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Food Drug Cosmetic Law JOURNAL

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

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Pesticide Residues—Legal Aspects.—*Charles M. Fistere,* the author of this article which begins on page 684, suggests a re-evaluation in all aspects of the pesticide amendment, Sec. 408 of the Food, Drug and Cosmetic Act. He discusses the problems the amendment brings to the proponents of new pesticides and, especially, to the dairy industry. Mr. Fistere then goes on to deal briefly with the subject of zero tolerance and concludes that not only is he convinced that the zero tolerance can and should be abandoned, but that safe finite tolerances can be established as needed to protect the public health.

Latin-American Food Code.—Chapters I-V, XII, XIII and XVII of the *Latin-American Food Code* appeared in previous issues of this Journal. The translation is done by *Ann M. Wolf* of New York. Chapter X, dealing with sugar and sugar-containing foods, begins on page 695. Definitions, regulations, ingredients and types of sugar and sugar foods, including honey and honey derivatives, and confectionery, are discussed.

Remarks at the Dedication of the FDA Building.—This article, presented by *John W. Gardner* at the dedication of the Food and Drug Administration building in Washington, D. C., outlines the work, the growth and the many achievements of the FDA. Beginning on page 711 the author relates the importance of the FDA to the American public. Its task is to protect the public from contamination, fraud, impurity and hazards in the food and drug products which are necessary to our lives. But, Mr. Gardner points out, this task is not only the responsibility of the FDA—it is also the responsibility of the consumer, the farmer, the druggist and the doctor. The protection of the public calls for a vast collaborative effort.

The FDA and Food Safety.—*Bert J. Vos,* the author of this article beginning on page 715, discusses the historical aspects and the current methods of operation of the Food and Drug Administration in the area of food safety. The agency is not only concerned with a safe food supply but also of one sufficient to feed the population of the world. Mr. Vos goes on to discuss the safety requirements of food additives, pesticides and color additives, and the necessity of voluntary compliance on the part of industries regulated by the FDA.

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Food·Drug·Cosmetic Law
Journal

Pesticide Residues—Legal Aspects

By CHARLES M. FISTERE

The following article was presented before the 60th Annual Meeting of the American Dairy Science Association, Lexington, Kentucky, June 23, 1965. Mr. Fistere is a member of Fistere and Habberton, Washington, D. C., and is General Counsel, Dairy Industry Committee.

THE PESTICIDE AMENDMENT from the point of view of a lawyer attempting to make an academic analysis, has its weaknesses and its strengths. By and large it has served a useful purpose. However, when we consider the rapidity with which scientific knowledge has advanced since the early 1950's, it is not unreasonable to suggest re-evaluation of the amendment in any of its aspects, legal, scientific, or practical.

We can begin by looking at the amendment itself from the point of view of the proponent of a new pesticide who wishes to market it for agricultural use. In reviewing the pesticide amendment, which is Sec. 408 of the Food, Drug and Cosmetic Act,[1] the first provision you encounter is the statutory condemnation as unsafe, of any pesticide chemical which is not generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety. This is strong language but not bad law. Its purpose was to force a pharmacological review of each new pesticide prior to its marketing and use in the production of crops for food or feed. Thus, regardless of the fact that "New Pesticide X" may in fact be less toxic and more

[1] Food Drug Cosmetic Law Reporter ¶ 54-101 and following.

effective than any which we know now, it is by statute condemned as unsafe in any amount in food. Subjected to the usual tests of logic and common sense, I doubt that any of you would disagree that this is a reasonable approach in dealing with substances which are ordinarily of high toxicity and intended to kill pests.

Problems of A New Pesticide Proponent

The first problem for the proponent of a new pesticide which has now been pharmacologically studied is to escape the statutory condemnation. This requires an action by the Secretary of Health, Education and Welfare, who has delegated the function to the Commissioner of Foods and Drugs. The new pesticide must become the subject of a regulation either establishing a tolerance for the pesticide on one or more raw agricultural commodities or providing an exemption from the requirement of a tolerance. I need hardly mention that milk has been denominated as a raw agricultural commodity. I might add parenthetically that a pesticide residue in a manufactured dairy product comes within the definition of a food additive, and accordingly would be the subject of a food additive regulation. In the application of the amendment, the Food and Drug Administration (FDA) has taken the position that unless one of the two escapes mentioned, tolerance or exemption from tolerance has been elected, the tolerance is automatically zero. In other words the statutory condemnation is in effect exactly as the law provides. As you well know there are no tolerances nor exemptions from tolerance for pesticides in milk or dairy products. Thus dairy products containing residue in any amount are defined by statute as unsafe and therefore adulterated.

Deputy Commissioner Harvey [2] in an address before the annual meeting of the American Dry Milk Institute in April of this year put it in the following words:

> To take care of the appeal rights of a petitioner, the concept of zero tolerance was introduced into the 1954 law whereby if we did not conclude that the evidence justified a finite tolerance we would establish one at zero. Under other provisions of the statute, a raw agricultural commodity bearing or containing a pesticide residue for which there was no finite tolerance or exemption from a tolerance by regulation would call for an automatic zero tolerance.

I believe that this automatic zero position overlooks the statutory requirement that the Commissioner shall establish tolerances by regulation, either upon petition of a registrant of an economic poison

[2] John L. Harvey, Deputy Commissioner of Food and Drugs, Food and Drug Administration.

with the Department of Agriculture (USDA) or upon the request of an interested person or upon his own initiative.

Next the amendment proceeds to place a rather substantial burden on the Secretary of Health, Education and Welfare by requiring that he do one of two things. His alternatives are as follows:

(1) *"To the extent necessary to protect the public health,"* and I should like to underscore those words, the Secretary shall promulgate regulations establishing tolerances with respect to the use on raw agricultural products of pesticide chemicals which are not generally recognized as safe. The reason for underscoring the words "extent necessary to protect the public health" is to accent the fact that aesthetic considerations are not to be taken into account.

(2) When such tolerance is not necessary to protect the public health, the Secretary shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities.

Some of you who are acquainted in detail with the sections of the amendment to which I refer, may at this point suggest that this is an over-simplification since the reference to zero tolerance has been passed by. May I say I will return shortly to that subject.

In paragraph (d) of the amendment an opportunity is also offered whereby any person who has registered or submitted an application for registry of a pesticide with the USDA, may submit certain information to the Secretary and propose that a regulation issue establishing a tolerance or exempting the pesticide chemical from the requirement of a tolerance.

At this point I may observe that it is difficult to decide whose obligation comes first, that of the Secretary or that of the proponent of the pesticide chemical. Logic would suggest that in the case of a new pesticide as yet unknown to the Secretary the proponent would have the obligation of proposing that a regulation issue. For a pesticide which is well known in government, industry, and agriculture it could well be that the obligation falls upon the Secretary to promulgate regulations establishing such tolerances as are necessary for the protection of the public health or conversely to exempt from the necessity of tolerance when such tolerance is not necessary to protect the public health. This would be especially true where residues are unintentionally and unavoidably present, as in the case of milk. The use of the word "shall" ordinarily imposes an obligation while the use of the word "may" indicates an optional course of action.

Our would-be proponent of a new pesticide next finds in the amendment more detail as to the mechanics of the preparation of his petition, the manner of processing by the Secretary, rights of review and appeal and the confidentiality of his petition.

Section (e) provides information as to the procedures by which the Secretary shall promulgate regulations. This prescribes the publication of a proposal and other details relevant to the ultimate promulgation of a regulation. The section authorizes the Secretary to propose a regulation at any time on his own initiative. Thus the way is clear for the Secretary to discharge the obligation which requires that he promulgate regulations to the extent necessary to protect the public health. Also, Section (e) provides that the Secretary may propose a regulation at any time on the request of any interested party. Presumably this could be any citizen concerned with the protection of the public health. We note that there is no burden upon the interested party to supply the detailed information for a petition as required by the proponent of a pesticide under Section (d). It is under Section (e) that the Departments of Public Health and Agriculture of the State of California are proceeding in requesting a tolerance for DDT and its analogs in milk.[3]

To return to the subject of tolerance, the charge to the Secretary to establish tolerances by regulation to the extent necessary to protect the public health includes a statement with respect to zero tolerance. I quote:

> In carrying out the provisions of this section relating to the establishment of tolerances, the Secretary may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Secretary does not justify the establishment of a greater tolerance.

Significant is the fact that this is an optional course of action as is clearly indicated by the words, "the Secretary may." A consultation of the pesticide regulations will indicate that some zero tolerances have been established—this is especially true of dairy cattle feed. By regulation zero tolerance for milk has been established for methoxychlor and toxaphene. No tolerances, zero or finite, have been established *by regulation* for the prevalent chlorinated hydrocarbons found in milk. FDA takes the position there must be an absence of residue in milk if neither of the two escapes previously mentioned has been elected.

[3] Notice of this proposal has since been published in the Federal Register of November 16, 1965, p. 14328, [30 F. R. 14328.]

