VOL. 22, NO. 5 MAY 1967

Food Drug Cosmetic Law JOURNAL

Completion of the Question and Answer Panel Presented at the FDA–FDLI Tenth Annual Educational Conference

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

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

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

May, 1967
Volume 22 • Number 5

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

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . May, 1967

VOLUME 22 NUMBER 5

Printed in the United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Question and Answer Panel of the FDA—FDLI Tenth Annual Educational Conference.—The Question and Answer Panel held during the morning session of the Tenth Annual FDA—FDLI Educational Conference is featured on page 264 in this issue of the JOURNAL. The panel held during the afternoon session of the Conference was presented in the April issue.

Members of the panel were: *Kenneth R. Lennington*, Salmonella Project Officer, FDA; *Robert G. Ruark*, with Corn Products Company; *Herbert S. Goldberg*, Ph. D., member of the Department of Microbiology, School of Medicine, University of Missouri; *Robert S. Roe*, Associate Director, Bureau of Science, FDA; *George R. Grange*, Deputy Administrator of Marketing Services with the Consumer and Marketing Service of the United States Department of Agriculture; *LaVerne C. Harold*, Dept. of Veterinary Medicine, FDA; and *Michael Markel*, with Markel and Hill.

Latin-American Food Code.—Beginning on page 285, Chapter XVI of the Latin-American Food Code is reproduced. Stimulating products, such as cacao and chocolate, coffee and coffee substitutes, processed tobaccos, and maté, are discussed. Chapters I-V, VII, X, XII, XIII, XVII and XVIII appeared in previous issues of this JOURNAL. The translation is by *Ann M. Wolf* of New York City.

FDA Goals in Labeling and Advertising Regulations.—Various goals which direct FDA in the drafting of regulations for the labeling and advertising of prescription drugs are the subject of *Julius Hauser's* article, which begins on page 300. Since physicians rely heavily upon advertising material circulated by the pharmaceutical industry, FDA's major goal is to insure that such information is the best available. The author, Assistant for Regulations with FDA's Office of the Assistant Commissioner for Compliance, delivered these remarks before the Food and Drug Law Institute Seminar in Chicago, Illinois on April 14, 1967.

Proposed Amendments to the Model Food and Drug Law.—This article, beginning on page 304, was presented by *George M. Burditt* at the Illinois Dairy Products Association Meeting on May 15, 1967 at Galesburg, Illinois. The author, a partner of Chadwell, Keck, Kayser, Ruggles & McLaren and a member of the Illinois Legislature, discusses the Food, Drug, Cosmetic and Pesticide Laws Study Commission, created by the Illinois General Assembly in 1965, and the bills recommended to the Legislature for changes in the Illinois Food Act and the Illinois Drug and Cosmetic Act.

Book Review: Fundamental Principles and Objectives of a Comparative Food Law, Volume 1, by E. J. Bigwood and A. Gérard, reviewed by Franklin M. Depew.—As its title implies, the book reviewed on page 307 first provides a functional classification of elements properly constituting a food law, and then examines the legislation of various countries in this context. Asserting that the tendency to construct laws upon either the system of prohibition or that of abuse creates an obstacle to harmonization, the authors recommend a mixed regime as more flexible. Mr. Depew is President of the Food and Drug Law Institute.

Vol. 22, No. 5 May, 1967

Food·Drug·Cosmetic Law
Journal

Question and Answer Panel of the FDA—FDLI Tenth Annual Educational Conference

The Following Material Is from the Morning Question and Answer Panel Featured on November 28, 1966 at the Tenth Annual Educational Conference of the Food and Drug Administration and the Food and Drug Law Institute. The Afternoon Question and Answer Panel Was Featured in the April Issue of the JOURNAL.

Questions Addressed to Kenneth R. Lennington

Q. What do you consider to be the most significant contributor to the Salmonella problem?

A. It is difficult to say what is the most significant contributor. However, from experience gained over the last ten years, we can look to substances and products of animal origin as highly suspect.

Q. What is the present status of dry milk with regard to Salmonella infection?

A. There is at this time an ongoing surveillance program being carried out by several agencies, including the Food and Drug Administration (FDA), the Public Health Service (PHS), the United States Department of Agriculture (USDA), and a number of state agencies.

Q. Is there a tolerance in individuals for Salmonella organisms (as in carriers), and can we expect a zero tolerance requirement in product examinations?

A. We have no tolerance for Salmonella in food and drugs. We may have such low incidences in a product that they would be insignificant. You need not at this time worry about an absolute zero tolerance because we are now concerned with problems of sufficient magnitude as to present a potential health problem.

Q. Does the panel feel that the usage of dried egg solids is safer in baked products than the usage of frozen eggs—both being pasteurized?

A. There is no real difference if both products are pasteurized.

Q. Can Salmonella be passed from feed to food products? What regulatory action is FDA taking to control Salmonella in feeds?

A. Yes, Salmonella can be transmitted from the feed to the animal, and in turn the Salmonella can be contained in the animal product. FDA has been considering and has in the development stage a program designed to cope with the problem of gross contamination of some of the basic protein feed supplements, particularly those of poultry, animal, and fish by-product origin.

Q. Is there a Salmonella problem in the utilization of wheat and wheat flour?

A. The Animal Health Division of Agricultural Research Service, USDA has done considerable work on seven different categories of feeds for Salmonella contamination. Results show that there is a low incidence of contamination of grain or grain feeds. Grains for human consumption are generally of higher quality than those used for animal feeds, and are less likely to be contaminated.

Q. Is the problem of Salmonella in powdered milk mainly one of instantized milk, or will this be a potential problem in all types of powdered milk?

A. It appears to be a potential problem for all types of powdered milk. Experience thus far indicates that contamination may occur in conventional spray-dry milk and roller processed dry milk, as well as instantized milk.

Q. If a food plant becomes contaminated with Salmonella, the food products can be destroyed or sterilized. What methods and materials are available for decontaminating equipment and building facilities, and where can details of these methods be obtained?

A. This can be answered in terms of an adequate sanitary program. Salmonella is susceptible to heat and many other bactericidal agents. If a plant is found contaminated and it is thoroughly cleaned and the equipment is effectively sanitized along with the elimination of the point of contamination, the problem should be resolved. For details, consult a competent sanitation specialist. The PHS/Division of Environmental Engineering and Food Protection may be in a position to offer some counsel and possible assistance.

Q. What precautions does FDA take to prevent their inspectors from carrying Salmonella into food plants in the course of plant inspection?

A. FDA inspectors wear clean coveralls, disposable head coverings and are provided with disposable plastic footwear for use in critical areas such as the drier. Our inspectors are trained in aseptic procedures and have a good understanding of likely or potential avenues of contamination. We cannot take a position that they are infallible, but if any of them engages in practices that plant management considers questionable, the man, his District office or headquarters in Washington should be advised.

Q. When the USDA tests for Salmonella traces and *certifies negative* and thereafter FDA inspects for Salmonella with *positive findings,* it creates a *serious inference* that contamination takes place *as a result* of reopening the package for inspection purposes. Is there any coordination between FDA and USDA? Please comment.

A. I feel this inference is not valid. Salmonella contamination is not uniform or evenly distributed in a dry product such as nonfat dry milk solids. Thus, sampling problems may yield results that are not necessarily reproducible. A negative finding cannot be construed as a guaranty that none of the particular lot is contaminated. The FDA and USDA are coordinating activities and maintaining liaison in the interest of avoiding duplication of effort. This will continue.

Q. Would it be possible to develop a new name or designation for Salmonella, and would such a request receive consideration? This is brought to your attention because of the unfavorable publicity that the U. S. domestic salmon industry receives because of the association of Salmonella with their product "salmon."

A. Probably nothing is impossible. However, the term Salmonellae is the official, national, and international name of this large genus of microorganisms. It has been in use for almost a century. It is used in all microbiological literature, tests and reports of scientific work. In all seriousness, it might be as feasible to develop a new name for the fish.

Q. For what period of time do you anticipate that the present *intensive* surveillance program for Salmonella contamination of dried milk products might be required?

A. It would be difficult to set a time schedule. It would seem that the combined efforts of industry, state and local regulatory agencies, equipment manufacturers, dairy technologists, and all involved, will

develop improved procedures and higher standards of sanitation and microbial control which would to some extent lessen the need for intensive surveillance. However, until the present levels of sanitation, microbiological control of air supply, pasteurization practices, equipment design, and knowledge of the mechanism of contamination are raised, continued surveillance will be necessary.

Q. Please comment on FDA's attitude on the presence of Salmonella in raw or frozen poultry?

A. FDA looks upon the presence of Salmonella in any food or feed as a potential health hazard.

Q. Does FDA consider the presence of one Salmonella organism sufficient to require seizure of the food?

A. Present methodology does not enable such finite analysis, hence this question is purely theoretical. We have not reached the point where the Salmonella problem is not of such magnitude as to constitute a potential health hazard.

Q. Both speakers seemed to join the chorus of those "scaring" the nation over this problem. Despite the serious nature of the few incidents hasn't there been an excessive reaction, out of proportion to its significance?

A. We are speaking in terms of 20,000 *reported* cases per year. Public health experts estimate the "reported" cases represent only one to five per cent of the actual infections. It becomes a matter of opinion, but to those infected, especially infants and weakened individuals, it would not seem that guarding against additional infections is out of proportion to the significance.

Q. In the case of dried eggs and dried milk solids, what is the main source of recontamination?

1. air in drying equipment?
2. surfaces of conveying, or packaging, or other equipment?
3. other?

A. The actual source of recontamination has rarely been established. It is believed by microbiologists and food technologists that air, plant sanitation and employee sanitation, all play a key role.

Q. To what degree can the lack of proper sanitation and food handling practices be equated with the Salmonella problem in the food industry?

A. Salmonella is an infection occurring in the intestinal tract of man and animals, hence the route of contamination is a fecal-oral one.

Where there is pollution, whether air-borne, or via contaminated equipment, hands, vermin or other means, Salmonella contamination is suspect.

Q. Will Salmonella survive wet, highly alkaline processing, that is a pH of 10-11? Can you indicate approximate time-temperature conditions necessary to destroy Salmonella under dry conditions?

A. I do not know of any study that would enable a positive answer to your question. Neither can one state with certainty the time-temperature factors necessary to destroy Salmonella under dry conditions. The nature of the material to be treated, the moisture content, the nature of the "adhesive" by which the bacteria are affixed to the material, even the strain of Salmonella, all enter into the consideration. Under ordinary "dry" conditions, 180°F for 20 to 30 mintues should result in an effective kill; how much less time and temperature would be effective, we do not know. These factors are being studied by the Sanitary Engineering Center, PHS, Cincinnati.

