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Food-Drug-Cosmetic Law JOURNAL

Problems of Food Additive Regulation . . . FRANKLIN M. DEPEW

Chapter X of the Latin-American Food Code . . . . JULIUS G. ZIMMERMAN

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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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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Comment from Canada.—The article in the April JOURNAL by Robert W. Gregg, depicting the proceedings of the United Nations Commission on Narcotic Drugs and the framing of a Single Convention on Narcotic Drugs, elicited the following statement from Mr. Robert E. Curran, Q. C., Director of Legal Services of the Canadian Department of National Health and Welfare and a member of the Editorial Advisory Board of this JOURNAL:

"The article prepared by Professor Gregg is not only an excellent presentation and analysis of the complicated structure of international narcotic control, but is also most timely in that it coincides with the completion of a Conference attended by some 73 countries which on the 25th day of March adopted the text of a Single Convention to replace some nine existing multilateral treaties. This marks a milestone in the last half century of continuous struggle to bring about unified and universal control of narcotic drugs both nationally and internationally. The subject matter of the article should therefore be of great interest to all who are concerned with this important subject."

A bulletin also came from health and welfare department last month: The Food and Drug Directorate warned that, as a result of recent investigations, the use of preparations containing Chloramphenicol, its salts and derivatives, has become associated with blood disorders, necessitating printed precautions prescribed by the directorate: (1) on the inner label of all oral and parenteral preparations, and (2) on the outer label or in the package insert and included with the promotional literature disseminated by direct mailing from wholesalers, manufacturers and distributors to practitioners.

Food Additives Legislation.—Three discussions of the food additives amendment appear in this month's JOURNAL, beginning with *Franklin M. Depew's* article at page 253. The author, president of the Food Law Institute, characterized recent legislation, such as the Pesticides Amendment, Food Additives and Color Additives Amendments, and the Hazardous Substances Labeling Act, as presages of a new and important era of regulation by the FDA. Special attention is given the Delaney "anticancer clause" and the problems of determining carcinogenic properties and the possibly tolerable use of trace amounts of such substances. It is the author's opinion that the clause will eventually be construed to permit the establishment of safe tolerances by improved scientific testing.

Beginning at page 261, *L. M. Beacham,* a member of the Division of Food, in

the Food and Drug Administration, surveys such implications of the Food Additives Amendment as have been elaborated and defined since its enactment. Speaking before the meeting of the Institute of Food Technologists in New York City, Mr. Beacham described the word of the FDA in interpreting and administering the amendment, as well as the evolution of policy behind these functions. Of that policy, the author cites a number of salient criteria, including the demand that the safety of an additive be convincingly demonstrated without reliance on manufacturers' claims.

The implications of the food additives law for the bakery production industry is explained in the article at page 281 by *J. Kenneth Kirk,* Assistant to the Commissioner of the Food and Drug Administration. Mr. Kirk related the events behind the extension of the effective date of the bill and considerations of time governing the extension. He delineates the procedures and precautions incumbent upon the users of additives and the proper means of determining what substances are to be regarded as food additives. Most importantly, Mr. Kirk warns that the granting of the extension cannot be regarded as a mitigation of the compliance which must eventually be exacted.

Progress and Policy.—The Commissioner of the Food and Drug Administration, Mr. *George P. Larrick,* maintains that the consumers of the nation want to and should know what ingredients are being put in the foodstuffs they buy. In the paper at page 267, delivered at the 1961 meeting of the Food Industries Advisory Committee, Commissioner Larrick sketches the effect of FDA policies on public health and public opinion. He describes the results of recent research on heated fats and oils, the requirement that antioxidants in fats be declared on the label, and the 900-calorie diets, and he issues a broadside against nutrition quackery, "possibly the most lucrative racket in this country today." The author protests that such fads as the recent sea water craze are not simply harmless conversation pieces, but, on the contrary, that they are dangerous misconceptions which, at the least, impair public confidence in their food supply.

Enforcement Problems.—The article beginning at page 274 is a discussion of FDA enforcement problems in the fishery industry given by Mr. *K. L. Milstead,* director of the Division of Regulatory Management, Bureau of Enforcement. The author explains his belief that vigorous regulatory action is necessary in many cases to fully protect the consumer, the first and overriding consideration in enforcement policies. Applying himself specifically to the fishery industry, Mr. Milstead takes up the problems of food additives, the adulteration of oysters, the use of fish oils in the treatment of heart and artery disease, misbranding, and programs associated with the importation of fishery products.

The Scientists' Forum.—*Bernard L. Oser,* president and director of the Food and Drug Research Laboratories, Inc., describes the effect of research into experimentally induced cancer on food law enforcement in the article at page 287. His lecture was presented before the Pesticides Subdivision of the American Chemical Society and was illustrated with slides, reproduced here in the footnotes.

Foreign Law Comment.—The comment this month is an English translation of the tenth chapter of the Latin-American Food Code, entitled "Sugar and Sugar Products." The chapter was translated from the Spanish by Ann M. Wolf.

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Journal

Problems of Food Additive Regulation

By FRANKLIN M. DEPEW

The Author, President of The Food Law Institute, Delivered This Paper Before the Commercial Chemical Development Association at Bedford Springs, Pennsylvania, on May 24, 1961.

I AM PLEASED to have this opportunity to address you in behalf of The Food Law Institute. The Institute is a nonprofit corporation supported by the food and related industries. The Institute endeavors to constructively develop the law of food, and other related laws, through basic research and education.

Recent new legislation, such as the Pesticides Amendment, the Food Additives Amendment, the Color Additive Amendments and the Hazardous Substances Labeling Act have opened an entirely new and very important era of regulation by the Food and Drug Administration. These laws have not only created many new problems for the industries formerly regulated by FDA, they have brought many new industries under FDA jurisdiction. A recent example of this was the publication in the *Federal Register* of April 29, 1961 of the proposed regulations for enforcement of the Hazardous Substances Labeling Act, which law requires consumer protection labeling on common household aids such as waxes, polishes, cleaning agents, bleaches, detergents, and wood finishes and their solvents, if there is a hazard in their use or storage around the home.

While the problems created by these new laws will undoubtedly continue to vex industry and the FDA as well, it is gratifying to report

that both the regulated industries and the FDA have approached them in a basically sound and constructive manner. No major difficulties have arisen between FDA and the regulated industries during their transitional stages. We are confident that those in government and industry will continue to work out these problems in a fair and equitable manner which will not stifle private enterprise.

The tremendous burden placed on FDA by the Food Additives Amendment alone is apparent from Commissioner Larrick's statement before the House Committee on Interstate and Foreign Commerce on February 28, 1961, when he reviewed the work that had been done or was still pending in the food additive field. He gave these figures:

Chemicals generally recognized as safe (exempt) and so listed	718
Substances given prior sanction (exempt) and so listed	112
Petitions received and reflected by issuance of regulations	59
Petitions now being evaluated	173
Petitions received, but not filed (incomplete)	100
Petitions received, but not related to food additives	42
Chemicals and uses for which extensions were granted	3,000+

Not only did FDA personnel bend their efforts toward solving these many food additive problems, but, when it became apparent that the 3,000+ items under extension to March 6, 1961, could not be acted on by that time, they urged the enactment of a law which would give FDA power to grant further extensions under certain circumstances. My first duty upon my election last January, as chairman of the Food, Drug and Cosmetic Section of the New York State Bar Association, was the pleasant one of appointing a committee to consider and suggest suitable amendments to the Administration food additives extension bill. Their objective was to secure consideration of industry objections to the bill while retaining the reasonable administrative objective of assuring the protection of the public interest. I am happy to report that Administration representatives gave sympathetic consideration to the suggestions of the committee with the result that the law as passed, Food Additives Transitional Provisions Amendment of 1961 (P. L. 87-19, 75 Stat. 42), did basically meet both objectives. A suggestion that the bill be amended to give FDA the additional power to grant limited extensions on old substances which might in the future present a food additive problem was not accepted. In connection with this point, the House Report on the bill (H. Rept. No. 53)

cited Commissioner Larrick to the effect that FDA has adequate authority to handle such situations in a judicious manner, and that FDA would not proceed immediately with enforcement action to ban the use of such substances in commerce until convinced of imminent hazard to public health.

The Commissioner's letter to Congressman Harris, Chairman of the House Committee on Interstate and Foreign Commerce, makes this point with reference to such a situation:

"It may be that some substances which we have listed as generally recognized as safe, and some for which we have granted prior sanctions, will change in status with the emergence of new scientific knowledge. If they do, the new knowledge would have to establish a serious question of doubt of safety. In any such case, we believe the best course would be to remove the substance from the food supply while the issue of doubt was being removed rather than to approve a blanket extension. If the doubt were not a serious one, there would be no need for immediate action."

The new law permits extension of the effective date of the Food Additives Amendment up to June 30, 1964, in respect of items for which an extension request was pending prior to March 6, 1961, upon a new request filed with FDA prior to July 1, 1961, if it is found that (1) continued use will involve no undue risk to the public health, (2) the substance was in commercial use prior to January 1, 1958, and (3) scientific investigations to determine safe levels of use are being pursued with due diligence. I believe this law will, at least temporarily, solve a large part of industries most pressing problems. If this reprieve had not been granted, industry would have had to remove some standard food products from the market.

The steps taken by FDA to solve or cope with these food additive problems are what we have learned to expect from this professional agency with its long record of administrative success. It is commonplace to say that FDA is staffed by able and experienced career officials who are outstandingly honest, efficient and devoted, who have consistently acted to protect the public health and other consumer interests with an informed understanding of the industry problems involved. The FDA career system has been very valuable to all parties concerned, including the consumers of our country.

The new problems of food law enforcement in relation to the safety of the substances used in foods have caused FDA to adopt new

scientific techniques and to explore the possibility of using new methods of detecting toxicity potential. Some of these new procedures, if successful, may be substituted for the long, costly animal feeding tests now used. If this should occur it would be a great boon to industry as well as to the FDA. Progress along these lines has been hampered by the limited size of the FDA research staff. Thus it seems clear that sound, effective administration of these new laws is not possible without an accompanying strong scientific research program directed by top-grade scientists, equipped with proper facilities, including the most modern instrumentation.

While these new laws have necessarily engaged a very large proportion of the time of the top management of FDA, they still have found time to consider other aspects of consumer protection. A Consumers Inquiry branch was recently established and the Consumer Consultant program reactivated. These are having a positive effect—they serve to educate the consumer to his or her needs based on up-to-date scientific knowledge. In addition, they should furnish FDA with the information needed to appraise the effectiveness of consumer protection. The steps taken by FDA as supplemented by the Department of Agriculture's meat and poultry programs, largely satisfy the increasing demands on all sides for expanded consumer protection. This FDA consumer program has not received the public recognition that it deserves. It is important that these activities should not be overlooked by those who are considering the many consumer protection proposals which have been suggested in recent years to both our federal and state governments. It would be a grave mistake to take any action which would impair the effectiveness of the foregoing agencies, traditionally acted in this field, by creating rival or overlapping organizations or otherwise. Such action would harm rather than aid the consumer.

For the reasons just reviewed, we of The Food Law Institute believe FDA should be furnished the tools and trained personnel with which to perform its job. We have, therefore, supported the FDA budget request by making a statement before the House Appropriations Subcommittee in favor thereof.

Of course, budgetary allowances do not entirely solve the pressing problems faced by FDA at this time. These recent major developments in the food law enforcement field make it necessary that the increased FDA staff in Washington and in the field should not only be competent and devoted, but properly and effectively trained to employ

equipment which was unknown or unapplied a few short years ago, and to otherwise administer the new laws. We must all recognize that FDA is going to have a difficult task in the next few years in securing such a staff. We do know, based upon past performance, that FDA can be expected to do its utmost to build a highly qualified staff as soon as possible.

If the FDA budget request is approved by the Congress we can expect the increased FDA staff to take resonably prompt steps to correct the delays which have occurred during the past few years. I think it is important to point out that some portion of this delay has resulted from industry insistence that practically all the substances they use in food and food packages be cleared with the government for safety.

I do not think the law intended this burden to be placed on FDA, but I do think that industry should have concluded on its own that many of these substances were generally recognized as safe (GRAS). In this connection I am glad to report that there has been a refreshing new approach to this aspect of food additive problems. On February 20, 1961, the Flavoring Extract Manufacturer's Association (FEMA) released a report concerning the establishment and findings of its expert panel relative to the safety status of over 250 flavoring ingredients. The panel which consists of six eminent experts in the field was organized by Dr. Bernard L. Oser, president of Food and Drug Research Laboratories, Incorporated, FEMA's consultant on food additive matters. Both Dr. Oser and Dr. Richard L. Hall, chairman of the FEMA food additives committee, met with the panel during its deliberations. Using the criteria outlined in the report the panel concluded that these flavoring ingredients were generally recognized as safe (GRAS).