Zero Tolerance

Though I believe the subject of the zero tolerance provides an opportunity for a rather interesting academic discussion, we do not have the time for it now and I will touch upon the subject very briefly. One further reason for not dwelling on the subject of zero tolerance at this time is the soon-expected release of a report of the so-called Jensen Committee of the National Academy [4] which was created to study and make recommendations concerning the zero tolerance concept as a result of the report of President Kennedy's Weisner Committee which reported on the pesticide problem in 1962. The problem was not grievous in the 1950's at the time the amendment was passed for the reason that analytical methods were then relatively crude. Later in that decade came the breakthrough with which you are much more familiar than I am. Instead of parts per million the physical chemist or analytical chemist now a physicist began to talk in terms of parts per billion and parts per trillion. There are whole batteries of electronic instruments now in the laboratory that didn't exist ten years ago.

Turning now to the modus operandi employed by the FDA, the Dairy Industry Committee on October 11, 1963 was advised pursuant to a previous understanding, that the methodology for pesticides in milk had been improved to the extent that the levels which could be detected with confidence had been reduced. For DDT, for example, from 2.5 ppm (fat basis) to 1.25 ppm (fat basis). At that moment this change did not particularly alarm me as a lawyer but it came as a bombshell to our Technical Advisory Committee of scientists whose techniques had already passed that point of sensitivity. It had become apparent to them that there was no real scientific reason why a further announcement of more sensitive methods could not follow very shortly if the rule for milk were to remain an absolute absence of residue. With further progress in analytical techniques it was inevitable that an ubiquitous pesticide such as DDT could be detected in all dairy products and there would be no legal dairy food on the market. The dairy industry is particularly vulnerable since the phenomenon of wind drift brings minute quantities of pesticide from field to field and from farm to farm. I fear that the forward progress of science is inevitable and analytical methods will become more and more sensitive.

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[4] See 20 Food Drug Cosmetic Law Journal 608 (November 1965).

The question arises—what solutions might there be? The solution which has been most commonly voiced in dairy circles has been that of finite tolerances for milk and dairy products. This has the advantage that once a finite tolerance has been established, the progress in analytical methods could go on its way ad infinitum with no legal problems arising by virtue of such progress. The Dairy Industry Committee favors the establishment of finite tolerances.

Another solution which has its proponents is that of retaining the zero tolerance and relating it to a method of known sensitivity. Regulations could be promulgated establishing a tolerance of zero by the method of John Doe, quoting the appropriate reference in a scientific journal. To some, this has its advantage in the area of public relations since the public image of zero pesticides in certain foods is preserved. The approach was used in the food additive regulation dealing with diethyl stilbestrol in animal feed. The order provides that no residue (ordinarily understood by the public as zero) shall be present in the edible portion of the animal as determined by the method of examination prescribed in the regulation. To me it seems that the application of this approach must lead to embarrassment. Sooner or later the analytical method becomes obsolete and is no longer used by any analyst except the government chemist who is required to do so by the regulation. Either that, or the more sensitive Richard Roe method replaces the John Doe method in the regulation.

To this point no useful application has been suggested for the zero tolerance. To me the zero tolerance with its statutory condemnation of any amount is a concept which has no utility and should be abandoned. As an exception to this rule it might be invoked as a means of statutory prohibition of some particularly dangerous chemical. Should a decision be reached that it is in the public interest to outlaw a pesticide from any use on crops producing food, fiber, timber, or on weeds, soil or animals, the zero tolerance on raw agricultural commodities might be considered. In that situation any amount regardless of whether or not it had any unsafe effect on man would be cause for condemnation of the affected article. As a practical matter the imposition of a zero tolerance even with current analytical methods may have a drastic effect particularly on an industry as vulnerable as the dairy industry.

Two of the subjects to which I have referred, the absence of useful applications for the zero tolerance and the advantages of a finite tolerance have their origins in the premise that for any substance there is a safe amount. This is in contrast to the concept that certain

pesticides are by their character alone, poisonous or deleterious. If we accept this latter view, it follows that we should tolerate none or zero of those pesticides. The other theory suggests that there is a safe amount of every substance and hence finite tolerances are in concord with the concept of safety. I should hasten to add that this theory proposes that there is also an unsafe amount for every substance. All things are poisonous yet all things are safe. Human experience with arsenic and other highly toxic substances attests the verity of this proposition. The crux of the situation is the amount you choose to talk about.

Lexington Mill & Elevator Co. Decision

Fortunately there is for the attorney some legal precedent in experience under food and drug law. Many years ago under the 1906 Act the government brought a seizure action against 600 bags of flour produced by Lexington Mill and Elevator Co. The flour had been bleached with nitrogen peroxide gas and the charge was made that the flour had been adulterated with a poisonous or deleterious substance, oxides of nitrogen. The firm contested this case contending that such traces of oxides of nitrogen as were residual in the product were safe by all possible criteria and the product was not adulterated within the meaning of the law. In a decision rendered by the Supreme Court the claimant was upheld.[5] The opinion makes very clear that substances are not inherently poisonous or safe, and safety must be evaluated in reference to the amount which is present and likely to be ingested. As a matter of law, logic, and science I believe we must conclude that for all substances there is a safe amount and conversely for all substances there is a poisonous or deleterious amount. No substance is inherently a poison and no substance is entirely innocuous.

To return to the subject of finite tolerances we can go back to the text of the amendment Sec. 408 (b) which prescribes the considerations to be taken into account when tolerances are established. To quote:

> In establishing any such regulation the Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certificate of usefulness under subsection (1) of this section.

[5] *United States v. Lexington Mill & Elevator Co.*, 232 U. S. 399 (1914).

Of these three requirements it will be my purpose to consider only the second. Since I have chosen to reject the concept of per se poisonous or deleterious substances I must reject the manner of use of the words, poisonous or deleterious in the text. It would be preferable to substitute some other language for example, "other related substances that may be present in amounts sufficient to be poisonous or deleterious." If more than lip service is to be given to the necessity for the production of an adequate, wholesome, and economical food supply, and particularly milk, the zero concept must be abandoned in light of the ubiguity of DDT.

Pesticides—A National Concern

Looking at the whole problem of pesticides as a matter of national concern we have an area with legal and scientific aspects colored with moral, ethical, and emotional considerations. There is much merit in the contention that we should reduce residual pesticides in food to the extent possible, even well below the level at which it must be deemed unsafe and removed from the market by government seizure. Regardless of what the tolerance is that divides the safe amount from that which must be deemed unsafe, those who produce, process and distribute food have an obligation to use the least effective amount. There would seem to be little incentive to do otherwise. The minimal optimum use of pesticides is an area of great challenge to agriculture and to the USDA which registers labels providing directions for use and publishes instructions for grower application of pesticides. In this push-button age where much of our food comes ready to eat or ready to cook, the food industries have an obligation to handle and prepare the raw agricultural commodity in such a way as to minimize pesticide carryover to the finished food. Even the housewife has an obligation to wash, peel and clean raw fruits and vegetables and to use pesticides prudently in her home to further minimize the domestic contribution to the total pesticide impact on the human. The search for less toxic but more effective pesticides and the search for more rapidly degradeable pesticides presents a challenge to the industry and research scientist that must be encouraged by all possible means.

Augmenting these efforts the law provides that the FDA shall protect the public health by removing from the channels of interstate commerce those articles which in fact must be deemed adulterated and unsafe. There is no provision in the law for statutory condemnation of an article bearing or containing more of a residue than is required

to produce it. However, the determination of the amount above which the article must be deemed harmful or unsafe, in the ordinary meaning of those words, while complex, is reasonable and logical. As we have observed, Sec. 408 provides rules for establishing tolerances which require that not only the amount on the article itself be considered but the sum and total of all other ways in which the consumer is being concurrently affected by the same pesticide and by other chemically and pharmacologically related substances. It would be reasonable to expect that the protection of the public health requires that there be a tolerance for pesticides in milk. It is also reasonable to expect that the tolerance in milk with its high per capita consumption should be lower than that for raw agricultural commodities consumed in relatively small amounts. The *Lexington Mill & Elevator Co.* decision provides an opinion which, while rejecting the per se concept of poisonous and deleterious substances, does recognize that in determining the point at which an article of food may be injurious to health, discreet segments of the population may be considered, "the strong and the weak, the old and the young, the well and the sick." The pharmacological decisions that must be made as to the point at which we divide between that which may be safely consumed and that which must be deemed unsafe is indeed complex and requires knowledge from many sciences. In the forefront of these are the chemists who must provide factual information as to the amounts of pesticides impacting on the consumer from his total environment. Since both the usage of pesticides and the food consumption habits of the nation are subject to change, this is a never ending task comparable in all likelihood to the watchfulness being maintained over radioactive isotopes. Nevertheless, I am convinced not only that the zero tolerance can and should be abandoned but that safe finite tolerances can be established as needed to protect the public health.

A Dairyman's Dilemma

The dairy farmer whose milk contains pesticide residues in amounts deemed by the government to require regulatory action finds himself in a serious dilemma.

If he ships the milk in commerce, he is committing an act prohibited by Section 301 (a) of the Federal Food, Drug and Cosmetic Act —the introduction, or delivery for introduction, into interstate commerce of a food that is adulterated. For this, under Section 303 of the Act, he may be prosecuted, and under Section 304 of the Act the milk is subject to seizure.

If he doesn't ship the milk, and destroys it, by reason of the government's having imposed a ban, he stands to sustain a severe financial loss unless and until the ban is lifted.