Q. In the production of foods which may be naturally contaminated with Salmonella organisms (fish, poultry, meat) and which are sold fresh, is irradiation the only means for eliminating Salmonella?

A. A high degree of sanitation, starting at the abattoir or dressing plant, and carried through to the consumer would greatly reduce the incidence and degree of contamination. This might likely entail redesign of equipment and processes as well as a higher level of employee personal sanitation. We know of no practical method of eliminating Salmonella from raw fresh foods. Irradiation procedures on a commercial scale have not as yet been approved under the Food Additives procedures.

Q. What is the regulatory criteria for Salmonella in food? For example, assume non-contaminated raw materials and processing equipment, and sound sanitary manufacturing practices. Notwithstanding all this, it is possible to find a positive sample on rare occasions in the finished food. What should a manufacturer do at this point?

A. The manufacturer should recognize that he has a potential problem and take vigorous measures to determine the source and course of the contamination and eliminate it. What may be a chance contamination today may, unless eliminated, develop into a line and plant contamination.

Q. Are fresh fruits and vegetables potential sources of Salmonella infection, and if so are they a significant source?

A. From literature and epidemiological information available to us, it would not appear that fresh fruits and vegetables are a significant source of infection. However, Salmonella might contaminate them in the field and orchard, and if introduced into a processing system resulting in favorable incubation conditions, contamination might result.

Q. Are food salvage dealers policed? They distribute broken, soiled, wasting products held under insanitary conditions. The sources of supply are railroad and truckline damaged goods and insurance losses.

A. Yes. Food salvage dealers, repackers, and distributors are inspected and suspicious lots of foods are sampled and examined. A review of Notice of Judgement will disclose seizure and criminal actions against this segment of industry.

Q. Are there examples you could give of precautionary labeling specifically oriented toward salmonellosis?

A. I do not recall offhand any particular examples other than that frequently seen on frozen prepared foods and freezer counters. I would not conclude that that labeling is *specifically* oriented toward salmonellosis.

Q. What is being, or can be, done to improve sanitational protection for the consumer at the retail level where cut meats, etc., are *handled* piece by piece by the retailer? Is this a vector for Salmonella?

A. A general upgrading of sanitation, from the abattoir to the kitchen, is needed. Certainly insanitary practices in handling of uncooked meats and edible organs is a potential vector of contamination.

Q. Since Salmonella were most likely on earth before man and before FDA and since we cannot and should not live in a sterile environment—was recent action and publicity against a producer of nonfat dry milk not excessive on the basis of the low incidence of contamination?

A. I referred earlier to the significance of salmonellosis, especially in infants and the debilitated. With respect to publicity "against a producer," FDA was confronted with questions from the news media and had no choice but to answer in a reasonable manner. Furthermore, no requests for recall of products have been made unless there was an incidence of contamination that was a public health hazard.

Q. Since Salmonella organisms are discrete particles and not homogeneously distributed, what rationale is used to determine sample size; what is the reasonable size for dried milk?

A. The FDA, USPHS, USDA, and industry in general, has agreed upon 100 gram samples for salmonella determinations. I do not know that this size sample has been studied and found statistically sound.

Q. Is it FDA policy to seize raw material containing Salmonella if the processing method to be applied to the raw material will destroy the Salmonella?

A. Each situation must be evaluated in the light of good manufacturing practices and the degree of sanitation maintained in a plant. I might add that, in general, we do not look with favor upon use of a contaminated ingredient simply on the premise that the processing will eliminate Salmonella. The opportunity for cross-contamination and seeding of a plant must be considered. The nature of the processing and opportunity for cross-contamination are weighed. The use of egg yolks for mayonnaise or salad dressing, where the acidity is sufficient to kill the organism, is an example of this type consideration.

Q. Will the use of Salmonella-contaminated raw materials cause a finished product to be *actionable* under the Food, Drug and Cosmetic Act (adulterated), if the finished product has been so processed as to kill all residual contamination?

A. The use of Salmonella-contaminated raw materials, per se, would not cause a finished product to be adulterated. However, their use, manner of handling, likelihood of cross-contamination, etc., would be considered in the light of section 402(a)(4) of the Act.

Q. In the past twelve months, what has been the frequency of Salmonella food poisoning from non-fat dry milk?

A. The only epidemiologic study on this subject was the *S. New Brunswick* work reported by the Communicable Disease Center, USPHS, Atlanta. Twenty-nine cases implicating dried milk were reported. It was exceedingly difficult to establish that salmonellosis was caused by a particular food. Furthermore, only the more serious cases are diagnosed and reported.

Q. Can it be assumed that food products (including beverages) under pH 4.1 are free from possible contamination with Salmonella? If not, what pH is a safe dividing line? What are the time-temperature requirements for Salmonella pasteurization?

A. I believe that a pH of 4.5 is deemed to be lethal for Salmonella. As indicated earlier, there are a number of variables such as moisture, number of organisms present, nature of the media, etc.,

which make it impossible to set a fixed time-temperature that can be relied upon for a complete kill.

Q. Does the USDA or FDA anticipate government standards or regulations on total bacteria (including Salmonella) on all 100 major food ingredients?

A. At this time, I do not know of any early plans in this direction.

Questions Addressed to Robert G. Ruark

Q. How can industry obtain Salmonella-free enzymes for use in food processing? Pasteurization will destroy the enzyme.

A. Keep the operation clean so that you do not have to depend on pasteurization for Salmonella-free products. Start off with sterile materials in the fermentation process and use care in the inoculation so as not to include extraneous materials. If handled properly you should not have this problem. I recognize the fact that certain enzyme preparations are prepared on dry substrates and that the enzyme activity would be destroyed in some cases by pasteurization. My only recommendation is that the cleanest possible raw materials be used in the manufacture of preparations of this sort.

Q. Can Salmonella be ingested in whiskey, which uses a lot of corn?

A. In the manufacture of whiskey and other alcoholic products, the first step involves a cooking operation which should be sufficient to destroy Salmonella. In the fermentation, alcohol is produced and the bacteria involved are killed as the alcoholic concentration reaches a range of about 16%. I would presume that this would also be effective on Salmonella organisms. The next step involves the distillation of the liquor in stills that operate at temperatures well over the destruction point for Salmonella bacteria. Further, the product emerging from the still is about 95% ethyl alcohol which is in itself a powerful antiseptic. I see no reason to expect that alcohol or other alcoholic products would present any Salmonella problem although I know of no literature on this subject.

Q. Is there a Salmonella problem in the utilization of wheat and wheat flour?

A. There has been very little Salmonella contamination found in wheat or in grain flour. It is destroyed in the wet processing of corn. There is no reason why it could not be a problem in grain and flour.

Q. What is the minimum test that establishes whether a batch of corn starch is Salmonella negative?

A. Corn starch is tested by the standard methods specified by USDA and other agencies. Direct reference to these methods may be obtained from the USDA Egg Regulations.

Q. Do you run this test on every single batch of corn starch?

A. Corn starch is produced in tremendous quantities and, consequently, each small lot cannot be analyzed separately. We use a statistical sampling basis for this purpose. We have checked this process thoroughly and find that the steeping operation completely destroys Salmonella. Therefore, corn starch is Salmonella-free at the time of production and packing.

Q. On the basis of this test are you willing to guarantee to another food manufacturer using your starch that every batch of your corn starch supplied to him is Salmonella negative?

A. It has been our practice to guarantee that food starch when shipped is not adulterated. Obviously, this would include Salmonella contamination, but no raw material manufacturer can guarantee that a product is completely satisfactory when delivered to a customer's plant because of possible mishandling either by the transportation agency, or mishandling at the customer's location.

Q. You advise laboratory examination of all food handlers. How can this be effective when the incidence of salmonellosis is widespread and the organism does not remain in the host very long after he has recovered from an onset?

A. My remarks on this entire subject range from the farm to the home or restaurant. Examination of food handlers is required by legislation in many areas. It is certainly a good practice in any food handling operation.

Q. Temperature and pH can destroy Salmonella—will you elaborate on conditions?

A. It is not possible to completely report the conditions since time-temperature and pH are all variables involved in the destruction of Salmonella. A few examples can be given. In the steeping of corn, a temperature of 122°F. is used for about forty hours. The pH of the steepwater is in the neighborhood of 4.0. Under these conditions complete Salmonella destruction takes place.

In the FDA regulations regarding egg pasteurization, mayonnaise and other salad dressings are exempted from this requirement provided they have a pH below 4.1 and an acidity in the aqueous portion of over 1.4 calculated as acetic acid.

Q. The conditions you would require would make pasteurization unnecessary for many foods. Would you expect this to be practical in the near future?

A. I do not quite understand this question but will try to make a few comments. If the question refers to elimination of pasteurization in toto, this will never come about. The examples given in the question above show ways of Salmonella destruction. There are certainly many other ways such as sterilization in canning operations, and there are potential ways such as application of irradiation.

Q. Do you advise the addition of warnings and instructions to labels on food packages as a Salmonella safeguard?

A. Warnings and instructions are common on many commercial packages and are actually required by law. An example involves the required labeling of unpasteurized eggs for certain food applications. This was expressed in the FDA regulation on egg pasteurization. In my talk I advocated that manufacturers pursue strongly the education of the ultimate user. This is the point where the most effective control can be exercised.

Q. In food plant sanitation should germicides be used in rinse water in all cleaning operations?

A. The application of germicidal preparations is certainly desirable where appropriate It is not possible to give any one specific recommendation. If there is a question in the manufacturer's mind, local authorities should be consulted or the advice of sanitation experts secured.

Q. Will Salmonella survive wet, highly alkaline processing, that is a pH of 10-11?

A. Alkaline processing will certainly have some effect on Salmonella destruction at pH 10-11. Time and temperature are also factors that must be considered, as well as the source of alkalinity. It is probable that an alkaline pH induced by caustic solutions would be effective, but if solutions of phosphates, for example, were used, there might merely be a buffering effect and the destruction would not be as complete. Each case must be considered on its own.

Q. Can you indicate approximate time-temperature conditions necessary to destroy Salmonella under dry conditions?

A. It is not possible to give a specific time-temperature recommendation covering all products. Each product will vary depending upon pH time and temperature and, in addition, the effect of moisture content. Each must be examined separately to assure proper time-

temperature relations for Salmonella destruction. An example of a specific time-temperature recommendation is given in the USDA regulations for egg pasteurization.

Q. In the production of foods which may be naturally contaminated with Salmonella organisms, (fish, poultry, meat) and which are sold fresh, is irradiation the only means for eliminating Salmonella?

A. Irradiation of foods for Salmonella destruction is in its infancy. There are certainly other pertinent factors in connection with naturally contaminated foods. In the case of fish, meat, and poultry, sanitary processing conditions plus refrigeration are pertinent. Again, the place for ultimate control is in the home or restaurant where, I repeat, education is required.

