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Food Drug Cosmetic Law JOURNAL

Papers Presented at the Food Standards Symposium of the American Medical Association Council on Foods and Nutrition

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

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The American Medical Association Council on Foods and Nutrition Symposium on Food Standards in the United States.—The following papers were presented at the Symposium on June 26 and 27, 1969 in Chicago, Illinois. Additional papers read at the Symposium will be published in a later issue of the JOURNAL.

"International Standards for Food Products: The Codex Alimentarius" is the topic of *Robert F. Anderson,* Executive Secretary for the American Butter Institute, National Cheese Institute, Inc. Mr. Anderson discusses the Codex Alimentarius, a program created to establish international harmonization in food standards. He summarizes the program's history, membership and basic format, and the progress it has made toward its ultimate objectives. The article begins on page 374.

D. M. Hegsted, Ph.D., in his article beginning on page 384, outlines some of the problems in the area of "Food Standards." Mr. Hegsted, who is Professor of Nutrition in the Harvard School of Public Health, sees an analogy between the university administration-student body relationship and that of the FDA and the food industry. In each case, the administrative group has a stake in rather rigid, universally-applicable rules. The food industries, like the students, are diverse, with varying and often conflicting points of view. The author believes that committees of the National Research Council-National Academy of Sciences are potentially best equipped to arbitrate differences while protecting the public interest.

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Quality Aspects of Imitation and Artificial Foods

By LESTER HANKIN

This Paper Was Presented at the New York Conference of Health Officers and Food and Drug Officials on March 9, 1969. Mr. Hankin Is a Biochemist with the Connecticut Agricultural Experiment Station, New Haven, Connecticut.

IT IS A PLEASURE to be with you today and to discuss some of my ideas on the assessment of the quality of artificial and imitation foods. Although the public health aspects of all foods are important, I shall not dwell on this aspect today. Whatever the food, if must be free of pathogenic organisms and toxic materials.

What are artificial and imitation foods, not from the legal aspect, but from the chemical point of view? A legal definition does not adequately describe the food nor does it fully tell us what it contains. The definitions themselves are quite arbitrary and we might differ as to whether a particular food is artificial or an imitation. This, however, is not germane to the discussion.

One type of food I am speaking of is, for example, the so-called artificial milks such as coffee whiteners. They usually contain no milk products but are fabricated from separate components to simulate milk. An example of an imitation food might be filled milk, in which the butterfat has been removed from the milk and vegetable fat substituted. Many more examples are possible but these will not add to our understanding of the problem since these definitions themselves are not clear at the present time. There are also many foods which fall in between artificial and imitation. They contain food

additives of many different types. Many of these foods, even though containing additives, are classed as natural foods. Whether foods are artificial, imitation, synthetic or semi-synthetic is not important except from the legal point of view. Many of you are interested in the legal aspects of food quality control, and rightly so, since it is your duty also to protect the consumer. I do not debate the relative merits of these foods, whether they are good or bad, whether they are nutritious or not, whether they will sell or not, or whether they have a good flavor or not. I only wish to look at them today from the standpoint of quality control; how we might test such foods in the laboratory and assess their quality.

Quality of course is a very nebulous term, meaning different things to different people. From the laboratory point of view when we say "good quality" we generally ask: Is the consumer getting what he paid for? Were good and wholesome ingredients used in the product and what is the potential shelf life or keeping quality of the food? The answer to these questions lies in the bacteriological and chemical analyses of the food as well as in an organoleptic evaluation. It is unlikely that artificial and imitation foods will ever be legislated out of existence. Some are already here, some are already being sold, and I am sure there are some types which we cannot even conceive of at the present time that will be offered for sale in the future. The foods will be here and they will undoubtedly have stringent restrictions placed on them. We must look to the future, we must be prepared to evaluate the quality of such materials for the sake of the consumer. We should not wait until the new foods come onto the market. We must look now for tests that will allow us to examine such foods and make an evaluation of quality so that in the long run we can assure the consumer of a good product.

Basically, all foods must meet certain specifications of quality. Artificial foods are no exception to this rule. They must be processed or fabricated under sanitary conditions which are the same as those for comparable food products now offered for sale. They must meet bacterial standards of quality of the comparable product, from the public health aspect as well as the keeping-quality standpoint.

Filled Milk and Fish Flour

What then do I have in mind when I say that we should anticipate tests that may be needed. A few examples may suffice. On the market

today are products called filled milks. We can test these products for total fat quite easily. But what if the product contains a mixture of butterfat and vegetable fat? There are tests which can be used to detect the presence of butterfat in vegetable fat (or vice versa) in dairy products, but they are long and tedious and hence not amenable for the routine analyses of a large number of samples. We need a quick and accurate test to detect adulteration and misbranding. One test for adulteration determines the amount of certain of the shorter fatty acids. These acids are prevalent in butterfat but not in vegetable fat. What of the product which uses vegetable fat and adds one of these acids (for example, butyric acid) adjusted to the same level as that in butterfat. Then the problem becomes a bit tricky, as chemists will appreciate. This sort of problem can recur. We therefore need a test to meet this possibility. Although gas chromatographic techniques may not be applicable now, on a routine basis perhaps the technique of thin layer chromatography could be useful.

Let us turn to the analysis of meat products. There is much talk of late concerning saturated fat in the diet and its effect on atherosclerosis. Is it not conceivable, for example, that a prepared meat product (such as a frankfurter), from which the animal fat has been abstracted and vegetable fat substituted, will be offered for sale? Of course these products will be labeled as containing vegetable fat. The detection of a mixture of animal fats and vegetable fats in such a product is difficult on a routine basis. What of the product which might be made from semi-synthetic materials such as dehydrated meat particles, vegetable fat, emulsifiers, vitamins, protein hydrolysates, etc.? How do you test the quality of such a material? The people who are interested in legal definitions would have a field day with this one.

Another example: Suppose a poor or substandard, perhaps partially decomposed, meat were used in the preparation of a prepared meat product. Then, to bolster the flavor, or even cover up a poor flavor, some plant protein hydrolysate was added. You are aware that many of the plant protein hydrolysates simulate quite closely the flavor of different meats. How do we test to ascertain whether the consumer is receiving a quality product, a product which contains wholesome ingredients? I do not really know the answer. There is not even a quantitative test for the determination of protein hydrolysates in meat products, and this material is allowed and listed

on the label of many products. I can only offer a suggestion. A method has been suggested to determine the age of meat and thus the quality. It is based on the volume of liquid released from the meat after it has been ground with buffer or water. Essentially, the older the meat, the longer it takes to collect a certain amount of filtrate, and this is then correlated with the age of the meat. It is possible that such a method would be applicable to prepared meats. Only experimentation can answer this question. At least it offers some avenues for research and the possibility to test the quality of such products.

Another example for the future: How far are we from the day when fish flour will be used in this country in baked goods and other types of products? Fish flour is now defatted and deodorized. The price is much cheaper than grain flour. Could not some of this flour find its way illegally into bread (or other baked goods) as a partial substitute for wheat flour? What sort of test do we use to detect such adulteration? There is much food for thought here.

There are many more examples I could cite. However, I think you realize what I have in mind on the assessment of quality of artificial, synthetic, semi-synthetic and imitation foods. We should look now for tests to assess quality of newer foods. Perhaps we should consider where the new tests should come from. One suggestion is that manufacturers should provide the test (before the additive may be used), as is now the case for materials to be added to animal feed products. Unfortunately this would be difficult, since the additives we are discussing are not deleterious to health as certain feed additives may be in large amounts.

Enzyme Chemistry

New tests usually come from the fields of organic and analytical chemistry and biochemistry as well as microbiology. One field often overlooked is enzyme chemistry. Recent advances in the preparation of purified enzymes and studies of enzyme-substrate relationships make enzymes a potent analytical tool. This area should be examined closely since many enzymes act on specific substrates and could be used in food analysis even when other materials are present which interfere with chemical tests. An example of a test developed in our laboratories at the Connecticut Station is the use of the enzyme

galactose oxidase to analyze prepared meat products for the quantitative determination of nonfat milk solids.[1] The lactose (from nonfat milk) in the meat product is first hydrolyzed with acid to glucose and galactose. The galactose is then used as a substrate for the enzyme galactose oxidase. Other constituents in the test mixture do not interfere in the determination.

From a bacteriological standpoint, our laboratory has begun to make an inroad into the rapid assessment of food quality. Although we are at the present time using natural foods for our tests, I believe that the methods we have now, and those we are developing, will be applicable to imitation or artificial foods.

Our recent work has been concerned with psychrophilic organisms, those that can grow at refrigeration temperatures and have the ability to produce obnoxious odors and flavors. These organisms use the food, or a part of it, as a substrate to produce the bad flavor. Many of the newer foods will also be subject to refrigeration, and off-flavors could develop in them from psychrophilic microorganisms. What will be the substrates for these psychrophiles in imitation foods? Will they grow better? Will they be able to develop off-odors at a faster rate than in natural food? Will these foods require different treatment to avoid psychrophiles? Many questions remain to be answered.

Present tests for the detection of psychrophiles take at least 7 days to perform; a time period which is lengthy when one considers that the food may have long been consumed, and the manufacturer may not be able to trace the source of contamination. We have developed a quick test for psychrophiles which only takes two days to complete. The test, called the oxidase test, takes advantage of one of the biochemical reactions of this group of microorganisms, namely its ability to produce the enzyme cytochrome oxidase.

Conclusion

To date we have examined fresh whole milk and have obtained some interesting data concerning shelf-life potential. [2,3] Artificial milk and filled milk could be examined in the same way and an

[1] Hankin, L. "Determination of Nonfat Dry Milk in Meat Products With a Specific Enzymatic Assay" 50 *Journal of the Association of Official Analytical Chemists* 1342-1348 (1967).