But the dairyman is not completely without recourse, although the action he might take to avoid prosecution is more theoretical than practical. But let us first consider the matter of possible prosecution.

As to this, the Federal Food, Drug and Cosmetic Act itself points the way. Section 303 (c) provides that no person shall be subject to prosecution for shipping adulterated food

> . . . if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person . . . from whom he received in good faith the article, to the effect . . . that such article is not adulterated or misbranded, within the meaning of this Act . . .

In the case of the dairy farmer, the "article" referred to would of course be the feeds that contained the offending pesticide residues.

The regulations promulgated under Section 303 provide that the guaranty referred to may be limited to a specific shipment or may be general and continuing, and these regulations set forth suggested forms to be used.

It is probably unnecessary to point out that this kind of relief, if the farmer could secure it, is available to the dairy farmer only with reference to the feeds he buys from others. As to the feeds he himself has raised, he is obviously on his own. As long as the government insists on a zero tolerance for residues on feed for dairy cattle, the farmer is not likely to be able to secure a warranty from his feed supplier.

Let us turn now to the situation in which the dairy farmer is prevented, by government intervention, from shipping his milk and is compelled to dump it. There have been several widely publicized instances of such occurrences.

Relief is provided here, on a temporary basis, in the form of indemnity payments to the farmer by the federal government. This is one of numerous programs authorized by the Economic Opportunity Act of 1964 (generally known as the "Anti-Poverty Act"), which was enacted by the 88th Congress as Public Law 452 and approved by the President August 20, 1964. The program for "Indemnity Payments" to Dairy Farmers is set out in Section 331 of the act.

Section 331, which is quite brief, reads as follows:

> Sec. 331. (a) The Secretary of Agriculture is authorized to make indemnity payments, at a fair market value, to dairy farmers who have been directed since January 1, 1964, to remove their milk from commercial markets because it contained residues of chemicals registered and approved for use by the Federal

Government at the time of such use. Such indemnity payments shall continue to each dairy farmer until he has been reinstated and is again allowed to dispose of his milk on commercial markets.

(b) There is hereby authorized to be appropriated such sums as may be necessary to carry out the purposes of this Act.

(c) The authority granted under this section shall expire on January 31, 1965.

The rationale of this program of indemnification is found in the fact that the residues in question must be "residues of chemicals registered and approved for use by the federal government" at the time of such use. In other words, it would be manifestly unfair to penalize the dairy farmer for doing something which was lawful at the time it was done. Pursuant to authorization, the sum of $8,800,000 was appropriated to carry out the purposes of the program.

I have said that the situation under consideration is that in which the dairy farmer is prevented from shipping his milk by *government intervention*. Actually, the situation is somewhat broader than this. The law itself refers to "dairy farmers who have been *directed* . . . to remove their milk from commercial markets" (emphasis supplied). And in the Secretary's regulations published in the Federal Register of October 31, 1964, he elaborated this language by defining the term "eligible farmer" as follows:

'Eligible farmer' means a person who produces milk which is removed from the commercial market any time from January 1, 1964, to January 15, 1965, pursuant to direction of a public agency or a milk handler because of detection of pesticide residue in such milk by tests made by a public agency or under a milk testing program deemed adequate for the purpose by a public agency.

Another important definition contained in the Secretary's regulations is that for the phrase "Removal from the commercial market." This is as follows:

'Removed from the commercial market' means milk or butterfat (1) produced and destroyed or fed to livestock, or (2) produced and delivered to a handler who destroyed it or disposed of it on a salvage basis (such as separating it, destroying the fat, and drying the skim milk), or (3) produced and diverted to other than the commercial market.

The program has subsequently been extended for a period of five months. Under the Second Supplemental Appropriation Act for 1965, the concluding date was changed from January 31, 1965, to June 30, 1965. And under new regulations published in the Federal Register of June 5, 1965, the Secretary has extended the date by which applications must be filed to August 31, 1965.

I am advised that as of this time, approximately three hundred indemnity payments have been made in the aggregate sum of approximately $280,000. These figures, which are lower than had been anticipated, reflect an improving technological experience. **[The End]**

Latin-American Food Code 1964 Edition

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

Chapter X: Sugar and Sugar-Containing Foods

Natural Sugars

Article 329—Natural sugars are sugars found in nature, especially in the vegetables used in the diet. The principal natural sugars are sucrose, dextrose, levulose, invert sugar, lactose and maltose. Several of these sugars are extracted from vegetables or animal products containing them; others are prepared by hydrolizing starchy substances of vegetable origin. They are organic bodies which possess various alcohol radicals with an aldehyde, acetone or ether-oxide radical.

The term "sugars," as used in this Code, covers sucrose, dextrose, lactose, invert sugar, syrups from glucose, corn, potatoes and sweet potatoes and the solids of said syrups which meet the requirements established herein.

Article 330—The plants at which sugars and by-products of saccharogenic raw materials are extracted and purified are called "sugar mills" or "refineries." These mills must comply with the general rules and in addition, must be equipped with a conveyor system that carries the raw material to the refining machinery. They must have premises suitable for the preparation, purification, packing and storage of the finished products.

Article 331—The name "sugar," used alone, identifies saccharose or sucrose.

Sugar is extracted from vegetables such as: sugar cane (genus Saccharum and varieties thereof), sugar beets (Beta vulgaris L., a beet variety), sugar sorghum (Sorghum saccharum Pers.), and rock maple (Acer Saccharum).

Article 332—Sugar must be brilliantly white or slightly yellowish white in color; it must be soluble in water, in which it must give a practically clear solution. It may contain not more than 1 percent of glucose or invert sugar and must not contain dextrins, starchy substances or foreign matter. The percentage content of sulphates tolerated is not permitted to exceed 0.03 grams, expressed as sulphur trioxide (SO_3), 0.005 grams of sulphur dioxide (SO_2) and small amounts of calcium sulphate. Ultramarine blue and indanthrene blue may be used in the minimal amounts required for bleaching, and such amounts of tin chloride and phosphoric acid may be added as are strictly necessary to fix the "demerara" color type.[1] Colors authorized by the competent authority may be added to fancy or luxury sugars.

Article 333—Depending upon its appearance, refined sugar is named: "cube sugar" or "tablet sugar"; "loaf sugar" (irregular pieces mixed with the powder resulting from crushing); "crystallized, granulated or coarsely granulated sugar" (crystals of different sizes); "pulverized sugar" (obtained by mechanical trituration of sugar loaves or by impact crystallization). All these refined sugars shall have a sucrose content of not less than 99.8 percent and an ash ratio of not more than 0.3 percent. Confectionery sugar shall have a sucrose content of not less than 98.5 percent. When cube sugar is marketed wrapped, the paper used must be white on the inside; its outside may be colored, provided that the dyes used do not come off and are not toxic.

The name "powder sugar" distinguishes finely pulverized refined sugar. Starch may be added to powder sugar in amounts of up to 3 percent to prevent it from forming lumps with the ambient humidity.

No refined sugar that circulates in commerce may contain non-pathogenic germs in a proportion of more than 100,000 per gram.

Note of the Translator:

[1] The "demerara" color type is a color used in Latin America, which is obtained from a golden colored honey fixed with phosphoric acid and tin chloride.

Article 334—In general, the designation "raw sugar" means unrefined sugar with a sucrose content of not less than 95 percent and an ash ratio of not more than 0.2 percent.

Article 335—The names "yellow sugar," "blond, brown or black sugar," "tapa sugar," [2] "panela," [3] "papelon," [4] "rapadura" and "raspadura" [5] apply to the product generally prepared in small villages by first bleaching the sugar cane juice with lime. then cooking it until it thickens and finally pouring it into cone-shaped or pyramid-shaped wooden moulds, in which it crystallizes and hardens. The resultant loaves, which are usually tied together in pairs, contain sugar and molasses. Average percentage composition: water—7; proteins—0.5; fats—0.5; assimilable carbohydrates—91; crude fiber—0; ash—1.1.

Article 336—The name "chancaca" (raw brown sugar) applies to an unrefined sugar which has the form of tablets or is wrapped in red mace forming the so-called "chancaca" bunches.

Article 337—The name "rock candy" distinguishes sugar obtained by slow crystallization. It comes in bulky crystals formed by transparent, hard rough prisms. It must contain sucrose in a proportion of not less than 99.9 percent.

Article 338—The name "molasses" applies to the thick syrups or liquids which are the residue of sugar manufacture, the sucrose content of which cannot be separated economically. Depending upon its origin, molasses is called: "cane molasses," "beet molasses," etc. Only cane molasses may be used as human and animal food. Molasses shall be sold with a labeling stating their density.

"Cane molasses" (Saccharum officinarum) is a thick, dark liquid with a pleasant odor. Its percentage composition may vary within the following limits: water—17 to 28; sucrose—25 to 40; invert sugar—20 to 40; and ash—4.5 to 8.

"Beet molasses" (Beta vulgaris L.) is a thick, dark liquid, with an unpleasant odor and taste and an alkaline reaction. Its percentage composition may vary within the following limits: water—15 to 28; sucrose—44 to 63; invert sugar—0.05 to 0.50 and ash—5 to 12.

Notes of the Translator:

[2] Term used in Venezuela to designate a dark-brown second grade sugar.

[3] Term used in Columbia to designate refined brown sugar.