I think that the action taken by FEMA is in accord with the understanding of industry lawyers who supported the enactment of the Food Additives Amendment. I believe they expected that the exception in that law relative to substances generally recognized as safe (GRAS) would be used by industry and the FDA to avoid unnecessary regulatory control. I believe this exception for substances generally recognized as safe expressed a philosophy that has long been followed by legislators in the United States. This philosophy is one of regulation rather than government permission control, except in rare instances where it is concluded that permission control is necessary for the protection of the public health. The language of the law

contemplates that a food manufacturer or a group of manufacturers may conclude that a substance is generally recognized as safe for its intended use by experts competent to evaluate its safety. Now that we are getting beyond the transitional period of adjusting to the Food Additives Amendment, I have no doubt but that other industries may conclude that they should follow a similar practice. The FEMA action is a fine example of what can be accomplished by cooperative effort on the part of an industry.

I am sure you would not feel that I had covered my subject unless I commented on the so-called Delaney anticancer clause. This clause classifies as unsafe, any new substance or one not previously evaluated for its safety "if it is found to induce cancer when ingested by man or animal, or it is found, after tests which are appropriate for the evaluation of food additives, to induce cancer in man or animal." A literal interpretation of the clause must lead to the prohibition of such a substance even though safely present in trace amounts. In the words of the Hon. Arthur S. Flemming, former Secretary of Health, Education and Welfare, before the House Committee on Interstate and Foreign Commerce relative to their consideration of the Color Additive Amendments, May 9, 1960:

"It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen."

The clause has created two basic problems:

(a) whether a substance is or is not in reality carcinogenic as determined histopathologically or by other criteria; and

(b) whether discretion can be exercised in determining a safe threshold does for an established carcinogen.

Both of these problems, in my opinion, must be looked upon at this time as being basically of a scientific nature. I think we must of necessity look to our scientists in the Food Protection committee of the National Research Council, in the Food and Drug Administration, The Nutrition Foundation and elsewhere in our universities and in industry to arrive at satisfactory answers based on the exercise of sound scientific judgment and discretion consistent with the protection of the public health.

The Food Law Institute was and remains a staunch supporter of laws which will assure the purity and safety of our food. My predecessor, Mr. Charles Wesley Dunn, as long as ten years ago urged that legislation of the type of the Food Additives Amendment was needed for the protection of the public health. There can be no question about the necessity for excluding potentially carcinogenic substances from the human diet. It is imperative to protect the public from the deliberate introduction of carcinogenic substances from this source.

The problem of so assuring the exclusion of carcinogens is increasingly engaging the attention of our scientific experts. The President's Science Advisory Committee convened a special panel whose report (commonly called the Kistiakowsky Report) was made public on May 14, 1960. The panel discussed in considerable detail the scientific problems that confront us in connection with the determination of the cancer-producing potential of chemicals. They pointed out the difficulties of designing and conducting an experiment to determine whether a substance is a cancer-producer for man, and the difficulties in evaluating the test data after they were obtained. I will not attempt to describe those difficulties. Suffice it to say that scientists working in the field believe that FDA's interpretation is too strict and requires the proof of a negative. Dr. Bernard L. Oser presented a report on the subject before the pesticides subdivision of the American Chemical Society, St. Louis, Missouri, on March 22, 1961. The President's panel also reported that they believed the probability of cancer induction from a particular carcinogen in minute doses may eventually be assessed by weighing scientific evidence as it becomes available.

Thus, at present, our scientific experts are divided into two groups with those in FDA taking the conservative view with respect to recognition of carcinogenicity of a substance. If I may speculate as to the future, I venture to say that we may expect that with increased experience in this field, our scientists, both in and out of FDA, will arrive at mutually agreeable methods for determining whether a substance is a carcinogen, and further that they will find a sound scientific basis for the establishment of safety tolerances for carcinogens.

If and when this time arrives, I believe the clause will be interpreted to permit the establishment of such tolerances. The Senate Committee in reporting out the Food Additives Amendment with the Delaney clause stated: "We believe the bill reads the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration." As so interpreted, the clause

would permit the establishment of a tolerance for a carcinogen on the same basis as for any other substance—that is, by the exercise of sound scientific judgment based on a fair evaluation of the scientific record as a whole.

If our scientists do not reach an agreement along the lines mentioned, the problems created by the clause will continue to increase—food industry scientists and nutritionists warn that a fat ban will hamstring the development of valuable new chemical compounds.

In closing, I would like to comment briefly on the FLI programs of university instruction. I am convinced this instruction in the law and the background of its philosophy and development represents a long-time protection against ill-conceived attempts to deal with food and drug law problems on a solely political basis. Lawyers so trained may inevitably be expected to assume leadership in the constructive development of the law and its administration in the public interest, an interest which is equally that of industry.

When you consider that the FLI programs also include publications and national and international conferences as well, I believe you will agree that they are worthy of the support of an integrated membership, representative of all industries regulated by FDA. We would welcome your support. **[The End]**

HEALTH RESEARCH GRANTS

Dr. Luther L. Terry, Surgeon General of the Public Health Service, has announced the award of 36 health research facilities grants, totaling $4,696,031, to 32 institutions in 20 states.

These funds, which complete the fiscal year 1961 distribution include monies temporarily turned back by institutions unable to begin construction before July 1, 1961. This transfer of funds is in response to the President's call to speed construction as a stimulant to the national economy. Institutions returning their unused funds will be reimbursed from the 1962 fiscal year budget.

The Health Research Facilities Program awards matching funds to nonprofit hospitals, medical and dental schools, schools of public health, and other institutions to build and equip health research facilities. Established on a three-year basis in 1956, the program, because of need, was extended through fiscal year 1962.

The program is administered by the Division of Research Grants at the National Institutes of Health, Bethesda, Maryland. Recommendations for grants are made by the Health Research Facilities National Advisory Council to the Surgeon General of the Public Health Service, who approves the grants.

Current Aspects of the Food Additives Amendment

By L. M. BEACHAM

The Author, a Member of the Division of Food, Food and Drug Administration, United States Department of Health, Education, and Welfare, Presented This Paper at the Meeting of the Institute of Food Technologists, New York City, May 9, 1961.

PREVIOUSLY in discussing the Food Additive Amendment before group audiences, I have generally begun with a brief exposition of its basic provisions, but it has now been two years and eight months since the amendment was passed and I feel sure that this audience is fully conversant with the text of the enactment. Note that I said "text" and not "requirements," for only the slow evaluation of administrative and judicial decisions will reveal what the requirements ultimately turn out to be. That process is already under way and is one of the things about which I wish to speak today. Therefore, let us consider for a moment what has been accomplished thus far.

First, procedural and interpretative regulations had to be formulated before any substantial progress could be made in putting into effect the provisions of the amendment. That took considerable time, but we believe it was time well invested.

We now see with clearer perception the dimensions of the food additive problem. At one time, early in the Congressional hearings on the subject, an estimate was made that perhaps 700 to 800 chemical substances were being added to our food in one way or another. These figures were rejected by some as being too high, but we now know that a closer estimate would be several-fold greater than these. For in proposed and final listings of those substances that are gen-

erally recognized as safe, more than 700 have been identified. In addition, in excess of 2000 compounds—that were employed prior to January 1, 1958, in such a way that they came within the legal definition of food additives—were granted extensions beyond March 6, 1960, in accordance with Section 6(c) of the amendment.

Since the above figures include both direct and indirect additives, we have now come to realize that, numerous as the direct additives are, the indirect ones—that is, those that must be considered because of their roles in packaging materials, processing equipment and handling facilities—are also legion, and are perhaps the more difficult to deal with. Certainly, they have required us to do a great deal of pondering in our efforts to formulate policies.

And that brings me to another accomplishment and one which was basic to any effective implementation of the amendment. I refer, of course, to the development of a reasonable, consistent administrative policy. A few of the salient features of the policy developed so far perhaps merit mentioning:

(1) In evaluating a food additive, we must have convincing evidence of its safety; we cannot gamble or speculate on that all-important point. We have urged those who have problems involving pharmacology in their solution to discuss with our Division of Pharmacology the work they plan before they start it. It is true our people sometimes advise that the program is not sufficiently comprehensive but there are other times as well when they are able to conclude that not all of the proposed work is necessary, or to advise other more promising approaches.

(2) A substance to be "generally recognized as safe among experts qualified to evaluate its safety" must be just that. It is not enough that the manufacturer have data that show him it is safe, or even that convince our experts. If from reasons of trade secrecy or for some other cause, little or nothing is known about it in the scientific community, it cannot be "generally recognized as safe." Such a substance is a food additive and requires a regulation to authorize its use, but if its safety can be convincingly demonstrated, there should be no difficulty in developing such a regulation.

(3) The law exempts from the definition of food additives those products which had been given approval—or as the statute terms it, "prior sanction"—by either FDA or the Meat Inspection Division or the Poultry Inspection Division of USDA before the enactment

of the amendment. We have held that these prior sanctions are applicable only to the specific usage of the product for which they were granted. Any different usage does not come under the exemption. However, a prior sanction granted one firm for a specific use of a substance applies equally to all others using the same product in the same way.

(4) An ideal food additive regulation defines the substance, describes its use, limits the allowable amount, and provides a proper analytical method for determining whether the limitation has been met. In the case of many direct food additives it is our policy to require this as a sound minimum objective, but in some instances limitations on the maximum amount permissible have been found unnecessary and, accordingly, the analytical method need not have the precision that is necessary when tolerance limitations have been set. With indirect additives, the need for suitable analytical methods constitutes one of our current problems that I shall advert to presently.

(5) Contrary to the view held by some in the industries involved, every item that may come in contact with food through the use of plant equipment, packaging, and the like, is not something which necessarily becomes a part of the food. Recall if you will that portion of the definition of food additives in the law which reads "reasonably be expected to result in its becoming a component" of food. If, because of its insolubility or for any other reason, it is not reasonable to expect migration, it will not be a food additive. On the other hand, where there is migration, such materials, or at least the migrating substances they contain, are subject to the amendment unless they are generally recognized as safe or are covered by a prior sanction. This does not necessarily mean that tolerance limitations with appropriately sensitive analytical methods are required for each such migrant, though this would be desirable if it were feasible. Approaching the problem on that basis would result in a tremendous and perhaps never-ending job. Therefore, our current policy towards the wrapping material, the conveyor belt, the can liner or similar articles that come in intimate contact with food is to regard the entire article (aside from those components that are clearly nonmigratory, are GRAS, or have prior sanctions) as the "food additive." It follows that instead of attempting to write individual regulations for, let us say, 100 substances in paper, or those equally numerous in a can enamel, that may conceivably migrate to food, we may develop one regulation specifying the ranges in composition, performance require-

ments, and conditions of use that will insure that the paper or enamel will be safe for its intended use. If this appears to be an oversimplification, like the directions for sculpturing a statue whereby you "get a block of marble and knock off all the pieces you don't want," it still offers a more workable approach than any alternative that we have considered. Thus, in dealing with the article as a whole, we can consider the ingredients from which it is made, the reactions they may have undergone in processing, their physical state, and we can subject it to tests and analyses that would not be practicable on food. By doing a thorough research job once and for all, we can write a regulation that will insure that if the article under consideration is made in a certain way, meets certain specifications and is used as prescribed, it will be safe for such use with food. Plant inspection can augment laboratory testing to insure compliance with such requirements. It is on this philosophical footing that we have constructed our regulations for polypropylene and the nylons, and are considering those for can enamels and similar substances.

These, of course, do not comprise all the policy decisions that we have had to hammer out, but they are illustrative of the major ones, and are all that time permits me to discuss.

Let me now touch briefly on some of the problems with which we are currently attempting to deal. By far the most impressive one is simply the magnitude of the workload—for in addition to the task of dealing in final fashion with the hundreds and even thousands of food additives that are now held in temporary abeyance on extension lists, there is a continuing and increasing inflow of petitions for newly developed direct or indirect additives, attesting the industry and the ingenuity of our nation's food technologists and research chemists. In calendar year 1959 we received 69 food additive petitions; in 1960 it was 246; and up to April 12, 1961, we received 159. We are hard-pressed for even the clerical personnel to deal with this volume of work, while properly qualified and adequately trained professionals are extremely hard to obtain.

Possibly the next most pressing problem is the need for definite information on composition, usage, and for analytical methods. The statute requires the petitioner for a food additive regulation to furnish "a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use." Yet even with direct additives it is surprising how often the petition is deficient in this respect, or in other

required information. Of the first 200 petitions we received, only about 70 could be filed. The remainder were incomplete in essential information. A critical study of 100 petitions not initially acceptable for filing shows that 81 lacked information required to satisfy the requirements dealing with identity and composition, usage, technical effect and methodology. Of these, the latter seems to be the chief stumbling block, and is certainly the one most vexing to us, particularly after the petition has been filed.

