to the food inspector, as to what constitutes a well-filled container. For some products, such as crushed pineapple, applesauce, pineapple juice, and packed nuts, where the consistency of the product is more uniform, or where there is no added packing medium that could serve to dilute the product contents, the required minimum fill of container is the total food contents, expressed as a percentage of the capacity of the container.

In the case of canned tuna (§ 161.190), which may be packed in oil or water, FDA has established minimum fill of container requirements, expressed in terms of the pressed cake weight, in ounces, depending on the size of the container used to pack the tuna. The minimum pressed cake weight requirement assures consumers that they will obtain a minimum amount of tuna flesh in each can. The measure of tuna obtained in the laboratory by the pressed cake weight procedure described in the standard approximates the measure that the homemaker would observe when the lid of the tuna can is removed and is used to press the tuna and drain the liquid. In the case of canned Pacific salmon (§ 161.170), in which no packing medium is added, the minimum fill of container is expressed in terms of a minimum net weight of salmon for each container size. The minimum net weight requirements established in the standard are slightly less than the water capacity of the container, thereby taking into account the irregular shapes of the salmon pieces, but at the same time, providing assurance that the containers will not be underfilled.

FDA regulations require that consumers be informed when foods do not comply with the applicable standard of quality or fill of container. Under § 130.14 (21 CFR 130.14), foods that fail to comply with the quality standards must bear bold label statements, such as ''BELOW STANDARD IN QUALITY,'' followed by a statement such as ''GOOD FOOD—NOT HIGH GRADE,'' or in the case of products that are substandard in fill, the statement ''BELOW STANDARD IN FILL,'' wherever the name of the food or any pictorial representation of the food appears so conspicuously as to be easily seen under customary conditions of purchase. The individual quality standards provide for an alternate label statement of the quality factor which makes the food substandard, such as ''EXCESSIVE COB'' on canned corn or ''EXCESSIVELY MEALY'' in canned peas instead of the general label statement, ''GOOD FOOD— NOT HIGH GRADE.''

Both the standards of quality and of fill of container provide detailed methodology for determining compliance. Because most of the methods included in the standards pertain only to the specific food identified by that standard, the agency has been of the opinion that this is the most efficient way to provide for such methods, e.g., the pressed cake weight method of analysis that pertains only to canned tuna. In some cases where the same method is used for multiple products, for example, the drained weight method of analysis for certain vegetables, FDA has simply referenced the method without repeating it in each of the standards (see § 155.3(a)). However, in the case of canned fruit cocktail, the drained weight method of analysis is incorporated in the standard of fill of container (§ 145.135(c)).

c. *Temporary marketing permits.* Under the agency's food standards program, FDA established a regulation providing for the issuance of temporary marketing permits (TMP's) in § 130.17. TMP's allow manufacturers to make products that deviate from applicable standards in specified ways and to test consumer acceptance of those foods in the marketplace. TMP's allow the manufacturer to market the product in interstate commerce to obtain data on the commercial viability of a change in a standard of identity before petitioning the agency to amend the applicable standard to provide for the deviation. Products marketed under temporary permits must be labeled in a manner whereby the consumer can distinguish between the food being tested and the food complying with the applicable standard.

FDA usually grants permits for a period not to exceed 15 months. However, with good reason, the agency may provide for a longer initial test market. Notice of the issuance of a permit, including a description of the deviations from the standardized food and the marketing conditions, is published in the Federal Register.

Under § 130.17, the TMP applicant may request an extension of the firm's permit, when such extension is necessary to obtain sufficient data to evaluate the test product. Requests for extensions must be accompanied by a description of the experiments conducted thus far under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered to be necessary. Such requests must also be accompanied by a petition to amend the applicable standard to provide for the deviation.

If FDA concludes, based on the information supplied, that extension of the time for test marketing the product is in the interest of consumers, the agency publishes a notice in the Federal Register stating this fact and inviting other interested firms to participate in the test market under the same conditions as set forth for the original applicant, except that the designated distribution area for the test product would not apply. These extensions usually continue until FDA publishes a final regulation either modifying the standard of identity in the manner sought or terminating the proposed rulemaking, whichever is the case.

This procedure has worked well in providing manufacturers the flexibility to test the commercial viability of new, reformulated versions of traditional standardized foods. It has also served consumers well, allowing new and nutritionally advantageous products to be marketed before rulemaking. The data generated under TMP's also assist the agency in its rulemaking decisions. For example, before the passage of the 1990 amendments, the agency responded to more than 100 applications for TMP's for modified dairy products, such as nonfat sour cream, nonfat cottage cheese, and light eggnog. The success of these test products assured the agency that these nutritionally modified foods were viable products, which could be made to resemble and substitute for the traditional standardized food and in a manner so as not to be nutritionally inferior to the traditional standardized food. Recently, FDA has issued TMP's for white chocolate, a food that deviates from the cacao product standards in part 163 because it contains none on the nonfat cacao solids usually present in chocolate products.

3. Developments Affecting the Food Standard Regulations

a. *Safe and suitable policy.* Passage of the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960 instituted premarket approval of new food and color additives. These amendments allowed FDA to develop its ''safe and suitable'' policy, codified in § 130.3(d), concerning functional ingredients used in foods. This policy provides that ingredients used in food must be listed food or color additives, or generally recognized as safe (GRAS) substances, and used at levels no higher than necessary to accomplish their intended functional effect in the food.

FDA first used this policy in 1961 in the standard of identity for frozen raw breaded shrimp (§ 161.175). At that time, it represented a significant change in the manner in which permitted