VOL. 19, NO. 7 JULY 1964

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 46, Ill. Printed in United States of America.

July, 1964
Volume 19 • Number 7

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

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Printed in the United States of America

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REPORTS

TO THE READER

About This Issue.—The fifth in a series of Food Update Seminars on the latest developments in the food industry was held in New York City June 15-19, 1964. The seminar, titled "Foods on the Move—'64," was sponsored by The Food Law Institute, Inc. An outstanding staff representing the universities, industry, law and government—experts in their fields—discussed the most recent and important trends in the food business.

This month's JOURNAL contains three of the papers which were presented at the session on June 18. "Getting FDA Clearance for Food Additives" is the title of a paper by *Kenneth Morgareidge* which begins on page 364. Dr. Morgareidge, who is vice president and asst. director of the Food and Drug Research Laboratories, Inc., analyzes what he considers to be the presently emerging ground rules covering food additive petitions. He concludes his analysis by predicting that there will be further legislation which will greatly augment FDA's enforcement powers in the food additive field.

L. I. Pugsley traces briefly some of the principles which have evolved over the years in Canadian food legislation and points out how these principles have been consolidated in the present Canadian Food and Drugs Act with their application to present-day conditions. Mr. Pugsley, Associate Director, Food and Drug Directorate, Department of National Health and Welfare, Ottawa, Canada, also reports on the August 1962 food legislation seminar which was held in Bangkok, Thailand, under the auspices of the Food and Agriculture Organization. This informative discussion begins on page 374.

The Deputy Commissioner of the Food and Drug Administration, *John L. Harvey,* discusses recent developments in the FDA pertaining to the enforcement of the Federal Food, Drug and Cosmetic Act, as well as the recent FDA reorganization. As chairman of the Codex Alimentarius Commission, Mr. Harvey emphasizes the wide-spread interest in the formulation of international food standards. His remarks appear on page 392.

"The Pesticide Chemicals Amendment of 1954" is the title of a paper which *J. Kenneth Kirk* presented before the Agriculture Committee of the United States House of Representatives on May 26, 1964. In that paper, which appears at page 404, Mr. Kirk states that he regards the enforcement of the pesticide program as one of the most important operations designed to protect the public health. He goes on to say that only with tolerances which are safe, plus a firm checking and enforcement program, can pesticides be used safely without resulting in a hazardous food supply.

Vol. 19, No. 7 July, 1964

Food·Drug·Cosmetic Law
Journal

Getting FDA Clearance for Food Additives

By KENNETH MORGAREIDGE

Dr. Morgareidge, Vice President and Assistant Director of the Food and Drug Research Laboratories, Inc., Presented This Paper at the Food Update Seminar, "Foods on the Move," Sponsored by the Food Law Institute. The Seminar Was Held in New York City on June 18, 1964.

THE SIXTH ANNIVERSARY of the enactment of the Food Additives Amendment of 1958 will occur on September 12, 1964. Otherwise known as Section 409 of the Food, Drug and Cosmetic Act, this piece of legislation has had a major impact on the food processing industries and on their suppliers. It has been responsible for the expenditure of both public and private funds and manpower to a degree only dimly appreciated in advance. A still-growing mass of federal regulations reflects the continuing activity which this law requires of those subject to its jurisdiction as well as of those responsible for its interpretation and enforcement.

The title assigned for this discussion is deceptively simple. It is also somewhat deceptive in its implication from a strictly technical viewpoint. It has been, and continues to be, the subject of discussion and debate in the lay and technical press and from every forum which offers a receptive audience. Despite the millions of words which have been published and spoken on the subject, almost continuous attention is required on the part of regulated industries to insure current understanding of an ever changing philosophy of enforcement and interpretation of the law.

In order to present the topic in useful perspective, it is proposed to first review briefly some of our experiences of the past five years.

On this foundation, one may assess what appear to be the presently emerging ground rules covering food additive petitions. Finally, some thought should be given to the problem areas still remaining together with a deep look into the crystal ball for future guidance.

Historical Perspective

In the course of the Congressional hearings and debates which preceded the enactment of the amendment, a number of witnesses offered estimates of the probable number of different chemical substances which might be added to foods for any of the legitimate recognized purposes (technical effects) common to food processing, preparation, and handling. Such estimates varied considerably but laymen were both concerned and alarmed to be told that the number might well exceed 700 "chemicals." When, subsequently, the full significance of the terms in Section 201(s), namely, *producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding,* as applied to food additive sources, was realized, the potential number of discrete food additives covered by the law increased several fold. As it turned out the term "packaging" encompassed the largest single category of new food additives for the simple reason that their existence, as such, had not been widely recognized previously. In any event, over 4,000 substances have now been included in various food additive orders or otherwise listed in Title 21, Code of Federal Regulations, Part 121.

Except for those listed as exempt from regulation, these have been included in the nearly 550 formal orders published in the *Federal Register* by the Food and Drug Administration since the law went into effect. There are currently some 200 petitions accepted for filing and awaiting final disposition. It is unofficially estimated that there may be as many as 400 to 500 additional petitions in various stages of preparation and processing which have not yet reached the state of completion suitable or acceptable for formal filing.

These statistics are cited merely to indicate the level of activity which has prevailed during the past several years, and it is significant to note that a large majority of the substances covered by regulations have been those actually in use since before September 1958. In other words, the major effort in the field of food additive regulation has up to now been expended in "clearing" old materials having well-recognized uses but which could not be "generally recognized as safe" (GRAS) as interpreted under the legal definition of a food additive.

It seems reasonable to assume that this phase has now been nearly completed and that henceforth the major emphasis will shift to newer chemicals and those for which experience in common use is not available. This trend is already evident in the decreasing number of new petitions recorded in the *Federal Register*. It is generally believed that this trend will continue for some time in the future as the cost of petitioning for new additives must be balanced against the competition of established substances in sufficient variety and number to meet most of the present needs of the food processor and packager.

Classification of Food Additives

For convenience, FDA has divided Part 121 of the Code of Federal Regulations (Title 21, Chapter I) into seven subparts, five of which categorize food additives as (1) those exempt from regulation; (2) those permitted in animal feeds and feed supplements; (3) those permitted in foods for human consumption; (4) those for which prior sanctions were granted; and (5) indirect additives arising from containers or equipment and miscellaneous sources. It is obvious that the first step in evaluating any substance as a potential food additive is to establish the category into which it falls. The second step is to determine whether or not it is covered by a pre-existing regulation, either for the specific intended use or for any other use. It is equally obvious that if it falls into classes (1) or (4) and the proposed use is identical with that already permitted, no further action may be required. If it is found not to be GRAS, previously sanctioned or approved, or covered by an appropriate regulation, the next step is the consideration of whether a new petition is justified in terms of the economic factors involved. A check list of pertinent questions is usually helpful at this stage:

(1) Is the substance a pure compound of known composition and structure?

(2) If it is a natural substance or mixture of unknown composition, can its uniformity and chemical constants be narrowly defined and reproduced?

(3) If it is a synthetic product of unknown composition purchased from a supplier under a trade name, can the cooperation of the primary manufacturer be obtained?

(4) Is the substance similar or closely related to one for which a valid regulation already exists, even though for another purpose?

(5) Are the manufacturing methods or isolation procedures such as to obviate contamination of the final substance by known toxic or deleterious substances? Can specifications for the limits of trace impurities be written?

(6) Have sufficient trials been conducted to establish the minimum amount required to accomplish the intended physical or technical effect?

(7) Is there available a suitable and reliable analytical method which can be used to determine the actual amount of the substance in or on food?

(8) If intended for use in animal feeds, will the substance transfer to meat, milk, or eggs? If so, are analytical methods available to determine the amounts present in these foods down to a level equivalent to a "zero tolerance"?

(9) If the substance is a component of a packaging material, will it migrate to foods held in contact with the package? If so, how much and under what conditions?

(10) Have the toxicological, pharmacological and/or biochemical properties of the substance been investigated to the extent required to establish the safety of a finite amount in food?

(11) If ingested, is the metabolic fate of the substance known? Is it or its end products eliminated from the body in recognizable form?

(12) Are there substances closely enough related to the proposed additive, either chemically or pharmacologically, to permit drawing inferences as to its safety?

(13) Has the substance or any related chemical ever caused or been suspected of causing cancer in man or animals?

(14) By what segments of the population and for what periods will the food or foods containing the additive be ingested?

Format of the Food Additive Petition

If detailed investigation of existing data indicates that all of the questions above can be answered, the basis is at hand upon which to decide whether or not to proceed further. If all or most of the answers are, in fact, favorable to the additive being considered, the drafting of a petition presents little difficulty in the majority of cases, and the

chances of obtaining a favorable regulation are correspondingly great. On the other hand, should most of the required information be unavailable, the cost of obtaining it must be weighed against the chances of success, both with respect to a satisfactory regulation and a satisfactory position in the market place.

An important by-product to be derived from the experience accumulated collectively by both industry and FDA during the past four or five years is the recognition of what constitutes acceptable safety data with respect to a wide spectrum of chemical entities intended for food additive use. A knowledge of the many criteria and an ability to evaluate, in terms of proof of safety, those which may be critical can often be an important factor in reaching a management decision when a new food additive is under consideration. Certain classes of substances are recognized as presenting greater hazards than others and certain end uses involve a higher potential level of consumer exposure than others. In the opinion of experts qualified to judge the safety of chemical additives, the proof of safety contained in a petition must be commensurate with the potential hazard.

An obvious, and by now trite, example is the futility of submitting a food additive petition for a substance known to be cancer-inducing or closely related to a carcinogen.

The general format of a food additive petition is stipulated in Section 409(b)(2) of the law and further amplified in the regulations promulgated thereunder (21 CFR 121.51). In brief, there are five mandatory sections or parts of every petition:

(1) The name of the additive and all pertinent information including, where available, its chemical identity and composition.

(2) A description of the proposed use of the additive including all directions, recommendations, and suggestions for its use, and specimens of its proposed labeling.

(3) All relevant data bearing on the physical or other technical effects such additive is intended to produce and the quantity of the additive required to produce the effect.

(4) A description of practicable methods for determining the quantity of the additive in or on food and any substance formed in or on food because of its use.