The inadequacy of the method is usually not apparent upon inspection, or the petition would not have been accepted and filed. Generally, two of our chemists working independently have to test out the proposed analytical method. This requires each man to spend time assembling reagents and equipment. He goes through the required procedure and obtains unsatisfactory results. Because most of our scientists are men of humility, his first reaction is—as it should be—that he himself is at fault, and so he studies again the directions to see if perhaps he has failed in some way to follow them. Then he repeats the procedure, and again is not satisfied with his results. Now our scientists are also men of ingenuity, so he is often tempted to experiment to see if he can remedy the faulty method. Whether he is successful or not, we soon find we have invested many man-days of critically needed analyst's time in a method which should have been thoroughly tested for each particular proposed use before submission to us. If the method could first be subjected to collaborative study and testing by several analysts working independently in the same or different laboratories, so much the better.

Methods, in addition to being reliable and of appropriate sensitivity, should, whenever possible, be improved to require a minimum of time and of specially designed equipment. Just as Pascal once wrote: "I have only made this letter rather long because I have not had the time to make it shorter," so I suspect some of our analytical methods are long and complex because no one has taken time to perfect short and simple ones. Furthermore, I would urge that the directions for carrying out the method should be as carefully worded as they would be if the method were being submitted for publication.

Along similar lines is the problem presented by a multiplicity of methods for making what is essentially the same determination. This arises when a number of interested parties, working independently, present petitions for regulations covering quite similar and often competitive substances. Each submits a proposed analytical

method as part of his petition. This procedure soon yields a rather bewildering array of different analytical methods for making closely related determinations. There is a great need for some consolidation, simplification, and standardization of such methods. That this is currently being undertaken by some of the industry groups involved is illustrated by the recent creation of an ASTM subcommittee on methods of testing flexible packaging materials. Some of our own personnel are cooperating with this subcommittee.

Specifications are needed for what we refer to as "food grade" chemicals that are to be used as food additives. This is a term of uncertain meaning that should be better defined with respect to identity limits of impurities, sanitary handling, and similar features. Steps are being taken now to develop such a code of specifications and the Institute of Food Technologists is taking an active lead in this work.

The wording of the original amendment was such that the Act became finally effective with respect to all food additives no later than March 6, 1961. As this date approached it became apparent that many substances which had been in use prior to January 1, 1958, would not have been dealt with conclusively. Extensions of the effective date of the Act to the cut-off date for many of these had been granted or were pending, but one could see that, in many cases, investigations under way, feeding tests, and evaluation of data could not be completed before the Act must become effective. The Secretary of the Department took the initiative in requesting the Congress to grant him the authority to allow further extensions. In a bill which became effective April 7, 1961, Congress gave this authority under these conditions: Steps to bring the substance into compliance must have been undertaken before March 6, 1960, and have been pursued with reasonable diligence. No extensions can be granted beyond June 30, 1964. Extensions once granted may be terminated for good and sufficient reasons at any time. By regulation, the Commissioner has continued until June 30 of this year all extensions that were in effect or pending on March 6, unless such extensions are terminated sooner by regulation or revocation. Applications for further extensions beyond June 30 must be filed, together with certain specified information, prior to that date.

With this slight legal hurdle behind us, we are moving ahead in our program of considering, approving and regulating permissible food additives. **[The End]**

Progress and Policies of the Food and Drug Administration

By GEORGE P. LARRICK

The Author, Commissioner of Food and Drugs, United States Department of Health, Education, and Welfare, Delivered This Paper at the 1961 Meeting of the Food Industries Advisory Committee, The Nutrition Foundation, Skytop, Pennsylvania, May 4, 1961.

THE FOOD AND DRUG ADMINISTRATION appreciates your invitation to the annual meeting of The Nutrition Foundation. On various occasions my predecessors, Dr. Paul B. Dunbar and the late Charles W. Crawford, addressed your meetings and took part in your discussions. These were beneficial because of our important mutual interests in the fields of nutrition science, public health and law enforcement. I am glad to be here again myself to report on new developments in these areas which are of particular concern to the Food and Drug Administration.

My talk will include some comments about our policy with regard to nutritional claims for unsaturated fats; research on the effects of heating of fats and oils; label declaration of food additives and other food ingredients; the new 900-calorie diets, and the ever-present problem of public deception by nutrition quackery.

Nutritional Claims for Unsaturated Fats

This audience is quite familiar with the newer developments relating to dietary fats in nutrition and to the association of the polyunsaturated fats with levels of serum cholesterol and the incidence of coronary artery disease. Some interpretations of clinical findings have led some members of the food industry to encourage the public to increase its use of products containing unsaturated fatty acids, with the implied promise of freedom from atherosclerosis. The Food and Drug Administration has studied this problem carefully and we continue to believe there is inadequate information upon which to

base such claims. A statement of our position was issued December 10, 1959, and has been affirmed since that time. We have recently received support for this position from the Chairman of the Food and Nutrition Board, by a reaffirmation of the Board's opinion as stated in its report of 1958, summarized by the following sentence, which I quote: "Until it is clearer which fats are more desirable nutritionally and which, if any, are undesirable—major changes in American dietary habits are not to be recommended."

Research on Heated Fats and Oils

Our research scientists have been studying the changes in food fats that may occur during the cooking process. In fats subjected to prolonged heating under extreme experimental conditions we have observed the formation of altered fatty acids identified by their inability to combine with urea. The so-called urea-filtrate fraction which contains these altered fatty acids, when fed to animals will cause injurious effects. Other types of deleterious substances have been reported from other laboratories where the experimental conditions of heating were somewhat different. The production of these undesirable alterations of the fatty acids under experimental conditions indicates a need for further knowledge of their possible occurrence under industrial processing conditions where there may be abuse of the fats and oils used. At this time, however, we have no basis for believing that ordinary cooking processes cause alterations of fats to such a degree as to constitute a hazard.

When the Food and Drug Administration published its proposed Generally Recognized as Safe Food Additives list in December, 1958, oleic and stearic acids were included but because of doubts in the minds of a number of investigators as to whether or not fatty acids commercially available for food use could be generally recognized as safe in the absence of specifications, they do not appear on the GRAS list. Their present status under food additives regulations is that their continued use has been permitted, through time extensions, only when free of the so-called "chick edema factor." Our investigations are continuing into what may be responsible for the presence of a foreign material which accompanies the oleic acid, and possibly the stearic acid, which are now sold for food processing. When we discover what this substance is and devise a chemical test, then fatty acids can be used in foods under specifications utilizing

such chemical tests. In the meantime we have only the time-consuming chick assay to assure us of the absence of the chick edema disease factor.

Label Declaration of Antioxidants in Fats

With the expansion and general improvement in the enforcement facilities in the Food and Drug Administration, following the study and recommendation of the Citizens Advisory Committee and its implementation by the Congress, we were able to resume and expand our regulatory operations in the general economic field of violations. This includes attention to food labeling with particular reference to the requirements of Section 403(i) and Section 403(k) regarding label declaration of ingredients of fabricated foods and added chemical preservatives. Very quickly our activity brought to light the fact that there were a number of fat antioxidants or fat preservatives being used in oils, fats and fatty foods without either the declaration of the ingredients or the fact that they were present as chemical preservatives.

Shortly after our interest in this field became known, in the summer of 1958, the United States Department of Agriculture published a proposed standard of identity for an article to be known as "lard shortening." The Food and Drug Administration's study of this proposal caused us to conclude that if formalized into a regulation it would result in nullifying the labeling requirements of Section 403(k) as applied to that commodity. Accordingly, we offered adverse comment on the proposal and there then resulted a long period of discussions between us and representatives of the United States Department of Agriculture in an effort to reach agreement on the facts and the law and we unfortunately were not successful in either area. This brought pretty much to a stalemate our regulatory program in this area during these pending discussions.

While the law is quite specific in its requirement that ingredients in fabricated foods be declared by their common or usual names, we were never satisfied about requiring labels to bear such complex terms as "nordihydroguaiaretic acid" and "butylated hydroxyanisole" and "butylated hydroxytoluene," etc., which are three of the preservative materials that have been used commonly in fats. We felt that such technical terms are not understandable to consumers and because they are long and complicated they may help to cause unwarranted concern about the presence of these substances in foods. Therefore, in an effort to make label declarations of these ingredients more

meaningful to consumers, we decided to propose a standard of identity for a class of foods to be known as "fat preservatives" or "fat antioxidants." This was published in the *Federal Register* of January 27, 1961, and considerable comment has been received.

There is no favorable comment from individuals or groups identified solely with consumers. We are studying the record now to determine what action to take on the proposal.

Consumers Want to Know Food Ingredients

We have had many communications from consumers and persons in a position to know of consumers' interests showing that they want labels to name the ingredients in foods. The section on the misbranding of foods in the federal law divides foods into two categories: (1) Those for which definitions and standards of identity have been established, and (2) Those which are not covered by such standards. The label on a food not covered by standards is required to show the common or usual name of the food, assuming the food has such a name, and if it has two or more ingredients, the common or usual name of the ingredients—with certain exceptions for spices, flavorings and colorings. On the other hand, the label on a food for which an identity standard has been established is required to show the name of the food as specified in the standard and the common name of those optional ingredients designated in the standard as ones to be declared on the label.

Consumers complain about foods with labels which do not tell what the ingredients are. Very often the food about which they complain is one covered by an identity standard. There is no way to respond to these complaints, explaining that the food standard does not require a full disclosure of ingredients, that is satisfactory to consumers.

Foods standardized shortly after enactment of the Food, Drug, and Cosmetic Act had not previously been labeled to name the ingredients used. Consequently, even though the standards did not require labels to name the optional ingredients, the labels after the effective date of the standards were not less informative than they had been previously. That situation no longer exists. Today when a proposal is made to establish a standard of identity for a food in which optional ingredients are permitted, the labels currently being used have been subject to requirements for the naming of optional ingredients. In

the food standards authorization the law requires that, to promote honesty and fair dealing in the interests of consumers, the standard shall designate those optional ingredients which shall be named on labels. Since consumers *do* want labels to name ingredients, we think they will not agree that a standard promotes their interests if it permits the food industry to use labels which convey less information as to ingredients than the labels which were required prior to the standard. Less informative labeling can be avoided by providing in the standard that any optional ingredient used shall be named on the label.

It is a fact, however, that in 1943 the Supreme Court held in the *Quaker Oats* case that "the purpose of the food standards provisions was to authorize the Department to promulgate regulations 'under which the integrity of food products can be effectively maintained' and to require informative labeling only where no such standard had been promulgated, where the food did not purport to comply with a standard, or where the regulations permitted optional ingredients and required their mention on the label."

We believe food manufacturing concerns have an opportunity to win much consumer good will by adopting complete ingredient labeling as a company policy—such policy to apply equally to standardized as well as nonstandardized foods.

900-Calorie Diets

I can hardly make a talk nowadays without some mention of the new 900-calorie diets. If I do not speak about them, someone is bound to ask a question. Just the other day we heard of a 900-calorie *shampoo.* It's for fat *heads!*

The popularity of these products has resulted in the Food and Drug Administration becoming concerned with the nutritional adequacy of such items. In general we have found that, although the protein quality does vary somewhat among the different brands, from the nutritional standpoint these products appear to be satisfactory for the relatively short period for which they would be the sole item of diet.

Since the primary purpose of these products is to reduce weight, we have had several conferences with various manufacturers in an attempt to evolve labels that will be truly informative to the consumer. A change from a customary diet of 3,000 plus calories to one

providing only 900 calories is quite drastic and could result in uncomfortable, although probably not harmful, physiological effects. We therefore feel that the label should caution the consumer to use these products under competent medical guidance. We are maintaining a close scrutiny of this aspect of the special dietary food market.

Education v. Nutrition Quackery

Nutrition nonsense and quackery continue to menace public health and bilk the public of a vast amount of money each year. In fact, misinformation about foods and diets is the basis of what is possibly the most lucrative racket in this country today—if one could total all of the "take" from its various branches.

This racket is growing. Its most recent manifestation is a nationwide swindle in the sale of *ocean water* at prices up to $15 per gallon. This provides an interesting case history which shows how nutrition quackery spreads, and how ignorant, unthinking or unscrupulous persons seek to cash in on the fads, notions and theories that are accepted and disseminated all too readily by the press and other media of public communication.

The current sea water fad is based on an old but popular misconception that because such water contains numerous mineral and trace elements, and the body needs some of these elements, therefore it will be healthful to take a little sea water every day. From this it is only a step to flagrantly false claims that sea water is a panacea for all the diseases of mankind. Ignored is the fact that the same mineral elements are present in common foods, and with the possible exception of iodine they are abundantly supplied by the ordinary diet. Here is another adaptation of the false premise that modern foods are nutritionally inadequate—a theory that is relied on and promoted by practically all nutrition quacks and food faddists.