[2, 3] For footnotes, see next page.

assessment made of its potential shelf-life. We have also examined raw milk from farms, and with this test have been able to judge the efficiency of the sanitary practices on the farm. In some cases we were able to predict potential bacterial problems weeks in advance of the Standard Plate Count.[4] Our methods could be used equally well on artificial and imitation milk products.

Recently we have examined refrigerated delicatessen foods by the oxidase test.[5] Our data indicate that sanitary conditions at manufacturing plants can be assessed quickly and, in addition, provide a means for determining if remedial action asked for by inspectors has been carried out. Such methods would indeed be applicable to any type of food, artificial, imitation or synthetic which could come on the market.

I have not given you many answers today concerning the quality of artificial and imitation foods. I feel I have succeeded if I was able to arouse your interest in the potential quality of these types of foods and encourage you to think about them from a somewhat different viewpoint. These foods are subject to standards of quality as are present-day foods, but they may also be subject to different standards inherent in their fabrication or method of preparation. This is inevitable because certain of the materials used in these foods were not even conceived of as food materials as recently as 10 years ago. Whatever we do in the way of assessing food quality eventually helps the consumer, and this is one of our prime goals.

[The End]

[2] Hankin, L. and Dillman, W. F. "A Rapid Test to Find 'Potentially' Psychrophilic Organisms in Pasteurized Dairy Products" 31 *Journal of Milk and Food Technology* 141-145 (1968).

[3] Hankin, L. and Anderson, E. O. "Correlations Between Flavor Score, Flavor Criticism, Standard Plate Count, and Oxidase Count on Pasteurized Milks" 32 *Journal of Milk and Food Technology* 49-51 (1969).

[4] Hankin, L. Pernice, A. R. and Dillman, W. F. "Quality Control of Milk Production by Means of the Cytochrome Oxidase Test" 31 *Journal of Milk and Food Technology* 165-170 (1968).

[5] Hankin, L. and Ullmann, W. W. "Application of the Oxidase Test to Refrigerated Delicatessen Foods" *Journal of Milk and Food Technology* (in press) (1969).

International Standards for Food Products: The Codex Alimentarius

By ROBERT F. ANDERSON

Mr. Anderson Is the Executive Secretary of the American Butter Institute, National Cheese Institute, Inc., in Chicago, Ill. This Paper and the Following Articles in This Issue Were Presented at the American Medical Association Council on Foods and Nutrition Symposium on Food Standards in the United States.

CODEX ALIMENTARIUS COMMISSION: What is it? Why is it? How does it affect YOU?

Food standards to protect the well-being of consumers are among the earliest forms of law. Examples of such laws, or what some might call the first "snack pacts," can be traced to earliest times. Nevertheless, it was not until the last century that "national food legislation" as it is known today was established.

Today most of the world's developed countries have complex and sophisticated national food standards. Even so, these countries are faced with continual need to revise their regulations to take account of new technological developments. On the other hand, newly independent and developing countries are now writing food laws and introducing systems of food control for the first time. These countries are learning that food standards should safeguard the national interests but should not conflict with the regular requirements of the world's principle sources of food.

Motivating Forces

Why so much sudden interest in international food standards? Probably the factor motivating most governments is the prospect of facilitating international trade in food by the removal of non-eco-

nomic barriers to trade, particularly in those countries dependent upon agricultural exports. However, this is only half the reason for the renewed interest in international food standards.

Equally important is the need to establish standards to ensure safe and wholesome food in international trade. Therefore, the two main motivating forces behind the development of international food standards are the protection of the health of the consumer and the need to facilitate international trade in foods.

Until recently, very little progress was made in the field of international food standards. Fifty or sixty years ago some attempts were made, but these were limited and did not lead to international agreements such as those now being considered. Recently several international organizations, concerned primarily with problems of better marketing, began work on intra-European projects closely allied to food standards. Other agencies, such as the Council of Europe, have concentrated on the public health aspects of food. They have sought international agreement among the six member countries of the European Economic Community and the United Kingdom on such matters as positive lists of food additives and tolerances for pesticide residues.

Unfortunately, much of the work of these agencies has been based on the needs and desires of too few countries. Early preoccupation with the technical and economic problems of producing and importing sufficient food into Europe was another factor which prevented governments from actively seeking arrangements to eliminate differences in national food regulations. More recent economic groups, such as the European Community, the Council for Mutual Economic Aid and Councils in Latin America and Africa, aimed primarily at creating common markets among the member countries, have stimulated new understanding of trade problems. Both inside and outside these groupings, there is a growing desire to remove not only economic but non-economic obstacles to international trade in food. Increased attention throughout the world has been focussed on the need to improve the rules of international trade. Agencies, such as the General Agreement on Tariffs and Trade and the United Nations Conference on Trade and Development, are attempting to liberalize and stimulate multi-lateral trade through reduction of tariffs and other economic agreements.

It was against this background of rapidly increasing interest in alleviating trade problems that the Member Governments of the Food and Agriculture Organization of the United Nations (FAO)

and of the World Health Organization (WHO) decided that the time was ripe to create a forum for international action to remove those non-economic obstacles to the trade in food caused by differing national food regulations. At the same time, the Member Governments of FAO and WHO emphasized the need to ensure that proper safeguards be maintained or established for the protection of consumer health. It might be of interest to recount briefly the story of how FAO and WHO became involved in this type of activity.

FAO and WHO

FAO and WHO are relative newcomers to the subject of international food standards. An FAO committee of Government experts, in collaboration with the International Dairy Federation, began work in 1958 on the establishment of a Code of Principles concerning milk and milk products. This is in fact a code of conduct for the use of the correct product description and fair practices in the international trade of dairy products. The Committee developed a working procedure which was somewhat new in international circles. It reached agreement on the technical aspects of the work, referred its decisions to governments for comments and then finalized the standards which were published for acceptance by governments.

Another development which took place in 1958, and which was to prove to be of great importance to both FAO and WHO in introducing an international program for the elaboration of food standards, was the creation of an agency known as the Codex Alimentarius Europaeus. This agency was set up jointly by the International Commission on Agricultural Industries and the Permanent Bureau of Analytical Chemistry. The prime mover of the plan was Dr. Hans Frenzel, a former Minister in the Austrian Government. The Codex Alimentarius passed a resolution suggesting that the work should be taken over by FAO and WHO. The concept of a Codex Alimentarius Commission in which governments from all over the world could get together to try and achieve harmony in various approaches to food standard questions had begun.

The governing conferences of FAO and WHO moved with great rapidity. They approved the establishment of a Joint FAO/WHO Food Standards Program. They created a joint subsidiary agency known as the Conference on Food Standards, and guidelines were set for the first session of the Codex Alimentarius Commission to be held in 1963. This briefly is the background of the Codex Alimentarius Commission. The present membership of the Commission is

65 countries with a ratio of 1.1 "developed" to "developing" countries. It can be reasonably claimed that the Commission has assumed the leading role in world food standards, and that the United States is committed to support the program.

The objectives of the Commission are to develop international food standards on world-wide or regional bases, to publish these standards in a food code known as the Codex Alimentarius, and to record the acceptance and implementation of these standards by governments. The Commission collaborates with a number of international and national bodies concerned with the elaboration or development of food standards in different parts of the world.

One of the basic objectives of the Commission is to try to coordinate all the food standards works of international governmental and non-governmental organizations and to focus them into a single, meaningful food code. Since the first session of the Commission in 1963, strong and valuable ties of cooperation and working relations on matters of mutual interest have been established with organizations interested in the various aspects of food standardization. A principal reason for the close harmony is that a genuine attempt has been made to avoid duplication of work among the organizations.

The Commission has begun a program of work dealing with the compositional, labeling, additive, contaminant residue, hygiene sampling, and analytical aspects of foods. Much of this work is being carried out by the subsidiary bodies of the Commission, or in cooperation with other international organizations. Fortunately, the Commission has not fallen into the trap which ensnared other organizations in similar fields in the past. Some organizations took existing national regulations and endeavored to harmonize them without regard to the substance behind the standards.

Standards of Acceptance

The Commission's approach was quite different. It set out to secure international agreement on the substance of food standards and then invite governments to accept these standards in various specified ways: "Full Acceptance" means that a country's standards comply with the Codex Standard; "Target Acceptance" signifies a country's intent to accept the standard at some future date; "Acceptance with Minor Deviations" is full acceptance with stated minor deviations. This variety gives governments the opportunity to proceed in accordance with their own national and constitutional procedures and to advise the Commission how implementation of the standards is to be achieved.

The Commission has held six regular sessions. Of necessity much of its work has been procedural, and therefore it might be of interest to briefly outline it. The technical details of developing standards is done by sixteen subsidiary bodies, which are known as Codex Committees. These Committees can be considered as two groups: six dealing with general subjects applicable to all foods and ten dealing with specific food groups.

A unique feature of the working method is that responsibility for running the various Codex Committees and for piloting the standards through the steps of procedure for the elaboration of Codex standards is undertaken by various governments which have indicated their willingness to take on this task. The fact that many governments have been willing to bear the expense of hosting Codex Committees is in itself a clear indication of the value and importance which these governments attach to this work. There are also subsidiary bodies which are not run by individual governments. These include two committees, one working on standards for fruit juices and one working on quick-frozen foods. There is also the Committee of Government Experts working on standards for milk and milk products.

The Commission has developed a ten-step procedure for the elaboration of Codex Standards. After a draft standard has first been considered by the Committee concerned, the procedure allows two rounds of comments by governments, two examinations by the Committee and two considerations by the Commission before the standard is formally sent to governments for acceptance. The procedure has been deliberately designed to give governments the fullest opportunity to comment on standards while they are still in draft, and to enable the Commission to satisfy itself that the standards are being prepared in accordance with its general principles.

