

Chapter XVII: Food Additives

Acidulants, Alkalizers and Buffers

Article 583.—The only acidulants, alkalizers and buffers permitted to be used in foods are the ones listed hereinafter and such others as the health authorities may approve in the future:

Product	Tolerance	Specific use
Acetic acid	—	—
Adipic acid	—	—
Aluminum ammonium sulfate	—	Baking powders
Aluminum sodium sulfate	—	Baking powders
Aluminum potassium sulfate	—	Baking powders
Ammonium bicarbonate	—	Biscuits
Ammonium phosphate	—	Baking powders and biscuits
Ascorbic acid*	—	—
Ascorbil palmitate	—	—
Calcium carbonate	—	Ice creams
Calcium chloride	0.25%	—
Calcium citrate	2%	—
Calcium gluconate	0.25%	—
Calcium hydroxide	0.01%	Green peas
Calcium phosphate	0.2 to 0.5%	Biscuits and milk products
Citric acid	—	—
Lactic acid	—	—
Fumaric acid	—	Dessert powders
Gluconic acid	—	—

* Ascorbic acid (Vitamin C) may be declared as a vitamin only when added to a product in a proportion of more than 15 mg. per 100 g.

Product	Tolerance	Specific use
Magnesium carbonate	—	—
Magnesium oxide	—	—
Malic acid	2%	—
Orthophosphoric acid	1%	Soft drinks, beer water and gelatines
Potassium acid tartrate	—	Baking powders
Potassium bicarbonate	—	—
Potassium carbonate	—	—
Potassium citrate	—	—
Sodium acid pyrophosphate	—	—
Sodium aluminum phosphate	—	—
Sodium bicarbonate	—	—
Sodium carbonate	—	—
Sodium citrate	—	—
Sodium phosphates	—	—
Sodium potassium tartrate	—	—
Sorbic acid	—	—
Succinic acid	—	—
Sulfuric acid	0.02%	Beer water
Tartaric acid	—	—

Artificial Sweeteners

Article 584.—The following products shall be considered permitted artificial sweeteners, always provided that the statement "contains artificial sweetener" is included in the labeling of the product containing them:

a. Saccharine, sodium saccharine and calcium saccharine in a proportion not exceeding 0.15 gr. per 100 gr. of food or beverage;

b. Sodium, potassium, calcium and magnesium cyclamates and mixtures thereof in a proportion not exceeding 2 gr. (expressed as cyclohexanesulfamic acid) per 100 gr. of food or beverage; and similar safe chemical substances which without being carbohydrates have a sweetening power exceeding that of sucrose, but not its nutritive properties, and have been approved by the health authorities.

c. Sorbitol, any amount of which may be used in foods and beverages, is considered a sweetener when present in an amount exceeding 15 per cent (See Article 592).

Unless specifically authorized herein or by the health authorities, artificial sweeteners may be used only in dietetic products for consumption by persons whose sugar intake may not exceed certain limits. They may be distributed freely, however, in the amounts required to sweeten a cup of coffee or tea at establishments which serve coffee and tea to the public.

Emulsifiers

Article 585.—The term "emulsifier" means not only any product which favors the formation of emulsions, but also any

product which acts as protecting agent for emulsions (See also Thickeners and Stabilizers).

The following products are permitted for the purpose: the mono-glycerides and di-glycerides derived from the glycerolysis of fats and edible oils, their esters with diacetyltartaric acid and derivatives thereof with sodium phosphates; propylene glycol; lecithins, methyl celluloses and any other substances which the health authorities may authorize in the future. The use of lauric acid derivatives is prohibited.

The Glyceryl Monostearate (G.M.S.) to be used in bakery products, confectionery, cookies, cakes, etc. must have a melting point of about 56° C. and may contain glyceryl-alpha-monostearate in an amount of between 30 and 33 per cent, glyceryl distearate in an amount of between 45 and 47 per cent, glyceryl tristearate in an amount of between 20 and 23 per cent, and free glycerol in an amount of between 3 and 5 per cent.

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

Thickeners and Stabilizers

Article 586.—The following thickeners and stabilizers shall be considered as suitable for use in the preparation of foods: thickeners and stabilizers obtained by the hydrolization of skins, tendons and bones of healthy animals, agar-agar or gelose; alginates, isinglass and other fish gelatins, carob gum from seeds of the European carob bean (Ceratonia siliqua L.), gum from the crown of thorns (Gleditsia amorphoides Griseb), guar gum (Cyanopsis tetragonaloba, starch and cellulose derivatives, all of which must meet the requirements fixed in this Code, and any other products which the health authorities may authorize in the future. They must be purified, dried and odorless and their sulfur dioxide (SO_2) content is not permitted to exceed 500 p.p.m.

Bromated vegetable oils may be used to stabilize flavoring bases used in the preparation of emulsions and alcoholic and nonalcoholic beverages, including dietetic ones (See Article 442, paragraph 3).

Article 587.—Edible gelatin obtained by the hydrolyzation of skins, ligaments and bones of healthy animals shall contain not more than 3.25 per cent of total ash and not less than 15 per cent of nitrogen. A 1 per cent solution shall have a pH of between 5 and 7.5. A 1 per cent solution in hot water shall, after cooling, form an odorless, flavorless jelly.

Article 588.—The term "pectin" identifies complex carbohydrates the basic skeleton of which contains poly-D-galacturonic acid, which are found in vegetable tissues, particularly in the mesocarp of certain fruits, such as apples, quinces, certain citrus fruits, etc. and form colloidal watery solutions.

Solid or liquid pectin preparations intended for the preparation of jams, marmalades, desserts, etc. shall be sold under names indicating their origin: citrus pectin ("Citropectin"), apple pectin ("Pomosin"), beet pectin, currant pectin, etc. and shall be free from starch, vegetable gums and foreign matter. Sodium benzoate or sorbic acid may be added to liquid pectins in amounts of up to 1 gr. per liter. Up to 40 per cent of sugar (sucrose, glucose, lactose) may be added to solid, dry or powder pectins.

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

Article 589.—Isinglass, a fish gelatin obtained from the air bladder of several fish, especially sturgeon, shall contain not more than 1 per cent of ash and have a melting point of 50° C. A solution of 1 part of isinglass in 24 parts of hot water shall, after cooling, form a transparent, odorless, tasteless jelly.

Article 590.—The names "agar-agar," "gelose" and "gelosin" apply to a product obtained from various species of gelidium and related seaweeds of the family rhodophyceae. It shall contain not more than 1 per cent of foreign organic substances, 6.5 per cent of total ash and 20 per cent of moisture. A solution of one part of agar-agar in 200 parts of hot water shall, after cooling, form a colorless, odorless, tasteless neutral jelly.

Sodium, ammonium and calcium alginates intended for use in foods are alkaline salts of alginic acid extracted in general from laminal algae (brown algae, especially laminariales and fucales). They shall have the form of a beige, odorless, tasteless powder with a moistening and agglutinating power. They may contain not more than 25 per cent of water and 1 per cent of insoluble matter (cellulose

and lignin) and shall not contain foreign matter. When calcinated, the residue of fixed substances of sodium alginate shall be less than 20 per cent and that of ammonium alginate less than 4 per cent.

Soluble alginates act not only as stabilizers, but also as emulsifiers, protective colloids, humectants, formers of protective films and ionic interchangers.

Article 591.—The methyl celluloses permitted to be used as thickeners, stabilizers and emulsifiers shall contain not more than 6 per cent of moisture and 1 per cent of ash and shall give watery solutions neutral to litmus.

Article 592.—The name "Sorbitol" means an officinal 70 D-sorbitol solution which at 25° C. has a density of between 1,285 and 1.305.

Sorbitol is considered a stabilizer and homogenizer when used in pastry, biscuits, confectionery and similar products in a proportion of up to 5 per cent, and in the manufacture of corks to be used in association with foods in a proportion of up to 1.5 per cent (see Articles 584, (c) and 594).

Article 593.—The names "guar gum" and "guar flour" apply to the gum obtained from the endosperms of the seeds of the leguminous Cyanopsis tetragonaloba. It may contain not more than 15 per cent of moisture, 1 per cent of ash and 2.5 per cent of crude fiber and its carbohydrate content must not be less than 75 per cent.

Humectants and Anticaking Agents

Article 594.—The term "humectant" means any substance intended to prevent food products from losing moisture. Glycerine, honey, propylene glycol, and sorbitol are permitted to be used as humectants, as well as such other substances as the health authorities may allow in the future.