The sea water craze was launched by a series of syndicated newspaper articles by Dr. George W. Crane, M. D. Large numbers of reprints of these articles have been used as promotional material for sea water (plain and concentrated) and sea salt. Thousands of copies of the articles have been seized along with these products.

There is no way of telling what harm is done to the public, except its pocketbook, by this kind of nutrition nonsense. But I am convinced that it *does* harm the public—if for no other reason than because it impairs confidence in our food supply and in rational methods of medical treatment.

Fortunately, there are indications of a growing awareness that nutrition quackery is a public health problem in this country. For example I was glad to notice that the National Health Forum, which this year was devoted to the theme of "better communication for better health," included "Food Fads and Medical Quackery" as one of its discussion topics. We are looking forward next fall to a law enforcement conference on quackery to be held in Washington with the cooperation of the American Medical Association. All types of organizations which are concerned with the problem will participate. Your own organization, The Nutrition Foundation, has undertaken important work in the areas of public information and education about nutrition.

These are encouraging developments, especially since they are predicated on recognition that sound nutrition education, like health education generally, is something that requires devoted and continuous effort. **[The End]**

HAZARDOUS SUBSTANCES LABELING ACT

Manufacturers of household aids have been advised by the Department of Health, Education, and Welfare that new types of labeling may be required under the recent Federal Hazardous Substances Labeling Act. Effective date of the enforcement provisions of the law has been extended to August 1, 1961, except for products which are highly toxic, extremely flammable and flammable. Interested persons may present their views on or before June 28, 1961, in writing to the Hearing Clerk, Department of Health, Education, and Welfare, 330 Independence Avenue, S. W., Washington 25, D. C.

The new law requires consumer protection labeling on such common household aids as waxes, polishes, cleaning agents, bleaches, detergents, and wood finishes and their solvents, if there is a hazard in their use or storage around the home.

Special precautionary labeling must include the common, usual or chemical name of the hazardous substance or of each component contributing significantly to the hazard; the signal word "DANGER" on substances which are extremely flammable, corrosive or highly toxic; the words "WARNING" or "CAUTION" on all other hazardous substances. An affirmative statement of the principal hazard or hazards is also required, such as "FLAMMABLE," "Vapor Harmful," "Causes Burns," or similar language descriptive of the hazard; precautionary measures describing the action to be taken or avoided; instruction, when necessary or appropriate, for first-aid treatment.

The word "Poison" must appear on any highly toxic substance, with instructions for handling and storages of packages which require special care in handling or storage, and the statement "Keep Out of the Reach of Children," or its practical equivalent. Among the substances in the "Danger—Poison" category are: carbon tetrachloride, diethylene glycol, kerosene, methyl alcohol and turpentine.

FDA Enforcement Problems in the Fishery Industry

By K. L. MILSTEAD

The Author, Director of the Division of Regulatory Management, Bureau of Enforcement, Presented This Paper at the Atlantic Fisheries Technological Conference in Williamsburg, Virginia, on February 20, 1961.

IN LOOKING over your program, I was impressed by the number of reports and papers dealing with problems that have been involved in regulatory actions under the Federal Food, Drug, and Cosmetic Act. It is apparent that you are not only well aware of your problems but that you are working to solve them. Many of our scientists in the Food and Drug Administration are working with you in a cooperative effort to find better criteria and better indices to measure and improve the quality of fish and fishery products. We are glad to be able to participate in these research projects since they represent the best type of enforcement—namely, preventive enforcement.

Before I discuss our enforcement work on fish and fishery products, I would like to make a few general remarks about the law and how it is enforced. I think you may also be interested in a summary of our enforcement work for the past year which will give you some idea of the magnitude and the vigor of our enforcement programs.

One of the basic purposes of the Federal Food, Drug, and Cosmetic Act is to insure consumers that their foods are safe, pure, and wholesome, and made under sanitary conditions, and that they are honestly and informatively labeled and packaged.

Our enforcement programs are designed to achieve a maximum degree of compliance with the requirements of the law and thus carry out the intent of Congress to safeguard the integrity of our basic food supply. It is the philosophy and policy of the Food and Drug Administration in administering the law to obtain as much voluntary compliance as possible through education and cooperation with the regulated industries and the consuming public.

But we also believe that vigorous regulatory action is necessary in many cases to fully protect consumers and have always carried on a strong enforcement program. Our present program is limited in scope and is based upon a priority selection according to the seriousness of probable violations in the following order:

(1) Violations that endanger public health (harmful additives or colors, et cetera).

(2) Violations having a hygienic or esthetic significance (filth, decomposition and insanitation).

(3) Violations involving economic fraud or cheat (short weight, misbranding as to name, et cetera).

Enforcement is carried out through planned and controlled inspections of factories, storage warehouses, carriers and retail establishments and by field and laboratory examinations of interstate and import samples. Serious violations of the law and those responsible for them are proceeded against in the federal courts.

Here is a summary of our resources for the current fiscal year and of our enforcement work for the calendar year 1960:

Appropriate fiscal year 1961—$20,786,000; Total number of employees—2,413; Number of field inspectors—625; Total inspections—35,252; Samples collected—33,785; Samples examined—14,412; Import samples—5,558.

Seizure actions—1,270: Foods—996; Drugs & Devices—253; Cosmetics—21.

Volume of food seized: Health hazard—6,139,854 lbs.; Filthy and decomposed—14,416,512 lbs.; Economic violations—269,375 lbs.; Total —20,825,741 lbs.

Voluntary corrections: Plant improvements—227; Cost—$6,799,000.

Lots voluntarily destroyed or brought into compliance—1,707: Drugs—value—$974,000; Foods—pounds—13,357,000.

Criminal cases: Filed—260; Terminated—232.

Criminal cases based on illegal sale of prescription drugs: Filed —169; Terminated—162.

Injunctions requested—26; **Injunctions granted**—14; **Import detentions**—5,320; **Recalls dangerous products**—51.

Trials—24: Won—19; Lost—2; Hung jury—2 (Defendant in one of the cases later plead guilty); Undecided—1.

As this summary shows, our enforcement programs are real and result in a considerable amount of litigation in the federal courts. Each regulatory action is carefully reviewed before it is filed to be certain that it represents a significant violation of the law.

Now let us consider some of the enforcement problems and potential enforcement problems in the fishery industry. According to the Annual Summary of the Bureau of Commercial Fisheries for 1959, the size of your industry is something of this magnitude on an annual basis.

Domestic including shellfish: Total catch—5,121,953,000 pounds, $346,051,000; Canned fish for both human and animal use—$430,364,000; Frozen fish and shellfish—336,600,000 pounds; Packaged fish and shellfish—147,237,022 pounds, $46,170,188 value.

Imports including canned products for both human and animal food: Volume—1,113,624,000 pounds; Value—$311,033,000.

In an industry as large and as diversified as yours, handling perishable or semi-perishable products, it is to be expected that you would have some problems from the standpoint of compliance with the food laws. But I am glad to say that your industry has made significant progress in solving these problems, particularly in the sanitation field, and the number of regulatory actions has been decreasing.

Here is the enforcement statistics for your industry for the calendar year 1960:

Establishment inspections—1,614; Total domestic samples examined—499; Import samples examined—1,243; Wharf examinations —969; Seizures—38; Prosecutions—4; Injunctions—1; Import detentions—372; Violation of probation—1.

At the present time, we have formal regulatory programs on the following:

(1) Fresh and frozen fish—(a) Decomposition; (b) Parasites: Domestic, Import; (c) Filth and plant sanitation; (d) Economic violations.

(2) Shrimp—fresh and frozen raw-headless, breaded, canned, cooked-peeled—(a) Decomposition; (b) Plant sanitation.

In addition to those formal programs, we are giving attention to many other segments of the fishery industry such as canned salmon, oysters, crabmeat, precooked foods, et cetera.

Also we give continuous attention to all fishery products from the standpoint of labeling and economic violations. Perhaps the best way to give you a picture of our enforcement actions involving fishery products and to also point out some of the problems we are encountering in your industry is to list the violations that have resulted in regulatory actions during the last several months.

During the calendar year 1960, we filed the following injunctions and criminal prosecutions:

Injunctions—1: Packer of frozen processed products, frozen breaded shrimp, and similar products—insanitary factory.

Prosecutions—4: 2 packers of fresh crabmeat—insanitary plants; 1 oyster packer—addition of water; 1 packer of frozen precooked products—insanitary plant.

Violation of Probation: Packer of frozen crabcakes, fish cakes, stuffed crabs—insanitary plant.

The following seizure actions were instituted under the law during the past 14 months:

Decomposition: Frozen uncooked crab—1; Canner salmon—2; Ocean perch fillets—11; Frozen boned shad—1; Dressed whiting—2; Crabmeat spread—1; Canned crabmeat—1; Frozen whole pink salmon—1; Halibut parts—3; Haddock fillets—4; Frozen carp—1; Canned anchovies—2; Frozen lobster tails—1.

Parasites: Ocean perch fillets; copepods—3.

Failure to comply with standards: Canned tuna (failed to comply with standard of fill)—3.

Short Weight: Frozen cooked dungeness crab—1; Smoked sliced salmon—1; Frozen canned oysters—1; Shrimp cocktail—1.

Other Violations: Canned tuna (contained bone pieces and scales)—1; Dressed whiting (incomplete evisceration)—1; Frozen

shrimp (fire damaged)—11 cars seized in New York, Los Angeles, and San Francisco; Canned bonito (unlabeled)—1.

As indicated by these regulatory actions, we still have enforcement problems, involving fishery products in the following areas: plant sanitation; decomposition; parasites; failure to comply with standards; short weight; mislabeling.

Plant sanitation is a continuing problem and, while great improvement has been made in practically all segments of your industry, there is considerable room for additional improvement. As you know, many groups are giving attention to this problem particularly from the standpoint of the application of microbiological standards. We believe this approach is sound and the Food and Drug Administration through its Division of Microbiology is carrying on studies on the correlation of bacteriological findings on food products with the factory conditions under which they were produced. One survey of frozen precooked foods has been completed and we found much to be desired from the standpoint of plant sanitation in handling these products. In view of the perishable nature of frozen precooked foods, including many seafood products, and their potentiality of causing serious illness, we consider this a regulatory problem of first importance, and are already carrying out field inspections in this area. The plant in New York that we have filed an injunction action against represents a serious threat to the public health. The preparation and packing of frozen breaded shrimp, breaded soft shelled crabs, and breaded scallops in a plant swarming with flies, without proper toilets and hand-washing facilities, with little or no cleaning of the equipment, and re-use of breading material that falls on the floor and is walked on cannot be permitted to continue. This is why we have asked the court to place this firm under an injunction and require it to discontinue operation until it is cleaned up.

We intend to give attention promptly to all packers of frozen precooked foods through inspection of factories and an evaluation of the sanitary conditions and practices by bacteriological methods, including the examination of factory samples and finished products.

There are several other enforcement or potential enforcement problems that I intended to discuss, but I have already taken too much of your time to go into details about them. So I will simply list them with a few brief comments.

Food Additives

No serious enforcement problems have been encountered in the fish industry under the Food Additives Amendment since its enactment. Many additives that are used in fishery products have been declared to be safe and others have been granted an extension of the effective date. Petitions for regulations are pending for use of ethylene diamine tetraacetic acid to prevent formation of struvite crystals in some canned seafood products and use of chlortetracycline, CTC, on fish fillets.

We have started our field inspection program under the Food Additives Amendment to determine whether there are an enforcement problems in this area and plants preparing fishery products will be among those covered.

Adulteration of Oysters

The excessive soaking and deliberate addition of water to shucked oysters represents a serious enforcement problem because of the lack of objective methods of measuring the amount of added water. As you know, this problem is being studied under the cooperative GICOR program. In the meantime, we are continuing our attention to this industry through factory inspection.

Fish Oils for the Prevention and Treatment of Heart and Artery Disease

We have seen some rather strong statements in the public press promoting the use of fish oils for the prevention and treatment of heart and artery diseases. These statements are based on the fact that oils containing a high percentage of unsaturated fats will have an effect on the blood cholesterol levels when consumed in adequate quantities by those who are on a controlled diet. But it has not been proved that there is a causal relationship between heart and artery diseases and blood cholesterol levels. It is, therefore, the opinion of the Food and Drug Administration that any claim, direct or implied, in the labeling of fats and oils or other fatty substances offered to the general public that they will prevent, mitigate, or cure diseases of the heart or arteries is false or misleading and constitutes misbranding within the meaning of the Federal Food, Drug, and Cosmetic Act.

We hope it will not be necessary to file any regulatory actions against fishery products because of false claims in this area.