[4] Term used in Latin America to designate raw sugar.

[5] Terms used in Cuba to designate loaf sugar.

Article 339—The name "goldensyrup" or "cane syrup" applies to the product prepared from the syrups that form during the crystallization of sugar, to which glucose may be added to prevent the crystallization of the invert sugar, the addition of a permitted color being optional. Its percentage composition must fall within the following limits: water—16 to 25; sucrose—16 to 35; invert sugar—25 to 35; ash—0.2 to 10. These products are prohibited from being designated by names containing the word "honey."

Article 340—Caramelized sugar, burnt sugar, or caramel shall be obtained by the direct action of heat on sucrose, glucose, or other sugars of vegetable origin, which may be neutralized only with alkaline substances whose purity degree makes them suitable for use in foods (hydroxides, carbonates, ammonia). To favor the stability of the products to be colored, a slight alkali excess shall be permitted, which, expressed as sodium hydroxide, may not exceed an amount of 3 grams per kilo.

Article 341—The name "invert sugar" (a mixture of dextrose and levulose) applies to the product obtained by hydrolyzing sucrose. It may be either a thick syrup or a paste; in the first case, it must contain not more than 30 percent of sucrose, and in the second, not more than 5 percent of sucrose.

Article 342—The names "glucose syrup," and "corn, sweet potato or potato syrup" (used according to the origin of the syrup) apply to the concentrated and clarified aqueous solution obtained by incomplete hydrolysis of starch. It must be sold with a declaration of the percentage content of reducing sugar, calculated as dextrose and expressed as dry substance (D.E. = Dextrose Equivalent) which must not be less than 28 percent. The ash ratio may not exceed 1 percent. Any solids obtained by the desiccation of these syrups must also be sold with the declaration of their D.E.

Article 343—The name "dextrose" applies to the solid product obtained by complete hydrolysis of starch, followed by refining and crystallization processes. It must not contain dextrin or starch and must contain not less than 90 percent of dextrose and not more than 9.5 percent of water, 0.60 percent of maltose and 0.25 percent of ash consisting chiefly of sodium chloride. A 50 percent solution in water must be clear and almost colorless.

Ultramarine blue may be added to dextrose in an infinitesimal amount just sufficient to bleach it, and sulphur dioxide (SO_2) may be added in a proportion not exceeding 5 milligrams per 100 grams.

Article 344—The lactose, milk sugar or lactine intended for use in foods (preparation of dietetic products, etc.) must be refined and contain not less than 99.5 percent of lactose (disaccharide). It may come in the form of a mass formed by rhombic prismatic crystals, with hard octahedron facets, or as an odorless white powder with a sweetish taste. It must be completely water-soluble and in water give a solution with a neutral reaction. The total ash ratio shall not exceed 0.1 percent.

Article 345—One sweetener of natural origin is glucoside (Esteroside), which is extracted from the leaves of Stevia rebaudiana Bertoni or sweet herb.

Honey and Honey Derivatives

Article 346—The names "bee's honey," "virgin honey" or simply "honey" may be used only to designate the natural product abstracted by domestic bees (Apis mellifica, Apis ligustica, etc.) from the nectar of flowers and the sugary exudations of plants, and stored by them in combs. Average percentage composition: water —18; protein—0.4; assimilable carbohydrates (invert sugar)—71; ash —0.3; acidity expressed as formic acid—0.10.

The trade in products of bees fed artificially with sweetened substances or other similar substances is prohibited.

Article 347—The names used to distinguish commercial products shall correspond with the following definitions:

1. Comb honey or honey in sections: This term may be used only for honey still in bee-built combs which have never contained brood.

2. Virgin-honey, fluid honey, cell honey: The product which flows spontaneously from honeycombs or cells that have never contained brood and has been extracted by way of mechanical processes (extraction or centrifugation).

3. Raw honey: The natural product as it is extracted from the comb without heat.

4. Extracted honey: Honey extracted from the comb by centrifugal force.

5. Strained honey: Honey obtained by cold straining from combs which have never contained brood.

6. Mucilaginous or gummy honey: Honey obtained by pressure under heat from honeycombs which have never contained brood.[6]

7. Overheated honey: Honey heated to over 70° C. until it loses its fermentative [7] properties.

8. Whipped honey: Honey obtained by heating the combs with the honey still in them.[8]

Honey must meet the following requisites:

9. It must contain not more than 20 percent of water, 0.8 percent of ash, 8 percent of sucrose, 8 percent of dextrins and not more than 0.25 percent of acidity expressed as formic acid.

10. It must not contain pollen, wax or other water-insoluble substances in a proportion exceeding 1 percent calculated on the moisture-free substance.

11. It must have a negative Fiehe reaction, which persists for 24 hours, and the Lund reaction must give a precipitate of at least 0.6 milliliters.

12. It must not contain insect parts, eggs, or other impurities or substances alien to its normal composition, such as natural or artificial sweeteners, aromatics, starch, gelatin, preservatives or colors.

13. It must not be altered, fermented, or caramelized by heat.

Article 348—The names "hydromel" or "mead" apply to the beverage obtained by the alcoholic fermentation of honey diluted in potable water. "Mead" is also the name of the juice obtained by scraping the root of the maguey (Agave americana L.) (See Article 516, par. 7).

The designation "mixed hydromel," or "fruit hydromel," applies to the product obtained by the fermentation of a decoction of diluted honey and hops to which various flavors or fruit juices have been added.

Hyromels artifically carbonated with carbon dioxide shall be named "artificially carbonated hydromel."

In hydromel, the following operations shall be permitted:

1. The addition of citric, lactic or tartaric acid in amounts of up to 250 grams per hectoliter, and the addition of potassium bitartrate in amounts of up to 25 grams per hectoliter.

Notes of the Translator:

[6] In the United States, mucilaginous honey is a natural gummy product and is never obtained by heat treatment of honey.

[7] "Enzymic" may be a better word here.

[8] "Whipped honey" in the United States is solidly crystallized honey that has been whipped up by a mechanical heating process, but not while still in the comb.

2. The use of selected yeasts and the addition of pure crystallized ammonium phosphate and pure bicalcium phosphate in the amounts required for proper fermentation.

3. The use of pure clarifiers, such as: albumin, casein, gelatin, isinglass, and the addition of tannin in the proportion required for clarification.

4. The coloring with caramel and the treatment with sulphur dioxide or pure alkaline bisulfites, provided that the hydromel does not retain sulphur dioxide in a proportion of more than 300 parts per million.

5. The carbonation with carbon dioxide suitable for the use for which it is intended (Article 462).

The following kinds of hydromel shall be considered unsuitable for consumption:

6. Hydromels which have abnormal characteristics or have undergone alterations.

7. Hydromels prepared with sucrose or dextrose solutions or other unauthorized sweeteners.

8. Hydromels prepared from honeys which fail to meet the standards established in this Code.

9. Hydromels the volatile acidity of which, expressed as acetic acid, exceeds 2.5 percent, or hydromels which contain sulphur dioxide in a proportion of more than 300 parts per million.

10. Hydromels which contain prohibited preservatives, colors, or essences, or foreign substances.

Confectionery

Article 349—The name "candy factory" designates any establishment that manufactures candy, chocolate candy and varieties thereof.

All confectionery products may as a rule be prepared with cream of tartar, edible gelatins, pectins, authorized acid substances, sorbic acid and sorbic acid salts in a proportion of not more than 1 gram per mil, essences and permitted colors, without requiring a declaration of these additives in the labeling, provided that no specific regulation to the contrary is established elsewhere herein. The addition of any food product allowed hereunder or authorized by the health authority is likewise permitted.

The following shall be prohibited:

1. The use of tin foil, bronze foil or other foil containing zinc, lead, nickel or antimony, to silver on gild confectionery, tablets,

lozenges, related products and confectionery decorations, which may be metal-coated only with gold leaf, silver leaf or aluminum leaf free from injurious substances.

2. The coating of chocolates, candy, confections etc. with shellac or other resins, and the use of alcohol other than neutral ethyl alcohol, except for "easter eggs" and "chocolate statuettes" which may be coated with varnishes with a base of ethyl alcohol, benzoin, gum Tragacanth and other permitted products.

3. The manufacture, possession or sale of chocolate candy, hard candy, confections and lozenges which contain injurious products, or products the use of which is prohibited.

Confections, chocolate candy, hard candy, lozenges, tablets, jams, fruit pastes or related products which undergo alterations with age are not permitted to be returned to the producer or seller, but must promptly be rendered unusable. Jam factories and warehouses are prohibited from keeping spoiled products for any reason whatsoever; such products must promptly be rendered unusable. The term "spoiled product" means any product which, due to the action of micro-organisms or other causes, has lost its original quality and harmlessness.

Article 350—The names "confectioner's shop" and "pastry shop" designate any place of business at which doughs, desserts, jams, chocolate candy and hard candy are manufactured and/or sold. They usually are parts of other establishments, such as bakeries and cake shops or may be combined with a bar, luncheonette, restaurant, etc.

Article 351—The name "candy shop" applies to places of business specializing in the retail sale of chocolate candy, hard candy, chocolates and related products.

Article 352—The name "candy" designates in general a product of soft, semi-soft or hard consistency, prepared with sugars to which permitted organic acids may have been added and which may contain various substances, natural or synthetic essences, and colors the use of which is permitted.

