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Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the 1964 Joint National Conference of The Food and Drug Administration and The Food Law Institute, Inc.

Second Session of the Codex Alimentarius Commission . . . FRANKLIN M. DEPEW

Papers Presented at the Food Standards Symposium

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

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

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TO THE READER

1964 FDA—FLI Conference. — The afternoon session of the conference was devoted to a series of five simultaneous panel workshops on the general topic of "What Industry Needs from FDA for Better Compliance." Papers from four of these workshops and two papers from the fifth workshop were in the January and February issues. Remaining papers delivered at the workshop, "What the Public Wants," begin on page 116. The authors are *Dr. Leonard A. Scheele,* Senior Vice-President, Warner-Lambert Pharmaceutical Company; *Charlotte Montgomery,* Contributing Editor, Good Housekeeping Magazine; *Aryness Joy Wickens,* Consumer Program Adviser, U. S. Department of Labor; *Edith Sherrard,* Associate for Social and Economic Issues, American Association of University Women; and *Mary E. Cunningham,* Chief, Consumer Education Branch, Division of Consumer Education, Bureau of Education and Voluntary Compliance, FDA.

Second Session of the Codex Alimentarius Commission.—*Franklin M. Depew,* President of The Food Law Institute, reports on the second session of the Codex Alimentarius Commission held at the Geneva, Switzerland, Headquarters of the World Health Organization, September 28—October 7, 1964. One of the important items considered was the financing of the Commission's activities and the possibility of a deficit in the 1965 budget. Member countries were urged to enlarge their contributions and a $30,000 contribution was suggested for the United States. It appears that Congress will not make an appropriation for this work, and American industry is called upon to furnish these funds. Another important item discussed was the principle of worldwide food standards. The principle was reaffirmed, and the Commission also adopted procedures for setting up regional standards.

Food Standards Symposium.—A symposium on "The Legal Basis and Regulatory Use of Food Standards," was held in Washington, D. C. on December 1, 1964. Sponsoring the program were The Food Law Institute, Inc.; The George Washington University Graduate School of Public Law; and The Food Protection Committee of the Food and Nutrition Board, National Research Council, National Academy of Sciences. Papers delivered at the morning session are in this issue. *Alan H. Kaplan,* Lecturer on Food, Drug & Cosmetic Law, Graduate School of Public Law, George Washington University, discusses food standard making procedures in his article beginning on page 149. The role of the states in establishing food standards is spelled out in an article by *Eugene H. Holeman,* Director, Division of Food and Drugs, and State Chemist, Tennessee Department of Agriculture. Concluding this issue is a paper by *George M. Burditt,* a member of the law firm of Chadwell, Keck, Kayser, Ruggles & McLaren in Chicago. Papers from the afternoon panel discussion, "Do FDA's Present Food Standards and Standard Making Policy Best Serve the Consumer?", will be in the April issue.

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Journal

What the Public Wants

Comments by LEONARD A. SCHEELE, M.D., Panelist

"What the Public Wants" Was the Subject of One of the Afternoon Panel Workshops on the General Topic of "What Industry Needs from FDA for Better Compliance." Dr. Scheele Is Senior Vice-President, Warner-Lambert Pharmaceutical Co. Comments by the Following Were Contained in the February Issue: James L. Trawick, Moderator; Paul S. Willis, Panelist.

MY RANGE OF EXPERIENCES in public health practice and in a pharmaceutical company make the assigned topic a very interesting one to me. In addition, I can say that I also appear before you as a consumer.

The program said, Consumer Education—What the Public Wants. I will speak on the first, attempting to limit my comments to so-called ethical and proprietary drugs, although many of my comments could just as well apply to foods and cosmetics. The ethical drugs are promoted only to physicians and may be sold only on prescription, or in other instances may be available over-the-counter without a prescription as are proprietary drugs which are advertised directly to the public.

Proper, Standardized Labeling

First of all the public wants pure, safe and effective prescription and non-prescription drugs, and wants those which it purchases over-the-counter to be properly labeled with proper instructions for use, and mention of any special considerations in their use. It expects manufacturers to exercise good quality control and expects two drugs that are labeled alike to be alike. Unfortunately, they are not always the same. Certainly the public can expect to have such drugs from reliable companies and should have them from all companies when the Food and Drug Administration (FDA) is adequately staffed and

housed to fully police compliance with current drug laws and regulations, many of which are of fairly recent origin.

Medical Journalism in Layman's Language

The public also wants more new drugs which will make a greater impact on disease prevention, alleviation, and cure. Despite great progress against infectious and communicable diseases, it knows that little progress has been made against major killers and cripplers. It therefore wants to know what is being done and if more should be done. Here many agencies, private and governmental, especially the FDA and United States Public Health Service (USPHS) in the latter category, should help to educate. All agencies have a responsibility to educate in the area of medical science. To emphasize this I would like to quote several paragraphs on this from the *Report of the Commission on Drug Safety* (June, 1964) :[1]

> The degree to which a layman can be brought into the atmosphere of science evidently depends upon the education and the intelligence of the individual. The Commission is convinced, however, that effective messages can be created to make the most essential points clear to a broad audience. The person who understands the danger in kitchen gas and uncovered electrical outlets can comprehend that all drugs, new and old, embody some risk and most of them require a physician's prescription and supervision. The man or woman who doesn't hesitate to drive on the highway, accepting some risk, can understand acceptance of minimal risk is part of the small price of medical progress. In each instance, a ripple of understanding can prevent a wave of misplaced and harmful indignation.
>
> The Subcommittee on Responsibilities of the Public in Drug Safety recommends increased efforts by pharmaceutical manufacturers, the medical profession, the government, and the universities to transmit drug therapy, and drug research. Material necessarily would have to be tailored to the intellectual needs of the audiences. The Subcommittee suggests that special emphasis be placed on trying to reach high school and college students. To reach the public at large, good medical reporting is particularly important, and the Subcommittee proposes that fellowships or other awards (independent of vested interests) be established to foster effective preparation for medical journalism.
>
> The Commission believes that much can be gained by enlisting the public's vicarious participation in the drama of research and drug development. Yet the public must not be misled. Only when the layman understands this process—of which he is the beneficiary—is attended by great benefit, but also potential disappointment or even chance of harm, will the informational effort be genuinely useful. The scientist can speak with candor to such a public, and the public can speak with some measure of understanding to the legislature.

Mrs. Wickens has mentioned education of low income consumers —who often have had little formal education. They are educable but

[1] Distributed by Federation of American Societies for Experimental Biology, 9650 Wisconsin Ave. N. W., Washington, D. C. 20014.

will require greater effort by more people and agencies than have put a shoulder to the wheel so far.

Public Education Programs

Next, I would like to speak briefly about programs of manufacturers in public education. Many activities by individual companies and by their trade associations, the Proprietary Association, and the Pharmaceutical Manufacturers Association are in progress. These fall in the general education field through speeches by individuals, participation in panel discussions, film strips, movies, publication of pamphlets and reports, and responses to direct consumer inquiries. Examples of pamphlets are the 25-page illustrated booklet, *Your Home Medicine Chest,* and the leaflet, *How Does the Label on Packaged Foods and Medicines Help You?,* designed for schoolroom use and certainly fitting into the urgent educational need. Both of these are by the Proprietary Association. The Pharmaceutical Manufacturers Association publishes several leaflets on pharmacy and pharmaceuticals designed to increase understanding of them, and publishes a list of movies useful in group education in the health and drug field. Several companies publish public service advertisements designed to help the public better understand disease problems, the need for seeking medical care, and some of the values of drug discoveries.

One area of education the public needs, but does not always have, is how to avoid quackery and fraudulent drugs and devices. This is one area in which the FDA, the American Medical Association and the Arthritis Foundation have been active.

Here the public must be educated to avoid frauds in drugs and devices. Ideally, these items would be kept off the market, but in many cases a variety of factors operate to prevent their early removal. A recent example is Krebiozen which was touted for cancer for over a decade. The FDA finally developed enough evidence to enable it to initiate badly needed legal action on this fraud and those associated with its promotion and sale.

The Washington Post Times Herald editorialized very appropriately on November 19, 1964 on the "Krebiozen Fraud", noting intensive investigation of Krebiozen by the Food and Drug Administration and National Cancer Institute before it was declared to have no therapeutic value and said

> promotion of the substance . . . is an offense of the utmost gravity . . .

Though it is impossible to estimate the full scope of the damage done, it has been enormous . . . If (Govt) charges can be sustained, it is obviously not a case of sincere disagreement over the merits of a product but a gigantic swindle of an especially despicable type.

Responsibility for Education Rests on Various Groups

I would like to mention some of the groups which should be involved in consumer drug education in varying degrees. Some of these are self-evident, namely manufacturers and distribution agencies like wholesalers, and retailers, the FDA, and the USPHS. Others may not be as self-evident and may or may not be active in the field now, namely the American Medical Association which is very active (its *Today's Health* should be subscribed to and read by everyone), voluntary health agencies which have categorical disease orientations, organizations of specialists such as pharmacists, health departments at State and local levels, schools and departments of schools training health professional personnel to the end that all in the health field play some role in the health education process later, public health schools to adequately train all their students and especially those working as health educators, schools and departments educating teachers, especially those who will teach biology and hygiene in primary and secondary schools, to mention some.

Schools of journalism must train more top-notch science writers whose materials will come back to the public through all media of mass and specialized communication. While I have concentrated on individuals and groups with major health orientation, there is also a major but somewhat more limited role for farm agents, home extension agents, and many others who deal directly with the public, to learn more about general problems in the health field so that they can help transmit information to those with whom they come into contact who need it. We must work hard deciding what to teach or communicate. We must decide on basics for the elderly, the young, the poor, and others.

Finally, there comes the question, "how can various groups be stimulated to do an adequate educating job?". I plan to leave this question unanswered for now because I am sure that our audience and the panelists will begin to suggest answers to the question and then we will all be participating and contributing. **[The End]**

Comments by CHARLOTTE MONTGOMERY, Panelist

Mrs. Montgomery Is Contributing Editor, Good Housekeeping Magazine.

THE FIRST AND MOST OBVIOUS observation I want to make concerns the difficulty of generalizing about consumers or of talking about "the average woman." She simply doesn't exist. This is easy to prove by watching the girls go by in the supermarket. Every basket carries a different load. What's more, one basket won't be filled with only the lowest priced meats and bare-essential staples while another is piled with gourmet foods and fancy dishes which are more fully prepared. Purchases are a mixed lot. Each basket illustrates a family choice in menu and flavor. Or the homemaker's choice of what energy she wants to give to the preparation of a certain meal or how much time she wants to expend on that particular cleaning job. There are women who shop with a mental slide rule and others that fly down the aisles as if these were race tracks.

By and large, women are good managers. In America, they are the custodians of the family pocketbooks and they do this job quite well. They serve up good meals, try to watch basic nutrition and keep an eye on the budget.

Practical Information Desired

Women want to be good consumers, good shoppers, wise buyers. But their idea of this is on a level which sometimes seems rather superficial to out-and-out experts: housewives want capsule advice, not a course in economics. They want help, not lectures. They want instructions that are easy to get at, easy to read, easy to understand, easy to keep where they can find it when they need it, easy to refer to. They want it to tell them what they want to know.

One difficulty in the dissemination of consumer educational material is the fact that the average woman doesn't know what is available to her or where to get it. There ought to be some clearing house, some constantly up-dated source where a woman who wants to make jam or put on a club program can find out what there is to help her.

What the woman wants to know are things that are close to her personal, day-to-day needs—to her job as a homemaker: Why do foods with sugar left out cost *more*? Why did the new cookie mix she liked disappear from the shelf? Why did the price of something go up though there are no more ounces in the jar? Why don't mayon-

naise jars list ingredients? Why are all those meaningless words listed as ingredients? Women look at a list of chemical-sounding ingredients in one of three ways—they find it funny or they find it frightening, or they *don't read it.* I would prefer to see words such as "plus preservatives" used rather than the names of specific chemicals.

Most women are only interested in information, help, buying guides, that relate to them and their daily lives. They are less interested in general economics, statistics, etc. By and large, they believe that both government and "big business" protect them. They tend to be optimists and believers.

Need for Palatable Materials with Wide Appeal

I feel that both FDA and industry are doing a good job of consumer education. It could be broader, reaching more people and especially the less informed, lower-income groups—who do, indeed, need help.

I also think that much of the educational material addressed to consumers is heavy. It should be brighter, lighter, more readable. The woman who is hungry for help still wants it palatable! The women's magazines have shown that it can be done.

Summary

In conclusion I would:

1. Inform consumers what is available.

2. Give consumers a constant flow of basic information. Simple facts on nutrition, quality, good buy-manship.

3. Urge consumers to make use of the help now provided for them—the directions on the package, bulletins on current subjects, leaflets provided with appliances—right up to broad material for group programs.

4. Continue to feed out more help through the media the woman reads, likes, believes in. I am thinking especially of magazines, who do take a responsible attitude.

5. See that everything the woman is told fits into her life and is written in her language.

And, please, don't always call what you're doing "consumer education" as you try to educate the consumer—she'd far rather think she was hearing hints on how to get the most for her money or how to be a good shopper and manager. **[The End]**

Comments by ARYNESS JOY WICKENS, Panelist

Mrs. Wickens Is Consumer Program Adviser, U. S. Department of Labor.

CONSUMER EDUCATION is for everyone. You and I can profit by it as well as the other fellow, even though we do not always believe it. In today's fast-changing food, drug and cosmetic markets, with their dazzling variety, there is not one of us—rich or poor, old or young, who could not be better informed about the things we buy—to our own advantage.

For you in The Food Law Institute and in the Food and Drug Administration, consumer education is rightly regarded both as an essential base and a continuing adjunct to laws designed to protect and inform consumers and the regulations that flow from these laws. Once we pass beyond the areas of minimum inspection for safety and health and reach the area of consumer information, it is not enough merely to pass a "good" law. The law can prescribe more general grading, or more informative labeling but it is obvious that if the consumer does not know how to use these informative tools, how to ask the right questions, how to use the safeguards and the protections provided for him or her, then our best efforts are only partially effective.