Misbranding Based on Terminology

An enforcement problem that is giving us concern involves the area of terminology of fishery products. This has several elements:

(1) Outright substitution: As for example the sale of pollack fillets as walleye or catfish fillets:

(2) Use of confusing names—the use of the same name for different fish, or the use of different names in different areas for the same fish: As, for example, "trout fillets" for both rainbow and lake trout fillets, "pike" for both Esox lucius and the pike-perch (Stizostedion Vitrium);

(3) Attempts to create new "common or usual names" to overcome sales resistance, actual or fancied, to an article under its true name: As, for example, "lake fish" for canned carp, "mackerel-pike" for saury (during a canned mackerel shortage);

(4) The problem of an informative, nonmisleading name for seafoods not previously marketed in the United States: As, for example, the imported "langostino" and the newly developed calico scallops of Florida.

Regulatory action will be initiated against violations in this area when they are encountered and where we can obtain support from industry representatives, and consumers to establish consumer deception.

Importation of Fishery Products

Our import programs are designed to keep unfit seafoods out of this country. Through our excellent cooperation with Canada the quality of products from that country in general is excellent. We are having some probems, however, with products from other countries, particularly frozen precooked products and frozen raw shellfish, since we do not have control over the sanitary conditions under which imported products are produced. This is an area that is being given increased attention in view of the potential hazard from such products.

These are the principal problem areas of your industry at the present time as far as the Federal Food, Drug and Cosmetic Act is concerned. I hope that my comments will not be construed as indicating that you have all problems and no virtues. That is far from the facts because we all know that the American consumer is for the most part being supplied with excellent products by your industry. They will be even better when you have overcome these remaining enforcement problems. **[The End]**

Food Additives Law As It Affects Bakery Production Men

By J. KENNETH KIRK

This Paper Was Presented to the American Society of Bakery Engineers, Chicago, March 8, 1961. The Author Is Assistant to the Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare.

AT YOUR ANNUAL MEETING in 1960, Mr. John Guill, director of our Chicago District, outlined for you the specific provisions of the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. He told you what progress had been made up to that time, and discussed something of the makeup of the Food and Drug Administration and how it operates on a regulatory basis. In the light of what he had to say, I will try not to repeat any more than is necessary.

When Mr. Doty and Mr. Marx got in touch with Commissioner Larrick last summer about participation in this meeting, he suggested that I would probably be in possession of information which this group would like to know about. Under the circumstances, I accepted the invitation to appear. Looking into the crystal ball, I had an idea that I was going to be able to come out here to Chicago and tell you that the Food Additives Amendment was now fully effective—and had been for three days. I thought I was going to be able to tell you of the problems that had been solved and of the status of some few items yet to be considered.

As all of you know, I'm not going to be able to do that at this meeting. Both FDA and the industries involved came up to March 5, 1961, with a great deal yet to be done under this Food Additives Amendment. In full recognition of this, we had asked the Congress for authority whereby we could grant further extensions of the effective date of this law where the facts warranted and where we could

be satisfied that the extensions would present no undue hazard to the public health. It was our view that this extension authority should apply to articles and uses of those articles for which extensions had already been granted and in a limited number of cases to products for which we had requests for extension prior to March 5, but which we had been unable to process. Parenthetically, I might say that most of the requests which could not be processed promptly under the previous extension authority were those which were designated to us solely by trade names. If we didn't know exactly what the product was, obviously we could not even consider the proposed extension.

Our proposed bill provided for the granting of extensions where there had been diligent effort to solve food additive problems. Included was a provision requiring progress reports and one giving authority for cancelling any extension granted where the facts warranted. Very deliberately, the bill was calculated to give no relief whatsoever to the firm or individual who had just sat back and done nothing to resolve his food additive problem.

This bill was introduced into the House of Representatives on February 7, 1961, as H. R. 3980. Hearings were held on February 28 and March 1 by the House Interstate and Foreign Commerce Committee under the chairmanship of Hon. Oren Harris. Secretary Ribicoff endorsed the bill and urged early enactment. His testimony was followed by that of Commissioner Larrick who also testified in favor of the bill and supplied the committee with many details of just what had happened under the Food Additives Amendment since its enactment in September of 1958.

The bill did not include a "closing date" but provided for extensions for whatever time the Secretary could conclude was necessary for the appropriate investigations with, of course, a requirement that the extension, no matter for how long, be one which would present no undue hazard to the public health during that period. Congressman Delaney of New York and Congressman King of Utah appeared as witnesses and, while expressing themselves as in favor of a law authorizing a further extension period, they took exception to the "open end" character of the bill.

The view was expressed that a period of approximately two years should be the limit for any extension authority. Commissioner Larrick stated that he would not object to such a time clause with the clear understanding, however, that if this did not prove to be sufficient time, and it now looks as though there will be cases where it will not

be sufficient, the Department will be back before the committee asking for further authorization.

The paper and pulp people offered a proposed revision of the bill which was stated to be designed to take care of a situation which might arise in the future, where some substance thought for years to be GRAS or not a food additive for some other reason, could be found to be a food additive. Commissioner Larrick pointed out that this was a highly speculative possibility and that the change was not, in his opinion, necessary. He added that if the speculation involved a substance which, in the future is classed as a food additive because it is presenting a real hazard to the public health, obviously this would call for immediate removal of the article from the market; on the other hand, if the substance became a food additive on a technical basis, the Commissioner would have ample authority to see that an appropriate regulation is issued without disruption of the marketing of the product.

Other witnesses endorsed the bill but urged that the two-year period suggested by Congressman Delaney and Congressman King be set at a longer period. A witness for the National Canners Association urged a blanket extension for six months to permit the submission of new requests for extension and to give time for the Food and Drug Administration to evaluate and process these requests. Commissioner Larrick took the position that such a provision would not be necessary.

He stated that obviously the present bill could not be enacted into law before March 6, 1961, but with the intensive consideration being given the bill by the Congress, it would be his purpose not to regard the present extensions as expiring on March 6. Then, if the bill becomes law, he will immediately notify all concerned by appropriate notice that the extensions already granted are to be continued administratively for a reasonable period, perhaps two months, during which time anyone would be at liberty to submit the required data seeking such further extensions as may be deemed necessary. Consistent with the terms of whatever extension law is enacted, the notice will, of course, delineate just what is to be submitted in support of each extension request.

The committee has favorably reported the bill with an amendment suggested by the Commissioner which would provide authority for further extensions not only of items for which extensions have already been granted, but also extensions in cases where we had before us requests for extension but had not acted upon these before March 6. A time limit was included.

We believe that it is safe to say that any fears that some people may have had to the effect that March 6 would be a day of chaos in the food industry were wholly unfounded.

Just to give you an idea of what we are talking about, we got together a few figures about food additives:

Since the enactment of this law in September of 1958, the Food and Drug Administration has responded to more than 4,200 formal inquiries dealing with requests for information or review of data involving food additive problems.

While no count has been made, there have been hundreds of discussions with industry people both on the administrative and technical side in an endeavor to resolve just what needs to be done under this law.

Items which are generally recognized as safe are exempt from this law for the uses specified and so far we have published lists of 718 items in this category.

Substances for specific uses which have prior sanction under this law are exempt. We have published only 112 of these but deal with requests for information about prior sanctions on an individual case basis. Among other reasons, this is because many of the prior sanctions which we granted involve formulations which are entitled to protection as trade secrets.

If anyone has a formulation, or single substance for that matter, which he believes is subject to a prior sanction, he is at liberty to write and ask whether or not such a sanction exists. It will help if he can tell us the name of the firm he believes got the sanction in the first place. We cannot, however, respond to requests asking whether XYZ company has a prior sanction for its product and, if so, to tell the inquirer what XYZ's formula was at that time.

We have received 391 petitions for food additive regulations. Of these, 100 were found to be inadequate and thus could not be filed pending the acquisition of additional information. There were 42 cases where the petitions were not filed because the substances involved were not food additives. A few were withdrawn. Of the 391 petitions received to date, 175 were for indirect additives involving approximately 1,675 chemicals; 216 were for direct additives involving approximately 257 chemicals.

We have issued 59 regulations to date.

We have pending before us, being actively evaluated, 178 petitions.

We have issued extensions of the effective date of the law covering some 3,000 uses of food additives, about 1,100 which are direct additives. The others are in the packaging and equipment fields although some of these may turn out not to be food additives requiring regulation.

We have pending before us about 50 requests for extension. In most of these cases, we are awaiting further information as to composition before any decision can be made.

Although this food additives law was enacted in September 1958, progress in solving food additive problems was generally quite slow for the first 15 months following that date. During the past year or so, however, there has been a marked step-up in this field and a look at the record readily points out one important factor in achieving this result. In our opinion, this was the action taken by such groups as the one represented here today. There was a realization that the man who ships the food in interstate commerce is the one who is going to be held responsible first if that food contains a food additive for which no authority has been granted for its use.

Users, therefore, took a second look at the ingredients they were using and concluded the time had passed when they could use somebody's "secret" formulation. They had to know what they were using to make a decision. The same considerations applied to packaging and equipment items. Here again, the user needed assurance that he was not inadvertently adding an unknown food additive to his product. This, of course, meant that suppliers had to go to those from whom they bought their products and thus, a chain of inquiry was set up all the way back to the original manufacturer.

This caused, in some areas, a demand that every single item in use or contemplated for use be accompanied by some sort of "approval" by the Food and Drug Administration. In some cases, it seemed to us that this was being carried entirely too far since certainly there should be no question under the Food Additives Amendment about the type of materials being used for walls and floors of a plant when you take into account that a substance which does not become a part of the food or, for that matter, is not one reasonably to be expected to become a part of the food, is not a food additive.

There should, we believe, be a recognition that nothing in the law requires anyone to come to the Food and Drug Administration with what he concludes is not a food additive. We have issued tests which may be applied to packaging and equipment items to determine

whether or not particular components are food additives. We have made it clear that if anyone applies these tests properly and finds no migration, he has every reason to go ahead without asking our concurrence. Assuming that he has conducted the proper tests and has drawn correct conclusions from the results therefrom, there would be no reason to expect any difficulty under the Food Additives Amendment.

In line with our basic policy, however, we are entirely willing to comment on data which is submitted to us along these lines, but we should make it patently clear that any such comment cannot be regarded as "approval" by the Food and Drug Administration. All we can say is that if you conducted the right tests and if the results are as outlined, then you have no food additive problem.

When you come right down to it, the only "approval" which we can grant involving a food additive is in the publishing of an appropriate regulation which authorizes that particular substance with or without a limit.

We understand that some of the letters we wrote earlier were used in advertising campaigns to the detriment of other firms who had the same product but had taken us at our word and had not invited our comment once they concluded that they did not have a food additive problem. We didn't intend our letters to be used in this way. We hope the ones we are writing now are so written that they cannot be "advertising."

If any of you here have not taken the close look I mentioned earlier at your own operations, I believe that it would pay you to do so in order to be sure that you are not adding, either directly or indirectly, a food additive which is not authorized either by regulation or extension; and even if you have an extension item, let us not overlook the fact that under the new authority it is expected that every extension will have a definite time limit so that he who has an extension has only passed the first hurdle of the race. **[The End]**

The Scientists' Forum

By BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

The Following Paper, a Lecture on Experimentally Induced Cancer in Relation to Food Law Enforcement, Was Presented Before the Pesticides Subdivision of the American Chemical Society in St. Louis on March 22, 1961. Dr. Oser Illustrated His Talk with Slides, Which Are Described in the Footnotes.

THE DESIRABILITY of excluding potentially carcinogenic substances from the human environment is unquestionable. However, those who rise in indignation over the apparent resistance or dilatory attitude of industry toward subjecting every suspected carcinogen to exhaustive animal tests are generally unaware of how recently there has been even provisional agreement among scientists as to what tests are appropriate, what time and effort are involved in such studies, and the uncertainties associated with relating the findings in animals to practical conditions of human exposure.

For more than a century after 1775, when an abnormally high incidence of scrotal cancer was recognized among chimney sweeps,[1] evidence for a relationship between cancer and occupational exposure to chemicals rested largely upon epidemiological grounds. The association of the products of the coal tar industry with certain forms of skin and bladder cancer was based upon clinical observations in industrial workers. With the growth of the chemical and dye industries from the mid-nineteenth century, and the concomitant advances in the biological sciences, it was inevitable that interest should develop in animal experimentation as a means of evaluating potential occupa-

[1] Sir Percival Potts, *Chirurgical Works of Percival Potts*, James Williams, Dublin, 1778.

tional hazards. Indeed, much of our present knowledge of chemical carcinogens is now derived from animal studies which in only a relatively few cases are supported by human experience.

Research in the field of carcinogenesis received particular impetus from the work of Japanese investigators who, in 1915, reported that cancer could be induced by painting the ears of rabbits with tar extracts.[2] The active components of these extracts were subsequently shown by British and French scientists to be polycyclic aromatic compounds, more specifically derivatives of anthracene and phenanthrene.[3] These discoveries led to the investigation of a large number of polycyclic hydrocarbons as well as of other aromatic and aliphatic compounds. Of the thousands of compounds catalogued in the surveys published in 1951 and 1957 by the National Institutes of Health,[4] some 2000 were tested for 30 days or more. About one fourth were reported to have induced tumors, approximately one third of them resulting from the administration or application of derivatives of benzanthracene and related polynuclear compounds.

