

statements and consider them to be useful in describing a processed product, whether it is important to the consumer to be able to distinguish between processed products made from fresh as opposed to processed (e.g., concentrated and then rehydrated or reconstituted) ingredients, and whether there are other appropriate means for making such distinctions on food labels. In addition, if designation of the ingredient as "fresh" is useful, FDA requests comments on whether the inclusion of blanching as a part of a continuous process at a facility should preclude labeling the ingredient as "fresh." For example, if fresh raw material mushrooms are blanched and then added to the product in a continuous process, should the label be permitted to bear the phrase "made with fresh mushrooms"? FDA will consider the comments it receives and determine whether to include a provision in the final rule addressing use of the term "fresh" to describe ingredients in processed foods.

An issue that has come to the agency's attention in its review of "fresh" claims is the use of remanufactured ingredients. The agency solicits comments on whether the use of remanufactured ingredients affects the attributes of a finished product, such as a tomato product, to such a degree that the consumer is misled about the product if its labeling does not specifically declare the remanufactured nature of the ingredient. For example, would it be useful to consumers for processed products made from remanufactured ingredients to bear a term on its principal display panel such as "made from _____ concentrate," "remanufactured," or "reconstituted"?

If the comments persuade the agency that such a declaration on the product's principal display panel is necessary to not mislead consumers about the nature of a product, the agency will consider including a provision in the final rule requiring such a declaration.

I. Extended shelf life foods. Extended shelf life (ESL) is a term that describes a category of foods made possible by relatively recent developments in food processing and packaging technology. Generally, ESL describes a food that is unprocessed or minimally processed (in some cases, the product is cooked just as it would be by a consumer) and thus is not shelf-stable, but that is packaged in such a manner so as to maintain its quality for an extended period of time in comparison to traditional packaging methods. Such products are often refrigerated (many require refrigeration for safe distribution) and often rely on

the use of "barrier" packaging and "modified or controlled atmospheres" in the package to retard aging of the food. For example, one such pasta product packaged in a barrier container with a modified atmosphere, reportedly has a refrigerated shelf life of 34 days (Ref. 52).

FDA notes that ESL do not meet the requirements of § 101.95(b) for the use of the term "freshly _____." However, FDA recognizes that such products may be of a degree of quality similar to that of traditional prepared foods that could appropriately be labeled as "freshly _____." FDA is requesting information on ESL foods that would enable it to determine whether any foods of this type merit use of the term "freshly _____" and if so, what factors about such foods justify the use of the term in a nonmisleading manner. If the comments identify nonmisleading uses of the term "freshly _____" to describe ESL foods, the agency will consider explicitly limiting the proposed definition in § 101.95(b) to foods prepared and packaged by traditional means, and it will consider including provisions in the final rule permitting the use of the term "freshly _____" or other terms to describe foods prepared and packaged using ESL techniques.

B. Natural

The word "natural" is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome. In the past, FDA has not attempted to restrict use of the term "natural" except for added color, synthetic substances, and flavors under § 101.22. In its informal policy (Ref. 53), the agency has considered "natural" to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there. For example, the addition of beet juice to lemonade to make it pink would preclude the product being called "natural."

The meaning and use of the term "natural" on the label are of considerable interest to consumers and industry. Data suggest that uses of "natural" claims are confusing and misleading to consumers and frequently breach the public's legitimate expectations about their meaning. For example, two FTC reports (Refs. 54 and 55) cite numerous studies indicating a general lack of consumer understanding and scientific agreement about the meaning of the term.

The term "natural" is used, however, on a variety of products to mean a variety of things. Because of its

widespread use, and the evidence that consumers regard many uses of this term as non-informative, the agency is considering establishing a definition for this term. FDA believes that if the term "natural" is adequately defined, the ambiguity surrounding use of the term that results in misleading claims could be abated.

In considering this issue, FDA has reviewed definitions of the term "natural" used by other government agencies, other countries, state governments, and industry. For example, USDA permits the use of the term "natural" on the labeling of meat and poultry products if: (1) They contain no artificial flavor or coloring, coloring ingredient, chemical preservative, or any other artificial or synthetic ingredient, and (2) they and their ingredients are not more than "minimally processed." "Minimally processed" may include traditional processes such as smoking, roasting, freezing, drying, and fermenting. It may also include those processes that do not fundamentally alter the raw product and that only separate a whole, intact food into component parts such as grinding meat or pressing fruits to produce juices. Solvent extraction, acid hydrolysis, chemical bleaching, and other such relatively complex processes do not meet the criteria for minimal processing, and, thus, if they have occurred, the product would not be allowed by USDA to be labeled as "natural" (Ref. 56).

USDA's policy also provides that all labels of meat and poultry products bearing the term "natural" must be accompanied by a brief statement informing consumers that the product is natural because it contains no artificial ingredients and is only minimally processed. This statement may appear either directly beneath or beside all natural claims or may be placed elsewhere on the principal display panel provided an asterisk is used to tie the explanation to the claim. USDA has approved labels for "All Natural Wingettes" and "All Natural Chili."

Some of the definitions established by other government agencies, other countries, state governments, and industry are more restrictive than the USDA definition, while others are less so. There are numerous inconsistencies among the definitions as well as unanswered questions. Consequently, FDA has concluded that more consumer and industry input is needed before it can develop a definition for "natural." However, the agency notes that after considerable input from various groups, including scientists, consumers, industry, and regulatory professions, the

Federal Trade Commission (FTC) was unable to establish a definition for "natural." (See Refs. 54 and 55 and 48 FR 23270, May 24, 1983—Termination of rulemaking proceeding).

One possible meaning of the term "natural" as it applies to food is the absence of artificial or synthetic ingredients of any kind. This meaning, however, has been degraded by inappropriate use of the term in the marketplace. Should FDA establish a meaningful definition for "natural" so that this term has a common consumer understanding? Because of the multiple and diverse meanings currently in use, establishing a definition for the term "natural" that will be readily accepted and understood will be difficult. The agency is seeking comments on whether it should define this term or should prohibit such claims entirely on the grounds that they are false or misleading.

In reaching a decision on any future FDA course of action, the agency seeks comments on how, or if, it should proceed in developing a definition for the term "natural." FDA is particularly interested in the views of consumers and industry on how "natural food" should be defined. Given past consumer confusion on what "natural" means, FDA seeks comments that provide examples of what a natural food is. In addition, FDA seeks comments on whether a food represented to be natural should be considered to be misbranded under section 403(a) of the act: (1) if it has undergone more than "minimal processing" (the agency also requests comments on what "minimal processing" means), or (2) if it contains any artificial or synthetic ingredients such as food and color additives.

How FDA proceeds will depend largely on response to the agency's concerns regarding a definition of the term "natural" and the identification of a suitable direction that the agency might explore in establishing a definition for such a term.

In addition to information on these broad uses of the term "natural," FDA is also seeking comment on how it distinguishes between artificial and natural flavors in § 101.22. The agency is concerned that its existing definition of "natural flavor" may not be consistent with the current interpretation of "natural" as implying minimal processing. For example, while removing the essential oil from a food is probably well understood to be minimal processing, and the oil is therefore a natural flavor of the food, it is less clear whether hydrolysis or enzymolysis of a food is minimal processing and therefore results in a natural flavor. The agency

requests comments with substantiating information to provide a basis for a clearer, more appropriate distinction between natural and artificial flavors.

C. Organic

A review of the comments from consumers to the 1989 ANPRM on the use of the term "organic" demonstrated that consumer perceptions of the term encompass more than is generally intended by the term. Many of the comments suggested that they wanted either:

- (1) Organic to mean "pesticide free" (organically grown) food;
- (2) Label declaration of any pesticide, growth enhancer, fungicide, chemical, or radiation used; or
- (3) At least label declaration of any potentially harmful pesticides and fertilizers used.

On November 28, 1990, Title XXI—Organic Certification, known as the "Organic Foods Production Act of 1990 (OFPA), was enacted as part of the 1990 Farm Bill. The purpose of the statute was:

- (1) To establish national standards governing the marketing of certain agricultural products as organically produced products,
- (2) to assure consumers that organically produced products meet a consistent standard, and
- (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA stated that to be sold or labeled as an "organically produced" agricultural product, an agricultural product must, with certain exceptions, (1) have been produced and handled without the use of synthetic chemicals, (2) not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the three years immediately preceding the harvest of the agricultural products, and (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

This statute charges USDA with establishing a certification program for producers and handlers of agricultural products that have been produced using organic methods. In addition, the USDA was instructed to permit each state to implement a State organic certification program for producers and handlers of agricultural products that have been produced using organic methods. The OFPA also established certain requirements under which a processed food could be labeled directly or indirectly as "organically grown."

The OFPA provides that exemptions to certain labeling requirements for

processed foods may be made to the extent that the Secretary of Agriculture, in consultation with the National Organic Standards Board and the Secretary of DHHS, determines that they are appropriate.

Because responsibility for regulating use of the term "organic" has been assigned by Congress to USDA, FDA will defer issuing of any regulations governing the term "organic" until USDA has adopted appropriate regulations. At this time, FDA will determine whether any additional regulations governing the term "organic" are necessary.

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the \$100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the Federal Register. The agency requests comments on the RIA.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. The proposed actions pertaining to food labeling meet the criteria in 21 CFR 25.24(a)(11) for exclusion from preparation of any environmental assessment and an environmental impact statement. The proposed regulations pertaining to petitions for nutrient content claims meet the criteria for exclusion described in 21 CFR 25.24(a)(8). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the