Article 353—The name "fondant" applies to a sweetened dough used as a base for many types of candy. It is prepared from a base of sugar syrup and water, with or without the addition of cream of tartar in a proportion of 1 per mil. This mixture is heated to the proper consistency, then cooled, stirred and shaped.

The name "fondant candy" applies to candy which has the property of dissolving quickly in the mouth. It is prepared from a base of the aforementioned fondant, to which various permitted flavors and colors are added; the moulded product is usually coated or glazed with sugar syrup or chocolate.

When fondant is used to coat fruit pastes or other pastes, the resultant product is named "stuffed fondant." A mixture of chocolate and fondant is named "chocolate fondant," and when strong coffee is used in the fondant instead of water, the candy is called "coffee fondant."

Article 354—Depending upon its composition, candy is divided into the following classes:

1. "Alfeniques" (sugar pastes): This name applies to candy prepared from a base of sugars, flavored with a natural flavor, to which a permitted color may have been added (See Article 328, paragraph 1).

2. Fruit and chocolate candy: Fruit candy shall be made of sugars, fruits and pectins; chocolate candy of sucrose, glucose, cacao, vanilla and/or cinnamon; permitted colors and essences may be used in both types.

3. Peanut candy (peanut brittle, etc.): This name applies to various kinds of candy prepared with shelled peanuts, sugars, milk and flavors.

4. Candied chestnuts (marrons glacés): This term designates half-cooked, large chestnuts repeatedly dipped into a sugar syrup, the density of which increases with each dipping, and boiled a few minutes while in the most strongly concentrated syrup. They are usually wrapped in silver or gold paper.

5. Fudge: This name applies to a type of candy whose consistency lies between candy and fondant. It is prepared with sugars, milk, butter, cream, chocolate, edible oil and/or fats, albumin or gelatin, pieces of nuts, almonds, etc. and flavored and colored with permitted substances.

6. Mint Wafers: This name distinguishes a candy prepared with sugar, beaten egg white and mint essence or syrup.

7. Nougat: This name applies to a type of torrone that consists of a paste made of sugars, egg white and/or edible albumin, to which almonds, hazelnuts or peanuts have been added; it may be flavored and colored with permitted substances.

8. Nougatines: This name applies to a paste of sugars, honey and almonds, coated with chocolate fondant.

9. Coconut flakes or tablets: These flakes or tablets are prepared with grated coconut, sugars and egg white. Milk candy [9] flakes or tablets are prepared by concentrating milk candy to the point at which, when cooled, it has the proper consistency.

10. Panforte:[10] This name designates a nougat prepared with a base of sugars, honey, roasted almonds, hazelnuts, lemon, chocolate, cinnamon, pepper and semolina.

11. Pralines: This designation applies to candy-sized confections made of pieces of fruits, walnuts, almonds, hazelnuts or peanuts, to which cacao and sugar are added. These components may come in chunks or ground to a paste. The same name designates also the ground and/or refined paste, made of the same components, which is used in the industry to fill or decorate desserts, candy, etc.

Starch or dextrose may be added to pralines in a proportion of up to 5 percent without declaring its presence in the labeling.

12. Egg yolk candy: This kind of candy is prepared by heating a sugar syrup to 103° C. and then adding egg yolks to it. The mixture is cooked, cooled for some time and then shaped into balls, the surface of which is coated with syrup heated to caramel consistency (174° C.). It may also be prepared with a mixture of cooked egg yolk and fine sugar shaped into balls, which are immersed in a sugar syrup heated to caramel consistency and, when taken out of the syrup, are cooled on a greased board. When cold, the balls are wrapped or packed in fancy transparent paper. Chunks of nuts, almonds, etc. are frequently added to this type of candy.

Article 355—The generic denomination "hard candy" ("caramelos") applies to confections made from a paste obtained by cooling a sugar syrup which has been cooked to the proper consistency. Depending upon the products added to it, such candy is named:

1. Sour candy or "alpinos":[11] This kind of candy contains permitted organic acids.

Notes of the Translator:

[9] "Milk candy" ("dulce de leche") is a type of very soft milk caramel popular throughout Latin America. It is made by boiling milk slowly with sugar and is flavored with vanilla.

[10] "Panforte" is the original name of an Italian spice candy (originally from Siena) sold wrapped in hard round loaves and eaten especially at Christmas time.

[11] "Alpinos" are a type of dark-colored hard candy which cause a sensation of freshness because of their menthol content. They are prepared with herb infusions and contain citric acid.

2. Soft candy (toffees): Toffees are prepared generally by adding to the sugar syrup products such as butter or other fats, cream, (whole, condensed or dehydrated) milk, milk candy, egg white, albumin and/or edible gelatin. Vanilla and other flavors and permitted colors may also be added.

3. Fruit candy: Fruit candy contains the permitted natural or synthetic essences of fruits, and authorized colors.

4. Coffee caramels: These are made by preparing strong coffee and adding to it sugars, (whole, condensed, or dehydrated) milk, or milk candy. This mixture is boiled to the desired consistency.

5. Milk or cream caramels: These are prepared with (whole, condensed, or dehydrated) milk, or milk candy, or cream. Usually, pieces of peanuts, walnuts, hazelnuts, almonds, fruits, confections etc. are added to them.

6. Chocolate caramels: These contain grated chocolate or bitter, ground or whole, cacao, in powder or paste form.

7. Soft and liquid centered candy: These kinds of candy have a center of jelly, fruit pulp, milk candy, liqueur, honey, etc.

8. Crunches: This name applies to a candy made with a base of almonds, hazelnuts or peanuts, sugars, lemon juice or lemon essence, citric or tartaric acid, cut into various sizes and shapes, which is used to decorate pastry or is sold in its original form. The same product, cut to size and dipped into chocolate, is called "chocolate crunch."

9. "Chewing gum" or "chicle": This name applies to candy made with a base of properly purified chicle gum (Achras zapota L.), spruce gum (resin of the black spruce—Abies nigra D.C.) or "caspi" milk (obtained by tapping Galactodendron utilisimum), to which sugars, paraffin, white wax, permitted aromatics, tolu or Peru balsam and permitted colors are added in special machines under pressure.

Chewing gum usually contains 22 percent of gum base and 50-60 percent of sugar, the rest being corn syrup, malt, 2 percent of calcium carbonate, and authorized aromatics and colors.

Article 356—To prevent children from committing possibly fatal errors, the preparation, possession and sale of hard candy and chocolate candy shaped like matches or other non-edible articles are prohibited.

Article 357—Hard candy and caramel-coated candy (egg yolk candy, stuffed dates, coconut candy or milk candy, etc.) are affected by humidity and for this reason must be stored in her-

metically sealed jars or containers. It is advisable to place inside such containers a small bag with quicklime, which should be replaced as often as necessary.

Article 358—The name "salted peanut" applies to the roasted peanut, fried in oil or another fat, and salted.

Article 359—The name "burned almonds" applies to whole, peeled or unpeeled, roasted or unroasted almonds, coated with a coarse coat of caramelized sugars of variable thickness. Candy made of other seeds which have undergone the same treatment shall be sold with the proper designation: "burned peanuts," etc.

Article 360—The name "sugar almond" ("peladilla") defines a product prepared with sugar-coated almonds. The same product prepared with peanuts shall be named "sugar peanut" ("peladilla de mani"). To give consistency to the sugar coating, starch or dextrin may be added in a proportion of up to 5 percent, which need not be declared in the labeling.

Article 361—"Confetti"[12] or "dragées" are confections of various sizes and shapes which have a center of sugar paste, pieces of almonds, hazelnuts or peanuts, crunch, fruits or liqueurs, and are coated with a hard sugar coating, to which permitted essences and colors may have been added. The addition of dextrin, starch and/or edible gums is permitted in a proportion not exceeding 5 percent.

Article 362—Lozenges have in general the appearance of variform small troches and may consist of:

a. Pastes containing sugars, flavored distilled waters, natural or synthetic essences and permitted colors.

b. The same as described at a, plus substances such as edible gums and gelatins, licorice and others and starch and/or dextrin in a proportion not exceeding 5 percent. When the basic mucilage is not formed by gums or gelatins, the use of the necessary amount of modified or unmodified starches shall be permitted.

c. Compressed lozenges may contain a binder of stearin, talcum, oil, acacia or another permitted product in amounts not exceeding 3 percent of the total composition.

Note of the Translator:

[12] The Spanish term "confites" used here is obviously derived from the Italian "confetti"—a candy prepared with whole almonds, nuts, etc. and sugar-coated in various pastel colors.

One distinguishes between the following lozenges:

1. Marshmallow lozenges: prepared with sugars, gum Arabic, gelatin and egg white, to which a permitted color may be added.

2. Eucalyptus lozenges: manufactured with edible gums or gelatins, sugars, eucalyptus essence or oil, and a permitted color.

3. Gum lozenges (also called "gum drops"): prepared with gum acacia, sugars, permitted essences and colors. The name "fancy gum lozenges" designates lozenges in which the gum Acacia has been replaced by edible gelatin.

4. Menthol lozenges: must be prepared with gums or edible gelatins, with or without the addition of glycerin or orange blossom water, to which menthol dissolved in rectified ethyl alcohol has been added. A permitted color may be added.