It is for this reason that Mrs. Peterson, as Special Assistant to the President for Consumer Affairs, and the members of the President's Committee on Consumer Interests are placing so much emphasis on consumer education and information. This is why those of us in the Federal agencies who are working with consumer affairs are particularly pleased with the widening interest in consumer education by manufacturers, retailers and Government agencies.

Consumer education for our young people in school *is* important, and it should be much more generally available than it is. Did you ever stop to think how many billions of dollars we pour into teaching our young people how to earn a living, and how few we spend teaching them to spend their earnings wisely for a better life for themselves and their families? In this area, we need new and better teaching materials to become a part of the curriculum of the regular subjects—arithmetic, social studies, as well as homemaking.

Use of All Communication Media Essential

But "consumer education" is so much more than schools and desks and "book learning". Since it is beamed at adults as well as at

students, its effective tools are not just the printed word, beloved of those of use who read books and magazines, the scientific pamphlets or the technical bulletins, but all the mass media of communication, —newspaper and magazine advertising, the store window displays, the labels on the cans, the articles and pictures in women's magazines, the "week's best food buys" on the local radio market news. These media offer more effective ways to reach and teach consumers how to protect the health and insure the safety of their families, as well as how to get the most for their money. This is why the accuracy—both of the text and the impression it gives—as well as the quality of the information given to the public through these media is so important.

Educating the Low-Income Consumer

The President, in his *Message on Consumer Affairs,* put particular stress on consumer education. He gave Mrs. Peterson and the President's Committee on Consumer Interests some special instructions. One of these was to undertake a program of consumer education for low-income families and to explore ways to apply the extension service concept, so useful in rural areas, to urban communities.

To carry out this directive, Mrs. Peterson last June appointed a panel of some 30 experts on Consumer Education for Persons with Limited Incomes. These experts come from the social agencies who know the poor, the Cooperative Extension Service whose home economists are working increasingly in this field, prominent retailers—food and variety chain stores, for example; representatives of the Better Business Bureau, the labor movement, the press, the universities and Government. This panel has surveyed what is now going on and finds there are several special groups whose incomes are limited which need particular kinds of information and education in consumer affairs. They must be approached in different ways, through different institutions, with different media:

1. The elderly, whose concerns are importantly with good nutrition, housing and medical care;

2. The growing group of young families, who want (and indeed expect) so much and have so little to spend and such limited experience in wise buying and financing;

3. The poor of our slum areas—both urban and rural, people of all ages. Here, perhaps, the need for consumer education is most spectacular. Those members of the panel who have been trying to help

train women on welfare rolls, for example, find that they need to learn some of the very simplest things about home management, cleanliness, how to use surplus foods, how to make over donated clothing, not to mention the elementary rules of home safety. Home economists and welfare agencies all over the country are conducting this kind of consumer education—still in a small way—but more widely than any of us knew until our panel met last July.

They find that the first problem is to reach those who most need help. Second, a person-to-person, neighborhood approach is most effective. The printed word is little use. Some do not read well, but those who can, have no access to and less interest in the technical materials that are generally produced for "middle class" consumers with considerable education. Those early experiments have taught us that we have to "throw away the book", that wholly new teaching materials are needed—that very simple single sheet pictorial materials work best; that demonstrations and actual participation in small groups—meetings in an apartment in a public housing development, for example, are especially effective in teaching very basic things.

Government agencies—and especially FDA and the Department of Agriculture—are beginning to produce exciting new materials—both for teaching classes and for individual use.

There is much that industry can do to help. It can provide materials for demonstrations, it can organize guided shopping tours, to help break neighborhood shopping barriers; it can use TV and radio spots aimed at getting across some quite simple how-to-do-it facts about safe and wise use of drugs, how to choose certain kinds of food etc. Sometimes materials in other languages than English are essential—Spanish in the Southwest, in the Puerto Rican areas in New York City.

The Community Action programs, under the President's "anti-poverty program", offer a way for many communities to put into action some organized consumer education efforts at the poverty level —based on local initiative, with the full cooperation of business groups, the schools, and the welfare agencies. Consumer education for some of our almost forgotten people can do much to give them a lift. Your imagination and cooperation in interesting local groups in this effort and in helping to provide materials could be very constructive.

[The End]

Comments by EDITH SHERRARD, Panelist

Mrs. Sherrard Is Associate for Social and Economic Issues, American Association of University Women.

I AM SUPPOSED TO BE THE SIMON PURE consumer in your midst.

That means that I'm not responsible for the law or its enforcement. That I'm not responsible for the product.

In this idyllic situation, all I have to do is figure out what the consumer *wants* to know and *needs* to know, and then I just tell you how to get this information to her, whoever she is. Then we will all march forward together, leaving the world a better place for our having been here today. That's all!

Current Consumer Information Material Presupposes Interest

As a preliminary to this meeting I read a great deal of the consumer information material put out by FDA and by industry. On the whole, I was genuinely impressed. For example, I read the American Medical Association's *Beware of Health Quacks* and found it a very sound little compendium of *do's* and *don'ts*. I read the list of fancy food supplements:

Honey and vinegar,

Wheat germ oil, which is supposed to cure arthritis

Ocean kelp, which is supposed to cure rheumatism

But as I read, I couldn't avoid thinking that those who eat kelp, or drink it, whichever is more appropriate, are the very ones who do not see this pamphlet.

I read *The Label Tells the Story* by the Grocery Manufacturers of America, Inc. and *It's on the Label* by the National Canners Association and I admire your clear, lucid, economical statement of the "nine points of law."

All of this is excellent, but all of it presupposes *interest* and *education.* And in a country where people are bombarded day and night with exhortations to enjoy this-or-that or warnings to worry about someing else, you can *not* presuppose that you have their interest. In a country where slightly more than half of the population over twenty-five years of age does not have a high school diploma, these pamphlets are pretty sophisticated stuff.

Who *is* this consumer we are talking about and whom we are trying to educate? I was amused and a little rueful when Mr. Depew said this morning, "It has been found difficult to determine the expectations of the 'average' consumer, and even more difficult to determine whether the 'average' consumer has been or will be misled. I sometimes wonder," he said wistfully, "if an 'average' consumer exists."

Well, I don't wonder anymore, Mr. Depew. I *know* she doesn't exist.

The consumer comes in as many varieties as any other brand of humanity and we have to take into account variations in her knowledge and interest as well. At one extreme we have the scientific purchaser who weighs pro's and con's before spending a dime, while at the other extreme we have the gullible shopper whose money burns a hole in her pocket. Variations in age and income have to be taken into account. Yet, unconsciously perhaps, most consumer education is directed to those who are highly literate relatively speaking, critical in the sense that they can weigh one consideration against another, and middle income in interest, taste, and spending habits.

All this is implicit in your means of communication: You have pamphlets that are available by mail in bulk. To whom? To those, of course, who write in and order them. And you have pamphlets that are distributed over the store counter. To whom? To those, of course, who stop to pick them up. There are excellent industry displays outside this room, which I looked at with great thought this morning. But why was I there to look at them? Because I deal in consumer problems.

Reaching Consumer Subgroups

Now, if it's really true, as Mr. Depew said, that "there is no difference in opinion between industry and the FDA as to the need to do a successful job in educating the public," if you really want to promote consumer understanding within the voluntary framework, you must aim for a wider consumer audience: You must improve your use of language by making it more easily comprehensible. You must determine what the consumer wants to know by categories of products. (This is a case where the questions you ask may be more important than the answers you receive.) You must promote a search for subgroups of consumers. Mrs. Wickens has mentioned the low-income groups. There are also the aged—18 million, half with limited incomes, others with shrinking incomes. There are those who are ill, or required to

observe special diets. All of these make up a promising group of consumers you should try to reach.

Let me redefine what I am saying about this "wider audience." I propose that you extend your horizon beyond the middle-income, college graduate who is already consumer-minded:

first—to those who are highly literate but whose interest is elsewhere. (In the American Association of University Women (AAUW) I think of members of the World Problems groups who are reading about Viet Nam right now and don't care to read about consumer problems.)

second—to those, not necessarily highly literate, but whose need to spend their income wisely is something they are consciously aware of. (I think of the aging.)

third—to those whose circumstances *require* consciousness of what they buy. (I think of those on diets and so forth.)

This is a small enough extension of your present audience but it will do for a beginning.

Now, how do you reach them? That has to become your second objective. I don't know how you reach them, but I have a suggestion to make: Why not set up a ready-reference service to which my less-than-fanatic consumer can turn *when she needs it?* I am informed that the Poison Control Center provides this kind of ready-reference information as does the National Institute of Dry Cleaning. NIDC will send you a little pamphlet that guides the consumer and the dry cleaner to a reasonable settlement for loss or damage. It suggests, on the basis of experience, what is a fair settlement for a suit of such and such value and such age.

Ready-Reference Service Proposed

So I propose that you start modestly. Pursue a small number of sub-audiences. Don't try to tell them everything about everything. And that brings us to the next decision you will have to make if you embark on such a program: With what territory of consumer goods should you concern yourself?

In the fall of 1961 I reported to this group on a survey of 250 AAUW members whom we questioned on foods, drugs, and cosmetics. *Safety* and *safe use* were the most prominent factors in their concern:

164 of the 250 mentioned this as their main interest in consumer matters. In addition, 116 of these members made 122 voluntary comments and 68 of these were seeking some form of improvement in labelling—more adequate or more conspicuous or more comprehensible labelling.

A ready-reference service of the sort I am thinking about might well start with *safety* and *safe use* and it might be limited to the *food* and *drug* area. I am thinking of your developing a loose-leaf binder which would permit simple one-page information for groups of products and would afford rapid changes in its contents when appropriate.

For example, of *drugs,* the ready-reference service might emphasize keeping of adequate records. I quote from *First Facts About Drugs:*

how often and when to take it,

how much to take each time,

when to check back with your physician on effects,

care for any special instructions physician has given.

The ready-reference service might also say, "throw out unused drugs when illness is over"—if, that is, you think this is wise or necessary. It might have a warning to keep drugs away from children, and so forth.

Of Household Materials, the ready reference service might tell the consumer:

how to store them safely,

how to apply them safely,

antidotes for misuse, etc.

Of Foods, most consumers need to know

why the freeze-thaw-freeze cycle is a bad thing.

circumstances in which slow cooking might be unwise.

I would also like to see some general information in a ready-reference service:

an index of language—terms, such as *additive.* Few people outside this room know what an additive is!

definitions of *common ingredients.*

And I'd like a page on how to read a label, the meanings of abbreviations, etc. I'd like a page on simple general information, perhaps at the very beginning. You might stress that old theme, which is a *new* theme to most consumers, that there is "No such thing as a *harmless* substance—only harmless ways of using it."

Distribution of Reference Binder

Now we have taken three steps toward my ready-reference service: We have extended the audience beyond the self-identified consumer enthusiast. We have defined the products and the dimensions of the products to be described, and we have considered the form of communication—the loose-leaf binder of basic facts about safety and safe use. It remains to consider how we distribute this binder, or publicize, so that the less than ardent shopper will know it is available for her use.

I would like a page on simple general information, perhaps at the beginning. You must stress that old theme. You need to put this compendium into the hands of those who *deal* with the consumer audience we have defined. Give it to the retailers and distributors who can consult it on request and quote from it. Make it available to the organizations and agencies that deal with low-income or aged or ill clients:

health welfare agencies
medical societies
home economics teachers in school systems
family service agencies
public housing authorities
Red Cross
Chambers of Commerce
labor unions

AAUW, for instance, has a write-in group of 100 consumers who participate in buying projects and who would be very glad to see such a service find its way to the right party. Seek out the National Association of Retired Persons. (How many people here are aware that this organization is running an educational program on consumer goods and services for older persons? Have you been around to offer *them* your pamphlets?) I personally would not put it in the schools. I would prefer that we let the schools concentrate on reading and writing.

We've been talking till now in effect about motivating the consumer. And, as in all these matters, you must first motivate yourself. It would appear that all this educational information is now available. It would appear that we all agree the consumer should be informed. Yet, this information is not reaching her, and it can be made to reach her. Guidelines exist, it seems to me, and anytime you want to interest AAUW's 100 write-in-consumers in helping you with such a venture, let me know. I will ask them to join in. **[The End]**

Summary Report by MARY E. CUNNINGHAM, Reporter

Miss Cunningham Is Chief, Consumer Education Branch, Division of Consumer Education, Bureau of Education and Voluntary Compliance, FDA.

THAT CONSUMER EDUCATION should be introduced into the schools; that consumer education, in itself, should not be part of the school curriculum; that consumer education material presently issued is excellent and reaching a wide audience; that consumer education material as presently structured is aimed at a limited elite and failing to reach those most in need of it—these were some of the diverse, provocative opinions voiced by the panel.

Joint FDA-Industry Sessions

The moderator sketched briefly the history of these joint sessions and said FDA and industry had worked together for years to insure two dimensions of cooperation in food law; namely, even-handed law enforcement and the encouragement of voluntary compliance. In these areas, he said we are on familiar ground.

The Consumer Panel of the afternoon, however, was concerned with a third dimension of cooperation between FDA and The Food Law Institute (FLI): How can the FDA and industries and firms represented help the consumer get maximum benefits from the laws entrusted by Congress to FDA for enforcement? What more does the consumer need to know? How can this knowledge be made available to him in the most effective manner?

The moderator outlined the need for consumer education by referring to the fact that the public spends upward of $1 billion on worthless or falsely promoted health products and services; that consumers are often unnecessarily concerned about the safety of their foods; that they do not appreciate their opportunity and responsibility for participation in governmental processes such as standards-making; and they do not take advantage of protection provided on labels to prevent thousands of accidental poisonings each year from hazardous household products. What can be done about these things through consumer education? This was the question put to the panel.

