The Federal Food, Drug, and Cosmetic Act prescribes that standards of identity, quality, and fill of container shall be set up by the Secretary. Misbranding is described as non-compliance with a food standard of identity, quality, and fill of container. Standards must be "reasonable" and adopted by the Secretary after public hearings. Provisions are made which permit a manufacturer to develop a new product and test it without risking competitive loss or regulatory action when the commercial procedures are conducted in compliance with specific permit provisions.

**LAW MISBRANDING**

Section 401 of the Federal Food, Drug, and Cosmetic Act says, "Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *** In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. ***"

To appreciate the meaning of Section 401 fully, we must give considerate attention to the implementing paragraphs of the law which declare a food to be misbranded "If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided in Section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food." [Section 403 (g)]. Further, "If it purports to be or is represented as (1) a food for which a standard of quality has been prescribed by regulations as provided by Section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or (2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by Section 401, and it falls below the standard of fill of container applicable there to, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard." [Section 403 (h)].

You will observe that the law defines as misbranding failure to comply with a definition and standard of identity. A number of states have laws and regulations that define such noncompliance as adulteration and this may be occasioned by the fact that the earlier food standards issued by the Federal Government for advisory purposes were called standards of purity for foods. Legislative considerations preceding the Food and Drugs Act of 1906, commonly and popularly referred to as "The Wiley Act", proposed to give to the Secretary of Agriculture authority to adopt standards of purity for foods because he had this authority by virtue of the Appropriation Acts beginning in June 1902; however, it lapsed with the passage of the 1906 Act. Obviously it was the theory then that failure to comply with standards that might be adopted would be considered substitution of one article of food for another, and this is usually defined as adulteration.

After the passage of the 1938 law, which contains the provisions and grants the authority for establishing standards, we approached the situation with the assumption that changes in the composition of foods for which standards were adopted could not be made at will by the manufacturer by resorting to the practice of stating the variation on the label. However it was some time before this very important difference between definitions and standards of identity under the 1938 Act and the advisory standards under the 1906 Act became routinely recognized in the regulated industries.

**STANDARDIZATION PROCEDURE**

You will have noted that the law provides for the promulgation of three different types of standards: (1) identity, (2) quality, and (3) fill of container, and each is required to be "reasonable." We are now thinking of the standardization of foods, so what do we mean by that term? The Encyclopaedia Britannica defines standardization as the establishing, by authority, custom or general consent, of a rule or model to be followed. In its broadest sense, standardization applies not only to such matters as weights and measures and material objects, but it permeates most fields of human activity.

Shelby T. Grey was born and educated in Texas. He entered the government service as Sea Food Inspector in 1934 in the New Orleans District, and became Supervising Sea Food Inspector on the Atlantic and Gulf coasts. He has served as head of the field inspection stations at Jacksonville, Florida, and at Charlotte, North Carolina, and then on to be Chief Inspector of the Philadelphia and Boston districts in 1949 and 1951 respectively.
Food Standards

Folkways, taboos, moral codes, ceremonies, religious rituals, educational procedures, social and business customs, industrial practices and law itself, are all forms of standardization. Language is the most important example of standardization. That man has brought about. Words are sounds whose meanings have become established and so form our principal means of communication. The main use of the term standardization is, however, in connection with technology, industry and business, their products and processes.

What is "reasonable"? Should a standard be reasonable from the standpoint of the manufacturer of the standardized food or must the standard be reasonably calculated to promote honesty and fair dealing in the interest of consumers? The distinction may be presumed to be one without difference, because if a standard is not reasonable from the viewpoint of the manufacturer, it is likely, in the final analysis, not to be in the interest of the consumer, since a standard that is commercially impracticable to meet would cause ethical manufacturers to turn to some other field of production.

The procedure set up by the Act for the adoption of standards is prescribed in Section 701 (e), which states, in part: "The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof, stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend or repeal any regulation contemplated by *** sections *** 401, ***. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency."

Much has been written and more said about the standards-making procedure, and I must admit that this is a controversial subject; we are in agreement with the conclusion that much remains to be done by all of us in simplifying and improving the techniques and procedures for formulating and prescribing standards, but it is not my intention to go further into this phase of the Federal standards at this time. There is now pending legislation designed to improve the standards-making procedures.

Standardization

Because of the stated objectives of the Act, and of the food standards, it is evident that in considering an identity standard there are at least issues in two broad groups: (1) the physical wholesomeness of the proposed ingredients, and (2) the economic problem of the proposed standards limitations or restrictions. The creed of the Food and Drug Administration, as stated by Dr. Dunbar, former Commissioner, includes a belief that most American food manufacturers are honest and imbued with the desire and ability to produce clean, wholesome food, properly labeled. Certainly we do admit that no responsible food manufacturer would actually desire to manufacture a noxious product.