(5) Full reports of investigations made with respect to the safety for use of the additive including full information as to the methods and controls used in conducting the investigations.

A sixth section or part may be added by the petitioner at his own option. This would include his own wording of a proposed regulation together with suggested tolerances, if any are needed. The Commissioner of Foods and Drugs is not bound to accept this proposal.

The petitioner should bear in mind the fact that he alone may be fully cognizant of details relevant to the chemistry and technology of the substance for which an order is sought. The administrative and reviewing staffs of the FDA cannot be expected to possess the expertise which is the special field of the petitioner. Therefore, to avoid unnecessary rejections and much loss of valuable time, the petition should be written in the most simple, straight-forward style consistent with technical accuracy and clarity and without the use of obscure terms or trade jargon. Each part of the petition should be preceded by an index of the material to be found in that section together with a brief synopsis of the conclusions which the petitioner believes may reasonably be drawn therefrom. Finally, there should be included a summary of the entire petition in succinct, readable language with as much use as possible of such visual aids as graphs, charts, and short tables. All raw data, calculations, and other pertinent details should be appended as separate addenda to the part or section to which they belong. It is highly desirable that citations to the literature be accompanied by complete reprints or reproductions of the original articles to which reference is made in the petition. Finally, a plea is frequently heard for good workmanship with respect to the physical quality of the petition itself. The paper should be of sturdy quality, the type-face should be legible, and a sound binding job is mandatory if the document is to survive intact the many hands through which it must pass in the course of review and evaluation.

While the above may appear to be unnecessary window dressing to some, it can be stated with assurance that attention to these recommendations is a matter of enlightened self-interest on the part of the petitioner. A reviewer exasperated by unclear language, typographical errors, poor organization of material, and a petition which is falling apart at the seams, cannot be blamed for a feeling of harassment and a strong impulse to react in a normal human manner, that is, negatively. A large proportion of the rejections received by petitioners on first submission of their documents could be avoided with a consequent saving in time and expense.

On the other hand, it is just as true that exemplary neatness and beautiful art work cannot overcome a real deficit in data.

Problem Areas

In approaching this part of our discussion one is faced with the realization that this is not the best of all possible worlds, either from the viewpoint of the enforcement agency or of the regulated industries. While undoubted progress has been made in terms of compliance, one has not far to look to find subjects where confusion and exasperation are still rampant. Broadly speaking, such areas are diminishing somewhat as better understanding of the law and mutual responsibilities under it continue to grow. Some strong mindedness is required, nonetheless, to avoid letting this phase of the subject degenerate into a listing of "gripes." Furthermore, the potential list of controversial or doubtful items is long. Perhaps a few are of sufficient moment to warrant mentioning in an effort to encourage constructive action on the part of all concerned.

In facing the important question, "To file or not to file," the prospective petitioner often needs answers to questions for which he cannot rely on his chief chemist or toxicologist. Even his most knowledgeable legal advisor may be at a loss. One of these questions which still plagues nearly every user of food chemicals at one time or another is the determination of whether or not a specific substance, as he proposes to use it, is or is not a "food additive" in the legal sense. In the approximate language of the law, the answer depends on whether or not experts qualified by training and experience to judge safety would generally recognize that the proposed use was safe. Five years of searching have not yielded a simple rule for answering this question. The manufacturer can, quite properly, make his own decision if his customers do not clamor for "official clearance." If FDA disagrees with him, it must assume the burden of proving that the substance in question is not GRAS. The net result of this situation has been, logically, that to play it safe, many petitions have included perfectly safe materials whose GRAS status could not be questioned.

Another basis for avoiding the classification of a substance as a food additive would be showing that it did not, in fact, become a component of food as it reached the consumer or that it could not reasonably be expected to do so. In the usual case, this is equivalent to the setting of a zero tolerance with all of the pitfalls which this much debated concept implies. Recent public statements by ranking officials of the administration are encouraging in that the fallacy of this principle is being recognized and constructive steps are reportedly

in progess which, hopefully, may lead to a remedy. The eventual solution with respect to Section 409(c)(3)(A)—the Delaney Clause—remains to be seen.

Still another important decision which often confronts the petitioner is the choice of strategy. If the additive in question constitutes an important ingredient in a secret formulation, the publication of his notice of filing in the *Federal Register* amounts to a tip-off to his competitors, especially when the end use is specifically stated. In certain broad fields, particularly in packaging materials, FDA has cooperated in adopting the omnibus petition in which a long list of possible ingredients provides a great latitude in formulating "approved" products of widely varying composition. Unfortunately, latecomers to the field find it difficult to amend such petitions anonymously.

Overlapping jurisdiction between several administrative agencies can present problems in the case of certain food additive petitions. It is prudent for the petitioner to evaluate his position with respect to such situations in advance. Several agencies of the Department of Agriculture (for example, the Meat and Poultry Inspection Divisions) and the Department of Commerce (for example, the Fish and Wildlife Service) may have concurrent interest in his proposed additive, and their respective methods of handling the matter may not be identical. Within the Department of Health, Education and Welfare itself, more than one service or division may become involved. Unlucky indeed is the petitioner who finds himself caught in a crossfire between two or more agencies.

The advancing forefront of scientific knowledge can also become a matter of concern to a petitioner. Chronic safety studies in laboratory animals usually extend over periods of two to three years. Test protocols which were recognized as adequate when the work was started have recently been subjected to reappraisal as new techniques or new criteria have come into use. When this occurs, expensive and time consuming studies may have to be repeated or extended in order to provide additional safety data with respect to criteria which were not in vogue at the inception of the work. The recent expansion of the requirement for reproduction studies in animals, and the increased emphasis on the need for human clinical pharmacology, can be cited as examples of the impact of new knowledge. The sudden advent of a new analytical technique or of improved instrumentation may make obsolete overnight the painstaking work upon which a tolerance was

to have been based. Perhaps these are the unavoidable occupational hazards associated with the food additive business, and the best advice which can be given is to keep constantly aware of all new developments which may affect a project in progress.

In concluding this catalogue of "problems" some reference seems needed with respect to the present dilemma which faces those food additives currently in use under the time extension provisions of the law. All extensions which have been granted expire at midnight on June 30, 1964. Many of the substances concerned are the subjects of petitions which have been submitted and/or accepted for filing but upon which formal action has not yet been completed. In the strict sense of law, their continued use after that date will be at the risk of the user. Bills have been prepared by interested industry groups for introduction into Congress for the purpose of providing further limited extension of time for those substances on which petitions are now pending. While there seems to be little chance that legislative action can be completed in time, barring some miracle, the fact that such action may be pending in Congress would undoubtedly provide FDA with a tenable basis for withholding seizures at least for the time being.

The Future Outlook

Finally, a look into the crystal ball reveals some very cloudy aspects and a few clear areas with respect to the future of food additives. There is no doubt whatever that their use is an established fact of modern agriculture and food technology. That this use will continue and even expand seems assured, albeit with an increasing degree of governmental supervision and surveillance. The long-range effects of increased regulation by government on the rate of expansion is not so clear. The cost of compliance can only increase, and the managerial risk entailed in the development of new additives will be weighed more and more carefully. Perhaps the ultimate consumer will eventually benefit more under this system in that those new products which do succeed in reaching the market will represent substantial breakthroughs in technology to a greater degree than formerly, since their commercial advantages will have to be pretty clearly evident to justify their cost. Of course, the cost is ultimately borne by the consumer himself.

The crystal ball also appears to reveal the ultimate passage of further legislation which will greatly augment the enforcement powers of FDA in the food additive field. This will most likely come in the

form of expanded factory inspection authority. With access to production records and formulas and with a knowledge of inventory records in manufacturing operations, it would seem reasonable to expect a lessening emphasis on analytical methods for enforcement purposes. While still within the framework of the basic law, the format of petition writing may change somewhat as greater reliance can be placed on stopping a product from reaching interstate commerce rather than on apprehending violations after the fact.

And last, the crystal ball clearly foreshadows that during the fall of the year 1968, there will occur a number of august gatherings of varying sorts at which the progress of a decade will be reviewed in respect to food additive regulation. It is even predictable that representatives of both industry and government will join in glowing tribute to the spirit of cooperation which is fostered by our democratic processes and which will have resulted in added assurance of the safest food supply on earth. **[The End]**

INDUSTRY AND GOVERNMENT COOPERATE ON PESTICIDE PROBLEMS

As a result of cooperative efforts by government and industry to solve serious pesticide problems in West Texas and the Rio Grande Valley last fall, five private and one state laboratory (in addition to FDA's own Dallas facilities) have now been equipped to analyze agricultural commodities for pesticide residues.

The sequence of events leading to this private and state control program began with the discovery of high residues of endrin on a sizable acreage of carrots, cabbage, and lettuce in the Hereford area of West Texas. FDA's Dallas district immediately was faced with the problem of alerting all growers and preventing the interstate shipment of any of the produce until analyses could be made.

The immediate solution came in a cooperative program in which the industry through its association, the Texas Citrus and Vegetable Growers and Shippers, agreed to withhold harvesting in the entire area until the Dallas district examined samples and reported to growers or shippers. The Texas Division of Food and Drugs worked closely with FDA's Dallas office to prevent the local marketing of crops from contaminated fields. Industry cooperation in this program resulted in maximum consumer protection and at the same time reduced the economic loss to growers by eliminating costly labor in harvesting contaminated crops that could not be salvaged.

Later in the season a similar problem arose in the Rio Grande Valley, further pointing up the need for a more permanent solution, one in which the burden of providing analyses for growers could be handled by private and state analytical laboratories.

With the Dallas district providing the technical assistance needed, the private laboratories now have been equipped and are fully operative.

Food Laws and Regulations in Canada

By L. I. PUGSLEY

The Author Presented This Paper at the Food Update Seminar, "Foods on the Move," Sponsored by the Food Law Institute in New York on June 18, 1964. Mr. Pugsley Is Associate Director, Food and Drug Directorate, Department of National Health and Welfare, Ottawa, Canada.

IT IS INDEED A PLEASURE and a privilege for me to participate in this seminar and to discuss with you some aspects of the Canadian food laws and regulations, as well as to report on the seminar held on food legislation for Asia and the Far East in Bangkok, Thailand, August 27 to September 3, 1962, under the auspices of the Food and Agriculture Organization of the United Nations.