Consumer Education for Those with Limited Income

Mrs. Aryness Joy Wickens, speaking on the subject of education for those of limited income, said that consumer education should be for everyone, that it should rightly be regarded as the essential basic of regulatory law. She said it was a shocking fact that Americans spend a billion dollars each year teaching people how to earn a living and pathetically little teaching them how to live. She urged the introduction of material on consumer education into the curriculum of the schools and advocated that this be done in multi-disciplinary ways. Don't teach a course labeled "consumer education." Introduce consumer education elements into mathematics, science, and economics.

Having urged consumer education for all people at all levels of life, Mrs. Wickens reverted to President Johnson's charge, in his consumer message to Congress of February 5, 1964, that particular attention be given to instructing those of limited income in proper consumer practices, so vital to them if they are to spend wisely the little income they do have. The President asked that the field of consumer information for this segment of the population be thoroughly explored, and, in fulfillment of his request, in mid-1964, Mrs. Esther Peterson, Special Assistant to the President for Consumer Affairs, established a panel on the subject. The panel has reviewed the field in depth and is readying a report. Mrs. Wickens gave us an advance peek at this report.

She said that one of the panel's major conclusions was that different groups needed different approaches in conveying consumer information, i.e., what is appropriate for the young married of moderate means is probably not appropriate for the elderly or the hardcore poor. Mrs. Wickens emphasized that in the latter case the person-to-person approach, in the home neighborhood, is the best. She advised that we should throw away the formal book or booklet, the erudite vocabulary, that we should explore pioneering new techniques, paying special attention to audio-visual and mass media.

Generally speaking, Mrs. Wickens urged industry to be particularly mindful of two things: first, to be aware that there is a necessity for seeing that the excellent consumer information material now available in mid-income, mid-educational level is put out in simplified form for those of more limited income; and, second, to be aware of the potential of the community programs even now being launched all over the country under the Office of Economic Opportunity as a media in disseminating consumer education materials.

Industry's Role in Consumer Education

Mr. Paul S. Willis underlined the food industry's historical concern with consumer education and referred to its part in the initiation of the FLI and the Nutrition Foundation. He pointed to the decreased percentage of income which the American consumer spends annually for his food as compared with the percentage of income his father or grandfather spent. He underscored the favorable balance in this respect when comparison is made with percentage of income spent by the average consumer in England, France, Italy, and other countries. He compared the time that the American consumer must spend to earn his daily bread with the much greater time spent by the average man elsewhere.

Mr. Willis attributed these gains in America to the cooperative efforts of farmers, manufacturers, and distributors. He referred to the fact that the food industry had supported the Food and Drug Law of 1906, and the Federal Food, Drug, and Cosmetic Act of 1938. He mentioned the recent cooperation between the food industry and the National Conference on Weights and Measures. He mentioned two recent consumer education publications of the Grocery Manufacturers of America (GMA): one million copies of one publication have been distributed and more than 600,000 copies of the other.

Finally, Mr. Willis summarized the results of the recent nationwide survey, conducted for GMA by Opinion Research Corporation, to learn what consumers think about the food manufacturing industry. He said the results show that consumers have a favorable view of the food industry and, in general, consumers are pleased with the packaging of foods.

Dr. Leonard A. Scheele developed the thesis that the consumer requires two things of his drugs: first, that they be pure and safe; second, if they are over-the-counter drugs, that they carry adequate instructions for their use. He emphasized that even those of limited education can be taught certain basic understandings in the field of drugs: first, there is some danger in all drugs; second, in using any drug, the user must be willing to accept this nominal risk; third, the drug user must take the responsibility of avoiding frauds and cheats. Dr. Scheele said the layman must be educated to accept a nominal

risk in using any drug, and drew a comparison with the man who drives an automobile and who thereby accepts a certain danger. It is the individual's responsibility to minimize that danger to the lowest possible extent, Dr. Scheele said.

Dr. Scheele agreed with his predecessors on the panel as to the importance of utilizing mass media in consumer education. He listed useful publications for consumer drug education and named helpful community organizations.

Mrs. Charlotte Montgomery said that one cannot generalize about consumers, that each is a law unto herself. The speaker made the point that she was using the pronoun "herself" since by and large she identified the consumer as primarily female. Mrs. Montgomery said that the consumer wants capsule advice, not a course in economics. The consumer wants information easy to understand, instructions easy to follow. Mrs. Montgomery said the average consumer today has really no idea of the wealth of consumer information currently available and, over and above that, she sometimes doesn't act on what she does know.

Mrs. Montgomery urged that industry and government alike:

1. Inform consumers what is available.

2. Urge consumers to make use of the help now provided for them—the directions on the package, bulletins on current subjects, leaflets provided with appliances—right up to broad basic material for group programs.

3. Continue to feed out more help through the media the woman reads, likes, believes in. Do not expect results overnight.

4. See that everything the woman is told fits into her life and is written in her language.

And, please, don't always call what you're doing "consumer education" as you try to educate the consumer—she'd far rather think she was hearing hints on how to get the most for her money!

Motivating the Consumer

Mrs. Edith Sherrard started with a tribute to the consumer education materials of both FDA and industry. But then she asked, "But this fine material, who is it for? Who is listening? Your mate-

rial is beamed at the literate, the reasonably well-educated, presupposes interest." She urged that industry and government alike seek a wider consumer audience. Make the language of publications more easily comprehensible. Reach for the groups Mrs. Wickens has spoken of.

Mrs. Sherrard advanced a suggestion that industry and government consider the possibility of setting up a ready-reference service to which the consumer can turn for the answer to a specific question. She cited such services from the Poison Control Center and the National Institute of Dry Cleaning.

Narrowing her suggestions down, she suggested that the ready-reference service might well start with the area of *safety* and *safe use* and be limited at first to foods and drugs. She said she was thinking of a loose-leaf reference to be stored in a ring binder. Speaking of drugs, she said the ready-reference might well follow the headings of FDA's *First Facts About Drugs.* On household chemicals, ready-reference material might tell the consumer how to store and to use safely, and antidotes against misuse. On foods, she would like to see an index of terms such as "additive," and definitions of common ingredients. She would like a page on *How to Read a Label.* She would make her service available to health and welfare agencies, medical societies, home economics teachers, family service agencies, the Red Cross, labor unions, Chambers of Commerce.

In concluding his talk, Dr. Scheele had thrown the panel and the audience the question, "How can various groups be stimulated to do an adequate consumer education job?" He went on to say, "I plan to leave this question unanswered for now, for I am sure that the audience and the panel will begin to have answers to the question." Obviously in an hour long session the answers had to wait. More such meetings as this joint session would go far toward finding these answers.

Moderator Proposes Establishing University Chairs of Consumer Education

The moderator closed the panel presentation with a question for Mr. Willis and Dr. Scheele. He noted that chairs of education in

various disciplines such has law, chemistry, and engineering have been underwritten at selected universities by concerned industries, and that the Food Law Institute sponsors a chair in Food and Drug Law at George Washington University. He asked whether sponsorship of a chair in Consumer Education, concerned specifically with the subject matter of this panel session, had ever been considered, and if not whether it might be mulled over as an industry project for consumer education. **[The End]**

SEMINAR TO ACQUAINT PHARMACEUTICAL STAFF WITH LEGAL CONSIDERATIONS

An intensive one-day seminar on legal considerations for pharmaceutical representatives will be sponsored jointly by The Food Law Institute and The Graduate School of Public Law of The George Washington University. The seminar will be held at The George Washington University, Washington, D. C., on Saturday, May 8, 1965.

The seminar is designed to acquaint pharmaceutical staff with the basic legal considerations that affect the medical detailman and his supervisors in regard to their company's research, promotion and sales efforts. It will acquaint pharmaceutical representatives with a broader knowledge of the motives and methods of the industry and their own role in presenting this information to the professions.

The principal speaker will be Sidney H. Willig, Esq., a pharmacist, attorney and special lecturer at St. John's University, New York, Faculties of Pharmacy and Nursing Education. Mr. Willig has for many years given a four-week course in this subject at St. John's University. Mr. Willig will be assisted in his presentation by a group of leading experts from government and industry. The luncheon speaker, Mr. Shelbey T. Grey, Deputy Director, Bureau of Education and Voluntary Compliance, Food and Drug Administration will discuss "The Government's Role in Pharmaceutical Promotion."

Topics to be examined in depth include the regulatory principles that govern drug manufacture and distribution, danger areas of communication between pharmaceutical representatives and other members of the health professions and the applicability of concepts of negligence, malpractice, product liability and warranty.

Registration forms and full details may be secured by writing to Franklin M. Depew, President, The Food Law Institute, Inc., 205 East 42nd Street, New York, New York 10017.

The Second Session of the Codex Alimentarius Commission

By FRANKLIN M. DEPEW

Mr. Depew Is President of the Food Law Institute.

THE CODEX ALIMENTARIUS COMMISSION held its second session at the Palace of Nations, Geneva, Switzerland, Headquarters of the World Health Organization (WHO), September 28—October 7, 1964. The Joint Conference on Food Standards of the Food and Agriculture Organization (FAO) and the World Health Organization which established the Commission was reported in 18 FOOD DRUG COSMETIC LAW JOURNAL 34, and the first session of the Commission was reported in 18 FOOD DRUG COSMETIC LAW JOURNAL 477. Some 140 participants, including representatives of 40 countries and observers from 17 international organizations were in attendance at the second session. I was invited to attend the meeting as an observer in my capacities as President of The Food Law Institute and as Vice-President of the Section of Food, Drug and Cosmetic Law of the Inter-American Bar Association.

The official United States delegation consisted of John L. Harvey, Deputy Commissioner, Food and Drug Administration, Delegate; Nathan Koenig, Special Assistant to the Administrator, Agricultural Marketing Service, U. S. Department of Agriculture, Alternate; and Advisers: John I. Kross, Agricultural Attache, Foreign Agricultural Service, U. S. Department of Agriculture; Clinton L. Brooke, Assistant Agricultural Attache to the U. S. Mission to the European Communities, U. S. Department of Agriculture; Dr. Andrew W. Anderson, Regional Fisheries Attache (Europe); Michael F. Markel, Senior Partner, Markel and Hill; Harry Meisel, Technical Manager and Coordinator, Corn Products International; Frank C. Elliott, Director, Overseas Department, National Canners Association; Dr. Howard C. Spencer, Biochemical Research Laboratory, The Dow Chemical Company.

Financing the Codex Program

An important item considered by the Commission was the question of financing its activities. The Twelfth Conference of FAO

directed the Director-General to make provision in the FAO budget for the Joint Food Standards Program in 1966-1967. The Seventeenth World Health Assembly requested the Director-General of WHO to study the problem of contributions to the Joint Food Standards Program during those years. The Commission recommended to the governing bodies of FAO/WHO that in view of the importance of this program to all Member Countries in both organizations the expenses of the program should be included in the regular budget of both from January 1, 1966 on. After the Commission had heard from countries which already contributed to the Trust Fund and had received promises of contribution from a number of other countries, it became clear that there was a possibility of a deficit in the proposed austerity budget of 1965. The Commission, therefore, strongly urged member countries to enlarge their contributions and to pay them as early as possible in 1965. The contribution suggested for the United States was $30,000.00, double that of previous years.

The official United States Government position has been that these expenses should be paid out of the regular FAO/WHO budgets. There appears to be no grounds for hope, however, that our government will change its position, or that the Congress will make an appropriation for this work in the budget. This means that American industry will again be called on to furnish these funds. The Food Law Institute has been instrumental in assuring that United States interests would be adequately represented in the past by securing industry contributions to the Trust Fund for the years 1962, 1963 and 1964. All food companies and their suppliers have an important stake in this matter. The Commission's food standards work will proceed in any event, whether for ill or good. Now is the time for decision as to whether or not the interests of American industry will be best protected by full participation in the workings of the Commission. We cannot expect that they will be unless we honor this Trust Fund request. Checks should be made payable to The Food Law Institute and should indicate that they are contributions to the Special Trust Fund for the Codex Alimentarius Commission.

Organization of the Meeting and Adoption of the Agenda

The Second Session of the Codex Alimentarius Commission was opened by Mr. John L. Harvey (United States) who had been elected Chairman at the First Session of the Commission to serve until the end of the second session. The Vice-Chairmen, also elected at the

previous session, were Dr. M. J. L. Dols (Netherlands), Dr. Z. Zaczkiewicz (Poland), and Mr. H. Doyle (New Zealand).

The Chairman then introduced Dr. F. Grundi, Assistant Director-General of WHO. In behalf of the Directors-General of FAO and WHO, Dr. Grundi welcomed the participants to Geneva and wished them a successful second session. Dr. Grundi pointed out that the particular concern of the conference should be the desirability of removing as far as possible economic as well as non-economic obstacles to the free movement of commodities in international trade. He assured the audience that both Directors-General felt that the Commission had a very important role to play in assisting the developing countries to acquire soundly based food technology and practices, and at the same time helping to do away with restrictions in world markets due to well-founded but often independently drafted national food legislation. He went on to say that it was particularly gratifying to the Directors-General that the Commission at its first session placed much emphasis on the need to elaborate international standards on the widest possible basis and that in most cases a worldwide standard was envisaged.

Chairman Harvey then reviewed the work done to date by the Commission and its Expert Committees and he introduced Mr. Graham Kermode of FAO who had been selected by the Executive Committee of the Commission as Officer in Charge, Food Standards Program, to replace Mr. Francis H. Townshend who resigned.

The delegates then discussed the provisional agenda which had been prepared by the Executive Committee of the Commission. After making a number of revisions the agenda was adopted. Since Chairman Harvey presided at all plenary sessions Mr. Koenig served as the Delegate of the United States throughout the meeting.

This second session was principally concerned with the detailed consideration of draft standards on which comments had been received from member governments and, in addition, with reports on work accomplished by the Expert Committees, working parties and other groups. To indicate the extent of this work, no less than 48 meetings dealing with food standards were held during late 1963 and early 1964, including three meetings of the Executive Committee. Most certainly a great deal of work was done by the various member governments, Codex Committees and other groups between the First and Second Sessions.