How satisfactory this procedure will prove to be will be known in a year or two by the extent to which standards are accepted by governments. Any procedure for the elaboration of international standards which fails to give governments adequate time to reflect on and consider the standards from all aspects would in the long run be self-defeating. The lack of proper procedures has been the downfall of many previous attempts to secure international agreement on food standards.

There are approximately 200 standards in the course of preparation by the various subsidiaries of the Commission. The standards are intended to be reasonably comprehensive. They will, as far as is necessary, define the food, prescribe "essential" composition and

quality factors, lay down maximum limits for food additives and contaminants including tolerances for pesticide residues, contain provisions relating to hygiene, weights and measures, and deal with the labeling of the food. In addition to these provisions, the standards will contain references to standard methods of analysis and sampling which would serve as referee methods in the event of disputes.

The Commission has laid down basic formats for the presentation of compositional standards and methods of analysis and sampling. Standards for meat and processed meat, sugars, cocoa products and chocolate, fruit juices, frozen foods, fish products, fats and oils, milk products, honey, edible fungi, and a range of processed fruits and vegetables are at various stages of elaboration. At its sixth session in March 1969, the Commission was able to adopt in final form 23 provisional standards. These, added to the eleven passed at the fifth session, makes 34 standards ready for formal acceptance at step 9 of the procedures for acceptance.

A great deal of progress has been made on matters which can be said to relate directly to the protection of the consumer's health. Of particular interest are the activities of the Commission regarding food hygiene, food additives, pesticide residues and labeling.

The problem encountered internationally, concerning the use of additives and the presence of pesticide residues, are from a safety point of view somewhat similar. Technologically, however, there are marked differences, and these need to be carefully considered and taken into account in determining the need for the use of these chemicals.

Food Additives

It is not too difficult for governments to reach agreement on the technological need for food additives and to determine the maximum level of use required to achieve any particular purpose. What has proved to be more difficult has been how to assess the total intake of a particular food additive in the diet and to relate this to the acceptable daily intake figure proposed by the toxicologists. Work has already begun in WHO concerning this problem, and an attempt is under way to try to establish a sound basis to calculate the daily intake of the various food additives in the total diet.

The Commission is closely watching all proposed uses of food additives, from the point of view of safety as well as technological need. One of the side effects of this work has been the stimulation of research in various countries, and in particular, toxicological research in the case of a number of additives which have been per-

mitted for many years in national regulations with little or no scientific assessment of their safety. Within the space of a few years, the Commission should have, in addition to approved specific provisions in Codex Standards, lists prescribing levels of food additives in specific foods. Member governments of FAO and WHO are examining at the present time some 50 to 60 specifications of identity and purity for food additives. These specifications will eventually be submitted to governments for acceptance.

At the international level, pesticide residues present more complex problems and difficult issues than food additives. The toxicological evaluation of these compounds and their degradation products is of vital importance. At the same time, it is to take into account "good agricultural practice." This is a relative matter which differs from country to country in accordance with different problems of pest control, infestation and climatic conditions.

Other difficulties are those concerned with the sampling and analysis of the residue. The Commission is making a painstaking examination of the various approaches which can be followed in the determination of the presence of pesticide residues, the extent to which these residues may be tolerated in raw materials, and, above all, the level of residue which may be safely ingested by the consumer. Some 30 compounds have been evaluated, and tolerances have been proposed for their residues in foods.

Work in this field is likely to be of a continuing nature due to the problem of pest resistance, which requires the formulation of new compounds as well as the increasing application of agricultural chemicals throughout the world under widely varying conditions. The Commission is therefore acting, with the aid of a Joint FAO/WHO Expert Committee on Pesticide Residues, as a clearing house for the latest information in this field, as well as affording a means, through its Codex Committee on Pesticide Residues, for governments to reach agreement on proper tolerances not likely to present a health hazard to the consumer.

Food Hygiene

Perhaps the most difficult aspect of the Commission's work has been how to tackle the subject of food hygiene internationally. The major concern of any government dealing with this subject is to establish proper arrangements which will ensure the wholesomeness of food. This is, of course, considerably easier to deal with nationally than internationally. The Codex Committee on Food Hygiene, which is sponsored by the United States, has to date held six annual ses-

sions. This Committee has received much advice and assistance from other international organizations that have been working on this problem. In particular, it has received valuable background documentation from the International Association of Microbiological Societies. Nevertheless, in spite of the vast amount of information supplied by governments and research agencies, it has proved to be a highly controversial subject from the point of view of Codex Standards.

There are the proponents of the advantages of establishing microbiological standards for all foods. Against this view are those countries which consider that microbiological standards could only be practical for a very restricted number of products and that even in these cases they would not justify any relaxation in plant inspection and detailed supervision of food throughout the whole chain of distribution.

When these opinions are considered from an international point of view, the question arises as to how a country can determine whether an imported food has been correctly prepared under proper conditions of hygiene.

Initially, the solution might appear to be the laying down of microbiological standards. However, the absence of agreement on microbiological tests, variations in methods of sampling and analysis of food, procedures followed by various laboratories and the significance to be attached to laboratory results make it extremely difficult to reach international agreement at this time. It cannot be claimed that the Codex Alimentarius Commission will find the answer to these difficulties.

The governments participating in the Codex Committee on Food Hygiene have concluded that, as a first step, codes of hygienic practice should be elaborated. This would be of assistance to all countries engaged in the international trade of foods. The Commission has adopted as a basic guide a code of practice entitled "General Principles of Food Hygiene" and a more specialized "Code of Hygienic Practice for Canned Fruit and Vegetable Products." In elaborating codes of hygienic practice, the Commission arranged for them to be submitted to governments at various stages in the same way as compositional standards.

Based on the experience of the problems and difficulties which some governments have had with certain imported foods, the Codex Committee on Food Hygiene has established a program of work designed to cover those products which can present serious public health hazards. In general, these codes of practice deal with the raw

material requirements including environmental hygiene in the growing and raw food materials, transportation, plant facilities (including construction layout), equipment and utensils, hygienic operating requirements and practices including laboratory control and other procedures and, where appropriate, end product specifications.

These codes may perform a useful educational role and may even form the basis of international agreement among some countries as to the basic hygiene conditions which will have to be met to ensure food fit for human consumption. It will be many years, if ever, before countries will be prepared to contemplate arrangements on an international level which might replace such voluntary practices with mandatory requirements, whereby the authorities of the importing countries have the right to inspect plants in the exporting country. Requirements concerning the methods of processing may prove to be a large part of the solution to these difficulties. The heat treatment of milk, egg, and meat products is being provided for in Codex Standards, but this will not permit any relaxation in the vigilance of the regulatory agencies and the food industry.

One of the most vexatious problems which the exporter of food is likely to encounter is the wide differences in national labeling requirements. The Codex Committee on Food Labeling has established, as its first priority, the elaboration of a general standard for the labeling of all prepackaged foods. Last March, the Commission passed this general standard to step 9 for acceptance by member governments. It is hoped that in a relatively short time a firm basis will have been established for labeling requirements of foods covered by Codex Standards and also international agreement on general labeling terms.

Controversy still exists concerning the need to declare ingredients. Some countries would like, in addition to a complete declaration of ingredients in descending order of proportion, a declaration of the constituents of these ingredients. Other countries would be prepared to exempt standardized foods from any declaration of ingredients. Another group of countries would require a minimum proportion of certain ingredients to be present in the product before any declaration could be made. The extent to which labeling can be controversial on a national level has been demonstrated several times both in Europe and in this country.

Conclusion

Where is all this activity going to lead? Will governments really be prepared to accept Codex Standards which would require them to

amend their existing legislation? These are just two of the more frequently asked questions. The main fear of those concerned with this work was that governments might not do more than compare the standards with their own regulations and accept only those which were exactly the same. If this happened, the Codex Alimentarius Commission would have failed in its principal objective.

However, it appears that governments are prepared to participate in this work with a spirit of compromise and to make concessions to secure international harmonization of food standards. This willingness to cooperate seriously is evident in the manner in which governments are commenting on Codex Standards. Much consultation is taking place within countries among governmental officials, agencies responsible for the enforcement of standards and the representatives of consumer and trade associations.

I urge you to work with the U. S. representative to the Codex Committee in which you have the most interest. You should start to participate in the formative stages of a proposed standard. You should not wait until an adverse standard is completed and submitted for acceptance. It is most important that our government representatives be provided with all the pertinent information and data they need to actively represent this country at committee meetings.

A small brochure outlining the objectives of the Codex Alimentarius Commission and containing a list of U. S. representatives to the various committees is available on request from the U. S. Department of Agriculture, Consumer and Marketing Service, Information Division, Washington, D. C. 20250. Ask for the latest edition of the brochure C&MS-52, Codex Alimentarius Commission.

In all events, adoption of a realistic policy of give and take by the participating government, in a spirit of cooperation, is vital to the success of this project. If acceptance of the standards becomes stalled and only a few governments accept and enforce them, then the concept of dealing with problems on a government-to-government basis through an international agency will be only a dream doomed to failure.

If the benefits of international food standards are to be realized, everyone will need patience, consideration and respect for the views and customs of others and a determination to overcome the inevitable difficulties and problems inherent in this type of endeavor. Coming together is a beginning—keeping together is progress—working together is success. **[The End]**

Food Standards

By D. M. HEGSTED

Mr. Hegsted Is a Ph.D., Professor of Nutrition in the Harvard School of Public Health, Boston, Massachusetts.

I ACCEPTED THIS ASSIGNMENT to discuss food standards with considerable trepidation. I am not certain I can define many of the problems or even my assignment. This, in itself, may indicate the need for a conference of this kind to start the dialogue, since I assume that I have more opportunity to hear and more reason to think about the problem than many other scientists on the periphery, and certainly more than most consumers.