The subject of food laws is a most timely one since, of the many laws which govern our activities, there are few that exercise a greater or more continuous influence on our daily lives and habits, as well as upon the agricultural and industrial life of a country, than those which govern the manufacture, production, transportation and distribution of foodstuffs. The social and economic aspects of food laws are far-reaching, extending from the home to many industries, as well as to domestic and international trade.

In reflecting on the theme of the seminar, it was considered of interest: first, to trace briefly some of the principles which have evolved over the years in food legislation in Canada; and secondly, to indicate how these principles have been consolidated into the present Food and Drugs Act with their application to present-day conditions.

Although the first federal food legislation in Canada was concerned with consumer protection, it may be looked upon as having a somewhat unworthy basis in present-day thinking, especially in the light of the vast array of fine food products on the market today. It is recorded that the question of intemperance was raised in the House of Commons in 1873, when members of the general public petitioned

Parliament to do something to remedy a situation that was claimed to be the cause of much poverty and ill health. In discussing the subject in Parliament, it was disclosed that the difficulties were not so much concerned with alcoholic beverages as such, but with bad alcoholic beverages which should be banned. From this, a resolution was passed that all compounders and mixers of alcoholic beverages be licenced and it was considered also that action should be extended to prevent the adulteration of food, drink and drugs. Out of this resolution and under the aegis of the Inland Revenue Act, an act was passed in Parliament in May, 1874, entitled "An Act to Impose Licence Duties On Compounders of Spirits and to Prevent the Adulteration of Food, Drink and Drugs."

This Act provided for the appointment of persons possessing "competent medical, chemical or microscopic knowledge as analysts of food, drink and drugs" and they were to analyse samples collected by revenue officers and inspectors of weights and measures. Food was adulterated if it contained any deleterious substance or any material of less value than was understood by name. Certain powers were given to inspectors to seize adulterated products, and where wilful adulteration was involved, a penalty of $100 was imposed with six months hard labour for the second offence.

Although this Act contained many of the principles taken from the Adulteration Act passed in England in 1872, the following principles of Canadian food laws were included in the Act.

(1) The appointment of technically qualified personnel to enforce the law;

(2) Provision of powers to inspectors to seize adulterated products;

(3) Definition of adulteration in terms of the addition of deleterious substances and debasing substances to foods;

(4) Provision of penalties for violations of the Act; and

(5) Provisions for the protection of the public against health hazards and frauds.

In order to deal more specifically with adulteration of foods, and to separate the activities of the legislation from the collection of revenues on alcoholic beverages, the above legislation was replaced in 1884 by what was termed "The Adulteration Act." Although this act retained the principles of the previous legislation, two new principles evolved. The first one concerned the declaration that a food was adulterated if it consisted in whole or in part of a diseased or

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decomposed or putrid or rotten animal or vegetable substance, whether manufactured or not, or in the case of milk or butter, if it was the produce of a diseased animal or an animal fed an unwholesome food. The second point concerned the exemption of products from certain provisions of the Act, namely:

> When any matter or ingredient not injurious to health has been added to a food because the same is required for the production or preparation thereof or as an article of commerce in a state fit for carriage or consumption and not fraudulently to increase bulk, weight or measure or to conceal inferior quality thereof provided such article is distinctly labelled as a mixture stating the components of the mixture.

Thus, we see in these requirements the authority to declare filthy and rotten foods adulterated and authority to provide for the addition of certain substances to foods within prescribed limits or in present-day legislation the principle of providing for tolerances.

In 1889 an amendment to the Adulteration Act was passed by Parliament providing for authority to prescribe standards of quality of foods:

> Food shall be deemed to be adulterated within the meaning of the Act if its strength or purity falls below the standard or its constituents are present in quantity not within the limits of variability fixed by the Governor in Council as hereinafter provided.

In this amendment a further advance in food legislation was made in the establishment of standards of quality and composition of foods to be fixed by the Governor in Council.

Delegated Legislation

The next advance in food legislation in Canada occurred in 1920 when a complete revision of the Adulteration Act was made. At this time the Parliament of Canada passed the first Food and Drugs Act as such. Although the Act of 1920 contained many of the provisions of the Adulteration Act, it embodied an additional feature, namely authority to be entrusted in the Governor in Council to make regulations for carrying out the provisions of the Act. The inclusion of this authority in the Act frequently termed "delegated legislation," or legislation by regulations, is very much the pattern and trend of legislation in Canada. It is particularly valuable in such rapidly changing fields as modern food processing, in providing flexibility and in permitting the law to keep pace with progress. This provision delegates to the Governor in Council powers to regulate and control the manufacture and sale of foods insofar as this may be necessary for the protection of public health and for the prevention of deceptive and

dishonest practices. Provision was made in the Act of 1920 that regulations made under its authority shall have the same force and effect as embodied in the Act.

The operation of this delegated type of legislation may briefly be described as follows. According to the Canadian constitution the assent of the Governor General, who is the representative of the Queen in Canada, is required to all legislation. Parliament is composed of the Senate, which is an appointed body, and of the House of Commons, which is an elected body. The government in power is the political party having the greatest number of elected members. The person chosen by the party in power as its leader is the Prime Minister. He in turn selects members from amongst those of his party who have been elected to Parliament as his Cabinet.

The Cabinet is composed of the Prime Minister as Chairman and Ministers who are sworn in as Ministers of the Crown. The Cabinet Ministers are responsible for the administration of the various departments of the government. Under this system of government, an order or a regulation of the Governor in Council is in fact an order or a regulation made by the Cabinet, since the Governor in Council, according to the constitution, is bound to accept the advice of the Cabinet.

In practice, in the delegated type of legislation, the basis of the need for amendments and revisions to Regulations under the Food and Drugs Act originates as circumstances require. There is no provision for an enquiry before a regulation is made, but as a matter of practice, a procedure has been developed through Trade Information Letters, which frequently involves a discussion or comments and suggestions from the trade.

Generally a request for amendments or additions to the regulations may come either from an organized group of industry or a professional association or from consumer groups or from the officers of the Food and Drug Directorate who are charged with the administration of the Act. The preparation of amendments to, and revisions of Food and Drug Regulations are carried out by the officers of the Food and Drug Directorate in collaboration with the Legal Division of the Department. The draft regulations are referred to the Department of Justice for final preparation and scrutiny as to authority and constitutionality. After these reviews, the proposed revision or amendment is referred to the Minister of the Department of National Health and Welfare for consideration and concurrence, followed by presentation to the Cabinet.

The Minister of the Department accepts the responsibility in the Cabinet for the proposed regulation and since all regulations must be laid before Parliament as soon as they are made, the Minister of the Department must answer to this body for such regulations as are enacted. In addition, the Minister, being an elected member of Parliament, is answerable to the electorate.

Thus, many safeguards and checks are attached to the making and administration of regulations which remove or at least diminish any suggestion of bureaucracy on the part of the officials of the Food and Drug Directorate. All Regulations under the Food and Drugs Act are published in the *Canada Gazette,* which is an official publication of the government.

The Food and Drugs Act, 1953

There were several amendments to the Food and Drugs Act of 1920 which were related more to legislation on drugs and cosmetics than to foods. However, in 1953 an extensive revision of the Food and Drugs Act of 1920 was passed by Parliament. The scope and subject matter of the 1920 Act was not extensively altered, however provision was made for the following additional principles.

(1) Authority for the Governor in Council to make regulations respecting the maintenance of such records by persons who sell foods as is necessary for the proper enforcement and administration of the Act and the Regulations.

(2) Authority to make it an offence under the Act to manufacture, preserve, prepare or store for sale any food under unsanitary conditions.

(3) Requirements were given for a means of judicial as well as administrative determination for forfeiture to the Crown of foods which were found in violation of the Act.

(4) Provision was made for trial of an offender upon indictment as well as by summary conviction.

Excluding from this discussion the sections of the Act dealing with drugs, cosmetics and devices, and turning to the sections dealing with foods, most of the general principles developed over the years were included in the 1953 Act. Since its promulgation in 1953, no additional amendments have been made with respect to foods.

The necessity of safeguarding the consumer against health hazards and commercial frauds, and at the same time protecting honest trade practices in food products against unfair competition,

requires well-founded basic principles. Foods, by their very nature, are products of many different varieties, composition, degree of purity, etc., and are subject, with respect to production, transportation and distribution, to many different nutritional hygienic and labelling requirements. With sound basic principles and delegated legislation, considerable flexibility is obtained in implementing the law and keeping pace with market trends.

Let us now turn to see how the basic principles set out in the Food and Drugs Act in Canada operate in protecting the consumer and at the same time protect honest trade practices from unfair competition.

As in any legislation, it is essential to define the meaning of key words in order that proper interpretation can be made of the terms used in the law, rather than rely on common usage or the dictionary meaning of words.

The first section of the Food and Drugs Act (1953), deals with interpretations. Since we are dealing with a food law, a definition of food is the first consideration. This has been defined as follows:

> Food includes any article manufactured, sold or represented for use as food or drink for man, or any ingredient which may be mixed with food for any purpose whatsoever.

This has been found to be a very practical and all-inclusive definition of food. It is noted that it includes any ingredient that may be mixed with an article represented as food for any purpose whatsoever. In common terminology, food is usually a substance which supplies energy to the body, but there are many substances added to foods which do not contribute energy or even nutritive qualities to food—for example, seasonings, salt, spices and chemical additives. Since these substances may be mixed with, added to, or transferred to food, they become foods in accordance with the above definition and hence are subject to the basic laws promulgated for foods.

In order that the consumer may know what, how much, and who takes the responsibility for an article of food in market channels, it is the practice for the product to carry a designation or a tag. In terms of the law, this is referred to as a label and has been defined as follows:

> Label includes any legend, word or mark attached to, included in, belonging to or accompanying any food or package.

Closely linked with the label of a food is the method of representation or display intended for the promotion or sale of the product. This leads to the following definition of advertisement:

> Advertisement includes representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food.