Article 595.—The term "antihumectant" means any substance which reduces the hygroscopic characteristics of foods. Since they prevent the caking of foods caused by moisture they are also called "anticaking agents." The following antihumectants may be used in foods, with the understanding that the health authorities may authorize others which must also meet the requirements fixed in Articles 7, 8, 9 and 10:

Product	Tolerance	Specific Use
Magnesium carbonate	2 per cent	Table salt
Tricalcium phosphate	2 per cent	Table salt
Calcium saccharate	2 per cent	Table salt
Aluminum calcium silicate	2 per cent	Table salt
Calcium silicate	2 per cent	Table salt
Calcium silicate	5 per cent	Baking powder
Magnesium silicate	2 per cent	Table salt

Yeasts and Fermentation Agents

Article 596.—The term "yeast" means a product with a base of microscopic fungi (saccharomycetaceae).

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

Article 597.—The names "compressed yeast," "moist yeast," "paste yeast," "pressed yeast," "grain yeast," "molasses yeast" mean any drained or centrifuged yeast grown on mashes of different origins. It shall be a uniform mass of firm, pasty consistency, with a smell sui generis, formed by cells, the majority of which are living. Its water content shall not exceed 75 per cent; it shall contain not more than 2.5 per cent of ash; its maximum acidity shall be equivalent to 5 milliliters of normal alkali per 100 grams and the leavening power (Haydück-Kusserow) of bread yeast shall be one liter of carbon dioxide gas liberated in two hours by the action of a weighed quantity of yeast that contains 10 grams of dry substance. Yeast must be kept under refrigeration. The addition of starch in amounts of up to 10 per cent is permitted.

Average percentage composition: water 70; proteins 12; fats 0.3; assimilable carbohydrates 16; crude fiber 0.2; ash 1.5; Ca 25 mg.; P. 400 mg.; Fe 2 mg.; B_1 0.5 mg.; B_2 1.5 mg.; Pp 10 mg; ascorbic acid 0.

Article 598.—The name "dry brewer's yeast" (dead, and free from bitter substances) applies to brewer's yeast, from which the bitter substances have been removed and which was dried in drying cylinders by spraying or under vacuum. It is light yellow in color and comes in flake or powder form. The cells appear dead.

Average percentage composition: water 8; proteins 54; fats 1; assimilable carbohydrates 30; crude fiber 0; ash 7; Ca 232 mg.; P 1.590 mg.; Fe 20 mg.; B_1 18 mg.; B_2 7 mg.; Pp 35 mg.; ascorbic acid 0.

Article 599.—The designations "yeast tablets" and "granular yeast" apply to compressed yeast or brewer's yeast, from which the bitter substances have been removed and which was granulated or pressed into tablets, with the addition of tapioca or corn flour, various starches, and sugars. The names and quantities of the substances added shall be stated in the labeling, and their total amount is not permitted to exceed 15 per cent.

Article 600.—The names "starter yeast" or "sour or soured dough" apply to the sour bread dough obtained from a kneaded dough which has been allowed to stand for some time at a temperature of between 20° and 28° C. (symbiosis of Saccharomyces minor with Saccharomyces cerevisiae and lactic bacteria).

Article 601.—The names "yeast powder," "bread powder," "pastry powder," "artificial yeast," "synthetic yeast" and "baking powder" (Backpulver) apply to certain preparations intended for use in specific bakery products which, under the influence of heat, moisture or the inter-action of their ingredients, produce the aeration which lends the dough the necessary fluffiness and sponginess. They generally have a base of sodium bicarbonate mixed with different acid components, potassium bitartrate, tartaric acid, fumaric acid, monocalcium phosphate, sodium pyrophosphate, calcium lactate, sodium and aluminum sulfate, and may contain 0.1 per cent of egg albumen, starch and flour, calcium sulfate, calcium carbonate or calcium silicate.

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

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

Article 602.—The following ferments or enzymes may be used, provided that the health authorities have first granted their permission:

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

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

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

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

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

Coloring Matters

Article 603.—Mineral colors containing antimony, arsenic, barium, cadmium, chromium, copper, tin, mercury, lead, uranium, zinc and hydrocyanic acid compounds are prohibited from being used to dye foods and beverages or any papers, boxes and wrappers used in association with the same, as is also prohibited the use for such purposes of coal-tar or aniline dyes and vegetable colors containing toxic products, harsh resin gums and alkaloids: "ancoche," barberry or unripe grapes, aconite or wolfsbane, "calafate," "gomaguta" or "cambodge," "quebradillo,"* dragon's blood, Canadian bloodroot, etc.

Article 604.—Colors which may be used in foods, beverages and other consumer products, in accordance with the specifications given herein for each case, are the colors of vegetable or animal origin specifically named in Article 605 hereof. These colors may be natural or synthetic and may come in the form of a powder, solution, paste, extract or as lakes of aluminum, calcium

* Note of the Translator: The names given in quotes are designations of Latin-American products and not translatable.

or magnesium of the raw material or pigment, or as an artificial derivative of the same (aminate, sulfonate, etc.), provided that the health authorities have recognized them as safe, that they do not have the general reactions of prohibited colors, and that the analytical characteristics of the vegetable substances from which they come have not been lost or changed due to the chemical treatment they have undergone.

Article 605.—The coloring matters obtained from juices or pulps of edible vegetables and fruits, the dyes named in the table hereinafter and such other colors as the health authorities may approve in the future are considered safe. Synthetic indigotine and alizarine and sulfonated derivatives thereof shall be assimilated to vegetable dyes, provided that they meet the purity standards fixed in Article 17 hereof.

COLORING MATTERS OF NATURAL ORIGIN

No.	Name	Origin of Color	Color Index (1924)	Schultz (1931)
	Red			
1.	Alizarine or Ruby Red	Extracted from Rubia tinctorum L.	1027	1141
2.	Anchusa or Orcanette	Extracted from the root of Alcanna tinctoria L.	1240	1382
3.	Catechu	Extracted from the wood of different acacias: Acacia catechù Willd.; Acacia Suma Kurz	1249	1385
4.	Campêche	Extracted from the wood of Haematoxylon campechianum L. (Haematoxylin, Haematein)	1046	1376
5.	Cochineal (carminic acid)	Extracted from dried insects: Coccus Cacti L.	1239	1381
6.	Orchil	Extracted from lichens of the genus Rocella Ochrolechia	1242	1386
7.	Brazilwood or Brazilin	Extracted from the wood of Caesalpinia brasiliensis L.	1243	1375
8.	Madder	Extracted from the roots of Rubia tinctorum L. and Rubia cordifolia L.	1240	1141
	Yellow			
9.	Annatto or Rocou	Extracted from the seeds of Bixa Orellana L.	1241	1387
10.	Saffron	Extracted from the styles and stigmas of Crocus sativus L.	—	1388
11.	Beta-carotene	Concentrate obtained from leaves, vegetables, palm oil, etc.	1249A	1403
12.	Curcuma	Extracted from the rhizome of Curcuma longa L.	1233	1374
13.	Yellow berries, or Persian berries	Extracted from the berries of Rhamnus catharticus e infectorius L.	1234	1369

No.	Name	Origin of Color	Color Index (1924)	Schultz (1931)
	Blue			
14.	Indigotine, or Indigo Carmine	Extracted from indigo and other plants of the genus Indigofera	1180	1309
	Green			
15.	Chlorophyll	Extracted from the leaves and green parts of plants, as well as their copper compounds containing not more than 0.15% of ionisable copper (free copper)	1249A	1403
	Brown			
16.	Caramel (See Article 340)	Obtained by heating sugars of vegetable origin above their melting point, but without charring	—	—
	Black			
17.	Vegetable carbon	Prepared from very pure charcoal	1308	1463
	Various Shades			
18.	Anthocyanins	Extracted from vegetables	—	1394
19.	Myrtillin	Extracted from various fruits	—	1400

Article 606.—As an exception to Article 604, dessert powders, gelatines, jams, alcoholic beverages, soft drinks and syrups, cheese rinds, dragees, lozenges and tablets and household articles are permitted to be colored with the coal-tar (aniline) colors listed hereinafter and such other coal-tar colors as the health authorities may authorize in the future. The preserved pulps of fruits may also be dyed with authorized synthetic colors when such treatment is required to restore their natural color.

The synthetic colors mentioned herein and such synthetic colors as may be authorized in the future shall be clearly defined and their identity shall be established by chomatographic and spectrophotometric comparison with a standard sample. Their labeling shall state clearly their purity degree, uses, amounts and whatever other data is required under the law. They shall contain not less than 60 per cent of the genuine dye and may be mixed only with declared nontoxic fillers, such as sugar or starch. They may not contain more than 5 per cent of sodium chloride and/or sodium sulphate. They may not contain cadmium and mercury salts or derivatives, or elements considered carcinogenic, such as chrome, in the form of chromates, selenium, uranium, polycyclic hydrocarbons or unsulfonated aromatic amines (Betanaphthylamine, benzidine, xenylamine). Water-soluble colors shall contain not more than 10 per cent of volatile substances

(at 135° C.); 0.5 per cent of ether-soluble substances and 0.2 per cent of substances insoluble in water.