European Proposal for Autonomy in Developing Standards

One of the most important accomplishments of the second session was the Commission's reaffirmation of the guiding principle that food standards will be set up on a worldwide basis. In connection with this the Commission adopted procedures for setting up regional standards where necessary and clarified the relationship between regional and worldwide standards. Agreement was also reached on the relationship of regional groups to the Commission.

In a letter dated June 24, 1964, Professor Otto Högl, president of the European Council, who had been designated by the Commission at its First Session as Coordinator for Europe, stated that a meeting had been held in Berne in May attended by delegates from 15 European countries and two European international organizations either as members or as observers for their countries. The letter went on to say that instead of serving as an "Advisory Group for Europe" of the Codex Alimentarius Commission, the Council of the Codex Alimentarius Europaeus proposed that it continue as an autonomous body with its own independent plenary assembly and executive body with power to establish, approve, and issue standards for the European area in those fields which are of interest only from the regional point of view.

Under these conditions, if accepted by FAO and WHO, the European Council would function as a regional organ, and not as an Advisory Group of the Codex Alimentarius Commission with respect to the European area. Moreover, the Coordinator for Europe would be appointed by the Commission on the proposal of the plenary assembly of the European Council instead of by the Commission itself as the Rules of Procedure provided.

In reporting to the Commission on the work of its Executive Committee Chairman Harvey explained the situation and the proposal of the European Council of the Codex Alimentarius to be affiliated with the Codex Alimentarius Commission in an autonomous fashion. At the request of the Commission, Professor Högl, in his capacity as the Coordinator for Europe, convened a meeting of countries of the European Region to discuss the proposal that had been made and the procedures that would be involved under it for the elaboration of regional standards.

At this meeting the European countries decided that they would only propose revised procedures setting forth the steps for the establishment of regional standards. Following a full discussion of

the agreement resulting from the meeting of countries of the European Region, the Commission established a Working Party under the Chairmanship of Mr. J. H. V. Davies (United Kingdom) and including representatives of the Delegations of Australia, France, India, and the United States.

This Working Party was given the responsibility of considering (making recommendations on any amendments or additions to the Rules of Procedure on any matters as might appear necessary) an extract of the report of the FAO Committee on Constitutional and Legal Matters which dealt with the Rules of Procedure of the Commission and the agreement reached by the meeting of the countries of the European Region, including the procedure listing steps for the preparation of regional standards. In order to carry out the agreement reached relative to regional standards Rule VI 3 was revised to read as follows:

> At the request of a majority of the countries constituting a given region or group of countries specifically enumerated by the Commission that a standard to be elaborated, the standard concerned shall be elaborated as a standard primarily intended for that region or group of countries. When a vote is taken on the amendment or adoption of a draft standard primarily intended for a region or group of countries, only members belonging to that region or group of countries may take part in the voting. The adoption of the standard may, however, take place only after submission of the draft text to all members of the Commission for comments. The provisions of this paragraph shall not prejudice the elaboration or adoption of a corresponding standard with a different territorial scope.

Under this provision it is clear that a standard developed for a region or group of countries cannot be adopted without the draft text first having been submitted to all members of the Commission for their comments. This provides protection as well as an opportunity for a member country to express its view on a draft standard in advance of its adoption. On the other hand this does permit the simultaneous establishment of standards in different regions for the same product. While there may be circumstances where such a development would be acceptable or indeed desirable, it could lead to restraint of trade and an actual increase in the differences in the food laws of the various countries contrary to one of the aims of the Commission's work. Thus, the main safeguard against these possible difficulties is the good sense and discretion of the members of the Commission.

Following the adoption of the amendments to the Rules of Procedure, the Commission established a Coordinating Committee for Europe. This takes the place of the Advisory Group for Europe

established at the First Session. The Commission defined the membership and terms of reference of the Coordinating Committee for Europe as follows:

Membership: All member governments of FAO and/or WHO within the geographical area of Europe, including Israel, Turkey, and the U.S.S.R.

Terms of Reference: To advise and assist the Coordinator for Europe on all matters concerning the preparation of draft standards and also to carry out any of the functions entrusted to coordinating committees as set out and adopted by the Second Session of the Commission.

Chairman: Ex officio, the Coordinator for Europe.

At its first session the Commission, acting on a proposal made by the European Region, designated Professor O. Högl as Coordinator for Europe for a period of two years. Under the terms of reference for that position, the Coordinator for Europe had the responsibility for advising and assisting the chairmen of the Codex Commission committees set up on the basis of countries in Europe in their common work on food standards throughout the region. With the elimination of the advisory groups through amendment of the Rules of Procedure, Professor Högl agreed to accept the chairmanship of the Coordinating Committee for Europe.

Other Important Amendments to the Rules of Procedure

Important progress was made by the Working Party in clarifying the Rules of Procedure including clarification of the Procedure for the Elaboration of Standards, not only with respect of regional standards, but for worldwide standards as well. This clarification was essential if the work of the Commission was to proceed in an orderly manner. The language used in the revision makes it clear that the Commission can, subject to the Rules of Procedure themselves, lay down the steps to be taken by the Commission, its subsidiary bodies and other bodies assisting it in its work in the elaboration and final adoption of standards. The amended Rules of Procedure also do away with the establishment of "advisory groups" as it was considered that the term "coordinating committees" would more properly express the proposed functions of these subsidiary bodies.

The Rules of Procedure were also amended in various respects to bring them in line with the requirements of the FAO Committee on Constitutional and Legal Matters. The Secretariat was requested by the Commission to submit the amended Rules of Procedure to the Directors-General of FAO and WHO for their approval.

General Principles

Another important matter which was discussed at considerable length by the delegates was the matter of general principles. Various delegates reviewed the comments which had been submitted by governments on the general principles that had been extracted from the text of the Codex Alimentarius Europaeus and the general provisions extracted from the draft Latin American Food Code, both of which had been considered in first reading by the Commission at its first session.

The delegate of France expressed the view that the Commission should draft its own general principles in order to remove any ambiguity regarding the purposes of its work. He then submitted a paper which outlined the kind of standards his country felt should be developed, the food field to be covered, and the relationship that the Commission should have with other international organizations. He stressed that standards developed by the Commission should exclude those of a strictly commercial nature, since such work is being carried out by a number of other international organizations. In response, Mr. Nathan Koenig, Delegate for the United States, pointed out that standards developed by the Commission should serve a purpose in facilitating international trade as well as safeguarding the consumer interest in wholesome food.

The Commission concluded that work should be undertaken to develop general principles of the "Codex" to be divided into three parts. The first part should consist of a statement of the purpose and scope of the Codex and the nature and type of standards to be included. Definitions would also be included to prevent any misunderstanding with regard to terminology. The Secretariat was requested by the Commission to prepare a draft paper utilizing, to the extent possible, suggestions included in the paper submitted by the French delegate.

The second part of the general principles should consist of the Rules of Procedure as they might be amended from time to time. The third part of the general principles, should consist of the general principles governing food standards, including general provisions and necessary definitions.

The Secretariat of the Commission was requested to develop a questionnaire as soon as possible and to submit it to member governments to obtain, on the basis of whatever legislation they may have, suggestions on general principles relating to food standards and re-

quirements for safeguarding consumers from unwholesome food. This information is to be collated by the Secretariat.

When the Secretariat completes its work in developing the three-part draft of the general principles, this paper will then be referred to the new Codex Committee on General Principles which was established by the Commission along with the collated responses received from Governments in reply to the questionnaire sent to them by the Secretariat. In addition, the Codex Committee on General Principles is to receive for its consideration the comments made by member governments on the general principles extracted from the Codex Alimentarius Europaeus and the general provisions extracted from the draft Latin American Food Code. It was suggested that France should serve as chairman of this committee. The delegate of France said he would refer to his government the suggestion made that his country serve as chairman of the committee and would in due course advise the Directors General of FAO and WHO of the decision.

Work of the Second Session

The Commission established two sub-committees to consider first and second readings of standards. These were as follows: Sub-Committee I—General Principles, Additives, and Labelling under the chairmanship of Dr. M. J. L. Dols (Netherlands); Sub-Committee II —Food Standards, under the chairmanship of Mr. K. P. Mollenhauer (Federal Republic of Germany).

The Commission received progress reports from representatives of the Member Governments chairing Codex Committees as well as organizations designated by the Commission at its First Session for the promulgation of draft standards or the development of other preparatory material. The actions taken by the Commission with respect to food additives and pesticides follow.

Food Additives

A progress report on the work of the Expert Committee on Food Additives was presented by Dr. M. J. L. Dols (Netherlands), Committee Chairman. Although specific tolerances for additives in particular foods had not as yet been proposed, the report indicated which antimicrobials and antioxidants were being considered. During the course of discussion of the report, efforts were made to clarify the interrelationship and the main functions of the FAO/WHO Expert Committee on Food Additives and the Codex Commission's Com-

mittee on Food Additives. It was brought out that the Expert Committee under the chairmanship of the Netherlands is made up of representatives of governments desiring to participate in its work. This Committee's responsibility is to establish tolerances for individual food additives in specific foods. It also has the responsibility for preparing lists of food additives to guide the Joint FAO/WHO Expert Committee on Food Additives in consideration of its future work.

It was also brought out that the Joint FAO/WHO Expert Committee on Food Additives was made up of experts invited by the Directors General of FAO and WHO to serve in their individual capacities because of their qualifications as experts in the field of food additives. This Expert Committee has the duty of establishing acceptable daily intakes for various food additives on the basis of toxicological evaluations and to prepare specifications of identity and purity for these additives.

Considerable discussion developed as to the procedure that should be followed in getting a food additive considered and cleared by either the Joint FAO/WHO Expert Committee on Food Additives or the Codex Committee on Food Additives, or both as the case may require, whereupon a procedure was adopted which sets forth the steps to be followed by governments desiring to have an additive considered for use in a food on an international basis.

Various committees, international organizations, and other bodies assigned responsibility by the Commission for developing draft food standards are expected to prepare lists of additives used in any of these foods and submit them to the Chairman of the Codex Committee on Food Additives. Information should also be supplied on levels of use consistent with good manufacturing practices, as well as information on the per capita consumption of the foods involved.

Acting on a recommendation adopted by Sub-Committee I, and originally proposed by Mr. Nathan Koenig, the U. S. Delegate, the Commission referred to the Codex Committee on Food Additives the comments made by member governments on the lists of the various food additives which were considered in first reading by the Commission at its first session and subsequently sent to governments for their views. Since these comments included suggestions for additions, deletions, and other modifications in the various lists of antimicrobials, antioxidants, emulsifiers, stablizers, and maturing and bleaching agents which had previously been considered in first reading, the Commission proposed that

member governments should supply either to the Codex Committee on Food Additives or to the Joint FAO/WHO Expert Committee on Food Additives, as appropriate, supporting data or any proposals made by them for changes in these lists.

The Commission confirmed continuance of the Codex Committee on Food Additives under the chairmanship of the Netherlands. The second meeting of this Committee is expected to be held during the last week of April 1965, in The Hague.

Pesticide Residues

A brief report on the status of work of the Expert Committee on Pesticide Residues, which is chaired by the Netherlands, was presented by Dr. M. J. L. Dols. This report indicated that the Committee can begin its work only after the FAO Working Party on Pesticide Residues and the WHO Committee on Pesticide Residues have met to discuss and list tolerances for selected pesticides.

Mr. Nathan Koenig, the U. S. delegate, urged that the Expert Committee on Pesticide Residues address itself initially to those pesticide residues occurring in or on foods which are important in international trade. He said the priorities thus determined should be furnished to the FAO Working Party on Pesticide Residues and to the WHO Committee on Pesticide Residues so that these bodies could consider the list at their earliest opportunity. The delegate of France agreed with the statement made by Mr. Koenig. The delegate of India also supported the statement but asked that priority attention be given to pesticides used on cereals.

In addition the Commission received progress reports from its Expert Committees and other organizations on Cocoa Products and Chocolate (Switzerland), Oils and Fats (United Kingdom), Margarine (International Federation of Margarine Manufacturers), Olive Oil (International Olive Oil Council), Food Hygiene (United States), Milk and Milk Products (Secretariat), Meat and Meat Products (Federal Republic of Germany), Fruit Juices (Joint ECE/Codex Alimentarius Commission Group of Experts), Frozen Food Products (Secretariat) Processed Fruits and Vegetables (United States), Fresh Fruits and Vegetables (Joint FAO/ECE Secretariat of the Committee on Agricultural Problems of the Economic Commission for Europe), Sugars (United Kingdom), Cocoa Beans (FAO Study Group), Wheat (International Organization for Standardization), and Sampling (International Organization for Standardization).

The Oils and Fats Committee developed specifications of identity for 21 crude fats and oils which have been circulated for comment to all governments. The next step will be to develop standards for products for direct consumption such as cooking fats and oils, lard, shortening and table oils. The scope of this committee was widened to include olive oil and margarine within its terms of reference. The International Federation of Margarine Manufacturers submitted a "trading" standard for margarine. It was decided this should be revised in the light of governments' comments which were to be sought by December 31, 1964, and then referred to the Oils and Fats Committee for consideration. The Joint ECE/Codex Alimentarius Group of Experts on Standardization of Fruit Juices reported that apple juice, orange juice and grape juice are to be given priority in the promulgation of standards. In discussing the report on wheat it was pointed out by some delegates that work in developing standards for all cereals should be undertaken in view of their importance in the diets of many countries, particularly in the developing countries. Consideration of standards for eggs, poultry, meat and soft drinks was deferred. It was reported that Austria had been unable to accept chairmanship of the Expert Committee on Methods of Analysis, and the delegate of the Federal Republic of Germany offered to accept this responsibility subject to confirmation by his Government.