The movement of food products through the various trade channels is usually brought about by a sale. A definition to cover the various steps that food follows from its source and through commerce to the consumer requires a broader and more all-inclusive meaning than is usually given to the word "sale" in a dictionary. Sale is defined in the Food and Drugs Act as follows:

> Sell includes sell, offer for sale, expose for sale, have in possession for sale, and distribute.

With the inclusion of the words "have in possession for sale, and distribute," the distribution of free samples has been interpreted as coming within the definition of sale. It is considered that the use of this word is basic to the operation of the Act.

Under the constitution in Canada, the Food and Drugs Act is considered to come within the aegis of criminal law and as such the majority of the requirements are of a prohibitive nature rather than permissive, for example, no person shall sell . . . unless, etc.; no person shall manufacture for sale unless, etc.

The unit in which food is held for sale is termed a package and in order to have an inclusive meaning for such a unit, package has been defined as follows:

> Package includes anything in which any food is wholly or partially contained, placed or packed.

In order that the party responsible for the food be known, the interpretation section of the Regulations under the Act defines manufacturer as follows:

> Manufacturer means a person who under his own name or under a trade, design or word mark, trade name, or other name, word or mark controlled by him, sells a food and includes a firm, partnership or corporation.

The sanitary and hygenic aspects of the production of food stuffs are very important, and in order to define conditions considered unsanitary the following definition is included in the Act:

> Unsanitary conditions means such conditions or circumstances as might contaminate a food with dirt or filth or render same injurious to health.

These are the basic definitions used in the administration of the Act with respect to foods.

Basic Principles

HEALTH AND SANITATION

There are generally recognized basic principles with respect to the health and sanitation aspects on which the manufacture, sale and

distribution of foods are prohibited. Section 4 of the Act states "No person shall sell an article of food that

"(a) has in or upon it any poisonous or harmful substance;

"(b) is unfit for human consumption;

"(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

"(d) is adulterated; or

"(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions."

With respect to sanitation, it is a principle that food should be manufactured under clean and sanitary conditions and not presented to consumers as filtered filth or sterilized bacteria. In this regard, Section 7 of the Act states:

No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

FRAUD AND DECEPTION

Let us turn now to see what basic principles are laid down with respect to fraud and deception. Section 5 of the Act states:

No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Section 5 of the Act further states:

Any article of food that is not labelled or packaged as required by the regulations, or is labelled or packaged contrary to the Regulations shall be deemed to be labelled or packaged contrary to the above section.

In this category we also have the requirement for food standards. Section 6 of the Act states:

Where a standard has been prescribed for a food, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for such food unless the article complies with the prescribed standard.

SCHEDULE DISEASES

There is another section in the Canadian Food and Drugs Act which is concerned primarily with drugs, but authority is also given for its application to foods. This section has been found useful in curtailing undesirable advertising practices. It deals with a list of diseases as a schedule to the Act, making it an offence to advertise food products to the general public as a treatment, preventative or cure for any of the diseases or abnormal physical states mentioned.

The list of diseases includes such conditions as cancer, diabetes, sexual impotence, tuberculosis, heart diseases, etc. It is well recognized that all these diseases and conditions require expert medical advice for treatment and are not conditions where self-treatment is in the best interests of consumers.

The above basic principles on health, sanitation, fraud and deception and schedule diseases are applicable to the manufacture, production, preservation, transportation, distribution and sale of any food.

Implementation of Basic Principles

Let us now see how these principles may be implemented through the delegated regulatory system of authority. As indicated above, the authority to make regulations under the Act is delegated to the Governor in Council which, in essence, is the Cabinet of the Government, on the recommendation of the Minister of the Department. Section 24 of the Act states:

> The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but not so as to restrict the generality of the foregoing, may make regulations.
>
> (a) declaring that any food . . . is adulterated if any prescribed substance or class of substance is present therein or has been added thereto or extracted or omitted therefrom;
>
> (b) respecting
>
> (i) the labelling and packaging and the offering, exposing and advertising for sale of food . . . ,
>
> (ii) the size, dimensions, fill and other specifications of packages of foods . . . ,
>
> (iii) the sale or condition of sale of any food . . . ,
>
> (iv) the use of any substance as an ingredient in any food . . . , to prevent the consumer or purchaser thereof from being deceived or misled as to its quantity, character, value, composition, merit or safety, or to prevent injury to health of the consumer or purchaser;
>
> (c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food . . . ;
>
> (d) respecting the importation of foods . . . in order to ensure compliance with this Act and the regulations;
>
> (e) respecting the method of preparation, manufacture, preserving, packing, storing and testing of any food in the interest of, and for the prevention of injury to, the health of the consumer or purchaser;
>
> (f) requiring persons who sell food, . . . to maintain such books or records as the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;
>
> . . .
>
> (j) exempting any food . . . from all or any of the provisions of the Act and prescribing the conditions of such exemption.

In restricting this discussion to the laws governing food, it is seen that the Canadian Food and Drugs Act provides authority for

the enforcement of basic principles concerning health, sanitation, fraud and deception in the manufacture, sale and advertising of these products. The implementation of these basic principles is carried out by means of the system of delegated legislation. The definition of food in the interpretation section of the Act is all-inclusive and with the authority provided to make regulations governing foods, any product coming within the broad definition is automatically covered—namely any article manufactured, sold, or represented for use as food or drink for man—chewing gum or anything which may be mixed with food for any purpose whatsoever. With the exception of chewing gum, the Act does not name or define any specific food or standards for food.

It is noted that the Act provides authority to make regulations declaring a food adulterated if any prescribed substance or class of substance is present therein or has been added thereto or extracted or omitted therefrom. This authority has not been used very extensively and at present is concerned with the addition of synthetic sweeteners and mineral oil to food. The use of these substances in foods, except as authorized in the Regulations is considered as an adulteration of the food.

The term "misbranded" has not been used in the Act as such and no authority is provided to declare a product misbranded. It was considered more appropriate to have the authority to deal directly with matters coming under this category. Authority is provided to make regulations respecting the labelling and packaging, and the offering, exposing and advertising for sale of any food to prevent the consumer or purchaser from being deceived or misled as to its quantity, character, value, composition, merit or safety and to prevent injury to the health of the consumer or purchaser.

There are a number of regulations enacted under this authority. Possibly the general food labelling requirements under Section B.01.003 of the Regulations illustrates very well the application of Section 24(b)(i) of the Act. In these requirements, the label of a package of food must carry on the main panel the common name of the food and in close proximity to the common name a correct declaration of the net contents of the package in terms of weight, measure or number. In addition, certain mandatory statements respecting preservatives, food colours and artificial flavours, as well as the list of ingredients in descending order of their proportion in the case of unstandardized foods, must be grouped together on a panel, but not on

the bottom of the package. The over-all requirement on labelling of foods is given in Section B.01.002 of the Regulations, and this states:

> Subject to Section B.01.010 no person shall sell a food that is not labelled as required by these regulations.

Section B.01.010 deals with the packaging of foods from bulk at the place where the food is retailed and such packaging is exempt from the labelling requirements unless a statement is made describing the ingredients other than the name of the food and the net contents. A violation of the labelling requirements would be a direct violation of the Section of the Regulations rather than one of misbranding.

Turning now to the procedure used in the enforcement of food standards, it is noted that Section 24(c) of the Act provides authority for the Governor in Council to make regulations prescribing standards of composition, strength, potency, purity or any other property of any article of food. Pursuant to this authority, standards for a number of foods have been included in the Regulations under the Act. The form and content of these food standards vary depending on their application. Firstly, there are standards which merely identify a food for its use in compositional standards. In order to prescribe compositional standards, for example, for such dairy products as evaporated milk, cheese, ice cream, etc., it is necessary to have a basic standard for milk and this has been defined as follows:

> Milk (Whole Milk) shall be the normal lacteal secretion obtained from the mammary gland of the cow genus Bos and shall be free from colostrum.

Secondly, there are standards which are in the form of legal definitions or recipes, for example,

> Canned vegetables shall be prepared by heat processing properly prepared fresh vegetables with or without sugar or dextrose, salt or a conditioner, and shall be packed in hermetically sealed containers.

Thirdly, there are standards which prescribe full specifications for the product. In the case of olive oil, for example, this is defined in terms of its specific gravity, refractive index, iodine number, saponification value and acid number.

It has been the practice where standards of identity and composition are defined in the regulations for a food that the list of ingredients need not be stated on the label, unless such is made a specific requirement of the regulations. Thus, in the case of canned vegetables, the addition of salt and sugar need not be declared on the label, whereas the presence of a conditioning agent such as calcium chloride, calcium citrate, etc., must be declared on the label.

Chemical Additives

The increasing use of chemicals in or upon foods has undoubtedly provided a greater supply of food, has increased the variety and attractiveness of food and has made available a number of convenience foods. The development of adequate laws to protect the public and to maintain the confidence of consumers, with respect to the use of chemicals in or upon foods, has been a timely topic for discussion among groups interested in food legislation during the past ten years, although in some respects the situation is not entirely new. Legislation respecting the use of preservatives, bleaches and colours in foods has been in effect in the regulations under the Food and Drugs Act for a number of years. However, the post-war expansion of the chemical industries has resulted in the production of a number of new compounds and these have contributed to the need for revised requirements to keep pace with the times.

In contrast to the chemicals added to foods to impart some desired quality or to serve some functional purpose, there are a group of chemicals frequently found in foods which do not impart any desired quality *per se* to the final product, but have been found necessary for the protection and production of foodstuffs against the ravages of the many pests which attack the foods.

In early food legislation dealing with the use of chemicals in food, it was the practice to establish a "prohibited list" of chemicals, for example, formaldehyde, fluorides, etc. The concept of a "permitted list" of chemicals and the establishment of safe residue tolerances is a relatively recent development in food legislation. Along with the establishment of a "permitted list" has been the requirement to establish the safety of use of the chemical, its technological justification or need, and analytical procedures for the control of the chemical in the food.

In the establishment of a "permitted list" of pesticides and for safe residue tolerances in food, it was not necessary to obtain additional authority under the Act to take care of the situation. Section 4(a) of the Act provided the basic authority prohibiting the sale of any article of food that has in or upon it any poisonous or harmful substance. On the other hand, Section 24(j) of the Act provides authority to make regulations exempting any food from all or any of the provisions of the Act and prescribes the conditions of such exemptions.