PERMITTED SYNTHETIC ORGANIC COLORS

No.	Name	Food Standards (1957)	Color Index (1956)	Schultz (1931)	Hecht (1955)
	Red				
1.	Amaranth, Bordeaux Red or Bordeaux S.	A 4	16,185	212	40
2.	Azorubin or Carmoisine	A 3	14,720	208	38
3.	Erythrosin J.	B 6	45,430	887	93
4.	New Coccine, Cochineal Red or Ponceau 4R	A 2	16,255	213	41
	Orange				
5.	Orange yellow S. or Sunset Yellow F.C.F.	A 39	15,985	215	29
	Yellow				
6.	Quinoline yellow	B 94	47,005	918	97
7.	Tartrazine	A 34	19,140	737	64
	Blue				
8.	Indanthrene Blue or Solanthrene Blue R.S.	B 95	69,800	1228	104
	Black				
9.	Brilliant Black B.N.	B 97	28,440	—	58

Article 607.—Any coloring matters not named in Articles 605 or 606 hereof may be used only after they have been approved by the health authorities. For this purpose, interested persons shall file a memorandum which proves their harmlessness, accompanied by conclusive scientific references and physiological test reports. If the health authorities consider additional tests as necessary, such tests shall be conducted at the expense of the interested persons (See Articles 7 to 10).

Article 608.—Manufacturers of foods and beverages and manufacturers who prepare or pack colors, essences and/or aromatics permitted to be used in foods and beverages, shall not be allowed to keep on the premises intended for the preparation of same any products whose use is prohibited; if they do keep such products they will be penalized with confiscation and whatever other penalties are applicable.

Article 609.—The name "artificial food color" designates a dye with a base of tartrazine to which new coccine has been added in a proportion of 10 per cent or more. No mention may be made of the word "saffron" in its name, labeling or advertising.

Improving Agents

Article 610.—The admixture of improving agents to mediocre products, or to products made from inferior raw materials, in order to improve their quality artificially is considered an adulteration. Any product sold to improve a food or beverage, no matter what its designation, shall for this reason be considered as intended to adulterate foods and beverages. Exceptions are provided for chemical and biological fermentation correctives, vitamins, amino-acids and mineral salts in enriched foods and the additives permitted by this Code.

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

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

Article 611.—Meat tenderizers or softeners with a base of protolytic enzymes, as provided for by Article 602, paragraph c, may be sold with the declaration "for home use exclusively." They are not permitted to be used at hotels, restaurants, eating places and similar establishments, nor may they be used in the meat industry, except for sausages and canned meat.

Article 612.—The manufacture, display, advertising, sale and/or possession of products intended to improve or enrich foods and beverages are prohibited, regardless of whether or not such products are meant to deceive the purchaser or consumer about the essential qualities, origin and grade of the product; or to lend a product the characteristics of a standard product in violation of this Code; or to give a synthetic product the appearance of a natural product or a quality it does not possess, thus falsifying the results of its analysis; or to neutralize or inhibit the incipience of spoilage. Such products shall be confiscated on the spot, without prejudice to the imposition of the respective penalties.

Flavoring Agents and Aromatics

Article 613.—The term "condiment" means any substance which, regardless of whether or not it has a nutritive value, is intended to become a component of or improve foods or beverages by giving them a flavor and/or aroma. In general, condiments (spices, salt, sauces, etc.) must be free from moulds, yeasts, parasite eggs, insect parts. They may not contain more than 500,000 nonpathogenic bacteria per gram and must be free from pathogenic bacteria of the coliform group or the groups staphylococcus, streptococcus, shigella and salmonella.

Vegetable Condiments

Article 614.—The generic names "spices" and "vegetable condiments" apply to certain plants, or parts of plants, which contain aromatic, sapid or stimulating substances and for this reason are used to season, dress or improve the aroma and flavor of foods and beverages.

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

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

Article 615.—Spice mills are the plants at which vegetable condiments are cleaned, selected, ground and packed. Such plants must meet the following requisites, in addition to the general rules:

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

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

Article 616.—The names "summer savory" and "savory" apply to the leaves and flowering tops of Satureia hortensis L. Savory shall contain not more than 10 per cent of total ash, not more than 0.5 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 0.7 per cent of volatile oil.

Article 617.—The name "ground, pressed, triturated or minced chili" applies to the coarse powder obtained by the trituration of different kinds of clean whole red pepper fruits which were crushed without removing their inside part or seeds.

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

Article 618.—The name "garlic powder" applies to the pulverized dried bulbs of Allium sativum L.

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

Article 619.—The name "basil" applies to the fresh or dried clean whole leaves of Ocimum basilicum L. (large variety) and Ocimum minimum L. (small variety); Average percentage composition (dried): water 8; proteins 20; fats 5; carbohydrates 45; crude fiber 16; ash 6.

Basil salt is prepared like garlic salt (see Article 623).

Article 620.—The name "capers" applies to the dried closed flower buds of Capparis spinosa L., pickled in vinegar and salt, or in salt alone. Capers shall contain not more than 30 per cent of nitrogenated substances and not more than 5 per cent of fatty substances (calculated on a moisture-free basis).

Article 621.—The names "anise," "common anise" and "green anise" apply to the dried clean whole fruit of Pimpinella anisum L.

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

Article 622.—The names "star anise" and "badiana" apply to the dried clean whole fruit of Illicium verum Hook, f. Star anise shall contain not less than 3.5 per cent of essential oil, not

more than 5 per cent of total ash and not more than 1 per cent of ash insoluble in 10 per cent hydrochloric acid.

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

Article 623.—The name "celery seed" applies to the dried clean whole fruit of Apium graveolens L. It shall contain not more than 10 per cent of total ash and not more than 2 per cent of ash insoluble in 10 per cent hydrochloric acid.

For celery seed extract, see Article 659, paragraph 4.

The name "celery salt" applies to a table salt (see Article 671), to which between 0.1 per cent and 1 per cent of essential celery oil and 2.5 per cent of sodium glutamate have been added, and also to a salt mixture containing at least 15 per cent of ground dried celery seeds. The addition of turmeric or another permitted color shall be declared on the label. Average percentage composition: water 5; proteins 5; fats 6; carbohydrates 6; crude fiber 3; ash 75.

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

Article 624.—The product named "saffron" or "crude saffron" shall consist of the dried filiform orange-red stigmas of the flower of Crocus sativus L., with or without the yellow styles.

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

"Coupe:" no white part

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

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

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

Crude saffron shall meet the following requirements:

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

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

3. It shall contain not more than 14 per cent of water and volatile matter when dried at 100-150° C.; its total ash maximum shall be 6

* Note of the Translator: A spurious kind of anise with poisonous properties produced in Japan.

per cent, and the ash insoluble in 10 per cent hydrochloric acid shall not exceed 1 per cent.

4. The aqueous infusion shall have an alkaline reaction.

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

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

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

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

Article 625.—The names "sweet flag" and "calamus" apply to the dried clean whole rhizome of Acorus calamis L. Sweet flag shall contain not more than 6 per cent of total ash and not more than 1 per cent of ash insoluble in 10 per cent hydrochloric acid.

Article 626.—The names "cinnamon" and "Ceylon cinnamon" apply to the dried bark of Cinnamomum zeylanicum (Breyne, Nees), from most of which the outer layers have been removed. Any cinnamon that does not meet the macroscopic and microscopic characteristics of Ceylon cinnamon shall be named common cinnamon (Chinese, Saigon, Malabar cinnamon, etc.).

Ceylon cinnamon and all other kinds of cinnamon (Chinese, Saigon, Malabar, Java, etc.) shall meet the following requirements: They shall contain not more than 14 per cent of moisture, 6 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid, and 22 per cent of starch, and not less than 0.8 per cent of volatile ether extract and 8.5 per cent of alcohol extract for Ceylon cinnamon, and 4.5 per cent for the other types of common cinnamon.

Article 627.—The name "cardamon" applies to the dried clean whole seeds of Elettaria cardamomum White and Maton and similar species.

Cardamon shall contain not more than 10 per cent of total ash, 3 per cent of ash insoluble in 10 per cent hydrochloric acid and 12 per cent of moisture, and not less than 2 per cent of essential oil.

Article 628.—The names "Indian curry" and "curry powder" apply to a mixture of several sharp-tasting spices, such as various kinds of peppers, ginger and turmeric, to which other condiments may have been added.

Although the proportion in which the different components were used in the mixture need not be declared in the labeling, their names must be stated in the order in which they are present. Curry may contain starchy matter, moisture and salt in amounts of up to 10, 10 and 5 per cent, respectively.

Article 629.—The names "caraway," "alcaravea," and "German cumin" apply to the clean whole fruit of Carum carvi L. Caraway shall contain not more than 14 per cent of moisture, 8 per cent of total ash and 2 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 3 per cent of essential oil.