5. Licorice lozenges: prepared in the same manner as gum lozenges, with the addition of at least 4 percent of licorice extract or juice.

6. The name "birthday cake decorations" covers statuettes and sundry decorative confections prepared with a base of sugar, natural essences and permitted colors.

Article 363—The name "marzipan" applies to the product obtained by cooking a mixture of sweet almonds, sugars and lemon peel, or lemon essence, or vanilla. It must contain not more than 20 percent of water and not more than 68 percent of sugars. Hydrocyanic acid may be tolerated in a proportion not exceeding 40 parts per million. When chunks of candied fruit are added, the product shall be named "fruit marzipan." Marzipan may be coated with chocolate or sugar.

Article 364—The name "pepipán" applies to a product obtained by boiling a dough prepared from triturated pips or seeds of various fruits, such as: plums, apricots, peaches, hazelnuts, peanuts, Brazil nuts, etc. and refined sugar and/or dextrose. It may not be flavored with bitter almond oil and may not contain hydrocyanic acid in amounts of more than 40 p.p.m. "Pepipán" comes in two different types: the semi-finished product intended for use by confectionery makers, bakeries, etc., and the product ready for consumption. The first type may contain not more than 40 per cent of total sugars and 14 percent of water. The addition of thickeners is prohibited, but for purposes of identification, it must contain potato starch in an amount of up to 0.5 percent. The term "marzipan" may not under any circumstances be used in the labeling of these products.

Article 365—The name "torrone"[13] ("turron") applies to a mass made with almonds, honey, egg white, albumin, or edible gelatin, to which pinons, hazelnuts, peanuts, walnuts, chestnuts, candied fruit, etc., or sugars are added at times. It must bear the name of the basic product used in its preparation, such as: almond, hazelnut, honey, Brazil nut torrone, etc. Any reference to Alicante and Jijona is prohibited.

The addition to torrones of coloring agents, feculae and starches is prohibited. All torrones, and the pieces in which they are sold (bars, tablets, etc.) must be wrapped in waterproof paper and each piece must be labeled as provided for by the law.

Article 366—The name "Alicante-type torrone" may only be used for torrones prepared with roasted almonds, egg white or edible albumin, honey, and/or sugars. This type of torrone distinguishes itself by its hardness. A torrone of like composition, but soft, containing ground almonds, etc., shall be designated as "Jijona-type torrone." The designations "Alicante" and "Jijona" alone may be used only for the genuine products manufactured in Spain in the cities so named.

The Cadiz, Cremona, French, fruit, egg yolk, provincial and other types of torrone shall be prepared with the raw materials indicated in Article 365 hereof and must be labeled in accordance with the nature of the ingredients used in their manufacture (almonds, hazelnuts, peanuts, etc.).

Article 367—The name "jujube lozenges" applies to small loaves made with the fruit of the jujube tree (Zyzyphus mistol Griseb), which have the consistency of a thick jam.

Article 368—The name "almond paste" applies to the plastic product obtained by cooking peeled triturated sweet and bitter almonds, to which sugars and water have been added. It must contain not more than 14 percent of water and 60 percent of sugar expressed as invert sugar, and the amount of hydrocyanic acid contained in them must not exceed 40 parts per million.

Note of the Translator:

[13] "Torrone" is the Italian name for the type of candy described in this article, which is sold in Latin America also under the Italian designation.

Article 369—The name "fruit stone paste" applies to the plastic product prepared by cooking peeled and triturated stones of one or several of the following fruits: plums, apricots, peaches, etc. with sugar and water.

Fruit stone pastes shall be named after the basic product used in their preparation. They are not permitted to contain hydrocyanic acid. They may contain water in an amount not exceeding 14 percent, and sugar, expressed as dextrose, in an amount not exceeding 40 percent.

Article 370—The name "sugared, candied, iced, frosted or glazed fruits and vegetables" applies to fruits or vegetables in which part of the vegetation water has been replaced by a sugar or honey syrup which by evaporation leaves a coat of sugar crystals on the surface of the fruit or vegetable.

Article 371—The generic name "jam" or "dulce" applies to any preparation obtained by boiling the edible parts of fresh or preserved fruits or vegetables with sugars or honey. When the sweetened solution has the consistency of a thin syrup, the product is a compote. When the consistency of the syrup is thicker, the preparation is designated by the name of the fruit or vegetable with the addition "in syrup" (plums in syrup, pumpkin in syrup, etc.). When the sweetened solution is thoroughly mixed with the fruit, the product is considered a marmalade. When the pieces of fruits or vegetables have been finely triturated, passed through a sieve and cooked to the consistency of a paste, it is called "paste" (quince, guava, fig, banana paste). When the preparation has been obtained by concentrating the juice or the aqueous filtered extract of the fruits or vegetables with sugars (sucrose, glucose) and has a semisolid, gelatinous consistency, the product is named "jelly."

Fruit and vegetable pastes, marmalades and jellies must contain a soluble solid substance of not less than 65 percent by weight, except for sweet potato paste, in which a minimum of 60 percent is permitted. Pressed residues first submitted to distillation or lixiviation and gelatins of animal origin are prohibited from being added to jams or preserves. Fruit pectin may be added, without a special declaration, in the proportion demanded by the nature or type of jam to be produced, and citric, tartaric or gluconic acid may be added in the amount lacking in the fruit, but required to obtain a good jam or to bring the pH to the minimum necessary for the jelling of the pectin (3.4)

or to prevent the corrosion of the tin plate used for the container (plums in syrup, etc.).

To give greater consistency to jams made of sweet potatoes and potatoes, edible gelatins or other authorized products may be added to them without a special declaration. Pumpkin may also be added to such jams in amounts not exceeding 3 percent. Jams made of quince, sweet potatoes and potatoes must be sold in their original containers, which are not permitted to be broken up for retail sales.

The word "mixed" shall be added to the names of jams made of several species of fruits and/or vegetables, without prejudice to the requirement that their components must be declared in the diminishing order of the amounts present.

Article 372—The color of certain jams may be reinforced with authorized colors without a declaration: quinces with nacarat carmine, cherries with erythrosine, etc.

The addition of thickeners to preserves in syrups and to natural peach, pear, plum preserves is prohibited.

Article 373—The name "fancy crystal jelly" or "artificial fruit gelatin" applies to preparations made of edible gelatins, sugars, permitted acids, flavored and colored with permitted products. If the name of a fruit is to be used in the designation of such products, they shall be named: "with red currant," "lemon," etc.

Article 374—The names "instant dessert," "dessert powder," "powder for puddings, custards, creams, etc." (pudding powders) applies to products which, diluted with milk and/or water, permit the quick preparation of desserts, such as puddings, creams, etc. They consist of various thickeners (starches, feculae, gelose, gelatin, alginates, etc.) with natural or artificial aromatics, cacao, fruit extracts, sucrose, dextrose and various products, depending upon their special name, to which citric, tartaric or fumaric acid, polyphosphates, turmeric and other permitted natural or synthetic colors may be added.

Article 375—The name "roselle blossoms" or "karkadé" applies to the dried floral calyz of Hibiscus sabdariffa L. which is used in the preparation of certain jams. Average percentage composition: water—14; protein—6.5; fat—4.5; assimilable carbohydrates—58; crude fiber—6; ash—9; tannin—2.

[End of Chapter X]

Remarks at the Dedication of the FDA Building

By JOHN W. GARDNER

This Article Was Presented at the Dedication of the Food and Drug Administration Building, Washington, D. C., on November 23, 1965. Mr. Gardner Is Secretary of Health, Education and Welfare.

IT GIVES ME A GREAT DEAL OF PLEASURE to accept this building, on behalf of the Department of Health, Education, and Welfare, and to dedicate it to the important and far-reaching work of the Food and Drug Administration (FDA).

For the first time in its 60 year history, the FDA has a building to house its headquarters offices and its laboratories. I think all of you know how hard and earnestly Commissioner Larrick has worked to bring that about, and how much this building embodies his hopes for the future of the agency. It is an achievement that he may justly view with pride as he nears the end of 42 years of honorable and devoted public service.

Many of us like to think that the building symbolizes the coming of age of a government agency whose work, though largely taken for granted, is vital to every American.

The FDA serves as the public's protector against contamination, fraud, impurity, and hazards in the products on which our lives depend.

It is not easy for the average citizen to comprehend the dimensions of the task. The products regulated under FDA laws account for about a fourth of what American families spend each year. They account for over $100 billion worth of the annual commerce of the United States. Nearly 70 percent of FDA's total commitment is to protect the food supply of this nation. It is not an easy job today. Technology has multiplied the problems of food safety. But the law has responded with new safeguards.

The FDA is in the business of making difficult decisions, not just occasionally but everyday of the week. Each year, FDA makes some 30,000 inspections of food factories and warehouses, analyzes more than 25,000 samples of pesticide residues, and tests more than 22,000 batches of antibiotics. In short, every working day the FDA makes hundreds of critical judgments, many of them life and death judgments, on behalf of American consumers. Very few of those decisions are open and shut. Most of them involve a delicate weighing of benefit against risk. In some cases a wrong decision could deny the public valuable, even life saving, protection, or could expose the public to devastating injury.