Pursuant to this authority, regulations were enacted setting up in tabular form a list of specific foods with accompanying permitted pesticide residue tolerances in parts per million for such foods and these are exempted from Section 4(a) of the Act. Until the food with its accompanying pesticide tolerance is included in the list, the sale of such food containing pesticide residues is prohibited by the regulations. For example, provision is made that citrus fruits may contain a maximum of 110 parts per million of biphenyl, a preparation added to citrus fruits to inhibit mold growth on the fruit.

In the case of a new pesticide or a revision of a tolerance, the pesticide manufacturer makes representation to the Food and Drug Directorate in the form of a submission containing the supporting data and information for the addition of the food to the list. Providing the data and information are considered complete, a recommendation is made to the Minister of the Department for the inclusion of this product in the list with its accompanying pesticide residue tolerance. If the Minister concurs, a recommendation is made to the Cabinet and an Order-in-Council is promulgated and published in the *Canada Gazette* providing for the use of the pesticide in an amount not exceeding the tolerance stated for the food listed in the table.

The requirements respecting the data to support the safety of use of the pesticides, the technological justification or need and the analytical procedures for the control of the chemical in the food have not been enacted in the form of statutory requirements to date. However, general administrative guides as to the type of information required to cover these points have been distributed to the trade.

Trends in Food Laws

It is quite evident that the public is becoming more conscious of the changes in the method of food production processing and marketing involving a greater use of an increasing number of chemical substances. They appear conscious that something is happening without being able to fully appreciate the significance of the use of all of these new procedures. The reports in the press and from consumer groups have expressed uneasiness. Demands have been made to governments for assurance that the necessary protection against possible hazards to health is provided. In this connection, two of the functions of food laws are: first, to take whatever feasible measures are available and necessary to protect public health; and second, to maintain consumer confidence that the food distributed is safe, wholesome and displayed in a factual manner.

The development of a consumer relations group within an enforcement agency is a recent trend of food regulatory agencies. Such a group tends to foster communications from the agency to consumers and from consumers to the agency. In this way a better understanding of problems is obtained. A Consumer Relations Section was organized within the Food and Drug Directorate in 1957.

The development of the so-called convenience foods during the past ten years has brought new problems to food law enforcement agencies. The "gentle touch" of a good cook in preparing food in the kitchen is being replaced by the food manufacturer on a mass-production scale. These changes in methods of production of foods have required the establishment of more rigid specifications for the basic food ingredients and the development of sanitation requirements for establishments involved in the processing of foods. Many of the basic food ingredients constitute an excellent media for the growth of bacteria, and hence the need for professionally trained personnel to supervise the production of foods. A recent incident in Canada traced the possible dissemination of salmonella organisms through the medium of prepared cake mixes containing powdered eggs. The cake mix containing the powdered egg, being fluffy material, permitted the bacteria to be transmitted in a dust to other foods and kitchen utensils in preparing the batter for the cake. In order to provide protection to the consumer, it was necessary to amend the regulations to require the absence of salmonella organisms in egg products, and thus curtail this potential hazard to health. It is anticipated that this type of legislation will be necessary for other foods as new problems arise in the dissemination of health hazards through the medium of prepared foods.

The labelling, advertising and packaging of foods are becoming more important factors than in the past in the marketing, display and distribution of food products. The development of competitive advertising within recent years, with the evaluation of the quality, quantity and safety of goods as expressed on the label or in advertising media, demands a keen sense of discrimination on the part of consumers. In order to provide protection to the consumer, a relatively new challenge has been presented to food law enforcement agencies. It appears that there is a tendency to confuse the outward appearance of products with inside integrity. This situation has come to the forefront with the introduction of self-service type of marketing and the so-called built-in maid services provided with the product, each in its own way seeking a portion of the consumer's dollar.

In this competitive situation the consumer has difficulties in making intelligent decisions on the choice of foods, while the ethical manufacturer has his problems in the maintenance of high standards of quality. While the display and advertising of foods in an attractive manner is essential to good merchandising in this competitive situation, it is essential for law enforcement agencies to ensure that it is done in a forthright, honest and factual manner. Where foods are displayed and advertised in such a manner so as to cheat and deceive, especially the so-called hidden cheats, regulatory requirements are essential for the protection of the consumer.

Amendment to Food Labeling Regulations

In this connection, a recent amendment to the regulations respecting the labelling of foods illustrates the necessity of maintaining a careful review of the trends in the display of foods. In a review of the labels of a number of foods, it was noted that a wide diversity existed in the method of indicating the net weight of the contents of packages of foods. It was evident that some manufacturers, through inadvertence or choice, seemed shy about informing the consumer how much of the product was in the package. It was evident that the "giant" or "king" size in one manufacturer's terminology was not the same with respect to net contents as that of another manufacturer. In discussing the problem with food manufacturers, there was general agreement that some corrective action was needed to obtain uniformity in the declaration of net contents. It has been our experience that ethical manufacturers are quite prepared to endorse regulatory requirements which are in the interests of consumers, especially laws which bring the unethical operator into compliance with sound merchandising principles. Accordingly, the regulations were amended to require the declaration of the net contents to be in close proximity to the common name of the food on the main panel of the label. The term "close proximity" was defined to mean, in reference to the common name, immediately adjacent to the common name without any intervening printed, written or graphic matter. With the net contents displayed in close proximity to the common name, the consumer can readily see how much of what he is purchasing.

With the many advances in food technology designed to improve the quality and appearance of foodstuffs there is never a dull moment for enforcement agencies to maintain the requirements abreast of the times.

FOOD LEGISLATION FOR ASIA AND THE FAR EAST

It was my privilege to attend, as a consultant to the Food and Agriculture Organization, a regional seminar held on food legislation in Bangkok, Thailand in August 1962. Thirty-two participants from 14 countries in Asia and the Far East attended the seminar. A few months prior to the seminar, Dr. Y. K. Subrahmanyan, Assistant Director General of Health Services of India, visited the participating countries and prepared a report on the existing food legislation. In addition, each of the countries submitted a statement on the actual status of the food legislation in their respective countries.

It was quite evident from the above reports that the scope of the food legislation enacted and enforced in these countries varied widely and was quite divergent in character. Some countries had enacted comprehensive legislation to prevent the sale of adulterated and misbranded foods, with accompanying high standard of codes of hygiene, while other countries were still in the process of revising the food laws which were in force prior to attaining their independence. It was evident that the governments of many of the countries were taking active steps to bring their food legislation up to date and to provide more comprehensive standards for foods.

Although the countries were interested in establishing laws to protect the people against health hazards and frauds, it was also quite evident that they were interested in the marketing aspects of food legislation, especially in establishing grade standards, in order to gain a reputation for their foods in world markets.

In discussing the problem as to whether the basic food law should be enacted at the federal level or at the state or provincial level, it was considered in the interests of the need for uniformity that it was desirable to have the food law enacted at the federal or central government level. In order to provide effective control and a flexible system for preparing regulations and amendments to the basic law, it was recommended that a standing committee of the government be empowered to make regulations and amendments to the law. In addition, it was suggested that government committees made up of members of interested departments of government, for example, Health, Agriculture, Justice, Finance, Customs, Industry and Trade, should act as advisory committees on food control and prevention of fraud to the standing government committee. The function of these committees should be to advise the government committee respecting:

(i) Questions of principle in the field of food legislation;

(ii) The drafting of food laws or amendments to the existing laws and regulations in the light of processing techniques, frauds, trade practices and consumer needs;

(iii) Coordination of action of the various departments of government interested in food control and prevention of fraud;

(iv) Review of the implementation of the basic law from time to time; and

(v) Establishment of technical subcommittees to recommend and advise the main committee on technical and scientific matters, for example, food standards, food additives, pesticide residues, method of analysis, etc.

It was considered that the function and purpose of the food law should be to provide protection to the consuming public against health hazards and frauds which may occur in the production, manufacture, storage, distribution and sale of foodstuffs. The basic food law should include general principles prohibiting the sale of food that is in any way harmful to health, that is adulterated, that consists in whole or in part of any filthy, putrid, repulsive, rotten, decomposed or diseased animal or vegetable substance or food that is insect-infested or otherwise unfit for human consumption or produced under unsanitary conditions. There should be provision for the protection of the consumer by making it an offence to sell or advertise a food in a manner which is false, misleading, deceptive or misbranded in any manner. In addition, there should be provision for setting up standards and prohibiting the sale of any food for which a standard has not been prescribed, unless such food conforms to the standard in all respects. In addition, provision should be made for making regulations in order to implement the purpose and the provisions of the basic food law.

It was noted in the reports from the countries that standards for raw, traditional and modern processed foods had not been laid down in detail by many countries. It was considered that without detailed standards for raw, traditional and modern processed foods, it would be impossible to enforce the legislation. It was felt that minimum standards for different food items or classes of foods which would be internationally acceptable should be established. Subject to these minimum standards, different countries may wish to draw up grade standards according to the requirements for export and internal consumption. It was felt that each country should set up an agency for the pretesting and quality marking of the different basic food articles offered for sale or export.

In respect to food additives, it was recommended that countries set up permitted lists of these substances adopting the standards and specifications drawn up by the Food and Agriculture Organization and World Health Organization. Similarly there should be a permitted list of tolerances for pesticide residues, and the manufacturer should be under an obligation to provide full details on method of application, toxicity, residue tolerances, method of analysis, etc., of the pesticide.

On the question of enforcement, it was considered highly desirable that the implementation of food legislation should be vested in the central administration. If this authority was delegated to the individual states or municipalities, then the central administration should reserve the powers to take over the implementation of food control in a specific local area in case of negligence or failure of the local bodies to discharge their duties adequately.

Although a number of other points were discussed, such as laboratory facilities, technical personnel, sampling, etc., the above is a summary of a proposed model food law drawn up for the countries in Asia and the Far East. **[The End]**

FDA PROPOSES NEW REGULATIONS FOR ANIMAL DRUGS

Two new regulations to increase safeguards in the testing of new drugs in animals and to protect consumers against drug residues in meat, milk, and eggs have been proposed by the Food and Drug Administration.