Q. Are there examples you could give of precautionary labeling specifically oriented toward salmonellosis?

A. Labeling is a separate problem for different types of food products. Certain products must be labeled. Again, the egg pasteurization regulations of the FDA are specific in terms of the labeling of unpasteurized egg products for certain classes of foods. There are probably other examples.

Q. Can it be assumed that food products (including beverages) under pH 4.1 are free from possible contamination with Salmonella? If not, what pH is a safe dividing line?

A. It is possible that food products under pH 4.1 are free from Salmonella contamination. There are more factors involved than just pH. Acetic acid is far more effective in Salmonella destruction than is hydrochloric acid. Each foodstuff should be studied separately, and if acidity is an answer, the requirements will certainly vary from one foodstuff to another, and the factors of time and temperature are also pertinent.

Q. What are the time-temperature requirements for Salmonella pasteurization?

A. This question cannot be answered directly because the time and temperature requirements will vary from foodstuff to foodstuff and other factors such as pH and moisture play a pertinent part.

Questions Addressed to Herbert S. Goldberg, Ph.D.

Q. Is salmonellosis caused only by the viable organisms, or is there a toxin produced which has the same adverse effect (as in botulism)?

A. The toxins associated with Salmonella are endotoxins—that is to say they are contained inside the cell, whereas botulism toxins are exotoxins found outside of the cell. With salmonellosis toxic materials are not released until the cell is broken down in the body of the infected host. It should be pointed out, however, that the relationship of toxic material from Salmonella is not clearly associated with disease in man as it is in a disease like botulism.

Q. How can industry obtain Salmonella-free enzymes for use in food processing? Pasteurization will destroy the enzyme.

A. This may be the place for sterilization processes other than heat such as ethylene oxide or other gaseous agents which if they do not interfere with the enzymatic activities may be suitable in their ability to cause sterilization. These would be investigative but worth pursuing as means of sterilization.

Q. What problems have become known through widespread use of veterinary medical and non-medical antibiotics?

A. I think we ought to clarify the status of bacterial resistance. It really is predicated on the fact that most bacteria are sensitive to antibiotics. However, in large populations a few may be resistant by virtue of natural mutations. Hence, when antibiotics are present in the environment, as a result of agricultural or other uses, the sensitive bacteria are destroyed allowing only the resistant to survive and grow. A process of natural selection occurs. This can be demonstrated by the fact that in some hospitals (where penicillin has been detected in the air) one can find 90% of the staphylococcus organisms (cultures) resistant to penicillin, whereas in another environment only 30% are resistant to penicillin. The fact is that the misuse or abuse of antibiotics creates the opportunity for selection of resistant organisms.

Q. a. What is known of the survival of Salmonella in the atmospheric dust?

b. How far can viable Salmonella be carried by air currents out-of-doors?

c. What infection load of Salmonella organisms does the average adult confront daily?

A. a. Salmonella is not particularly resistant to disinfectants, antiseptics, or changes in temperature and hence, would survive for only a short period of time. This would be a question of hours or at the most days; it would depend upon the temperature and the amount of organic matter present. It is difficult to answer this question.

b. Insects undoubtedly serve as mechanical carriers of Salmonella organisms, and the organisms can be carried as far as the insects can travel and deposit the organism in food. There is no definite distance.

c. It has been established that it takes a large number of Salmonella organisms to cause disease. One study on Salmonella Typhosa concluded it usually requires from 10^3 to 10^4 numbers to cause typhoid as contrasted to *Tubercule bacillus* where one organism theoretically can cause tuberculosis.

Questions Addressed to Robert S. Roe

Q. What has been the Administration's experience so far as compliance with the approved antibiotics in food-producing animals is concerned—or, in other words, have residues been found in meat, milk, or eggs?

A. Ten years ago residues of antibiotics (some of penicillin which was of primary concern) were found in market milk—about 11% of samples being positive. Steps were taken to reduce this by revising the existing regulations governing dosage levels and to improve the usage of certain preparations for mastitis control. Information programs by FDA, USDA, and other agencies and regulatory sampling programs have reduced the incidence, and now less than 1% of the samples are found positive. Limited sampling programs have not indicated residues in eggs. I do not believe we have examined meat, but the USDA has found indication of some residues in meat in certain instances.

Q. What problems have become known through widespread use of veterinary medical and non-medical antibiotics?

A. Table No. 1 of Dr. Goldberg's presentation showing a considerable increase in the poundage of antibiotics used in feed supplements and other medical and non-medical uses, the presentation to FDA of several proposals for use of antibiotics as preservatives in food products and the indications of the likelihood of many more proposals, and considerations such as Dr. Goldberg has just discussed with respect to resistance and cross-resistance, have led FDA to decide to take a broader look at the usage of antibiotics. Hence the appointment of an advisory committee two years ago. This committee filed a report last summer, and it is in connection with the implementation of some of their recommendations that we have held some interdepartmental conversations and have a program under the direction of the Director of the Bureau of Veterinary Medicine

(BVM) to consider further steps in the implementation of these recommendations.

Q. Did we understand you to say that FDA is satisfied that all residue data on file for antibiotics for which food additives regulations have been issued for animal use are adequate—particularly those where no finite tolerances have been imposed?

A. At the time these food additive regulations were established, the data presented in support of the proposals were adjudged adequate to show effectiveness and safety. Some of the regulations of earlier years do need to be reviewed now. In light of the types of protocols that we have come to understand in recent years, it may be necessary to make these reappraisals. But for the most part, food additive regulations involving antibiotics are on a sound basis. Some of the authorizations that do exist from eariler considerations did not have as much data in support as we now require and it is these that are being reviewed at the moment. It is in this connection that we have called on manufacturers and interested parties, in a policy statement issued last August, to present us, within six months following that issuance, such data as they have in this area to supplement our knowledge.

Q. What is the rate of antibiotics in foods (not including those permitted by regulations)?

A. I presume this question means the incidence of antibiotic residues in foods. We believe the incidence is low but extensive data have not been obtained except in the case of milk previously mentioned.

Q. What action is FDA taking on foods found to contain antibiotics?

A. In this case of the milk findings, I have already pointed out that we revised certain of the antibiotic regulations relative to mastitis preparations; we participated in and encouraged extensive educational programs and also regulatory activity on the part of state and local governments as well as FDA.

It is my understanding that the Meat Inspection Service of the USDA has found occasional evidence of antibiotic residues in meat—perhaps as a result of misuse or residues remaining at injection sites. It is my further understanding that the Service has condemned carcasses or portions thereof where residues were encountered.

Q. Do any of the presently approved veterinary antibiotics survive the time and temperatures of food canning?

A. Sufficient information is not available at this time for a meaningful answer to this question.

Q. If antibiotic safety for food preservation use requires proof that no development of bacterial strains resistant to the antibiotic used in preservation, or to a medically used antibiotic, shall result, then what is the time limit on such a test?

A. This question also cannot be answered with any degree of definiteness. Test protocols, I believe, would vary to some extent depending upon the characteristics of the antibiotic, the food products involved, and various other factors. Until more information and experience are obtained, I would not undertake to outline a test protocol.

Questions Addressed to George R. Grange

Q. What has been the Administration's experience so far as compliance with the approved antibiotics in food producing animals is concerned or, in other words, have residues been found in meat, milk, or eggs?

A. USDA runs many tests every year and have found very few instances where residue levels were found to be over tolerance where the tolerance is 0, or where a finite tolerance has been established.

Q. How will "formal" approval be given by the U. S. to the Codex Alimentarius?

A. USDA, FDA, and United States Department of the Interior (USDI) agree on the acceptability of the standards under consideration, and make their views known to the State Department. The State Department then advises the Food and Agriculture Organization/World Health Organization (FAO/WHO) on the position of the U. S. Government.

Q. Is salmonellosis caused only by viable organisms, or is there a toxin produced which has the same adverse effect (as in botulism)?

A. No toxins are present.

Q. How can industry obtain Salmonella-free enzymes for use in food processing? Pasteurization will destroy the enzyme.

A. Both USDA and FDA Regulations regard pasteurization as the destruction of pathogenic bacteria by means of heat over a specified period of time or other acceptable methods. Any other method would be appropriate if equally effective for bacterial destruction.

Q. Can Salmonella be passed from feed to food products?

What regulatory action is FDA taking to control Salmonella in feeds?

A. I do not believe that Salmonella could contaminate raw milk/via the feed route. Most of the problems in milk drying plants resulted from environmental contamination. In an egg plant the organism is found on the outside shell, and contaminates the magma either upon breaking or through cracks and checks in the shell.

Q. What is known of the survival of Salmonella in the atmospheric dust? How far can viable Salmonella be carried by air currents out-of-doors? What infection load of Salmonella organisms does the average adult confront daily?

A. USDA has run the "most probable count" and has found a great variability in the range from very few to several hundred on individual examinations. Samples with only a few numbers of Salmonella organisms will hardly cause a well person to become ill.

Q. Is the problem of Salmonella in powdered milk mainly one of instantized milk, or will this be a potential problem in all types of powdered milk?

A. USDA and FDA have been looking at this problem very closely. The bulk of the milk drying plants are surveyed under the USDA approved for grading service program. Only one or two instances were found where regular dried milk was found contaminated in the test run. The remainder of the samples found positive (about 10) were obtained from instantizing plants. This is apparently the case because of the type of equipment used and the difficulty in cleaning and sanitizing the instantizing equipment.

Q. Is there any collaboration between "Codex Alimentarius and the U. S." and "Food Chemical Codex," being finalized now, to cover specifications for raw materials used as food ingredients? Do these two compendia duplicate?

A. Collaboration—no, unofficial coordination—yes. "Food Chemical Codex" is used as resource material in preparing U. S. comments on proposed food additives for the Codex Alimentarius. The two compendia are not duplicates. However, the food additive sections of both may very well be the same.

Q. Our standard-making procedure is established by a Congressional Act. By accepting an international (Codex) standard are we (U. S.) not avoiding the requirements of standard-making established by Congress? (For example, a food labeling codex that differs from either a food and drug standard, a meat inspection act standard, or a fair labeling bill regulation.)

A. None of the standard-making procedures established by Congress are by-passed by accepting a Codex standard because only those Codex standards which can be enforced under existing U. S. laws or regulations will be recommended for full acceptance. If there is not a law or regulation applicable to a product covered by a Codex standard and if such a law or regulation would be in the interest of the U. S., then appropriate steps would be taken, either by industry or the government agency involved, to seek the legal provisions needed for the U. S. to accept the Codex standard.

Q. a. Where a standard is sent to member nations for acceptance, what procedure will the United States use to determine acceptance?

b. How will industry opinion be solicited?

