

336. Some comments suggested that terms that refer to packaging technology (e.g., "freshness seal," "Stay Fresh seal") would be prohibited under the agency's proposed definition for "fresh." These comments suggested that FDA does not have the authority to [*2407] prohibit the use of such terminology as it relates to packaging, specifically in cases where use of these terms are properly qualified. The comments said that such a prohibition would hamper the development of improved packaging technology. Comments also stated that the agency does not have sufficient evidence to suggest that consumers are misled when code dates and freshness guarantees (e.g., guaranteed fresh until) are used on foods. Some comments argued that phrases such as "vacuum packed," "vacuum sealed to lock in freshness," and "for maximum freshness use before a specific date," serve as tools for consumers to distinguish "fresh" product from "stale" product. One comment stressed that vacuum packaging is analogous to blast freezing in that both techniques allow foods to maintain their fresh state.

A small number of comments opposed permitting this use of the term "fresh." Another comment stated that the use of "fresh" in a guarantee statement (e.g., guaranteed fresh) should be restricted and should only be allowed if a food in question meets the definition for "fresh."

The agency has reviewed these comments and has concluded that the use of terms such as "freshness seal," "guaranteed fresh until," "and vacuum packed to preserve freshness," when they relate only to the function of the package and do not imply or suggest that the food itself is unprocessed, is outside the scope of this rulemaking. FDA acknowledges that these terms are used on numerous food products in the marketplace. To the extent that these terms might be used in any manner that is misleading, the agency will review specific situations on a case-by-case basis under the general misbranding provisions of section 403(a) of the act.

B. Natural

Although the use of the term "natural" on the food label is of considerable interest to consumers and industry, FDA's intent was not to establish a definition for "natural" in this rulemaking. However, the agency did note in the general principles proposal (56 FR 60421 at 60466) that, because of the widespread use of this term, and the evidence that consumers regard many uses of this term as noninformative, the agency would consider establishing a definition. Further, the agency stated that it believed that if the term "natural" is adequately defined, the ambiguity in the use of this term, which has resulted in misleading claims, could be abated. Therefore, the agency solicited comments on several issues that the agency must consider in deciding how to address the use of this term on foods, including: (1) Should the agency establish a definition for "natural" so that the term would have a common understanding among consumers, or should "natural" claims be prohibited altogether on the basis that they are false and misleading? (2) If a definition should be established, how should the agency define "natural?" (3) How should the agency proceed in developing a definition for "natural?" (4) Should a food that is represented as "natural" be considered to be misbranded if it has undergone more than minimal processing (and what constitutes minimal processing?), or if it contains any artificial or synthetic ingredients? In addition, FDA asked that identification of "natural" foods accompany the comments. FDA also solicited comments on how the agency distinguishes between artificial and natural flavors in § 101.22, and on how the agency should provide for a clearer, more appropriate distinction between natural and artificial flavors.

337. The comments provided a wide range of ideas for the agency to consider on the issue of developing a definition for "natural." Some comments stated that the term "natural" should be prohibited entirely on the basis that it generates confusion when used on the label or in the labeling of foods, and that the term is also false and misleading. Some comments stated that the agency should eliminate statements such as: "all natural," "100 percent natural," and made from "100 percent natural ingredients." Some comments suggested that the agency should not consider defining "natural" while it is implementing the mandatory requirements of the 1990 amendments.

Other comments suggested that the agency should address the use of the term "natural" in a separate rulemaking.

Some comments suggested that if FDA does establish a definition for the term "natural," it should encompass those foods that do not contain artificial or synthetic ingredients. A few comments stated that processing should not necessarily preclude a product from being deemed "natural." Other comments stated that the term "natural" and claims for natural ingredients should be permitted, provided that the manufacturer uses the term in a truthful, nonmisleading manner. Comments recommended that the use of natural color ingredients should not be precluded in foods that are represented as "natural." One comment suggested that manufacturers should be allowed to make claims for natural ingredients, regardless of any policy established for labeling finished foods as "natural." One comment stated that foods containing refined sugars should be allowed to be represented as "natural," whereas foods containing artificial sweeteners should not be represented as "natural."

None of the comments provided FDA with a specific direction to follow for developing a definition regarding the use of the term "natural." However, it was suggested that FDA should work with USDA to harmonize its definition for "natural."

A small percentage of comments addressed "minimal processing." Some of these comments proposed somewhat similar definitions under which "minimal processing" would refer to those processes that are familiar to consumers and that can be performed in the home (e.g., milling, grinding, baking). One comment suggested that "minimal processing" should include fermentation. Another comment implied that "minimal processing" should include traditional processes such as smoking, roasting, freeze drying, fermenting, and the separation of a product into component parts. The remaining comments defined "minimal processing" as those processes that do not fundamentally alter a raw food or any material derived from the raw food. Finally, some

comments stated that FDA's current regulations for labeling natural flavors should not be changed.

After reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated. However, as the comments reflect, there are many facets of this issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term "natural." Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for "natural" at this time. The agency will maintain its current policy (as discussed in the general principles proposal (56 FR 60421 at 60466)) not to restrict the use of the term "natural" except for added color, synthetic substances, and flavors as provided in § 101.22. Additionally, the agency will maintain its policy (Ref. 32) regarding the use of "natural," as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlined in § 101.22.

[*2408]