In recent decades, scientists and writers on the subject of cancer have hardly overlooked a single aspect of the human environment from the viewpoint of the possible causal relation of chemicals to this disease. Attention has been directed to atmospheric smoke, smog and dust; to occupational exposure; to medicinal agents; to tobacco smoke; to pesticide residues and additives in food; and to polluted water supplies. One wonders whether the alleged carcinogenic hazards like estrogens, arsenic and food colors, have received a degree of emphasis out of proportion to their real significance. Broad generalizations and speculations with regard to chemical carcinogenesis are often based on exceedingly fragmentary and unsubstantiated evidence. Exaggeration of hypothetical, suspected or potential hazards is not in the best public interest since it can divert the efforts of scientists and the attention of legislators away from problems where they more properly belong.

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[2] K. Yamagiwa and K. Ichikawa, *15 Tokyo Igakkai Zassi* 295 (1915); *3 Journal of Cancer Research* 1 (1918)

[3] Kennaway, E. L., "Cancer-Producing Tars and Tar Fractions," *5 Journal of Industrial Hygiene* 462 (1924); A. Lacassagne, *"Les Cancers Produits Par des Substances Chimiques Endogenes," Librairie Scientifique,* Hermann & Cie, Paris, 1950, p. 170.

[4] Hartwell, J. L., "Survey of Compounds which Have Been Tested for Carcinogenic Activity." 2d ed. *Public Health Service Publication No. 149.* (Washington, U. S. Government Printing Office, 1951), 583 pp.; Shubik, P., and J. L. Hartwell. Supplement 1 to the above. (Washington, U. S. Government Printing Office, 1957), 388 pp.

There can be no denial however that this is an area where more research is sorely needed to gain better perspective. The motivation for investigations in experimental carcinogenesis is by no means limited to the discovery and evaluation of potential hazards. The possibility that a carcinogenic response to a known chemical substance may reveal the existence of etiologic agents in cancers of unknown origin, or that it may shed light on the mechanism of action of factors responsible for the initiation or stimulation of cancerous growths, has intrigued many workers in this field. The so-called known carcinogens have furnished a useful tool for the study of species and strain variations in susceptibility and resistance. Most of the work on cancer chemotherapy has involved the use of test animals in which tumors have been induced by transplantation. However, chemical carcinogens are proving increasingly important as an experimental device for the investigation of anticancer agents.

Current interest in the study of chemical carcinogenesis derives largely from the problems related to air pollution, tobacco smoking, and the use of chemicals in food production and processing. There is no question of the need for preventing, insofar as possible, any human contact with potent carcinogens. However, the problem of evaluating the potential risks of weak or borderline carcinogens is beset with many difficulties. Well-meaning legislators in this and other countries have placed upon the shoulders of scientists a responsibility which can be met only by the application of reasonable judgment, since the factual bases upon which to design the truly critical studies and to extrapolate experimental findings from animals to man with absolute certainty, do not yet exist.

The criterion which distinguishes potent from weak carcinogens is the magnitude of the total dose necessary to elicit the effect, regardless of the route of administration. Potent carcinogens are considered to be those which, after a single dose, or after repeated administration of extremely minute doses, induce a high incidence of malignant tumors. In contrast, weak carcinogens require dosing in relatively large amounts and for long periods, perhaps continuously for a lifetime. Their effects may be only marginal or of extremely low incidence. When the evidence indicates the potency of a carcinogen to be of a high order, there is generally no dispute as to the decision to be taken from the standpoint of health protection. But in the case of weak carcinogens, certain questions arise: first, as to the suitability of the testing procedure, particularly with respect to the dosage levels

compared to the predicted exposure level; secondly, as to the validity of the interpretation of minimal histopathological changes; thirdly, as to the degree of probability to be assumed in the statistical analysis of the data, that is, the justification for considering differences between test and control groups to be significant.

In the past five years many toxicologists, pathologists and cancer experts have individually and in committees, both nationally and internationally, weighted the problems of methodology and interpretation and have recommended certain guidelines in the appraisal of the potential carcinogenicity of orally ingested substances. While there is general agreement as to the indispensibility, in the present state of our knowledge, of chronic feeding studies in animals, the multiplicity of factors to be considered and the differences in the recommendations of various expert groups illustrate the complexity of the problem. Slide 1 lists the major factors which must be taken into account in designing a study of the carcinogenic potential of a food component.[5]

The next slide [6] illustrates the variations in the design of carcinogenic feeding studies published recently by several representative bodies (respectively the United States Food and Drug Administration, the Food Protection Committee of the National Academy of Sciences—National Research Council, the British Ministry of Health, and the Joint Expert Committee of the World Health Organization and the

[5] Factors in Experimental Carcinogenesis—*Test Substance:* Identity; Purity (freedom from contaminants); Physical state; Diluents; Vehicles. *Animals:* Number; Species; Strain; Sex; Generations. *Conditions:* Basal Diet; Housing; Sanitation; Pest control. *Dosage:* Amount; Route; Frequency; Duration. *Observations:* Physical examinations; Functional tests; Biopsies; Necropsy; Histopathologic examinations. *Statistical Evaluation, Interpretation.*

[6] Recommendations for Carcinogenicity Tests of Food Additives

Source	*Species (Strains)*	*Number groups Control/Test*	*Number each sex/group Control/Test Beg.*	*End*	*Route*	*Duration Dosage/Total years*
FDA	Rat (2)	1/3	100/50	q. s.	Oral	2/2
	Mouse (2)	1/3	100/50	q. s.	Oral	2/2
	Dog	1/3	6/6	q. s.	Oral	7/7
FPC	Rat	1/3	25/25	q. s.	Oral	2+/2+
	Mouse	1/3	25/25	q. s.	Oral	2/2+
	Dog	1/3	8/8	q. s.	Oral	4+/4+
BMH	Rat	1/1+	25/25	12/12	Oral [b]	1/2−
	Mouse	1/1+	25/25	12/12	Oral [b]	1/1.5+
WHO/FAO	Rat (2 [a])	1/3	q. s.	20/20	Oral	Life
	Mouse (2 [a])	1/3	q. s.	20/20	Oral	Life

[a] If pure strains are used.
[b] Parenteral also, whenever possible.

Food and Agricultural Organization of the United Nations). It shows, for example, that the use of the dog (or other nonrodent species) as a test animal is stressed only in the United States. All groups recommend both the rat and the mouse, one strain of each being generally considered sufficient, unless "pure" strains are used. Other nonrodent species are considered optional. Among the reasons why the dog is not favored as a test subject by many investigators is the fact that four or even seven years represents too small a fraction of the normal life span, whereas the full span of 12 or 15 years, not to mention a statistically sufficient number of animals, would be quite impracticable.

Except for the British Ministry of Health, all agencies specify for multiple test levels, although a finding of cancer at any dosage would, under the Federal Food, Drug, and Cosmetic Act as officially interpreted, preclude the use of the substance in question. It will be noted that there are substantial differences in the proposals for the size of each test and control group, varying in combined totals from 200 to 500 rats of each strain. However in all cases it is required that there be a sufficient number of survivors at the termination of the test to permit statistically valid comparisons of tumor incidence among the test and control groups. The recommended duration of the dosage period in rodent studies ranges from a minimum of one year to the full life span of the animals. FDA has regarded two years as a sufficient period of observation in both chronic toxicity and carcinogenicity investigations in rodents but the trend is definitely toward continuing carcinogenicity studies for the full life span of these species since cancer in animals, as well as in man, is associated with advancing age.

All expert groups agree on the necessity for the oral route of administration of test substances which may become components of food. On the subject of parenteral administration, however, opinions vary somewhat.[7] Most of the evidence for the more potent carcino-

[7] *Parenteral Administration* — FDA: "Carcinogenesis . . . by one route of administration does not imply carcinogenesis . . . by another route of administration."

FPC: "When large doses of material must be given repeatedly, the subcutaneous route of testing substances for their carcinogenic activity is of *limited value* and of *dubious interpretation.*" More research needed.

BMH: "Tests by the oral route will invariably be required in the case of substances proposed as food additives . . . Although tests by parenteral injection *should be performed whenever possible,* it is recognized that there are some materials which are not suitable for administration in this way."

WHO/FAO: Induction of local sarcomas by subcutaneous administration is *not proof* that substance will be carcinogenic by oral route . . . *Some countries,* however, consider this sufficient basis to reject such substances for use in food pending more proof of safety. More research needed. (Italics supplied)

gens, such as the polycyclic aromatic hydrocarbons and certain of the azo dyes, has been based on dosage by either the topical or subcutaneous routes. Relatively little basis exists for predicting from such findings the potentiality of each compound for inducing cancer by ingestion. Moreover, wide variations exist in the choice of species, conditions of dosage, and duration of observation in parenteral studies. Subcutaneous tests are further complicated by trauma resulting in local sarcomas at the site of injection. Time will not permit the detailed discussion of more than a few of these test recommendations. Suffice to say, however, that in addition to the use of normal animals on normal diets, it has been proposed that metabolically or nutritionally disturbed animals, and pregnant and lactating females, be employed in evaluating potential carcinogens; and that the studies be extended for the full life span of more than one generation of animals. However, most investigators agree that some practicable limitations must be placed on the extent and expense of these investigations if they are to be done at all.

The Delaney anticancer clause in the Food Additives Amendment forbids the establishment of a tolerance for any substance which "is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal . . . ." At least for the present, this clause is being applied by FDA only to substances which are, or may be, ingested. However no restriction is contained either in the statute or in the regulations on the level, frequency or duration of dosage in animal tests. Obviously, therefore, the degree of exaggeration of dosage levels and other conditions employed in an experimental evaluation of a potential weak carcinogen are of critical importance. On the subject of maximum dosage, various authorities have made the recommendations stated in abbreviated form on the next slide.[8] One might ask "Why feed more than one dosage level?" Under present interpretations, a positive response at any level would preclude the promulgation of a tolerance even if no tumors were observed at lower dosages and on the other, a negative response at a single dosage, namely, the highest tolerated level, might justify the presumption of no effect at lower levels.

[8] *Highest Dosage* — FDA: As high as possible without inducing inanition or early mortality; FPC: Maximum that can be tolerated without affecting long-term survival; BMH: As high as can be administered without materially reducing the life span; WHO/FAO: One which produces a minimum to moderate amount of short-term toxicity and does not materially decrease life span.

The answer usually given is that the information accumulated from multiple dosage studies is needed in order, some day, to establish a basis upon which safe levels of dietary carcinogens may be permitted. It should be noted that any dose high enough to bring about the initial organic or functional effect produces a metabolically stressed test animal. The continued addition to the causative insult to the primary injury, throughout the lifetime of the animal, represents an exaggeration of experimental conditions far beyond that simulating use conditions. There are reports of swamping effects of normal metabolic pathways with subsequent overflow into replacement pathways. The consequence of continuous saturation of metabolic pathways throughout the life of an animal may in large part depend on the functional capacity of an organ system at various stages of its life cycle. Excessive dosage levels may alter toxicological manifestations to a degree that the parameters being evaluated no longer represent the same physiological mechanisms.

Some investigators believe that the principle of the safety margin can be applied to potential carcinogens just as well as to any other type of toxic substances, with the reservation that the ratio between the no-effect level and the use level be substantially greater than the arbitrary 100:1 factor generally imposed. If, for example, a food color intended for use at a dietary level of 20 ppm induced no effect in chronic feeding studies at 1000 times this level, or 2 per cent, it might be considered safe even though tumors were observed at a level above 2 per cent. This concept was considered reasonable and legally acceptable prior to enactment of the Delaney clause.

However another, less arbitrary, approach to the setting of safe levels for weak carcinogens could be predicated upon the fact that precancerous (that is, noncancerous) changes frequently precede the appearance of cancer. Such precursory symptoms were associated with certain of the substances recently regarded as carcinogens by FDA, for example, thyroid depression in the case of aminotriazole, or liver hyperplasia in the case of Aramite, safrole and FDC Red No. 1. In each case there was experimental demonstration of no-effect dosage levels in the test animals but, what is more significant, the precancerous effects induced at higher dosages were probably of a regressive nature. Substances such as these have been designated "indirect secondary" carcinogens because their action results from metabolic disturbances in certain target organs, rather than directly (as in the case of aromatic amines or polycyclic hydrocarbons) or through the

production of endogenous carcinogens (certain metallic compounds, radiations, etc.). In fact one of the more common findings in toxicological tests in rats is liver damage, including hyperplasia, cirrhosis and hepatoma, and under conditions of chronic feeding these may result in liver cancer. Similar changes can also be induced by dietary means.