A. a. If the provisional standard sent to us at step 9 for acceptance is in our best interest and if existing laws or regulations would permit the product described to be freely distributed within the U. S., then USDA, FDA, or USDI would recommend to the State Department that the U. S. accept the standard.

b. In the development of a Codex standard from step 1 (decision to elaborate an international standard) through step 9 (formal acceptance of the provisional standard), industry and government work together at each step of the elaboration procedure to evaluate the standard evolving and assist the U. S. representative to the Codex Committee in formulating the U. S. position regarding the proposed standard. The U. S. representative to the Codex Committee is responsible for developing and maintaining liaison with industry representatives.

Q. Is there any relationship between the Codex Alimentarius Program and the question of tariff barriers on the export-import trade? If so, please explain?

A. No, Codex standards are essentially international standards of identity developed to provide uniform criteria for trading and protection to consumers by providing a sound wholesome product, correctly identified.

Q. Is every piece of meat which passes through interstate commerce inspected for residues of antibiotics or are samples taken?

A. All carcasses are visually inspected for evidence of injection lesions. In addition, we have a biological residue surveillance program under which samples are analyzed.

Q. If a Codex standard is acceptable to FDA:

1. Is there any sanction for violation?
2. Can it be "acceptable" prior to adoption via food standard regulations?
3. Constitutionally, could this Codex acceptance by international agreement override current food standards without using any Food, Drug and Cosmetic Act procedures?

A. A Codex standard can not be fully accepted unless there is an applicable U. S. standard or regulation. Also, in the event a Codex standard is less detailed than an existing U. S. standard or regulation, acceptance will be modified by stating the additional details of all U. S. requirements which are more stringent than those in the Codex standard. Thus, violation of the U. S. regulation or standard would automatically mean that the corresponding Codex standard had been violated. However, there is a Codex Alimentarius provision called "target" acceptance which could apply in the event there is no U. S. regulation or standard. We could pledge not to interfere within our territorial jurisdiction with the free movement of products meeting the Codex standard and in the meantime work for legal provisions which would enable us to fully accept the Codex standard.

Q. Do we understand from the answer to a previous question that a "Codex Alimentarius Standard" will go into effect in the U. S. A., on agreement between FDA, USDA, and USDI, without publication of proposed regulations, invitation to comment by interested parties, or the other procedural safeguards that apply to domestic standards?

A. To repeat, full acceptance of Codex standards by the U. S. is not possible unless there are existing U. S. regulations to support the Codex standard. Therefore all of the safeguards which are a part of the U. S. system of elaborating regulations or standards must have been used or, if new regulations or standards are needed, must be used before a Codex standard can be accepted.

Q. Are there published international standards which define minimum requirements on imports of butterfat-sugar mixtures?

A. There are no international standards for this mixture. As for U. S. import requirements, the FDA routinely inspects imported foods for evidence of adulteration or contamination. Also U. S. import controls limits the amount of products containing 45% or more butterfat or 25% or more sucrose that can be imported. And so, to

be free of import controls, the mixture generally contains slightly less than these amounts of sucrose and butterfat. Therefore, the U. S. monitors the mixtures for composition compliance with import control limitations.

Q. What is the extent of USDA sampling of poultry meat for Salmonella contamination? If done, what have results shown?

A. Each eviscerated bird is inspected for wholesomeness as it passes along the processing line. Any evidence of unwholesomeness, such as fecal contamination, a source of Salmonella, causes the bird or contaminated parts to be discarded. The results of the studies made so far indicate that when birds are handled properly with correctly engineered equipment the incidence of Salmonella in poultry meat can be controlled.

Q. Does the USDA or FDA anticipate government standards or regulations on total bacteria *(Including Salmonella)* on all 100 major food ingredients?

A. The USDA does not anticipate requiring bacterial limitations for all 100 major food ingredients. However, several of our grade standards specify that the product must be *Salmonella* free, or set a maximum tolerance for other bacteria based on public health significance or effect on product quality.

Questions Addressed to LaVerne C. Harold

Q. What criteria does the FDA use in determining antibiotic safety and residue level?

A. It is important that we know the toxicological capabilities of the drug. There are several systems of measuring this—the LD 50, acute, subacute, chronic, biochemical, microbiological, and clinical studies in the specific species. Once we know the toxicological capabilities of the drug we can then determine the levels at which it can be safely used and safe levels of any residues.

Q. What problems have become known through widespread use of veterinary medical and non-medical antibiotics?

A. There are a number of problems appearing which cause us concern:

1. The development of resistant organisms to antibiotics and also the development of transferable antibiotic resistance. The ecological changes which may be taking place due to the feeding of antibiotics to animals.

2. Sensitivity of animals receiving the antibiotic and the individual who may consume the food product which contains a residue.

3. Also, we can expect changes in the intestinal tract—changes in the microflora of the animal receiving the drug—upsetting the animal to some extent. We do not know the extent or the magnitude of these problems.

FDA is taking a number of steps to try to determine the magnitude of the ecological effects taking place. We have had interagency meetings with different departments within the government to determine what data is available and the steps to be taken. The Commissioner has appointed the Director of the BVM as coordinator of activities and to make recommendations to the Commissioner.

Q. How significant do you think antibiotics in feed (as promotion substances) are in the development of resistance transfer factors?

A. Numerous concepts and theories have been advanced regarding bacterial resistance to a number of the effective antibiotics widely used today. Just how significant this is in relation to the level of growth-promotant antibiotic drugs administered in animal feeds, remains unanswered. A portion of the upcoming public symposium program, Scientific Aspects of Medicated Feed, to be held June 5 through 7, in Washington, D. C., has been given to discuss this important subject.

Q. Knowing that many milk cows may eventually wind up as beef carcasses, are there any *tissue residue* regulations on mastitis preparations?

A. Except for mastitis preparations administered intramuscularly, only milk residue data are required for intramammary infusion preparations to demonstrate that the antibiotic is eliminated from the milk. Tissue residue data is required for antibiotic products administered parentally to food producing animals.

Questions Addressed to Michael Markel

Q. Is a specific guarantee against Salmonella contamination necessary or desirable as a part of the usual continuing guarantee under the Food, Drug and Cosmetic Act? If so, and the product is found contaminated, is the guarantor responsible for damage due to publicity, etc?

A. As I understand the question, it is (a) whether a specific guarantee regarding Salmonella is required in the presence of an existing general guarantee in the form suggested in the general regulations; and (b), if so, or provided the purchaser insists on one, what should its form be?

As to (a), the answer is "no." No specific guarantee regarding Salmonella is required in the presence of an existing guarantee, whether that be a continuing form or limited to one shipment. The provisions of the suggested forms include the guarantee that the product is not adulterated. Since the presence of Salmonella in any food constitutes it an adulterated product, these provisions cover that specifically plus whatever else might be wrong with the product.

As to (b): many purchasers insist on a specific guarantee even after they are told that their existing guarantee covers Salmonella contamination. In such cases, we suggest a specific form of guarantee patterned closely after the suggested form in the Food, Drug and Cosmetic Act, and then stress that, in the light of the ever present and real likelihood of contamination wherever the product may be found, special care be taken to restrict its application to the product covered when shipped by the seller.

It is deemed appropriate in this connection to mention also that many purchasers who hold a guarantee in the form suggested in the regulations are in danger of being lulled into a feeling of security which is not warranted because of the extremely narrow limits of the guarantee. Such a guarantee protects its holder against criminal prosecution by reason of having received or shipped an adulterated food or drug in interstate commerce, provided—and this is an important proviso—that he has received the shipment under such a guarantee and has passed it on in the form in which it was received.

The courts have held that no person may rely upon any guarantee unless, in introducing the product into interstate commerce, he has acted merely as a conduit through which the guaranteed product reaches the consumer. Failure to have inspected and discovered the contamination which could have been discovered by an inspection reasonably indicated under existing circumstances renders the shipper liable for shipping an adulterated product in interstate commerce even though the product was adulterated when received under an existing guarantee against adulteration. **[The End]**

Latin-American Food Code 1964 Edition

In August, 1964, the Latin-American Food Code Council Published the Second Edition of the Latin-American Food Code. Information Concerning the Code and the Table of Contents of the New Edition Appeared in the April 1965 Issue of the Food Drug Cosmetic Law Journal (Vol. 20, page 238). The First Five Chapters Were Published in the September 1965 Issue; Chapters XII and XIII in the October 1965 Issue; Chapter XVII in the November 1965 Issue; Chapter X in the December 1965 Issue; Chapter VII in the June 1966 Issue; and Chapter XVIII in the August 1966 Issue. Chapter XVI Appears Below. The Translation Is by Ann M. Wolf of New York City.

Chapter XVI: Stimulating Products

Cacao and Chocolate

Article 538—The names "Cacao" and "Cacao beans" mean the sound clean seeds (beans) of Theobroma cacao L. from which the shell has been removed.

The name "cacao shell," or simply "shell" means clean cacao shells in a perfect state of preservation.

The name "shelled roasted cacao" means roasted cacao seeds, ground and relatively free from skins, germs and other impurities.

Article 539—The name "Chocolate liquor" means the product obtained by grinding shelled roasted cacao beans. It must meet the following requirements: Moisture, not more than 8 percent; natural cacao starch, 8.5 percent; cellulose, 3 percent; total ash, 4 percent; water-insoluble ash, not more than 3 percent; alkaloids (theobromine and caffeine), between 1 and 4 percent. Chocolate liquor shall contain cacao fat in a proportion of not less than 45 percent and when heated shall melt completely and evenly.

The name "medium-fat cacao" means chocolate liquor from which part of the fat has been extracted by pressure or by the action of permitted solvents. Medium-fat cacao shall contain fatty matter in a proportion of not less than 8 percent and not more than 6 percent of shells and germs.

The term "low-fat cacao" means chocolate liquor from which practically all fat has been extracted by means of permitted solvents. It may be used in foods after deodorization. It may not contain fatty matter in a proportion of more than 8 percent or shells and germs in a proportion of more than 6 percent.

Article 540—The name "powdered cocoa"* means the product obtained by pulverizing medium-fat cacao. The alkalinity in its ash may not exceed 3.75 grams per centum, calculated as potassium carbonate on the dry defatted product. Sweetened powdered cocoa may contain sugars in an amount of up to 68 percent.

The name "soluble cocoa" means powdered cocoa alkalized by way of the Dutch process or a similar method with an amount of alkali sufficient to neutralize the natural acidity of the cacao, on condition that the resultant product be always slightly acid and never alkaline. The total ash of cacaos thus treated may not exceed 15.5 percent and its alkalinity calculated as potassium carbonate (K_2CO_3) shall be less than 6.5 percent; both values apply to low-fat dry products. The designation "sweetened soluble cacao" means a mixture of soluble cacao and sugars whose proportion may not exceed 68 percent.

Both soluble and insoluble powdered cocoa may be flavored with permitted substances (vanilla, vanillin, and spices).

