Under the 1906 act, the Government established advisory definitions and standards for use in food inspections. However, these definitions and standards had no effect on the enforcement of the law. To establish a violation of law, the Government had to introduce testimony showing that an undeclared variation was not one expected by consumers in an article bearing the name of the food. It was also necessary for the Government to show that the variation was not the prevailing good commercial practice. Without standards or guidelines, judgments under the 1906 act varied widely. Manufacturers could not be assured that their products would not be found to be violative, nor were consumers' interests effectively protected. Manufacturers were not protected against disreputable competitors who could affect competitive pressures and, more importantly, reduce consumer confidence in the food supply.

Eventually, the Government and the industry came to the conclusion that a new statute was needed to ensure the integrity of food by keeping economically adulterated foods off the market. This recognition resulted in inclusion of three key provisions (sections 401, 403, and 701 of the act (21 U.S.C. 341, 343, and 371) for standardization of foods.

*C. History: Post-1938*

1. The 1938 Act

a. *Authority to establish standards.* The authority to establish standards is set forth in section 401 of the act. This section provides that:

> 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: *Provided,* That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. * * *

Early standards of identity established under the act were primarily ''recipe standards,'' defining in considerable detail the specific ingredients (both mandatory and optional ingredients) to be used and, in many instances, the procedure to be followed in manufacturing the food, much like home recipes. In addition, they provided assurance that only ''harmless'' ingredients would be used in the food and designated which optional ingredients must be declared on the label.

Standards were intended to prevent economic deception. They were intended to protect consumers from receiving debased or watered down food products in which water or other fillers had been substituted for more valuable constituents. For example, the early standards for flour products established a maximum level of not more than 15 percent moisture in these foods. They also included a referenced method of analysis for moisture content to allow the manufacturer to use the same procedure as the Government inspector in testing the food for compliance with the standard.

In defining the composition of foods, the definitions and standards of identity provided an added measure of assurance that the food supply would be safe. The standards designated the specific ingredients that should be used by name or limited them as ''harmless ingredients'' where class names were used. For example, only harmless and assimilable forms of iron or calcium salts could be added to enrich farina, and, in the case of vitamin D addition, only harmless carriers that do not impair the enriched farina could be used (§ 137.305). Because the statute did not have in place, at that time, a mechanism for preclearance of food additives or other functional optional ingredients that were used in foods, inclusion of such a limitation on ingredients provided further assurance that the foods would be wholesome and not adulterated.

b. *Misbranding provisions of the act.* To ensure compliance with the definitions and standards established under section 401 of the act, Congress included two paragraphs under the misbranding provisions that effect food standards.

Section 403(g) of the act, states that a food shall be deemed 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 by 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.

In addition, section 403(i) of the act, as originally enacted, provided that a nonstandardized food (i.e., ''If it is not subject to the provisions of paragraph (g) of this section) was misbranded * * * unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; * * *.''

Thus, the act, as originally enacted, required that foods purporting to be, or represented as, the standardized food comply with the compositional provisions of the applicable standard and bear the name designated in the definition and standard for the food. However, the act only provided for label declaration of the optional ingredients used in standardized foods and not the mandatory ingredients. Nonstandardized foods, on the other hand, had to list all ingredients used in the food, except that ''spices,'' ''flavorings,'' and ''colorings'' could be declared collectively using those terms.

c. *The standards setting process.* As enacted in 1938, section 701 of the act (21 U.S.C. 371) provided in paragraph (e)(1) and (e)(2) that ''any action for the issuance, amendment, or repeal'' of any standard of identity must be accomplished under formal rule making procedures where interested persons are given an opportunity to participate in a trial-type hearing.

d. *Preemption.* As enacted in 1938, the act contained no provision providing that Federal food standards preempt State laws. While the standards provided a minimum below which the States could not go, it did not prevent the States from adopting more stringent standards. (See *Grocery Manufacturers of America* v. *Gevace*, 581 F. Supp. 658 (S.D.N.Y. 1984), aff'd in part and rev'd in part, 75S F.2d 993 (2d Cir.), *cert. denied* 474 U.S. 820 (1985).)

2. Agency Implementation of the Standards Provisions

a. *Standards of identity.* FDA has implemented section 401 of the act by adopting over 280 standards of identity. These standards establish the common or usual name for a food and define the nature of the food, generally in terms of the types of ingredients that it must contain (i.e., mandatory ingredients), and that it may contain (i.e., optional ingredients). Standards may specify minimum levels of the valuable constituents and maximum levels for fillers and water. They may also designate the manufacturing process when that process has a bearing on the identity of the finished food. Finally, standards provide for label declaration of ingredients used in the food and may require other specific labeling, such as the declaration of the form of the food, packing medium, and flavorings or other characterizing ingredients as part of the name of the food or elsewhere on the principal display panel of the label.