In any event it would seem that the maximum dosage level which induced no evidence of a precursor effect could serve as a reasonable basis for arriving at safe tolerance levels, assuming of course the judicious application of a safety factor. This would be entirely consistent with the view expressed by Dr. G. Burroughs Mider of the National Cancer Institute in his report to the Secretary of Health, Education, and Welfare, namely, "some arbitrary decision must be made as to the margin of safety to be used in translating data obtained from animal experimentation to man, taking into consideration all known facts concerning the carcinogen in relation to its proposed use in the human environment."[9] This statement appears to offer some promise for the extrapolation of safe levels for man from animal data. Hope vanishes, however, when this statement is contrasted with the same author's oft-quoted assertion that: "No one at this time can tell how much or how little of a carcinogen will be required to produce cancer in any human being." One wonders whether such an objective can ever be attained short of quantitatively controlled, lifetime studies in man.

Those who are called upon to interpret and apply the results of animal experiments thus find themselves on the horns of a dilemma from which only corrective legislation can extricate them. Legislation which would permit the exercise of reasonable scientific discretion is now denied by the Delaney clause, according to its many critics.

In all fairness it should be pointed out that some scientists do not accept the view that the absence of a precancerous lesion precludes the ultimate appearance of a malignant tumor. Some support the idea that even a minimal exposure to a potential carcinogen, for example, ultraviolet radiation, will induce some degree of cellular damage which, given enough time, will inevitably lead to cancer. The fact that extrapolation of time:response data indicates that it would require several times the normal life span to induce the carcinogenic response seems to be ignored in translating such observations to man.

[9] G. Burroughs Mider. Report Submitted in Testimony before the Committee on Interstate and Foreign Commerce, House of Representatives, 86th Cong., 2d Sess. (January 26, 1960).

Reference has been made to the problem of the histopathological lesions induced by weak or borderline carcinogens. The key specialist in the assessment of the results of a carcinogenicity experiment is the pathologist. Training and experience in human pathology is important but is not enough. The pathologist should be familiar with the particular species of laboratory animal, with strain variations in the types of so-called spontaneous tumors, and on the basis of past experience or of periodic observations, he should be able to predict or extrapolate progressive histopathologic changes. There is often the need for expert appraisal of pathology in specific organs, particularly where species variations are known to exist.

Pathologists seldom disagree on what they see but they not infrequently differ in their interpretation of its significance. The following slide shows the classification of neoplasms as defined in the recent report of the Food Protection Committee.[10] It will be noted that a distinction is drawn between hyperplasia, a localized increase in cell numbers which is regressive, and tumors or neoplasms which generally are persistent and progress to fatal termination. Benign tumors are distinguished in various ways from malignant tumors or cancers but because a benign tumor may, if given enough time and favorable pathogenetic conditions, become malignant, many pathologists attach as much weight to the one as to the other. For this reason some cancer research workers are dubious about the classification of the ubiquitous insecticide DDT as a noncarcinogen on the basis of the observation that at the dietary level at which tumors resulted "there was only a minimal and late tendency in the formation of hepatic cell tumors" described as benign.[11]

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[10] Neoplasms (Tumors)

(Nonregressive, in contrast with Hyperplasia)

Benign	*Malignant (cancers)*
Structure resembles tissue	Structure atypical
Growth slow, expansive, encapsulated	Growth rapid with mitosis, infiltrative, progressive
Nonmetastatic	Metastatic (Transplantable)
Nonlethal	Lethal
Examples:	Examples:
Adenoma (gland-like)	Carcinoma (epithelial)
Papilloma (wart-like)	Sarcoma (mesenchymal)
Chondroma (cartilage)	Lymph sarcoma (lymphatic)
Osteoma (bone)	Leukemia (hematopoietic)

[11] O. G. Fitzhugh and A. A. Nelson, *89 Journal of Pharmacology and Experimental Therapy* 18 (1947).

The entire subject of environmental carcinogenesis, from experimental methodology to practical interpretation, is one where sound scientific judgment and discretion must be applied. Without animal studies the evaluation of potential carcinogens is impossible; with animal studies unequivocal proof of noncarcinogenicity is impossible. The application of animal tests to the control of safety of foods, drugs and other aspects of our external as well as internal environment, demands not only objectively determined facts but the considered judgment of qualified scientists. To the extent that these are precluded under present laws, repeal or amendment will be essential to progress. **[The End]**

CONVICTIONS IN SALE OF ADULTERATED ORANGE JUICE

Four officials of companies in Texas and Missouri have been convicted in the sale of over $750,000 worth of sweetened water in place of pure orange juice in a 1½ year period.

The convictions were the result of long and painstaking work by Food and Drug Administration inspectors, who resorted to the use of field glasses and cameras to get evidence on the surreptitious operation.

The company officials were convicted in Federal District Court in Houston for violation of the Food, Drug, and Cosmetic Act by shipping in interstate commerce an orange product labeled "Fresh Orange Juice —As Nature Made It . . . nothing added." The product was actually adulterated with added water and sugar. The sweetened water constituted one third to one half of the product distributed over a 20-state area between November 19, 1958 and October 8, 1959.

The government charged that the defendants had conspired to distribute adulterated and misbranded orange juice, with intent to defraud and mislead. The jury found the defendants guilty of conspiracy and all charges of introducing the adulterated product into interstate commerce, but not with the intent to defraud or mislead.

Evidence presented during the trial indicated that vast quantities of sugar and water were used in the product in a clandestine manner.

Cover-up tactics were used in cash purchases of 750,000 pounds of sugar. One employee testified that, when sent for sugar, he was given a check on the company petty cash fund which he first cashed at a bank before purchasing the sugar. Employees who bought sugar were required to divest themselves of all indentification connecting them with the company. They used unmarked trucks in the operation.

The sugar was not transported directly to the plant but to an adjacent shed. There it was transferred to buckets which were carried into the plant. FDA inspectors made numerous inspections of the plant but never were able to locate the sugar. Eventually they rented a nearby apartment overlooking the plant, enabling them to use field glasses and cameras, and to make movies.

Foreign Law Comment

By JULIUS G. ZIMMERMAN

Editor's Note: The *Food Drug Cosmetic Law Journal* Is Pleased to Present to Its Readers an English Translation of Chapter X of the Latin-American Food Code, Translated from the Original Spanish by Ann M. Wolf, New York. The Introduction to the Code by Carlos A. Grau and the Index Were Published in the October, 1960 Issue, and Chapter IV Was Published in the February, 1961 Issue of the *Food Drug Cosmetic Law Journal*.

The Latin-American Food Code

CHAPTER X—SUGAR AND SUGAR PRODUCTS

Natural Sugars

Article 313—*Natural Sugars* are sugars found in nature, especially in vegetables used as nutrients. 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 one aldehyde, acetone or ether-oxide radical.

The name "*Sugars,*" as used in this Code, means sucrose, dextrose, lactrose, invert sugar, syrups from glucose, corn, potatoes and sweet potatoes and the solids of said syrups which meet the requirements established herein.

Article 314—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 315—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.), *rock maple* (Acer Saccharinum Wang).

Article 316—*Sugar* must be brilliantly white or slightly yellowish white in color; it must be soluable in water, in which it must give a practically clear solution. It must contain not more than 1 per cent 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 and indanthrene blue may be used in the minimal amounts required for bleaching, and the strictly necessary amounts of tin chloride and phosphoric acid may be added to fix the "Demerara" color type.[1] Colors authorized by the competent authority may be added to fancy or luxury sugars.

Article 317—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 at least 99.5 per cent and a maximum ash ratio of 0.2 per cent. *Confectionery Sugar* shall have a sucrose content of not less than 98.5 per cent. When cube-sugar is marketed wrapped, the paper used must be white on the inside; its outside may be colored, provided the dyes used do not discolor and are not toxic.

The name *Powdered Sugar* distinguishes finely pulverized refined sugar. Up to 3 per cent of starch may be added to powdered sugar to prevent it from forming lumps with the ambient humidity.

Article 318—The names *Crude Sugar, Yellow Sugar, Blond, Brown* or *Black Sugar, "Tapa" Sugar,*[2] *Unrefined Sugar, "Panela,"* [3] *"Papelon,"* [4] *"Rapadura"* and *Raspadura"* [5] apply to the product generally prepared

[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.

[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 crude sugar.

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

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 resulting loaves which are usually tied together in pairs, contain sugar and molasses. *Average percentage composition*: water—7; protein—0.5; fat—0.5; assimilable carbohydrate—91; crude fiber—0; ash—1.1.

Article 319—The name *"Chancaca"* (crude 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 320—The name *Rock Candy* distinguishes sugar obtained by slow crystallization. It has the shape of bulky crystals, formed by rough, transparent, hard prisms. It must contain at least 99.9 per cent of sucrose.

Article 321—The name *Molasses* applies to the thick syrups or liquids which are the residue of sugar manufacture. Their sucrose content cannot be separated economically. Depending upon its origin, molasses is called: *Cane Molasses, Beet Molasses,* etc. Only cane molasses may be used for human and animal nutrition.

Cane Molasses (Saccharum officinarum) is a thick, dark-colored 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 vugaris L.) is a thick, dark-colored liquid, unpleasant in odor and taste, with 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.

Article 322—The name *Goldensyrup* or *Cane Syrup* applies to the product prepared from the syrups obtained during the crystallization of the sugar, to which glucose may or may not have been added to prevent the crystallization of the invert sugar, with or without the addition of a permitted color. 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 323—*Caramelized Sugar, Burnt Sugar* or *Caramel* shall be obtained through the direct action of heat on sucrose, glucose or other sugars of vegetable origin. They may be neutralized only with properly pure alkaline carbonates.

Article 324—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 per cent of sucrose, and in the second, not more than 5 per cent of sucrose.

Article 325—The names *Glucose Syrup, Corn, Sweet Potato* or *Potato Syrup* (used according to the origin of the syrup) apply to the concentrated and clarified aqueous solution obtained through the 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 per centum. The ash may not exceed 1 gram per centum. Solid products obtained through the desiccation of these syrups must also be sold with the declaration of their D. E.

Article 326—The name *Dextrose* applies to the solid product obtained through the complete hydrolysis of starch, followed by processes of refining and crystallization. It must not contain dextrin or starch and must contain not less than 90 per cent of dextrose and not more than 9.5 per cent of water, 0.60 per cent of maltose and 0.25 per cent of ash consisting chiefly of sodium chloride. A 50 per cent solution in water must be clear and almost colorless. Ultramarine 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 centum.

Article 327—*Lactose, Milk Sugar* or *Lactine* intended for foods (preparation of dietetic products, etc.) must be refined and must contain not less than 99.5 per cent of lactose (disaccharide). It may have the form of a mass formed by prismatic rhombic crystals, with hard octahedron facets, or of a white, odorless powder with a slightly sweet 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 per cent.

Honey and Honey Derivatives

Article 328—The name *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 saccharine exudations of plants, and stored by them in combs. Average percentage composition: water—18; protein—0.4;

assimilable carbohydrate (invert sugar)—71; ash—0.3; acidity as formic acid—0.10.

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

Article 329—The names used to distinguish commercial products shall correspond with the following definitions:

1. *Comb honey or Honey in sections:* This term is reserved for honey still in bee-built combs which have never contained brood.

2. *Virgin-honey, Fluid honey, Cell honey:* This is the product which flows spontaneously from honeycombs or cells that have never contained brood and is 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 beating the combs and the honey contained in them.[8]

Honey must meet the following requisites:

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

10. It must not contain pollen, wax or other water-insoluble substances in a proportion exceeding 1 per cent 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.

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[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 beating process, but not while still in the comb.

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

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

Article 330—The name *Hydromel* or *Mead* applies to the beverage obtained through the alcoholic fermentation of honey diluted in potable water.

The designation *Mixed Hydromel* or *Fruit Hydromel* applies to the product obtained through the fermentation of a decoction of diluted honey and hops, to which various flavors or fruit juices have been added.

Hydromel artificially 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.

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 the 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 exceeding 300 parts per million.

5. The carbonation with carbon dioxide suitable for the use for which it is intended.

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 with other unauthorized saccharine products.

8. Hydromels prepared with honeys which fail to meet the requirements established in this Code.

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

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

Confectionery

Article 331—The name *Candy Factory* and/or *Chocolate Candy Factory* designates the establishments manufacturing candy and chocolate candy and varieties thereof.

All confectionery products may as a rule be prepared with cream of tartar, edible gelatins, pectins, organic acids, essences and permitted colors without requiring a declaration of these additives in the labeling, provided that no specific provision to the contrary is contained in another article hereof. The addition of any food product regulated hereunder or authorized by the health authority is likewise permitted.

The following shall be prohibited:

1. The using of tin foil, bronze foil or other foil containing zinc, lead, nickel or antimony, to silver and 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 deleterious 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, tragacanth gum and other permitted products.