Throughout much of its history, FDA has existed on crumbs when it had responsibilities that would test the strength of a giant. Its resources were limited. It was understaffed and underbudgeted. Its laboratories were in scattered and inadequate quarters.

In its first 50 years, FDA grew at a snail's pace. In the last ten years, its growth has been explosive. Ten years ago, FDA had a staff of 829 people and a budget of $5 million. Since 1957, both its staff and its budget have increased five-fold.

In this same period, five major new laws dealing with areas of FDA concern have been enacted, each representing a massive new program.

It is clear, then, that the FDA has a strong mandate from Congress. The American people, through their elected representatives, have handed us an immensely important task. We must set our sights on new standards of excellence in administering the laws entrusted to us.

Let me say a word about how I view that responsibility.

The integrity of this agency and its laws must be maintained. The laws must be enforced, vigorously and honestly. The FDA must have the people and the tools it needs to get the job done, and I intend to give the agency the strongest possible backing in that respect.

But the job is not ours alone. The task of consumer protection must be widely shared. When a pharmacist discovers a discrepancy in drug labeling; when a doctor reports unexpected results from a drug; when a farmer exercises prudence in the use of pesticides; when a homemaker keeps medicines and other potentially hazardous products out of reach of children—they all contribute to consumer protection. And the greatest of all contributions to consumer protec-

tion are, of course, the efforts of responsible businessmen to comply with the law and to turn out reliable products.

The role of government in these protective efforts is one of regulation. But the regulatory process is, I'm afraid, widely misunderstood. Some, particularly in industry, see regulation as a form of regimentation. And others see venality in every attempt to work with industry to do a better job. I find little merit in either of these extremes. Regulation need not involve the dead hand of conformity, the iron hand of authority, or the glad hand of conviviality.

The goals of regulatory activity in a democratic society are akin to the goals of democracy itself. In a democracy, we accept rational and humane values as ends, and we work toward these ends with a minimum of coercion and a maximum of voluntary assent. Democracy puts a great burden on the individual and on non-governmental institutions. We expect the individuals and institutions of a free society to behave responsibly. In short, regulation in a free society puts a heavy burden of responsibility on the industry or enterprise that is regulated. Only when that responsibility is neglected does enforcement in a punitive sense become necessary.

Make no mistake about it. We will not hesitate to use the authority given to us to protect the public health. Every time this does become necessary, however, it represents a failure of the cooperative enterprise we value so highly.

Regulatory action also needs to be based on sound scientific and technical grounds. This requires solid factual knowledge based on research. The building we are dedicating today will enable the FDA to step up its research activities. But FDA must also have access to the best talents of the entire scientific community if it is to do the job that needs to be done.

Practicing physicians also share the responsibility for the safe and effective use of drugs. They need to have access to the latest information on drugs and therapeutic devices so they can discharge their obligation to their patients. We need to do all we can to get the information to them promptly and fully.

In sum, protection of the public calls for a vast collaborative effort. We intend to play our role in that collaboration. And we are going to expect others to play their role. The stakes are high. The responsibility is great. It is a venture worthy of our best resources of talent and energy.

In closing I want to pay tribute to all the men and women who over the years have contributed their skill and integrity and courage to the work of this agency. Without them and without the standards they have set, this building, for all its magnificence, would be no more than a shell. They deserve our thanks.

So now, as we dedicate this building, let us rededicate ourselves to the task ahead. **[The End.]**

GEORGE P. LARRICK RETIRES AS FDA COMMISSIONER

George P. Larrick will retire as Commissioner of Food and Drugs on December 27, 1965. He has had this position since 1954. John W. Gardner, Secretary of the Department of Health, Education, and Welfare, in accepting the resignation, praised Mr. Larrick's forty-two years of dedicated public service in protecting the American people from impure and unsafe food and drugs.

Before appointing a successor to the Commissioner, Secretary Gardner will seek a reappraisal of major organizational and substantive problems affecting the future of the Food and Drug Administration, in light of the increased statutory authority and greater resources available to it. For this purpose, Secretary Gardner has appointed a five-man committee headed by Rufus Miles, recently retired Assistant Secretary for Administration of the Department. Other members are John Corson, of Princeton University; Edward Dempsey and Boisfeuillet Jones, former Special Assistants to the Secretary for Health and Medical Affairs; Bruce Cardwell, Budget Officer of the Department and former Executive Officer of the Food and Drug Administration.

The Committee is to report to the Secretary in January 1966 and will also advise Secretary Gardner on the desirable professional qualifications of a successor to Mr. Larrick.

The FDA and Food Safety

By BERT J. VOS

This Article Was Presented at the Symposium on the Safety of Foods and Drugs, Washington, D. C., on November 22, 1965. Mr. Vos Is Associated with the Division of Toxicological Evaluation, Bureau of Scientific Standards and Evaluation, Food and Drug Administration.

WHILE OUR AGENCY BY LAW is charged with protecting the American consumer from harm caused by unsafe foods, drugs, and cosmetics, yet in a larger sense we are engaged with peoples of all nations in a common fight against hunger, malnutrition, and disease. The production not only of a safe food supply, but also of one adequate to feed the exploding population of the earth is our common battle—perhaps the most titanic one of this century.

We help insofar as we assure the safety of the new scientific aids to farming and food processing.

Use of pesticides, for example, can be an enormous factor in increasing productivity. Recently, it was said that weeds, disease, parasites, insects, and other hazards presently limit the yields of crops and livestock in this country by an amount estimated to be equal to present yields from 120 million cropland acres—about a third of our present harvest. This loss can be minimized by the proper use of pesticides but this must not be at the cost of increased risk to the public in the form of dangerous pesticide residues.

In my discussion of food safety this morning I should like to tell some of the ways in which the Food and Drug Administration (FDA) functions to help assure safety of food to the American consumer. I shall discuss historical aspects, as well as current methods of operation, of both a day-to-day and of an emergency nature.

History

The Pure Food and Drugs Act of 1906 was the first comprehensive measure of control in this area in the United States. It was the

product of long evolution and was recognized at the time as a compromise rather than an ideal law. Nevertheless, under it federal officials were able to cut down on the misbranding and adulteration of foods. They banned several injurious preservatives and checked some flagrant abuses in the patent medicine trade. Both consumers and producers of food became aware of the need for purity in foods, with increased emphasis on sanitation and sterilization. Chemists developed new means for detecting adulterations. Better ways of enforcement evolved. The enforcing agency developed a high order of morale, and its staff led the fight for a new and more effective law.

A crusade, mounted in the '30's to correct some inadequacies of earlier law, culminated in passage of the Food, Drug and Cosmetic Act of 1938. This law increased penalties and provided the FDA with a new weapon, the injunction. Factory inspections for sanitation were authorized. Labels were required to give much more information, particularly on special dietary foods. Provision was also made for formulation of food standards. In the area of food safety, foods were deemed to be adulterated not only if they contained any poisonous or deleterious substance which might render them injurious to health, but also if they contained any *added* poisonous or deleterious substance which was not necessary in their production or which could be avoided by good manufacturing practice. This latter section had the weakness that it required the FDA to (1) learn of the use of the added substance, (2) demonstrate its presence in food, and this often involved developing new, sensitive analytical methods, and (3) establish that the substance was poisonous or deleterious, and this frequently required extensive animal feeding tests. The lack of a clear bench mark for separating the harmless substances from the poisonous or deleterious ones was a further handicap, and this concept of "toxicity per se," as it came to be called, gave rise to much discussion.

Thousands of technological discoveries and developments have been made since 1938. These include new drugs, new food additives, new pesticides, and time-saving, ready-to-eat foods which require special care in manufacturing to prevent bacterial contamination. These developments have called for, and resulted in, new legislative acts to help assure the American consumer that the food he eats is safe. These include the Pesticide Chemicals Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additive Amendments of 1960.

With passage of the color additive law it could be said, for the first time, that no substance can be legally introduced into the United States food supply unless it has first been determined that it is safe.

Satisfying Safety Requirements

How does the producer or marketer of a food additive, pesticide, or color additive satisfy the FDA that such product is safe?

To do this, he submits a petition which, in brief, specifies the nature of the item or product, the reason for its use and proof that it accomplishes this, as well as proof of its safety to the consumer.

Since, by law, the petitioner is responsible for assembling this information, or for developing it experimentally if it does not already exist, the petition may run to many pages or, even, volumes; it may contain results of very lengthy and expensive experimentation.

Review of a petition starts with its examination by the chemists. They must satisfy themselves that the product is fully and accurately described with respect to chemical composition; that it can be manufactured to give a consistently reproducible material; in the case of a food additive—that it will produce the intended effect; and that the amount required to so do is correctly specified.

They review the proposed method of analyzing for food additive or pesticide which will be used for enforcement purposes. Is it sufficiently accurate, sensitive, specific, and reproducible?

Further, the chemists check to see whether the additive or pesticide in a food reaches the consumer in the same chemical form originally used by farmer or processor. If not, they require information as to how, and how much of it, is chemically changed. Finally, they determine what amounts can be expected to remain in the food or agricultural commodity under the conditions of use proposed by the petitioner.