For perhaps obvious reasons, the discussion between the Food and Drug Administration (FDA) on the one hand and the Food Industries on the other reminds me of certain current problems affecting the universities, their faculties and students. The universities and their faculties see considerable need for certain standards—standards for admission and standards of performance—by which students may be evaluated. Some of the current standards are rooted more in tradition than rational thought; certainly most are based upon the opinions of people who are now the older generation.

One often sees in faculty actions the desire to so define policies of admission, of curriculum, of grade performance, etc., so that these can be applied universally and by the staff of the Dean's Office, and so that no particular thought need be given to any individual student. Such rigid, clean-cut rules are never satisfactory. Every student is indeed a particular problem. Rules should be broken. I take considerable pride in those students who I thought were adequate material and who I did succeed in getting through school, even though they failed to meet one or more of the established rules and regulations. Yet it is perfectly obvious that some rules are required. The school as a whole does have some responsibility and the total authority cannot be a matter of the whims of a member of the faculty or a minority of faculty or students. Consistency is the hobgoblin of small minds, but some consistency is required.

Indeed, one of the major problems that university faculties must guard against these days is the tendency to be too inconsistent. Many people, both students and faculty, are unhappy about many things these days and one can see in our faculty, at least, an increasing tendency to change the rules, to institute new rules, to reinstitute rules that were only abandoned recently, with, one suspects, insufficient thought and consideration.

An Analogy

There is an analogy between the Food and Drug Administration and the food industry and the university and the students. The FDA has a stake in relatively few and rather rigid rules and regulations which are easily interpreted. The food industries, on the other hand, are as diverse as the students in a university. Their points of view are far from homogenous and they often are in direct conflict with one another. It is not clear to me who speaks for industry in the broad sense. We do know who speaks for the FDA. This, too, is similar to the university. The faculty or the administration is reasonably defined and fairly stable. It is much more difficult to determine who speaks for the students, and they change rapidly.

Of course, in a changing world, attitudes of nearly everyone change. Certain regulations that food industries fought for and were temporarily advantageous, now appear to be disadvantageous. It is my opinion that the dairy industry is suffering and unable to respond to certain developments because they boxed themselves into too rigid definitions.

The Food and Nutrition Board has a broad interest in assuring that there is a safe and adequate food supply in this country. Looking at the problem in the broadest terms, there is, or should be, no difference in the objectives of the Food and Nutrition Board and the FDA. This basic assumption of a common objective has been greatly weakened in the last year or so by the current hearings on dietetic foods. Although the Board has not been asked for an opinion, and has not taken an official position, I know that I speak for the great majority of the Board in saying that we oppose many of the proposed regulations. We believe they are based on an inadequate scientific base; we do not approve the procedure used to arrive at the proposed regulations; we object to the hearings themselves and the tremendous costs; we do not see an adequate solution coming from these hearings. Indeed, the general scientific nutritional community now has less confidence in the FDA than it formerly had.

Having made these rather derogatory remarks about the FDA,

I believe that when the chips are down, most would agree that the agency is on the side of the angels. We can assume that their intentions are correct even though we do not like the *modus operandi.* It must be apparent to everyone that there is a growing lack of respect in the community for both government and industry, but industry remains the most suspect. A pertinent example is the growing concern about the pollution of the environment. Many more people would now agree that Rachel Carson had something to say than at the time she said it. This leads many to believe, with reason, that industry in general will not respond to a problem until they are forced to. Failure of government to produce a response, suggests that there may be collusion. The whole "establishment," whatever that is, is suspect.

The current situation in the pharmaceutical industry and in agricultural industries probably has lessons for the food industry. The pharmaceutical industry is being forced to demonstrate that their products are "useful," and the fact that they can create a demand for them in the marketplace is not enough. In agriculture, the primary factors determining the use of pesticides, fertilizers, land use, etc. have been whether or not it was profitable for the producers. Broader criteria of more social interest are going to be forced upon agricultural producers. The situation in the food industries has some similarities. As I see it, the current criteria of an acceptable food product are, "Can we create a market? Can we make a profit? Is it non-toxic?" There is little consideration as to whether a product is "useful" in the broad social sense. Is the fact that people will buy a product when it is effectively promoted an adequate criterion of need? I raise this question because I have an uneasy feeling. As the new food products are spawned in profusion, it may often become more difficult for the consumer to select an adequate diet. Some products do, indeed, compete and compete successfully with more nutritious products. I suspect that it is easier to select a bad diet now than it was 25 or 40 years ago. It is questionable whether we can claim any particular success with nutrition education, in spite of extensive efforts, and we may soon have to consider the broad social consequences of the new products, lest we lose all control over what the public consumes.

The above no doubt sounds severe to many of you. It is obviously true that companies vary greatly in their philosophy. Presumably those with the most public spirit and those who have done the most to improve the nutritional status of the American population are represented here. But we are talking about the industry in general.

Some companies by the very nature of the type of products they happen to produce are less vulnerable than others. Some are very vulnerable. Furthermore, one cannot predict the future. Who would have guessed 25 years ago that the dairy industry would have the problems they have today?

Inadequate Monitoring

Some additional monitoring of the results of prior decisions must also be provided. A case in point which is now under consideration by the Food and Nutrition Board is the matter of iron enrichment of food products. This was instituted upon sound evidence of iron deficiency in the population many years ago. Now, suddenly, many years later we are confronted with the unpleasant and discouraging fact that we do not really know whether the procedure was effective. If it was effective, we do not know to what extent, but it is not sufficiently effective now. There is evidence. not yet satisfactory evidence it is true, that iron added to cereals may not be sufficiently available, and that the iron we are adding now may not be the same as that used before even though it carries the same label. If the iron we add is unavailable, the label may be factual but actually misleading. Who is responsible for determining that the iron added to foods is available?

Inadequate monitoring of the food supply and feeding practices is probably also indicated by recent findings with regard to vitamin A. As some of you have no doubt heard, reports from Canada based upon the analyses of livers obtained at autopsy indicate that there may be a fairly large group with no liver reserves of vitamin A. This concept is supported by preliminary reports of the National Nutrition Survey indicating rather low serum vitamin A levels in many of the subjects examined. These data appear to confirm the conclusion of the United States Department of Agriculture that vitamin A intakes were low or unsatisfactory in large numbers of the families surveyed. Something has apparently happened to the food supply or the nutrition practices that we have been unaware of.

The opposite problem is apparently represented by the widespread occurrence of hypercalcemias of infancy in Europe and England a few years back. Although the picture seems somewhat unclear to me—why this country escaped, for example—this disease appears to have been due to excessive vitamin D fortification and to have been controlled by vitamin D limitation. Prominent pediatricians said that the hypercalcemias caused by vitamin D were worse than the rickets it prevented.

The Uninformed Consumer

As the problems multiply and become increasingly confused, there is and will be a tendency to pass our confusion to the public. We have all been through these arguments in recent years. On the one hand we can say, "Put everything on the label" so that the consumer is informed. Then it is his problem not ours. We may get some moral satisfaction from this but we know full well that it is an inadequate solution. While I was writing this, I took a package of dehydrated soup that my wife had just brought home and noted the following: "Ingredients: enriched egg noodles, salt, hydrogenated vegetable oil, monosodium glutamate, maltodextrin, hydrolyzed milk and plant protein, powdered chicken, chicken fat, corn sugar, wheat starch, dehydrated onion, dehydrated parsley, vegetable gum, seasonings and turmeric." Having read that, I do not feel particularly assured of anything. Just having learned of the Chinese restaurant syndrome, I wonder how much glutamate there is in the soup mix. I know very well that my wife never read it and, if she had, it would mean even less to her than to me—and that is not much. Furthermore, if I had not had my bifocals on, I would not have been able to read it at all. Who are we kidding? Do we think a housewife is going to carry a dictionary and a volume of FDA regulations with her every time she goes to the grocery store?

On the other hand, I would and have argued that the fact that much of the population is ignorant should not penalize those who are intelligent enough to use intelligent labeling. This becomes particularly important when we are dealing with foods that have medical or public health usefulness. The physicians and their patients, who may include a large percentage of the public, ought to be able to identify those products which are appropriate.

Another solution is to push all of this on to the shoulders of the physician. Give him the information and let him instruct the patient. The American Medical Association has supported this position for many years, and we know very well that it does not work either. The physician is not any easier to educate than many housewives, and we know that even when he is educated, he has relatively little opportunity to pass this information on to the patient. It has not worked in the past. Unless we develop something new, it will not work in the future.

You recall that some years ago, the Council had a Seal of Approval. The usefulness of this was never quite clear. As the numbers of products multiplied, it became less useful and more difficult to

manage. The Council has explored somewhat similar schemes on occasion for specific products with the idea that only certain products which met specification would be identified by a special label. Not surprisingly, the industry does not like this approach. Those who produce products which do not meet the specifications feel that this would hurt them, which it probably would; those whose products are better than the minimal specification lose their competitive advantage, so they do not like it either. Indeed, not even the Council members who proposed the system were happy. Patients also vary. Some patients require more severe restriction of diets than others. If one has available only two classes of a product, those acceptable and those not acceptable, one cannot do as well in devising diets as when a whole range of products is available.

In all of this confusion, the Council and the Food and Nutrition Board feel that they have a role to play, a role that is partially that of an interpreter, partially that of an arbitrator. While the federal and state agencies are the ultimate guardians of the public, we feel there is adequate evidence that they may and do get bogged down in the bureaucracy, become self-serving, and dominated by the legalistic talents they possess rather than the scientific talents.

On the industrial side, generalizations are indeed difficult. However, although we admit we cannot live without you, there is little general evidence that you can police yourselves. This may be possible, but it appears to me that even the trade associations are usually uneasy alliances where only very broad generalizations can be agreed upon. If a product or a company is put in an unfavorable position by a ruling, our assumption is that they will fight. Reputable companies do have a public conscience; the question is how clearly the lines must be drawn for them to accept it when there is an apparent difference between the public interest and the company interest.