One set of proposed regulations would set up procedures for marketing the products of food-producing animals used for testing new veterinary drugs and food additives under conditions which would insure safety of the products. These proposals would formalize the consideration FDA now gives on a case by case basis to requests for marketing food products (meat, milk, eggs, etc.) derived from treated animals.

The other proposed regulations would govern the distribution of new drugs used for clinical investigations in food-producing animals and poultry. They would also cover investigational drugs used in laboratory animals and for pet animals.

Both proposed regulations were published in the *Federal Register* of June 19. FDA invited interested persons to submit their views in writing within 60 days of that date to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue, SW, Washington, D. C. 20201.

The full text of the proposed regulations for marketing procedures appears at ¶ 59,102.018 of FOOD DRUG COSMETIC LAW REPORTS. The full text of the proposed regulations concerning distribution of new drugs appears at ¶ 80,074 of FOOD DRUG COSMETIC LAW REPORTS.

Food Laws and Regulations

By JOHN L. HARVEY

The Following Paper Was Prepared for Delivery at the Food Update Seminar, "Foods on the Move," Sponsored by the Food Law Institute, in New York, on June 18, 1964. The Author Is Deputy Commissioner of the Food and Drug Administration.

IT IS A PLEASURE to have been asked to join this distinguished group for a second time, and to contribute, with my colleagues from Canada and Mexico, to a discussion of food laws and regulations. I am grateful for the opportunity to hear from our neighbors and I think it most likely that I shall learn more than I give out.

Time will not permit a detailed discussion of United States food laws and regulations—for this audience, it is not necessary or particularly helpful. With the chairman's permission, I shall therefore assume that the present audience is probably as familiar with the basic requirements of the Federal Food, Drug and Cosmetic Act as I am, and confine my remarks to recent events, program changes, and related current matters of which you may not be quite as well informed. If I am wrong, perhaps the question period will bring that out. Should there arise questions of similarity or differences of our laws with those of our neighbors to the north or south, we will be glad to explore such details at that time.

At my last appearance in 1962 before the Food Industry Science School in session at Asbury Park, we discussed in some detail the Food Additives Program of the Food and Drug Administration. You will recall that the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act was enacted in September 1958. It represented the culmination of substantial congressional interest in the subject of the safety of chemicals added to food over a period of almost 10 years. This amendment provides for control of such food additives whether they be added directly or intentionally to the food and whether they become a part of the food indirectly through migration from machinery or packaging materials.

Time Extensions Granted for Some Substances

In recognition of the tremendous amount of work necessary to positively prove or confirm the safety of the many food additives then in use, Congress provided a delay in the effective date of the statute for some substances until March 1961 on a showing that the uses for the additive would present no undue hazard to the public health and extensions in time were necessary. As we approached this deadline, it was obvious that even more work than was anticipated needed to be done. We proposed and actively supported legislation to allow further extensions. Although we recommended that with appropriate safeguards a somewhat later date could be set, or even none at all, a finite extension of our exempting authority was passed, with a new deadline of July 1, 1964, prior to which all food additives must be the subject of an appropriate regulation. Following this enactment, a great many extensions were granted in which case the petitioners were required to demonstrate a prima facie case for safety, a need for the extension, and were required to make periodic reports of progress on the testing program.

We are now approaching this latest deadline, and again it is obvious that in some instances there is legitimate need for still more additional time. We have been asked to grant such additional time administratively. To this we must answer that we have no such authority, and that such grace, if extended, must be by congressional action. We have suggested that industry take the initiative and get appropriate legislation introduced. We have indicated that we would not object to a properly considered bill that would maintain the safeguards now in effect and that would not include any "Johnny come latelys," but only those products which already had extensions and those products whose complex testing programs demanded additional time. It would provide only for the completion of investigations already in progress. We cannot agree to "new business" extensions. We do feel that on work underway, all in good faith, it would be a pity not to extend time reasonably, if no danger to the public is involved.

Provisions of the 1962 Amendments Pertaining to Animal Feed

I should report one rather significant change, possibly not of particular interest to the food industry generally, but of tremendous importance to the animal feed people. I refer to changes in the food additives section of the Act by the Kefauver-Harris Drug Amend-

ments of 1962. This was in the "Delaney Clause" which originally provided that we may not issue a regulation for the safe use of any food additive which had been found to induce cancer when ingested by man or animal, or found, after tests which are appropriate for the application of the safety of food additives, to induce cancer in man or animal. Congress amended this clause by making it inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions or use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food, such as meat, milk or eggs yielded by or derived by the living animal.

Therefore, it is now possible to issue a regulation for an additive for animal feed even though under some laboratory conditions the chemical might produce cancer in animals. We believe that the conditions under which this exemption is allowed are sufficient to provide the human consumer with all possible safeguards, and that no hazard to the public health has been added. First, the substance must be shown to be safe for the animal under the intended conditions of use. If this is clearly established, then the petitioner must demonstrate that the edible products of the animal—meat, milk, or eggs—are free of any residues of the carcinogenic substances.

Amendments Affecting Color Additives

Slow but definite progress can be reported on the Color Additive Amendments passed by Congress on July 12, 1960. Prior to these amendments, the Act provided only for the listing of *harmless* coal tar colors in foods, drugs and cosmetics. The FDA took the position that *harmless* meant harmless in *any* amount and that the law would not permit us to list colors for use in limited amounts even though these lesser amounts were safe. The courts agreed with us on this interpretation. The amendments provide a procedure whereby all color additives, not only those of coal tar origin, but regardless of origin, may be placed on an approved list by FDA with quantitative and/or qualitative restrictions if necessary for their safe use and for the protection of the public health.

Thus, colors may be listed for use in foods, drugs, cosmetics, or any of these, without restriction; they may be listed for use under

restrictions with limitation as to quantity or other conditions; or they may be listed for use under restriction with the further requirement that each batch be certified by the FDA after appropriate analyses of samples.

After considering the comments received from interested parties concerning proposed regulations published in January 1961, final procedural and interpretative regulations were published on June 22, 1963. Although some controversies have developed in the cosmetic area which may require adjudication in the courts, there do not seem to be any serious problems in the food coloring area.

The amendments provide a transitional, or "phasing in" period to adjust to the new rules. During this time, provisional listings will prevail until the more extensive work showing safety can be completed on many of the colors. The final approved list will then be controlling. As in the case of food additives, the clinical and laboratory work required to show safety is substantial, and the time originally allotted was found to be less than necessary. This statute does contain the necessary authority, and provisional listings of all noncoal tar color additives have been extended twice; the first time to January 1, 1964, and more recently to January 1, 1965.

Exemption of Previously Certified Colors

A regulation which becomes effective June 22, 1964, and which will be of interest to this group, is Section 8.30(b) CFR 21. This section exempts color additive mixtures for foods and drugs from further certification if the straight color (or colors) has been previously certified or the diluents are on a "safe" list, which we hope will be published very soon. This represents a significant change over the present rules, which require recertification of color mixtures or dilutions, even though the basic color material had gone through the certification procedures.

Eight regulations which include identity, labeling and, in some instances, limits in the quantity that may be used, have been issued and are now in effect for color additives, for foods. They are:

(1) B-apo-8′-carotenal,
(2) Annatto,
(3) B-carotene,
(4) Toasted Partially Defatted Cooked Cottonseed Flour,
(5) Citrus Red No. 2 (for oranges only),

(6) Caramel,

(7) Tagetes Meal—both to enhance yellow color of chicken skin and eggs, and

(8) Dried Algae Meal.

Development of Improved Chemical Pesticides

No discussion of Food and Drug activities would be complete without a status report on pesticides. Through a best seller book, through newspapers, and through reports of Congressional hearings, it is a subject that has been of interest to all and in the public eye for some time.

The President's Science Advisory Committee reporting on the use of pesticides recognized that pesticides are indispensable to the economy of the nation. The report and the evidence presented at the recent pesticide hearings show that there is at present no other economical replacement system for chemical pesticides. The problem is, therefore, not one of eliminating pesticides, but one of developing sounder methods for use without hazard to man and his environment. Under the Food, Drug and Cosmetic Act the FDA is not primarily concerned with the pesticide as it is sold to the farmer or householder, but is concerned with the residue that remains on the agricultural product as it comes to the housewife.

Under the Pesticide Amendment of 1954 we have now established about 2,500 tolerances on some 130 pesticides on food crops.

These tolerances are not considered static but are under constant appraisal and reappraisal by our scientists as new facts become available. Essentially we group pesticides into four categories:

(1) Tolerances which are considered sound and in need of no further review or revision in the light of new information;

(2) Tolerances which, in the light of present information, are not based on all the evidence which would be required today but on which the deficiencies are such that even though we would not grant any additional tolerances for the same chemical on other commodities, we believe that the original petitioner should be given an opportunity to bring the total data up to date.

(3) Tolerances on which our scientists have reviewed the data available and have decided that outside expert assistance is needed. Advice will be requested of a group from the National Academy of Sciences. Dieldrin and aldrin are recent examples of this category.

(4) Tolerances for which our scientists conclude that the evidence is grossly deficient by present-day standards and the tolerances are not supported. In these instances, we will forthwith propose action to cancel the tolerances as we recently did for chlordane. Under the law, of course, the affected parties can request an expert committee to review the evidence.

We analyzed for spray residues last year, over 25,000 samples of fruit or vegetables. This is actually about 1 percent of interstate shipments.

Current Studies at Rutgers

We need the best minds and resources to solve the many problems that arise in this area and we are indeed pleased to acknowledge the active participation by the scientists of Rutgers University in two current studies. Establishing pesticidal residues on minor crops is a problem. Although a particular pesticide may be a very good one, the economic incentive for industry to obtain the necessary supporting safety, residue and collateral data is not present when the total amount of pesticide to be used on a particular crop is very small. In a study headed by Dr. C. C. Compton, sponsored by the Association of State Agricultural Experiment Stations and the United States Department of Agriculture, scientists at Rutgers are assembling the necessary data for the use of pesticides on such crops, and will make such data available to industry. This we feel is a very worthwhile project.