Article 541—The name "cacao fat" means the fatty substance extracted from soluble or insoluble cacao by mechanical extraction. Its melting point shall be between 30 and 34° C.; it shall have an iodine index of between 33 and 38, and at 45° C. a refractory index of between 1.4546 and 1.4549.

To extract cacao fat intended for use in foods, the same solvents may be used as authorized by Article 162 of the present Code. The extraction may only be performed directly from shelled, germ-free cacao seeds, or from chocolate liquor. The fat obtained shall be refined by way of the same processes as used for edible oils.

Article 542—The name "Chocolate" (in form of a paste, a powder, wafers, tablets or chips) means a homogeneous blend of chocolate liquor (prepared by means of the usual process) in a proportion of not less than 32 percent, and sugars and

* Note of the Translator: This name seems to designate what in the United States is known as "breakfast cocoa."

aromatics (cinnamon, vanilla, vanillin, spices, etc.) in a proportion of not more than 68 percent.

The moisture content of chocolate may not be more than 3 percent, and its total ash not more than 2.5 percent; it shall contain cacao fat in a proportion of not less than 16 percent.

Article 543—The name "Milk chocolate," or similar names, may only be used for chocolate containing not less than 15 percent of solids obtained by the evaporation of milk, of which 3 percent must be milk fat.

The name "powdered chocolate" means the product obtained by eliminating the water from a preparation made with a base of whole milk and chocolate. Its water content may not exceed 6 percent.

The names "Chocolate fondant," "Fondant," and "Swiss type chocolate" mean soft chocolate that melts easily and contains cacao fat in a proportion of not less than 30 percent.

Article 544—The name "White chocolate" means a homogeneous mixture of cacao fat in a proportion of not less than 25 percent and milk solids in a proportion of 25 percent, obtained by the usual chocolate manufacturing process, with the addition of authorized aromatics.

Mixtures of white chocolate and rice flakes, fruits, almonds, peanuts, walnuts, etc. shall be designated by names which include the name of the product added.

Chocolate coatings intended for candy and other confectionery products shall contain cacao fat in an amount of not less than 22.5 percent and sugars in a proportion of not more than 50 percent. Glyceryl monostearate may be added to the cacao fat in amounts of up to 2 percent.

Article 545—Chocolates with almonds, hazelnuts, peanuts, walnuts, honey, fruits, cereals, etc. are mixtures, in varying proportions, of chocolate liquor, sugars, permitted aromatics, and other products as specified in their name. The use of fillers or additions is prohibited.

Article 546—The following products are prohibited from being added to cacaos and chocolates: cacao shells, inert matter, dextrines, preservatives, colors, and other products alien to their normal composition. Cacaos and chocolates may not be sold when they are poorly preserved, punctured by insects or acarids, spoiled or damaged. Any product found in such condition

shall be seized summarily. Excepted herefrom are chocolates whose color has changed due to the addition of almonds, hazelnuts, peanuts, etc., or to the crystallization of the fatty matters and sugars.

Vegetable gums, gelatin, glucose and glycerin may be added if declared in the labeling. Vegetable lecithin may be added to cacaos and chocolates in a proportion of up to 0.3 grams per centum without a declaration.

Alien fats or oils of no matter what origin are prohibited from being added to cacao fat.

Coffee and Coffee Substitutes

Article 547—The names "Coffee," "green coffee," and "raw coffee" mean the sound clean seeds of Coffea arabica L. and other species of the same genus, from which the outer skin (spermoderm) has been removed by sun-drying but from which none of the caffeine has been removed.

No green or raw coffee being distributed, stored or offered for sale may contain more than 10 percent of the imperfections peculiar to coffee (broken, immature or black beans, pods, shells, sticks and peduncles); more than 1 percent of stones and dust; more than 13 percent of moisture; at 500-550° C., more than 5 percent of total ash; more than 1 percent of ash insoluble in 10 percent hydrochloric acid; more than 0.7 percent of total chlorine in the ash; no sodium (Na_2O) may be found in the ash; it shall contain caffeine in a proportion of not less than 0.9 percent.

Article 548—Coffees sold with an indication of origin shall have the characteristics of the coffee named. If they are sold in beans, the color and size of such beans must be uniform and of the declared type: round (Bourbon Mocha); short and oval (Brazil, Colombia, Central America); elongated (West Indies); pointed (Bourbon), etc.

Article 549—The name "Roasted coffee," in beans or ground, means ordinary green coffee which, by the action of heat, has turned dark and acquired the characteristic aroma. Roasted coffee must be homogeneous in appearance, not burnt, and may not contain carbonized beans in a proportion of more than 5 percent.

Any roasted coffee being distributed, stored, exhibited or sold shall meet the following requirements:

1. It shall not contain more than 5 percent of moisture, 5 percent of total ash (expressed on the dry product) or 1 percent of ash

insoluble in 10 percent hydrochloric acid; the ash may not contain chlorine in a proportion of more than 0.7 percent, sulphates in a proportion of more than 4 percent, or sodium.

2. It shall not contain sugars in a proportion of more than 2 percent, except for roasted coffees on which the sugar content is declared, in which sugars may be present in an amount of up to 12 percent.

3. It shall contain caffeine in a proportion of not less than 0.9 percent, whose aqueous extract shall fluctuate between 21 and 33 percent and the methylic extract between 10 and 12 percent.

Article 550—The term "coffee blend" may only be used to distinguish a blend of coffees sold with a labeling that includes the qualitative declaration of the origin and variety of such coffees, beginning with the variety used in the largest proportion.

Article 551—*Coffee roasting plants* shall meet the following requisites in addition to the general requirements:

1. The stock rooms and storage rooms for raw materials and finished products shall be separate from the departments in which the coffee is roasted, ground and blended, and all shall have waterproof floors and wainscots, the latter up to a height of 1.80 m.

2. The roasting rooms must be equipped with smoke and soot removers.

3. Plants which perform accessory operations, such as caffeine extraction, preparation of concentrates or extracts, etc., shall perform such operations in departments separate from the roasting rooms.

Article 552—The term "Coffee and Tea Store" ("Casa de cafés y tés," "cafeteria") means stores in which coffees and similar products, such as tea, maté and chocolate are sold. The name "Coffee House" (Café) means the commercial establishment at which coffee and similar beverages, such as tea and chocolate, breakfasts and afternoon snacks and several alcoholic and nonalcoholic beverages are sold and consumed.

Retail establishments which grind coffees at the request of the customer shall keep the grinding machines and the coffees to be ground within the sight of the public, and the grinding and weighing shall be performed in front of the customer.

Article 553—The name "Coffee roasted with sugar" means ordinary green coffee roasted with the addition of sucrose and/or

dextrose in an amount not exceeding 10 percent; the use of any other sweetener (liquid or solid molasses, liquid glucose, etc.) is prohibited. The percentage of sugar must be declared in the labeling of the containers.

Coffees roasted with sugar shall meet the same requirements as roasted coffees (Article 549, paragraphs 1 and 2), except for their moisture which may reach 8 percent; the aqueous extract which may fluctuate between 30 and 38 percent, and the methylic extract which may fluctuate between 18 and 20 percent.

Article 554—The labeling of roasted coffees, in beans or ground, shall state the month and year of packing. Roasted coffees not packed under vacuum or with inert gas shall be considered unsuitable for consumption after 180 days from the packing date.

Retailers or re-sellers are prohibited from carrying and selling loose coffee, in beans or ground. They may carry and sell ground coffees, the sale of which has been permitted, only in containers sealed by their packers and labeled in accordance with the legal requirements.

By way of exception, roasters who sell their product directly to the public, in their own shops and in properly labeled containers, shall not be subject to this prohibition.

Article 555—The beverage sold simply as "coffee" (without any specification) shall be prepared by lixiviation or by infusion in hot water of ground roasted coffee free from coffee substitutes (malt and other roasted cereals, molasses, caramelized sugars, etc.) and extraneous substances, or by dissolving coffee extracts, coffee concentrate, soluble coffee or instant coffee in hot water. Commercial establishments which sell coffee (coffee shops, confectionery stores, luncheonettes, restaurants, hotels, canteens, etc.) are not permitted to keep molasses, molasses derivatives, or coffee substitutes on their premises.

Article 556—The names "coffee extract" and "coffee concentrate" mean the product (liquid extract) obtained by exhausting freshly roasted and ground coffee with water. This water may be evaporated, even if not completely, by means of special heating systems (powdered extract, soluble coffee, instant coffee). Liquid coffee extracts must at 15° C. have a density of not less than 1,100 and a dry residue of not less than 25 percent, and both

liquid and powdered extracts must contain natural caffeine from coffee in a proportion of not less than 1.5 percent.

Small amounts of glucosides (glucose syrup), or such other substances as the health authority may authorize from case to case, may be added without a declaration to preserve or retain the sapid and aromatic components, whereas the addition of artificial aromatics is prohibited. Concentrates prepared from a base of coffee roasted with sugar shall be labeled accordingly.

Coffee tablets are made by concentrating the coffee extract defined in the first part of this article in the presence of sugar and then compressing the mixture with a small amount of gum mucilage or another authorized binder.

Article 557—The name "Coffee flakes" means the product obtained by having the ground roasted and slightly moistened coffee pass at high pressure through cylinders with a smooth polished surface. They shall be packed under vacuum or preferably by replacing the air inside the container by inert gas.

Article 558—The term "decaffeinated coffee" means ordinary coffee from which a large proportion of the caffeine has been removed by a special process.

The name, or an equivalent name, is prohibited from being used to sell exhausted or poor coffees, coffee grounds or substitutes.

The term "caffeine-free coffee" means coffee from which so much of the caffeine has been removed that not more than 0.10 percent of caffeine remains in the finished product.

Such coffees may not contain any residue of the substances used in caffeine extraction.

Article 559—Coffee substitutes are not permitted to be sold under a name including the word "coffee." An exception is made for the so-called "Sultan Coffee" or "Sakka Coffee," always provided that it was made with the shells of real coffee and therefore contains caffeine, chlorogenic acid, etc.

All coffee substitutes must be named according to their origin: "Roasted beans," "roasted cereals," "chicory," "roasted malt," etc. in a clear labeling not leaving any doubt as to the type of product used in their manufacture. Spoiled or worthless raw materials, such as coffee grounds, brewery and distillery wastes, etc. may not be used in any case, nor may minerals be added in order to increase the weight.

Malt may be roasted with sugars in a proportion of up to 10 percent, always provided that their presence is declared in the labeling.

Article 560—None of the types of coffee described may be processed, ground, held, distributed or sold if the coffee is damaged by salt water or moisture, fermented, spoiled, artificially colored (with iron salts, colors, etc.), polished (with resins, dragon's blood, etc.) or moistened with glycerin or unauthorized substances, exhausted, or deprived of all or part of its caffeine content (except in the cases provided for by Article 558); the same applies to coffees which contain coffee substitutes, such as chicory, malt or other cereals, resins or other substances intended to change the color, appearance, brilliance or intrinsic composition of the genuine standard product.