Article 630.—The names "lemon-scented verbena" and "herb louisa" apply to the fresh or dried clean whole leaves of Lippia citriodora Kanth.

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

Article 631.—The name "cloves" applies to the dried ripe flower buds of Caryophyllus aromaticus L.

Cloves must meet the following requirements:

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

2. They shall contain not more than 15 per cent of moisture, 8 per cent of total ash, 1 per cent of ash insoluble in 10 per cent hydrochloric acid, and not more than 10 per cent of crude fiber;

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

Article 632.—The names "cumin," "common cumin" or "Spanish cumin" apply to the dried clean whole fruit of Cuminum cyminum L. Cumin shall meet the following requirements: It shall contain not more than 12 per cent of total ash, not

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

Article 633.—The name "coriander" applies to the dried clean whole fruit of Coriandrum sativum L. Coriander shall contain not more than 7 per cent of total ash, not more than 1.5 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 0.6 per cent of essential oil.

Article 634.—The name "turmeric" applies to the dried clean whole rhizome of Curcuma longa L. Turmeric shall meet the following requirements:

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

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

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

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

Article 635.—The name "juniper" applies to the dried clean whole fleshy berries of Juniperus communis L.

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

Article 636.—The names "dill," "dill seed," "dill fruit" apply to the dried clean whole fruit of Anethum graveolens L. Dill shall contain not more than 10 per cent of total ash, 3 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 2.5 per cent of essential oil.

Article 637.—The names "estragola," "esdragon," and "tarragon" apply to the dried clean whole leaves and flowering tops of Artemisia dracunculus L.

The name "tarragon extract" applies to the extracts prepared by the maceration or digestion of tarragon with vinegar.

Article 638.—The name "fennel" designates the dried clean whole ripe fruits of different varieties of Foeniculum L. Fennel shall contain not more than 12 per cent of water, 9 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 3 per cent of essential oil.

Article 639.—The name "ginger" applies to the washed dried rhizome of Zingiber officinale Rosc., decorticated (white or peeled ginger) or not (grey ginger). Ginger shall contain not more than 14 per cent of water, 1.5 per cent of total ash, 2 per cent of ash insoluble in 10 per cent hydrochloric acid, 9 per cent of crude cellulose, 1 per cent of calcium calculated as oxide, and not less than 1 per cent of essential oil, 42 per cent of starch and 12 per cent of cold-water extract.

The names "bleached ginger" and "limed ginger" apply to whole ginger, coated with calcium compounds for purposes of preservation (slaked calcium, calcium carbonate and calcium sulfate). In such ginger, total ash and calcium calculated as calcium carbonate are tolerated in amounts not exceeding 11 per cent and 4 per cent, respectively.

Article 640.—The name "bay" applies to the dried clean whole leaves of Laurus nobilis L., which shall contain not more than 6 per cent of total ash, not more than 1 per cent of ash insoluble in 10 per cent hydrochloric acid and not less than 2 per cent of essential oil.

Bay salt is prepared like garlic salt (see Article 623).

Article 641.—The name "mace" applies to the dried arillus or hull that covers the nutmeg (Myristica fragrans Houtt.).

Mace shall meet the following requirements: It shall contain not more than 17 per cent of moisture, 3 per cent of total ash, 0.5 per cent of ash insoluble in 10 per cent hydrochloric acid, and 10 per cent of crude fiber, and not less than 4 per cent of essential oil. The ether extract shall fall between 20 and 30 per cent and the alcohol extract between 19 and 25 per cent.

Article 642.—The names "marjoram," "oregano" and "leaf marjoram" apply to the dried clean whole leaves and flowering tops of Origanum majorana L. and its different varieties.

Marjoram shall contain not more than 16 per cent of total ash, not more than 4.5 per cent of ash insoluble in 10 per cent hydrochloric

acid, and not less than 0.5 per cent of essential oil. Stalks and harmless foreign substances are tolerated in amounts not exceeding 19 per cent.

Marjoram salt is prepared like garlic salt (see Article 623).

Article 643.—The names "balm," "sweet balm" or "lemon balm" apply to the fresh or dried leaves of Melissa officinalis L.

Article 644.—The generic name "mint" ("hortela pimenta") distinguishes the leaves and flowering tops of several cultivated or wild plants of the family labiatae. Mint shall contain not more than 12 per cent of water.

The designations "mint," "common mint," "garden mint," "spearmint," and "yerba buena" or "hierba buena" apply to the dried clean whole leaves and flowering tops of Mentha viridis L. and Mentha rotundifolia L.

The names "menta peperina" or "menta peperita" apply to the leaves and flowering tops of Minthostachys verticillata Griseb.

The names "peppermint" ("menta piperita"), or "English mint" ("menta inglesa") apply to the leaves and flowering tops of Mentha Piperita L.

Article 645.—The term "mustard" applies to the product obtained by grinding the seeds of black mustard (Brassica Nigra L. Koch.), brown mustard (Brassica Juncea Hook.), white mustard (Sinapis alba L.) or mixtures thereof.

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

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

Mustards in liquid or paste form, also named "table mustard," "prepared mustard," "French mustard," "Tarragon mustard," "German mustard," "Düsseldorf mustard," "Frankfurt mustard," etc., may con-

sist of mustard flour, wine must, wine, vinegar, salt, sugar, citric, lactic or tartaric acid, oils and other condiments. The addition of turmeric is permitted with a declaration to that effect.

Such mustards shall contain not more than 24 per cent of carbohydrates calculated as starch, not more than 12 per cent of crude fiber, not less than 5.6 per cent of nitrogen and not less than 0.10 per cent of natural mustard essence, all calculated from the dry product.

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

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

Containers used for mustard or condiments containing vinegar shall comply with the provisions fixed in Article 700.

Article 646.—The name "nutmeg" applies to the dried seed of Myristica fragrans Houtt., from which the testa have been removed. Nutmeg may be given a coating of lime to protect it from insects, provided that the weight of such coating does not exceed 1 per cent. It shall also meet the following specifications: It shall contain not more than 5 per cent of total ash, not more than 0.5 per cent of ash insoluble in 10 per cent hydrochloric acid, not more than 10 per cent of crude fiber and not less than 25 per cent of nonvolatile ether extract, 2 per cent of volatile ether extract and 10 per cent of alcohol extract.

Oregano: see Article 642.

Article 647.—The name "parsley" applies to the fresh or dried clean whole leaves of Petroselinum sativus Hoff. Average percentage composition (fresh): Water 83; proteins 4; fats 1; carbohydrates 7.5; crude fiber 2; ash 2.5.

* Note of the Translator: The Italian word for "mustard," used to designate an Italian type of mustard.

Article 648.—The generic names "red pepper" and "paprika" apply to products obtained by grinding selected dried fruits of different red varieties of the genus Capsicum.

Red pepper shall be sold in its original container which indicates its provenance (Argentina, Spain, Hungary, etc.) and retailers are forbidden to break up containers for retail sales.

In general, red pepper may contain not more than 14 per cent of moisture, 9.3 per cent of total ash, 1 per cent of ash insoluble in 10 per cent hydrochloric acid and 20 per cent of nonvolatile ether extract.

Red peppers sold as "fancy" shall contain not more than 23 per cent of crude fiber and 8 per cent of total ash; red peppers sold as "choice" shall contain not more than 26 per cent of crude fiber and 8.5 per cent of total ash, while ordinary red peppers may contain crude fiber in an amount of up to 31 per cent.

Article 649.—The name "white pepper" applies to the dried whole or ground decorticated ripe berries of Piper Nigrum L.

White pepper, in corns or powder form, shall meet the following specifications: It shall contain not more than 3.5 per cent of total ash, 0.3 per cent of ash insoluble in 10 per cent hydrochloric acid and 9 per cent of crude fiber; not less than 40 per cent of starch, 7 per cent of alcohol extract and 6 per cent of nonvolatile ether extract.

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

Black pepper, in corn or powder form, shall meet the following requirements: It shall contain not more than 7 per cent of total ash, 1.5 per cent of ash insoluble in 10 per cent hydrochloric acid and 14 per cent of crude fiber, and not less than 32 per cent of starch, 5.5 per cent of nonvolatile ether extract and 6 per cent of alcohol extract.

The name "allspice" applies to the whole or ground fruit of Pimenta officinalis Berg.

The sale of allspice under the name "clove pepper" is prohibited.

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

The names "Malagueta pepper," "Guinea grains," and "Paradise grains" apply to the dried clean whole seeds of Amomun Meleguetta Roscoe.

