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Food Drug Cosmetic Law JOURNAL

Concluding Papers and Panel Discussion

1962 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.

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

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REPORTS

TO THE READER

This issue of the FOOD DRUG COSMETIC LAW JOURNAL contains the concluding papers of the 1962 Joint National Conference of the Food and Drug Administration, which was held in Washington, D. C. on November 26, 1962. The December, 1962 JOURNAL contained the papers delivered at the morning session of the Conference. Except for the addresses presented by *William T. Brady* and *Dr. Detlev W. Bronk*, these two issues comprise a complete record of the 1962 Conference.

T. C. Byerly, looks at the future of the food industry in an article which appears at page 4. Mr. Byerly is Administrator, Cooperative State Experiment Station Service, Department of Agriculture, and Chairman of the Division of Biology and Agriculture, National Research Council, National Academy of Sciences.

Technological advances in the food and drug industry have antiquated the use of present procedures and controls. *George P. Larrick*, Commissioner of Food and Drugs, discusses on page 13 steps being taken to remedy the situation.

The Conference concluded with a panel discussion of the questions submitted to a panel composed of five prominent men in the food and drug law field, which is at page 19. Panel members from the Food and Drug Administration were: *Franklin D. Clark*, Assistant to the Deputy Commissioner; *J. Kenneth Kirk*, Assistant Commissioner; *Dr. O. L. Kline*, Assistant Commissioner for Science; and *Winton B. Rankin*, Assistant Commissioner. The fifth member of the panel was *William W. Goodrich*, Assistant General Counsel Food and Drug Division, Department of Health, Education and Welfare.

The most important international food law development in 1962 was the Food and Agriculture Association-World Health Organization Conference, which was held in Geneva, Switzerland, October 1-5. *Franklin M. Depew*, President of the Food Law Institute, represented both the Food Law Institute and the Inter-American Bar Association. The Conference formulated guidelines for the Food Standards Committee which will start work on formulating worldwide and regional food standards next June. These guidelines will be helpful in assuring that unwarranted trade barriers will not be established or continued by the food standards adopted. Mr. Depew's report on this Conference is found on page 34.

Wayne D. Hudson discussed food standards at the San Francisco meeting of the American Bar Association Section on Food, Drug and Cosmetic Law on August 8, 1962. Mr. Hudson is Secretary and Chief Counsel of Foremost Dairies, Inc. The paper appears on page 54.

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Food·Drug·Cosmetic Law
Journal

Food in Our Future

By T. C. BYERLY

This Paper Was Presented at the Afternoon Session of the FDA-FLI Conference Which Was Held on November 26, 1962 in Washington, D. C. The Author Is Administrator, Cooperative State Experiment Station Service, United States Department of Agriculture and Chairman of the Division of Biology and Agriculture, National Research Council, National Academy of Sciences.

IN CONSIDERING PROBABLE FOOD CHANGES, we should also consider trends in estimate of food required for good nutrition. As background, I have compared the first table on "Recommended Daily Allowances" released by the National Research Council in 1941 with the current one released in 1958.

Allowances for protein for moderately active men are the same—70 grams per day. Calories have not been reduced; ascorbic acid and calcium are the same; iron, vitamin A, thiamine and riboflavin allowances have been reduced and niacin allowance increased. Significantly, the 1958 allowances include a weight for height guide. For moderately active women, calories, protein, thiamine and riboflavin allowances have been reduced; calcium, iron, vitamin A and ascorbic acid remain the same; niacin has been increased. Allowances for calories and protein for pregnant and lactating women were substantially increased in the 1958 allowances over the 1941. Recommended niacin allowances for children in the 1958 allowances were increased rather sharply over 1941.

[1] NAS NRC, National Conference on Nutrition. Table I in "Planning Diets," Bureau of Home Economics, United States Department of Agriculture, 1941. Table 1. National Academy of Sciences, National Research Council, "Recommended Dietary Allowances." Publication 589 (1958).

In 1941 our Bureau of Home Economics commented: "The flavorful sugars and fats are inexpensive sources of calories, but they should not unduly displace the foods that safeguard diets in minerals, vitamins, and protein of high quality."

In 1958, the NAS NRC said: "It is not yet possible to state definitely a reasonable allowance for fat in the diet or to indicate the characteristics of a fatty acid mixture most favorable for the support of health. A diet selected from a wide variety of foodstuffs, both vegetable and animal, is most likely to maintain good health."

"Average" Citizen's Food Consumption

The "average" citizen of the United States eats rather well. Some eat too well, that is, too much. Others, especially among the lower income groups, eat rather restricted diets, often deficient in one or several nutrients. The "average" citizen has available about 3,170 calories per day which meets or exceeds the recommended allowance for all groups except lactating women and 16-19 year old boys. The average citizen consumed 95 grams of protein daily, more than enough for all groups except the two just cited. We consumed an average of 0.98 grams of calcium, adequate for ordinary adults, but too little for growing children, youths, pregnant and lactating women. We consumed 16.6 mg. of iron, exceeding the recommended allowance for all groups. We consumed 6,900 IU of vitamin A, exceeding all recommended allowances except that for pregnant women. Thiamine consumption of 1.76 mg. per cap per day was adequate for all groups. Riboflavin at 2.2 mg. per cap per day exceeded the allowance for all groups except 16-19 year old boys and latcating women. Niacin at 20.4 mg. per cap per day intake exceeds the allowance for all groups except 16-19 year old boys. Ascorbic acid at 103 mg. per cap per day exceeds recommended allowance for all groups except lactating women.

We get about 40 per cent of our calories from fat. While there is no requirement for fat per se, there is a requirement for certain fatty acids. A few nutritionists (considered extremists) would cut the proportion of calories from fat to 15 per cent, which would be difficult to achieve since about half of the fat we ingest is eaten as an unseparated portion of our meat, poultry, fish, eggs, milk, cereals and other foods. We could cut it to about 20 per cent of calories by eliminating all visible fats and oils including butter, margarine and fat cuts.

About three-fourths of our calcium intake is from milk; meats and other animal products provide about 40 per cent of the iron; about

30 per cent of our vitamin A comes from leafy green and yellow vegetables and fruit; about a third of our thiamine comes from cereals; about 46 per cent of our riboflavin comes from milk; about half our niacin comes from meat, poultry and fish and about 35 per cent of our ascorbic acid from citrus fruits and tomatoes.

Nutritional Shortage of Fat in the World

Using as a reference standard for fat, 15 per cent of standard calories (2,300 to 2,710 per day) there is a nutritional shortage of fat in the world of about 3.2 million metric tons. Most of it is in the Far East.[2]

"Fats are the most concentrated energy sources provided by the diet. Some fats provide important amounts of vitamins A, D, E and K. Fats are required in the human diet because they provide certain polyunsaturated fatty acids, linoleic and arachidonic acid, because they facilitate utilization of fat-soluable vitamins, and because fat enhances the efficiency of utilization of carbohydrate and protein. Fats contribute important but elusive features of palatability and satiety to the diet." [3]

"Evidence to support the concept that high levels of plasma cholesterol in man are atherogenic are not conclusive. Circumstantial evidence indicates that the kind, or amount, of dietary fat is in some way related to atherosclerosis in man. A change in intake of the more saturated fats in the diet may ultimately prove desirable for health but is not mandated by currently available evidence."

The same source cites the content of linoleic acid in some of our common food fats as: lard, 3.1 per cent; beef fat, 1.8 per cent; butter fat, 3.6 per cent; chicken fat, 21.8 per cent; corn oil, 56.3 per cent; cottonseed oil, 47.8 per cent and soybean, 50.7 per cent.

Margarine and shortening are generally made by hydrogenation of liquid fats. Hydrogenation raises the melting point and changes unsaturated fatty acids to saturated fatty acids. "Hydrogenated fats are comparable to natural fats of similar firmness as sources of essential fatty acids and are equally well used as energy sources."

Total fat available for consumption has increased from about 135 grams per capita per day in 1930 to about 145 grams per capita per day in 1962. The increase is the result of higher consumption of meat, poultry,

[2] Anderson, W., "The World Food Budget." Foreign Agriculture Econ. Report No. 4.

[3] NAS NRC—Committee on Fats in Human Nutrition 1962. "The Role of Dietary Fat in Human Health." Publication 575, at p. 24.

fish, eggs and dairy products, except butter. Total consumption of food fats, per se—lard, shortening, cooking and salad oils, margarine, butter and fat cuts—hasn't changed much. Butter and lard consumption have dropped sharply while margarine, shortening and oils have increased. In sum, increase in beef fat has offset decrease in butter fat as saturated fatty acids are concerned. We ate about 52 grams of saturated fatty acids per capita per day in 1930 and we eat about the same now. We have increased our consumption of unsaturated fatty acids about 10 grams per capita per day between 1930 and 1962. Four of these 10 grams are linoleic acid. This is about a 30 per cent increase.

Questions to Be Answered

The question of how much linoleic acid we should ingest, of how much fat, what calorie : protein ratios we should observe, what combinations of kinds of fat and kinds of carbohydrate remain to be answered. There is clear evidence from experimental rats that kinds of carbohydrate may be important. Male rats fed a synthetic diet with 15 per cent corn oil and sugar as the principal carbohydrate source had 356 mg. per cent cholesterol at 400 days which was significantly higher than that for similar groups fed hydrogenated vegetable oil or lard with a sucrose diet and higher than a 15 per cent corn oil group fed corn starch instead of sugar.[4]

It is well to remember the comment of the committee on fats in Human Nutrition [5] that "The only animal to develop human atherosclerosis is man."

A study of business and professional men recently reported by Adelson and Keys [6] compared nutrients ingested in the diets of the men on the basis of the high and low thirds in serum cholesterol of the sample studies. The high cholesterol group got about 20 per cent more calories from alcohol, fruits and sweets and fewer calories from starchy foods than the low cholesterol group. Men in the high cholesterol group ate more meat, poultry and fish, but less fats, oils, milk and eggs than the low cholesterol groups.

These are statements of observed fact; not conclusions.

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[4] Marshall, Hildebrand, Dupont and Womack, 69 *General Nutrition* 371-382 (1959).

[5] National Academy of Science, National Research Council Publication 575, at p. 27.

[6] Adelson, S. E. and Keys, A., "Diet and some health characteristics of 123 business and professional men . . ." Agricultural Research Service 62-11. United States Department of Agriculture.

Increased Market for Polyunsaturated Fatty Acids

However the merits of the case may be, there seems to be an increased market for polyunsaturated fatty acids and new products are being offered to meet the demand. If the demand continues to grow it may affect the kind of meat we eat during the next 10 years. We have pointed out that chicken fat is relatively high in linoleic acid. It has long been known that the linoleic acid content of pork fat can be sharply increased by feeding. Ellis and Isbell reported that fat from hogs fed whole soybeans had fat containing 35.6 per cent linoleic acid.

With respect to beef fat, or butter fat or mutton fat, change through diet of linoleic acid content may not be feasible. Ruminants reduce ingested carbohydrates and fats to short chain fatty acids, for example; acidic propionic and butyric, by bacterial digestion in the rumen.

These acids are assembled into characteristic fats in milk and storage depots. Research is underway to determine the feasibility of alteration of the ratio of butter to nonfat milk solids. It is possible that genetic means can be used. If we must eat leaner beef, there is no problem in producing it *but* there is a very real, perhaps difficult, problem in producing lean beef excelling in all of the organoleptic qualities which have accounted for its rapid and substantial increase in per capita consumption.

For we have become a nation of beef eaters and chicken eaters. No longer is it "Chicken on Sunday." Chicken is cheap; pan ready, generally cheaper than hamburger; but not so cheap on a serving basis.

Our series begins in 1909 when per capita beef consumption was about 74 pounds. Consumption declined to a low of about 47 pounds in 1932 and has risen since that time to its present level of about 88 pounds. A rather sharp increase took place in 1953 when beef consumption increased to almost 78 pounds from the 1952 level of 62 pounds.

Increased Beef Production

The increase in beef production has been one of the major adjustments made by farmers. From 1940 to 1955 we replaced a beef cow for a horse rather consistently; since then we've exchanged beef cows for dairy cows. Beef for the future depends on increased efficiency of

[7] Ellis, N. R. and Isbell, H. S., "Soft Pork Studies," 69 *Journal Biological Chemistry* 239 (1926).

production if our supply is to continue to be mostly domestic and our appetite to be satisfied. It takes twice as many nutrients to produce a pound of liveweight on our beef herd as it does to produce a pound liveweight on our swine herd and ten times that required to produce a pound of live broiler. Of course, we may be apt to increase our imports. There are limited possibilities here.

Milk

In the United States, in north European countries, in New Zealand, milk supplies most of the calcium and is a principal source of high quality protein. We in the United States currently obtain about 75 per cent of our calcium and one-fourth of our protein from milk.

Our use of the nonfat solids portion of our milk supply has shifted very greatly. In the 1925-29 period, about 48 per cent of nonfat milk solids were used for human food. The remainder was fed to animals or, to a minor extent, wasted. During the 1958-62 period, more than 81 per cent of nonfat milk solids were used for human food at home and abroad.

Our civilian per capita consumption of nonfat milk solids during the 1925-29 period was about 35 pounds, during the 1958-62 period about 43 pounds. Peak per capita consumption, 46.9 pounds, occurred in 1946.

Milk fat consumption has been rather unlike nonfat milk solids consumption. The portion used for human food has increased from 97.1 per cent of production in the 1925-29 period to about 98 per cent in the 1958-62 period. This reflects more sparing use of whole milk for dairy calves made possible by advances in calf nutrition knowledge. Per capita civilian consumption has decreased from about 32 pounds during the 1925-29 period.

Convenient Foods

The use of convenience foods has increased very rapidly during the past few years. Convenience foods may be defined as foods that have undergone some preparation ordinarily done in the home before they are retailed.

Problems in the preparation and distribution of convenience foods which have been solved through research include development in the checking of rancidity and dehydration in frozen meat products. Research has demonstrated that low storage temperatures and appropriate packaging materials will retard deterioration, but additional research in this

area is needed. The same problems, plus the problem of maintenance of color and development of spoilage organisms limit the shelf life of packaged fresh meat, poultry and fish products.

Frozen precooked problems are limited by flavor and texture problems. Research has developed gravies which will maintain texture on thawing after freezing. The rancidity problem is only partially solved for the frozen precooked meat products.

A dehydrated whole milk which may be stored without refrigeration and be instantly reconstituted into a product organoleptically equal to fresh milk could greatly extend milk use. Present products in the pilot stage at the United States Department of Agriculture EURRD has a shelf life of about four months without refrigeration when nitrogen packed. We may anticipate institutional use of such a product with accompanying benefits to our dependent orphans and other wards of the community and possibly an acceptable product for household use.