The Council and the Food and Nutrition Board, in a sense at least, has available all of the scientific talent in the country. We have to be smart enough to identify the appropriate talent at the right time. If we do our job well, we have the ability to mobilize the scientific opinion of the country. I think there is an inherent advantage in the opinion of a committee of the National Research Council-National Academy of Sciences as compared to a special advisory committee appointed either by government or industry. On the other hand, we have not developed adequate lines of communication either with government or industry. We hope to improve them. We invite suggestions and ideas from all sources **[The End]**

Remarks Made at the Symposium on Food Standards

By W. B. MURPHY

Mr. Murphy Is the President of the Campbell Soup Company.

MR. BREELING'S LETTER OF INVITATION to attend this Symposium contained this paragraph:

Your presentation should be directed specifically to a discussion of the ways in which industry's ability to deliver improved food products to the consumer is enhanced or impeded by current food standards and standard-setting procedures. . . . [Y]ou may wish to touch upon the argument that the consumer does not know how good a product might have been, and industry, locked into a rigid standard of identity, cannot easily offer the consumer any significant variation of the product.

Before discussing food standards and government controls, and so that you will understand our position on the matter of government relations, I would like to read a memorandum which was sent to all of our Department Heads and Plant Managers dated June 1, 1962 under the subject, "Relations With Government Inspection Services."

1. We can expect frequent visits from government inspectors in the future and probably the frequency of these visits will be somewhat greater than in the past.

2. Since it is our policy to operate our plants at consistently high standards of housekeeping, cleanliness and sanitation, we welcome visits from government inspectors at any time.

3. As it is also our policy to adhere strictly to product weight requirements, we are happy to have inspectors sample our products at any time to see that they conform to declared weights.

4. We favor government requirements that raise industry standards of plant sanitation, but we should regard them as minimum. Since we do our own policing, we should not be concerned about the presence of government inspectors, but rather, we should welcome them.

5. In summary, we treat government inspectors as allies in the maintenance of quality standards.

Now, I would like to quote from an address made by the new Chief Justice, Warren E. Burger, delivered at Ripon, Wisconsin in 1967. Because I have selected two paragraphs from these remarks

does not mean that they are taken out of context because I think these two paragraphs are complete in their meaning.

> It is a truism of political philosophy rooted in history that nations and societies often perish from an excess of their own basic principle. In the vernacular of ordinary people, we have expressed this by saying, "Too much of a good thing is not good."
>
> We know that a nation or a community which has no rules and no laws is not a society but an anarchy in which no rights, either individual or collective, can survive. A people who go to the other extreme and place unlimited power in government find themselves in a police state, where no rights can survive.

Further, here is a quote from an interview with one of our leading scientists in the electronics field, Dr. John R. Pierce, in which he is queried about recent writings as to the effects of technology on our society and further as to the needs for greater government controls on our society. In response to the question, "What are your thoughts on our society controlling threats that devolve from technology, such as pollution, insecticides, etc.?" he said:

> I think some sort of social effort is necessary to control pollution. Yet, it is best if the people in the business can somehow be prevailed upon to set up voluntary controls rather than being forced to comply with complicated codes of conduct. There is one thing that worries me very much; it is the notion that before a thing is scarcely started you should set up elaborate regulations for it. People are not that good at predicting what will or will not be needed. If you hem things in too much with controls you will never get anything new. There is still so much work to do in this world that I think it's both dangerous and a waste to worry about things before you can see that they really do pose a social threat.

I have quoted from these two sources because I feel the need for some company. These days the food processor finds himself in a defensive posture, even though he may not deserve to be.

Control for Controls' Sake

There appears to be a trend toward controls for controls' sake. All of the evidence points toward greater and greater degrees of government controls. This is not good because of its threat to the progressive development of the food industry. The industry already is subject to much duplication of government inspection, and this is costly, if not yet deadening.

Why does the food industry question greater and greater government controls? That's an easy one to answer. In government, things that start, seldom end, but always seem to expand. This is a truism that hardly needs proof, although it could be easily proven. Mr. Parkinson wrote a whole book on this subject.

Now it is obvious that, in a complex society, intelligently conceived and executed controls are needed. One can readily subscribe to that statement. As a corollary, one can just as readily subscribe to the statement that the control of all for the purpose of policing the few is a pretty expensive and unnecessary practice. Unfortunately, it is a growing practice.

It is important to warn the public against clearly-defined and soundly-studied dangers. It is also important not to alarm the public about ill-defined and superficially-studied so-called dangers if for no other reason than "crying wolf" is not a practice to be recommended.

One of the unfortunate things about our society is that it affords the opportunity for great publicity for superficial, spectacular statements. This sort of thing has happened time and time again. There is the supposed scientific disclosure pointing to a potentially great danger from some customarily used item which turns out to be based on marginal research work. This, I suppose, ought to rate pretty high as a potential deception. The penalty on industry is that this sort of thing adds to the demand for more control besides, of course, scaring many people out of their wits.

I am sure no one here subscribes to the practice of jumping to conclusions based on incomplete research, but we all know that this has happened. For example, the many saturated fat studies and statements and their evolution has tended to confuse many people. In fact, we don't yet know the whole story on saturated fats and what the consumer should do about them, except possibly that, as with all foods, they should be consumed by the normal person in moderation and in a balanced diet.

As a company, we have so much respect for the complexity and the workings of the human systems and so much appreciation of the little that is known about these systems and about nutrition that we are very hesitant about drastic conclusions, and we are most careful in the use of ingredients that are new to the human body unless they have been subjected to extensive and thorough examination and testing.

In my previous quote, I indicated that under too many controls, initiative will be stifled. It is in order to mention several examples. For example, if all foods were controlled so as to be sterile or to have impractical low tolerance levels of certain organisms, there could not be a frozen food industry, nor, for that matter, a fresh food industry.

As we all know, the human body develops tolerances to certain bacteria by being exposed to absorbable levels of those bacteria, but

this is a rather ineffective defense against impractical bacteria level controls from the public relations standpoint. Of course, without those tolerances, the human body is a ready victim for bacterial attack.

If all side effects of body inputs are to be ruled out, drugs will disappear and we will no longer have a population problem, nor will we have a population.

If the conveying of electricity or the ways in which electricity is used had been fully controlled, it is unlikely that this country would have invented the many new electronic industries or techniques which have meant so much to our economic development.

The railroads of our country are subjected to many kinds of government operational regulations. Can anyone deny that this has had a strangling effect on transportation development and productivity?

The question of the degree of governmental controls raises some rather fundamental philosophic considerations. For example, too much of an essential amino acid can do harm—too little can do harm also. So are we to have government controls of lysine consumption, for example, or methionine, tryptophan or leucine? If so, then we need controls of water intake, of air intake, of exercise, of sleep, and on and on, since too much or too little of these things also is dangerous. Too much of anything is a poison. Too little of many things also does harm.

The many attacks on miscellaneous food items and the clouds placed over the heads of food processors seem a bit out of tune with the following which is excerpted from the Technique Book of the Hospital of the University of Pennsylvania under the heading "Poisoning."

> CAUSES. The five products most frequently involved in acute poisoning are baby aspirin, household insecticides, bleach, disinfectants and sedatives. The major categories of products responsible for acute poisoning are:

Internal medications	38%
Household preparations	19%
Household pesticides	10%
External medications	9%
Cosmetics	6%
Paint, varnishes, solvents	4%
Petroleum distillates	2%
Others	12%

I am happy to note that there are no commercial foods mentioned in this handbook for the hospital staff.

There are a few other observations that apply to this field of regulatory matters. If the nature of packaging or the package shape or size are to be under full control, a wide area of innovation and product development will be effectively curbed, and that would not be good for our industry's economic development nor for the consumer.

The way food ingredients are shown on labels has been a subject of much discussion. The way they are now listed seems to be about all that is practical and necessary. I question whether it is possible to list the really essential ingredient information. To us the word "essential" implies the essential nutrients, which means the individual amino acids, the individual minerals, vitamins, the particular lipids, etc.

There are scores of important and complex chemicals in each fruit or vegetable or meat including many different esters, ketones, alcohols and aldehydes, and the important sulfur-containing components. There is a wide range of relative nutritive quality in any ingredient depending on variety or breed, degree of maturity, how the ingredient is handled by the processor, etc. I am not much impressed by the value of a detailed listing of ingredients as a means of knowing whether a product is good as nutrition or attractive as food. I understand the astronauts subscribe to the importance of flavor, texture and appearance as important nutrient factors and these do not appear in the ingredient listing. It is possible to have a piece of beef of excellent nutrient qualities or to have one of relatively poorer nutrient qualities. How would we list such information? Flavor chemicals are highly complex and, we believe, highly important to nutrition. How do we label these effectively? They are elusive and constantly changing with time.

A sophisticated approach to detailed essential ingredient labeling runs into great difficulties. Is it wise to insist on a refinement of ingredient listing beyond what we now have without going all the way? Of course, going all the way doesn't seem to be very practical.

On the other hand, when we try to have contents in terms of fluid ounces adopted for canned products so as to simplify things for consumers, we run into insurmountable bureaucratic hurdles which, I guess, shows that controls can work to create confusion. As you know, in the United States we must use avoirdupois weights which vary fractionally from one product to another within the same can size. I would not like to be asked to defend that regulation on

the basis of logic. In most countries, we are free to use the less confusing fluid ounce designation.

The theory that the consumer must be protected in great detail from making his own decisions is gaining ground. It is the justification for all kinds of regulation. The fallacy, of course, is the assumption that the consumer is incapable of thinking or acting on his own. Anyone who is in the consumer products business knows that the consumer may be burned or short-changed once, but then is wary, and that the business engaged in that burning or short-changing is short-lived.

In World War II, when I was working on military production, one of the large installations engaged in the making of aircraft engines was under inspection by a zealous inspector who decided that he would tighten up on the tolerances under which machinery parts were to be made. The production in that plant ground to a halt in a hurry, and it was not until the tolerances were restored that the production of the aircraft engines could be started and, after some time, brought to the pre-zealous control level. This was an unfortunate and expensive experience because we needed those aircraft engines badly.

Food Controls and Standards

I would like to recommend that food controls and standards be administered along these lines:

(1) Controls and standards for the food industry should be applied generally only when they are needed generally. The exceptional case should be dealt with without placing heavy control loads on the majority.

(2) There needs to be a high degree of professionalism and practical knowledge by those who set up controls and standards, else they can do great damage.

(3) The setting of controls and standards should be done only after thorough and sound research. There needs to be a realization that controls and standards tend to stultify innovation and progress. Also, there must be an understanding that the implementing of controls and standards is costly to industry and government and, therefore, to the consumer. The consumer, of course, in the end pays for all the costs of controls.

(4) We should constantly review controls and standards to see when they may be reduced, for it is of great advantage to

our country to operate on as free a basis as practicable when this can be done without undue hardship to the public welfare so as to stimulate innovation.

Now, just so that you know that the food industry is not without controls, standards, inspections, etc., let me list some of the many food regulations we must follow and the many kinds of inspections that we are subjected to. For example, at one of our plants recently, we had inspections from five government agencies in the plant on one day.

(a) First, there are food standards we place upon ourselves.

1. In the kinds of buildings we occupy and the materials of construction.
2. In the kinds of machinery and the materials in that machinery.
3. In the environmental conditions inside and outside the plant.
4. In formulating products.
5. In ingredient specifications.
6. In preparatory requirements including sanitation.
7. In the removal of foreign matter and the rejection of defective material and in processing specifications to insure sound product.
8. In the final product specifications.

(b) There are standards placed upon us by the Food and Drug Administration.

1. Naming of the product.
2. Labeling of the product.
3. Regulations as to the contents.
4. Fill of the container.
5. Limits on pesticides and additives.

(c) There are also standards placed upon us by the Department of Agriculture.

1. Inspection of meat content for wholesomeness and amount.
2. Fill of the container.
3. Processing.
4. Construction of the building.
5. Use of the building.
6. Employee behavior and cleanliness.
7. Continuous inspection 24 hours a day.
8. Naming of ingredients.
9. Naming of product.
10. Limits on pesticides and food additives.

(d) There are controls and standards placed on us by the state governments, county governments and city governments. Here there are a myriad of requirements which must be dealt with according to the individual state, county and city requirements.

(e) There are international standards to be met. Sometimes these apply to labeling, sometimes to contents; sometimes they permit a product only if made in a certain way. We think international standards are influencing our government agencies in their work. The European Economic Community and the Codex Alimentarius Commission are active in promulgating food standards in addition to the work being done by individual countries.

(f) Finally, there are standards placed on us by the consumer in order that we may merit her patronage and here we get into the most important standards of all because we are talking about quality of product, value of product, appearance, flavor, texture, attractiveness, nutrition, fill of the container, and all other matters which the consumer observes relative to the product.

These, of course, are in addition to all the many government controls and inspections that apply to industry generally in the financial, employment, wage and hours, transportation areas, and on and on.

Conclusion

We know there must be some food standards and there must be some controls. We also know that there must be a large measure of common sense in the establishment of food standards and controls, and that those who establish the standards and controls must have a high level of competence, else there can be great damage to the industry, to the country and to the consumer. Further, those who establish controls and standards must not be panicked by superficial attacks and questionable evidence.

Now, have I responded to Mr. Breeling's points as cited at the start of this talk? I think I have, for I have said, in essence, these things:

The food industry is now under a host of regulations and controls. They are expensive. Many of them may not be needed for most food manufacturers. At the very least there now is enough government control of the national food processor. Controls and standards are not yet excessively stultifying, but if expanded, they will hinder innovation and development.

Previously I said, "anything taken in excess is a poison." I might add that this applies also to excessive governmental controls.

[The End]

Food Standards

By DON MUHM

Mr. Muhm Is the Farm Editor of the
Des Moines (Iowa) Register and Tribune.

THIS IS, I THINK, THE AGE OF TRUTH. It is a time when the vocal young of this nation clamor for people to "tell it like it is," a time when presidents of this great nation quickly appoint "consumer representatives" to pitch for Truth in Packaging, a time when others are screaming for Truth in Lending, while others publicly appeal for safeguards, pesticide control, less pollution, wholesome meat and so on.

It is a time when there's a lot of talk about nebulous things like the so-called "creditability gap," the virtues of spending billions to put man on the moon and the costs of the Vietnam War in dollars and in blood.

All of this—all of the dirty linen of our nation—is hung out on the line by a variety of people and represents the penalty of a well-informed citizenry. We are exposed to all sorts of news and knowledge in the climate of a free press that brings us the word, the opinion, the idea and a bundle of worries about everything from the amount of DDT in the Coho salmon in Lake Michigan to the amount of lives lost on a steamy peninsula 10,000 miles distant where the military engages in combat on a place called Hamburger Hill.

I remember Pork Chop Hill in Korea . . . and reading about Hill 609 in Tunisia . . . and Cassino in Italy . . .

All of this, I suppose, seems a bit afield of your subject here today, but really it isn't. It is all a part of this time of great protectionism in which we live, and thrive, and worry and pray.

Your symposium had identified me for you as a participant termed "consumer." In this respect, I share company with a couple

of hundred million fellow Americans who enjoy the best in food output this world has ever known. Where so many millions about the globe worry about where the next bite of food is likely to come from, we are mainly more concerned about calorie counting, jogging, the Canadian Air Force exercises, Diet Cola and heart disease.

Most assuredly, we here live in abundance, surrounded by mountains of food. This is a nation for which, since the time Abraham Lincoln was in the White House, farm surpluses have been easily—and readily—achieved. Just for the record, Lincoln's agricultural commissioner reported that farmers in the early 1860's were plagued by the normal, mundane hazards of their occupations—insects, poor weather and over-abundant production.

This has changed little during a time of technological invasion into farming. The locusts have been replaced by the rootworm and the European corn borer, for example, and arsenic-based poisons by the chlorinated hydrocarbons and organophosphate insecticides. Such is change, I guess.

But while food production has grown, with fewer and fewer hands at work feeding us (there has been a 30 per cent decline in the U. S. farm population in less than 10 years, and U. S. taxpayers this year will pay farmers $3.5 billion to hold land out of production), there have been many moves to help guarantee that this food supply is wholesome and nourishing. All of this effort to protect us is part of the antiseptic society of which we are a part. Man is guarded against plagues and disease by a myriad of immunizations, against bacteria in what he drinks and eats, is assured of quality by a federal government grade or stamp—and all such things in the interest of purity and good health.

Era of Protectionism

Let's look at the average consumer on an average day. He arises from bed (the mattress has been inspected prior to sale by the State Department of Agriculture) and alights on a nylon carpet (also inspected) and brushes his teeth with a compound endorsed by a dentist's association. When he arrives at the breakfast table, he drinks Florida orange juice blessed by the state citrus association but produced in a plant that was inspected. He eats Grade A eggs with his fried bacon (inspected at Plant No. 3801), and he wipes his chin with paper napkins untouched by human hand.

He walks out the door of his mortgaged dwelling (owned by one of the nation's foremost insurance companies and inspected by the government when he applied for an FHA-guaranteed loan). He walks to the garage, built after the city inspector okayed the site, the distance from the house and the materials used. Then he climbs in his car, made much safer now, some say, because of consumer-minded Ralph Nader who caused shoulder straps, side lights and a few other touches to be added to better protect the driver and occupants.

Our average Mr. American cruises down the freeway built largely with federal funds—and to federal specifications—to work. He smokes a cigarette enroute, despite the government-backed warning on the package that this smoke may be hazardous to his health. He cuts out for an early morning coffee break in a cafe which was recently inspected by both state and city health officials.

While his coffee cools, our friend picks up the coffee whitener—a non-dairy product that has its stamp of clearance on the bottom. If he has cream for his coffee, then he has a big list of inspectors who are making sure that it is pure and healthful. The cream would be Grade A—and from a dairy plant that is inspected, via a bulk tank that was also inspected, from a dairy farm where premises and facilities are periodically inspected, and from cows that in turn have been inspected.

Almost everything we come into contact with these days at one stage or another has been inspected by some one, some unknown guardian of our fate who for various reasons looks out for our general welfare. Even the suit our average American buys in ready-to-wear has a small white tag in one pocket informing the buyer that it was inspected by No. 32.

Such things are to be expected in an era of protectionism. And these unknown protectors arm themselves with standards, or ideals, or codes, or regulations, or specifications, or something they can use as a bench-mark to compare a thing with a mythical thing all in the interest of our general welfare.

Who should establish such standards? Should it be Uncle Sam, Ralph Nader, the president's consumer representative, the producer, the processor, the retailer, or who? That is a good question.

King Consumer

The consumer, in this great country, is king. He is wooed by pretty girls on television selling everything from a new brand of cigarette to a fast-back sports car, in newspaper and magazine ads, via billboards and you-name-it. These entrepreneurs all want his business—his dollar, his sale.

What's best for the consumer? This is difficult to answer. He relies, I think, on others to help him reach a decision. There is little doubt that he does rely on the government. In buying meat, he, of course, wants this product inspected—and the headlines about "dirty meat" or "dirty plants" that were a part of the hubbub which led to the passage of The Wholesome Meat Act of 1967 made the consumer much more conscious of "clean" meat.

To a lesser degree, the consumer relies upon the U. S. government grade affixed to most meat products. Everyone has an image of what prime beef is, that a prime rib or a U. S. Choice grade beef is pretty fancy eating. To many people, such ranking related to quality is important.

Out in my home country, the pig is big. Iowa farmers produce about 23 per cent of the nation's pork. Hogs are appraised on the basis of a government rating: U. S. No. 1, No. 2 or No. 3. These grades relate to the predicted meatiness of these porkers—no such rating is given to the pork itself, as is the case with beef. So telling consumers about U. S. No. 1 hogs is somewhat of a wasted effort—they buy pork that is not graded.

This briefly, is the background related to why I think the consumer does rely on the government as far as food standards are concerned. He knows, for example, that the government has a consumer protection program related to a safe and wholesome food supply. He knows that meat and poultry are inspected, as are other foods, and that the U. S. grades are given in relation to quality.

The Consumer and Marketing Service of the U. S. Department of Agriculture, for example, has 14 program divisions, in relation to seven commodities: cotton, dairy, fruit and vegetable, grain, livestock, poultry and tobacco. Consumer food programs are carried out by the government for school lunches, commodity distribution, the Food Stamp Program and other programs.

In general, the Consumer and Marketing Service stands for dependable quality, clean and wholesome food, competitive markets where these products are traded and better meals for more people.

In addition, the Food and Drug Administration (FDA), at various points about the nation, monitors things like pesticide content in food, accomplishing this in the main under a market-basket food survey system. They buy something like 60 pounds of food to analyze for residues.

This 60 pounds of food is the equivalent of what one 19-year-old human male will consume in a week. And it includes everything from soda pop to potato chips, and from pizza to pickles, in that typically American institution, the super-market, where buyers choose from something like 7,000 items.

Recent Government Actions

This mountain of food is analyzed by the FDA workers, who have scientific machines that measure into parts per million or smaller amounts. This monitoring of our food supply is an important aspect of this age of protectionism in which we live. It's just another inspection to make sure that what we are consuming is safe for man.

In Iowa, we have had FDA action against the producers of milk because pesticide residues were found in this product. We have had government action against an egg producer because his eggs contained minute amounts of a common poultry pesticide. And we had a firm that sold beet pulp (to be fed to beef cattle) lose part of its beet pulp because the material contained pesticide residues.

And we had a load of popcorn seized by the government because the farmer had loaded this product into a truck which earlier had been used to haul pesticide materials. Somehow, some of the pesticide material was absorbed by the popcorn—and the FDA saw to it that this popcorn was not sold as human food.

The government's interest in our food supply stretches even overseas. All of you have heard about, or have consumed, imported food—cheeses, meats and other goodies from abroad. In the case of imported meat, usually canned hams and fresh, frozen boneless beef, U. S. inspectors actually visit foreign plants where this food is processed and inspect those exporting facilities.

Imported meat is no small item. Last year about 3 per cent of all of our beef came from overseas. In 1964, it was estimated that 10 per cent of our beef was of foreign origin.

The overseas inspection of meat packing facilities is just another facet of our protectionism—the effort to guarantee a safe, and wholesome food supply. Despite this effort, some consumers still raise questions as to whether or not the imported meat has to pass the same type of rigid meat inspection standards used in the U. S.

Many livestock-oriented groups, who have a vested interest in the meat business, ask questions about the quality and wholesomeness of this foreign meat being brought into our country. And it is proper that they do raise questions, since the average consumer in Des Moines can buy Danish canned bacon, Holland hams, Canadian kippers or smoked oysters from Mexico in a local dime store on Walnut Street.

A discussion about food standards would not be complete without reference to new foods, the imitation and filled milk products and, the newest food market invader, the soybean protein product.

First, let us look at the imitation or filled milk products. These products are being packaged and sold in containers resembling those of ordinary Grade A milk products. Instead of butterfat, these milk-like products contain vegetable oil and, in some cases, coconut oil.

Dairy-minded persons have asked questions about how these milk-like products stack up nutritionally. They naturally feel that these milk-like products are not as nutritional as milk, the product they have labeled "nature's most nearly perfect food."

Some dairy groups want these products banned by law, others want them priced the same way milk is priced so that any competitive price advantage between real milk and imitation milk is eliminated, while others want medical groups to point out whatever nutritional difference exists.

The dairy farmer has been beseiged by imitation products—from ice milk to coffee whiteners to even non-dairy whipped "cream." And he long ago lost the battle to ban oleomargarine, after efforts to fight it by law, and a great share of the butter market has been lost.

Soybean Controversy

Now, along comes the soybean protein family of foods—the newest upstart in imitations. The soybean, which we imported in the 1920's from Manchuria, is a fantastic crop. Henry Ford grew thousands of acres of soybeans near his auto plants in Michigan and hired scientists who were instructed to build a car out of soybeans. And they tried it—even to the point where automobile engine blocks were built out of soybeans.

Now, the soybean is widely used to produce a protein supplement for livestock and poultry feeds. But in recent years, some of the big food manufacturing concerns became interested in the edible soy protein fiber.

This soy protein is a versatile product which can be flavored, colored and manufactured in many ways. You can make everything from soup to nuts out of soybeans—literally.

For several years, a church-owned food plant in Ohio has produced weiners, hams, chicken, beef steak, hamburger, meat-loaf, cold meat cuts and so on, out of the soybean.

Then the big names—General Mills, Ralston-Purina, Central Soya, Archer-Daniels-Midland, Swift & Co. and others—became interested.

General Mills recently broke ground at Cedar Rapids, Iowa, for a plant which will produce soybean foods. Its first product is Bac-O's, a soybean food resembling bacon bits and used for dressing up salads, casseroles, sour cream for baked potatoes and so on.

General Mills takes soybean meal and can transform this conventional livestock feed ingredient into fish, or fowl, or fruit, or vegetable, or nuts or meat items. The purified protein can be spun into fibrils which readily absorb flavor and color, and can be prepared in slices, chips, chunks, dice or crumbles, or into a piece of meat resembling a hot dog, a chicken drumstick or a New York cut steak.

General Mills' trade name for this soy protein is Bontrae. Archer-Daniels-Midland extrudes soy protein and calls it TVP—textured vegetable protein. Swift and Company calls its soy protein concentrates Texgran, while this same firm calls its soy flours Mellasoy.

What is the potential for these new foods? Some livestock groups are worried, and have passed resolutions at meetings asking

that laws be passed so these meatless but meat-like products must be colored green—or any color not associated with red meat products.

Soy protein officials, however, say that these new foods do not pose a threat to the livestock or poultry industry, and that the soy foods represent a means of supplementing the already excellent American diet. And some, in humanitarian fashion, point out that these foods may offer hope in combatting world hunger in some areas.

James P. McFarland, president of General Mills, said in the ceremony at the Cedar Rapids plant this spring that the potential for soy foods is virtually unlimited. He said:

> These foods can be tailored into any desired food framework. These foods can be used for vegetarians, for the kosher market, for polyunsaturated foods, for foods high or low in carbohydrates, or low in animal or vegetable fats, with zero cholesterol, or with or without vitamins and minerals added, and with a precisely controlled calorie content. These foods can be refrigerated or frozen, or canned or dried.

In summary, the soy foods sound like what the doctor ordered—a special food for special cases. A food that can be prescription-made.

The obvious question now is, what standards do you set up for a whole family of such soy protein foods? I doubt if there was ever a time like this in all of history when such a broad range of food products are on the verge of being put into the American food system.

Who will set the standards—the processor? The consumer? The government? I don't know. But it is time someone started thinking about how you cope with this far-reaching development in food technology.

Millions of dollars have been invested in the development of these new foods, just as millions of dollars have been invested in growing soybeans and producing meat animals. So you have strongly-interested parties involved.

Dr. Herrell DeGraff, president of the American Meat Institute, feels that tomorrow's foods will be what the consumer accepts out of what the food technologist innovates. "The consumer," Doctor DeGraff says, "has the greatest degree of effective free choice among abundant alternatives in her food supply that the world has ever known. The innovator can propose but the consumer will dispose."

Doctor DeGraff notes that the food animal production in the U. S. is small by comparison to the potential of food proteins from

plants. Meat and animal proteins have been "complete" proteins because they contain all of the ten essential amino acids. But now these amino acids have been synthesized in the laboratory, opening the door to combining the abundant plant-originated proteins with amino acid supplementation.

Doctor DeGraff says that it is possible now to create foods composed of precisely the ingredients of all natural foods, and that the greatest limitations encountered by food technologists are in texture and in flavor. In other words, nutritionally we can make any food. The immediate problem is taste-appealing texture and flavor.

High-Lysine Corn

Let's mention one more new "food" possibility. This is the development at Purdue University of high-lysine corn. This is a modified protein corn which has two major potential uses: First, it produces good weight gains on hogs without the usual soybean meal supplementation in the ration; secondly, this corn is a more complete food for humans.

The promoters of high-lysine corn believe that in the food-rich U. S., hog use of this grain will be dominant, while in the global hunger realm, the new modified protein corn poses a promise of fighting malnutrition in those countries where corn-consuming populations exist. This new type of corn is being planted on a limited basis now in the nation's Corn Belt. Tests are planned to follow up with swine-feeding and pork carcass tests. Overseas, efforts are being made to get this modified protein corn planted in food-short areas where malnutrition is a perpetual enemy of man.

In conclusion, I feel that we all need to be alert to what is taking place—from demands for greater assurance of a safe and wholesome food supply to interest in the new foods that technologists are bringing forth.

Coming from a livestock and grain state, I believe, too, that there is a great need for a closer working relationship between all facets of the food industry, from the livestockman to the packer, retailer and others—including physicians.

A case in point is the heart disease-cholesterol debate, with meat producers, on one hand, arguing that their products are being blamed

for many of the health sins of our humanity, while the heart and medical groups, on the other hand, are urging less animal fat intake in order to fight heart disease.

Sometimes, one group will conduct research, reach a conclusion and issue a press release. Then, the counter-attack comes, as the opposing or disagreeing group completes its study, reaches a different or contrasting summation and issues another press release. Caught in the middle, between the headlines, is the undoubtedly confused consumer.

In our paper, we have printed such items, ranging from the quality of peanut butter to the amount of fat which should be permitted in the hot dog. And we have had items about possible hazards in that great American pastime of grilling steaks over a charcoal fire in the back yard. We even carried a recent item in which some authority expressed concern about the possible amount of DDT babies received through nursing at their mother's breast.

It is possible in this nation for a man like Nader to come forth and question the safety of our cars and to gain national press coverage. It is possible for a person like Rachel Carson to raise questions about the use of agricultural chemicals as she did in her book, "Silent Spring." It is possible for a man to write newspaper articles about the meat-packing industry and cause new federal meat inspection legislation to be passed as Nick Kotz of The Des Moines Register did in 1967.

The consumer, as I said earlier, is king in this country. Many people, from the government inspector to the processor to his family doctor, look out for his welfare. This is an excellent relationship—and a fruitful relationship. And it is a relationship that should be continued. I for one have a degree of confidence in knowing that a government meat inspector is at work, and that a city inspector is checking the milk supply, and so on.

And it seems to me that the consumer should never have any shadow of doubt about the safety or the wholesomeness of his food supply—not in a nation where food is produced so abundantly and actually is such a good bargain. When we have the technology to produce plentiful supplies of food and to create new families of food, there is no reason for not guaranteeing that this food is safe and nutritious. **[The End]**

Standard-Setting—FDA

By J. KENNETH KIRK

Mr. Kirk Is the Associate Commissioner for Compliance, Food and Drug Administration, Consumer Protection and Environmental Health Service, Department of Health, Education, and Welfare.

UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, administrative procedures are established for the development and issuance of standards of identity, quality and fill of container for food products. Once established, these standards have the force and effect of law.

On its face, the procedure set forth in the statute appears quite simple; either the Commissioner of Food and Drugs or any interested party, including industry, consumers or State officials may propose such standards.

The procedures for actual operation have changed quite a bit since the law was enacted in 1938. Initially, every standard was required to be based on evidence adduced at a public hearing. It was necessary for proponents of a standard to introduce evidence on every point, even to show that yeast is necessary in making bread. The same procedure had to be followed for even minor amendments.

Looking back, it is amazing that so much progress in standard-making was achieved during the dozen years that this mandatory hearing procedure was in effect.

The procedural burden was lessened materially by the Hale Amendment which eliminated the need for hearings on items which were noncontroversial. The procedure at that point became one of publishing any proposal which was supported by reasonable grounds, inviting comment from all concerned, issuing a final order with opportunity for objections, and then holding a hearing only where the objections appeared to warrant this course. As always, of course, there was opportunity for appeal to the courts on a final order issued after a hearing.

It must be remembered that when we started to establish food standards, we did not have any requirement in the law which called for preclearance of additives, and there was a very strong feeling that no federal standard should authorize an ingredient about which there was any question of safety.

The logical result of this policy was that we issued the so-called "recipe" standards, where every ingredient which might be used was specified by name, with the possible exception of some flavors, colors and spices. This meant that any ingredient not named could not legally be used in the standardized food.

Two Major Disadvantages

From the safety standpoint, there was no question but that those standards had achieved the purpose intended. There were, however, two major disadvantages:

This listing of every ingredient ruled out opportunities for the Commissioner to require label declaration of most of the ingredients so that, in general, ingredient listing on standardized foods was limited to artificial colors, artificial flavors and chemical preservatives. Certainly this lack of ingredient declaration on standardized foods was the subject of rather substantial objection by many consumers. I don't know how many letters we have received raising questions about mayonnaise labeling because of the absence of an ingredient declaration.

The second disadvantage was that the producer of the food was essentially locked into a formulation whereby he could not make desirable changes without amendment to the standard; and we must admit that even minor amendments took time, notwithstanding the procedural changes of the Hale Amendment.

So it was not unexpected that many in industry held to the view that the establishment of standards for their products should be avoided, at least until such time as they ran into cut-throat competition from those who were producing essentially debased competitive products. Of course, at that point good legal, enforceable standards were wanted.

In 1958, the Food Additives Amendment was enacted, providing for pre-clearance of food additives for safety. This eliminated the need for the kind of safety consideration under the food standards procedures which had been followed up to that time, and the Food and Drug Administration (FDA) concluded at that point that the old-time "recipe" standards were no longer needed. Optional ingredients

should now be named only where such designations are needed to promote honesty and fair dealing.

The first of the standards to come out under the new procedure were those for breaded shrimp, whereby the shrimp content was specified as a minimum, but the breading and other ingredients were set forth in quite general terms, with two provisos: that none of the ingredients could be food additives unless they had been cleared under the Food Additives Amendment, and that the packer would be required to name on the label the specific optional ingredients that he did use.

This policy, of course, makes it unnecessary for constant amendments to the standards, and yet the public interest is served as well, if not better.

At the time the breaded shrimp standards were issued, FDA contemplated that it would be desirable to review all of the standards issued to date to get rid of the "recipe" approach and to require more label declaration of optional ingredients actually used. I regret to say, however, that in the years since it was decided that this was a good idea, FDA just has not had the facilities to take on this review.

I mentioned earlier that when there is controversy over a standard, the statute provides for a public hearing to take testimony on which the final legal standard will be based. The opinion is widely held that in actual practice this hearing procedure has not worked out to the best advantage of all concerned.

The idea was good—that we would have a public forum whereby those who had competence to discuss the various issues involved would present the scientific facts on which decisions would be based. In practice, some of our hearings have developed into clearcut adversary proceedings, making the hearings more like a trial in a court of law than a scientific fact-finding operation.

Recently I have seen substantial evidence that even the lawyers who have been involved in these hearings have recognized that there ought to be a better way of getting facts into the record. Personally, I am hopeful that one will be found.

Separate Standards

The original idea of food standards was to assure the integrity of food products sold under readily-recognized names, but as the program proceeded, it became quite apparent that there was need for providing for special nutritional needs. This was accomplished quite readily by the procedure of establishing separate standards for en-

riched foods, such as bread, flour and macaroni. Even in the case of margarine, we made provision for the optional use of vitamins.

In each case where the standards provided for the added vitamins and minerals, provision was made to insure that the foods involved would have enough of the added vitamins and minerals, but that unreasonable overages which would be of no value to the consumer or, in some cases, might even be detrimental, were prohibited.

Among other advantages of the top limit was the avoidance of opportunity for the consumer to be misled by a numbers game on the part of the promoter who would take the position that if enough is good for you, several times that must obviously be better.

The enriched foods standards, some of which have been in effect for over 25 years, have been so successful in providing foods with adequate nutrition that it was, at best, somewhat surprising to have the tremendous hue and cry which resulted when FDA undertook to establish comparable maximum and minimum standards for various other fortified foods and for the vitamin and mineral pills which are so widely marketed.

This issue, as many of you know, is currently the subject of an ongoing public hearing, which itself has been the subject of a very great amount of criticism.

In our opinion, it is essential that we consider nutritional values in the establishment of standards. There is, of course, a Supreme Court decision which essentially provides that a standardized food which does not meet the standard can get out from under its requirements by being labeled as "imitation." But when we learned that imitation milks were becoming more important items on the market place, we felt it would be contrary to the public interest to take the position that an imitation milk could be made according to any particular formulation that might be desired. Certainly it is to be expected that a consumer buying a product labeled "imitation milk" would do so in the belief that the product at least supplied the nutritional values of milk, even though it might be sold at a lower price and obviously was not the product coming from the cow.

So FDA undertook to develop standards of identity for these imitation milk items. We published proposals inviting comment. We have received a lot of valuable comment, but, perhaps not unexpectedly, quite a bit of objection to the idea of setting up such a standard. Decision on this matter is expected shortly.

A Need for Participation

This brings me to a point which has bothered us for some time, and that involves the question of how we get better participation in our food standards operations, particularly from consumers who should be especially interested in the kinds of standards that we put out.

We publish a proposal in the *Federal Register* and invite comment. Our invitation is sincere. We have no problem in getting comment from those in industry who are involved in the manufacture or distribution of the product and who do not like some feature of the proposal. On the other hand, we do not get very much comment from that segment of industry which may agree with our proposal. Neither do we get very much comment from consumers.

Now we realize that consumers generally do not read the *Federal Register*. We have explored various ways of getting this information to consumers, both individually and as groups. May I offer an invitation to all of you to give us any ideas you may have as to how we may better involve consumers in this important operation.

Mr. Anderson has told you about the Codex Alimentarius Commission and its programs. We strongly recommend that industry and government continue to participate extensively in this program.

However, because of the many cases where there have been misunderstandings about such standards as the Commission may issue, I would like to say again that, as far as the U. S. is concerned, no standard issued by the Commission can be adopted or enforced in this country, whether we are talking about domestically produced or imported foods, unless that standard has been formally adopted under the procedures of the Federal Food, Drug, and Cosmetic Act.

There is nothing automatic about this, but if the Codex Commission comes up with good standards for foods for which we do not now have standards, or if the Codex standard is a better one than the standard we now have, certainly FDA would want to publish this as a proposal looking to have it adopted under U. S. law.

The day of the caveat emptor concept has long gone in the area of marketed foods. Industry has an obligation to supply clean, sound, wholesome foods which are honestly represented for what they are. The development of food standards is, in many instances, a major aid in achieving this objective.

We must not set up standards just for the sake of setting them. They must be reasonable, carefully worked out to avoid any loopholes or opportunities for debasement of the food, and finally, efficiently enforced across-the-board. [The End]

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