"Cayenne pepper" or "Cayenne" is the,whole, or ground, dried ripe fruit of Capsicum frutescens L., Capsicum baccatum L. and other Capsicum varieties with small berries. It shall contain not more than 1.5 per cent of Cayenne starch; 20 per cent of crude fiber; 8 per cent of total ash of which 1.25 per cent may be insoluble in 10 per cent hydrochloric acid, and not less than 15 per cent of nonvolatile ether extract.

Article 650.—The name "pennyroyal" applies to the fresh or dried leaves and twigs of Lippia turbinata Griseb. The fresh or dried leaves and twigs of Lippia integrifolia Griseb are known by the same name, or by the name "Inca tea" ("Té del Inca").

Article 651.—The names "wild radish," "horseradish," "scurvy grass," "Cochlearia of Brittany" apply to the grated or triturated clean whole root of Cochlearia armoracia L., to which vinegar may have been added. Average percentage composition (fresh): water 74; proteins 3; fats 0.2; carbohydrates 19; crude fiber 2.3; ash 1.3.

Article 652.—The name "rosemary" applies to the whole clean leaves of Rosmarinus officinalis L.

Article 653.—The name "sage" applies to the clean whole leaves of Salvia officinalis L. Sage may contain not more than 12 per cent of stalks (not including the petioles). It shall meet the following requirements: It shall contain not more than 10 per cent of total ash, 1 per cent of ash insoluble in 10 per cent hydrochloric acid and 25 per cent of crude fiber, and not less than 1 per cent of ether extract.

Article 654.—The name "thyme" applies to the dried clean whole leaves and flowering tops of Thymus vulgaris L. Thyme shall comply with the following requirements: It shall contain not more than 12 per cent of total ash and 4 per cent of ash insoluble in 10 per cent hydrochloric acid, and not less than 1.5 per cent of essential oil.

Article 655.—The name "vanilla" applies to the unripe fruit of Vanilla Planifolia Andrews and of closely related varieties of the orchid family, which has been subjected to a special drying

process that promotes the fermentation of the heterosides (glucosides) responsible for the characteristic aroma and the formation of vanillin.

Vanilla shall be sold with the indication of its origin: Mexico, Bourbon (Réunion), Tahiti, Java, Brazil, etc. The indications of quality "high grade" and "fancy grade" are considered synonyms. The commercial classifications under which they are sold shall meet the following specifications:

Commercial Classification	Appearance	Average Bean Length (cm.)	Weight per Bean (grams)
Fancy Grade	Brown, greasy, perfectly smooth	20	6.2 to 6.65
First Grade	—idem—	19	3.5 to 4.2
Second Grade	Brown, greasy, some ligneous elements	17	4.4 to 4.7
Third Grade	More pronounced lignification and desiccation	17	3.3 to 3.6
Fourth Grade	More pronounced lignification and desiccation	19	2.9 to 3.8
Common ordinary Grade	Somewhat dry, clearly ligneous and whole	10	1.3 to 1.6

Vanilla shall meet the following requirements:

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

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

The name "vanillon" applies to the fruit of Vanilla pompona Schiede.

The name "vanilla extract" applies to a vanilla tincture, at least 10 per cent of which shall be 35° to 55° alcohol. It shall contain not less than 0.10 per cent of natural vanillin, shall have an acidity of not less than 28 milliliters of normal alkali per 100 grams and contain not less than 0.5 per cent of ash. It shall not contain artificial vanillin, coumarin or acetanilide and shall give a precipitate with a solution of lead acetate. The synthetic product prepared with vanillin and/or ethyl vanillin or propenyl guaethol, which may be colored with caramel, shall be designated "artificial vanilla extract."

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

The designation "sugared vanilla powder" applies to a mixture consisting of 75 per cent of sugar and 25 per cent of vanilla.

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

Article 656.—The name "vanillin sugar" ("azucar con vainillina") applies to a mixture of sugars and not less than 0.7 per cent of (natural or synthetic) vanillin or 0.2 per cent of ethyl vanillin or propenyl guaethol. The product may not contain coumarin.

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

Flavoring Extracts

Article 657.—The names "essential oil," "essence" and "natural essence" apply to solid or liquid products of natural origin, free from foreign substances and solvents, which contain the odorous principles of plants, or plant parts, and whose characteristics comply with the requirements of the Pharmacopoeia. Similar products prepared synthetically with a base of hydrocarbons, alcohols, acids, aldehydes, ketones and esters used in different combinations shall be distinguished by the name "artificial . . . essence."

A "soluble essential oil" or "soluble essence" is any alcoholic solution which contains not less than 25 per cent of the natural essence. Any product not containing this proportion of essence shall be named "extract."

The designations "flavoring extract" and "food and beverage flavor" apply to any solution of essences in water, ethyl alcohol, glycerin, propylene glycol, which may be combined. Extracts shall be designated according to whether they contain natural or artificial essences.

Natural essences and extracts in the composition of which an artificial essence was used shall be considered artificial. Exempted herefrom are natural flavors and essences which contain traces of synthetic products added in order to reinforce or fix their odor and flavor. In such cases, the products shall be designated: "reinforced natural flavor," or "reinforced essential oil."

The designation "Extract for the home preparation of . . . liquor" or ". . . drink" (the blank to be filled in with the name of the product) shall be used for solutions of permitted essences and/or permitted

components, to which an authorized color may have been added, which are sold for the home preparation of liquors and/or soft drinks. These products may be marketed only in containers of a capacity not exceeding the quantity required for the prepartion of one liter of beverage and the label shall bear a large legend "For home use." This type of extract is prohibited from being sold for use in the preparation of liquors and/or soft drinks which may result in a violation of this Code; of beverages with a registered trademark, or of distillery products such as: cognac, gin, grappa,* rum, whiskey, etc.

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

Article 658.—Flavoring extracts shall be unsuitable for consumption if they contain toxic essences or principles with an active medicinal action, such as: ethyl chloride and bromide, free amyl alcohol, salicylic aldehyde, compounds of the pyridine group, hydrocyanic acid, nitrous ethers, nitrobenzol, coumarin, Tonka bean and any others which the health authorities may determine.

Article 659.—The following generic names shall apply to the products listed hereinafter:

1. Bitter almond flavor or extract is, from the bromatological point of view, an alcoholic solution containing bitter almond oil, free from prussic acid, in a proportion of not less than 1 per cent by volume.

2. Anise flavor or extract is an alcoholic solution containing essential anise oil in a proportion of not less than 3 per cent by volume. It shall contain not less than 2.4 per cent of anethole.

3. Badiana or star anise flavor or extract is an alcoholic solution containing star anise oil in a proportion of not less than 3 per cent by volume. It shall contain not less than 2.4 per cent of anethole.

4. Celery flavor or extract is an alcoholic solution containing essential oil obtained from celery seeds in a proportion of not less than 0.3 per cent by volume.

5. Cinnamon flavor or extract is an alcoholic solution containing cinnamon oil in a proportion of not less than 2 per cent by volume. It shall contain cinnamic aldehyde in an amount of not less than 1.3 per cent.

Coffee flavor or extract: See Article 556.

6. Clove flavor or extract is an alcoholic solution containing essential clove oil in a proportion of not less than 2 per cent by volume. It shall contain eugenol in an amount of not less than 1.6 per cent.

* Note of the Translator: Originally an Italian drink prepared from grape waste.

Tarragon flavor or extract: See Article 637.

7. Ginger flavor or extract is an alcoholic ginger extract prepared with not less than 20 per cent of rhizomes.

8. Ginger ale flavor or extract is a preparation obtained from ginger extract and lemon essence, the addition of other flavoring ingredients and fruit juices being optional.

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

10. Lemon flavor or extract may be prepared from essential lemon oil or lemon peel, or both. It shall contain not less than 5 per cent of essential oil and 0.2 per cent of citral. Soluble lemon extract is the aqueous or alcoholic solution of lemon oil from which all or part of the terpenes have been removed. It shall contain not less than 0.3 per cent of citral derived from the oil.

Maté flavor or extract: See Article 583, paragraphs 4 and 5.

11. Peppermint flavor or extract is an alcoholic solution containing peppermint oil in a proportion of not less than 3 per cent by volume. It shall contain not less than 1.5 per cent of menthol.

12. Orange flavor or extract may be prepared from oil of Portugal, the peel of sweet oranges, or both. It shall contain essential oil in a proportion of not less than 5 per cent by volume and not less than 4.5 per cent of limonene. Soluble orange extract is a solution in water or alcohol of the essential oil deprived of all or part of its terpenes. It shall contain not less than 0.45 per cent of d-limonene.

13. Nutmeg flavor or extract is an alcoholic solution containing nutmeg oil in a proportion of not less than 2 per cent.

14. Oregano or marjoram flavor or extract is an alcoholic solution containing marjoram oil in a proportion of not less than 2 per cent.

15. "Peperina" flavor or extract is an alcoholic solution containing "peperina" oil in a proportion of not less than 3 per cent by volume. It shall contain menthane in a proportion of not less than 1.5 per cent.