Considerable discussion developed among the delegates as to the scope of work that the Committee on Hygiene should undertake. The Chairman proposed a small working party to clarify the scope of the work embodied in the terms of reference of the Committee on Food Hygiene and designated as a working party Canada, France, Germany, India, and the United States with Mr. Nathan Koenig, the U. S. Delegate, serving as Chairman. On completion of its assignment, the working party made its report which set forth in some detail the responsibilities of the Codex Committee on Food Hygiene. After discussion by the Commission the report was adopted in principle.

The United States chairmanship of the Codex Committee on Food Hygiene was confirmed by the Commission.

Food Labelling

A paper on general food labelling provisions prepared by the FAO Legislation Research Branch was considered by the Commission. This paper contained information supplied by governments on their food labelling requirements. The Commission decided that when

revision of the paper is completed, it be given the widest practicable circulation. In addition, the revised document should be offered to the Codex Committee on Labelling which the Commission established for the purpose of developing food labelling standards. The Commission accepted an offer by the Canadian Delegation that Canada would serve as chairman of the Committee. This Committee would function under the following terms of reference:

1. To draft provisions on labelling applicable to all foods.

2. To draft provisions on labelling concerning products given priority by the Commission, namely products referred to specific Codex Committees for the elaboration of standards.

3. To study specific labelling problems assigned to it by the Commission.

Election of Officers for Third Session

The election of the Chairman and three Vice-Chairmen for the next year was held toward the end of the session and was presided over by Dr. J. V. A. Nehemiah, who represented the FAO Director General. All of the officers were reelected.

High tribute was paid to Mr. Harvey by a number of delegations for his outstanding performance as Chairman. This tribute was well deserved.

Accomplishments of Second Session

The second session of the Commission appears to have cleared the way for the serious consideration of food standards which may be expected to lead to their ultimate adoption. Because of various frames of reference and differing national cultures, it has been somewhat difficult for the delegates to communicate fully at these meetings. However, an increased spirit of mutual understanding was apparent among the delegates at the second session as to the problems involved in furthering international food standardization. This resulted in a strengthening of the fundamental principles under which the Commission operates.

From the standpoint of the United States the second session was one of successful accomplishment. Much of the credit for this accomplishment should go to Mr. Nathan Koenig who worked so diligently and effectively throughout the session to this end. Mr. Koenig submitted the Official Report of the United States Delegation to the

Second Session of the Codex Alimentarius Commission with the U. S. Secretary of State on December 8, 1964. Copies may be secured by writing to Mr. Koenig, c/o The U. S. Department of Agriculture, Washington, D. C. The American food industry can take pride in the fact that Mr. John L. Harvey was elected Chairman of the Commission for another year. This assures the continuity of guidance which is essential to assure the adoption of food standards on a truly international basis.

Important Future Problems

Looking ahead it seems likely that the next matter of major importance which will be reviewed at length by the Commission is the scope and kind of standards which will be developed.

This may be expected to be spearheaded by France, a leading member of the Common Market. The first indication of this was given during the second session, when the delegate of France expressed the view that the Commission should draft its own general principles regarding the purposes of its work and in that connection submitted a paper which revealed much of what was involved behind the French proposal. Essentially, the underlying objective appears to be confining the scope of the Commission's work to the development of standards which are primarily designed for the protection of consumer health. This would in effect remove the Commission from the field of standards that would provide (1) a common language between buyers and sellers, and (2) facilitate international trade. The French view appears to be that work in developing such standards is already being carried on by a number of other international organizations, of which there are those that function under agreements with governments outside the scope of the Commission.

The Commission recognized the need to develop general principles to guide its work, but the French argument that the field of its activity should be narrowed did not appear to find support. It was decided to establish a Codex Committee on General Principles of which France was selected as Chairman. From the standpoint of the United States and its interest in the Codex Alimentarius Commission as originally conceived, it appears of utmost importance that this country participate fully in the work to be undertaken by the Codex Committee on General Principles. **[The End]**

Food Standard Making Procedures

By ALAN H. KAPLAN

Mr. Kaplan Presented This Paper at the Symposium on The Legal Basis and Regulatory Use of Food Standards, in Washington, D. C. on December 1, 1964. He Is Lecturer on Food, Drug and Cosmetic Law, The Graduate School of Public Law, George Washington University.

IT HAS BEEN OBSERVED, and only in a partially jesting manner, that a lawyer can devote time throughout his entire professional career to a particular food standard making proceeding but, if judicial review of the administrative standard adopted is sought, the work entailed in obtaining such review will have to be passed on to the next generation. This is not necessarily an undesirable situation, from the lawyer's financial viewpoint. It may also be considered by some, as an unavoidable incident to administrative due process of law.

Notwithstanding the seemingly interminable time involved in the adoption of many food standards, since the enactment of the Federal Food, Drug, and Cosmetic Act in 1938, such standards have been formally promulgated for 17 broad categories of foods into which fall approximately 250 different food varieties. It has been estimtaed that the foods subject to these federal standards comprise over 60 per cent of the packaged food products available on the retail market today. A somewhat higher percentage is involved when those foods are taken into consideration which have been standardized directly by Congress and administrative agencies other than the Food and Drug Administration (FDA). The Department of Agriculture, for example, has promulgated standards for various meat and poultry food products. Under any circumstances, it is evident that the bulk of commercially marketed packaged food products today are controlled directly by the Federal government with respect to many of the specific attributes of their composition. Of course, all food products, standardized or not, whose basic components have been in, or which themselves enter into, interstate commerce are subject to the general adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

The statutory authority for the adoption of food standards under the Federal Food, Drug, and Cosmetic Act is contained in section 401

of that statute. Section 401 authorizes the Secretary of Health, Education and Welfare (which authority has been delegated to the Commissioner of Food and Drugs) to promulgate regulations fixing *reasonable* standards of identity and quality for all foods other than butter and most fresh and dried fruits and vegetables whenever, in the judgment of the Secretary, "such action will promote honesty and fair dealing in the interest of consumers." Standards of fill of container, as distinguished from standards of identity and quality, are authorized for all foods which may be packaged. The adoption of such standards is also premised upon the basic considerations that they be reaonable and that they promote honesty and fair dealing in the interest of consumers.

Reasons for Food Standards

Why is there a concept of standardized foods? Basically, such standards were authorized in 1938 in order to effectively regulate foods, which though not composed of dangerous or deleterious ingredients, were considered to be cheapened in the economic sense; that is; economically adulterated. In the case of the identity of a product, economic adulteration might involve the entire or partial replacement of more expensive and desirable ingredients in the food with substitute ingredients considered as inferior. With respect to the quality of a food, economic adulteration involves the marketing of substandard food items as concerns their texture and appearance. The concept, as it applies to fill of container, relates to the package of food appearing to contain a greater quantity than it in fact might actually possess. Thus, the concept of food standards is premised largely upon economic considerations with the economic interests of the consumer being foremost, rather than upon considerations of physical health and safety. The concept of food standards, particularly those concerning identity, has been stated to "reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other." Thus, though informative labeling has been one of the prime objectives of the Federal Food, Drug, and Cosmetic Act, in the case of certain foods at least, even the attainment of that objective was not considered sufficient to protect the consumer adequately. Accordingly, the concept of mandatory food standards came into being. While the concept may appear a reasonable one in theory, there is broad disagreement today as to whether it has proved to be so in fact.

Procedure in Adoption of Food Standards

The formal statutory procedure involved in the adoption of all food standards under the Federal Food, Drug and Cosmetic Act, whether they pertain to identity, quality, or fill of container, is set forth in rather specific terms in section 701(e) of the Act. (The informal procedures involved are not contained in any written protocol, statutory or otherwise.) Section 701(e) provides that a regulation (which is, of course, what all of the food standards are) may be proposed either by the Secretary, on his own initiative, or by petition of "any interested person" who shows "reasonable grounds" for the regulation. In practice, it has turned out that most of the original standards which have been adopted have come about on the initiative of the FDA (at least in the formal sense) but that amendments to these standards have resulted from industry requests. Regardless of whether a basic standard or an amendment to an existing standard is involved, the basic considerations in its adoption are the same—that is, that it be reasonable and that it "promote honesty and fair dealing in the interest of consumers."

There is no specific form or content prescribed by the Federal Food, Drug, and Cosmetic Act for the "petition" of the "interested person" seeking the food standard or the amendment other than that it show reasonable grounds for the standard. Under regulations which have been promulgated by the FDA, the term "reasonable grounds" has been interpreted to mean that the proposal include a statement of the facts that the petitioner asserts he is in a position to substantiate by evidence in the event a public hearing is ultimately held on his proposal; that such asserted facts furnish substantial support for the proposal and warrant a conclusion that the proposal is reasonable; and that the proposal if adopted, would meet the other basic statutory requisite of promoting honesty and fair dealing in the interest of consumers.

Regardless of whether a food standard is proposed by the FDA on its own initiative or by way of a petition of an interested person showing reasonable grounds, it is required by law that the proposal be published in the *Federal Register* in order to "afford all interested persons an opportunity to present their views thereon, orally or in writing." Traditionally, the FDA has requested that such views be made known in writing by filing them with the FDA's Hearing Clerk in Washington. Generally, a period of about 60 days is provided in

which to submit such comments although this time period is of no controlling significance. It can be assumed that all relevant comments which are submitted before a final order is prepared will be considered by FDA officials.

After the comments to the proposal have been considered, to a greater or lessor degree, and after the FDA has formed its own opinion with respect to the merits of a proposal submitted by an "interested person," that is, anyone other than the FDA itself, a publication of a presumably "final order" is made in the *Federal Register*. At times, particularly where a proposal to amend a food standard has been made by an industry member, it is possible for years to pass before FDA action is forthcoming. It is not infrequent for time delays of the same general order to take place, however, even where the FDA itself has initially proposed the standard. Perhaps a major reason for these time delays is the fact that the FDA frequently insists upon limiting optional ingredients in the food, even those performing a specific function such as emulsifiers, to particularly named substances. While some justification for such a practice may have existed prior to enactment of the Food Additives Amendment of 1958, with the passage of that amendment all such arguments became obsolete. No longer is there any basis whatever for the FDA to concern itself, in food standard making proceedings, with whether a proposed optional ingredient is or is not established to be safe for use. Concern with problems of this type has been wholly eliminated by the Food Additives Amendment. Rather, under the existing statutory structure, it would seem reasonable to permit the use of any ingredient as an optional one so long as it is either generally recognized as safe or is an approved food additive. Approximately two years ago it appeared as if the FDA were in fact adopting such a policy, at least partially. At that time, a food standard was proposed for frozen raw breaded shrimp. With respect to the breading ingredients, no specific substances were listed in the proposal. Rather, it was provided that "such ingredients consist of suitable substances which (1) are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Food Additives definition section) or (2) if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act." However, continued adherence to such a policy has not been forthcoming in subsequent food standard proposals. Thus, for example, the recently revised proposal to standardize peanut butter,

though substantially modified from the proposal as originally published in 1959 and from the "presumably final order" which issued in 1961, still lists the specific optional ingredients which may be used in the food.

The presumably final order mentioned previously, which is ultimately issued, is not necessarily identical in content to the proposal which preceded it. Frequently, regardless of the identity of the person who initially proposed the standard, the FDA, after passing judgment upon the proposal and having evaluated the comments received, changes it substantially. By virtue of such changes by the FDA an interesting question is presented as to whether the FDA becomes, in a legal sense, the proponent of the standard. This can have a significant bearing upon the procedure followed should a public hearing ultimately come about.

When the presumably final order is published in the *Federal Register,* a presumably effective date is given which may not be less than 31 days after the order's publication. In practice, the presumably effective date is generally set at either 60 or 90 days after the publication of the presumably final order. At any time during the 30 day period following publication of the order, any person who, in the statutory language, will be "adversely affected" by it if it is placed into effect may file objections to the particular provisions of the order he deems objectionable. The status of an "adversely affected" person with respect to the filing of such objections is a somewhat more limited one than the status of an "interested person" who may propose a food standard initially. At any rate, if objections are filed by an adversely affected person, and the grounds for the objections are stated, and a public hearing is requested upon such objections, the filing of the objections themselves stays the effectiveness of those provisions of the order to which objection has been raised.

Criticism of New Food Standard Hearings

The procedure last described, relating to objections staying the effect of the presumably final order, has been part of the food standard making procedures only for the last 10 years. Prior to 1954 it was required that in the case of every proposed food standard a public hearing be held with respect to the merits of the proposal. This procedure was found to be extremely wasteful and unnecessarily time consuming in the case of those proposed standards, the contents of

which satisfied everyone, or at least were not particularly objectionable to anyone. In 1954, as a result of the Hale Amendment, the procedure for standard making was changed so that a hearing was required only when objections to a proposal were raised. The purpose of the Hale Amendment was one of simply avoiding unnecessary public hearings. An incidental and unfortunate result of it, however, has been the turning topsy-turvy of the procedure at a standard-making hearing, based upon an FDA proposal. This result has not come about from the Hale Amendment itself but rather, from a somewhat unusual interpretation given to part of its language by the FDA.

As stated, section 701(e), the hearing section of the Federal Food, Drug, and Cosmetic Act, provides that a person filing objections to the presumably final order must request "a public hearing upon such objections." The FDA has concluded that the fact of the requesting of the hearing makes the person so seeking it the proponent and, therefore, that person has the burden of going forward with the initial evidence at the hearing. This view is typified by the following quotation taken from one of the more recent transcripts of a hearing based upon a standard of identity proposed and advocated by the FDA. The person quoted is the hearing examiner in charge of the proceeding:

> Now, further, since section 701(e) provides that this hearing is on the objections raised to the Commissioner's order, as we have done in the past we will take evidence first from the objectors to the order, and then from those who intend to appear in support of the Commissioner's order . . .

It is submitted that this construction of the Hale Amendment is unreasonable and, to a large degree, productive of much of the confusion which frequently takes place at standard making proceedings. It is submitted further that this construction is inconsistent with the purpose of the Hale Amendment and wholly at odds with the FDA's own regulations. It is submitted, too, that this procedure is followed only when it suits the purposes of the FDA and not uniformly. Thus, where a hearing takes place as a result of a proposal which has been advocated by someone in industry, rather than by the FDA, the rule as to the burden of going forward initially with the evidence is somewhat different. In such an instance, as illustrated by the transcript of a hearing held just this year, it was stated by the Hearing Examiner that "under the rules under which we operate this hearing, the proponent, of course, goes forward, that is those who are asking for the amendment to the standard." Thus,

by applying the rule it desires, the FDA always seems to push the burden of going forward initially with the evidence upon the other side. Never does it seem to assume such burden itself, even when it is the initiator of the proposed rule. This state of events becomes even more perplexing when it is realized that the FDA's own regulations with respect to hearings of the standard making type state that

> To promote orderliness and clarity of the record, evidence shall be received with respect to the subject matter of the hearing in the following order, . . . (3) At each stage of the hearing, whether general or specific, evidence shall be received first in support of the proposal, followed by the evidence opposing the proposal.

This procedural rule is a reasonable and proper one and there are few, if any instances, which would warrant departure from it. It casts the burden upon the proponent of a standard, or an amendment to a standard, to demonstrate initially through his evidence that the proposal is meritorious and reasonable and would accomplish the statutory objective of promoting honesty and fair dealing in the interest of consumers. The presentation of the proponent's evidence first provides a basic and necessary foundation to the hearing which enables those who object to the proposal, whether they be segments of industry, consumer groups, or the FDA, to direct their own testimony to specific points. This makes for a much more meaningful and orderly presentation. The procedure which up to now has been followed, however, which frequently requires the objectors to the standard to put forth their case first, amounts to the making of shots in the dark and results too often in a confused and almost incomprehensible record.

The incumbent Hearing Examiner for the FDA, who is thoroughly familiar with past practices followed at food standard making hearings, has stated that in future matters which arise before him the procedure which will be followed will be to have the proponent of the standard, be it the FDA or another party, present its case initially. Such a practice, of course, will merely give effect to the procedural regulations long ago adopted by the FDA.

Until recently, another aspect of the procedure followed at food standard hearings was subject to serious question. This involved the status of the person sitting in the role of Hearing Examiner at the proceeding. As you may know, under the Administrative Procedure Act (APA)[1] it is required that in the case of certain hearings, includ-

[1] Act of June 11, 1946, 60 Stat. 237, 5 U. S. Code, Secs. 1001-1011, as amended.

ing food standard hearings, "there shall preside at the taking of evidence . . . one or more examiners appointed as provided in [Section 11 of the APA]." Among the requirements imposed with respect to such Hearing Examiners by Section 11 is one that states the Examiners "shall perform no duties inconsistent with their duties and responsibilities as examiners." One of the basic reasons for this requirement was to insure the independence of the Examiners from control by the agency for which they are appointed. However, for several years the Hearing Examiners assigned to preside at food standard making proceedings, as well as at other hearings held under the Federal Food, Drug, and Cosmetic Act, were, in addition to being duly appointed Hearing Examiners, also attorneys in the Office of the General Counsel handling the legal affairs of the FDA. Thus, in addition to their duties as Hearing Examiners, which were supposedly independent of control by the FDA, such persons were also performing duties as advocates for the FDA. Moreover, on at least one occasion, the Examiner in a hearing proceeding was also the subordinate of the attorney advocating the views of the Agency. It takes little imagination to conclude that the occupation of such a dual status by the examiner was wholly inconsistent with the requirement of the APA that he "perform no duties inconsistent with [his] duties and responsibilities as [an] examiner." It might be argued that it really makes no difference in these so-called "rule-making" proceedings, whether the Hearing Examiner is or is not wholly independent of the FDA to which he is assigned, since the Examiner in such proceedings makes no order whatever with respect to the matter before him. It is to be remembered, however, that the Hearing Examiner does rule upon the admissibility of the material offered in evidence at the proceeding and that he controls the entire procedure followed at the hearing and that, through such powers, he can unquestionably affect the record that is made at the hearing. This becomes exceedingly important since the final rule which issues must be based upon substantial evidence of record at the hearing. Fortunately, during this past year the situation has changed. No longer is the Hearing Examiner assigned to the FDA also employed as an attorney for the FDA. Rather, his duties are now the full-time duties of a Hearing Examiner and his independence of action and freedom from internal pressures are more properly assured. This may be one reason why, with respect to the evidentiary procedure to be followed at future standard making hearings, full adherence may be expected to be had to the published procedural regulations of the FDA.

In those situations where a public hearing is required to be held because of objections having been raised to a proposed food standard, or to an amendment to an existing food standard, any interested person who desires to participate in the hearing may do so. Participation is not limited to those who filed the objections or to those who would be "adversely affected" by the standard. Each party participating at the hearing must personally arrange for the presence of those witnesses he proposes to have heard. All of these witnesses, of course, appear voluntarily since there is no compulsory process provided for under the Federal Food, Drug, and Cosmetic Act. The evidentiary rules applicable to the hearings are much less rigid than those which prevail in the courts, the only criteria being, under the FDA's regulations, that such evidence be "relevant and material." The specific rules concerning testimony and evidence are contained in section 1.707 of the FDA's regulations. Much discretion, however, with respect to evidentiary matters, is left to the Hearing Examiner.

A complete verbatim transcript is made of all testimony given at the hearing. Notwithstanding the fact that the Hale Amendment has to a large degree resulted in a reduction of the duration of hearings, it is not infrequent for the transcripts to come to six or seven thousand pages.

At the conclusion of the hearing proper, under existing rules of practice, the Hearing Examiner's function wholly ceases. While proposed findings of fact and briefs may be submitted within a specified time period by all persons who appeared at the hearing, these proposed findings are not submitted to the Hearing Examiner but to the FDA itself through the Hearing Clerk. Thereafter, the FDA issues its proposed order together with its proposed findings of fact based upon the record of hearing. While such a proposed order is not required by either the Federal Food, Drug, and Cosmetic Act or the APA, it is provided for by the Agency's regulations. Again, under the Agency's regulations, exceptions to the proposed order may be filed by any interested person whose appearance was filed at the hearing. Thereafter, a final order is adopted by the Agency which may be subject to judicial review in the U. S. Court of Appeals. With all of this procedure, it is probably now quite obvious how a lawyer can devote several years of his professional career to a particular standard making matter.

It seems quite strange, to me at least, that the function of the Hearing Examiner at standard making proceedings ends before

the fact-finding stage begins. It would appear that of all persons, he is the best suited to find the facts objectively. Under existing procedures, however, all fact finding duties, at both the initial and the terminal stages, are given to the Commissioner of Food and Drugs directly. While there is no statutory objection to this practice, neither is there statutory objection to changing it so that the duty of issuing proposed or tentative findings of fact rests with the independent Hearing Examiner who presided at the hearing. Perhaps, in the not too distant future, such a procedure will be adopted.

There is much more to be said concerning food standard making proceedings but time is running out. For example, while from the legislative viewpoint these proceedings are considered "rule-making," in fact, they are frequently more adjudicative than many court cases. Too, the large numbers of persons participating in such hearings and often representing widely diverse views frequently renders the hearings unwieldy and resemblant of a Roman circus. There is more to be said with respect to fact findings based upon substantial evidence of record and judicial review, but such comments will have to be for another time—or another generation. **[The End]**

DRUG ABUSE CONTROL BILL PASSED BY HOUSE

On March 10, 1965, the House of Representatives passed the "Drug Abuse Control Amendments of 1965," (H. R. 2). The bill would provide increased controls over barbiturates, amphetamines, and other stimulants or depressants which the Secretary of Health, Education and Welfare finds have a potential for abuse. After passage by the House, the bill was sent to the Senate Committee on Labor and Public Welfare for further action. It would become effective on the first day of the seventh month after enactment.

All persons in the distribution chain, from manufacturer of basic materials through the retailer (or dispensing doctor) would be required to inventory all covered drugs as of the effective date. Thereafter, complete records of receipt and distribution would have to be maintained.

Possession of covered drugs by a person not in the legitimate chain of distribution would be a prohibited act, subject to fine and imprisonment, except as to household use. In addition, the bill would strengthen existing controls over counterfeit drugs by eliminating the necessity of establishing that the drugs have moved in interstate commerce before proceeding against the drugs or the illegal possessor, and by authorizing the seizure and condemnation of equipment used in the manufacture of these drugs.

Other provisions would permit designated officials of the Department to carry firearms, make arrests and seizures, and permit temporary detention of goods pending issuance of an appropriate seizure order by a court.

The bill as introduced in the House of Representatives was included in FOOD DRUG COSMETIC LAW REPORTS Number 104 with House floor amendments included in FOOD DRUG COSMETIC LAW REPORTS Number 105.

The Role of the States in Establishing Food Standards

By EUGENE H. HOLEMAN

Mr. Holeman Is Director, Division of Food and Drugs, and State Chemist, Tennessee Department of Agriculture.

IT IS MOST APPROPRIATE that we should meet to discuss food standards—our abundant, wholesome food supply being one of our great blessings. What an amazing collection of visionaries and practical workmen the framers of our Constitution must have been —to put together the scaffolding for future greatness of a country and people. They saw and spelled out checks and balances against the greed for power and possession which is present in the hearts of everyone—so food standards are one of the checks in modern food law enforcement.

Within the depths of our religious faiths we can confess our sins, resolve to do better and take a fresh start—in our political and economic life can we admit mistakes, resolve to do better and take a fresh start? We shall see.

From the Simple to the Complex

"A Model Food Law?"

"A food shall not be adulterated or misbranded!" and

"An advertisement of a food shall be deemed to be false if it is false or misleading in any particular!"

Is there anything else needed in a pure food law? Nothing else, as far as the wholesomeness of the food and truthful representations are concerned. For enforcement purposes we would have to designate the enforcement authority, prescribe freedom of inspection, give industry a chance to be heard, prior to prosecution, then attach the penalty clause and go to work. We take a more difficult route however.

History shows that our legislative and standards making processes move in the direction of the complex and shy away from the simple, direct and easily understood approach. The Association of Food and Drug Officials of the United States (AFDOUS) sponsors the "Uniform Food, Drug, and Cosmetic Bill." The original purpose of AFDOUS was to shorten and simplify the Federal Food, Drug, and Cosmetic Act yet retain the meaning of the Federal Act. Such a draft would stand a better chance passing state legislative bodies and would be more conducive to uniform enforcement action. During the past two years AFDOUS, with the help of legal counsel, has tried to accomplish this simplification purpose on the 1962 New Drug Amendments. If you have had occasion to study these 1962 amendments you will smile at our naivete.

So in food standardization, especially in complex processed foods, we move from the simple and direct attack on adulteration, misbranding and false advertising to the complex. Perhaps the increased complexities of food production, processing and merchandising make this inevitable. There are signs of a change however.

Historical Background: States Have Primary Role

Food standards started before we had a federal government (in the colonies) and state standards and state demands to clean up our food supply antidated the 1906 Federal Pure Food Law by a number of years, then the Brandeis Supreme Court decision of 1916 (242 U. S. 153; 37 S. Ct. 28) paved the way for the application of state food standards to foods moving in interstate commerce.

The role of the states is a primary one in the development of food standards. In the 1880's the State of Massachusetts had a practical system of food and drug inspection. Albert Leach, Chief Analyst of the Massachusetts State Board of Health and later Chief of the Denver Food and Drug Inspection Division of the Bureau of Chemistry of the U. S. Department of Agriculture (USDA), Dr. Andrew Winton, USDA Bureau of Chemistry and then Mr. Herman Lythgoe, Massachusetts Board of Health are the pioneers in the establishment of food standards. They cleaned up the spice and condiment trade and the standards they adopted in the State of Massachusetts and then by the Bureau of Chemistry are intact or little changed in the advisory standards of the Food and Drug Administration (FDA) and in many states today. Dr. Harvey W. Wiley took up the fight for pure foods, work-

ing with the state officials and the national food association of his day to establish definitions for foods.

Milk and cream; other dairy products, particularly cheese and frozen desserts; flavorings; seafoods; the above mentioned spices and condiments; some cereal flours and meals; cocoa products and fruit juices and beverages; and wines and spirits first were standardized by state governments and then pushed to uniform action by FDA and other federal departments and agencies.

There have been established over 200 standards or advisory standards in the Department of Health, Education and Welfare (HEW) by the FDA and the U. S. Public Health Service, over 2000 in the Department of Agriculture and other important food standards by the Department of Interior, Department of Commerce, the Department of Defense and the U. S. Treasury Department and the Veterans Administration.

The federal departments and individuals can and do initiate action in the development of standards for foods, yet the safe, sure way is to develope such standards on a partnership basis with the states and the food industry. AFDOUS, through the years, has by resolution, by consultation, by conferences with federal officials, other states and the regulated industry, proposed food standards. AFDOUS has also taken a leading part in bringing about uniformity of enforcement when food standards have been adopted. Without uniform enforcement, uniform standards lose a great deal of their value and effectiveness. And now we add to this array of food standard-making bodies, the Food Standards Program of the Codex Alimentarius Commission. With Deputy Commissioner John Harvey having served as Vice-Chairman and then chairman of this commission and with Lowrie M. Beacham, FDA, heading the U. S. delegation on the commission's Expert Committee on Fruit Juice and Fruit Products we can all be assured that a turn to simplification and reason in food standards has been made.

The Role of Food Standards: The Present Situation

Have you heard any criticisms of canned peas lately or frozen lemonade concentrate, of cheddar cheese, of frozen whole eggs or apricots with rum, or of hundreds of other standardized foods? No!!!

Let us not overlook the fact that standards, grade standards and definitions have been established for several thousand basic foods. Voluntary and compulsive grades and standards are generally serving a great and useful purpose in the production and trading in foods, in procurement and processing and to some extent in consumer protection. In the production, procurement and processing of foods, the value of standards can be assessed in dollars and cents, in man hours and time and effort to get a fixed quality or grade at a firm price. Then the selling price and mark up can be fixed to this grade and sold at the market value.

Can the value of food standards to the consumer be fixed in this precise way? Perhaps Agricultural Marketing Service (AMS) or FDA can give the answer. It would involve the making of a physical comparison of standardized foods with unstandardized: quality, fill of container, accuracy and truthfulness of labeling and advertising, freedom from adulterating ingredients etc.,—here is a difficult analytical field. We do know that good quality foods, with processing controls, will produce a high-grade consumer product.

Our present discussions revolve around the standardization of complex process foods: peanut butter, dilute fruit juice beverages—the old bread standards—to keep out or put in food and color additives. Because of their position in initiating standards, in adopting uniform standards and in enforcing standards the state food officials and particularly AFDOUS are major participants.

Suggestions

A. Let us quit spending our time, money and talents on the "theory of preemption." The trends of the times, unless reversed, favor uniform laws and standards anyway, and besides the states of New York or Wisconsin or California are just as sure of their rights and responsibilities for developing and enforcing food standards as are Tennessee, North Carolina, or Mississippi (or all other states). Uniformity in food standards is progressing, don't stifle it.

B. The food industry needs to meet with and participate in the committee and association work of AFDOUS. This is just as much a federal and municipal organization as it is a state one, so the greatest amount of good can be accomplished by consulting with its active and associate members.

C. Mandatory review of food standards would be the same as setting up another "Food Standards Committee," or "Bureau" in FDA. It would slow down the process of standards revision and review. Bring about changes by (1) petition and consultation with FDA; (2) court tests; or (3) make an unstandardized product and forget your headaches.

D. Correct adulteration, misbranding and false advertising by the time-honored and proven means of intelligent, active plant and product supervision. (Don't depend on a standard to do these things.)

E. Continue to prove to the country and the world that we have the most wholesome and varied food supply ever known to man.

F. Take the pledge to work together.

G. Think on these things—if a chemical additive meets the test of safety, need, and usefulness, can it be denied use?

H. At this stage in the food industry and in protecting the consumer microbiological methods and standards are of more importance than food standards. The AFDOUS Frozen Food Standards of 1957 and cooperative work with FDA and the frozen food industry, laid the groundwork for developing new methods and establishing standards of food bacteriology. The U. S. Public Health Service and Association of Official Agricultural Chemists are now undertaking a task force to continue and expand this work. Industry can make a major contribution in this field of food control and consumer protection.

Recommendations

A. Repeal the Bread Standards. The American public has set the standards for bread—(1) a firm, tasty, aromatic and naturally nutritious loaf, and (2) a large, light, soft, enriched loaf also. The firm loaf is the counterpart of the original standard whereas, the soft loaf is the result of modern food technology and some consumer preference. Compulsory enrichment should be retained with no prohibitions on safe, wholesome necessary additives. It is a travesty on all food standards to maintain one which has outlived its usefulness or lost its meaning. It will take courage and intelligence to make this historic move. There are plenty of those virtues here and the reward will be great in respect for the job done.

B. Cooperation between federal agencies, industry, and the states is of greater concern today than it has ever been. Two Citizens

Advisory Committee reports have emphasized the need for cooperation in all areas of food law enforcement. Federal departments engaged in food standardization are not acting in the public interest when the accumulated data and knowledge of state officials and AFDOUS is ignored. It is recommended here that a continuous exchange of information should also be carried out between HEW and USDA and other departments engaged in food standardization.

C. Trading and processing food standards should be the sole responsibility of the USDA and consumer standards for all foods should be the sole responsibility of HEW, and where overlapping occurs the standards should be made to agree—to the letter.

D. *The Codex Alimentarius Commission Report* should be studied and their principles of simplification applied to our standard-making procedures. They are:

Purpose: To simplify and harmonize international food standards, to establish priorities, to coordinate and supplement work of other organizations in the same field, and to provide for review and consideration of proposed standards at the government level by participating countries.

Guiding Principles (4 of 10)

(a) Unless clearly necessary, avoid recipe standards, i.e., those which exclude the use of other than specified ingredients.

(b) Product definitions should be no wider than strictly necessary. In particular they should be stated in positive, not negative terms and should not resort to statements of exceptions.

(c) Products similar to standardized products shall be sufficiently designated by a fancy name accompanied by adequate labelling.

(d) General layout recommended for standards includes: (1) definition, (2) designations and standards, (3) permitted additions, (4) marking and labelling.

E. The definition of "imitation" and its application to food standards and labelling should be clarified by Congress.

F. The President of the United States is invited to appoint a committee, composed of members from the principal Federal Government departments and outside advisors, in order to unify food standardization, and to coordinate methods and practices. There is excellent precedent for such a coordinating committee in the recently appointed interdepartmental committee on all phases of pesticide uses, standards, and residues. The newly appointed National Advisory Committee of FDA could consider coordinating and cooperative activities and initiate review of the question for Presidential consideration.

[The End]

The Need for New Uses of the Regulatory Power to Establish Food Standards

By GEORGE M. BURDITT

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PARTICIPATING IN THIS important and forward-looking program is a privilege and an opportunity which I greatly appreciate. The papers presented by Mr. Kaplan and Mr. Holeman have made a significant contribution in defining and clarifying the present food standards situation under federal and state law, both substantive and procedural, and I know that this afternoon's panel will be a most constructive review of whether the present federal standards and the Food and Drug Administration's (FDA) standard-making policies best serve the consumer. Partly, at least, to help set the stage for the afternoon panel, I have been asked to speak on the need for *new* uses of the power to establish standards.

Let me refute at the outset the possible inference that might be drawn from my topic that it would be desirable for the Federal Government to expand its regulatory power over the food business. No such inference should be drawn. The subject is new *uses* of existing power, not new *powers*. Indeed one of the new uses might well be *less* use.

Let me also express to FDA our appreciation for the efforts which they are making in the food standards area. Assistant Commissioner Malcolm Stephens, Mr. Goodrich, Dr. Roe, Mr. Beacham, Mr. Bellis and the other officials who work on standards are all thinking men, just as interested in improving standards making as are those of us in industry. Many of the points which I am going to cover today are already under consideration by FDA and need only further implementation and perhaps a little more encouragement and cooperation from us.

One advantage of the topic which was assigned to me is that I must necessarily step back from the tedious problems of drafting and promulgating food standards and let my imagination go to work on ways to improve our system. The only statutory guideline to which we must of course adhere is that a new standard, or an amendment to an old standard, must "promote honesty and fair dealing in the interest of consumers."[1] Beyond this, our, in a sense "brainstorming," session today should be unfettered by statutory mandate, judicial precedent or administrative interpretation. Our question, then, is what can be done in the food standards area to promote consumer interest by *helping* those of us in industry to produce and honestly market better products.

Consumer interest in many respects is promoted by a regulation which erects a framework within which industry must operate in manufacturing and labeling its products. Hopefully, the standard is *only* a framework which allows industry to add improvements as technology advances. But if we are not careful, the framework can, by sheer detail in construction, become a closed, rigid box. To prevent this, the FDA has wisely established the policy of granting temporary permits[2] and Congress has properly, by the Hale Amendment,[3] facilitated the procedure for adopting new or amending old standards. But this is an area in which I suggest that future uses of the regulatory power to establish standards should, when a new standard is first promulgated and when old standards are amended, make technological advances easier to accomplish. A standard of identity need go no further than to ensure, rather than freeze, product integrity.

So let me brainstorm on a few *new* uses of the regulatory power to establish standards and make ten specific suggestions designed to promote consumer interest by facilitating technological advances.

Limit Standards to Essentials

1. First suggestion: *Limit standards to basic essentials.*

Industry is continually complaining about recipe standards. And recipe standards are bad for consumers *and* industry because they regiment production, reduce competition based on quality, and stifle improvements.

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[1] 21 U. S. C. 341, FOOD DRUG COSMETIC LAW REPORTS ¶ 51,051.

[2] 21 CFR Sec. 10.5, FOOD DRUG COSMETIC LAW REPORTS ¶ 51,305.

[3] 21 U. S. C. 701, FOOD DRUG COSMETIC LAW REPORTS ¶ 2617.

The suggestion to limit standards to basic essentials was advanced by Michael Markel in his excellent article entitled "Unshackle the Improvement of Food Products" which appeared in *Food Processing* in June 1957. Mr. Markel suggests that

> Much could be done to ease the food processors' burden of food standardization without compromising the indicated legitimate consumers' interests. This could be achieved by restricting standardization to basic essentials. These are fixing of the required ingredients to insure the identity and fixing of their ratio to other ingredients by establishing floors for the expensive ingredients and ceilings for the inexpensive ingredients.[4]

A corollary of this proposal is that a manufacturer could use any optional ingredient he chose to use, subject to all of the protective provisions of the Federal Food, Drug, and Cosmetic Act. For example, the standardized food could not be made to appear better or of greater value than it is, and the label would have to reveal the common or usual name of each optional ingredient used. Now that the Food Additives Amendment is part of our basic law, the question of safety need not be considered in the standard making procedure.

Why couldn't we ask FDA to try Mr. Markel's suggestion on one standard, either an old one or a new one? Commissioner Larrick's comments on the proposal[5] have not been too favorable, but any step forward is going to require an experimental attitude on the part of the FDA, as well as cooperation and understanding on the part of industry. It seems to me that Mr. Markel's ideas are constructive and that at least one experimental step along his suggested path should be taken.

Generic Terms for Optional Ingredients

2. Second suggestion: *Designate optional ingredients by generic terms in the standard and on the label.*

This is an alternative to Mr. Markel's proposal, and is of course followed to some extent at the present time: (1) Spices, flavoring and coloring, because of the specific exemption in section 403(g) of the Act, are now designated by the appropriate generic term in many standards. (2) Any one of several vegetable gums may be used in cream cheese or neufchatel cheese with a simple label declaration of "vegetable gum."[6] (3) Any "suitable batter and breading ingredient" may be used under the breaded shrimp standard,[7] an excellent step

[4] Michael F. Markel, "Unshackle the Improvement of Food Products," *Food Processing*, June 1957.

[5] George P. Larrick, "'Recipe Writing' Necessary," *Food Processing*, Sept. 1957.

[6] 21 CFR Secs. 19.515(c) and 19.520 (c), FOOD DRUG COSMETIC LAW REPORTS ¶ 51,493 and ¶ 51,495.

[7] 21 CFR Sec. 36.30(d), FOOD DRUG COSMETIC LAW REPORTS ¶ 51,885.

forward. (4) The cocoa standards permit the label statement "emulsifier added" or "with added emulsifier."[8] (5) The Meat Inspection Division of the United States Department of Agriculture permits the phrase "oxygen intercepter added to improve stability." (6) The Association of Food and Drug Officials of the United States (AFDOUS) diluted juice beverage code permits the use of "sweeteners, true fruit flavors, colorings, stabilizers, emulsifiers, buffering salts and preservatives" in fruit drinks without attempting to list the specific names of these ingredients in the standard, although the code is silent on the next important step, authorization to use a term such as "emulsifier added" on the label.[9]

Why not make the effort to follow these precedents as far as they can reasonably take us in all federal standards? For example, the standard for pasteurized process cheese spread[10] lists a total of 37 specifically-named emulsifiers, gums, acidifying agents and sweeteners which may be used. How much simpler it would be—and how much more encouraging to scientific development—if *any* emulsifier, *any* gum, *any* acidifying agent and *any* nutritive sweetener were permitted as long as the finished product meets the basic requirements for composition set forth in the standard.

Before the Food Additives Amendment was passed there may have been valid reasons for naming the specific emulsifiers, stabilizers, acidifiers, etc., which were permitted in a standard. But the Food Additives Amendment removed at least one major reason for specificity, and I suggest that consumer interest requires the encouragement of technological development through the use of generic terms in both new and old standards.

Let me point out some of the benefits of this suggestion. Research would be stimulated and rewarded promptly and fully. It simply *must* be discouraging to scientists to know that if they do find a way to improve a standardized product by adding a new ingredient, the fruit of their labors can't be picked for as long as two years even if the proposal is noncontroversial and for substantially longer than two years if a hearing is necessary. If generic terms are used, the scientist's discoveries can be put to use immediately.

[8] 21 CFR Sec. 14.6(e)(2), FOOD DRUG COSMETIC LAW REPORTS ¶ 51,346.

[9] Association of Food & Drug Officials of the United States, *Quarterly Bulletin, Proceedings Issue,* Vol. 27, 1963, p. 42; *Report of the Committee on Uniformity of Interpretation of Food and Drug Laws and Regulations,* Sec. 5(b).

[10] 21 CFR Sec. 19.775, FOOD DRUG COSMETIC LAW REPORTS ¶ 51,603.

Consumers would be the primary beneficiaries, because better products would be produced sooner and more frequently. And consumers would, of course, continue to be protected by all of the adulteration and misbranding provisions of the Act. *Industry* would profit by reaping the rewards of a constructive research and development program without being required to divulge all of the trade secrets developed in the program, and also by being able to change from one emulsifier to another without costly label changes which in any event have to be passed on to the consumer in the long run. *FDA* would be benefitted by having a greatly reduced work load since the overworked Food Standards Branch would not have to be plagued with all of the immense paper work involved in such comparatively inconsequential matters as amending a cheese standard to permit guar gum or sorbic acid or sodium aluminum phosphate, or a dressing standard to permit EDTA. So it seems to me that everyone would benefit and no one would be penalized. The use of generic terms could become the general rule; specific names the rare exception.

Now there may be some question as to FDA's legislative authority to permit the use of generic terms on labels of standardized foods. Section 403(g) of the Federal Food, Drug, and Cosmetic Act provides that a food shall be deemed to be misbranded if it is a standardized food unless its label bears

> . . . insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food.

Deputy Commissioner Harvey, in construing this section in the light of sections 403(i)(2) and 403(k), before the American Bar Association in 1959 said that

> . . . it would seem that the validity of the doubts as to whether Congress provided or intended that the substitution of functional purpose language for names of ingredients are of sufficiently persuasive quality that the Secretary should not come so close to legislating as would be the case if he chose to issue a regulation which had the effect of substituting a functional purpose declaration for the name of the ingredient.[11]

But the six examples which I mentioned a moment ago are all instances in which ingredients are *currently* shown on the label by a generic term. And at least one Court of Appeals, as Commissioner Harvey also points out

> . . . has upheld the generic description of such ingredients, i.e., emulsifier added.[12]

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[11] John L. Harvey, "Common or Usual Name," 14 FOOD DRUG COSMETIC LAW JOURNAL 555, 558.

[12] *American Lecithin Company, Inc. v. McNutt*, 155 F.2d 784 (C. A. 2d, 1946), *cert. den.*, 329 U. S. 763 (1946).

The benefits to be gained by generic designation are so great that FDA should continue down the path on which it has started. Legal tests may be necessary, but if so I am sure that Mr. Goodrich will more than adequately represent what in this case seems to me to be the best interest of the Government and consumers and industry.

But if Congress has to help somewhere along the way, so be it. Industry and FDA have cooperated before to accomplish a desirable end—the Hale Amendment and the Food Additives Amendment being two prime examples—and if another joint effort is needed to permit generic-term designations, let's get at it!

Standardization of Terms

3. Third suggestion: *Standardize generic terms.*

The legislative authority to promulgate a standard for a generic term is fairly clear. As Commissioner Harvey pointed out in his ABA speech:

> . . . the ingredients of a food that we are talking about are themselves food. That is to say, the components which are used in fabricating foods are each by law designated as foods themselves. This suggests that an ingredient which now bears a name in the jawbreaker class, if made the subject of a definition and standard of identity could enjoy whatever power the Secretary has under the standard making procedure to specify the name by which our component food is to be known on labels.[13]

So I take it that FDA does have authority to promulgate standards for generic terms, that is, to standardize ingredients as well as finished foods.

FDA has followed this procedure at least part way and should be complimented on their forward-looking proposal to standardize "fat preservative, fat antioxidant."[14] To list the common or usual name of a specific fat preservative on a label is virtually meaningless to consumers. But to describe the purpose of the additive is to give the consumer information which she wants and understands.

This is a fertile field. Standards for generic terms such as "emulsifier," "acidifier," "stabilizer," "whipping aid," and "vegetable oil," to mention just a few, could be promulgated.

Let me take whipping aid as an example. Whipping aids commonly in use in foods which contain egg whites include ox bile extract

[13] John L. Harvey, page 559 in article cited at footnote 11.

[14] 26 F. R. 847, *Federal Register,* January 27, 1961.

(which does not sound particularly appetizing), desoxycholic acid and taurocholic acid (which sound like acids produced by Taurus the Bull when he was afflicted with colic), isopropyl citrate and triethyl citrate (which sound as if they ought to be put in your automobile radiator or gas tank respectively rather than your stomach), oleic acid (which has the appetite appeal of any oily acid), cholic acid, glycocholic acid and triacetin. I venture to say that not one consumer in ten thousand would have the slightest idea what any of these substances is. How much more meaningful it would be to put "whipping aid" on the label! And this could easily be done if we in industry will cooperate with FDA in proposing and drafting a suitable standard. And it should be a simple standard. It isn't necessary to specify the types of foods in which the whipping aids could be used, or the maximum amount which could be used, since these are already covered by food additive regulations. But it does take initiative on the part of industry, an understanding of the problem on the part of consumers, and cooperation on the part of FDA.

More Liberal Standards Needed

4. Fourth suggestion: *Liberalize standards.*

A standard is necessarily a restricting regulation. But I suggest that standards have become *too restrictive,* unrealistically so, in several respects. Let me give a few examples:

a. Industry is in just as good a position as FDA to know the common or usual name of a product, and we have a duty to see that a food is standardized under its common or usual name. Now I realize that section 401 authorizes a standard for a food "under its common or usual name *so far as practicable.*" But if a food has a common or usual name, FDA ought to use it. Personally, I am not sure that "pasteurized orange juice" or "reconstituted orange juice"[15] are the common or usual names of the single-strength orange juice we drink for breakfast. Certainly different methods of preparation are used, but the finished product is "orange juice", since it is *never,* let alone commonly or usually, called anything else by consumers. And I *know* that "chilled 50% fruit juice drink orange"[16] is not the common or usual name of anything! So I urge FDA to be a little more realistic

[15] 21 CFR Secs. 27.107(d)(1) and 27.111(c), Food Drug Cosmetic Law Reports ¶ 51,767 and ¶ 51,771.

[16] 29 F. R. 11626, *Federal Register,* August 13, 1964.

in establishing the common or usual name of a food. If additional explanatory labeling is necessary, let it be required, but the *name* of the food should not be distorted beyond what consumers expect.

b. A second way in which standards could be liberalized is in the positioning of the ingredients clause. Under section 403(f), every ingredients clause, whether on standardized or nonstandardized foods, must appear "with such conspicuousness . . . as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." Why, then, should standardized foods be discriminated against by the requirement that the ingredients clause be placed in juxtaposition with the name of the food, without intervening written, printed or graphic matter? Wouldn't consumer interest be just as well served if labels are uncluttered, as long as we have the basic protection of section 403(f)?

c. Thirdly, type size should not be specified, and

d. Finally, the percentage of basic ingredients should not be required to be divulged on the label, as the Commissioner's proposal for diluted fruit juice beverages requires,[17] since it is established by the standard itself.

Revise Temporary Permit Procedure

5. Fifth suggestion: *Revise the temporary permit procedure.*

Implementation of the regulatory power to establish food standards has been greatly facilitated by the use of temporary permits to deviate from an existing standard. The temporary permit gives a manufacturer time and experience which is frequently necessary to determine whether a petition for an amendment should be filed, and if so, to develop information needed to support the petition. Again FDA deserves commendation on the temporary permit procedure.

But let's brainstorm again. And let's set the pattern by remembering first, the Food Additives Amendment, second, the time and difficulty required to obtain a temporary permit, and, third, the desirability of encouraging better food products. With these three things in mind, what would be wrong with permitting short-term deviations from a standard without preclearance from FDA? Several safeguards would of course have to be imposed:

[17] 29 F. R. 11625 and following. *Federal Register*, August 13, 1964.

a. The manufacturer should be required to notify FDA, submitting the same type of data as is now required for temporary permits.

b. No deviations without preclearance should be permitted in what Mr. Markel calls the basic essentials, for example the 45% fruit requirement in jellies and preserves.

c. The manufacturer should be required to complete his experiment within a specific time period, probably one year. At the end of the period he should either terminate the deviation or obtain a temporary permit or file a petition for an amendment.

d. FDA should be authorized to veto a deviation if it obviously would not promote consumer interest.

e. And finally, of course, manufacturers should be aware that all of the other provisions of the act—additives, adulteration and misbranding—would be applicable to their deviated food.

When Government gets into a field, the easiest thing in the world is to run down to Washington before you turn around; I am suggesting that food manufacturers should be allowed and perhaps even required to take the initiative and responsibility of improving standardized foods without preclearance by FDA.

Need More Informal Conferences

6. Sixth suggestion: *Expand informal conferences.*

FDA's formal program of prehearing conferences has proved very helpful in narrowing the issues to be covered in the subsequent hearing. Informal conferences have been even more helpful in arriving at satisfactory solutions of disputed issues developed at the hearing or in appeals taken after the final order is issued. It has been my experience that the frank discussions which can occur off the record bring results which cannot be equalled with thousands of pages of direct testimony and cross-examination. We in industry have an obligation and a rare opportunity to match the statesmanship of the FDA officials in carrying on such negotiations in an atmosphere of cooperation and desire to reach mutually satisfactory orders beneficial to consumers and industry alike. Almost without exception, an order which benefits consumers also benefits industry, since the food industry *exists* to benefit consumers and prospers in direct proportion to its success in benefitting consumers. One of the chief stumbling blocks to prompt promulgation of standards, in my opinion, is the

unjustified fear that consumers will be hurt by industry proposals; if consumers *are* hurt by an industry proposal, the industry *itself* is hurt, and it is high time that we forcefully impress on both consumer groups and food officials that our proposals *must* benefit consumers or they are doomed to failure. One way we can do this is by articulate presentation of our case in informal conferences.

Standards Which Impede Progress

7. Seventh suggestion: *Avoid standards which impede technological development.*

The prime example, in my opinion, of a standard which impedes technological development, and is therefore self-defeating, is the legislative butter standard.[18] The purpose of the standard, of course, was to protect the integrity of butter. The butter consumption figures since the statute was passed graphically demonstrate the result: the integrity of butter has certainly been protected, but the entire butter industry has suffered dramatic reverses. Using a little hindsight, how much better it would have been to protect integrity with an 80% fat requirement, while at the same time allowing industry to use its imagination and technical resources to stimulate consumption by producing a better butter.

Some of the administrative standards probably fall in this same category, the egg standards,[19] for example. The single-strength orange juice standards,[20] I predict, will be another example. Less-than-single-strength juices are being developed with optional ingredients which are going to make better looking, better tasting, longer lasting, and more nutritious products than single-strength juice can ever be, unless it too is given the advantage of the same optional ingredients. This may be heresy to the Florida Citrus Commission, but look what's happened to butter! The sooner we get away from the superstition that we can't improve on mother nature, the better off consumers will be. And I urge industry and FDA *and* Congress to avoid putting a straightjacket on products which can be improved by the addition of optional ingredients.

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[18] 21 U. S. C. 321a, FOOD DRUG COSMETIC LAW REPORTS ¶ 781.

[19] 21 CFR Part 42, FOOD DRUG COSMETIC LAW REPORTS ¶ 51,941—¶ 51,953.

[20] 21 CFR Secs. 27.105—27.108; 27.111—27.113, FOOD DRUG COSMETIC LAW REPORTS ¶ 51,765—¶ 51,768; ¶ 51,771—¶ 51,773.

Specific Dietary Food Standards Needed

8. Eighth suggestion: *Promulgate specific standards for dietary foods.*

FDA took a long step forward in this regard in the standards for artificially sweetened jellies and preserves.[21] Certainly this is a more meaningful designation than "imitation jelly" which could mean about anything, good or bad. In this day of low-fat products, vegetable fat products, low-sodium products, high protein and vitamin products, the word "imitation" is nothing more than a red flag. How much better it is to declare, as part of the common or usual name of the food, the specific dietary property which has been adjusted, for example, low calorie french dressing or vegetable fat whipped dessert topping. Perhaps this suggestion requires an amendment to section 403(c). Several of us in industry don't think it does,[22] but more relevantly, Commissioner Larrick seems to think so.[23] Here again, if legislation *is* necessary, then let's cooperatively sponsor an amendment to the act.

Elimination of Delays

9. Ninth suggestion: *Act!*

The Food Standards Branch is grossly and unfairly overburdened. They simply must get more help. But the delays in simple proposals are, I am sure, caused also by the heavy load in other divisions of FDA which must review and approve food standards proposals. Most of us in this room are all too aware of proposals which could easily have been acted on in a week or two—at least by publication of the proposal for comments. FDA has been severely and I think on the whole fairly criticized for its explicable but unjustifiable delays in the food standards area. I know that the FDA officials are all too aware of the problem, and are taking action to correct it.

Let me make three suggestions:

a. Once a standards matter is taken up by FDA, it should be completed promptly or tabled altogether, with all interested persons being advised of the tabling. The fat preservative standard,[24] and the di-

[21] CFR Secs. 29.4 and 29.5, Food Drug Cosmetic Law Reports ¶ 51,794—¶ 51,-795.

[22] George M. Burditt, "Imitation," 19 Food Drug Cosmetic Law Journal 72 (February, 1964).

[23] George P. Larrick, "To change FDA's 'imitation policy' would require legislation since this policy is based on the framework of the present law," *Food Processing,* December 1963, p. 65.

[24] The fat preservative proposal was published four years ago in the *Federal Register* for January 27, 1961.

etary regulations[25] are examples of very constructive thinking by FDA and industry's comments on both of these have been copious and I hope also constructive. But let's get on with the job.

b. Perhaps a clock should be instituted on food standards proposals as in the case of the Food Additives Amendment. Certainly the unwarranted delays in noncontroversial proposals are leading many of us to conclude that a legislative time schedule may be necessary.

c. Along this same line of clocks and action, the suggestion has been made by Dr. Kenneth G. Weckel that standards should be reviewed on a periodic and mandatory basis.[26] Virtually all standards do need periodic review as technology advances, and in theory it is difficult to argue with Dr. Weckel's suggestions. If the amending procedure were not so slow, or if recipe standards were not so detrimental to scientific development, mandatory periodic review would probably not be desirable. But if we can't speed things up and unshackle standards substantially, Dr. Weckel's suggestion may have merit, although it would require a substantial increase in FDA personnel.

Final Suggestion

10. Tenth and final suggestion: *Let's be specific.*

Commissioner Larrick wants us to be specific[27] and we certainly should be. It would be presumptuous of me to draft any specific proposals, and that was not my assignment today. But the Food Law Institute, and the other sponsoring agencies today, are ideally suited to prepare specific proposals for presentation to FDA. Or perhaps a joint informal committee of industry, consumers and FDA could begin work on the vital project of preparing statutory and administrative proposals designed to facilitate the improvement of the American standardized food supply. Looking over any new horizon is likely to reveal mountains of problems and deserts of pitfalls, but the green valley on the other side makes all the trials and tribulations worthwhile. So I would hope that FDA would approach the mountains and deserts with determination and would call on industry to help carry the load. The need is obvious; the talent is available—indeed in this room; and the accomplishment of the result is a goal worthy of our immediate and united dedication **[The End]**

[25] The dietary regulations proposal was published two and one-half years ago in the *Federal Register* for June 20, 1962.

[26] Dr. Kenneth Weckel "'Status quo' standards are strangling research incentives," *Food Processing*, February 1964, p. 73.

[27] George P. Larrick, "'Recipe Writing' Necessary," *Food Processing*, September 1957.

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