The scientists at Rutgers University are also working on a much more fundamental problem under a recent Public Health Service grant. This is a study of the "fate of pesticides" in the soil and that of topographical drift. These problems have been with us for some time but become more pressing as our analytical methods become more acutely sensitive. We need to know much about what happens to the pesticide that remains in the field or orchard after the crop is harvested; what crops have the ability to systemically withdraw pesticides from the soil; what effect various soils and soil microorganisms have on the retention of pesticides; the suspension, movement, and breakdown of pesticides in water; the influence, if any, on fish in water carrying pesticidal runoffs; and the tumorigenic effects and other resultant changes in cellular patterns and the intercellular localization of insecticides in insects. The long-term goal of the study as summarized by Dr. Leland G. Merrill, Jr., Dean of the College of Agriculture, is to "understand better the full implication of pesticides in the human environment as influenced by various environmental

interrelationships." We are indeed pleased that Dr. Billy Ray Wilson and his staff of scientists have started on the detailed work necessary to give us this understanding.

"Reasonable" Inspection for Protection

If I may digress for a moment, may I point out that the Kefauver-Harris Drug Amendments of 1962 substantially clarified our authority by amending the factory inspection language of the Act with reference to prescription drug manufacturers, and thus strengthened our ability to protect the public health. Another amendment placed specific responsibilities on drug manufacturers to make periodic reports to us when injuries or untoward effects involving new drug products became known to them. Evidence adduced at the hearing that preceded the enactment of this legislation plainly showed that the government's armamentarium needed this bolstering in order to obtain all of the facts. Obviously, this need had become more acute as drugs became more and more lifesaving but at the same time occasionally more and more life threatening. Food additives, color additives, and pesticides also may be life threatening and we still lack clear authority in all cases to obtain all the facts in order to protect the consumer. For prescription drug establishments, we now are granted access to all things which have a bearing on violation of the law with respect to drug products, including files, papers, processes, controls and facilities. In the case of a plant producing or using a food additive, color additive or pesticide, we are still operating under the statutory language where we are allowed to inspect "in a reasonable manner." As you might suspect, the government's definition of "reasonable" and that of manufacturers do not always coincide and in spite of the thoroughly cooperative attitude on the part of most firms, we have a rather imposing list of food manufacturers who have refused to allow our inspectors to make what we consider an adequate inspection.

The administration has submitted to Congress, and bills have been introduced in both Houses, to extend the kind of clarifying legislative authority now in the statute with regard to prescription drugs, nonprescription drugs, foods, cosmetics, and therapeutic devices. We are hopeful that such legislation will pass. Upon passage of the 1962 amendment, we heard predictions of the dire effects that would proceed from Congressional approval of such bureaucratic authority. We are aware of no such results. We do feel, however, that when

we are dealing with potent chemicals in our foods, that we should not have to debate the meaning of the word "reasonable" before we can obtain facts that may save lives.

Illustrative of problems of possible toxicity of a food additive, may I mention that a nonintentional food additive has given rise to a recent problem with peanuts. Peanut meal from Africa was found by chemists in the United Kingdom to contain a very toxic substance which has now been identified as a micotoxin, called aflatoxin, resulting from a particular strain of aspergillus flavus, a widely distributed storage mold. A recent symposium on micotoxins in foodstuffs held at the Massachusetts Institute of Technology drew scientists from many countries where the problem of dangerous food contamination due to mold infestation was discussed. The aflatoxin produced by mold in peanuts was found to have an effect level, in some species of animal and fish, as low as one part per billion. Aflatoxin is definitely carcinogenic to some animals and its action is irreversible. We do not know of the effect on human beings but because of the physiological effect on animals, we cannot be complacent. In investigating problems such as this, we cannot rely entirely on voluntary cooperation and we certainly cannot be satisfied with less than all the information available.

Recent FDA Organizational Changes

Probably the most important recent step taken to prepare FDA to meet more adequately its responsibilities in all areas, including foods, was the recent reorganization. This reorganization was the result of the many studies that have been made of the FDA, both by outside groups, such as the Second Citizens Advisory Committee, and by ourselves. It is the most far-reaching reorganization that FDA has ever experienced in its over half-century of existence.

In effect, the reorganization does the following:

(1) It facilitates and elevates consumer and industry information and education and enhances the promotion of voluntary compliance through the establishment of a separate Bureau of Education and Voluntary Compliance. This bureau has responsibility for leadership and direction of all educational, informational, and voluntary compliance programs that had heretofore been scattered in a number of organizational units.

(2) The reorganization upgrades the FDA's scientific programs and elevates the role of the scientist in FDA affairs through the estab-

lishment of two new positions. These are an Associate Commissioner for Science, responsible for the over-all direction of FDA's scientific activities and for representing the scientist at the highest level in important decisions and policies, and an Assistant Commissioner for Science Resources who serves as staff advisor for science communications, professional development and extramural research.

Three scientific bureaus are now in FDA's organizational structure. The Bureau of Medicine, relatively unchanged by the reorganization, will continue to provide expert medical evaluation to all FDA programs. A Bureau of Scientific Research has been established and is responsible for broad and long-range research and for the development of expertise in a number of scientific disciplines necessary for the support of FDA's various activities. Finally, a new Bureau of Scientific Standards and Evaluation has been created to be responsible for the review and evaluation of industry proposals related to drugs, pesticides, food additives, etc., and for the certification of antibiotics, insulin and colors. Under the former organization, scientific research activities and the scientific review of industry proposals were undertaken by the same organizational unit with resulting competition between the two functions for time and resources.

(3) The reorganization improves long-range and policy planning by the establishment of an Assistant Commissioner for Planning to give full time to the important job of developing long-range and policy plans for FDA. In turn, responsibilities for developing day-to-day operational plans have been lodged with the bureaus closest to the operations for which such plans are required. In the former organization, both top level planning and day-to-day planning came under the same direction and competed for time and resources.

(4) The reorganization facilitates coordination and leadership by the Office of the Commissioner by removing from this office and reassigning elsewhere programs and operational work loads, such as those relating to education, food additives, color additives, and activities falling under the Hazardous Substances Labeling Act, that were formerly undertaken by the Office of the Commissioner. In addition, new Assistant Commissioner positions have been created to provide the Commissioner with top-level staff advice in specific areas.

(5) The reorganization improves the supervision and coordination of regulatory and enforcement operations, including improved communications between field and headquarters operations, by the establishment of a Bureau of Regulatory Compliance to be responsible

for all field activities, as well as for all work related to the processing and development of regulatory actions. Prior to the reorganization, responsibility for field operations was in one unit while responsibility for managing regulatory actions, such as seizures, injunctions and prosecutions, was in another unit, making coordination of these important activities difficult.

(6) The reorganization facilitates the utilization of assistance from sources outside FDA. This is accomplished by the creation of a National Advisory Council to FDA. The council will permit FDA to establish a closer relationship with any outside groups and persons having special interests in FDA and knowledge and experience of value to FDA. The reorganization also establishes in the Office of the Commissioner the position of Special Assistant to the Commissioner for the National Advisory Council who will serve as liaison between the Council and FDA and supervise committee activities formally.

(7) It establishes a more effective means of processing proposals submitted by industry for new drugs; investigational drugs; pesticide, food additive and color additive tolerances; and for food standards. This is accomplished by consolidating into one new bureau all responsibilities and operations required in the processing of industry proposals.

With five month's experience under the reorganization, we are very pleased with the small number of "bugs" that have become evident. We are convinced that our rather extensive study and exploration of alternatives prior to making the move was well worthwhile and that we now have a basic structure on which to build for better and more efficient consumer protection for many years.

International Food Standards

When Mr. Depew invited me to appear on today's program, he stressed the fact that the theme of your seminar would be "Food on the Move," and that my experience with the Joint Food Agriculture Organization/World Health Organization Codex Alimentarius Commission might be particularly appropriate. It is not modesty alone which dictated that I conclude with such a discussion, but because it seems most fitting, in view of the speakers who will follow, that I close on such an international theme.

Those of you who have followed to any degree the formulation of a food standard for just one country, as for instance the ice cream or fruit juice standard in the United States, will appreciate the feeling

of trepidation which I experienced by being asked to serve as the United States delegate to the Joint FAO/WHO Conference on Worldwide Food Standards held in Geneva in October, 1962. This session was attended by food expert representatives from 44 countries and with observers from 24 international organizations including Franklin Depew himself, who rendered outstanding support to the United States Delegation as the representative of the Food Law Institute. The session recommended, at the operating level, a Codex Alimentarius Commission, which at its first meeting in Rome from June 25 to July 3 of last year became a going concern. I was again privileged to represent the United States Government as its principal delegate. A good attendance was present with 120 representatives from 30 countries and observers from 16 international organizations. Again, the delegation from the United States was backstopped by industry—Frank Depew doing double duty as President of the Food Law Institute and Vice President of the Inter-American Bar Association. The Commission honored the United States and me by electing me as their Chairman for a two-year period, clearly a recognition of the leadership position of the United States and not necessarily reflecting any particular ability of mine.

The objectives of the Codex Alimentarius Commission are to establish food standards which will serve as a sound basis for international trade and aid in eliminating trade barriers set up in the guise of "standards." The Commission will attempt to simplify and harmonize international food standards work by allocating priorities; will coordinate and supplement the work of other bodies in this field; and will provide for finalization of draft standards at the government level and their publication in a consolidated Codex Alimentarius. The principle was firmly established at Rome, not without some dissension it is true, that the food standards developed by the Commission would be truly international, and only in those instances where no alternative is available (such as highly perishable products) should standards be on a regional basis. The FAO/WHO Joint Conference recommended that the Codex should, in time, include all of the principal foods of the world, whether processed, semi-processed or raw, for direct sale to the consumer or, where appropriate, for manufacturing purposes. The need for special attention to pesticides and food additives was particularly pointed out as was the need for basic food hygiene even though we must be prepared to show patience in some geographical areas with accepted sanitation practices. Thus, Codex standards will be of familiar types—standards

of identity, quality, fill of container; limitations of additives; and standards of cleanliness.

In view of the fact that a great many organizations, committees and groups are already engaged in the elaboration of international food standards, one problem of the Commission will be to become accepted by these diverse groups as the point of guidance and coordination and hence most efficiently harvest the tremendous expertise in this field.

In planning work for the immediate future, the Commission saw the need for several expert committees to develop or coordinate subject matter and to draft standards in areas where there was not now a body in existence. Eleven such committees were formulated, each under the leadership of a member country. The United States is privileged to have the responsibility for the Committees on Food Hygiene and for Processed Fruits and Vegetables. Recent meetings of these expert committees have been held and we believe definite headway has been made.

International food standards are not going to be completed in a year or two, nor will we ever have a complete set of standards which will be accepted by all the nations of the world. This Utopian result is actually not necessary for the fruits of our work to benefit consumers of all nations. It is important to recognize that every member nation retains its own sovereignty and final codex standards are accepted or rejected by each country as it sees fit.

I have endeavored to touch upon the recent developments which to me seem appropriate to an up-to-date discussion. Your questions may relate to matters either new or old. We believe that the principles on which we are proceeding are sound and the results that will be obtained will slowly but surely improve "food on the move" as it is shipped between nations in our ever-shrinking world. [The End]

BILL ALLOWING NONNUTRITIVES IN CANDY CLEARS HOUSE GROUP

The use of nonnutritive substances in confectionery would be permitted under a bill (H. R. 4731) approved by the House Committee on Interstate and Foreign Commerce. The committee said that the present Section 402(d) of the Federal Food, Drug, and Cosmetic Act discriminates against the candy industry by prohibiting the use of substances which may be used in all other foods. The food additives section of the Act is adequate to insure the use of only safe substances, the committee said. Furthermore, it expressed the opinion that any requirement which would restrict the use of nonnutritive substances to only those that have technological value would also be discriminatory.

The Pesticide Chemicals Amendment of 1954

By J. KENNETH KIRK

The Author, Assistant Commissioner, Food and Drug Administration, Department of Health, Education and Welfare, Made This Statement Before the Agriculture Committee of the United States House of Representatives, on May 26, 1964.

THE TERMS of the Federal Food, Drug and Cosmetic Act do not deal with the marketing or labeling of pesticides. However, the Pesticide Chemicals Amendment, as enacted in 1954 and subsequently amended, represents an important part of this statute. Under this amendment any interstate shipment of a raw agricultural commodity is deemed to be adulterated, and thus contraband, if it bears or contains a residue of a pesticide chemical which is not within a safe legal tolerance as established by the Secretary of Health, Education and Welfare, or which has not been exempted from the requirement of a tolerance by regulation.

Procedure for Establishing Pesticide Tolerances

The law provides a very good system whereby tolerances may be established on petition of interested parties or on the initiative of the Secretary. The procedure calls for the submission of a petition which contains full information, including the chemical, pharmacological, nutritional, microbiological and other data about the pesticide and such residues as may remain from the use of the pesticide. These residues may be the chemical itself or may be other compounds which are formed after the pesticide has been used. When such a petition is received it is first considered by the Department of Agriculture and no action is taken by the FDA until the Secretary of Agriculture has certified that the pesticide is useful in agriculture and that the residues shown to be present as a result of the proposed use of the pesticide would be within the requested tolerance.

Once this certification is received, and assuming the petition appears to be complete, a notice of the proposal is published in the

Federal Register, along with a reference to the method of analysis which the petitioner proposes be used for enforcement of the tolerance proposed.

The next step is for the scientists of FDA to review all facets of the petition and usually to conduct trials of the analytical method submitted to determine whether it is a practical and accurate one. Assuming the provisions of the statute are met and a determination of safety of the proposed residue tolerance is established, the next step is for the publication in the *Federal Register* of the order establishing the tolerance which is based on the results of feeding studies on at least two species of animals, with a very substantial safety factor, usually at least 100 to one. Research is continuing to try to find even better ways to do this testing work. The tolerance may not be set higher than is needed. The law provides that if a finite tolerance cannot be established as safe, a tolerance of zero shall be set.

There is a provision whereby objections to these tolerances, whether they be zero or higher, may be filed and safeguards are set up for the consideration of our decisions in public hearings, by special scientific committees nominated by the National Academy of Sciences and, ultimately, appeal to the courts.

"Total Diet" Studies

Once a tolerance is established it is not considered as a closed matter, but rather is subject to continued re-evaluation as science progresses. There are procedures in the law whereby we can revise tolerances, even to zero, where we believe the facts justify such a course. Additionally, we conduct studies on the residues present in or on foods as prepared for the table. These "total diet" studies have shown very small residues of pesticides. These studies, which are most reassuring, are being continued and expanded.

So far, of the several hundred pesticide chemicals used in agriculture, we have established tolerances or exemptions from tolerances for over 125 of these covering some 2,500 crop items.

Concept of Zero Tolerance

Where a pesticide is used on the basis that there will be no residue in or on a crop, there is no requirement that any tolerance be established, but in the absence of a finite tolerance, there is an automatic zero tolerance. For example, no finite tolerances for pesticides

have been established in milk. Thus, the tolerance for residues in milk is zero.

This concept of a zero tolerance presents a real problem in that proof that no residue is present depends upon the sensitivity of the method used by the chemist. As science progresses, methods are improved and there is always the concern that a product showing no residue today may be found to contain a residue by a new method. Because of the problem here, the Secretary of Health, Education and Welfare and the Secretary of Agriculture have joined in a request to the National Academy of Sciences that a committee of distinguished scientists be established to review this whole "zero" and "no-residue" problem. The Academy has agreed to undertake this study and has indicated that we should have the recommendations of the committee by the end of 1964.

Additionally, this year the Secretaries of Health, Education and Welfare, Agriculture and Interior have signed an agreement to deal, among other things, with the pesticides proposed for marketing on the basis that their use will result in no residue. Briefly, this provides, as far as FDA is concerned, for us to be sure that the other two Departments are fully informed about any proposed tolerance or exemption from tolerance, and we have an opportunity to determine whether our scientists believe that there is sufficient data submitted to the Department of Agriculture to conclude that the reasonably expected use of the pesticide will not result in the production of crops which would be in conflict with the Food, Drug and Cosmetic Act.

Essentially this agreement formalizes a procedure which has been followed in some, but not all, cases in the past, and has the added advantage of being sure that up-to-date methodology is taken into account at all times.

The Pesticide Chemicals Amendment does not apply directly to processed foods, but the Food Additives Amendment of 1958 takes over to deal with those items. The procedures here are very much the same as in the case of the Pesticide Chemicals Amendment. Tolerances may be established and published as regulations.

We spend a great deal of time and effort in publicizing the need for using pesticides so that no illegal residues will be encountered. We have worked successfully with many industry groups designed to achieve this objective.

Enforcement Activities

Our enforcement activities with respect to pesticide residues are conducted by our 18 field district offices and laboratories. The first step is to examine spraying and dusting practices in the area to determine whether there may be situations where, either through carelessness or as a result of unusual growing conditions, it appears that pesticides may be used in quantities greater than called for or at times closer to harvest than they should be. We collect and examine many samples, both before and after shipment in interstate commerce, to determine whether illegal residues are present. Taking into account those samples which are collected because of some suspicion of misuse of the pesticide, and those which are collected on a survey basis, our goal for the last two years has been to examine not less than 25,000 samples of raw agricultural commodities each year.

Several years ago, we inaugurated a program whereby the results of these samples are reported to the grower, to the state regulatory officials, and to any other person who may have a legitimate interest in the particular lot sampled. Obviously where such a report shows a violative residue before the crop has been harvested this will often give the grower the opportunity to avoid shipping illegal products. He may be able to correct the situation by letting the crop weather further or, in the case of such an item as lettuce, he may be able to trim the article to get rid of the excess residue.

We have encouraged state officials and industry groups to conduct this type of preharvest testing, and in some areas this has worked extremely well in preventing the marketing of illegal crops.

Where we find interstate shipments which are over the tolerance or which contain residues of pesticides for which no finite tolerances have been established, the law provides for removal of the shipments from the market by seizure. Such actions are taken through the federal district courts. There is provision in the law also for the institution of criminal proceedings against those responsible for shipment of illegal products and additionally an injunction may be invoked to prevent shipments of known violative materials.

For fiscal year 1963, we examined 29,244 domestic and 832 import samples for the presence of pesticide residues, and found illegal residues in 2.1 per cent of the domestic and 0.1 per cent of the import samples. Forty-two seizure actions were instituted.

For the first six months of fiscal year 1964, we examined 17,123 domestic and 360 import samples. 2.9 per cent of the domestic and 1.9 per cent of the import samples contained illegal residues. So far in fiscal year 1964 we have instituted 32 seizure actions.

We regard this pesticide program as one of our most important operations designed to protect the public health. With only tolerances which are safe, plus a firm checking and enforcement program, we are convinced that pesticides can be used safely without resulting in a hazardous food supply. **[The End]**

BILL TO EXTEND TIME FOR TESTING OF FOOD ADDITIVES INTRODUCED

Senators Humphrey and McCarthy have introduced a bill (S. 2977) which would give the Secretary of Health, Education, and Welfare the authority to provide for the continued use of food additives until December 31, 1965; present food additive extensions have been granted only through June 30, 1964. The bill has been referred to the Committee on Labor and Public Welfare.

The bill, however, requires the Secretary, before granting additional extensions, to again make the findings that a good faith action leading to a determination of the safety of the additive was begun before March 6, 1960 and was thereafter pursued with reasonable diligence, that extensions are necessary to complete those investigations, that an extension will involve no undue risk to the public health, and that conditions exist which necessitate the prescribing of an extension.

The bill also provides for extensions for those substances which were classified as "pesticide chemicals" by the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959.

Secretary Celebrazze noted, in a letter to Senator Humphrey, that "[w]hile it has been possible for both the industries concerned and this Department to complete the work involved on most of the 3,000 extensions, there are still some 250 uses of food additives and pesticide chemicals on which we are not yet prepared to take final action. The problems on most of these will be resolved within the next 6 to 12 months. However, there are a few cases in which scientific work now in progress could not be completed and evaluated by us within 1 year. In our opinion, the cases pending can be resolved finally within 18 months if pursued with diligence and the expiration date stated in the bill should therefore be December 31, 1965."—FOOD DRUG COSMETIC LAW REPORTS ¶ 60,072.

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