The sale of coffee dregs is strictly prohibited, the term "coffee dregs" meaning the residue of raw or roasted beans that remains after sorting and cleaning, the residue (grounds) from the infusion or preparation of the beverage, and coffees exhausted during manufacture of the coffee concentrates and extracts (instant coffee) defined in Article 556. Such residues or dregs may be sold after they have been treated with substances that ensure their effective and even denaturation and render them unsuitable for human consumption. Otherwise, they shall be destroyed at the plant by incineration (in which case they may be used as fuel) or burial. The coffee grounds left over from coffee brewing at coffee houses, luncheonettes, confectionery stores, restaurants, hotels and other commercial coffee outlets must before disposal be denatured effectively and evenly by the addition of substances that render them unusable as food.

By way of exception, inferior grades of coffee may in coffee-producing nations be distributed within the country if the authorities decide to "paint" them with iron salts (oxide and sulphate) to signify that they may not be exported.

Article 561—The name "Chicory" means the root of the plant Cichorium intybus L., properly cleaned, dried, roasted and ground. Sugars may be added during roasting in a proportion of up to 10 percent.

Chicory may not contain more than 15 percent of water or less than 60 percent of soluble substances; the ash of chicory in grains or grits may not amount to more than 10 percent, that of powdered chicory not to more than 12 percent.

The word "chicory" may not be used in the names of products sold as chicory substitutes or equivalents; nor may the chicory blends sold contain any such substitutes.

Article 562—The name "roasted malt" means malted and roasted barley; the name "sweetened roasted malt" means the same product roasted with sugars in a proportion of up to 10 percent, the presence of which must be declared in the labeling.

The use of the name "malt coffee" or of any other name including the word "coffee" is prohibited.

Processed Tobaccos

Article 563—The name "tobacco" means the well-preserved, uncontaminated leaves of different varieties of Nicotiana tabacum L., properly dried and processed.

Article 564—Tobacco, cigarette and cigar factories shall meet the following requirements in addition to the general conditions:

1. Manufacturers shall always take every precaution to assure clean and hygienic operating conditions, in accordance with the regulations established in this Code and by the health authorities.

The work rooms shall have natural or forced permanent ventilation and shall be constructed so as to be suitable in every respect for the work done in each department.

2. None but the following products may be used in the processing of tobaccos, cigars and cigarettes: water, ammonia, acetic acid, lactic acid, citric acid, tartaric acid, honey, sugar (cane, fig, maple or invert sugar), molasses, licorice, vinegar, authorized aromatics, menthol, cacao, glucose, gum, salt, alkaline carbonates and chlorides, 1 percent of lime in the form of lime water, concentrated fruit juices, tonka bean seeds (Diptery odorata, or Coumarouna odorata), tonka bean extract, wild vanilla (Trilisa odoratissima), saccharine, wines, alcoholic beverages such as rum, cognac, or pure alcohol.

3. For purposes of preservation, the following substances may be added to 1 kilo of tobacco: 0.5 grams of sulfurous acid, or 0.8 grams of benzoic acid, or 1 gram of sodium benzoate, or 1.5 grams of formic acid, and in the special case of pipe tobacco, 1 gram of boric acid and 8-hydroxyquinoline potassium bisulfate.

Article 565—Tobaccos to be used in the manufacture of cigars, cut tobaccos, chewing tobacco, snuff, cr cigarettes shall meet the following requirements:

1. Only sound leaves, free from biological contamination, shall be used in their preparation.

2. They may not contain alien vegetable substances (adulterants).

3. They may not contain preservatives other than those named in the preceding article or authorized by the health authority.

4. They may not be in direct contact with papers which contain lead in a proportion of more than 1 percent or antimony in a proportion of more than 3 percent.

5. As hygroscopic agents, glycerin, ethylene glycol or propylene glycol, sorbitol, glucose syrup or invert sugar shall be given preference.

6. The binders used in the manufacture of cigars and cigarettes shall preferably have a base of water with casein, starch, Tragacanth gum or other harmless products.

7. They may not contain any substance intended to increase their weight fraudulently.

Article 566—Ordinary cigarette paper shall meet the following requirements:

1. It shall be made from cellulose of flax, hemp, esparto grass, ramie, cereals, cotton or rice straw.

2. To facilitate combustion, it may be impregnated with calcium, ammonia or magnesium salts, phosphates and titanium dioxide. Any other substance to be used must be authorized especially by the health authority.

3. It shall be free from substances which, by their nature or when subjected to combustion, are injurious to the health, irritating, and/or capable of producing an unpleasant odor or flavor.

4. It may not contain sodium and/or potassium nitrates in amounts of more than 0.02 percent.

5. The waterproof paper used for cigarettes to be smoked in the rain shall be tasteless and colorless and may not contain any dangerous substances.

6. Other papers and special papers which lend cigarettes particular characteristics must be especially authorized by the health authority.

Article 567—The term "Tobacco Paper" means paper prepared from tobacco midribs and stalks, which may have been boiled in lime water and may contain a semi-finished paste of Manila paper, or a similar paper, in a proportion of not more than 10 percent.

Article 568—The term "low in nicotine" may only be used for cigars which contain nicotine in a proportion of less than 0.8

percent, calculated on the dry substance, and for cigarettes and pipe tobacco, etc. which contain nicotine in a proportion of less than 0.5 percent, calculated on the dry substance, and the term "nicotine-free" or "nicotine content harmless" may be used only for processed tobaccos (cigars, cigarettes, etc.) which contain nicotine in a proportion of less than 0.1 percent, calculated on the dry substance. Designations such as "not toxic," "detoxicated" and similar terms may not be used in connection with tobaccos with a low nicotine content.

Article 569—In view of the limited effectiveness of anti-tar, anti-gas and anti-nicotine filters (which catch only 30 percent from the first four cigarettes smoked through them), the properties of such filters are prohibited from being built up in oral, radio, television and written advertising or from being praised for their supposed beneficial action with a view to encouraging excessive smoking. Filter cigarette advertising is also prohibited from stressing health factors.

Tea

Article 570—The term "Tea" may only be used for the product which consists of young leaves and sound clean leaf buds of various species of the genus Thea, offered for consumption in different types, green or black, depending upon their origin and method of manufacture.

The name "Tea," used alone, may only be applied to the product defined hereinbefore or, concentrated or unconcentrated, infusions of the same. Other teas shall be designated by the name of the plant from which they come, such as: Boldo tea, camomile tea, herb tea, etc.

Teas are divided into the following types, depending upon their origin:	Length of Leaves: cm	Width of Leaves: cm
Ceylon, Indian, Java, Brazil, Argentine tea	10-14	4-5
China tea	4.5-7	2-3
Annan and Sana tea	up to 23	up to 2-3

Article 571—Green tea sold under any one of the names specified hereinafter shall meet the following requirements:

1. Hyson Tea: consists of the shoots and first crop of leaves, of uniform size which roll up in lengthwise spirals.

2. Skin Hyson Tea: consists of inferior and discarded Hyson leaves, rolled up sidewise and lengthwise.

3. Gunpowder tea: the leaves are cut lengthwise into three or four pieces and rolled into small balls, 1 to 3 mm. in diameter. It is usually flavored with wild olives (Olea fragrans).

4. Pearl Tea or Imperial Tea: the leaves are first rolled lengthwise, then sidewise, and rolled into small balls, 3 to 5 mm. in diameter, and flavored with wild olives.

Article 572—Black tea is graded according to the age of the leaves. Teas made from crops in which only the terminal buds and finest leaves were picked, may be sold as "fine." The general name "Pekoe" may be used for these teas, the name "Flowery Orange Pekoe" applying to teas consisting of terminal buds and tender leaves, "Orange Pekoe" to the next crop, and Pekoe No. 1 to the third crop.

The name "Souchong" may only be used for teas consisting of large thin leaves from the first and the second crops, the name "Pekoe Souchong" for the quality between this and Pekoe tea. The name "Congous" may only be used for teas consisting of leaves from the third crop, which are larger in size than the others.

The aforesaid names designate China teas, while the names of similar products from other regions shall include the place of origin, such as "Ceylon Pekoe No. 1," "Ceylon Souchong," etc.

Article 573—Teas of different origins and qualities may be blended, always provided that the purchaser be notified thereof. It is not necessary to declare on such blends the proportions of the various teas used; only their origin shall be stated in the order of the amounts present.

Blends of teas from different geographical regions are not permitted to be sold with the indication of just one indication of origin.

Article 574—Green or black tea, decaffeinated or not, must in general meet the following requirements:

1. It may not contain stems and reddish, practically leafless stalks in a proportion of more than 35 percent;

2. It may not contain more than 12 percent of moisture, 8 percent of ash, of which not less than 50 percent must be soluble in water, or 1 percent of ash insoluble in 10 percent hydrochloric acid;

3. It may not contain caffeine in a proportion of more than 1 percent (0.1 percent in the case of decaffeinated, or low-caffeine tea), or have an aqueous extract of less than 24 percent, in the case of black teas, and less than 28 percent, in the case of green teas;

4. Powdered tea, or ground tea may be obtained only by finely grinding the tea defined in Article 570 and shall comply with the requirements set forth in paragraphs 2 and 3 of this article.

Article 575—The following teas are prohibited from being sold: exhausted, damaged, or spoiled tea; tea to which gum, starch, iron oxide, alien colors (except green teas colored with authorized colors), talcum, gypsum, kaolin, etc., leaves from other plants or other substances have been added.

Article 576—The name "Tea extract" means the product obtained by exhausting tea with a sufficient amount of water which is later evaporated long enough to reduce the product to the consistency of a liquid or dry extract. It shall contain caffeine in an amount of not less than 0.5 percent.

Tea concentrate, soluble tea, instant tea, or powdered tea extract is the product obtained by drying a tea extract in special chambers or cylinders. Small amounts of carbohydrates may be added to them to fix the aroma.

Article 577—Tea Tablets are obtained by concentrating liquid tea extract in the presence of sugar and then binding the product by means of a small quantity of gum mucilage or other permitted substances.

Maté

Article 578—The terms "Yerba Maté" and "Maté" mean the product consisting exclusively of dried, lightly roasted and crushed leaves of Ilex paraguariensis Saint Hilaire, which may be mixed with small parts of young branches, leafstalks and peduncles. Actually, "Yerba" means the leaf of Ilex par., and "Maté" (which means "gourd" in Quechua) is the container in which the infusion is started or prepared.

Boldy ground yerba maté which contains more than 10 percent of dust that passes through a sieve with 16 openings per linear centimeter is considered processed yerba maté.