16. Licorice flavor or extract is the product obtained by extracting the soluble substances contained in the licorice root.

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

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

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

The names "glycyrrhizin" and "commercial glycine" apply to products consisting of mixtures of ammoniated glycyrrhizin and other substances obtained from licorice extract.

Tea flavor or extract: See Article 576.

17. Thyme flavor or extract is an alcoholic solution containing thyme oil in a proportion of not less than 0.2 per cent by volume.

Vanilla flavor or extract: See Article 655.

18. Sarsaparilla flavor or extract is a solution containing a mixture of essential oils of gaultheria, sassafras, anise and cassis in a proportion of 3 per cent by volume.

Article 660.—The designation "smoke oil" applies to a product derived from the carbonization of nonresinous woods.

Smoke oil shall meet the following requirements:

a. It shall be free from toxic substances and practically free from methanol, acetone, formol, creosote, acetaldehyde and 3,4-benzpyrene;

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

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

d. It shall not contain prohibited preservatives.

Edible Mushrooms

Article 661.—The term "mushroom" means the product formed by the fresh or dried cell tissue of acotyledonous plants (basidiomycetes, hymenomycetes and gastromycetes).

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

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

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

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

Article 662.—Cultivated mushrooms, also called "champignons," have in general the same characteristics as Agaricus (Psalliota) campestris, Fr. ex L. Preference shall be given to water culture (aqueous medium) which is the cleanest.

Canned mushrooms marked "natural mushrooms" must have been prepared from whole clean fresh mushrooms in a good state of preservation and water or mushroom broth; the addition of salt, spices, flavors, citric acid, vinegar and ascorbic acid is optional. As many mushrooms must be packed in the containers as they can normally hold.

Article 663.—None of the genera of poisonous mushrooms listed hereinafter may be used as food, even if they have undergone special treatments to remove their toxic principles:

1. Amanita: Mushrooms with fleshy green pilei (green amanita), or red pilei with white warts (amanita pantera), or dark warts (fly agaric or amanita muscaria) arranged in concentric circles, with stipes which are at first solid, then hollow, with a generally disagreeable smell, especially on fully grown specimens.

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

Article 664.—The fresh mushrooms sold on the market shall not be fully ripened, shall possess all the characteristics required to identify them and shall be in a perfect condition of preservation, without larvae, insects or worms; each species shall be sold separately.

Mushrooms may be dried and preserved only under official control. Dried mushrooms shall not be cut into pieces so small as to render their identification difficult or impossible.

Article 665.—The fresh or dried mushrooms sold on the market shall be neither suspect nor poisonous and shall be in a perfect

condition of preservation, free from worms, insects and mites. Dried mushrooms shall be protected from soil and moisture and shall be stored and sold in closed containers made of waterproof paper, tin plate, glass, cellophane, etc. They shall contain not more than 10 per cent of total ash and not more than 2 per cent of ash insoluble in 10 per cent hydrochloric acid. Alcoholic solutions of dried edible mushrooms take on a color when exposed to ultraviolet light (wood), whereas poisonous mushrooms of the amanita genus remain colorless.

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

Mushrooms intended for consumption may be bleached with sulfur dioxide or alkaline bisulfides in amounts not higher than strictly necessary for the purpose. Bleaching with tin salts is prohibited, even if the mushrooms are thoroughly washed thereafter.

Article 666.—The name "truffles" applies to a product which consists of the sporogenous apparatus of several types of subterranean tuberaceous fungi (Tuber melanosporum Vitt., Tuber cibarium Burr, etc.). Truffles shall be sold thoroughly washed and brushed, and their labels shall state if they are black (ripe), violaceous black, white or grey (not fully ripened) truffles, and the location at which they were gathered.

Salt

Article 667.—The name "salt," used alone, applies to the commercially pure or purified product which, in chemistry, is known by the name "sodium chloride."

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

Article 668.—Any plants engaged in the manufacture of salt for consumption and/or for use by the food industry shall comply with the general regulations and, in addition, meet the following requirements:

1. They shall make sure that the salt prior to packing contain not more than 20,000 nonpathogenic bacteria per gram and be free from bacteria of the groups Coli, Staphilococci, Streptococci, Shigella and Salmonella. All salts sold in the trade as table or kitchen salts must meet this bacteriological requirement.

2. They shall have premises suitable for crushing, grinding and packing salt.

3. They shall use hygenic containers which have not been used before.

4. Establishments which, without being salt factories, engage in the packing or distribution of salt for use in foods may receive their shipments of salt for the purpose only in new bags and are not permitted to keep on the premises or in the storage rooms to be used for packing, salt packed in second-hand containers.

5. Industries not engaged in the production of foods, and plants engaged in the purification of salt for use in foods are the only ones permitted to receive salt got up and shipped in bulk (without a container) directly from its place of origin.

6. Food industries, such as bread factories, sausage factories, factories canning land and marine animal products or salted tripe, and any other industries engaged in the preparation of food products are not permitted to store salt in bulk or salt packed in second-hand bags. Refrigeration establishments must have separate storage rooms for salt intended for use in foods and salt intended to cure hides, to be used in water bleaches or for any purpose other than foods.

Article 669.—Common salt can come in the form of and be sold as culinary salt, table salt and superfine salt. The degree of trituration or grinding may vary, depending upon the use for which the salt is intended.

Whatever its form, common salt shall always meet the following requisites:

1. It shall come in white, odorless, water-soluble crystals with a clearly saline flavor;

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

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

Article 670.—The names "washed and/or purified, culinary, table and superfine salt" apply to common salt subjected to a washing and centrifugation process. Such salts shall be perfectly clear and shall contain not more than 2 per cent of water; not more than 0.3 per cent of water-insoluble residue (impurities), and not more than 0.7 per cent of sulphates calculated as calcium sulphate. Maximum turbidity: 25°.

Article 671.—The names "fine running salt" or "table salt" apply to finely ground salt, or to salt produced by evaporation, containing crystals which pass through a 420 micron sieve, most of which are caught by a 125 micron sieve in which not more than 10 per cent of "powdered" salt is tolerated. It shall meet the same standards of quality as common salt, except for its water content which may not exceed 0.5 per cent and for the water-insoluble residue which may not exceed 0.3 per cent. In order to prevent caking due to moisture, the addition of sodium phosphate, calcium phosphate, magnesium carbonate, calcium saccharate or another authorized product is permitted in amounts not exceeding a total of 2 per cent (See Art. 595). The amount of additive used shall be stated on the label.

Article 672.—The designation "topping salt" applies to very pure crystal salt (99.5 per cent of sodium chloride) which comes in transparent crystals.

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

Article 673.—The names "iodized table salt," "iodized cooking salt," and "antibocigenic salt" apply to salt to which sodium or potassium iodate has been added in a proportion of 20 mg. per kg. of salt and to which calcium or magnesium carbonate has been added as a stabilizer in a proportion of 10 gr. per kilo. Its composition must be declared in the labeling.

Article 674.—The name "antimalaria salt" is a salt to which chloroquine diphosphate and calcium or magnesium carbonate have been added in proportions of 3.33 gr. and 10 gr., respectively, per kg. of salt. Its composition must be declared in the labeling.

Article 675.—The name "antimalaria and antibocigenic salt" applies to a salt to which chloroquine diphosphate, potassium or sodium phosphate and calcium or magnesium carbonate have been added in proportions of 3.33 gr., 20 mg. and 10 gr., respectively, per kg. of salt. Its composition must be declared in the labeling.

Article 676.—The name "fluorinated table salt" distinguishes salt to which sodium monofluophosphate or other stable fluorinated salts have been added in a proportion of 50 p.p.m. or

higher. The designations "mineralized salt" and "phosphated salt" apply to salt to which different mineral salts and/or phosphates have been added. In all cases mentioned in this article, the composition must be declared in the labeling.

Basil salt: see Article 619.

Garlic salt: see Article 618.

Celery salt: see Article 623.

Onion salt: see Article 390.

Bay salt: see Article 640.

Marjoram salt: see Article 642.

For potassium salt, dietetic salt, dietary salt, sodium-free salt, see Article 712.

Article 677.—The designation "tenderizing salt" (see Article 611) and similar names apply to salt to which 2-4% of officinal papain has been added, the addition of other permitted additives, such as lactose, sucrose, spices, monosodium glutamate being optional.

Article 678.—The name "brine" applies to a solution containing not less than 10 per cent of salt, to which saltpeter (sodium or potassium nitrate) in a proportion not exceeding 50 grams per kilo of salt and commercially pure sodium nitrite in a proportion not exceeding 6 grams per kilo of salt may have been added.