Pre-packaged meats, vegetables, fruits, pre-mixed cakes, frozen, pre-cooked foods such as TV dinners, dehydrated potato flakes and soup mixtures, frozen orange and other fruit juice concentrates have rapidly found fervor. Frozen fruits and vegetables, frozen fish and poultry also have assumed limited roles. For the future, dehydro frozen products of many sorts will find a place.

Popularity of Convenience Foods Grows

A recent study indicates that 14 per cent of total food sales in United States grocery stores consists of convenience foods. There are hundreds of such items. The use in their sales has paralleled the increase in the number of homemakers employed outside the home. In some cases, for example, potatoes, availability of convenient food forms has checked declining consumption of a commodity. From 1956 to 1960, several new potato products were put on the market, including frozen potato puffs, dehydrated au gratin, scalloped, hash-browned and mashed potato flakes and granules. During those 5 years, per person use of processed potatoes doubled, which was more than enough to offset the long term decline in potato use.

Research has shown that while[7] some convenience foods are more expensive than their less highly processed counterparts, others are less expensive. In the aggregate, the housewife spent $14.03 for con-

[7] Hays, H. H. and Dunham, D. F., "Convenience Foods in the Grocery Basket." Marketing Bulletin No. 22, 1962.

venience foods which in the fresh or homemade form would have cost $15.10. Calculated value of the homemaker's time in preparing potato products available as convenience foods varied from 4 cents an hour for French fries to $1.15 for boiled potatoes.

In my opinion, the future growth and use of convenience foods must depend on quality of such products as well as cost. Quality and economy are compatible as evidenced by the wide acceptance and economy of frozen orange concentrate. Purchase of this product amounts to almost 5 per cent of all convenience food purchases. The cost of fresh orange juice is about twice that of juice prepared from the frozen concentrate.

Imported Foods

Sugar, coffee, tea, spices, bananas and cocoa beans are traditional food imports. In 1961 they had a dollar value of about $1.75 billion But there were also imported in 1961, 665 million pounds of beef and veal and about one million live cattle representing about 250 million pounds carcass equivalent. Thus about 5 pounds per capita of our 1961 beef supply was imported. There appears to be an upward trend in meat importation. The average annual dollar value of meat imports in the 1950-54 period was about $146 million and for the 1955-59 period about $230 million. The 1961 preliminary value was $372 million. These meats came from 31 countries of which Australia was the largest supplier.

We also imported about $62 million worth of nuts, of which cashews accounted for about 40 per cent, about $88 million worth of fruits and fruit preparations other than bananas, of which about a fourth consisted of olives. Vegetables and vebetable preparations imported amounted to about $78 million. Tomatoes and tomato products account for about 35 per cent of this amount.

These imported products add variety to our diet. Twenty-five fruits, 11 nuts and 30 vegetables were imported in sufficient quantity to receive separate statistical listing. They also provide a challenge to our own producers and merchants. Long shelves of imported items are now available in some of our chain stores.

Since the '30's we have increased our consumption of meat, poultry, fish and eggs by about 36 pounds per capita per year, from 166 pounds during the 1935-39 period to 202 pounds in 1961. We have increased our per capita consumption of nonfat milk solids from about

37 pounds during the 1935-39 period to about 43 pounds during 1961 while butter fat consumption fell from about 32 pounds to 24 pounds.

Our consumption of fresh fruits fell from 139 pounds per capita during the 1935-39 period to 92 pounds in 1961, while consumption of fruit in all forms was 189 pounds farmweight equivalent during the 1935-39 period and 191 pounds in 1961. Consumption of fresh vegetables and melons dropped from about 140 pounds per capita to about 129. Consumption of vegetables and melons in all forms rose from 193 pounds to 229 pounds. Consumption of potatoes and sweet potatoes fell from 152 pounds per capita during the 1935-39 period to 111 pounds in 1961. Consumption of dry beans and peas fell from 10 pounds per capita to about 8 pounds. Consumption of cereal products fell from about 205 pounds per capita in the 1935-39 period to about 147 pounds in 1961. Sugar consumption, the sum of beet, cane and corn sugar showed little change at about 100 pounds per capita. I have not reviewed the caloric intake of alcohol, a highly variable, sometimes substantial contributor of calories.

As disposable income has increased since the '30's, consumption of all food has increased but little. Future affluence will change the consist of our diet but not the amount.

Summary

In sum, then, we have changed from unprocessed to processed foods to a substantial degree; we're eating more meat, especially beef and poultry; we've cut our consumption of starchy foods.

It is reasonable to assume that during the next 10 years, meat consumption, especially beef and poultry will continue to increase as will the use of processed foods; in my opinion per capita consumption of cereals, potatoes and sweet potatoes will and should increase a bit at the expense of fat. We are likely to pamper ourselves with a wider variety of exotic foods in order to convince ourselves that we are indeed free and able to eat what we please, whether we like it or not. [THE END]

A Look at the Future

By GEORGE P. LARRICK

The Author, United States Commissioner of Food and Drugs, Presented This Paper Before the Afternoon Session of the Food and Drug Administration-Food Law Institute Conference.

IT IS WITH GREAT PLEASURE that we welcome you to another conference sponsored jointly by the Food and Drug Administration and the Food Law Institute. Through these meetings we have for several years achieved a greater understanding of the problems that confront all of us, and have been able to discuss in a spirit of mutual cooperation the steps that each of us can take to arrive at solutions that are in the public interest.

In previous conferences we have considered in some detail the application of some specific pieces of legislation. This time, despite the fact that another very important law has just been enacted, the leadership of our two sponsoring agencies thought it would be a mistake to limit the scope of the discussions by confining them to one piece of legislation. Changes are taking place in all of the fields in which we are interested, so we can perhaps better profit by standing back from any specific amendment to a single law, and taking a look at the broad food and drug field to plan for the future.

The technological advances in our areas are already occurring so rapidly that some responsible, thoughtful people are raising questions as to the ability of our society to contain the advances and make beneficial use of them with present procedures. I am confident that we will be able to do so. We cannot do it, however, with the procedures and controls of the past.

We both must continue to keep abreast of the new developments and evaluate our own operations in the light of these developments. And we must continue to add our own contributions to the increase in general knowledge.

Education Programs

A key to successful participation in such a program is continued and expanded education. This part of our work has received increasing emphasis in recent years. It is being carried forward through several measures designed to acquaint all who are interested with the laws we administer, and the way we administer them. During the eight-year period since 1954, our personnel have presented over 7,400 educational speeches and articles in outside journals, or an average of over four per working day. To permit this activity to go forward with even greater benefit to all, we are studying the advisability of designating an individual in each of the Food and Drug Administration field districts to devote his time to coordinating such work for the field.

In addition we issue a large amount of educational material through the mailing lists that are maintained in Washington. With more than 40 such lists, we are able to supply anyone who cares to ask with specific types of information on current developments in food and drug regulation. Our mailings are made to consumers, consumer organizations, professional organizations, libraries, industries, cooperating government agencies, the press and others. Since 1954 we have made, by use of these lists, almost 1 and ¾ million mailings of material of interest to consumers, and almost 3 million mailings of educational material of interest to the regulated industries. Adding FDA publications distributed to other groups and sold by the Government Printing Office, over 6 and ¼ million pieces of educational material have been issued by FDA in the past eight years. This figure does not include press releases or the many millions of articles based on such releases.

Additionally, we maintain continuing and extensive contracts with organized groups, and seek their views and assistance in our operations. You know of many of these activities—the formation of the Public Service Advisory Committee, the consumer consultant program which is now being expanded, the very extensive work our analysts perform with outside groups in the development of better analytical methods and standards (the Association of Official Agricultural Chemists, the United States Pharmacopeia, the Institute of Food Technologists, and the Contact Section of the Pharmaceutical Manufacturers Association, for example). This however is only a small part of the picture.

Cooperation with Industry Organizations

In recent years FDA and various government and industry organizations have worked together extensively to promote better understanding of and compliance with the laws. Examples are the work we have done with the American Butter Institute, National Cheese Institute, International Association of Ice Cream Manufacturers, Dry Milk Association, Evaporated Milk Producers Federation, National Agricultural Chemicals Association, the United States Department of Agriculture, and many state departments of agriculture and extension services to encourage the production of dairy products that are free from harmful residues of drugs and pesticides. Our joint efforts have been quite successful, as have similar efforts in other fields such as:

1. The joint program to encourage farmers to use agricultural sprays and dusts strictly according to directions to keep their crops safe;

2. The clean grain program participated in by several agencies;

3. The clean candy and clean bakery programs;

4. Programs to acquaint handlers of drugs with the steps they should follow in dealing with drugs that may not safely be sold without prescription. This involved not only the splendid cooperation of drug groups outside of government, but also equally encouraging assistance from various associations and agencies concerned with nonmedical use of barbiturates and amphetamines by drivers;

5. Programs participated in by several industry groups to promote voluntary compliance with the food additives and hazardous substances laws;

6. And, while time does not permit mention of all such cooperative endeavors, I do not want to pass without mentioning again the very worthwhile results of the FDA-FLI Conferences.

At this point I would direct your attention to the exhibits you have no doubt already observed. These exhibits demonstrate the tremendous effort that the regulated industries themselves are putting forth to promote voluntary compliance with the law. It is our purpose to encourage and support these efforts to the fullest extent possible through our educational programs.

National Congress on Medical Quackery

An outstanding example of educational activity was the National Congress on Medical Quackery sponsored jointly last year by the American Medical Association and the Food and Drug Administration. This was attended by approximately 700 persons in the fields of law enforcement and health education. The result was the most comprehensive discussion to date of medical quakery as a national health problem. The proceedings of the Congress have been published and widely distributed by the American Medical Association. A second smaller conference was held this year, and several states have held their own conferences on quakery. The result is that the quacks are under greatly increased surveillance and successful control of their activities is increasing.

A number of professional organizations are cooperating with us in a drive against nutritional quakery, and we have several other cooperative programs underway with professional groups.

The success of these numerous programs points to the desirability of expanding our educational efforts of this nature. Particularly, we would like to invite any association or group which has a need for information from FDA that is not being met to discuss it with us. We want to know what these needs are and cooperate in meeting them.

Citizens Have Opportunity to Be Heard on New Policies

But no scientific, professional, consumer or industry association represents all of the people who have a right to be heard in food and drug matters. No matter how successful the cooperative efforts just discussed, a government agency has an obligation to give every citizen an opportunity to be heard on new policies or rules that affect him.

We have a procedure that accomplishes this, and it is perhaps the most important of all of our educational activities. This is the method sanctioned both by the Food, Drug and Cosmetic Act and the Administrative Procedures Act which permits, and in many cases requires, public notice of proposed rules. These notices are published in the *Federal Register*—the government newspaper, and they give everyone a chance to write to us to state his views. As you know, we publish various notices of proposed actions—notices both on general regulations and on specific actions such as the filing of pesticide or food

additive petitions. The notices are widely publicized outside the *Federal Register*. Each of these notices tells you and everyone else of a possible action to be taken under or interpretation to be made of a law that we administer. And in each case you have the opportunity to write us to state your approval, or if you do not approve, the reason that you object.

Certainly the free exchange of information permitted by this procedure—the opportunity for us to tell you and everyone else what action is being considered, and the opportunity for you to tell us how you think the action should be taken—is an educational tool that should and will be utilized with greater frequency. The increase of recent years may surprise you if you have not been in close touch with it. In 1955, FDA published 51 notices of proposed rule making, or about one a week. In 1961 we published 323, or considerably more than one every working day.

"Open Door" Policy

But you don't even have to wait for a notice to be published in the *Federal Register* to speak your views to the Food and Drug Administration. Over the years we have maintained an "open door" policy. Anyone can phone, write or visit us to state what he knows and thinks, and why, about any matter that concerns him and us. He will receive respectful attention. Furthermore, with few exceptions, he can get from us the best comment that we can give, and he can get it without formalities or procedure. The exceptions involve cases in which we are on trial, or about to be, and the United States attorney is our lawyer, and cases in which a formal hearing must be followed by a ruling by one of us on the basis of the evidence of record.

This open door will continue. We expect to be able to deal with all proper requests for our views. Those of you who deal with us on food additive petitions, new drug applications and similar proceedings can help us give the best service by making sure that your representatives avoid repetitious visits or phone calls to our medical officers and other scientists in an effort to get them to push your petition or application through faster than would normally be possible; such "bird-dogging" consumes time that could otherwise be spent on productive review of the petition, and thus results in slower processing not only of your request but of others as well.

Survey to Begin This Year

In addition to the educational efforts that are of immediate interest to you, we are preparing for a survey, to start this year, of state and local food and drug laws and the facilities for their enforcement. This will be made possible by funds included in this year's appropriation to underwrite such a study. The survey is being planned in cooperation with representatives of the Association of Food and Drug Officials of the United States. It will enable all levels of government to take stock of the total resources available today, to examine their respective roles so each can make the best use of what is available, and to estimate the resources needed at each level of government in the coming years. When such estimates are available, we will be in a position to prepare plans to provide and best use the additional resources.

To what extent joint educational efforts will reduce the need for formal enforcement actions, no one can say. There is no doubt that the various programs that I have mentioned today, and others, have led to increased voluntary law compliance. We sincerely hope that even greater successes will mark our future efforts. But there is one thing we must not overlook—the Food and Drug Administration is a law enforcement agency. We will continue to make every effort to help the industries understand the requirements of the law. We will continue to make every effort to see that our rules and policies place only those restraints on industry that are required in the interest of the consumer. And we will continue to give the American public honest, vigorous enforcement of the statutes we administer. This means that there will be court actions where there are violations of the law.

It would indeed be wonderful if we could reach the point where there were no violations, and thus no court actions. I am afraid we won't get there during your lifetime or mine. But we would like to invite all of you in industry to make a sincere effort in the coming years with all of us in government to see how much progress we can make toward the goal.

[The End]

Panel Discussion of Questions Submitted to the 1962 FDA–FLI Conference

An Informal Question and Answer Session on the Afternoon of November 26 Concluded the 1962 Joint National Conference of the Food and Drug Administration and The Food Law Institute, Inc. Mr. Franklin M. Depew, President of The Food Law Institute, Was Moderator of the Session.

MR. DEPEW: In view of the hour I'll start right in asking the questions. Mr. Rankin.

Does FDA anticipate a need for additional legislation in the near future?

Mr. Rankin: When you consider the fact that each of our appropriation bills is a piece of legislation, I would say very definitely yes. However, the person who asked the question probably was not referring to appropriation bills but rather to substantive legislation. Last March President Kennedy outlined in his consumer protection program several items of legislation in the food and drug field. A number of these were not considered fully by the Congress this year. I would assume that those will be up for consideration in the 88th Congress.

Mr. Depew: Thank you. A question for Mr. Goodrich.

Section 801(d) of the law pertains to the shipment to foreign consignees of foods and drugs which meet all foreign regulatory requirements, even though they may not meet United States regulatory requirements if labeled "For Export Only." As used here, does the word "drug" necessarily include "new drug"? If not, why not?

As a question of fundamental policy, why would the FDA *prevent* shipment of new drugs which it has not approved to foreign countries, if such new drugs are legal there? It would seem that since they could be manufactured abroad in any case, this policy accomplishes only the employment of foreign citizens rather than United States citizens.

Is this an appropriate result of the policy of a United States government agency?

Mr. Goodrich: This is a policy of the United States Congress. It has provided in Section 801(d) that drugs shall be exempted from the provisions of adulteration and misbranding when they are marked for export, meet the specifications of the foreign purchaser and comply with foreign laws. But when Congress enacted the "new drug" provision, they did not classify an unsafe new drug as an adulterated product. This in effect precluded its exportation. This policy is, as I said, a Congressional policy, and it is consistent with the Congressional policy recently adopted under 304(d) on export of products after seizure, that no article that has a potentiality of harm can be exported from this country even under the 304(d) provision.

Mr. Depew: Thank you. A question for Mr. Kirk.

Are prospects encouraging for a reconciling of the views of FDA and the Meat Inspection Division of the Department of Agriculture for the labeling of products containing preservatives or antioxidants and pending the resolving of this question what enforcement activities does FDA anticipate where labeling meets only the MID requirements?

Mr. Kirk: This obviously goes to the fat preservative matter which we have had under consideration for quite some time. We very deliberately put this aside because of other matters which called for first attention and personally I hope that we will be able to resolve this in coming months. Meanwhile, we have not taken exception to the labeling of products produced under federal meat inspection where the labeling, with respect to the preservative, meets the provisions that are outlined by the MID people.

Mr. Depew: Thank you. Another question for you.

October 9, 1962, was the closing date for receipt of comments on the proposed regulations pertaining to the exemption of new drugs for investigational use from other requirements under the new drug section of the law. It is now rumored that a revised proposal will be published shortly, to become effective in early 1963, if further serious comments thereon are not elicited. Please confirm, deny or comment on the "rumor." Specifically, is there now an anticipated date of publication?

Mr. Kirk: No firm date. October 9, as stated, was the deadline for filing comments, but we didn't close the doors to any that came in

after that date. During the time that we had these proposals under consideration we received a great deal of very constructive comment from many sources. Then we had meetings with a number of groups who were very concerned and interested in this whole field. As a result of all of the comments and views we received, we have, we believe, come up with some good regulations which we are hopeful can be completed, approved and issued very shortly.

Mr. Depew: Thank you. A question for Mr. Goodrich relative to the Factory Inspection Amendment. I assume this question refers to proposals for further amendment. What are the major points of contest and what is the status of this proposed legislation?

Mr. Goodrich: The proposed legislation died with the end of this Congress. It will have to be reintroduced if it is to have further consideration. The principal point of controversy has to do with the inspection of records. The constitutional controversy, I believe, has been eliminated by the fact that Congress enacted in the last session a broad comprehensive factory inspection bill having to do with drugs. Of course, the major controversy here has to do with the scope of the authorized inspection.

Mr. Depew: Thank you. A question for Dr. Kline.

Let us have a popular "Book About Food"—how it is grown, prepared and marketed. The question says "Do not mention 'Silent Spring.'"

Dr. Kline: Food experts and nutrition experts have tried for some time to encourage the writing of a popular book giving the facts of nutrition and of food science. This is not easy. I am sure you appreciate that it's difficult to present such facts in a dramatic manner, and as far as I know this has not been accomplished in a very successful manner thus far. Perhaps the question contains an implied suggestion that we should encourage the person who wrote "Silent Spring" to consider some nutritional facts and see what she could do with those.

Mr. Depew: Thank you. A question for Mr. Kirk.

When does FDA plan to have hearings on the Standard of Identity for Peanut Butter?

Mr. Kirk: We are hoping to have those hearings early in 1963. The proposals for sending out a notice in the *Federal Register* are now before us.

Mr. Depew: A question for Mr. Goodrich.

When may consumers hope to find ingredients listed on ice cream containers?

Mr. Goodrich: The standards of identity for ice cream have been put in effect with a single exception for the requirements for the labeling of flavors. We have developed, we think, a plan for quite informative declaration of flavors for ice cream, which is the major item of composition that consumers are interested in. We have no proposal to require the declaration of milk fat or of the amount of milk fat. The standards require those things and require a minimum on them. They require that the expected ingredients be in frozen desserts in the proportions that would normally be expected, and the label declaration provisions of the standards relate to the declaration of flavor, the natural flavor, and the artificial flavor that have been used.

Mr. Depew: Question for Mr. Kirk.

What government agency gave permission to farmers in Washington, Oregon and Idaho to treat their soils with Dieldrin and Aldrin which treatment subsequently resulted in *excess* residues of both pesticides in western baking potatoes?

Is it now safe to feed baking potatoes to babies, young children and the ill?

Mr. Kirk: I don't know any government agency that gave permission for farmers to do this. They operate independently but, of course, are supposed to know, and obey the law. The pesticides themselves, Aldrin and Dieldrin, are marketed under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, which is enforced by the Department of Agriculture. That law requires that pesticide labels be registered and that they bear adequate directions for use with adequate warnings. These labels tell farmers how to use pesticides to avoid excessive residues on food, residues which would result in a product which is not in conformity with the Food, Drug and Cosmetic Act. In this instance some of the growers who used Aldrin and Dieldrin came out with potatoes which exceeded the tolerance of one-tenth of a part per million in or on the potatoes. We made a number of seizures. The industry immediately found out what the facts were. They have started their own programs of examining samples, which programs are well under way now and many of the violations or possible violations are being avoided through peeling and

processing right at the point of production so that the products being marketed are not in conflict with the tolerances. As far as the second part of the question is concerned, we see no reason why the people who could ordinarily eat baked potatoes should not continue to do so. We believe those now on the market are safe.

Mr. Depew: Another question Mr. Kirk.

When will FDA be able to check 1 per cent of fruits and vegetables moving in interstate commerce for residues of pesticides and chemical preservatives?

Should not at least 10 per cent of such produce be checked for dangerous residues of farm poisons when many states are not equipped to make such checks?

Mr. Kirk: 1 per cent of the interstate shipment of those commodities would be roughly 25,000. It so happens that that is exactly our goal for examining samples this year in that area, and at the rate we are going now we expect to meet it. If any of you have visited any of our field laboratories, you will probably be impressed with the amount of pesticide work going on with fruits and vegetables loading up our laboratories. Incidentally, if you haven't been and you get a chance to go to one of our laboratories, you are certainly invited. Whether 1 per cent is the right figure or not, we don't know. It is our plan as soon as we finish this year's program of examining the approximately 25,000 samples to give the results a very thorough examination to see where we should go from there. Can we cut out examinations in some areas where there is no problem? Should we step up examination in others where there is or where there appears there may be? In other words, let's give this year's results a look and see whether next year's should be higher or lower.

Mr. Depew: Another question for you, Mr. Kirk.

After the first rush of food additives petitions the Administration is processing petitions with due diligence within the time prescribed by the law. However, petitions with respect to Standards of Identity are still subject to long delays. What is the Administration doing to speed up the processing of such petitions?

Would the Administration support legislation prescribing set times in which definitive actions must be taken on such petitions, including, of course, provisions for postponement for proper cause?

Can the Administration legally, and would it be willing to practically, promulgate regulations setting forth procedures of this type?

Mr. Kirk: First, thanks for the first part of that question about the food additives operation. Secondly, we are, I believe, doing better in the food standard business than we were last year. We have had quite a backlog, but we have increased the staff in our Food Standards Office, and while we are not up-to-date, I believe we are doing better and I think we will continue to do better. As far as legislation is concerned, I really doubt that I should comment on that other than to say that any idea of a time schedule for filing of petitions and for something to become effective automatically should, I believe, be opposed right down the line. We had that very thing in the new drug field and, as you know, the Congress changed it so that there are no more automatic approvals. There shouldn't be in the food standards area either.

Mr. Depew: A question for Mr. Rankin.

Until three years ago, an officer of the New Drug Division usually had the courtesy to carefully study and comment on a New Drug Application within a month to six weeks following receipt—thereby offering the applicant an opportunity to "complete" the application within the then prescribed statutory 60-day period.

In more recent times, a series of successive declarations of "incompleteness" of NDA's have been regularly received on the 59th day following submission of the original and usually several supplemental applications. The bases for these series of declarations must surely have been evident at the conclusion of the first 60-day review period.

Now that the FDA has a statutory 180-day review period, is it the hope and intent that the previous practice will be followed, stating, in a *single document,* and therefore "using up" a *single* review period, *all of the bases* for citation of alleged "incompleteness"? I hope the answer is affirmative, for the recent approach smacks of small chicanery and an attempt to subvert by administrative means the Congressional intent that the FDA *shall act* in a meaningful way within the review period specified.

Mr. Rankin: I would like the record to show, Mr. Depew, that I have also stopped beating my wife. This question of the handling of new drug applications is one that has been presented to us in more or less this form on other occasions recently. There seems to

be a belief that the Food and Drug Administration has been doing nothing for 59 days and then on the 59th day rushes around to work up a letter saying "your application is not complete, let us have more information." The way to deal with a report of that type is to take a specific application and go through it, see what the facts are, and if the facts show that the government has been derelict, let the government bring about appropriate correction. If the facts show that the man who made the complaint was in error, let him say so. We have invited the drug industry to call our attention to specific examples in which this alleged type of operation has taken place. Two firms have taken advantage of the opportunity and have come in to review with us in detail the handling of applications that they thought were inordinately delayed through the type of procedure mentioned in the question. In both of those cases, top management of the drug firms acknowledged that there were scientific facts involved that had not been brought to their attention. Now, we may have handled some applications in the way mentioned. If you believe we have, let us know what the product is, send a key official or officials from your firm to sit down with us at a mutually convenient time and we will go into the matter. With respect to the latter part of the question, when are you going to adopt a procedure that allows the manufacturer to find out at first blush everything that needs to be done to complete his application if it is not judged complete, I must answer quite frankly that I am not sure we will ever be able to reach that stage. If our medical officers or pharmacologists or other scientists in reviewing the application find that there are serious questions left unanswered by the evidence in the petition, quesions of safety for example, they must ask the applicant to answer the questions. It obviously will not be possible for us to tell exactly what labeling may be needed for a product when it is still under study. All of the scientific evidence will have to be before us on which we ultimately act before we can make final comment on the label. But to the extent that we can offer full comment the first time, we certainly will try to do so.

Mr. Depew: Thank you Mr. Rankin. I think you have answered that question most fully and fairly. A question for Mr. Goodrich.

For a prescription drug which is an approved new drug, which has some 25 active ingredients, how do the new "half as large" type size requirements apply? (No fanciful trade name is used to identify *any one* of the ingredients, but a trade name *is* given to the product.)

Does the FDA anticipate issuing proposed regulations pertaining to this complex situation? If so, when?

Mr. Goodrich: This is a complex product with 25 ingredients. It is probably an irrational mixture of vitamins and minerals, but to answer the basic question, the requirement of half-size type applies only when a trade name is used for the drug or for its ingredients. If the fanciful name for this magnificent combination of good health is not a generic name or an official name, then there is no half-point size requirement. And if there is no trade name used for any of the ingredients, there is no requirement for half-size declaration of the generic names of the ingredients. I should add here, however, that where you use a fanciful name of this kind there is a general requirement of prominence and conspicuousness in the declaration of ingredients under the general terms of the law.

Now, what was the other question? When are the regulations coming out? As soon as possible. We started working on the regulations even before this law was finally passed. We have drafts in preparation now, we have set a deadline for ourselves which is too ambitious I am afraid, but which is mid-December for the draft, and we hope to meet that.

Mr. Depew: Thank you. A question for Mr. Clark.

In weighing packages of food at store level, is loss of moisture taken into consideration? Please be specific about coffee in a paper container.

Mr. Clark: Yes, in considering the net weight of the product at the retail level the normal moisture of the product is one of the factors taken into consideration. To this end the Food and Drug Administration is frequently seeking through authentic samples to learn the normal shrinkage of food products. This provides us with data so that we can take into consideration the normal moisture of a product like coffee in a paper container.

Mr. Depew: Another question for you Mr. Clark.

Does the inclusion of the word "salt" in the ingredient statement meet the requirements of the exemption of the hazardous labeling regulations?

Mr. Clark: I am assuming we are not talking about a food product containing salt, which would, of course, exempt it automatically from

the provisions of the Federal Hazardous Substances Labeling Act. The exemption referred to means that if a product is a hazardous substance within the provisions of the law and is hazardous because of its salt content, the warning labeling due to that hazard is satisfied with a declaration that the product does contain salt.

Mr. Depew: Thank you. A question for Mr. Kirk. I believe part of this question has been already answered.

What is the current status of: (1) Peanut Butter Standards of Identity; (2) Cottage Cheese Standards of Identity; and (3) Frozen Dessert Labeling?

Mr. Kirk: Well, as I said, we are hoping for the peanut butter hearing to be set up early in 1963. In the case of cottage cheese we published a notice of filing of the petition, set a time for comment, received the comments and a draft which takes the comments into account is on my desk. I expect to get it going promptly. The third one was frozen desserts. There we have for filing, presented by two groups, a proposed revision of the section dealing with the flavors and the labeling of flavors in the ice cream standards. That would be under the Hale Amendment procedure. There is another petition involving whey and a third one involving the use of mineral salts. We propose to publish all three of those as proposals inviting comment.

Mr. Depew: A question for Dr. Kline.

Is it the opinion of FDA that so-called Dietary Foods, including *beverages* should be displayed on retail stores shelves separately and apart from the place where foods and beverages normally prepared with nutritive ingredients like sugar are displayed?

Dr. Kline: Yes, we have agreed that it is desirable in the retailing of foods of this type to set them in shelf space separate from general purpose foods. In this case you could say, I guess, that segregation is both desirable and permissible.

Mr. Depew: Another question for you Dr. Kline.

When does FDA anticipate that the proposed Dietary Regulations will become effective?

Dr. Kline: October 18 was the closing date for comment on the proposed changes in the regulations on foods for special dietary use. We have had some response to those proposals. Many constructive comments have been received and we appreciate this very much. We

have not found it possible to begin the review of this material because of the pressures of regulation-making in the drug area, and probably will not get into these problems before January of 1963. I have no way of predicting a final date either for publication of the final regulations or the final effective date because there is the possibility that a public hearing may be required after the publication of our final regulations.

Mr. Depew: A question for Mr. Goodrich.

Final regulations have not yet been issued under the Color Additives Amendment of 1960. Why? Provisional listing of various color additives will expire January 12, 1963, unless the Secretary of Health, Education and Welfare postpones the closing date.

The Certified Color Industry Committee has requested extension of that date with respect to the FD&C, D&C and Ext. D&C colors now provisionally listed. It is not considered feasible to petition for permanent listing without final regulations.

Mr. Goodrich: Why? To answer the question, the responsibility for the delay is largely mine. I accept it. The fact is that this law became effective the same day the Hazardous Substances Labeling Act did and we gave high priority to regulations under both laws. You will remember that we put out the provisional transitional regulations for the color additives very promptly and that operation has been running along smoothly under this planned transitional period through almost the two and a half year period. Meanwhile, we had Hazardous Substances Labeling Act regulations. Drug Amendments of 1962, the Dietary Food regulations, Investigational Use regulations, and two or three other things to take care of. I simply have not been able to give the attention to the Color Additives to get them out finally. We are struggling with the problem of what to do with color mixtures and where to draw the line between straight colors and color mixtures that have to be listed and that have to be certified. We plan to come out with regulations very promptly. We have reached a stage where I feel that the draft will not be long delayed before publication.

As to whether there will be a blanket extension at the end of the two and one-half year period, we are bound by the terms of the law itself as to the conditions of any further extension.

We know the status of our own scientific investigation, but we do not know and have had no application to tell us the status of the investigations of these other colors. When the transitional period runs

out, of course, we are bound by the law just as the color industry and the food industry is. The Congress in giving us authority to extend past the two and one-half years conditioned it on the finding that the extension could safely be granted and I doubt very much that we would be able to give a blanket over-all extension without a look-see at whether we meet the statutory provisions. I know we won't.

Mr. Depew: So would you recommend that petitions be filed?

Mr. Goodrich: As soon as the science is ready I would think the first obvious step is to start establishing regulations; at least sending the data in for review.

Mr. Depew: Thank you. A question for Mr. Clark.

What does the Food and Drug Administration think about displaying frozen foods with fresh foods in fresh food cases? Fish for example.

Mr. Clark: It would seem to me if I understand the question correctly, Mr. Depew, it would be almost self-regulating. It is a matter of storage conditions. Storage conditions for fresh vegetables wouldn't necessarily apply or be proper for frozen fish or some other product. Have I misinterpreted the question? The proper labeling would have to be applied and the proper storage conditions provided. It seems to me that's the responsive answer.

Mr. Depew: I don't think you've missed anything unless I've missed it too. A question for Mr. Rankin.

In connection with the upcoming session of Congress, may we expect the FDA to press for legislation in the food, cosmetic and devices areas on bases similar to the legislation introduced in the last session of Congress?

Mr. Rankin: That doesn't differ very much from the question that I commented on earlier. The items of food and drug legislation that were included in the President's consumer message earlier this year and were not passed upon by the 87th Congress I would expect to be a part of FDA's recommendation to the Department for new legislation next year.

Mr. Depew: Another question for Mr. Rankin.

With special reference to devices, as the law now stands this term is very broadly defined in the statute and, in fact, is virtually

open-ended. While this may be a satisfactory situation when the philosophy behind a law is of a policing nature, it is probably not satisfactory when the law is to become of the licensing or pre-clearance variety. Has any thought been given to this question and, if so, would it not be in the public interest to re-define the term "devices" so as to prescribe limits of a more workable nature?

Mr. Rankin: I don't know of any basis for concluding that the definition of the term device or therapeutic device as it appears in the law today would fail to be in the public interest if we get an amendment to the law to require therapeutic devices to be proved safe and effective before they are placed on the market. If there is some reason for changing the definition, we would be glad to have it brought to our attention. I would point out, however, that in the legislation that was before the Congress this past year, the second Harris Bill, we did propose a new drug type of clearance for therapeutic devices and we did not propose any change in the definition of device.

Mr. Depew: Thank you. A question for Mr. Goodrich.

Under the new drug law, must the generic name of a single entity prescription drug be used every time the brand name appears on the label, labeling or advertising of the drug?

Mr. Goodrich: That seems to be the plain requirement of the law, and certainly in terms of the legislative history it was stated three or four times that every time we have a statement of the trade name it should be followed by the generic. Just exactly what's going to come out of these regulations, we don't know. We certainly will have to bear in mind this legislative history, as well as the explicit language that says wherever the trade name is used the generic name shall also be used. We have been exploring, at the request of the drug industry, the possibility of not requiring a repetition of the generic name each time, particularly in the brochures where you have the name repeated over and over. Whether we can legally do anything about that, or whether we should, whether we can come up with a proposal that would make these names more noticeable, which is after all the objective of the law, is something we will have to consider in the regulation.

Mr. Depew: A question for Mr. Kirk.

Why did the FDA decide to invade the field of price regulation on label statements as to economy size?

Mr. Kirk: I didn't know we were invading. The law has a prohibition against any false or misleading statements on labels and in labeling, and in this particular case, which I assume to be the coffee case, we felt that there was a clear-cut false statement.

Mr. Depew: Mr. Goodrich.

What is the attitude of FDA as to "cents off" labeling?

Mr. Goodrich: When we testified before the Hart Committee we explained that there was plenty of provision in the general false and misleading labeling area to deal with this type of promotion where it was false and misleading in any particular. As most of you probably know, the Hart Bill, which has now been introduced, has a proposal which would authorize the general outlawing of "cents off" sales. This will require that this Department and the Federal Trade Commission and other interested persons in the Executive Branch consider this policy and make recommendations with respect to Senator Hart's bill. Therefore, we have not arrived at an over-all opposition to "cents off." We do have a generally continuing interest in "cents off" where it may be misleading.

Mr. Depew: A question for Mr. Kirk.

Why on such matters as minor short weights should be manufacturer not be notified and given opportunity to correct without the odium of seizure and publicity?

Mr. Kirk: First, may I say that over the years I have found a lot of differences of opinion as to what is minor and what isn't. But in this particular case involving short weight of food products, we started out by talking to just about everyone we could we thought was interested in this need for checking weights, being sure the products being marketed were up to the declared net weight. Then we undertook a widespread survey several years ago and published the results of that, gave it wide circulation, again showing that we were interested in short weight. After that had been given time to sink in, let us say, we started our regulatory program which is still being continued. We found significant violations. We took legal actions against them. We found minor violations and did not bring formal actions because of them. But very frankly I just can't conceive of anybody in the food

industry today that does not know that the Food and Drug Administration is checking quite extensively on the net weights of food packages.

Mr. Depew: Mr. Goodrich.

Do you have any remarks on present federal thinking on preemption in the food law area?

Mr. Goodrich: I recommend that all of you read what happened on this issue in the Drug Amendments of 1962. This is the latest thinking of the Congress.

Mr. Depew: A question for Dr. Kline.

What *fresh* fruits and vegetables did the 19-year-old boy select that were relatively free of pesticide residues? Did he select fresh lettuce, kale, spinach, broccoli *and* Western baking potatoes and *fresh* apples and pears and grapes?

Dr. Kline: Yes, I think all of those items were included in the market basket that was collected in this study of a diet that would be consumed by a 19-year-old boy. The pesticide residue content of this diet was determined in our laboratories on the total food mixture. There has not up to the present been an attempt to examine each of the items separately so that the report that some of you may have seen relates to the determination of the food items as a whole.

Mr. Depew: Another question Dr. Kline.

In discussions of the saturated versus unsaturated fats why is there complete avoidance of mention of pesticides in them and harmful effect of said pesticides: I don't know which fat the "them" refers to. Perhaps you could comment on both.

Dr. Kline: I know of no particular relationship between unsaturated or saturated fatty acids and pesticide residues. In our examinations of food products fats are examined and they must meet certain legal tolerances. The fact that these fats contain saturated or unsaturated fatty acids has no bearing on a possible pesticide residue content.

Mr. Depew: I would like to ask one final question. Is there anyone on the panel who would like to amplify Commissioner Larrick's comments about the display in the back of the room? Tell us a little bit more about it.

Mr. Rankin: Mr. Depew, our Division of Public Information has placed on display a very small sample of the tremendous educational work that is being carried on day after day primarily by individuals outside the government. If your firm or your organization has educational material that does not appear on this display, it is due simply to the fact that we didn't have any more exhibit room.

Mr. Depew: That concludes the question and answer session. I hope that you all feel that this conference has served its usual purpose. Thank you very much. **[The End]**

FDA SCIENCE PROTECTS CONSUMERS OF FROZEN FISH PRODUCTS

A new and reliable method of identifying fresh and frozen skinless fish fillets where the true identity is otherwise nearly impossible for the consumer buyer to recognize is now being put to good use by the Food and Drug Administration. The method, first published in November, 1960, has been found to be an exceedingly useful tool to determine whether cheaper fish are being substituted for the more desirable and expensive varieties.

FDA has from time to time had reason to believe that various types of skinless frozen fish fillets were not what they were labeled to be. Substitution of an inferior variety for what the consumer expects is a violation of the Federal Food, Drug and Cosmetic Act. But proof of the substitution has been difficult.

The application of the "starch gel electrophoresis" method by Robert R. Thompson of FDA's Division of Food makes it possible to establish the true identity of the fish. Although most samples to date have been examined in Mr. Thompson's Washington, D. C., laboratory, FDA's 18 district laboratories have now been furnished the necessary equipment and will soon be conducting their own tests.

The electrophoresis test is based on the premise that the protein makeup of each fish species is different and characteristic. In the test, a small electric current passed through the extracted protein suspended in a starch gel causes the protein to move into characteristic patterns or "bands," a different one for each type of fish.

To prove the new test, Mr. Thompson devised a method using the enzyme system of the fish for double checking. No two species have the same enzyme system, although varieties of species often do. The technician pours a chemical solution on it which reacts with natural fish enzymes. When dye is later added, it forms a characteristic color pattern. Identification of species has always been the same with the two tests.

The electrophoresis method may also he used to detect the substitution of various meats for beef in hamburger and sausage. FDA expects to apply it to frozen egg products in an effort to detect incubator reject eggs in products labeled as fresh chicken eggs.

The Joint FAO-WHO Conference on Food Standards

By FRANKLIN M. DEPEW

Mr. Depew, President of The Food Law Institute, Inc., Represented Both The Food Law Institute and the Inter-American Bar Association at the Joint FAO - WHO Conference.

THE JOINT FAO-WHO CONFERENCE on Food Standards held at the Palace of Nations, Geneva, Switzerland, October 1-5, 1962, under the auspices of the Food and Agriculture Organization and World Health Organization of the United Nations, was without question the most important recent development in the food law field.

The Conference was held on the recommendation of the FAO Conference at its Eleventh Session of November, 1961 and of the WHO Executive Board at its Twenty-ninth Session of January 19, 1962, to consider a Joint FAO-WHO Program on Food Standards. The Conference was called to endorse or reject the proposal that international food standards should be established and to pass on the recommendation that the principal organ to carry on this work be the *Codex Alimentarius* Commission set up by the FAO Conference Resolution. It immediately became apparent that the work of the *Codex Alimentarius* Commission in establishing food standards would directly affect, to a large extent, agricultural exports from the United States in both raw and manufactured form, as well as food chemicals and other additives. Trade in several agricultural and other food commodities of the United States has in the past encountered barriers imposed by diverse national food laws and regulations. A great many of these trade barriers still hamper international trade. These could be resolved by a harmonization of national food laws and regulations. It seemed clear that in order to protect American interests in this vital foreign trade area, the United States should have full representation in the *Codex Alimentarius* Commission work and that the official United States

delegation to the Conference should include representatives of agriculture and industry as well as government.

Under the circumstances it was unfortunate that the American government and American agriculture and food manufacturing interests were notified of the Conference at a time when they had little opportunity to prepare for it. Time was too short to take steps to secure an appropriation by the Congress of funds to enable the United States government to make a contribution for 1962 to the Special Trust Fund established by an FAO Conference Resolution. Monies contributed to this trust fund are allocated exclusively to the joint program of food standardization. The FAO had suggested that an appropriate annual contribution from the United States for the years 1962 and 1963 would be $15,000 per year.

Subcommittee Formed

Fortunately, many governmental and industry people immediately got to work to do what could be done in the time available. A subcommittee on *Codex Alimentarius,* under the Chairmanship of Nathan Koenig, Assistant to the Administrator, Agricultural Marketing Service, United States Department of Agriculture, was established at the January 23, 1962 meeting of the United States Food and Agriculture Organization Interagency Committee, for the purpose of considering the question of United States participation in the *Codex Alimentarius* program. The subject was studied by two action committees of the subcommittee and was considered by the subcommittee as a whole. The two action committees were concerned with specific phases of the subject. One, headed by Dr. H. L. Haller, Agricultural Administrator, Agricultural Research Service, dealt with (1) the extent to which the United States wishes to participate; and (2) the nature and extent of the United States participation in the Joint FAO-WHO Conference on Food Standards. The other, headed by Jacob Schaffer, Director of the Food Industries Division, Business and Defense Services Administration, United States Department of Commerce, dealt with (1) the manner in which business, foundation, and other possible contributions might be encouraged and sought; and (2) the mechanism by which participation would be coordinated. Shortly after the establishment of the action groups The Food Law Institute was instrumental in assuring that United States interests would be adequately represented at the Joint Conference by securing industry contributions to the Special Trust Fund for the work of the *Codex Alimentarius* Commission.

These monies were forwarded to FAO prior to the Joint Conference through the offices of the United States Department of State.

Symposium Regarding International Trade

European governments and food industries, because of their new economic relationships, seem to have been much more aware of the significance and effect on trade that may result from this *Codex Alimentarius* activity. The great interest they have in the subject undoubtedly accounts for the Symposium on Food Regulations in Relation to International Trade which was organized by the Food Group of the Society of Chemical Industry and held in Church House, London, on September 24, 1962, just prior to the Joint FAO-WHO Conference. Among the some four hundred persons in attendance at this symposium were Frank T. Dierson, Secretary-Treasurer of The Food Law Institute, and Dr. C. Olin Ball, President-Elect of the Institute of Food Technologists, Chairman of the Department of Food Science, Rutgers University and Food Law Institute Trustee.

The speakers at this Symposium were the Chairman, J. P. van den Bergh of the United Kingdom, T. McLachlan of the United Kingdom, Dr. J. Mahoney of the United States, Dr. K. Durrenmatt of Switzerland and F. H. Townshend of FAO. The talks were followed by a so-called "Brains Trust" discussion, with Dr. J. G. Davis of the Society of Chemical Industry as Chairman, and the participants being four of the five earlier speakers (Mr. van den Bergh did not participate) plus Mogens Jul of Denmark, W. M. Shortt of the United Kingdom, and Dr. H. Weiss of West Germany.

International Harmony Important

All of the speakers stressed the importance of harmony among the nations in the provisions of food laws and regulations. They pointed out that no international agreements have been reached regarding descriptions given to foods, hygienic requirements for the foods, the additives that may be present, or the control of labeling. Many illustrations were presented to emphasize these points, particularly with reference to standard definitions and additives. Examples were given of difference in the legal concepts of the food laws in different countries as well as the effect of differences in eating habits and in the interpretation of scientific facts in shaping the food laws. These examples of difficulties were so impressive, that at the outset, those in attendance expressed a fear that the problem was insurmountable.

Dr. Durrenmatt and Mr. Townshend gave some assurance that this was not the case. They cited in support of their view the progress that FAO had made in connection with the Code of Principles for Milk and Milk Products and the plans for the Joint FAO-WHO Conference on Food Standards. Their remarks encouraged the audience to believe that with patience and effort it would be possible to achieve some improvement.

The "Brains Trust" discussed the value of a short list of prohibited additives as compared with a long generally recognized as safe (GRAS) list. It was their conclusion that the former would greatly simplify the job of the analyst but that the compilation of such a list would be extremely difficult.

Members of United States Delegation Chosen

On September 12, 1962 the Directors-General of the FAO and WHO extended an invitation to The Food Law Institute and to the Inter-American Bar Association to be represented by an observer at the Joint Conference, and I accepted in behalf of both organizations. Meanwhile the official United States Delegation was selected with John L. Harvey, Deputy Commissioner of Food and Drugs, heading the delegation and Nathan Koenig as alternate. The other government representatives were A. W. Anderson, Regional Fisheries Attache, and Dr. H. L. Haller. Industry was represented by Frank Elliott, Michael F. Markel and Harry Meisel. Mr. Markel also represented the United States Department of Commerce.

The Conference convened in an assembly hall which had been recently redecorated, redesigned and arranged for meetings of this kind. The accommodations and other arrangements were all that could be desired. Representatives from some 45 member countries of FAO and/or WHO attended together with observers from some 24 international governmental and nongovernmental organizations. Dr. Pierre Dorolle and Dr. Norman Wright, Deputy Directors-General respectively of WHO and FAO extended a warm welcome to the delegates. Monsieur Josué de Castro of Brazil nominated Dr. E. Feisst, Vice President du Comite National Suisse du Codex Alimentarius, as Chairman. The nomination was promptly seconded by the Austrian and Netherlands delegations, and Dr. Feisst was thereupon elected by acclamation. John L. Harvey of the United States and Dr. Thianar N'Doyé, Director du Service d'Alimentation et de Nutrition Appliquée, Ministére de la Santé et des Affairs Sociales,

Senegal, were thereupon elected Vice-Chairmen. J. H. V. Davies of the British Delegation and Gérard Weill of the French Delegation, were appointed rapporteurs.

Dr. Feisst in his acceptance address stated that he supported world-wide standards, but in the meantime he recommended that regional groups consider regional standards. He stated that in his opinion standards have to be carefully tailored to fit the tastes and food habits of various regions. It immediately became evident that the discussions would go beyond the two basic food law precepts, namely—protection against harmful ingredients and deceptive practices, and might extend to trade and industrial barriers.

The Conference then proceeded to endorse the proposals for a Joint FAO-WHO *Codex Alimentarius* Commission. By these means the facilities of both FAO and WHO would be available to tackle the problems involved in their many aspects. It was also recognized that any intended expenditure involved would be covered by the Special Trust Fund set up for this purpose until at least the year 1964.

Summary of Discussions

The Conference next considered the guidelines for the work of the *Codex Alimentarius* Commission. The discussions of these guidelines got to the very heart of the problems posed by the existing situation. The highlights of the extended discussions and points of view expressed may be summarized as follows:

Mr. Weill of the French Delegation expressed the French point of view of disagreement with the spirit in which the objectives were being approached so far as consumers health was concerned. He stated that regional standards would better achieve these objectives. He also objected to having a Special Trust Fund for food standards work. Mr. Harvey for the United States stated it was important that other countries should have an opportunity to consider regional standards before they are adopted. The Danish, Canadian, United Kingdom and Netherlands delegations expressed agreement with this view. Mr. Davies of the United Kingdom pointed out that what purported to be health considerations were sometimes used to achieve economic advantages, such as fat content of butter, color additives, and so forth. Dr. Carlos A. Grau of Argentina reported on the progress of the Latin-American Food Code and mentioned that The Food Law Institute had been most helpful in securing the views of United States industrial, technical and university personnel.

Professor O. Högl of the Swiss Delegation and President of the Council for the European *Codex Alimentarius* suggested that committees with world-wide members are difficult to operate. He proposed that regional commissions, whose members can work closely together, would be the best way to operate.

Arguments Against Regional Commissions

Denmark, New Zealand, Australia, the United States and Canada pointed out the need for integrated international food standards and that appointment of standing regional committees might interfere with this aim. They stressed the need to assure full participation by all countries in order to secure proper standards on either a regional or world-wide basis. Mr. Koenig in behalf of the United States stated it was the United States view that the activities of the *Codex Alimentarius* Commission initially should be confined to those spheres of activity where international standards clearly would be helpful in facilitating international trade and where there is general agreement that international cooperation is needed to bring about greater uniformity in particular types of standards. He further stated that it should be possible to elaborate regional or world-wide standards by a single commission open to all member countries of both FAO and WHO. When a majority of countries in a region require a regional standard, such a standard should be proposed without prejudice to the concurrent or later preparation of similar standards for other regions or on a world-wide basis. When the draft standard (either world-wide or regional) comes before the Commission for discussion, views and comments should be obtained from interested countries. A broad agreement by the countries should be necessary and sufficient for its approval. He further stated that although the United States has a procedure established by law for developing and establishing certain types of standards, there is sufficient flexibility under this procedure to permit formal amendment of these standards to correspond to international standards where reasonable grounds are shown.

There was extended discussion of the types of standards that should be adopted. It was decided they should be of two types—minimum "platform" standards and the higher standards generally referred to as "trading" standards. India, Senegal and other developing countries emphasized the need for minimum standards in order to secure economic and trading acceptability in international markets for their exportable raw materials.

Language Barriers

An interesting sidelight to the discussions was the difference of meaning of terms—not to mention difficulty of language translation. For instance the use of the term "functional" was felt by some delegates to apply to any food as all aspects of food were "functional." When it is realized that the delegates from all these countries expressed themselves in three different official languages it is astonishing that they were able to agree unanimously on the guidelines for the *Codex Alimentarius* Commission. We must give a great deal of the credit for the successful outcome of the Conference to the Joint FAO-WHO secretariat and to the rapporteurs. Their continued diligence and good humor under trying circumstances was an example for all.

These highlights make it apparent from the multicolored and varied viewpoints expressed that many diverse opinions remain to be reconciled by the *Codex Alimentarius* Commission. National interests soon became apparent at the Conference. These interests will not have disappeared by the time the Commission starts its work. They may be expected to exercise a continuing influence on that work.

The guidelines adopted, which basically reflect the points of view expressed by the United States delegation, are appended hereto. These guidelines afford all nations an opportunity to take appropriate steps to present their views in connection with any standard proposed or considered by the *Codex Alimentarius* Commission. Thus, if a regional group should suggest a standard which establishes or maintains trade barriers in favor of that region, on the alleged ground of protection of health, the question of the validity of the basis of the proposal can be fully reviewed by the scientists of the countries outside the region prior to the final adoption of the standard. While this may not operate to prevent the adoption of unsatisfactory standards in every instance, at least it will afford an opportunity for full publicity relative to all reasons which were considered in relation to the standard.

The Conference then went on record as expressing the belief that following these guidelines, the *Codex Alimentarius* Commission would be able effectively to continue and build upon the tradition and further the aims of the far-sighted European Council of the *Codex Alimentarius* founded by Minister Hans Frenzel of Austria, as well as the *Codigo Latino-Americano de Alimentos,* launched under the leadership of Dr. Carlos A. Grau of Argentina. It later suggested that the Commission hold its first session at FAO headquarters in Rome commencing Thursday, June 27, 1963.

In respect to the method of finance, the Conference noted that it appeared that some governments preferred to see the costs borne by the regular budgets of the two international agencies instead of by a Special FAO Trust Fund. It was further noted that this matter would be reviewed by the FAO Conference at its fifteenth session in November, 1963.

M. G. Candau and B. R. Sen, the Directors-General, respectively of WHO and FAO, graciously tendered a reception to the assembled delegates and the staff of their secretariat on the evening of October 3. This affair enabled everyone to mingle on an informal basis and contributed to the successful outcome of the Conference.

I was privileged to address the Conference, as President of The Food Law Institute, and pointed out that if more varied, more nutritious and more plentiful diets were to be made available to the peoples of the world, all unjustified barriers to international trade must be eliminated from the world's food laws. I acknowledged that this would be hard to do, but expressed the hope that the guiding principles expressed at the Conference would bring about standards that would wipe out barriers to free trade among the nations.

The splendid results that were achieved by the United States delegation, headed by John L. Harvey and Nathan Koenig, and by the other like-minded delegations with whom they worked, will have to be implemented in the future by the delegates to the *Codex Alimentarius* Commission. Constant vigilance will be required to assure sound and fair standards. In this connection, the experience the United States has had in the development of food standards should be invaluable to the proposed *Codex Alimentarius* work.

Most of the steps to be taken in preparation for the meeting of the *Codex Alimentarius* Commission will fall upon the Secretariat. However, the governments must take appropriate steps to select the members of their delegations to attend in their behalf. Governments have also been urged to make available their 1963 contributions as soon as possible.

The Secretariat is proceeding to distribute to all FAO-WHO member nations approved texts of material completed by the European Council of the *Codex* (these cover general rules, sampling and edible fungi) and those chapters of the Latin-American Food Code which cover the same subject matter. They will also supply governments

with positive lists together with specifications of identity and purity for colors, preservatives and antioxidants as well as emulsifiers, based on work carried out under the Joint FAO-WHO Program on Food Additives. The standards for milk and milk products (Report Paragraph 56(a)) and fresh fruit and vegetables (Report Paragraph 56 (b)) will be supplied to those governments which have not already received them. With respect to the products given priority in paragraph 58 of the Report it is planned to submit to the Commission as a basis for discussion a resume on each of these groups of products summarizing the principal national standards involved and containing, where possible, a draft international standard.

It is planned to hold two associated meetings just prior to the meeting of the *Codex Alimentarius* Commission. From June 17-22, 1963 the Sixth Session of the Code of Principles Committee (now the joint FAO-WHO specialist body on milk and milk products) will consider and possibly approve standards for cheeses, methods of sampling and analysis, and so forth. From June 24-26, 1963 the Second Joint FAO-WHO Conference on Food Additives will review the work done, determine areas of future work, and proceed to evaluate the contribution of the FAO-WHO program on food additives to the work of the *Codex Alimentarius* Commission.

Tentative Agenda

That Commission will hold its meeting from June 27-July 3, 1963. The tentative agenda is as follows:

(1) Adoption of rules of procedure.

(2) Election of officers.

(3) Review of existing food standards work at the government level, including:

(a) Work started by the European Council (except areas of future work on food additives to be considered by the Conference on Food Additives);

(b) The Latin-American Food Code;

(c) ECE (U. N. Economic Commission for Europe) standards for fresh fruit and vegetables and the OECD (Organization for Economic Cooperation and Development) scheme for their application;

(d) Food standards work of OECD;

(e) Food standards work of the European Common Market;

(f) Food standards work of COMECON (Council for Mutual Economic Assistance);

(g) Standards for olive oil under the International Olive Oil Convention;

(h) FAO/WHO work on food additives;
(i) FAO/WHO work on milk products.

} Formal items to take note of results of two preceding meetings.

(4) Allocation of new work following the priorities recommended by the Joint Conference, with particular reference to work already in hand with international bodies (—especially specialist NGO's (non-government organizations) and ISO (International Organization for Standardization) and the geographical coverage sought for each standard.

(5) Discussion with a view to acceptance of the following completed texts: general rules; sampling; edible fungi; permitted lists and specifications of identity and purity for colors, preservatives and antioxidants and emulsifiers.

(6) Plans for an international documentation service on food.

American agricultural and industrial interests should be alert to make certain that the United States continues to be effectively represented in this important food standards work. They should express such interest to the Congress, at least to the extent of urging an appropriation to the Trust Fund for *Codex* work in 1963 in the amount of $15,000. This is the amount which was pledged for this work by the United States delegation and will have to be met by private subscription if Congress fails to take appropriate action. They should also urge the United States Departments of Agriculture, Commerce, and Health, Education and Welfare to take prompt steps to select the members of the United States delegation, who can best represent our government at this meeting. No interested party can afford to underestimate the importance of this coming meeting. It is essential that the delegation contain the necessary experts who must be selected in sufficient time that they may be adequately prepared to work effectively for sound food standards which may be expected to protect American agricultural and industrial interests.

GUIDELINES FOR THE *CODEX ALIMENTARIUS* COMMISSION *

Part I

PURPOSE AND SCOPE OF THE *CODEX ALIMENTARIUS*

Purpose

1. The *Codex Alimentarius* is a collection of internationally adopted food standards presented in a unified form. These food standards aim at protecting consumers' health and ensuring fair practices in the food trade. Their publication is intended to promote the standardization of foodstuffs in the various parts of the world, to facilitate harmonization of standards and in so doing to further the development of the international food trade.

2. The pursuit of these objectives will help to simplify international food standards work and avoid duplication.

Scope

3. The Conference recommended that the *Codex* should in time include all the principal foods whether processed, semi-processed or raw, for direct sale to the consumer or, where appropriate, for manufacturing purposes. The *Codex* should in particular take in the whole range of food additives and contaminants, since this highly complicated problem affects practically all processed foods as well as an ever-increasing number of raw foods.

4. Many food codes (for example the Spanish, the Swiss, and the *Código Latino-Americano de Alimentos* among others) also include cosmetics and other objects of everyday use, components of which may be ingested by the human organism. It is not proposed that the *Codex* include these products.

5. Food hygiene rules are in many countries handled independently of the food standards based upon them. On the other hand, an international programme of food standards having among its primary aims assistance to developing countries in this sector, cannot take these rules for granted: a product may well conform to an exacting standard of composition and labelling but not be acceptable due to unhygienic manufacturing conditions. Moreover, the need for basic food hygiene rules has become increasingly apparent from international food standards work already under way. It is therefore proposed that such rules be included in the *Codex*.

6. Given this wide scope, the question of priorities is clearly of great importance (see Part IV below).

Part II

NATURE AND TYPE OF STANDARDS TO BE INCLUDED IN THE CODEX

Nature

7. Before considering the nature of standards to be set up by the Commission, the Conference recalled a general observation of basic importance: a food standard aims at ensuring the marketing of a sound, wholesome product, correctly labelled and presented. It does not intend to affect consumer preference, but aims at ensuring that the consumer can know what he is buying. This observation applies with even greater weight to an international food standard.

8. The Conference considered two sorts of standard: the minimum "plat-

* Certain material is attached as appendices to the Guidelines as published by the FAO. References to such appendices are omitted as not needed for the purpose of this publication.

form" standard and the higher standard generally referred to as a "trading" standard. By the acceptance of a minimum platform standard, a government merely undertakes to ensure that its own corresponding national standards shall not be less rigorous. On the other hand, this does not preclude their use for trading purposes (in respect of both hygiene and other requirements), provided it is understood that they would not support price decisions for a product conforming to higher standards. National standards may well be, and in many cases often are, more exacting in their requirements than such minimum platform standards, and would of course apply to all imports into that country. In this case, national standards are said to be "higher" than the international minimum platform standards.

9. International minimum platform standards have been successfully established under the current FAO programme on the "Code of Principles concerning Milk and Milk Products." The basic standard worked out under this programme, the "Code of Principles" itself, has been accepted by no less than 50 governments.

10. Minimum platform standards can be of real use for trading purposes to developed countries where national standards are usually rigorous, as well as to developing countries. A striking example of this is given by the minimum standards for dried milk, also elaborated under the Code of Principles and now accepted by all the main producers of this product. When the standard becomes applicable after an already agreed transitional period, it is expected to have a substantial influence on international trade in dried milk.

11. The acceptance of trading standards by a government implies that all products must conform to them if they are to be freely imported and sold within its jurisdiction. Such standards can either be recommended for voluntary acceptance or, in highly integrated communities, can directly form the object of interstate legislation after passing through appropriate machinery. This second method is now being followed by the countries of the European Economic Community (European Common Market), through its secretariat in Brussels.

12. The Conference therefore recommended that the Commission work both on the establishment of a minimum platform standard for each product, acceptable on as wide a basis as possible (on the understanding that acceptance of the minimum standard in no way limits the existence or establishment of higher national standards) and, concurrently, on additional realistic higher international standards appropriate to individual regions, whenever this appears desirable. The last group of standards would aim at being used as actual trading standards amongst the countries accepting them (each standard published in the *Codex* should be accompanied by a list of such countries). A number of developing countries have already set up dual standards on the same lines, minimum standards for provisional home use and higher standards for export. The minimum standards to be published in the *Codex* will be of primary use to such countries.

13. In this connection, the Conference considered it useful to clarify the meaning of the expression "higher" standard. It is often said that a standard should be as "high" as possible, but the expression is used very loosely. It is in general correctly used in relation to standards of hygiene and purity. It is ambiguous in the case of non-nutritional compositional elements: a standard prohibiting the use of a certain additive is not necessarily "higher" than one which permits it. It can be misleading in the case of nutritional compositional elements: a milk powder standard providing for a greater fat content is said to be "higher" than one providing for a lower fat content. This last statement is correct if by "higher" is understood "richer," but it would be incorrect if the "higher" standard were intended to be more desirable as such and therefore on all counts superior to a "lower" standard. In fact,

subject to the establishment of a minimum level and adequate labelling requirements to avoid misleading the consumer, "richness" is largely a matter of consumer preference and does not necessarily imply superiority of the product, nor of the corresponding standard.

Type

14. The Conference recommended that the *Codex* in due course cover all the principal foods and their components in international trade, as stated in paragraph 3 above. The types of standard to be included on the same long-term view should aim at covering all facets of the problem, especially: definition, composition, quality, designation, labelling, sampling, analysis and hygiene.

These facets should be studied in their scientific, technical, economic, administrative and legal aspects in order to ensure that the products to which they apply are in all respects suitable for consumption from both the hygienic and commercial points of view, and are correctly described.

The question of priorities among these aspects is covered in Part IV below.

15. Wherever the question of standards of identity poses special difficulties, the Conference recommended that the Commission, having laid down minimum requirements to be satisfied by a product in order that it may bear a group designation (for example, "cheese" or "groundnut oil"), designate subcategories by an appropriate term not implying quality preference where compositional differences alone are involved. It should consider as of secondary importance the descriptive designation of these subcategories (for example, "full fat cheese," "skimmed milk cheese," "refined groundnut oil"). Agreement by the Commission on standards designated in this way would already be a notable achievement. Such designations should, of course, always accompany any descriptive designation employed under national standards or by the trade.

16. In respect of methods of analysis, the Conference recommended that only reference methods and not routine methods should be included in the *Codex*.

Part III

METHODS OF WORK OF THE COMMISSION: ELABORATION AND ACCEPTANCE OF STANDARDS

17. The key to the methods of work of the Commission as approved in outline by the FAO Conference is given by the purpose of the Commission itself. This purpose is to simplify and integrate international food standards work by allocating priorities, by co-ordinating and supplementing the work of other bodies in this field, and by providing for finalization of draft standards at the government level and their publication in a consolidated *Codex Alimentarius*.

18. The Commission's work will depend upon draft standards prepared by ad hoc expert groups and by outside bodies, for example, by international nongovernmental organizations, whose own activities are therefore to be fully encouraged in the common interest of the Joint Programme: the Commission's function, except in the finalization and publication stages of a standard, is essentially one of distribution and co-ordination of the work involved. It will thus be possible to ensure the preparation of drafts by experts from public administration, from research institutes and from industry in daily contact with the subject matter, as well as to handle simultaneously a wide range of differing food standards.

19. The Conference considered the need for both world-wide standards

and for those of primary interest to a specific region or groups of countries and drew attention to the following factors:

(a) International food standards are largely conditioned by similar food habits. As a result, international trade in food is often localized within regions but may also cut across regional groups. In some cases, therefore, a standard will be required for a given region but in others by groups of countries belonging to more than one region or even for world-wide use. Health aspects, being of the widest interest, will usually need to be handled on a world-wide basis.

(b) The Statutes of the present European Council of the *Codex Alimentarius,* whose work is to be continued by the *Codex Alimentarius* Commission, within the new FAO/WHO framework, expressly state that the European *Codex* foreseen by the Council should also apply "to all extra-European countries having similar food habits."

(c) There was great interest in the establishment of minimum platform standards for international use, particularly for developing countries. In some cases the minimum standards could be elaborated in the process of establishing higher standards urgently required for certain regions or groups of countries.

20. The Conference therefore recommended methods of work to the *Codex Alimentarius* Commission which would allow the unhindered development of standards for regions or other groups of countries, whilst at the same time having regard to the interests of both developed and developing countries outside these areas. To this end, the Conference put forward the following detailed recommendations for the application of the general provisions of the Commissioner's Statutes laid down in FAO Conference Resolution 12/61.

21. The Conference felt that the Commission should be free to decide in every case whether a standard upon which it was proposed to work should be elaborated on a world-wide or on a narrower basis. Where the Commission determined that a majority of countries in a region required a standard for that region, such a standard should be prepared, without prejudice to the concurrent or later preparation of similar standards for other regions or groups or on a world-wide basis.

22. In order to encourage further food standards work among countries with similar needs in this field, the Conference recommended that the Commission should have the power to appoint from amongst its members one or more co-ordinators for individual regions or groups of countries whenever experience might show this to be desirable. The Conference further suggested that the task of these officers of the Commission would be actively to assist and co-ordinate the work of the various bodies engaged on draft standards within the region or group of countries and to keep the Commission fully informed of these activities, as well as the wishes of countries concerned as to priorities among standards to be elaborated.

23. By these means, the Conference felt it would be possible to enable standards to be elaborated either on a world-wide or more restricted basis according to the nature and need for each standard among the countries concerned. In particular, they allowed the participation of interested countries from outside the region or group of countries for which a standard was primarily intended without in any way restricting the nature or methods of preparation of the regional standard itself.

24. The Conference therefore recommended that the Commission work on the following lines:

(a) determination of general lay-out of the *Codex;*

(b) determination in detail of priorities;

(c) allocation to outside bodies of preparatory work;

(d) discussion of completed drafts by the Commission;

(e) acceptance by governments of standards approved by the Commission;

(f) publication of standards in the *Codex;*

(g) review and amendment of published standards.

These phases of the work are outlined below.

25. *Determination of lay-out of the Codex* (division into chapters on general provisions, individual products, and so forth). Although clearly subject to later change as a result of experience, early agreement by the Commission on a skeleton lay-out would provide a unifying scheme for the whole work of the Commission. It would also simplify the question of priorities and the delegation of preparatory work. The present European Council of the *Codex Alimentarius* has proposed the following subdivisions for the *Codex* which the Conference recommended that the Commission should take into full consideration:

Section I, General.—Basic definitions, labelling, sampling, positive lists of additives, and so forth.

Section II, Individual Products.—Detailed requirements for each product (see paragraph 14 above).

Section III, Methods of Analysis (see paragraph 16 above).—These methods may be included in the *Codex* either directly or by reference.

26. *Determination in detail of priorities* on the basis of the proposals approved by the present Conference (see Part IV below). Account will be taken of the fact that the decentralized methods of work on draft standards permit the simultaneous preparation of a wide range of standards. Judging from experience, some of these drafts would well involve several years' work, whilst others would be completed much earlier. The number and length of sessions of the Commission dealing with standards in the finalization stages would be adjusted accordingly.

Allocation of Preparatory Work

27. Preparatory work should be carried out by *ad hoc* export groups and outside bodies, full account being taken of work already in hand. For this purpose, reference may be made to the *Survey of international organizations working on food standards.*

28. In some cases work is already being undertaken or can conveniently be referred to an inter-governmental organization of regional or subregional coverage which has its own methods of preparation and of finalization of standards at the government level. Examples are the Permanent Commission of the Latin American Food Code, the Organization for Economic Co-operation and Development (OECD) working in conjunction with the Economic Commission for Europe (UNECE) and the European Economic Community (EEC, the European Common Market). In such cases, the Conference recommended that the Commission make full use of the work carried out by these organizations.

29. In allocating preparatory work on standards, full use should likewise be made of the wide technical knowledge and facilities offered by existing nongovernmental specialist organizations and by the International Organization for Standardization (ISO). In agreement with these organizations, draft standards prepared by them would be made available to the Commission for finalizing at the governmental level in accordance witth paragraphs 32 to 38 below.

30. Wherever it appears to the Commission that no appropriate outside international body already exists or can conveniently be set up, for example to handle the general part of the *Codex* (labelling, and so forth, see paragraph 25 above), preparatory work can be undertaken by an *ad hoc* expert group of representatives of national *Codex Alimentarius* Committees, wherever such bodies have been established, under the leadership of one of their number specifically appointed for this purpose by

the Commission. These committees already exist in a number of member countries of the present European Council of the *Codex Alimentarius* and the Conference recommended that they should be set up by all active members of the successor *Codex Alimentarius* Commission. A number of these *ad hoc* expert groups are already functioning under the present European Council of the *Codex Alimentarius* (see Part IV below). When establishing a standard for a region or group of countries, the *ad hoc* expert group concerned should consist of representatives of all interested countries from that region or group of countries, and will be open to observers from outside interested countries.

31. Co-ordination of food standards work among outside bodies is one of the main tasks of the Commission. Particular attention will be needed to ensure that there is no undesirable overlap which could be avoided between regional or subregional organizations working on standards for the same products. The full support of the Commission will be available to further the work of each of these bodies if they so desire.

Discussion of Completed Draft Standards by the Commission

32. A draft completed by the methods outlined above is then submitted in good time to all governments for consideration in order that they may make their comments available to the Commission for discussion at its next session. When the draft has been so considered and gains a favourable consensus of opinion in the Commission, full account being taken of the countries principally interest in the standard concerned, it is again referred to governments on this occasion for their acceptance. When a draft regional standard comes before the Commission for discussion, broad agreement by the countries of that region will be a necessary and sufficient condition for its approval. What constitutes a consensus of opinion in any given case depends on the nature of the standard under discussion (for example is it a food traded primarily within a region or on a world-wide basis), as well as on the geographical coverage desired for the standard. In no case is it therefore possible for a standard desired by one region to be rejected, as respects countries of that region, by outside countries. If such a division of views arises, two or more standards can be proposed, each with its own area of application clearly indicated in the *Codex*.

33. In order that the Commission be in a position to discuss simultaneously, in separate committees-of-the-whole, technical drafts coming from widely differing fields, it is highly desirable that each country's delegation to sessions of the Commission include an expert for each of the specialist fields affected by the session's agenda. The Commission's rules of procedure, to be adopted at its first session, should reflect this need.

Acceptance by Governments of Standards Approved by the Commission

34. On approval by the Commission, standards are communicated to Member Governments of FAO and/or WHO through these agencies. Irrespective of the geographical coverage intended for a given standard by the Commission, all approved standards are submitted to all Member Governments with a request that they indicate whether the standards are acceptable *and* what action they propose to take to implement any acceptance made. In the case of a standard elaborated for a given region or group of countries, acceptance by an appropriate majority of these countries, as decided by the Commission (see paragraph 32), will be a necessary and sufficient condition for its inclusion in the *Codex*.

35. It will be noted that the FAO Conference in approving the Statutes of the Commission included a proviso to Article 1(c) stating that during the first four years of the Commission's

work acceptance by European governments alone would be a necessary and sufficient condition for the publication of a standard in the *Codex*. This clause was intended to underline the urgent need for food standards applicable to the European market and to provide for the publication of European standards even if agreement on a wider basis should prove impracticable in any given case. The recommendation now made by the Conference that both regional and world-wide standards should find their place in the *Codex* effectively applies the spirit of the clause in practice and at the same time extends its benefits to all other regions.

36. As in the case of standards issued under the Code of Principles concerning milk and milk products, mention of government acceptances is accompanieed by an indication of any more rigorous national requirements applicable in the accepting country. This is a useful method of indicating the practical value of any acceptance of a minimum platform standard and should be followed wherever standards of this nature (see paragraphs 8 to 12 above) are included in the *Codex*.

37. *Publication of standards in the Codex*. When, in the view of the Commission, sufficient government acceptances (see paragraph 34) of a standard have been received, account being taken of the nature of the standard and of the product involved as in the case of the Commission's earlier discussion of the final draft, the standard is published in the *Codex* together with a list of the accepting countries. It is intended that the *Codex* be published in loose-leaf form in a separate edition for each language.

38. *Review and amendment of published standards*. Although the term "finalized" standard is often used to describe an approved draft, no text of a standard is ever "final," but requires constant adaptation to rapidly moving economic and technical conditions. For this reason, the Commission should review and amend published standards at appropriate intervals. Each outside body responsible for preparing a draft standard should be requested to keep the text under regular review and to submit proposals for a revised version to the Commission whenever this appears justified.

39. *Position of the FAO Code of Principles concerning Milk and Milk Products*. In approving proposals for the present programme, the FAO Conference stated that existing FAO work on food standards should gradually be integrated into it, noting in particular that care would be taken "to avoid adversely affecting the methods and progress of the Code of Principles concerning Milk and Milk Products." The present Conference approved the proposal to carry out these recommendations in the first place by treating the present FAO Committee of Government Experts on the Code of Principles as henceforth being the specialist body of the *Codex Alimentarius* Commission for all questions concerning milk products and as such extending its membership to all member countries of both FAO and WHO.

Part IV

Priorities

40. Given the wide range of standards which it is proposed to include in the *Codex*, the establishment of a list of priorities is of great importance. The task, however, is not a simple one since it can be viewed from several different standpoints, particularly in the case of compositional standards, and many factors need to be considered before making a choice. The Conference considered that the establishment of priorities would be the responsibility of the Commission at its first session. As a guide to the determination of priorities, the Conference made the following

recommendations. In any case, before undertaking the development of a standard for a particular product on a world-wide or regional basis, the Commission should be guided by the existence of a demonstrated need for such a standard.

Food Additives

41. The Conference felt that high priority should be given to food additives (colours, preservatives, emulsifiers, and so forth). Food additives enter into practically all processed foods, with the result that disagreement among countries as to which may be used can have the effect of making many laboriously agreed standards of composition and labelling of little practical value in protecting the consumer's health and in promoting international trade. In this respect, the Conference regarded the work at present being undertaken by the joint FAO/WHO programme on food additives as complementary to the work outlined here for the Commission and should therefore be continued, subject to the decisions of the Second Joint FAO/WHO Conference on Food Additives (see paragraph 42 below).

42. The Conference therefore proposed that the Commission have as a principal item on the agenda of its first session a survey of the food additives problem, with a view to the early inclusion in the *Codex* of purity standards and permitted lists of additives. In this way, the Commission would combine the already planned Second Joint FAO/WHO Conference on Food Additives, also scheduled for 1963. In its work the Commission should draw on the reports and manuals issued since 1955 as a result of the first world-wide joint FAO/WHO Conference on Food Additives, as well as on the permitted lists established by the Council of Europe and the European Economic Community. Material might also then be available from the *ad hoc* groups set up by the present European Council of the *Codex Alimentarius* on this problem. Valuable information might in addition be gained from the experience of several governments which have made a special study of these problems, from the series of symposia held by the International Commission of Agricultural Industries (CIIA) and from the work on methods of analysis undertaken by the International Union of Pure and Applied Chemistry (IUPAC).

43. Unintentional additives or contaminants (especially constitutents of packaging materials, pesticides and processing treatment residues) also present problems of the first importance for the work of the Commission. A survey has been commenced on one aspect of this field, antibiotics in animal feedstuffs, under the present European Council of the *Codex Alimentarius* as well as by WHO. Some work on pesticides has also been undertaken by FAO/WHO and further proposals are expected by the *ad hoc* FAO Conference on the Use of Pesticides to be held later this year.

44. *General provisions.* The Conference recommended that high priority should also be given to the general provisions on food standards to be published in the *Codex*, especially those on labelling. Early agreement on these basic principles will greatly facilitate work on individual standards as well as help to avoid repetition. The present European Council of the *Codex Alimentarius* recently accepted a text for the general section of the *Codex*. This text should be submitted to governments for study prior to the first session of the Commission. A related long-term undertaking is the preparation of an international glossary of food terminology already foreseen by the present European Council of the *Codex Alimentarius*.

45. *Methods of sampling and analysis* are also of very great importance. In most cases agreement on a standard of composition is meaningless in practice without an agreed method of analysis. It is therefore often necessary to determine a method of analysis before attempting agreement on the standards of composition affected. An international

collection of methods of analysis has been initiated by the present European Council of the *Codex Alimentarius*. Methods of sampling should also be studied.

46. *Basic food hygiene rules* are of great importance to all countries and especially to developing countries in tropical climates.

47. *Standards of composition in general.* As an over-all guide it was suggested that processed products be given first consideration over raw products, with the exception of certain raw products intended for processing (for example, cocoa beans) where the need for standard grades is already pressing.

48. *Joint UN/FAO World Food Programme.* This programme which is just starting, may require standards to be set up through the *Codex Alimentarius* Commission for certain of the foods it will handle. The Commission should therefore co-operate closely with the Executive Director of the World Food Programme in any requests of this nature and give them priority.

49. As recommended by the FAO Conference, standards should be drawn up for the principal foodstuffs in international trade with special emphasis on products entering the European market. In carrying out this recommendation, the products mentioned in the following paragraphs were proposed for the early attention of the Commission:

50. *Fats and oils.* A draft is under discussion for these products in an *ad hoc* group set up by the present European Council of the *Codex Alimentarius*.

51. *Preserved fruits, including jams, canned fruits, jellies and marmelades.* Substantially similar drafts for jams are under consideration by the European Economic Community and an *ad hoc* group set up by the present European Council of the *Codex Alimentarius*.

52. *Fruit juices.* The International Federation of Fruit Juice Producers (IFJU) and the Liaison Committee for Mediterranean Citrus Fruit Culture (CLAM) are working on a number of draft standards and an FAO Working Group under the Committee on Commodity Problems (CCP) has started work on citrus fruit juices. The Economic Commission for Europe has also started work in this field.

53. *Cocoa beans, cocoa and chocolate.* Draft standards for cocoa beans are under consideration by an FAO Group under the Committee on Commodity Problems, whilst proposals for cocoa and chocolate are under discussion both in the European Economic Community and in an *ad hoc* group set up by the present European Council of the *Codex Alimentarius*.

54. *Honey and sugars.* Work on honey has been started by the present European Council of the *Codex Alimentarius*.

55. Early attention should also be given to products for which draft international standards are already available. An interesting example is the standard for edible fungi recently accepted by the present European Council of the *Codex Alimentarius*. Though edible fungi are not a product of first importance in international trade, this standard has been elaborated by the countries most interested and could usefully be included in the *Codex*.

56. In particular, the following international standards which have already been discussed at the government level by a number of governments should also receive early consideration by the Commission. To this end the Conference recommended their distribution by the Secretariat together with supporting material wherever appropriate, to all governments in good time prior to the first session of the Commission:

[1](a) The general provisions, standards for milk products and their methods of sampling and analysis, issued under the FAO Code of Principles concerning Milk and Milk Products.

[1] Subject to the procedures mentioned in paragraph 39 above.

(b) The ECE/OECD standards for fresh fruit and vegetables.

[2](c) The standards for the principal varieties of cheese in international trade, set out in Appendices A and B of the Convention on Cheese Designations ("Stresa Convention") of 1951.

(d) The standards for olive oil from the International Olive Oil Agreement of 1956.

(e) The decisions on food colours and preservatives issued by the Council of Europe (Partial Agreement).

57. The Conference suggested that consideration might also be given to wheat, fish and fish products, meat and meat products, processed vegetables.

58. *Summary list of priorities.*—

(a) food additives

(b) general provisions (labelling, etc.)

(c) methods of sampling and analysis

(d) basic food hygiene rules

(e) fats and oils

(f) preserved fruits, including jams, canned fruits, jellies and marmelades

(g) fruit juices

(h) coca beans, cocoa and chocolate

(i) honey and sugars

(j) wheat

(k) fish and fish products, meat and meat products

(l) processed vegetables

(m) milk and milk products

(n) fresh fruit and vegetables

(o) olive oil

This list is given as a guide only and is not intended to limit the discretion of the Commission in determining priorities.

[The End]

SPECIALIST EMPLOYED TO HELP DETERMINE WHAT LABELS MEAN TO CONSUMERS

The Food and Drug Administration has employed a psychologist to help determine consumer reactions to labeling claims and statements, including the subtle use of statements which may be factually true but misleading as used. While FDA has for years consulted outside authorities as to what labeling statements mean to consumers, this is the first full-time specialist to be employed.

Food and Drug Commissioner George P. Larrick has expressed increasing concern over the use of statements cleverly designed to mislead the unwary in the purchase of foods, drugs and cosmetics. An early but still pertinent Supreme Court decision under the Federal Food and Drugs Act of 1906 condemned the work of "word smiths" in deceiving the public. In that case the court said:

"The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act . . ."

Appointed to the new position of opinion research specialist is Jan Eindhoven, A.B., M.S. He previously worked at the Armed Forces Food and Container Institute, Chicago, where he conducted studies on attitudes of men in the Armed Forces towards their rations.

[2] See footnote 1.

Food Standards–Thesis, Antithesis and Reconciliation

By WAYNE D. HUDSON

This Paper Was Delivered Before the Division of Food, Drug and Cosmetic Law of the American Bar Association Section of Corporation, Banking and Business Law in San Francisco, California on August 8, 1962. The Author Is Secretary and Chief Counsel, Foremost Dairies, Inc. of San Francisco.

IT IS OFTEN OBSERVED that every man is unique. We are each without a like or equal, and have a capacity for creativity and change all our own. Too, it is often observed that all men are basically the same. Both observations are true. We are basically the same and we are basically different. We take a great deal of comfort from conformity—from being and remaining the same. At the same time, we insist upon some room for our restless individuality. In this and in other areas, the problem of life seems to be that of accommodating, as best we can, values which are conflicting, opposite, antithetical.

So too with government. Most, if not all, legislation deals with conflicting values. The hope for legislation is that it will promote a given value without at the same time unnecessarily impairing the conflicting or opposite value.

The proponents of food standards legislation championed the security that conformity to standards would provide. Those who opposed were concerned over the threat to the freedom they saw as essential to the development of improved foods. Security as opposed to change; order as opposed to freedom.

President Roosevelt's Opinion

President Franklin Roosevelt, in support of the legislation, said in a message to Congress on March 22, 1935:

> The various qualities of goods require a kind of discrimination which is not at the hand of consumers. They are likely to confuse outward appearance with inward integrity. In such a situation as has grown up through our rising level of living and our multiplicity of goods, consumers are prevented from choosing intelligently, and producers are handicapped in any attempt to maintain higher

standards. Only the scientific and disinterested activity of Government can protect this honor of our producers and provide the possibility of discriminating choice to our consumers.[1]

Not much seems to have been said in Congress for the interest of consumers in change nor in the interest of freedom for an advancing food technology. President Roosevelt did refer to "a necessary flexibility in administration as products and conditions change." There were warnings at the time, however, that governmentally administered food standards would lay a dead hand on the foods standardized. Today, some 24 years after the enactment of the legislation, it is fair to assess the state of food standardization. In doing so, not much need be said of the security side of the antithesis of security and change. Standards do promote security; security to the consumer in purchasing, and security to the producer in selling. My concern is whether in promoting this interest the administration of the food standards law has failed to give account to the equally valuable interest in change.

Foremost Dairies has developed a new type of evaporated milk. It represents the first advance in the technology of producing evaporated milk that has occurred in 60 years. In the old style evaporated product, the concentrated milk is put in the can and then sterilized by cooking the can. The result is a viscous product with a cooked flavor. With the new process, the concentrated milk is flash sterilized and then canned under sterile conditions. The result is a less viscous product without the cooked flavor. Because of the lesser viscosity it is necessary to add a stabilizer to retard fat separation. We use a small amount of Carrageenan, which is an extract of red seaweed. It is simply a carbohydrate. For nonstandardized foods it may be used indiscriminately. Since the standard for evaporated milk did not name Carrageenan as a permitted ingredient, amendment of the standard was necessary. Foremost's proposal to amend the evaporated milk standard was filed with the Food and Drug Administration on August 3, 1960. Four months elapsed before the proposal was first published in the *Federal Register*. The first formal action was received on April 5, 1962, and the standard amended as of June 4, 1962. Thus, it took 22 months to accomplish this uncontested amendment to a food standard.

Reddi-Sponge is one of our new industrial products. It consists of a minute quantity of L-cysteine, an amino acid, carried in a matrix of dry whey. This product is for use in making bread. The whey

[1] 79 *Congressional Record*, Part 4, 4262.

supplies milk solids. The amino acid has a functional capacity merely. Reddi-Sponge serves to hasten the leavening process and can reduce a 7-hour bread making process by 4 hours. L-cysteine is an approved food additive. In nonstandardized foods it may be used indiscriminately. It was not included in the bread standard as an optional ingredient and the standard had to be amended. Foremost's proposal to amend the bread standard was filed with the Administration on March 16, 1961. Seven and one half months went by until on November 3, 1961, our proposal was first published in the *Federal Register*. The Commissioner's formal order was published on December 28, 1961, and the amendment became effective on February 26, 1962, which was roughly one year after our original petition.

These two amendatory proceedings serve to illustrate the situation confronting industry. The backlog of standards work which the Administration has and has had and is unable to cope with is well known. It is agreed by all to be deplorable.

The Food and Drug Administration is under-staffed. I understand that three men have been working on food standards. This staff is now to be increased substantially. There are some correctives, however, that do not depend on manpower. There are some things with respect to which we may be worse off with 20 men than we are with three.

Pertinent Statute

I should like now to refer to the enabling statute which reads in part:

> Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: . . .[2]

This provision was enacted by Congress shortly after the *Panama Refining Company*[3] and *Schechter Poultry Corporation*[4] cases. It must have raised a judicial eyebrow or two, though no one today would question its constitutional sufficiency. While the administrators seem to be conscious of the necessity of giving heed to the standard prescribed by Congress in its delegation of legislative power, they appear to misapprehend what the legislative standard is. The legislative standard for a food standard is one of reasonableness only—nothing more.

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[2] 21 United States Code 341.

[3] *Panama Refining Company v. Ryan*, 293 U. S. 388, 55 S. Ct. 241, 79 L. Ed. 446 (1935).

[4] *Schechter Poultry Corporation v. United States*, 295 U. S. 495, 55 S. Ct. 837, 79 L. Ed. 1570 (1935).

Promoting honesty and fair dealing—suppressing dishonesty and unfair dealing—is not part of the Congressional standard for the substance of a food standard.

A situation in the market place where traffic in a food product is accompanied by dishonesty and unfair dealing provides the basis for jurisdiction to promulgate a food standard. The administrator's exercise of judgment that conformity to a standard would promote honesty and fair dealing invokes the jurisdiction. Beyond this, in the exercise of the jurisdiction, it is a question of reasonableness under all of the circumstances of any given case.

Fish Flour Standards

There is presently pending a proposed standard for fish flour; that is, flour made from fish. The proposal, published September 15, 1961, sought to permit the inclusion of the fish heads and viscera. The Commissioner's proposed order, published January 25, 1962, set up a standard, but permitted neither the heads nor the entrails. The matter was set for a public hearing, but the hearing has been postponed indefinitely.

Have any of you been confronted lately with dishonesty and unfair dealing in buying fish flour? Unless I am badly mistaken in the facts, the jurisdictional predicate for a standard for fish flour simply does not exist. In my opinion, any standard resulting from this proceeding could not withstand any well directed opposition.

The bread standards were promulgated many years ago. Foremost wanted to be able to add a minute quantity of amino acid to bread so as to reduce the time it takes to make bread. In talking to a high official of the Administration he said; "Granting the utility, how can we make a finding that it would promote honesty and fair dealing?" Tommyrot! Yet, listen to this from the Commissioner's order in this proceeding:

"Upon consideration of the views and comments submitted and other relevant information, it is concluded that it will promote honesty and fair dealing in the interest of consumers to adopt the amendment as proposed." [5]

The Administrator knew that honesty and fair dealing were not involved. He also knew that it would be very unreasonable not to amend the standard. What he apparently did not know is that common sense is an entirely sufficient basis for amending an existing standard or for the substance of a new standard. How much of the very considerable delay we experienced in amending the bread standard was

[5] 26 *Federal Register* 12563.

attributable to this misapprehension? How much of the laborious handling of food standards could be avoided with a more enlightened view of the responsibility involved? A reading of the findings of fact resulting from some of the hearings indicates that much could be simplified.

Referring to the statutory provision again, you will note that the Administrator, having invoked his jurisdiction, is to establish "a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: . . ." The definition and standard of identity, identifies the product. Obviously this must be done if you are going to have either a standard of quality or a standard of fill. The "and/or" makes it clear that you may have either and need not have both. But can you have a definition and standard of identity standing alone without it being accompanied by either a quality standard or a standard of fill? The language would seem to indicate that you may not, though there is other language in the section that confuses the matter. In any event, administrative practice has probably foreclosed the issue.

The consequence of a standard of identity differs from that of a standard of fill or of a quality standard. The standard of identity is absolute and unless it is met, the product cannot be sold. A product may deviate from a standard of quality or of fill if the label so specifies. The difference can be important, it seems to me. Yet the Administration has not promulgated a quality standard for many years. Everything is identity. Everything is identity and much of the identity looks like quality. In the proposed standard of identity for fish flour some of the identifying characteristics are as follows: it shall have no more than a faint fish odor and taste; it shall show no spoilage as judged by the development of off-flavors, mold growth, or by deterioration in protein quality; and, the product shall be free of *Escherichia coli*, *Salmonella*, and pathogenic anaerobes, and the total bacterial plate count shall not exceed 2,000 per gram.[6] Is this identity or quality?

The concepts of identity and quality are not mutually exclusive, of course. When the distinction is clear, however, the matter of quality ought to be left either to a standard of quality or to the general adulteration and misbranding provisions of the law. It is the standard of identity that impedes food technology.

[6] 27 *Federal Register* 740.

Example of Ice Cream Standards

Moreover, standards of identity need not be as particularized as they are in many standards. They can be written in a more generalized way comprehending variants of ingredients and yet still do the job they were meant to do. The ice cream standard provides an example. The permissible dairy ingredients are identified as follows: "Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, and skim milk that has been concentrated and from which part of the lactose has been removed by crystallization."[7]

Cheese whey in its presently known forms will be added to this list. When it is the particularized standard will comprehend every source of milk solids that I know. Why isn't the specification simply "milk solids"? If there are exceptions as to source these could be specified and excluded. As it is, however, this standard will inevitably have to be amended and amended again to accommodate technological developments.

From the Administration's point of view, confining standards to those of identity and particularizing the identity facilitates enforcement. Handcuff the prisoner and he is easier to handle. Conformity is assured. Security and order are greatly enhanced. Freedom and change are ignored and our society suffers accordingly.

I should like to suggest that there should be no work undertaken in connection with new standards so long as the Administration is unable to accommodate procedures for the amendment of existing standards. Yet, there seems to be as much effort put into the promulgation of new standards as there is in amendatory proceedings. That the Administration undertakes to promulgate new standards under the circumstance that exists today seems to me to indicate that they have lost sight of the public interest. The detriment from fixed and unchangeable standards surely outweighs the benefit to be derived from new standards.

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[7] 21 C. F. R. 20.1; 25 *Federal Register* 7138.

If the points that I have raised have merit, they point a finger at the Administration and ask that a better job be done. If any fault is to be assessed, however, not much of it can rightly be laid with the Administration.

The assigned purpose of the administrators in setting a standard is to establish order and foster security. This is and will inevitably remain their principal motivation and their bias. If a proper balance of freedom and order, of security and change, is to be realized, if the antithesis is to be reconciled, the values of freedom and change must have their own champion.

Our economy is predicated on the essential freedom of the individual and the unrestrained initiative of management. Our industrial plant and our record of efficiency, which are the envy of the world, were built by individuals working out their own destiny. This is the keystone of our economy. Yet, we have found it necessary in some instances to curb the freedom allowed in the conduct of ordinary business. In such cases regulatory legislation has resulted. The administrative agency has been chosen as the instrument for effectuating the desired control. The economic organization of the United States today is one of capitalism accompanied by a measure of government control. This is an accomplished political fact and is no longer a matter of serious political controversy. A system of limited and enlightened regulation, it seems to me, is the most important single bulwark which we have against the threat of a complete undermining of our free economy. By this means we retain the advantages of capitalism. At the same time we avoid the injurious excesses of unfettered economic conflict. This is the setting in which government in business has become such an important subject to us all.

Suggestions for Trade Regulation Field

Every political corrective carries with it the danger that it will lead to an opposite and equally harmful extreme. The food standards legislation is a corrective, the administation of which may lead to an equally harmful opposite extreme. As I see it, it is left to the regulated industry to see that this does not occur. With respect to the discharge of this responsibility I content myself with a few DO's and DON'T's for consideration by those associated with industry, all of which apply to the field of trade regulation generally.

DO play a more affirmative part in the legislative process. When a trade regulation statute is being considered by Congress or a state legislature, the affected industry usually spends large sums of money

lobbying against the whole, or some part. Even when enactment becomes inevitable, little if any effort goes into positive improvement of the legislation or into assuring that it provides for adequate enforcement. I know of no instance where industry would not be better off to have the regulatory measures to which it is subject thoroughly, comprehensively and vigorously enforced.

DO combat *regulitis*. Regulitis is a disease that afflicts able, conscientious administrative officials It manifests itself in an exaggerated sense of responsibility. Given a statute of limited application to administer, they come to feel that every facet of the regulated industry is their concern. This is industry's fault, largely. The agency reaches out in small, well-intentioned ways that are irksome to the industry, but not of sufficient importance to any one member to cause it to take a firm stand. Occasion builds on occasion until the original limited purpose of the agency is all but lost sight of.

DON'T be afraid to take the government to court. It is very important in the administrative regulatory process that the courts play their full part. When a trade regulation statute is enacted, it is an imperfect attempt to deal with some socio-economic problem. Court decisions dealing with specific case situations are necessary to beef up the statute, chink up the gaps, resolve the ambiguities, and to otherwise develop the law into a mature regulatory measure. Yet, too often, needed court decisions are not obtained—for a variety of reasons. The specific involved may not be sufficiently important to justify any one member bearing the expense. An idea prevails that challenging an agency will turn the agency against the challenger in the future. Management seems to feel that to have the company's name involved in a suit with the government has a serious, adverse effect with the public. I think this is over-emphasized but it is not without some basis. You often hear the remark that there is no use suing the government because you will lose anyway. This isn't so, but the government does have an undue advantage. This is partly the fault of the courts. They are presented with complicated situations in the trade-regulation field and too often decide the crucial issue with the bromide that the administrator is the expert and the court should not go behind his decision. A better bench will help. Today, most of the judges sitting have never had a course in administrative law of trade regulation.

DON'T use the term "bureaucrat" as a damning generality. This bigotry has no justification and has caused many good men to leave government service. It is unfair to the good men who remain. I spent some time as an attorney in the California Department of Justice. I

remember running across a friend who, not having seen me for some time, inquired as to whether I were still eating out of the public trough. He meant no offense. Yet, the question, as put, is indicative of a general attitude that is more harmful than is the lack of adequate pay

FDA Commended

I should like to end on a personal note. Lest I be misunderstood, I should like to say that I affirm food standards. Even more so do I affirm the Food and Drug Act and the people who administer it. Of all of the administrative agencies with which I have dealt, which are many, I rate the Federal Food and Drug Administration as the best. Tribute to the men who man this agency is richly deserved, and I should regret to have my critique interpreted as other than an attempt at constructive co-operation in their endeavor. I once had a Jewish professor of legal philosophy who, in making a point, commented that it is much easier for a Catholic to forgive a pagan than a Protestant. The reason given was that in the Catholic's mind the Protestant has reason to know better. This is the basis of my remarks about the administration of food standards—the agency, manned as it is, has reason to do better! Of men like John Harvey, whom I have admired over the years, and of men like William Goodrich and McKay McKinnon, whom I number among my most respected friends, we may rightfully expect a great deal. [The End]

RECOMMENDATION APPROVED FOR STUDY OF STATE AND LOCAL FOOD AND DRUG LAWS

Secretary of Health, Education and Welfare, Anthony J. Celebrezze announced that he has approved a recommendation from George P. Larrick, Commissioner of Food and Drugs, for a study of state and local food and drug laws and their administration. The study was first suggested by the Association of Food and Drug Officials of the United States. It is made possible by a sum of $300,000 included in the Department's current appropriation for this purpose.

Secretary Celebrezze said the study was strongly supported by the Citizens Advisory Committee on the Food and Drug Administration, which submitted its report last October. He said it would be made by a qualified nonprofit organization, such as a foundation or university operating under contract with the Department.

"This survey will cover State and local activities with respect to foods, drugs, therapeutic devices, cosmetics, and hazardous substances used in the home," the Secretary said.

"It should bring to light any needed improvement in laws, organization, and support for Federal-State coordination. The organization conducting the study will be requested to include in its report specific proposals for bringing about the improvements they recommend."

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

January Food Seizures Report.—Contaminated food seized during December totaled 5,084,455 pounds (2,595 tons). In the danger-to-health category were 49 tons of soybeans contaminated with poisonous crotalaria seeds, and 3.4 tons of carrots containing excessive pesticide residues. The remainder was due to filth or spoilage of food. Insanitary warehouse conditions accounted for the largest quantity (4,475,943 pounds).

Labeling and standard violations resulted in seizures of 51,063 pounds. Among these were inferior quality fish sold under the name of a higher quality product, swiss cheese with artificial "eyes" to simulate the preferred variety, "country sorghum" made with saccharin and a sirup other than sorghum, a blended oil containing undeclared artificial olive oil flavor, canned vegetables below quality — or fill-of-container standards, and short-weight relish.

Drugs and Device Seizures.—Nineteen federal court actions were instituted against adulterated and misbranded drugs, six against defective prophylactics, and 15 against therapeutic devices charged with false and misleading claims for the diagnosis and treatment of diseases.

Included were a number of dietary supplements and drugs claiming effectiveness in reducing, new drugs without safety clearance, medicated feeds containing antibiotics but not properly certified, and antibiotics below their labeled strength.

Hazardous Substances.—An extremely flammable water repellent formula was seized because of failure to bear warning labeling required by the Federal Hazardous Substances Labeling Act, including the signal word "Danger," a statement of the principal hazards, instructions for handling and storage, and the statement "keep out of the reach of children."

Cosmetics.—Toothpicks containing toxic oil of cinnamon.

Voluntary Actions by Industry.—Voluntary compliance actions taken by the food industry in December resulted in the removal of 579,329 pounds (289 tons) of food from human consumption channels. Of this total, the major part was converted into animal feed or otherwise reconditioned by salvage operations to remove unfit portions of the lots. Some of the largest voluntary food destructions included 20,000 gallons of apple juice made from partly from decomposed apples, 21,250 pounds of flour that had become rodent-contaminated in storage, and about 14,000 bags of cabbage containing residues of endrin, a pesticide for which no residues are permitted at harvest.

The drug industry, physicians, and other health practitioners withdrew $74,240 worth of drugs and devices from the market or from use. Approximately $19,000 of this represents the original retail price for 30 more of the Microdynameter diagnostic machines which were held worthless and potentially dangerous by the United States

Circuit Court of Appeals last March. The remainder included antibiotics which had lost their potency due to unrefrigerated storage or which had passed the expiration date; repackaged physicians' samples which did not contain required labeling information; old stock drugs and vitamins; a medicated feed containing an uncertified antibiotic; stilbestrol originally intended for treatment of poultry but no longer permitted for this use; a counterfeit drug; new drugs marketed without the required safety clearance; a large lot of drugs damaged during a fire; and quantities of a drug that had been recalled by the manufacturer earlier because of side effects not anticipated when it was marketed.

An Ohio soup manufacturer spent $400,000 on new heat processing equipment and on sprays and a high-pressure water pump to improve the washing of raw tomatoes received at the plant. A Texas food plant rebuilt its kitchen, installing tiled floors and walls and new conveyors, pumps, stainless steel steam cooking vats, a new air filtering system, and other equipment. The costs totaled $181,700.

A Georgia peanut company has spent $122,000 over a period of two years in changing from wooden to metal equipment and floors, and the installation of a pneumatic conveyor system. A cotton oil and peanut corporation in Oklahoma invested $80,000 on new construction and repairs in its shelling plant, oil mill, and warehouses. New metal conveyors and elevators are designed to prevent contamination by insects and rodents. Two other cotton oil plants, in California and Texas, spent $63,500 and $42,200, respectively, on cleanup operations to raise sanitary standards in their mills.

A Michigan grain elevator company spent $50,000 to improve storage conditions by installing a new dryer and ventilating system and metal grain bins. A Minnesota macaroni manufacturer installed pneumatic flour storage, handling and mixing equipment at a cost of $35,000 to protect against insect infestation.

FDA's Busiest Year.—At the end of 1962 the Food and Drug Administration had completed its busiest year. Here are the final tabulations: More than 56,000 inspections were made of food, drug and cosmetic establishments during the year, compared with 36,000 during calendar year 1961.

Inspectors collected 86,500 samples and FDA field chemists analyzed 72,500 samples to determine their compliance with the federal Food, Drug and Cosmetic Act. Comparable figures for 1961 were 67,000 and 46,000 respectfully. Foods seized in 753 federal court actions totaled more than 43,341 tons, in comparison with 703 actions and 9,880 tons in 1961. The sharp increase in tonnage was the result of the seizure of more than 33,804 tons of insect-infested cocoa beans in storage under insanitary conditions at two warehouses.

The food and drug industries of the country also played an important part in protecting the public from unfit products. Over 2,762 tons of deteriorated or contaminated food commodities and products were voluntarily destroyed or converted to animal feed in over 980 such actions reported by FDA inspectors. Adulterated drugs and devices originally priced at $545,316 were disposed of in 478 individual actions. And FDA inspectors reported a total of 260 plant improvements to prevent future violations of the law at a cost of $9,658,463, up from $8,986,000 last year.

Criminal prosecutions filed in the federal courts in 1962 totaled 287. Of these, 93 involved adulterated or misbranded foods; 184 were concerned with defective or dangerous drugs and medical devices. Of the latter, 133 charged illegal sales of dangerous drugs without prescription. Twenty-four injunctions were requested from the federal courts during the same period—11 to prohibit shipment of illegal food items and 13 involving drugs and devices.

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