Article 579—The term "yerba maté mill" means the establishment at which the product is sorted, crushed, ground, roasted and packed. Yerba maté mills must meet the following requirements in addition to the general conditions:

1. Their premises must be large enough to store the raw materials and finished products; the processing and packing rooms shall have

waterproof floors and wainscots up to 1.80 m. high; the grinders, sieves and appliances used to mix matés shall be equipped with devices preventing the dispersion of dust.

Dust sucked up mechanically during processing which has had no contact with the ambience may be used, provided always that it consists of maté suitable for consumption.

2. Pieces of maté stalks, and maté substitutes or adulterants are prohibited from being ground.

3. The mixing of matés for the preparation of different blends may be performed only by means of mechanical blenders.

4. The preparation of maté extracts (soluble maté) and similar products and the extraction of caffeine must be performed in separate rooms.

5. Processed maté shall be sold to the public in new containers, made from materials which guarantee the good preservation of the product and are equipped with an air-tight closure (seal, strap, band, etc.). The contents of such containers may not be broken up for retail sales.

6. Maté packers are not permitted to keep on their premises containers belonging to other processors or packers without a specific authorization from the latter.

7. The marketing of loose stalks and the storing of vegetable substances intended to adulterate matés are prohibited: if found they will be seized on the spot. The same shall be done with spoiled or damaged maté, and with maté stored in unhygienic conditions, or in conditions affecting its purity. Mills may keep a percentage of loose stems as fixed by the competent authority in proportion to their total maté stock and in line with the type of product they manufacture.

Article 580—Any processed maté which is stored, exhibited or offered for sale shall be considered as unfit for consumption when:

1. Its moisture content is more than 11 percent, or when it contains more than 9 percent of total ash or more than 1.5 percent of substances insoluble in 10 percent hydrochloric acid;

2. The content in dried, crushed or pulverized leaves is less than 70 percent; when the proportion of parts of whole young dry branches (stalks), whole or crushed petioles and peduncles is more than 30 percent; not more than half of this percentage is permitted to be stalks, the term "stalks" meaning the young dry branches which are caught on a sieve with openings 2.5 mm. wide and not less than 70 mm. long.

3. It contains less than 0.6 percent of caffeine (in the dry residue) and an aqueous extract of less than 25 percent.

4. It contains saponins or extraneous products, or is burned, altered or exhausted.

Article 581—Blends of matés from different geographic origins are not permitted to be sold with the indication of only one such origin.

Article 582—The following terms are used to designate the products listed hereinafter:

1. *Stalkless maté:* maté which does not contain any stalks. On the other hand, maté containing stalks shall be called "with stalks" ("con palos" or "con palillos"). The use of names such as "Argentine type," "Paraguay type," etc. is prohibited.

2. *Roasted maté:* processed maté subjected to a roasting process. This is the maté generally used in the preparation of maté tea.

3. *Maté infusion:* the product obtained by exhausting maté leaves with water. It is also named: boiled maté, maté tea, yerba tea, and when served cold, iced maté.

4. *Maté extract:* the product obtained by exhausting maté with water which is later evaporated until the product has the consistency of a liquid extract or dry extract. It is used in the preparation of beverages and refreshments.

5. *Soluble maté, powdered maté, maté concentrate, or powdered maté extract* is the product obtained by drying a maté extract in special chambers or cylinders; to this extract, small amounts of carbohydrates may be added to fix the aroma. These products must contain caffeine in a proportion of not less than 0.7 percent, calculated on the dry substance, which must be free from sugars. They may not contain water in a proportion of more than 6 percent and may contain sugars in a proportion of 35 percent which must be declared in the labeling.

6. The name *"powdered milk maté"* and similar or equivalent names mean the product obtained by evaporating an infusion or decoction of maté herb and milk which is suitable for consumption under this Code. It may not contain water in a proportion of more than 6 percent and may contain sugars in a proportion of up to 35 percent which must be declared in the labeling.

7. *"Maté tablets"* or *"lozenges"* are obtained by concentrating liquid maté extract in the presence of sugars and then binding the product by means of a small amount of gum mucilage or another authorized substance. **[The End]**

FDA Goals in Labeling and Advertising Regulations

By JULIUS HAUSER

This Article Was Presented at the Food and Drug Law Institute Seminar at the School of Law, Northwestern University, Chicago, Illinois, on April 14, 1967. Mr. Hauser Is Assistant for Regulations, Office of the Associate Commissioner for Compliance, Food and Drug Administration.

THIS IS AN UNUSUALLY PROPITIOUS TIME for a restatement of the Food and Drug Administration's (FDA) goals in labeling and advertising regulations for prescription drugs. Recent events in this area have done more than kindle controversy. Fortunately, they have constructively directed the attention of pharmaceutical manufacturers, advertising agencies and FDA to the real problems of communication among us. Surely, it is to our mutual advantage and in the public interest to work together to resolve the problems.

A broad understanding of FDA's goals in regulating the labeling and advertising of prescription drugs may not be reached until there is full recognition of the implications of the fact that the pharmaceutical manufacturing industry is the principal source of the drug-use information relied upon by physicians. No other source of drug-use information matches the impact on physicians of manufacturer-sponsored detailmen, the *Physicians' Desk Reference (PDR)*, mailing pieces, detailing pieces, house organs, medical exhibits, films, symposia, advertisements in medical journals and research reports published in the journals and disseminated as reprints. We are discussing the use of potent drugs that have an immediate and profound effect on the life and health of millions of Americans. In these circumstances, pharmaceutical manufacturers and all of their instrumentalities have a grave responsibility for the quality of the drug information they convey to physicians and for the quality of medical care resulting. In this context and within

the framework of federal law and regulations, it is the goal of FDA to assure that the labeling and advertising of prescription drugs convey to physicians truthfully, adequately and effectively the best available drug-use information. Simply stated, the goal is this:

> The labeling and advertising of a prescription drug shall faithfully furnish the doctor the information each of us wants him to have in mind when he is about to use a drug on us or on those we love!

Related Goals

This broad goal may be analyzed to define a number of related goals. It is a goal of FDA to assure that the labeling of a prescription drug effectively makes available to physicians "full disclosure" information, including "indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions," under which physicians can use the drug with maximum safety and effectiveness. You will recognize that some of this language is quoted from section 1.106(b)(3) of the regulations under the federal Food, Drug and Cosmetic Act, which requires such information to appear on the drug package. This is the only way manufacturers can be required to furnish such "full disclosure" information under existing law. The advertising of drugs is not mandatory. When advertising in journals or other periodicals is employed, the law requires information in "brief summary" only. The package insert is not the most effective means for communicating drug-use information to physicians, but until more effective communication can be required or is voluntarily established as an alternative, the package insert requirement must be retained.

It is a goal of FDA to assure that every form of prescription drug labeling and advertising is truthful and presents in fair balance with claims for the effectiveness of a drug, limitations on its effectiveness, contraindications, side effects, needed warnings and precautions. We are concerned not only with eliminating false statements, but with assuring effective disclosure of the information needed for the physician to determine whether the potential benefits of a drug to his patient justify the risks of its use. It is necessary that this goal apply to all forms of labeling and advertising, because many of them reach the physician more directly and effectively than the package insert.

It is a goal of FDA to obtain maximum cooperation from pharmaceutical manufacturers and advertising agencies in complying with the letter and spirit of the law and regulations governing the labeling and advertising of prescription drugs. Our purpose is to protect the public

health. It is not the goal of FDA to develop a maximum number of criminal prosecutions, drug seizures, "remedial" letters or injunctions, but these enforcement actions must be initiated to the extent necessary to assure a maximum of compliance.

It is a goal of FDA to assure that labeling and advertising furnish the best available drug-use information to physicians. For this purpose, the labeling worked out by FDA and manufacturers on the basis of the scientific evidence of safety and effectiveness in the case of new drug or antibiotic applications establishes the pattern for all labeling and advertising. The re-evaluation of the drugs pre-cleared by FDA before the Kefauver-Harris Drug Amendments of 1962 which now is being conducted by panels of the National Academy of Sciences-National Research Council is expected to improve the basic pattern of labeling for many drugs. The availability of new information from clinical experience through the "records and reports" requirements of the Act and regulations, through the "adverse reaction reporting program," and through special studies will continually improve the body of drug-use information establishing patterns for drug labeling. In this connection, one of the important FDA goals is to assure that significant new information with respect to the hazards or effectiveness of drugs is promptly transmitted to the medical profession through labeling and advertising. The development of new evidence concerning drugs with "grandfathered" labeling will be coupled with enforcement actions to the extent necessary to assure that the labeling and advertising of such drugs is truthful and informative.

All of these measures to determine what is the "best available drug-use information" will result in progress toward the ultimate FDA goal of assuring that all representations in the labeling and advertising of prescription drugs are supported by substantial scientific evidence. Industry cooperation, especially through lending the support of its scientific facilities, can be most helpful in accelerating progress toward this goal.

Purpose of Revisions in Regulations

It is a goal of FDA's proposed revisions of the regulations on the advertising and labeling of prescription drugs to clarify the rules. This will not only make it easier for industry to comply voluntarily, but will make it easier for FDA to enforce the law concerning failure to comply.

We intend that the proposed regulations define as false or misleading a number of deceptive advertising practices. Additions could be made to this list by amending the regulations as necessary to reflect the dynamics of advertising, while maintaining the clarity of the rules.

The proposed advertising regulations should establish specific rules for compliance with the requirement of "fair balance." The proposed revision of the labeling regulations would retain the "full disclosure" requirement for labeling on the drug package and in publications, file cards, comprehensive labeling, etc., disseminated to physicians as references to drug-use information.

Conceivably, the rules for other labeling could be eased to give manufacturers some options:

1. "Full disclosure" labeling.

2. Use information limited to selected indications, but including complete information on side effects and contraindications.

3. Information relating to side effects, contraindications and effectiveness in brief summary following the same rules applicable to advertising.

4. "Reminder-piece" labeling.

Conclusion

Finally, it is a goal of FDA to revise the regulations on prescription drug advertising in conformity with the provisions of section 701(e) of the federal Food, Drug and Cosmetic Act, which include opportunity for a hearing, without being reminded by drug manufacturers that this procedure must be followed. We anticipate constructive cooperation from industry in the development of these regulations. **[The End]**

NEW REGULATIONS ON PRESCRIPTION DRUG ADVERTISING AND LABELING PROPOSED

The Food and Drug Administration has proposed amended regulations on prescription drug advertising and labeling which more clearly define the scope and substance of information about a drug's side effects, contraindications, and effectiveness that must be included in various types of advertisements and labeling. The proposed amended regulations also list 34 specific practices which would brand an ad as "false, lacking in fair balance, or otherwise misleading." Proposed Reg. § 1.105(e) and § 1.105(l), 32 *Federal Register* 7533.

Proposed Amendments to the Model Food and Drug Law

By GEORGE M. BURDITT

The Following Article Was Presented at the Illinois Dairy Products Association Meeting on May 15, 1967 at Galesburg, Illinois. Mr. Burditt Is a Partner of Chadwell, Keck, Kayser, Ruggles & McLaren and a Member of the Illinois Legislature.

THE MODEL FOOD, DRUG AND COSMETIC ACT[1] has served for many years as an outstanding example of the salutory effect of cooperation among representatives of the Executive and Legislative branches of government, industry and consumers. Sponsored primarily by the Association of Food and Drug Officials of the United States, and based on the Federal Food, Drug and Cosmetic Act of 1938,[2] the Model Act has brought modernization and uniformity to our state laws governing this very important segment of our legal system throughout the United States. Therefore, any changes in a state law which is based on the Model Act should be made only after very careful consideration. As a matter of fact, there are those who believe that the Model Act should be as inviolate as the Ten Commandments[3] or should at least be as difficult to amend as the Constitution of the United States!

The Food, Drug, Cosmetic and Pesticide Laws Study Commission

On the other hand, the development of modern technology, the constantly changing demands of consumer interest, and the new ideas and concepts concerning food and drug law enforcement probably place food law in a slightly different category from the Ten Commandments and the Constitution. Having surmounted religious and legal obstacles, the Illinois General Assembly in 1965 created a two-year Food, Drug, Cosmetic and Pesticide Laws Study Commission.[4] Their responsibility is to review all Illinois laws in these areas and to

[1] CCH Food, Drug, Cosmetic Law Reporter ¶ 10,100.
[2] 21 U. S. C. § 301 and following.
[3] Exodus 20:3-17.
[4] House Bill No. 984, 74th General Assembly.

make recommendations to the current session of the Legislature for such changes as might be necessary to give Illinois the best food and drug law in the United States.

The Commission which was subsequently appointed consisted of five senators (Senators Collins, Dennewald, Kinnally, Latherow and Laughlin), five representatives (Representatives Connelly, McDevitt, Smith, Stevenson III and Burditt) and five public members (Mrs. Esther O. Kegan, Messrs. Harvey L. Hensel and Richard W. Kasperson, and Drs. Howard B. Petty and J. B. Stine). Since the Governor had vetoed the appropriation for the Commission, the Commission members were kind enough to elect me as their chairman, and Adlai Stevenson III served as vice-chairman. While the senators and representatives made a substantial contribution to the Commission's work, we really could not have operated efficiently or effectively without the invaluable contribution made by the public members, to whom we owe a deep debt of gratitude for their contributions in terms of time and ideas in accomplishing our stated legislative purpose.

The Commission recommended about 25 bills to the current session of the Legislature. Many of these bills merely repealed outmoded sections of the Illinois law which were rendered unnecessary by the Uniform Food Act which was passed in Illinois in 1965. Several other bills, and these of course are far more important, recommend specific changes in the Illinois Food Act[5] and the Illinois Dry and Cosmetic Act.[6] It is these bills which I would like to discuss with you.

Recommended House Bills

House Bill 453 would amend the Illinois food law to make it identical with Section 403(k) of the Federal Food, Drug and Cosmetic Act[7] by exempting butter, cheese and ice cream from the requirement that artificial coloring be declared on the label. For some reason this provision is omitted from the Uniform Food Act.

House Bill 454 is in my opinion the most important bill in the entire package. In substance, the bill would provide for automatic adoption in Illinois of federal standards of identity, and federal pesticide, color additive, food additive and dietary regulations. If the bill becomes law, any such regulation promulgated by the Food and Drug Administration (FDA) will become a part of the Illinois law without further action of any kind by the Illinois Department of Public Health. Thus, we hope to take full advantage of the expertise which goes into the promulgation of these federal regulations.

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[5] Ch. 56½ I. R. S. § 401 and following.

[6] Ch. 111½ I. R. S. § 401 and following.

[7] 21 U. S. C. § 343 (k).

Of course it is desirable, and perhaps necessary from a constitutional point of view, to add a saving clause which would permit an interested person to raise objections and ask for a hearing in Illinois on any federal regulation which would be automatically adopted. Any such objection operates as an automatic stay of the regulation until the Department of Public Health has had an opportunity to rule on the matter.

House Bill 469 would add to the Illinois food law a provision similar to that now contained in Section 405 of the Federal Act[8] exempting from the labeling requirement of the Act small open containers of fresh fruits and fresh vegetables, and food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked at establishments other than the original plant, on condition of course that the food is not adulterated or misbranded at the time of shipment from the second plant.

House Bill 487 corrects an erroneous cross reference in the 1965 Uniform Food Act. At the present time, this is the only bill which has passed both Houses and has been approved by the Governor! Hopefully, our other bills will do as well.

House Bill 489 would add to the Illinois food law a provision similar to that now contained in Section 301(j) of the Federal Act[9] prohibiting any person from using to his own advantage or revealing except in the line of official duty any information acquired under authority of the Act concerning any method or process which as a trade secret is entitled to protection. This provision also, for some reason, is omitted from the Uniform law.

House Bill 1659 changes the outmoded factory inspection provisions presently in the Illinois law and the Uniform Act, and would adopt the more modern provisions incorporated in the Federal Act in Section 704.[10]

House Bill 775 is a lengthy bill which in general does two things:

1. It combines the provisions of the Uniform Drug and Cosmetic Act which were passed in Illinois in 1959,[11] and the provisions of the Uniform Food Act which were passed in 1965.[12] Back in 1959, the Legislature went to the very extensive trouble of separating and passing the drug and cosmetic provisions of the Uniform Food, Drug and Cosmetic Act, and left for the 1965 session passage of the food provisions of the Uniform Act. House

[8] 21 U. S. C. § 345.
[9] 21 U. S. C. § 331 (j).
[10] 21 U. S. C. § 374.
[11] Ch. 111½ I. R. S. § 401 and following.
[12] Ch. 56½ I. R. S. § 401 and following.

Bill 775 recombines these two parts of the same act, which currently appear in different chapters in the Illinois statutes into a Uniform Food, Drug and Cosmetic Act.

2. House Bill 775 also incorporates into the Uniform Act all of the various changes which I have just mentioned and which are covered in separate bills. We anticipate that if House Bill 775 passes both Houses of the Legislature, the Governor will sign this bill and will veto the several miscellaneous bills covering the same points.

Conclusion

The Illinois Legislature adjourns on June 30th, so we will know in the immediate future whether the Commission's work has been worthwhile. Because so much work remains to be done, the Commission has recommended that a new commission be established by *House Bill 893*. This also would be a two-year commission, hopefully with an appropriation to continue to carry out the modernization of our Illinois law.

If the changes which we are recommending in the Illinois food law are enacted, and if they prove to be sound, we are very hopeful that other states will incorporate our proposals in the various state laws, and that the Association of Food and Drug Officials will see fit to recommend the same changes in the Uniform Food, Drug and Cosmetic Act. **[The End]**

BOOK REVIEW

Fundamental Principles and Objectives of a Comparative Food Law: Volume 1, General Introduction and Field of Application. By E. J. Bigwood, Director of the Food Law Research Centre of the Institute of European Studies of Brussels University, and A. Gérard, a Belgian Lawyer and a Member of the Food Law Research Centre. 128 pages. S. Karger, Basel, Switzerland or P. O. Box 352, White Plains, New York. 25 Swiss francs, $6.00 U. S. Currency, plus postage. Reviewed by Franklin M. Depew.

Messrs. Bigwood and Gérard have undertaken a substantial task in endeavoring to draw up a functional classification of the various elements which should form the basis of a food law in accordance with abstract, theoretical concepts, and then discussing the degree to which the legislation of Canada, the United States and the countries of Europe conform thereto.

This first volume examines the type of legislation which should be considered "food law," within the meaning of that term, from a legal, philosophical, historical, sociological and technological viewpoint. Basically, these laws have in common the protection of the consumer against damage to his health as well as against exploitation through commercial or industrial mal-

practice. It is pointed out that, in recent years, the laws in Western Europe and North America have shown a tendency to separate into those grounded on the legal system of prohibition (that is, everything is prohibited unless specifically permitted) and those following the system of abuse (that is, everything is permitted unless specifically prohibited). The words "prohibition" and "abuse" are terms which recently have come into use in European circles to describe the two differing methods of providing for the enforcement of food laws, and they are used throughout this book as a handy way of distinguishing between the two methods. Upon examining the laws and regulations of most European countries, it appears to the authors that the present laws combine, in widely varying proportions, both the principle of prohibition and the principle of abuse. In some countries, the prohibition system is applied only to certain specific categories of additives or foodstuffs. It is the writers' conclusion that a rational mixed regime is better and more flexible. The view is expressed that this type of law might serve as a common basis for a harmonized food law in all countries. In the authors' view, in order to achieve this, it usually would not be necessary to modify the existing legal framework in each country.

On page 18, the hopeful view is expressed that harmonization of food regulations in many instances may merely require bringing them up to date, and the recommendation is made that such a process should take place at regular and frequent intervals in order to follow the rapid development of scientific knowledge.

The various elements which make up a food law are discussed at some length under the general categories:

A. Elements of Motivation (objectives of food laws)

B. Elements of Qualification (terminology and basic concepts)

C. Structural Elements (national food law structures)

D. Institutional Elements (procedures of elaborating legal regulations)

E. Elements of Control and Sanction (organization and procedures of control, civil sanction, punitive sanctions)

In the course of describing these categories, the following points are made: there are good reasons to believe that overly conservative food habits are likely to create obstacles to innovation in the field of new sources of unconventional foodstuffs; in the field of food additives, an objectively considered risk always is to be evaluated and must be recognized as an acceptable one; the primacy of natural products is a myth to be destroyed, and the prejudice against synthetic chemicals is equally mythical.

The first volume ends with a discussion of the basic concepts inherent in the terms "food" and "food additive" and a review of the current legal sense of the words in some dozen European countries, Canada and the United States. It also describes the steps taken by the Joint Food and Agriculture Organization—World Health Organization (FAO-WHO) Codex Alimentarius Commission to define these words for the purposes of its work in furthering international standardization of foods. This compilation should prove most useful to those engaged in the manufacture and distribution of foods in European markets.

In conclusion, however, I must point out that the authors' interpretation of the laws of Canada and the United States appear to be in error on occasion; as expressed, for instance, on pages 35, 47 and 90, where the authors are dealing with such subjects as the nature of substances which may be considered as GRAS ("generally recognized as safe"), the extent to which food additives may be authorized in the United States, and the question of whether the word "food" includes "food additive" within the meaning of Canada's Food and Drugs Act.

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