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

Sauces, Dressings and Seasoning Extracts

Article 679.—The generic names "sauce," "seasoning," "dressing" or "seasoning extract" apply to different preparations made from acid, aromatic and/or pungent, natural or manufactured condiments, with or without sugars, which are sold to dress salads, soups, roasts and other dishes; they may be creamy or liquid, clear or cloudy, and may contain constituents in suspension.

Article 680.—In general, sauces and dressings shall meet the following requirements:

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

2. The names of their components shall be stated in the labeling, and if turmeric or another safe vegetable color is present, the declaration "colored with turmeric" etc. is compulsory.

3. They shall not be adulterated or fermented and shall not contain copper, unauthorized preservatives or foreign substances in a proportion exceeding 1 cgr. per 100 gr.

4. They shall not contain glycogen.

5. The containers of vinegar-containing sauces shall comply with the requisites fixed in the last paragraph of Article 698.

6. Sauces and dressings may be packed in aluminum tubes coated with a protective varnish, and also in aerosol containers.

Article 681.—The designations listed hereinafter shall apply to the following products:

a. The names "alioli" and "ajiaceite" apply to a dressing prepared with a base of crushed garlic, oil and egg.

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

c. The names "soup and gravy juice," "soup and gravy flavor," and "meat flavor" apply to a product with a base of amino acids obtained by the acid hydrolisis of vegetable (yeast extracts, wheat and cereal gluten, etc.) or animal proteins (meat extract, caseine, etc.) to which condiments, flavors, monosodium glutamate and other permitted products may have been added. Its density at 15°/4° C. shall not be less than 1.25 and its aminated nitrogen content may not be less than 3 per cent calculated on the dry residue.

Ketchup: See Art. 432, paragraph 11.

d. The name "nut ketchup" or "nut catchup" distinguishes a sauce prepared with a base of vinegar, soya sauce, meat extract, garlic, onions, salt and nuts.

"Mushroom catchup" is prepared in a similar manner from mushrooms and different condiments.

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

spices, monosodium glutamate and, natural or synthetic, B-carotene in an amount of up to 2mg.% may be added. The resultant emulsion consists of a discontinuous internal phase of oil drops dispersed in a continuous external phase of vinegar with water, the whole stabilized by the lecithin in the egg yolk. If its starch content exceeds 0.5 per cent it must be declared in the labeling. Mayonnaise may be vacuum-packed in an atmosphere of nitrogen or carbon dioxide. Egg powder, ovalbumen and other emulsifiers are forbidden from being used as substitutes for fresh or frozen eggs. Mayonnaise sauces containing smaller amounts of oil and egg shall be named "dressing," "seasoning" or "X sauce with a base of mayonnaise."

f. The names "pebre," "chimichurri" and "criollo"* distinguish solid or liquid seasonings used to prepare or dress meats before or after cooking. They are made with a base of vinegar, citric acid, salt, bay leaf, sweet basil, ground garlic and other condiments.

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

h. The names "soya sauce," "soy sauce," "Japanese brine" and "choyu" distinguish a sauce obtained by the fermentation of a decoction of soya beans, cereals, salt and water to which different condiments and molasses may have been added.

i. The name "Lincolnshire sauce" applies to a sauce prepared from garlic, various red peppers, nutmeg, soya sauce and vinegar.

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

k. The names "tuco,"† "mojo"† and "sauce extract" distinguish sauces intended to be used on cooked foods such as noodles, ravioli, etc. and made of meat extracts, vegetables and various condiments.

l. The names "tucupay" and "cassaripe" apply to a sauce prepared from the juice that drips from fresh yucca pulp, placed in a bag of palm fabric to remove the hydrocyanic acid, which concentrates partially under the influence of heat, in the presence of chili and other spices, the resultant product being a sharp sauce which keeps well if it has boiled long enough.

Article 682.—99 per cent pure monosodium glutamate (M.S.G., Ajinomoto, etc.) may be added to food products in order to accentuate or heighten their flavor.

---

* Note of the Translator: Names of local dressings not translatable into English.
† Note of the Translator: A spaghetti sauce.

Bitters

Article 683.—The name "bitters" distinguishes various safe substances of a vegetable origin, or extracts and active principles of such substances, which are used, especially in the preparation of beverages, not only because of their bitter flavor, but also because of their corroborative or appetite-stimulating properties.

Article 684.—The following substances are considered harmful bitters, the use of which is prohibited:

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

2. Bitters containing irritating, drastic or purgative principles: Aloe, Spanish fly, Eastern coca, colocynth, paradise grains, rue, with the exception of those specifically permitted under Articles 535 and 537 of this Code.

Foaming Agents

Article 685.—The name "foaming agents" or "whipping agents" applies to substances which have the capacity of producing or favoring persistent foam.

Article 686.—Permitted foaming agents are foam-producing substances of a vegetable origin, with a base of licorice root, glycyrrhizin, alfalfa, sarsaparilla, albumens, gums, gelatin, carboxymethylcellulose, and such others as the health authorities may authorize in the future.

Article 687.—Foaming agents containing principles used for therapeutic purposes are considered harmful and for this reason may not be used in foods or beverages.

Article 688.—Foam inhibitors are substances which, when added to a liquid, diminish the formation of foam. Methylpolyxyloxane and such other substances as the health authorities may permit in the future may be used as foam inhibitors.

Protective Agents

Article 689.—The term "protective agents" means any preservatives, antiseptics, anti-fermentation agents and antioxidants which are added to foods to prevent or retard their spoilage or decomposition.

Article 690.—The following substances are in general considered permitted protective agents:

Acetic and dehydroacetic acid

Ascorbic and isoascorbic acid, ascorbyl palmitate, calcium ascorbate, sodium ascorbate

Carbon dioxide

Erythorbic acid

Formic acid

Propionic acid and propionic acid salts

Sorbic acid and sorbic acid salts

Limewater

Ethyl alcohol

Sugar

Glycerin

Smoke

Potassium or sodium nitrate (saltpeter)

Nisin

Common salt

Salt with condensed smoke

Tocopherols

Moreover, the following gases may be used to disinfest cereals, vegetables, and fruits: carbon sulfide, hydrocyanic acid, methyl bromide, chloropicrin, ethyl formate, carbon tetrachloride and ethylene dichloride, which may be mixed with carbon dioxide. The health authorities may authorize additional protective agents whenever they deem it advisable.

Article 691.—The use of the following protective agents shall be considered as limited to the cases specified hereinafter; their use in amounts exceeding 5 per cent over and above the established limits shall not be permitted:

	Food	Protective Agent	Parts per million
1.	Starches and feculae	Sulfur Dioxide (SO_2)	100
2.	Sugars (sucrose, dextrose)	Sulfur Dioxide (SO_2)	70
	Sugars hydromels	Sulfur Dioxide (SO_2)	300
3.	Caviar, fish pastes and canned shellfish	Hexamethylenetetramine	1,000
	—idem—	Benzoic acid and its salts	1,000
4.	Beers	Sulfur Dioxide (SO_2)	70
5.	Canned vegetables	Sulfur Dioxide (SO_2)	40
6.	Liquid and pastous condiments (except mayonnaise)	Benzoic acid and its salts	2,000
7.	Pickles	Benzoic acid and its salts	250

	Food	Protective Agent	Parts per million
8.	Coffee, guaraná, mate and tea extracts	Methylic or propylic esters of p-oxybenzoic acid and its salts	100
9.	Dried fruit	Sulfur Dioxide (SO_2)	1,500
	Fruits, marmalades and jellies	Sulfur Dioxide (SO_2)	40
	Fruits and pulps to be used in preparations	Sulfur Dioxide (SO_2)	350
	Liquid fruits, juices and pectins	Sulfur Dioxide (SO_2)	150
	Liquid fruits, juices and pectins	Benzoic acid and its salts	1,200
	Fruits-concentrated juices	Sulfur Dioxide (SO_2)	600
	Fruits (except grapes, tangerines, pears and citrus fruits)	Formic acid	1,500
10.	Gelatins	Sulfur Dioxide (SO_2)	1,000
11.	Fats and fat-containing products (powdered milk, condensed soups, sausages, cookies, chocolates, etc.)	Norhidroguaiaretic acid (NDGA) and resins containing it*	100 to 500
	—idem—	Butyl hydroxyanisole (BHT)*	200
	—idem—	Butyl hydroxytoluene (BHT)*	200
	—idem—	Esters of p-oxybenzoic acid*	200
	—idem—	Octyl and dodecyl gallate*	50 to 500
	—idem—	Propyl gallate*	100
	—idem—	Butyl gallate*	500
12.	Mayonnaises and similar products	Benzoic acid and its salts	2,500
13.	Table mustard	Sulfur Dioxide (SO_2)	500
14.	Sausages	Benzoic acid and its salts	1,000
15.	Ciders	Sulfur Dioxide (SO_2)	200
16.	Wines	Sulfur Dioxide (SO_2)	450
17.	Artificial fillers for sausages	Formaldehyde, up to	500

Article 692.—The following substances are considered prohibited protective agents, unless specific exceptions are provided for in this Code:

Alpha-bromopropionic and alpha-bromoisovaleric acid, their derivatives and sales

Para-oxybenzoic and similar acids; their esters, derivatives and salts

Boric acid, its derivatives and salts

Bromoacetic acid and its derivatives

Cinnamic acid and its derivatives

* Ascorbic, citric or phosphoric acid may be added as a synergist in amounts of between 5 and 10 mg. per 100 grams.