3. The maufacturing, possessing or selling of chocolate candy, candy, confections and lozenges which contain deleterious products, or products the use of which is prohibited.

Confections, chocolate candy, 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 altered products for any reason whatsoever; such products must promptly be rendered unusable. The term "altered" means that the product, due to the action of microorganisms or other causes, has lost its original quality and harmlessness.

Article 332—The names *Confectioner's Shop* and *Pastry Shop* designate any place of business at which doughs, desserts, jams, chocolate candy and 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, Lunch-room and Restaurant.

Article 333—The name *Candy Shop* applies to places of business specializing in the retail sale of chocolate candy, candy, chocolates and related products.

Article 334—The name *Candy* designates in general a product of soft, semi-soft or hard consistency, prepared with sugars to which permitted organic acids may or may not have been added, which may contain various substances, natural or synthetic essences, and colors the use of which is permitted.

Article 335—The name *Fondant* applies to a sweetened dough used as a base for many kinds of candy. It is prepared with a base of a sugar syrup and water, with or without the addition of cream of tartar in a proportion of one per mil (see Article 655, point 10). This mixture is heated until it reaches the proper consistency; then it is cooled, stirred and moulded.

The name *Fondant Candy* applies to candy which has the property of melting quickly in the mouth. It is prepared with 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 resulting product is named *Stuffed Fondant*. A mixture of chocolate and fondant is named *Chocolate Fondant* and when instead of the water strong coffee is used in the fondant, the candy is called *Coffee Fondant*.

Article 336—Depending upon its composition, candy is divided into the following classes:

1. *"Alfeñiques" (Sugar pastes):* This name applies to candy prepared with a base of sugars, flavored with a natural flavor, to which a permitted color may be added.

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, sugar, milk and flavors.

4. *Iced Chestnuts* (Marrons glacés): This term designates half-cooked, large chestnuts dipped repeatedly into a sugar syrup the density of which increases which each dipping. While in the most strongly concentrated syrup, they are boiled for a few minutes. They are usually wrapped in silver or gold paper.

5. *Fudge:* This name applies to a type of candy whose consistency lies between hard candy and fondant. It is prepared with sugar, milk, chocolate and butter. The dough is beaten before it is cooled. It is flavored with vanilla. Usually pieces of nuts, almonds, etc. are added to it.

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 paste made of sugar, egg white and/or edible albumin, to which almonds, hazelnuts or peanuts have been added; it may or may not be flavored and colored with permitted substances.

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

9. *Coconut Flakes or Tablets:* These flakes or tablets are prepared with grated coconut, sugar 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 sugar, honey, roasted almonds, hazelnuts, lemon, chocolate, cinnamon, pepper and semolina.

Article 340—The name *Salted Peanut* applies to the roasted peanut, fried in oil or another fatty substance, and salted.

Article 341—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 must be sold with the proper designation: *Burned peanuts,* etc.

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[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. *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, hard candy, etc.

Starch or dextrose may be added to pralines in a proportion of up to 5 per cent without requiring a declaration.

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 the stage of caramel (174° C.). It is prepared also with a mixture of cooked egg yolk and fine sugar shaped into balls which are immersed in a sugar syrup heated to the stage of caramel, and when taken out of the syrup, 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 337—The generic denomination *Candy* ("Caramelos") applies to confections made with a base of a paste obtained by cooling a sugar syrup which has been cooked to the proper consistency. Depending upon the products added candy is named:

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

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 permitted flavors and 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 cooked 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

[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.

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 jellies, fruit pulp, milk candy, liqueur, honey, etc.

Crunches: This denomination 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."

The name *Chewing Gum* or *Chicle* applies to candy made with a base of properly purified chicle gum (Achras sapota L.), spruce gum (resin of the Black Spruce—Abies nigra D.C.) or "caspi" milk (obtained by tapping Galactotendron utilisimun), to which sugars, paraffin, white wax, permitted flavoring substances, Tolu or Peru balsam and permitted colors are added in special machines under pressure.

Article 338—The preparation, possession and sale of candy and chocolate candy shaped like matches or other articles unsuitable for consumption are prohibited in order to prevent children from committing possibly fatal errors.

Article 339—Both caramels 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 hermetically sealed jars or containers. It is advisable to place inside the same a small bag with quicklime which should be replaced as often as necessary.

Article 342—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 outer sugar coat, starch or dextrin may be added in a proportion of up to 5 per cent without a declaration to that effect.

Article 343—*"Confetti"* [12] and *Dragées* are sweetmeats of various sizes and shapes which have a center of sugar paste, pieces of almonds,

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

nazelnuts or peanuts, crunch, fruits or liqueurs, and are coated with a hard sugar coating, with or without the admixture of permitted essences and colors. The addition of dextrin, starch and/or edible gums is permitted in a proportion not exceeding 5 per cent.

Article 344—*Lozenges* have in general the appearance of variform small troches and may consist of:

1. Pastes containing sugars, flavoring distilled waters, natural or synthetic essences and permitted colors;

2. The same as described at 1., plus substances such as edible gums and gelatins, licorice and others and starch and/or dextrin in a proportion not exceeding 5 per cent. 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.

3. Compressed lozenges may contain a binder of stearin, talcum, oil, gum acacia or another permitted product in amounts not exceeding 1 per cent of the total composition.

One distinguishes between the following lozenges:

4. *Marshmallow lozenges:* prepared with sugar, gum arabic, gelatin and egg white, to which a permitted color may be added.

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

6. *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.

7. *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.

8. *Licorice lozenges:* prepared in the same manner as gum lozenges, with the addition of at least 4 per cent of licorice extract or juice.

9. The name *Birthday Cake Trimmings* covers statuettes and sundry decorative confections prepared with a base of sugar, natural essences and permitted colors.

Article 345—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 per cent

of water and not more than 68 per cent of sugars. Hydrocyanic acid shall 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 cholocate or sugar. A similar product prepared with other raw materials (cores of fruits, chestnuts, hazelnuts, peanuts, etc.) shall bear the name of the ingredient: *Hazelnut Marizpan,* etc.

Article 346—The name "Torrone" [13] ("Turrón") applies to a mass made with almonds, honey, egg white, albumin, or edible gelatin, to which piñons, hazelnuts, peanuts, walnuts, chestnuts, candied fruit, etc., or sugars are added at times. It must bear the name of the raw material used in its preparation, such as: almond, hazelnut, honey, Brazil nut, torrone, etc. Any reference to Alicante and Jijone is prohibited.

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

Article 347—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 "Jijone Type Torrone." The designations "Alicante" and "Jijone" alone may only be used 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 346 hereof and must be labeled in accordance with the nature of the ingredients (almonds, hazelnuts, peanuts, etc.) used in their preparation.

Article 348—The name *"Jujube Lozenge"* applies to small loaves made with the fruit of the jujube tree (Zyzphus mistol), which have the consistency of a thick jam.

Article 349—The name *Almond Paste* applies to the plastic product obtained by cooking peeled triturated sweet and bitter almonds, to

[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.

which sugars and water have been added. It must contain not more than 14 per cent of water and 60 per cent of sugar expressed as invert sugar, and the amount of hydrocyanic acid contained in them must not exceed 40 parts per million.

Article 350—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, with sugar and water.

Fruit Stone Pastes shall be named after the raw materials used in their preparation. They are not permitted to contain hydrocyanic acid. They may contain water in an amount not exceeding 14 per cent, and sugar, expressed as dextrose, in an amount not exceeding 40 per cent.

Article 351—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 syrup of sugars or honey which, when evaporated, leaves a coat of sugar crystals on the surface of the fruit or vegetable.

Article 352—The generic name *Preserve* or *"Dulce"* [14] applies to any confection 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 light 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 sweentened solution is throughly 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 and has a semi-solid, gelatinous consistency, the product is named *"jelly."*

Fruit and vegetable pastes, marmalades and jellies must contain a soluble solid substance of at least 65 per cent by weight, except for sweet potato paste, in which a minimum of 60 per cent is permitted. Pressed residues first submitted to distillation or lixiviation and gela-

[14] A "dulce" is a type of paste of marmalade-like consistency.

tins of animal origin are prohibited from being added to pastes or preserves. The juice or pulp of sour apples, oranges, lemons, quince, and other pectin-rich fruits may be added, without a special declaration, in the proportion demanded by the nature or type of the "dulce" to be produced, and citric, tartaric and gluconic acid (see Article 655, point 6) may be added in the amount lacking in the fruit, but required to obtain a good "dulce" 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 containers (Plums in syrup, etc.).

To give greater consistency to "dulces" 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 "dulces" in amounts not exceeding 3 per cent. "Dulces" 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 "dulces" 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 353—In special cases the health authorities may permit the color of certain "dulces" to be reinforced with authorized colors without a declaration.

Article 354—The name *Fancy Crystal Jelly* or *Artificial Fruit Gelatin* applies to the 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.

The name *Fancy Dessert Powders* (creams, custards, and puddings) (pudding powder) applies to products made of mixtures of starches or feculae with natural or artificial flavors, cacao, fruit extracts, sucrose, dextrose and various products, according to their special designation, to which edible gelatins, citric, tartaric, or fumaric acid and permitted colors may or may not be added.

Article 355—The name *"Roselle Blossoms"* or *"Karkadé"* applies to the dried floral calyz of *Hibiscus sabdariffa L.* which is used in the preparation of certain "dulces." *Average percentage composition*; water —14; protein—6.5; fat—4.5; assimilable carbohydrate—58; crude fiber—6; ash—9; tannin—2.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

FDA Report on Drug Counterfeiting. —The Food and Drug Administration has released the results of its nationwide investigation of drug counterfeiting. Selections from random samples (almost 2,700 from 900 drug stores) showed nine specimens from nine different stores to be counterfeit. Six drugs were chosen for sampling, all of them known from previous experience to have been counterfeited.

The Commissioner of Food and Drugs, George P. Larrick, said that all of the counterfeits whose origin has thus far been determined came from the same Eastern pharmaceuticals house. Commissioner Larrick said:

"Counterfeiting of new and potent drugs has been a recurrent problem of varying intensity for years. Our legal actions in this field date back to 1951. Because of the economic incentive and the lure of easy profits, the problem will recur.

"However, it has been and still is our view that the facts to date do not warrant disturbing sick people about the quality of the medications they have been taking. The survey results support this conclusion and indicate that the vast majority of our drugs are authentic. Still, the origin of counterfeits and the possibility that they have not been properly manufactured leaves us no room for apathy or complacency.

"Potentially, the problem is an explosive one and unless constant vigilance is maintained by law-enforcing officials and tough enforcement pressure constantly applied, the problem could get out of hand to the detriment of public health and welfare. We have directed and are directing every available resource to the task of putting this racket out of business and to that end are planning a continuing, broad investigation.

"Marketing of counterfeit drugs is a bootleg operation easily detected by the retail pharmacist. I again urge, as I did last October, that retailers insist upon receiving drugs only in original, sealed manufacturer's packaging. The racket could not exist without the cooperation of unethical druggists."

Actions brought as a result of the investigation just past include criminal suits in the federal courts against a drug company, packing company, and retail druggists, as well as three seizures of stocks of counterfeit drugs. Selective coverage of suspected retailers, which is still in progress, has revealed that 59 out of 1,020 samples collected (5.8 per cent) were counterfeit. In addition to these surveys, a special random survey of Washington, D. C., was conducted. A total of 293 samples of the same drugs were collected at 100 stores. All proved to be authentic.

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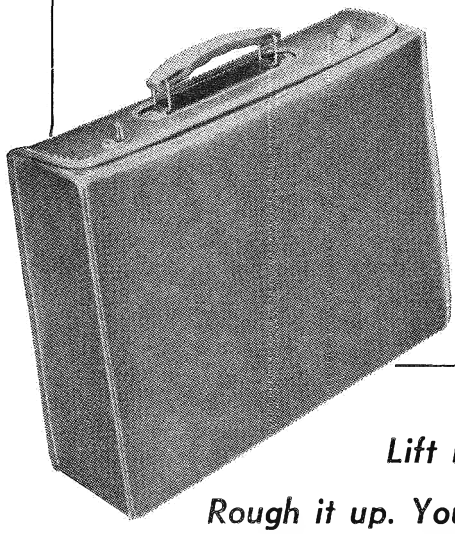

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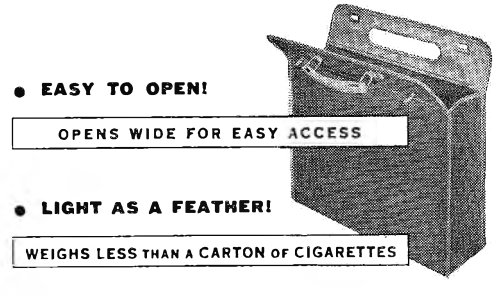

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