Once the chemists are fully satisfied on these counts, it becomes the responsibility of the toxicologists to determine whether the anticipated residue from the proposed use of the additive is safe. They do this by carefully studying the results of animal tests, noting what type of toxicity appeared, how it varied in frequency and severity from one dose level to the next, and how the effect in one species of experimental animal compared with that in another. If there is much difference between the species, information on how the chemical is

metabolized, i.e., chemically changed, by the different species is of great value, particularly if comparable data are available for man. Finally, using their broad knowledge of the relative sensitivity of man and other animals to the toxic effects of chemicals of different structural or toxicological classes, they reach a decision as to whether the proposed use will be safe.

Since the substance in question will end up in the food supply, the toxicologist places emphasis on long-term—even lifetime—studies. The general requirement is for two-year studies in two species of animals, such as the rat and the dog, as well as a test for effects on reproductive processes. In case of suspicion that a food additive might cause cancer, even more extensive testing, involving more animal species and larger number of animals is in order.

When the scientists have completed the petition review process, an appropriate regulation is drawn up by the members of the administrative staff and published in the Federal Register. Those adversely affected by the regulation can request a public hearing (in the case of food additives) or review by an advisory committee (in the case of pesticide chemicals or color additives). This in turn may be followed by judicial review in the United States Court of Appeals.

This, in brief, describes how the FDA entertains proposed use of pesticides, color additives, and food additives and decides which are admissible and which are not.

Now that the burden of developing both evidence of safety and adequate analytical methods has been shifted to the proponent of a new pesticide, food additive or color additive, it might appear that there is no longer any need for scientific investigations in this area by the FDA, and that our scientists could settle comfortably at their desks and devote the remainder of their careers to reviewing data generated by industry. Nothing could be more pernicious. Only by participating in an active research program can our scientists maintain a mental alertness and an up-to-date knowledge in their areas of expertise. These research programs cover a wide range of subject matter and involve several bureaus. Typical problems include: (1) searching for animal species which will more accurately predict the response of man to toxicants; (2) developing new methods for measuring toxicity in experimental animals and man; (3) perfecting analytical methods for screening food samples for pesticide residues,

and; (4) developing a method to detect staphylococcal enterotoxin, a common cause of food poisoning.

Unfortunately, not all our scientists are able to participate actively in laboratory research. Those who do not are able to share in the stimulus of the research programs through seminars, staff meetings, informal discussion groups and the ordinary day-to-day give-and-take in the lunch room, the snack bar, and the car pool.

The complexity of the problems which confront us today in the field of food safety can hardly be overemphasized. This complexity arises from the number and variety of new chemicals which may intentionally or inadvertantly place residues in or otherwise affect foods. Some of these chemicals, notably the pesticides, are extremely toxic. The possibility that this toxicity may become even greater through an interplay of the biological or chemical forces of two or more of them must be considered. Some of the compounds are toxic in subtle and unexpected ways. These serve to remind us that while toxicity when it occurs is very real, safety is a negative sort of thing which can vanish with the development of new evidence. They serve to remind us that to get the right answers we have to ask the right questions. The same old questions, too often, just won't do.

The consequences of evaluating a new chemical by old standards is well illustrated by an example taken from an early phase of the pesticide revolution: parathion. Prior to parathion it was assumed that the adverse effects of a compound in experimental animals could be adequately judged by observing its effect on their behavior and growth followed by a gross and microscopic examination of their organs and tissues. True, allowance had to be made for the fact that man could be expected to be considerably more susceptible than any of the test animals, but by and large it was believed that pesticides could be correctly ranked in order of toxicity on the basis of data of this sort. As judged by these standards, parathion was far less toxic than DDT. However, research in our laboratories in which we measured cholinesterase levels in rats and dogs receiving parathion in their diet showed effects at levels which were only a fraction of those at which DDT produced no observable effect on any system. Instances such as this reinforce our belief in the importance of our scientists having first-hand experience in the problem they are evaluating. Sometimes so simple a thing as a check on the results reported by a petitioner turns up something of interest, as when our chemists found some ten times more of a component of a proposed

food packaging material migrating into the food than the petitioner had claimed.

Voluntary Compliance

For many years the FDA has made efforts to promote voluntary compliance on the part of the various industries it regulates. There are many advantages to this approach. In the first place the public is obviously better served if unsafe foods are kept off the market rather than if those responsible for placing such foods on the market are subsequently punished for their offense. Secondly, a comparison of the size of our resources with the output of the industries we regulate makes it obvious that a safe food supply is possible only because the great majority of producers and processors is already dedicated to this goal.

We encourage voluntary compliance in many ways: through talks and exhibits at meetings of trade and professional associations, through pamphlets and other publications, through motion pictures.

The FDA inspector in the field is in the front ranks in this effort to promote voluntary compliance. He is trained to understand good manufacturing practices, and he checks for these in inspecting food processing operations. Any deficiencies he sees—such as sources of contamination, insanitary operations, or lack of, or improper, quality control—will be called to the attention of responsible officials of the firm.

Partly as a result of such effort on the part of the field inspectors there is each month a growing list of voluntary actions taken by industry to improve consumer protection. This includes voluntary diversion to non-human use, or destruction of, contaminated, adulterated, or mislabeled products.

For example, during a recent month, FDA Districts reported 258 such actions, 143 involving foods, 75 involving drugs, and 40 concerning plant improvements. Examples (and some are cited each month in the publication, *FDA Report on Enforcement and Compliance*) included voluntary destruction by a pie company of 500 pounds of raw dough, which a FDA inspector had discovered to be contaminated with extraneous pieces of blueberry and cherry pie filling and to be stored in an unclean dough trough; hiring an exterminator and sanitation consultant at a cost of $600 per year by a food storage warehouse, as well as building storage racks, installing screens, caulking cracks, constructing a metal shield for two of the doors, and painting several areas, at a total cost of $1,800; destruction of 200,000 "Cracker Balls",

torpedo-type fireworks which resemble candy-coated pellets—by burning, burying in the ground, or submerging in water—by merchants in eight different states.

A less publicized phase of our voluntary compliance effort takes place daily here in Washington when our scientists sit down informally with representatives of industry and discuss petitions or other proposals with them. These discussions may occur at any stage: advice before any work is begun as to the type and amount of data that will be needed to support a proposal, evaluation of experiments in progress to see if there is need to change the approach, or a last look-see prior to submission to pick up any glaring omissions. Not all our recommendations are as some seem to fear, for more animals, higher dose levels, longer time or for more sensitive and specific analytical methods. Upon occasion we are able to point out data or relationships of which the visitors were unaware and which were of great value to them. We believe everybody profits from cooperation of this sort. The public gains because new compounds or processes are investigated more thoroughly. Industry gains by learning how the general principles of safety evaluation apply to its specific problem. The FDA gains because the better quality of the petitions facilitates review.

Unfortunately, voluntary compliance has not yet progressed to a stage where more formal methods can be abandoned. To illustrate this latter let me describe our enforcement activities in connection with pesticide residues. Last year our inspectors collected and our chemists made pesticide analyses on some 25,000 samples of food. Many of these samples were "selective," that is, they were collected because local conditions, such as weather or pattern insect distribution made excessive residues likely. Other samples were "objective" to give us a broad picture of the occurrence of pesticide residues throughout the nation.

All samples were examined by validated methods. Results of analyses were reported to the grower and also to State officials who worked with the growers to remove violative crops on the local level. The remaining crop could often be salvaged by waiting longer to harvest, by stripping outer leaves as in the case of cabbage, or by being plowed under for its value as fertilizer when hopes of salvaging for food use are absent.

Where violative shipments had already been shipped to market they were removed from the channels of commerce by seizure. Where warranted, further regulatory action by injunction or prosecution was taken.

Of the samples collected and examined for residues of pesticide chemicals, 85 to 90 percent were raw agricultural commodities while the remainder were processed foods, principally animal feeds. Twenty-five violative lots were removed from food channels by seizure. Many additional lots bearing illegal residues were destroyed by producers or under State action. Federal actions during the same period included two prosecutions.

Hurricane Betsy, which hit New Orleans two months ago, provides an example of how FDA safeguards our food supply under more difficult circumstances. A force of approximately 60 of our inspectors and chemists, some of them flown in from other districts, worked side by side with local authorities for a two-week period to make certain that storm damaged foods and drugs were properly disposed of. They visited over 900 establishments. On the New Orleans docks alone they examined foodstuff valued at more than 5 million dollars of which a tenth had to be destroyed. They supervised the reconditioning of river-water-damaged canned goods by washing and sanitizing with a chlorine solution. They worked around the clock at grain elevators to maintain proper surveillance and supervision of the reconditioning of contaminated grain. Finally after two weeks the immediate problems had been taken care of and many of the men were able to return to their normal activities.

I think that from even this brief account of our varied activities in the field of food safety it will be apparent to you that now in this scientific age more than ever before, the FDA must develop and maintain recognized scientific competence and leadership in the areas of its regulatory responsibility. That the FDA scientists have in the past and are now contributing to the development and analysis of scientific information is evidenced in their scientific publications and their participation in scientific societies. That the FDA is committed to continued scientific growth is reflected in the new laboratories, new equipment, expanding research programs, and the active development of training programs—all in all, an atmosphere conducive to continued scientific growth. We cannot be content with less than this for the ability of the FDA to administer the complex and important laws assigned to it requires the broadest and firmest scientific foundation.

[The End.]

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