We find though that this premise does not always hold true when we consider the potential economic problems of proposed standards restrictions. In this connection, I am reminded of a statement made by Mr. L. M. Beacham, Chief of our Canned Foods Branch, Division of Foods, in considering the complex ramifications of attempting to develop a standard that will encompass all these variables. He said: "I have been reminded of an old colored man on my father's farm when I was a boy. He was sent out to the barnyard to count the new arrivals in a fresh litter of pigs. It seems there was one more pig than nature had provided nutritional outlets for, and he, not content to remain a 'have-not' was rooting and scrounging aggressively among his more fortunate brethren trying to displace one or another of them. When he succeeded, the one displaced would take up the fight to get back into the circle of the elect, with the result that the litter was kept in a state of writhing, dynamic turmoil. The old fellow stood off and counted slowly and laboriously, only to have his count thrown off time after time by one pig suddenly scampering from the counted to the uncounted area or vice-versa. Finally he came back and reported that he had counted all of the pigs except one because he had never been able to get that one to stand still long enough to be counted." So it seems to be with the identity standards; no matter how many variables we try to foresee, we frequently find we have overlooked one.

The authority for the promulgation of standards of quality, and of fill of container, with provisions for compulsory labeling of products failing to comply with these standards and the so-called "crepe label," is similar to the authority granted the Secretary of Agriculture in 1930 to establish such standards for certain canned foods by amendment to the 1906 Act known as the McNary-Mapes Amendment. It is generally recognized that it is difficult to enforce Section 403 (d) of the Act which reads, "A food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading," in the absence of a standard of fill of container. Failure to comply with the latter means that the product must be labeled "Below Standard in Fill" in specified type, enclosed in a lined rectangle, and occasionally more specific labeling may be required to indicate the degree to which the container is slack-filled. On the other hand, a product whose container is so filled as to be violative of 403 (d), i.e. "filled as to be misleading," must be repackaged to legalize it.

Quality standards have possibly caused more discussion and contro-
It must be recognized that to formulate a quality standard it is necessary to determine first where the dividing line between standard and substandard quality should be. Our experience has been that there is a natural inclination on the part of many food manufacturers of standardized products to draw the dividing line such that only a small proportion of a particular type of food will be substandard in quality. We have tried to approach the problem from the viewpoint of the average consumer and to draw the line so that all products that are of unsatisfactory quality for ordinary use will fall below it.

Section 401 contemplates definitions and standards of identity for single foods and for classes of food. Obviously, distinction between these types of definitions and standards has brought up a number of problems. It has been our theory that definitions and standards for individual foods should be specific and mutually exclusive. This theory, although apparently simple and easy to follow, has led to unexpected difficulties. For example, flour, or wheat flour, is generally recognized as a single definite food. However, a special type of flour is widely sold as cake flour. Cake flour is flour, but not all flour is cake flour.

**Standards in Relation to Progress**

We often hear the fear expressed that food standards retard progress. Hypothetical cases have been cited where a food manufacturer, after long and costly years of research and experimentation, discovers an ingredient suitable for use in a standardized food. Before it may legally be used, the manufacturer must request the Secretary to hold a hearing in a proposal to amend the standard; he must assume the risk of being able to show at the hearing the new ingredient will promote honesty and fair dealing in the interest of consumers. To do so he will have to disclose the identity of his new ingredient and if he succeeds in getting the amendment, all of his competitors may use it and reap the benefits of his costly and time-consuming research, unless the ingredient or the process of producing or using it is patentable. We then hear that manufacturers would indeed be rash to spend their assets in efforts to produce better foods if they are to run such risks that may result in the fruits of their ingenuity being lost to competition. It is true that an amendment must be obtained to permit use of a new ingredient in a standardized food but this has not been such a barrier to progress as is shown by the record of a long series of amendments, the hearing of which in several cases lasted not more than one-half day. I suggest that if the amount of an ingredient has not adequately safeguarded inventive genius, it would seem that its sale be changed rather than the consumer protective provisions of the Federal Food, Drug, and Cosmetic Act.

The Department of Health, Education, and Welfare has made the following provision for including new ingredients in standardized foods:

"The Department recognizes that appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the usefulness and consumer acceptance of new ingredients in foods for which definitions and standards of identity have been prescribed under section 401 of the Act. It is the purpose of the Department to permit such tests where they are necessary to the completion or conclusiveness of the investigation and where the interests of consumers are adequately safeguarded. The Department will therefore refrain from recommending regulatory proceedings under the Act on the charge that a food contains an ingredient not permitted by an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds a permit from the Secretary for the use of the new ingredient in such food and the permit is in effect at the time of such introduction."

"Any person desiring a permit may file with the Secretary a written application in triplicate containing as part of the application the following:

1. name and address of the applicant;
2. a statement of whether or not the applicant is regularly engaged in producing the food involved;
3. a reference to the applicable definition and standard of identity;
4. a full description of the new ingredient proposed for use in the food;
5. basis upon which the ingredient is believed to be wholesome and non-deleterious;
6. amounts of the ingredient to be used in the food;
7. purpose for which the ingredient is to be used;
8. labeling to be used for the food containing the ingredient;
9. period during which the applicant desires to introduce the food into interstate commerce; and where they are necessary to the investigation and where the needs of the applicant are adequately safeguarded."

"The Secretary may require the applicant to furnish such additional information as deemed necessary for action on the application. If the Secretary concludes that the ingredient to be added is harmless, may serve a useful purpose, and will not result in failure of the food to conform to any provision of the Act except Section 403 (g), he may issue a permit to the applicant covering the interstate shipment of such food containing such ingredient. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Secretary may deem necessary and state in the permit."

"The terms and conditions of the permit may be modified by the Secretary in his discretion or upon application of the permittee during the effective period of the permit. The Secretary may revoke a permit if he finds that the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit, or that the application for a permit contains an untrue statement of a material fact, or that the need for the permit no longer exists. During the period within which any permit is effective, the Department will deem it to be included with all other terms of any guaranty or undertaking otherwise effective pursuant to the provisions of Section 303 (e) of the Act."

"Information contained in an application will be held confidential
unless and until publicly revealed by the applicant. The fact that a permit has issued or is in effect will also be held confidential." (21 CFR, 1952 Supp., 3.12)

One of the problems of standard making is to promote a better understanding on the part of the food industry as to the probable results of the adoption of new standards. Since the adoption of a standard may cause some basic changes in manufacturing procedures, at times the reaction by the manufacturer is that he does not want a standard; however the modern industrial trend of food manufacturers is toward standardization, and they take a forward-looking approach by furnishing all pertinent data and cooperating in framing proposals and giving testimony so that the finally adopted standard will embrace only wise restrictions and will accomplish its purpose.

SUMMARY

In summary the purpose of standards of quality is to assure the consumer of obtaining a product of reasonably good quality, especially in foods where there are great variations in quality, or to advise of low quality before the product is bought. In the case of identity standards, the basic purpose is to assure the consumer of obtaining a worthwhile article without the necessity of studying and interpreting the label or labeling to determine what is being purchased. In the case of fill-of-container standards, the purpose is more directly connected with prevention of fraud or deception from slack-filling.

Better understanding between regulatory officials and the food industry is often facilitated by well-established trade associations. We in the Food and Drug Administration believe that all trade associations in the food industry should have regular committees interested in and dealing with the subject of food standards.

ERRATUM

The authors regret to report an error in their paper entitled “Determination of Protein Reducing Value of Milk As An Indication of the Protein Content of Nonfat Dry Milk Solids,” published in this Journal, volume 16, pp 241-246, 1953. On page 242 column 1, line 14, the factor given for converting the potassium ferrocyanide reading from the reference curve to protein reducing value expressed as milligrams of potassium ferrocyanide per 100 milliliters of milk is incorrect and should have been 40 instead of 66.7 as published. Since the factor 66.7 gives a protein reducing value for 167 milliliters of milk, all of the protein reducing values given in the paper, therefore, should be changed from the basis of 100 milliliters of milk to the basis of 167 milliliters of milk. To convert the reported protein reducing values to the basis of 100 milliliters of milk, these values should be multiplied by the factor 40/66.7 or 0.60. This error in the conversion factor, however, does not in any way affect the reliability of the method.

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Dr. Arnold H. Johnson has been elected as president of National Dairy Research Laboratories, Inc., Oakdale, L. I. He has been associated with the research work of National Dairy for over 24 years and, since 1950, has served as vice-president and research director of the Laboratories at Oakdale. He received his Master of Science and Doctor of Philosophy degrees in biochemistry at the University of Minnesota, teaching biochemistry there in 1925 and 1926. He was a Strietmann Fellow at the University. He was a Rockefeller Foundation Fellow at the Carlsberg Laboratories in Copenhagen, Denmark in 1927.

Dr. Johnson was formerly Technical Advisor to the Quartermaster Corps of the U. S. Army and is a member of many scientific societies. In 1946 he won the C. E. Gray award for “achievement in research, development of standards for dry milk, and for general industry and public welfare.”

NEW YORK STATE ASSOCIATION NEWS

“Progress Through Cooperation by Affiliation.”

There is strength in numbers, providing each contributes to the objectives of the whole. A handful of milk sanitarians recognized this fact when they met in Milwaukee, Wisconsin, forty-three years ago to found the International Association of Milk Sanitarians. For the next twenty-five years, they attempted to increase their strength through the collective efforts of their individual members. In 1938, progressive sanitarians who were members of both the IAMFS and similar state sanitary associations, foresaw the advantages to be gained by coordination and affiliation to attain a common goal.

The New York State Association of Milk Sanitarians is proud to have been one of the first, if not the first, state association to make application to the International Association for affiliation. Affiliation was granted in 1939 but it was not until twelve years later that an appropriate certification was issued. The benefits that accrue from such affiliation were soon recognized and at present, 25 state or regional associations are cooperative members of the International Association.

What is good for the goose is good for the gander. Here in New York State, our Association has grown so large that it could not supply the needs and desires of all of our members through an Annual Conference. Two years ago, a Committee was appointed to study and report on the feasibility and desirability of providing a liaison with local groups. That Committee recommended that our con-

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