Chloric acid, its derivatives and salts

Hydrofluoric acid, its derivatives and salts

Monochloroacetic acid

Salicylic acid and its derivatives and salts (in amounts exceeding 2 mg. per kilo, which is considered natural)

Iodoacetic acid and its derivatives

Oxygenated water and peroxides

Abrastel and napthol derivatives

Formaldehyde

Hydroxyquinoline

Hexamethelenetetramine

Quinosol

Mercury salts

Thymol

Thiourea thio-acetamide

By way of exception, and because of its origin, the natural presence of traces of the following substances shall be tolerated: formaldehyde in smoked products and caviar; boric acid in certain cooking and table salts and in certain apple, pear, and quince varieties, pomegranates, grapes and by-products thereof; salicylic and benzoic acid in certain grapes, strawberries, plums, red currants and other fruits; formic acid in various fruits; fluorine in certain drinking waters and specific varieties of grapes and wines; bromide in pineapple juice, grape juice, wines (up to 1 p.p.m.), and other substances on which the health authorities may have favorable data in the future.

Article 693.—Ion sequestrants, which cause changes in certain products, act as preservatives without being preservatives, for which reason they are also mentioned here as protective products. The following substances are permitted to be used, as well as such others as the health authorities may approve in the future:

Calcium acetate

Calcium chloride

Calcium citrate

Calcium diacetate

Monocalcium acid phosphate

Calcium gluconate

Calcium hexametaphosphate

Calcium phytate
Citric acid
Dipotassium phosphate
Disodium phosphate
Potassium citrate
Sodium acid phosphate
Sodium citrate
Sodium diacetate
Sodium gluconate
Sodium hexametaphosphate
Sodium metaphosphate
Sodium phosphate (mono-, di-, tri-)
Sodium potassium tartrate
Sodium pyrophosphate
Sodium tartrate
Sodium tetrapyrophosphate
Sodium tripolyphosphate
Tartaric acid

Vinegars

Article 694.—Vinegar or wine vinegar is the product obtained from the acetous fermentation of wine. Vinegars obtained from the fermentation of beer and malt, cider, hydromel, fruit juices, sweetened solutions and diluted alcohol shall be sold under a name denoting their origin.

Article 695.—Vinegar factories shall meet not only the general requirements, but also the following requisites:

1. The rooms in which raw materials and finished products are stored and the rooms in which the vinegar is prepared and packed, shall have waterproof floors and waterproof wainscots not less than 1.80 m. in height.

2. The raw materials used, i.e., wines, beers, alcohols, etc., shall not contain substances which make them unsuitable for consumption other than the mycoderma aceti which may develop in them. The preparation of vinegars is prohibited from raw materials (fruits, sweetened solutions, etc.) which are unsuitable for consumption for reasons other than the one stated hereinbefore; from wines which are

not genuine, have foreign odors or flavors, are altered by mannitic fermentation, have turned sour or are otherwise diseased, or from wines left over at eating establishments, taverns, beverage outlets, etc.

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

4. The following operations are permitted in the manufacture of vinegars: The dilution of the wine in a sweetened or alcoholic solution in the proportion required for normal acetification (to be carried out at the vinegar factory, never outside); the use of permitted wine clarifiers; the decoloration with charcoal; the flavoring with tarragon, bay leaf and spices, and the addition of alkaline phosphates and sulphates or alkaline earths in a proportion of not more than 200 p.p.m.

5. The names of specific wine regions are prohibited from being mentioned in the labeling used on containers of vinegars not manufactured from natural wines from said regions. Any statement to the effect that the vinegar was manufactured from an aged or choice wine is likewise prohibited.

Article 696.—The following vinegars shall be declared unsuitable for consumption:

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

2. Vinegars which contain toxic metals, unauthorized colors, irritating or toxic acidic substances, acetone, or other unauthorized substances. The only preservative permitted is sulfur dioxide of which vinegars of no matter what origin are not permitted to contain more than 400 p.p.m. of total SO_2 or more than 40 p.p.m. of free SO_2.

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

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

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

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

Article 697.—Wine vinegar shall comply with the following requisites:

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

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

3. It shall contain not less than 4 per cent of acetic acid, and have a dry residue free from reducing sugar of not less than 1 per cent, and not less than 0.1 per cent of total ash.

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

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

Article 698.—Vinegars not made from wine shall be marketed under designations denoting their origin:

Alcohol vinegar (spirit vinegar): Produced by the acetous fermentation of rectified or neutral alcohol solutions. Percentage composition: density at 15° C.: 1.005 to 1.013; total acidity as acetic acid: 4 to 9; alcohol: 0.2 to 1°; dry residue: 0.06 to 0.30.

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

Beer or malt vinegar: Obtained from beer with the proper alcohol content or produced by alcoholic fermentation and subsequent acetous fermentation of a mash of malted hops or cereal, whose starch has been saccharified. Average percentage composition: density at 15° C.: 1.017; acidity as acetic acid: 6.6; dry residue: 2.5; ash: 0.25.

Fruit vinegar (dates, grapes, raisins, apples, pears, carob beans, etc.): produced by alcoholic fermentation and subsequent acetous fermentation of infusions, macerations or decoctions of sweetened fruits. Average percentage composition of grape vinegar: density at 15° C.: 1.010; total acidity as acetic acid: 4; alcohol: traces; dry residue: 1.2.

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

Honey vinegar: Obtained by alcoholic fermentation and subsequent acetous fermentation of honey solutions. Average percentage composition: density at 15° C.: 1.047; total acidity as acetic acid: 4; alcohol: traces; dry residue: 10.6.

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

Milk whey vinegar: Obtained by alcoholic fermentation and subsequent acetous fermentation of sweetened solutions of milk whey.

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

The names listed above shall be placed on all containers holding such vinegars and shall also appear in any books, invoices, bills of lading and other documents used in connection with their sale or circulation.

Article 699.—The vinegars other than wine vinegars permitted by this Code shall be prepared from raw materials that meet the standard requirements and shall have an acidity of not less than 4 per cent, with the exception of beer and cider vinegars, whose minimum acetic acid content may be 3 per cent.

Article 700.—The metal caps used on bottles and jars containing vinegars, pickles, mustard and other products with a vinegar base are not permitted to contain lead in an amount exceeding 10 per cent, or arsenic in an amount exceeding 0.01 per cent unless the cap is completely separated from the neck of the container and the cork by a sheet of fine tin foil (containing not more than 1 per cent of lead) at least one half tenth of a millimeter thick, a sheet of aluminum foil of another impervious material which is not affected when boiled half an hour in a solution of 4 per cent acetic acid, to which 5 grams of sodium chloride and 0.25 grams of citric acid have been added. **[End of Chapter XVII]**

Now Ready . . . Reflects 1965 Tax Changes Throughout!

1966 U. S. MASTER TAX GUIDE

"America's Number One Tax Book"

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

Better than ever before, the MASTER TAX GUIDE explains the basic rules affecting business or personal income tax questions, protects you against overpayments and costly mistakes in year-end tax planning. Here you have clear-cut examples—based on typical tax situations—to illustrate the explanations. Moreover, the GUIDE is eager to assist in the preparation of 1965 income tax returns to be filed in 1966.

Based on the Internal Revenue Code—as amended to press time—Regulations, controlling Court and Tax Court decisions, the 1966 U. S. MASTER TAX GUIDE is a compact source of tax facts and figures immediately useful in working out sound answers to tax problems.

Leading the field, the GUIDE is the highly polished product of more than fifty years' experience in federal tax reporting. Completely dependable, it's produced by the seasoned CCH editorial staff.

Ready Now—Order Today!

As a convenient desk tool . . . it can't be beat. So don't let tax "puzzlers" beat you, when you can have 560 pages of top-flight tax help for only $4 a copy. Fill in and mail the attached Order Card today.

Yours will be one of the first-press copies for that wanted "head start" on year-end tax planning.

CCH PRODUCTS COMPANY

A DIVISION OF

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS OF TOPICAL LAW REPORTS

HARD BOUND EDITION

The 1966 U. S. MASTER TAX GUIDE is also available in a handsome, hard bound permanent edition. Contents are identical to the paper-covered edition, but hard bound (two color, gold-stamped covers) for permanent reference. Price, $8.50 a copy.

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION