DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130
[Docket No. 91N-0317 et al.]
RIN 0905-AD08

Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term

AGENCY: Food and Drug Administration, HHS.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the General Provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (21 CFR part 101) (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (for example "reduced fat sour cream"). FDA is taking this action to assist consumers in maintaining healthy dietary practices by providing for modified versions of certain standardized foods that bear descriptive names that are meaningful to consumers. FDA believes that this action will promote honesty and fair dealing in the interest of consumers. This rule applies only to standards, of identity and not to standards of quality or fill.

EFFECTIVE DATE: May 8, 1994.

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SUPPLEMENTARY INFORMATION:

I. Background

One of the main purposes of the Nutrition Labeling end Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) was to establish the circumstances in which claims could be made that describe the nutrient content of food. In response to the requirements of the 1990 amendments, elsewhere in this issue of the **Federal Register**, in a document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule), FDA is establishing in part 101 definitions for such nutrient content claims together with general principles and procedures governing their use.

In the **Federal Register** of November 27,1991 (56 FR 60512), FDA published a proposal to amend the General Provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (e.g., "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (e.g., "reduced fat sour cream"). Interested persons were given until February 25, 1992, to comment on the proposed regulation.

FDA received, approximately 200 responses, each of which contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, retailers, consumer groups, State groups, private organizations, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., serving size and nutrition labeling) that will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

II. Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term Under the 1990 Amendments

A. General Comments

1. Appropriateness and Need for Regulation

In the proposal, FDA invited comments math respect to the appropriateness and need for a general standard in proposed § 130.10 to establish the requirements for modified foods named by use of a nutrient content claim and a standardized term (56 FR 60512 at 60517).

1. Several comments stated that it is important to keep the present standards of identity as they are. One comment stated that, while allowing for the establishment of standards of identity for products like "light sour cream" and "lowfat ice cream," FDA must ensure that the existing standards for "milk," "sour cream," "ice cream," or "butter" are not diluted or debased. These comments stated that under no circumstances should a product that has undergone any form or degree of defatting be allowed to be called simply "milk," "sour cream," or "ice cream."

The agency agrees with these comments. FDA is not amending any of the existing standards of identity with this regulation. Under section 403(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(g)), a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulation, unless it conforms to such definition and standards.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule entitled "Food Labeling; Use of Nutrient Content Claims for Butter Products," which adds new § 101.67. Except as provided in new.§ 101.67 for "butter," any food whose name includes a standardized term must conform to the standard of identity for that food found in parts 131 through 169 (21 CFR parts 131 through 169) or in new § 130.10. For example, a food labeled as "ice cream" must conform to the standard for ice cream in § 135.110, or it is misbranded. Similarly, a food labeled as "lowfat ice cream" must comply with new § 130.10. New § 130.10(a) states that the nutrient content claim must comply with the requirements of § 101.13 and with the requirements of the regulations in part 101 that define the particular nutrient content claim that is used. Thus, use of the term "lowfat" on a label for "lowfat ice cream" must comply with § 101.13 and § 101.62(b)(2) (i.e., the food must contain 3 grams (g) or less of fat per serving and per 50 g of food). New § 130.10(a) also provides that the "lowfat ice cream" must comply with the relevant standard in all other respects (e.g., major ingredients and the freezing process) except as provided in new § l30.10(b), (c), and (d).

2. One comment expressed concern that each modified food permitted to use a standardized food name meet consumer expectations. The comment suggested that if consumers no longer want or expect standardized products to have certain characteristics, the standards should be changed.

FDA appreciates the concern expressed by the comment. Section 401 of the act (21. U.S.C 341) gives the agency authority to establish definitions and standards of identity for foods whenever such action will promote honesty and fair dealing in the interest of consumers. FDA has traditionally established individual standards to provide consumers with foods that include a modifier, such as a nutrient content claim or some other descriptive term, and a standardized term in their name. For example, the agency has established a standard of identity for milk in § 131.110 (21 CFR 131.110), but there are 17 other standards in part 131 (21 CFR part 131) that use the term "milk" in the name of the food (e.g., "cultured milk" (§ 131.112). "evaporated milk" (§ 131.130), and "skim milk" (§ 131.143)). FDA does not believe that use of these modifiers with

the term "milk" is confusing to consumers because these terms are defined by the standards.

FDA believes that establishing a general definition and standard of identity for modified versions of standardized foods that qualify for use of a nutrient content claim is a more efficient way to provide consumers with these foods than having to issue temporary marketing permits to each manufacturer desiring to market test a new modified food and, ultimately, establishing individual new food standards for each new modified version. New § 130.10 provides that the nutrient content claims that are used with standardized terms must be defined by FDA regulation. The food must comply with the nutrient content claim definition and with the requirements in new § 130.10 concerning performance characteristics, addition of nutrients and other ingredients, and labeling. Such requirements will ensure not only that a "lowfat" version of a standardized food is low in fat, but also that the food appropriately bears the standardized name. Therefore, FDA concludes that use of nutrient content claims with a standardized name will promote honesty and fair dealing in the interest of consumers.

2. Scope of Regulation

3. One comment stated that it presumed that the agency did not intend that proposed § 130.10 be mandatory.

FDA advises that the comment's presumption is incorrect, at least to the extent that a firm wants to make a food under the provisions of new § 130.10. The agency is establishing a general definition and standard of identity for such foods. Section 403 (g) of the act states that a food is 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 of the act, unless it conforms to such definition and standard, and its label bears the name of the food specified in the definition and standard. Therefore, modified foods that conform to the definition and standard established in new § 130.10 must be labeled with the name provided under new § 130.10 or be misbranded under section 403 (g) of the act. For example, sour cream must contain not less than 18 percent milkfat (§ 131.160). A sour cream product containing 12 percent milkfat and conforming to the standard of identity for sour half-and-half (§ 131.185) must be labeled in compliance with § 131.185(d) as either "sour half-and-half" or "cultured sour half-and-half." A sour cream product containing 9 percent milkfat that conforms to new § 130.10 and to the definition of "light" in § 101.56 must be labeled as "light sour cream."

4. One comment stated that proposed § 130.10(a) should be revised to make the intended scope of the regulation explicit. It stated that, as written, proposed § 130.10(a) creates an undesirable ambiguity with respect to foods that substitute for standardized foods that are themselves substitutes for one another (e.g., butter and margarine or cream cheese and neufchatel cheese). The comment suggested that FDA revise the language of proposed § 130.10(a) to limit the scope of proposed § 130.10 to "foods that substitute for a standardized food * * * and that use the name of that standardized food in their statement of identity but that do not comply * * *." The comment noted that a statement in the preamble limited the intended scope of proposed § 130.10 to substitute foods whose statement of identity includes the name of a standardized food. The comment added that an alternative way to solve the problem would be to provide in proposed § 130.10(a) that, in the case of a food that substitutes for more than one standardized food, the modified food needs to comply with proposed § 130.10 only with respect to one standardized food.

The agency agrees with the comment. Foods that comply with any standard of identity established in parts 131 through 169, are not subject to new § 130.10, even if they would qualify for a nutrient content claim as a modified version of a standardized food (e.g., sour half-and-half (§ 131.185) cannot be labeled as reduced fat sour cream under new § 130.10). However, foods that do not comply with a standard, that are modified versions of standardized foods, that qualify for use of a nutrient content claim, and that use the traditional standardized name in their statement of identity are the standardized foods that are defined by new § 130.10. This is consistent with the approach that FDA took in the proposal (56 FR 60512).

The agency has been persuaded by the comment that new § 130.10(a) should be revised to limit the scope of the regulation. Therefore, FDA is revising new § 130.10 (a), as requested by the comment, to state: "* * * foods that substitute for a standardized food * * * and that use the name of that standardized food in their statement of identity but that do not comply * * *." In addition, FDA is revising the title of the regulation to delete the term "substitute" because new § 130.10 applies only to a certain category of substitute foods and not to all types of substitute foods as defined under §§ 101.3(e)(4) and 101.13(d). FDA believes that those revisions will more clearly establish the scope of the regulation and eliminate confusion as to foods that may substitute for other foods in a more general sense. Therefore, FDA concludes that these revisions will promote honesty and fair dealing in the interest of consumers

FDA also agrees with the comment that in the case of a food that qualifies as a modified version of more than one standardized food, the food must be named under new § 130.10 only with reference to one standardized food. The § 130.10 product is a substitute for the standardized food that is named in its statement of identity. For example, cream cheese is defined in § 133.133 (21 CFR 133.133) as a product containing at least 33 percent milkfat by weight of the cream cheese. Neufchatel cheese (§ 133.162 (21 CFR 133.162)) is a product similar to cream cheese except that the milkfat content is not less than 20 percent but less than 33 percent by weight of the finished food. A reduced fat cream cheese-type product containing 15 percent milkfat may be considered a modified version of either cream cheese or neufchatel cheese because it contains at least 25 percent less fat than either food. Under new § 130.10, if the product is called "reduced fat cream cheese," it is a modified version of "cream cheese" because "cream cheese" is the standardized term used in conjunction with the nutrient content claim. If the product is called "reduced fat neufchatel cheese," it is a modified version of "neufchatel cheese."

5. One comment asked how this regulation would affect the nonstandard substitute cheese category (e.g., cheese containing vegetable oil in place of milkfat). It also asked if the regulations regarding "imitation" and "substitute" foods cited in § 101.3(e) would remain intact, or if this regulation would trigger the development of new requirements.

This final rule only sets forth the requirements for certain modified versions of standardized foods that qualify for the use of a nutrient content claim. Foods that do not use a traditional standardized term but use a nutrient content claim must comply with the general requirements of § 101.13 and the specific requirements for the particular nutrient content claim as well as the other provisions on common or usual names (§ 102.5 (21 CFR 102.5)). A modified food that does use a traditional standardized term but that does not comply with the traditional standard of identity or with

new § 130.10 must be labeled either as an "imitation," if it is nutritionally inferior, or as a "substitute," "alternative," or other appropriate term, if it is not nutritionally inferior, as specified in § 101.3(e) which will remain in effect. For example, a mozzarella cheese product made with skim milk and vegetable oil does not comply with the standard for mozzarella cheese (§133.155) or with new § 130.10(d)(2) and, therefore, must be labeled as "imitation mozzarella cheese" if nutritionally inferior to mozzarella cheese or as "mozzarella cheese alternative" or "mozzarella cheese substitute" if it is not nutritionally inferior. For this reason, FDA concludes that there is no need to amend the definitions for "imitation" or "substitute" foods in § 101.3(e) at this time.

6. One comment stated that there should be some listing of the standards as to which proposed § 130.10 is intended to apply. It stated that there was uncertainty as to when a particular food is subject to the general rule or requires individual agency action. Another comment stated that there is no reason to exclude any category of standardized foods from this proposal and urged FDA to retain the general applicability of the generic standard to all standardized foods in the final rule.

The agency disagrees that it needs to establish a specific list of standards to which new § 130.10 is to apply. New § 130.10(a) states that the foods prescribed by this general definition and standard of identity are those foods that substitute for a standardized food defined in parts 131 through 169. Thus, a modified version of any food defined by a standard of identity would be subject to new § 130.10, and no more specificity in new § 130.10 is necessary. This generic standard will minimize the need to establish individual new standards or to amend existing standards. FDA will establish new standards or amend existing ones if it determines that such action is necessary to promote honesty and fair dealing in the interest of consumers.

However, FDA notes that at the present time some standardized foods that are merely processed (e.g., canned green beans and canned wax beans (§ 155.120 (21 CFR 155,120)), tomato juice (§ 156.145 (21 CFR 156.145)). canned oysters (§ 161.145 (21 CFR 161.145))) cannot be modified so that the food does not comply with the traditional standard of identity, although they may still qualify to bear a defined nutrient content claim. For example, salt is an optional ingredient in the standard of identity for canned green beans and canned wax beans (§ 155.120). Therefore, if the product contains no added salt, the product remains the standardized food under § 155.120 and outside the scope of new § 130.10, although it may still qualify to bear a "no added salt" claim.

B. Product Deviations

In the proposal, FDA requested comments concerning how far a product may deviate from a standard and still qualify for use of the standardized name (56 FR 60512 at 60518).

7. Several comments stated that it is unnecessary for FDA to try to establish specific, quantitative limits. One comment stated that the agency should apply the general criteria for determining whether a food is a "substitute" for a standardized food. It stated that those criteria, which have been developed primarily through case law over the years, are based on everyday characteristics of the food that would be significant to the consumer, such as taste, texture, and appearance. Importantly, such an approach would conform to the President's directive, which requires regulations to use performance standards, not command and-control techniques.

Several comments urged the agency to establish guidelines as to how much a modified food can deviate from the standardized product arid still comply with proposed § 130.10.

The agency agrees that general requirements as to how far a modified food may deviate from the standard of identity and still use the standardized name are necessary. FDA also acknowledges that general criteria concerning significant characteristics of foods that are important to consumers have been developed primarily through case law, and the agency will use these criteria as needed for enforcement purposes. Some general requirements were included in the proposal and are now mandated by new § 130.10. A § 130.10 food must not be nutritionally inferior to the standardized food (new § 130.10(b)) and must have similar performance characteristics as the standardized food, including physical properties, flavor characteristics, functional properties, and shelf life (new §130.10(c)).

In addition, under new § 130.10(d)(1), ingredients mandated to be present in a food by a standard of identity must also be present m the § 130.10 food. FDA believes that consumers expect certain ingredients to be present in specific foods. For example, the agency believes that consumers expect that a product such as "light mayonnaise" contains a significant amount of vegetable oil and egg yolk because these ingredients are required to be present in regular mayonnaise (§ 169.140). Thus, FDA has added new § 130.10(d) (4) to require that mandated ingredients must be present in a significant amount if the food is to be considered a modified version of the traditional standardized food. A significant amount is defined in that paragraph as at least that amount of the ingredient that is necessary to achieve the technical effect that the ingredient provides to the traditional standardized food. FDA concludes that this requirement in new § 130.30(d)(4) will promote honesty and fair dealing in the interest of consumers because it will ensure that a § 130.10 food will bear an appropriate relationship to the traditional standardized food.

8. One comment requested that FDA recognize that the removal of sugar and calories from a juice would result in a product that is still juice (e.g., "reduced calorie orange juice" or "light orange juice"). It added that the principles for naming products that are nutritionally modified versions of standardized products, should be no different for standardized juices than together standardized products. The comment requested that FDA ensure that this regulation is consistent with the regulation on percent, juice labeling.

FDA agrees that the principles for naming products that are modified versions of standardized juice products should be no different than for other modified products. The agency recognizes that the reduction of sugars from a juice, and the subsequent sweetening of the product with a safe and suitable sweetener that provides an insignificant amount of calories, results in a modified juice product. Use of a sweetener with the same caloric density as the sugar naturally present in the juice is prohibited under new § 130.10(d)(2) because it would be replacing the sugar component of the juice with a similar ingredient from another source. For example, sucrose and glucose that have been removed from orange juice (§146.135 (21 CFR 146.135)) could not be replaced with fructose even though fructose is sweeter than the sucrose and glucose that are naturally present in orange juice. If, on the other hand, the product has been reduced in sugars so that it qualifies for use of a nutrient content claim and complies in all other aspects to new § 130.10, then the product is a food defined by new § 130.10 and must be labeled accordingly.

FDA notes that juices are defined in part by their Brix level or soluble solids content. The soluble solids of juices consist primarily of sugars. If any of the

sugars have been removed from a juice, the resulting product is a modified juice. As discussed in the final rule on percent juice labeling published elsewhere in this issue of the **Federal Register**, modified juices cannot use the percent juice labeling values in § 101.30 because of the reduced soluble solids content. The manufacturer would have to develop an alternate means of determining the percent juice in modified juice products.

9. Several comments stated that they considered the allowance of additional moisture in a modified cheese product to be necessary. One comment added that maximum moisture content requirements are as much barriers to lower fat versions of standardized products as minimum fat requirements.

Another comment added that other deviations from the standard, such as different levels of total solids or the use of modified processing conditions, are frequently required to meet the performance characteristics of the traditional standardized food and should be explicitly permitted in this regulation. It recommended that the last sentence of proposed § 130.10(a) be changed to read, "The food shall comply with paragraphs (b), (c), and (d) of this section." It further recommended that the following sentence be added at the beginning of proposed § 130.10(c):

> Deviations from noningredient provisions of the standard of identity (such as moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possess performance characteristics similar to those of the standardized food.

FDA agrees that there are noningredient requirements mandated by some standards in parts 131 through 169 that could restrict manufacturers' ability to produce modified foods under new § 130.10. The agency recognizes that in some standardized foods, such as cheeses, the standard mandates a maximum moisture content, and that modified foods may not conform, to this requirement and still retain the necessary performance characteristics to use the standardized name.

New § 130.10(a) states that the foods prescribed by this general definition, and standard of identity are those foods that substitute for a standardized food but chat do not comply with the standard because of a deviation that is described by a nutrient content claim. FDA noted in the proposal that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used (56 FR 60512 at 60519). Thus, under new § 130.10(d)(1) the agency is providing for the addition of safe and suitable ingredients not normally found in the standardized food so that § 130.10 foods are not inferior in performance characteristics to the traditional standardized food. In like manner, FDA believes that the modified aversion of the standardized food should comply with, the noningredient provisions of the traditional standard with only those noningredient deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used.

For the above reasons, FDA has been persuaded by the comments that modifications to the regulation are needed to allow for deviations from the noningredient requirements of the standards. Therefore, the agency is adding a new sentence at the beginning of new § 130.10(c) which states:

> Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food.

In addition, the agency is amending the last sentence of new § 130.10(a) to read: "The food shall comply with the relevant standard in all other respects, except as provided in paragraphs (b), (c), and (d) of this section." The agency believes that this action will: (1) Increase the manufacturers' ability to produce modified foods under new § 130.10, (2) provide consumers with a greater variety of such foods, and (3) assist consumers in maintaining healthy dietary practices. The agency notes, however, that this exception does not apply to processes that are important to public safety such as pasteurization. FDA concludes that this action will promote honesty and fair dealing in the interest of consumers.

10. One comment stated that the requirement of nutritional equivalency (new § 130.10(b)) for lower fat ice creams mitigates the need for lower fat ice creams to meet the 4.5 pounds per gallon requirement in the standard of identity for ice cream in § 135.110.

FDA agrees with the comment. FDA published an advance notice of proposed rulemaking (ANPRM) (Docket No. 88P-0251) in the **Federal Register** of January 22, 1991 (56 FR 2149) concerning the filing of several petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, lowfat, and nonfat ice creams. The petitions requested that FDA establish a minimum weight of 4.0 pounds per gallon for the lower fat products.

A comment received in response to the ANPRM that opposed the reduction in weight stated that the change could be construed as intentionally deceiving the consumer. The comment stated that while there are economic and competitive advantages, there appears to be no other serious justification for such cheapening of the product.

However most of the comments received in response to the ANPRM that addressed the minimum weight issue supported the proposed minimum requirement of 4.0 pounds per gallon. They stated that the processing and formulation changes that accompany the removal of fat in the manufacture of fat reduced ice cream products result in a less dense product. According to these comments, creaminess and product stability, which are lessened by fat removal, can be improved by increasing the amount of air incorporated into the product or by utilizing more precise control of the freezing process.

FDA concludes that it is reasonable to exempt modified ice cream products from the minimum weight requirement of 4.5 pounds per gallon, so that these products can achieve the performance characteristics (e.g., creaminess) of ice cream, as long as the product is not nutritionally inferior to ice cream. The agency concludes that this exemption will assist consumers in maintaining healthy dietary practices by providing for modified ice cream products that have performance characteristics that are similar to ice cream. This exemption is provided by the new sentence that is being added to the beginning of new § 130.10(c). However, FDA does not believe that fat reduced ice cream products should contain less than 4.0 pounds per gallon, as recommended by the petitioners of these ice cream products, because the desired effects can be achieved within this allowance and the modified foods should resemble the traditional standardized foods as closely as possible.

The inclusion of air in § 130.10 foods (e.g., nonfat ice cream, light margarine, and reduced fat peanut butter) in excess of that which is reasonably required to achieve the performance characteristics of the standardized food for which it substitutes constitutes deception and will be deemed to adulterate the food under section 402(b)of the act in that excess air is substituting for a valuable constituent. Therefore, FDA is including in new § 130.10(c) a requirement that deviations from provisions of the standard must be the minimum necessary to achieve this effect, the

food will be deemed to be adulterated under section 402(b) of the act. FDA believes that this requirement will promote honesty and fair dealing in the interest of consumers.

Serving size issues relating to "aerated" products (i.e., products that include added air) that are sold by weight are addressed elsewhere in this issue of the **Federal Register** in a document entitled "Food Labeling: Serving Sizes."

C. Nutrient Content Claims

11. Several comments stated that the use of nutrient content claims such as "lowfat" "lite," and "reduced" should not be allowed on the label of standardized foods because they are confusing, even if they ere defined.

Other comments expressed concerns about the required labeling, arguing that it is excessive. One comment urged FDA not to include too many restrictions on the wording or use of nutrient content claims because such restrictions would only befuddle the consumer and defeat the purpose of the claims.

FDA is establishing definitions for a number of nutrient content claims in the nutrient content claims final rule. In defining these terms, FDA has carefully considered each nutrient content claim to ensure that it will be meaningful to consumers. The definitions for the claims and § 101.13 prescribe the specific labeling that must accompany the claim. As consumers learn what a claim means, they will be able to understand that a product such as "light margarine" has been modified in a way that has reduced its fat content. Thus consumers will be able to easily identify the food and will be able to find out more about the food through information on the label. Therefore, FDA concludes that no action is necessary in response to these comments.

12. One comment stated that only expressed nutrient content claims should be used with the name of standardized foods. It stated that implied nutrient content claims such as "light" or "healthy" should not be used in this manner (e.g., "healthy ice cream").

The agency agrees with the comment However, the term "light" is not an implied claim and is being defined as an expressed nutrient content claim as discussed in the nutrient content claims final rule. In § 101.13(b)(1). FDA defines an "expressed nutrient content claim" as any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium." An "implied nutrient content claim" is defined in § 301.13(b)(2) as any claim that describes the food or an ingredient therein in such a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "health, contains 3 g of fat").

Because the name of a new modified food distinguishes it from the standardized food, the claim must be expressed for consumers to understand how the new modified food differs from the traditional food. Therefore, FDA concludes that only expressed nutrient content claims may be used in the name of the food under new §130.10. Implied claims may be used as provided in § 101.13(b)(2) but not in conjunction with the name of the § 130.10 food. Therefore, the agency is modifying new § 130.10(a) and (e) to state that the nutrient content claim must be air expressed claim. FDA believes that this revision will promote honesty and fair dealing in the interest of consumers.

D. Nutritional Inferiority

13. One comment stated that in determining nutritional inferiority, there is no clear indication of the nutrients and levels thereof that a § 130.10 food is expected to match. It stated that some specifications should be made, or provisions should be included, for developing nutrient data bases for those standardized foods that § 130.10 foods with nutrient content claims must match to avoid "nutritional inferiority."

FDA disagrees with the consistent New § 130.10 sets forth general requirements for foods named by use of an expressed nutrient content claim and a standardized term. Under new § 130.10(b), the modified product must not be nutritionally inferior as defined in § 101.3(e)(4), to the standardized food. FDA believes that this general requirement is adequate because § 101.3(e)(4) sets very specific requirements defining nutritional inferiority. The agency concludes that new § 130.10 should not specify required amounts of essential nutrients that must be added to a modified food, and that no change is necessary in new § 130.10.

The agency adds that nutrient values for the traditional standardized product can be found in a current valid composite data base.

14. One comment agreed that § 130.10 foods should not be nutritionally inferior to the traditional standardized food. However, it stated that inferiority in any single nutrient should be defined as a "significant" reduction, that is, a reduction of 10 percent or more of the Reference Daily Intake / Daily Reference Value (RDI/DRV) of a nutrient that is present in a "measurable amount." In addition, the comment stated that nutritional inferiority of the product itself should not be based on inferiority in a single nutrient. It stated that in such cases, the unavoidable reduction of one nutrient could be compensated by meaningful additions or improvements in one or more other nutrients. For example, the comment stated, there are some foods for which it is difficult or impossible to reduce the amount of a component such as fat without also reducing the amount of a nutrient, such as protein. It stated that the reduction in protein could be balanced by additions of vitamin A and riboflavin.

FDA disagrees with this comment. According to § 101.3(e), a food that is nutritionally inferior to another food is an imitation of that food and must be labeled as such. Section 101.3(e)(4)(i) defines nutritional inferiority as any reduction In the content of an essential nutrient that is present in a measurable amount (excluding fat or calories). Section 101.3(e)(4)(ii) defines a measurable amount of an essential nutrient in a food as 2 percent or more of the DRV of protein or the RDI of any vitamin or mineral listed under § 101.9(c)(7)(.iv). The agency considers a measurable amount to be a significant amount for this purpose. All nutrients that are considered in determining the status of a food under § 101.3(e)(4) are important, and the agency does not believe that the addition of one nutrient could compensate for another. Therefore, FDA concludes that foods that have significantly less protein or other essential nutrients than a standardized food are not modified versions of the standardized food, do not comply with the requirements of this regulation, and must be labeled as "imitation."

15. One comment stated that the agency should reconsider the requirement that any modified food, identified as a "light," "reduced," or "low-fat" version of a standardized food, in which there is a nutrient reduction be fortified in order not to be called "imitation," The comment stated that such nutrient addition was not necessary because the comparative nutrition label will clearly identify the nutritional differences between these two different foods.

The agency disagrees with the comment. Although FDA agrees that the nutritional differences between these products would be apparent from the nutrition information, foods that are

nutritionally inferior to the standardized food must be labeled as "imitation" under section 403 (c) of the act New § 130.10 does not include imitation foods.

16. One comment requested that the agency clarify that when the modified food substitutes for more than one standardized food, the modified food should be deemed in compliance with proposed § 130.10 if it is nutritionally equivalent to any of the several standardized foods. The comment stated that cottage cheese (21 CFR 133.128) and lowfat cottage cheese (21 CFR 133.131) may vary in vitamin A content based on their different fat levels. Thus, the comment stated, a nonfat cottage cheese should be considered nutritionally equivalent under new § 130.10 if its vitamin A content is equivalent to that required by either food standard because it clearly is a modified version of either food.

FDA disagrees with this comment. The agency recognizes that a nonfat cottage cheese product could be compared to cottage cheese (§ 133.128), dry curd cottage cheese (§ 133.129) or one of the lowfat cottage cheese products (§ 133.131). The agency acknowledges that target levels for nutrients necessary to determine nutritional equivalency of a food will depend on whether the food is compared to one food or another. However, the § 130.10 food must not be nutritionally inferior to the standardized food whose name is used in the name of the food. FDA concludes that because the reference food in the name "nonfat cottage cheese" is "cottage cheese," it would be misleading to consumers to make the comparison of nutritional equivalency to any other cottage cheese product.

E. Performance Characteristics

n the proposal for this final rule, FDA requested comments concerning: (1) The requirement that the performance characteristics of the new product be similar to those of the standardized food, (2) the performance properties that are of greatest importance to consumers, and (3) what differences in performance characteristics a modified standardized product should be able to have and still be considered to resemble the standardized food closely enough to be included in that product category (56 FR 60512 at 60519 and 60521).

17. Several comments stated that it would be acceptable to a consumer that wants lower fat foods to have products with fat replacers resemble the original products as closely as possible, especially with respect to texture, taste, and nutrition. One comment urged FDA to set high standards for performance requirements for § 130.10 foods. It stated that without appropriately high standards, consumers may be misled by the use of familiar names, and that, ultimately, the value of the standards themselves will be diluted.

Two comments suggested that, in order to use the name of the standardized product with a nutrient content claim, the product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product. Consumers can then choose to purchase the modified product instead of the standardized product for use in that function. One comment added that a reduced fat cheese must at a minimum be suitable for eating directly from the package or for melting and cooking. It stated that the product need not serve both purposes, so long as the performance deficiencies are clearly and prominently labeled on the front of the package.

The agency agrees that the § 130.10 food should resemble the standardized food in as many ways as possible. FDA also agrees that at a minimum, a modified food must perform at least one of the principal functions of the standardized product as well as the standardized food. FDA believes that consumers should be able to count on using a modified food in the same manner that they use the traditional standardized food in, at the very least, one of the principal functions as the standardized food. To achieve this objective, FDA is requiring in new § 130.10(c) that modified standardized foods must resemble the standardized foods, and that differences in the performance characteristics must be clearly stated on the principal display panel of the label. In addition, the agency is adding a statement to new § 130.10(c) to require that "the modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product." FDA believes that this action is necessary to ensure the minimum necessary similarity between the modified and traditional products and, thus, will promote honesty and fair dealing in the interest of consumers.

18. One comment questioned what methods the agency would use to measure significant differences in product quality and to monitor critical performance characteristics.

FDA expects that modified versions of standardized foods will perform in a manner that is generally acceptable to the public. New § 130.10 requires that the performance characteristics of the food be similar to those characteristics of its standardized counterpart unless the differences between the two foods are explicitly stated on the label. In addition, the § 130.10 food must perform at least one of the principal functions of the standardized food substantially as well as the standardized product. Although it was not the agency's intent to develop specific performance standards for each product, FDA plans to examine the performance characteristics and product quality of these modified versions of standardized foods, as it would for other types of food products, through scientific reviews or experimental investigations. In addition, FDA will use all avenues available to the agency (e.g., sample analysis, inspections, surveys, and followup investigations of consumer and trade complaints) to identify products that do not comply with the new regulation and will enforce this regulation as the need arises.

F. Labeling of Performance Characteristics

19. Several comments objected to the requirement in proposed § 130.10(c) that if there is a significant difference in performance characteristics between the food under proposed § 130.10 and the standardized food, the label must include a statement informing the consumer of such difference. One comment stated that some performance characteristics (e.g., flavor or texture) tend to be more subjective, and that if a flavor comparison is not favorable, manufacturers would not be inclined to call attention to such a difference. It stated that it would be a disincentive to food manufacturers to reduce the fat content in food. Another comment stated that a regulation to require a label statement pointing out differences in performance is not necessary unless health or safety is involved. One comment stated that the most specificity FDA should include in this regulation regarding performance characteristics is a reference to substantial equivalence in organoleptic and nutritional qualities.

One comment stated that manufacturers would find it advisable, for marketing reasons, to inform the consumer how a modified version of a standardized food performs differently than the standardized product. One comment supporting the label statements noted that bread spreads currently on the market are erratic about stating whether they can be used for cooking, and that consumers are confused as a result. Other comments expressed concern about diluting the value of the standards if consumers are

misled by the use of familiar names on modified products.

Under sections 201(n) (21 U.S.C. 321(n)) and 403(a) of the act, the label or labeling of the food must disclose to consumers what they are buying when they purchase these modified foods. Information disclosing differences in performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading, and the product would be misbranded under section 403 (a) of the act.

Therefore, a provision in new § 130.10(c) that requires disclosure of differences in performance characteristics between the modified food and the traditional standardized food is fully consistent with the act.

FDA is providing for noningredient deviations in new § 130.10(c) (e.g., moisture content) and for the use of safe and suitable ingredients for certain specified purposes in new § 130.10(d)(1) (e.g., to add flavor) in order that the modified food may possess similar performance characteristics as the traditional standardized food. FDA believes that these provisions in new § 130.10 provide manufacturers ample latitude in producing modified products.

20. Two comments recommended that the label statement be mandatory only for differences in performance characteristics that materially limit the uses of the modified food compared to the traditional standardized food that it resembles. One comment stated that market forces will encourage manufacturers to inform consumers about positive differences, and that consumers who select a product for its reformulated nutrient content will not be misled if they are not told about a positive change that the manufacturer believes is not sufficiently important to highlight on the product label. The comment noted that FDA would not object if the label did net alert consumers to a minor improvement in a performance characteristic that consumers consider to be relatively unimportant for that food, such as the freezing point of eggnog. In addition, the comment stated, a product may have several differences in performance characteristics, and several label statements could be confusing to consumers. The comment recommended that FDA modify new § 130.10(c) by limiting the labeling requirement to adverse changes that materially affect the use of the product.

The agency has been persuaded by these comments. FDA agrees that there are differences in performance characteristics that consumers may not deem to be important, such as the freezing point of eggnog. Consumers commonly store eggnog at refrigerator temperatures, and, therefore, the freezing point of this product is not of material interest to consumers. In addition, FDA believes that unnecessary label statements may be confusing to consumers and may detract from other important information on the label.

Therefore, the agency is revising new § 130.10(c) to state that:

> * * * if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking").

21. Comments also suggested that FDA affirm in the final rule that statements of differences in performance characteristics can be presented as recommendations for use.

FDA agrees with the comments suggesting that differences in performance characteristics may be presented as recommendations for use. For example, a reduced fat margarine may not perform the same as margarine for use in frying. A statement such as "not recommended for frying purposes" or as "recommended for use only as a spread" would be acceptable to advise consumers of the difference in performance characteristics.

22. Comments also asked whether shelf life could be presented as a date by which the product should be used.

The agency agrees that a dale by which a product should be used is an appropriate manner to express differences in shelf life.

23. Several comments objected to the requirement in proposed § 130.10(c) that label statements concerning differences in performance characteristics must appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, in type that shall be no less than one-half the size of the type used in such claim but no smaller than one-sixteenth of an inch. One comment noted a conflict with proposed § 101.13(d)(1) with regard to location of this information on the label. Some comments addressed concerns about label clutter on the principal display panel and stated that these concerns are enhanced by the proposed requirement that the bottom 30 percent of the principal display panel contain a statement of any differences in performance characteristics between the § 130.10 food and the standardized food. Comments urged FDA to allow the statements to appear on any panel of the food product. One comment added that a simple requirement of proximity and appropriate prominence should be more than adequate to prevent consumer confusion. One comment stated that the proposed requirements are excessive and fail to meet the requirements of the President's directive that regulation should rely on market mechanisms to the maximum extent possible. It stated that consumers who buy nutritionally modified versions of familiar foods and are disappointed with their performance, because they did not know in advance what to expect, simply will not buy again, and the products will quickly fail. It added that FDA does not need to regulate this guaranteed result. Some comments stated that they did not believe it necessary to prescribe a minimum type size for this disclosure statement, but that the statement should appear on the principal display panel in a clear and conspicuous fashion.

The agency disagrees with these comments. Different brands of a particular modified food may have different performance characteristics depending on the manufacturing technology used in making the § 130.10 food. For example, reduced fat cheddar cheese made by one manufacturer may be suitable only for melting and cooking, while another brand may be suitable only for eating directly from the package as a snack. Therefore, consumers must be informed about the characteristics of a food to make judgments concerning the use of a product before purchase. The necessary information must appear on the same part of the label as the name of the §130.10 food (i.e., the principal display panel) so that consumers can make informed choices. Moreover, this regulation is consistent with the President's directive because it is providing increased flexibility to the market in that it provides that qualifying versions of standardized foods may be sold under names that consumers recognize.

Under section 403(f) of the act, FDA believes that the statement informing consumers of differences in performance characteristics must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. The agency concludes that the statement must appear in the same area of the label as the statement of identity for the

modified product so that consumers will know where to find such information. Moreover, because the statement is a material fact that helps to describe the differences between the modified food and the traditional food, it must appear in close proximity to the statement of identity. See, e.g., *United States v. An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D. N.Y. 1974).

FDA recognizes that it inadvertently proposed in § 130.10 to require statements informing consumers of differences in performance characteristics to appear in possibly two separate locations on the label. The agency acknowledges that one statement is sufficient to inform consumers. To be consistent with the labeling of other foods, the agency concludes that the statement concerning differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d)(1). Thus, the agency has modified new § 130.10(c) to state that the statement explaining differences in performance characteristics must appear on the label in compliance with the requirements of §101.13(d).

G. Ingredients

1. Ingredients Provided for By the Regulation

24. Two comments objected to FDA restricting the major ingredients used in § 130.10 foods to those specified in the standard. One comment stated that this provision would not empower consumers to select a healthy diet but would restrict the number of apparent "healthy" choices available by requiring products made with alternate ingredients to bear unappealing names. It also stated that this provision would not provide an incentive to manufacturers to develop nutritionally improved foods but would restrict their ability to develop such products by unnecessarily limiting the technology available.

The agency disagrees with these comments. The agency believes that foods named by use of a nutrient content claim and a standardized term must resemble the standardized food in as many ways as possible, or the use of the standardized term would be misleading to consumers. Therefore, FDA concludes that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard, with only those deviations necessary to attain an acceptable finished product that meet the requirements of the nutrient content claim that is used and new § 130.10.

2. Safe and Suitable Ingredients

25. Several comments stated that proposed § 130.10(d) should provide for the use of safe and suitable ingredients generally in accordance with current good manufacturing practices rather than limiting them to specific functions. One comment stated that the language in proposed § 130.10(d) concerning ingredient substitutions should be broadened to encompass all of the product characteristics embraced by proposed § 130.10(c) and by the definition of "substitute" in § 101.13(d). Another comment added that safe and suitable ingredients should be allowed for purposes of improving appearance as well as the other characteristics mentioned in the proposal.

FDA disagrees mat the use of safe and suitable ingredients should be extended for all purposes. The agency believes that § 130.10 foods should deviate from the standard of identity only when necessary to achieve the functions of ingredients or components of ingredients that are no longer present in the mandated quantities. As required in new § 130.10(c), the performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) of the modified food must be similar to those of the traditional standardized food. FDA believes that the use of safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, and extend shelf life adequately compensates for any deficiencies in performance characteristics. As discussed previously, § 130.10 foods do not include all substitute foods. Therefore, FDA does not believe that new § 130.10(d) should be broadened to encompass all types of substitute foods.

However, FDA concedes that the use of safe and suitable ingredients to improve the appearance of a product has merit. For example, modified foods with significantly less fat may appear more translucent than the standardized food. Thus, such ingredients are necessary to ensure that the product is not inferior in performance characteristics. Therefore, FDA is amending new § 130.10(d)(1) to provide that safe and suitable ingredients may be added to improve the appearance of a modified food named by use of a nutrient content claim and a standardized term.

26. One comment stated that it believes that to "add flavor" includes sweetness and requested that FDA confirm this interpretation by including a parenthetical "(including sweetness)". following "add flavor" in proposed §130.10(d)(1).

FDA disagrees with the premise of this comment. In § 170.3(o)(12), FDA defines "flavoring agents and adjuvants" as substances added to impart or help impart a taste or aroma in food. FDA defines nonnutritive and nutritive sweeteners separately from flavoring agents in § 170.3(o)(19) and (o)(21). In addition, labeling requirements for flavors differ significantly from those for sweeteners.

However, FDA does agree that the use of safe and suitable sweeteners to add sweetness should be provided for in new § 130.10 for modified foods. Many standards of identity provide only for the use of safe and suitable nutritive sweeteners or nutritive carbohydrate sweeteners (e.g., sour cream (§ 131.160). eggnog (§ 131.170), and margarine (§166.110)). Nonnutritive sweeteners could be effectively used to add the sweetness, but not the calories, that would otherwise be contributed by nutritive sweeteners in the traditional standardized food. Therefore, FDA believes that the use of safe and suitable sweeteners to add sweetness would assist consumers in maintaining healthy dietary practices. Thus, the agency is revising new § 130.10(d)(1) to provide that safe and suitable ingredients may be added to add sweetness to a modified food named by use of a nutrient content claim and a standardized term. When a sweetener that meets the "safe and suitable" definition in new § 130.3(d) is used in the formulation of a modified food for the purpose of adding sweetness to that food, the sweetener must be declared on the food label in accordance with all applicable regulations. FDA believes that this action will promote honesty and fair dealing in the interest of consumers.

27. One comment questioned whether the provision for the use of "safe and suitable" ingredients in § 130.10 foods would promote long-term product development, even though short-term product innovation may benefit from this policy. This comment farther contended that allowing these foods into the marketplace would: (1) Erode the market share of traditional standardized foods, (2) harm the integrity of traditional standardized foods, and (3) lead to consumer confusion by blurring the differences between these standardized foods and their modified counterparts.

FDA disagrees with this comment. The agency believes that providing for the use of "safe and suitable" ingredients to improve texture, add flavor, prevent syneresis, extend shelf

life, improve appearance, or add sweetness in modified versions of standardized foods should not stifle long-term product development, nor should the introduction of these foods into the marketplace be damaging to the food industry on the whole.

On the contrary, standards of identity have been criticized as being too strict and confining, and because they limit food companies from achieving true product innovations. For instance, the dairy industry purportedly has been harmed because many of the products that dairy processing companies manufacture are subject to rigid standards of identity that require specific fat content. As a result, these firms have not been able to create new dairy food products that respond to consumer needs and demands for products that are reduced in fat and in calories.

FDA anticipates that there will be shifts in dietary consumption patterns from traditional foods that are higher in calories or in fat to modified forms of these foods that are reformulated to be lower in calories or in fat. However, this pattern of increased consumption of modified forms of traditional foods should help consumers to achieve recommended nutritional goals and should have a beneficial impact on the public health. In addition, FDA believes that the development, production, sale, and consumption of these reformulated foods will contribute to overall industry growth. Although the agency acknowledges that there is the potential that sales of certain standardized foods may remain stagnant or may even decline, these changing patterns in consumers' food purchasing habits in relation to recommended nutritional goals should create new opportunities for innovative food processors to develop a virtually limitless array of new products that will ultimately lead to an overall increase in sales and an expansion into new markets.

Regarding consumer confusion about the differences between a traditional standardized food and a modified form of such food bearing one or more nutrient content claims on its label, the agency believes that the use of carefully defined nutrient content claims as a part of the statement of identity on the label will enable purchasers of the modified versions of standardized foods to distinguish these foods from their standardized counterparts. New § 130.10 provides for proper labeling of these foods and the listing of all ingredients in the ingredient statement, Adequate product labeling, including defined nutrient content claims, accompanying label statements, and nutrition labeling, will enable consumers to distinguish traditional foods from modified versions of these foods, thereby contributing to improved consumer understanding of the characteristics of the products that they are purchasing.

28. One comment inquired whether specific casemates would meet the "safe and suitable" definition and be permissible for use in § 130.10 foods.

FDA advises that the "safe and suitable" definition in new § 130.3(d) would permit the use of caseinates in foods subject to new § 130.10 provided that the standard of identity for the traditional food in question provides for such use. For example, the standard of identity for ice cream in § 135.110 permits the optional addition of one or more of the caseinates listed in § 135.110(c) in an ice cream mix containing not less than 20 percent total milk solids. Caseinates may be added to ice milk (§ 135.120) when the content of total milk solids is not less than 11 percent. FDA believes that it is reasonable to permit the use of such caseinates in modified versions of ice cream, provided that the product contains equivalent levels of nonfat milk solids to those contained in a 10 percent milkfat ice cream. That is, the modified product must contain at least 10 percent nonfat milk solids, and casemates could be added after this minimum nonfat milk solids requirement has been met. FDA believes that modified ice cream, regardless of the milkfat content, should contain at least 10 percent of nonfat milk solids to ensure that the § 130.10 ice cream is not nutritionally inferior to ice cream with respect to calcium and protein. The addition of caseinates to replace the milk solids content constitutes deception and will be deemed to adulterate the food under section 402(b) of the act (21 U.S.C. 342(b)) in that caseinates are substituting for a valuable constituent.

On the other hand, the standards of identity for cheeses and related cheese products in part 133 (21 CFR part 133) do not provide for the use of caseinates. Therefore, under new § 130.10(d)(1) manufacturers may not use this class of ingredients in modified versions of cheese products as replacements for the optional dairy ingredients listed in the standards of identity in part 133. However, use of small amounts of safe and suitable caseinates may be used for the reasons listed in new § 130.10(d)(1) (e.g., to improve texture) in modified versions of standardized foods as appropriate.

Any casemates used in a §130.10 food must be declared in the ingredient statement according to new § 130.10(f), including identification with an asterisk if the use of caseinates is not provided for by the traditional standard.

3. Addition of Water and High Moisture Ingredients

In the proposal, FDA requested comment from interested persons concerning the appropriateness of the addition of high moisture ingredients and water to foods as ingredients to replace fat and calories in modified products (56 FR 60512 at 60520).

29. A number of comments requested that FDA provide for the addition of water. Two comments stated that the addition of water is critical to the manufacture of modified standardized products such as modified salad dressing and mayonnaise. One comment added that the emulsifying properties of certain gums are activated only by the addition of water. Several comments stated that it is appropriate to allow for the addition of water as long as it is appropriately labeled. Conversely, two comments requested that FDA not permit the addition of water to a food subject to proposed § 130.10.

A number of comments stated that the addition of high moisture ingredients to foods subject to proposed § 130.10 is appropriate. One comment noted that moisture content variability may occur because of water contributed by safe and suitable ingredients that are components of such foods. It added that provision should be made to require that such moisture differentials are accurately and adequately reflected on the label of foods subject to new § 130.10. Another comment stated that where, with current technology, the production of reduced fat products is not possible without the addition of high moisture ingredients, their addition should be permitted.

One comment stated that most current fat reduction technologies require the addition of high moisture ingredients and water. It recommended that FDA allow high moisture ingredients and water to replace fat in § 130.10 products, and that FDA use performance standards rather than deviations from a "recipe" to protect consumers. Another comment recommended that FDA allow the use of high moisture ingredients and water to the level necessary to replace fat and calories, as long as the modified food is not nutritionally inferior to the traditional food.

FDA agrees that the addition of water may be necessary for the hydration of some ingredients that would be permitted under the safe and suitable ingredient provision. In addition, FDA notes that there is consumer demand to

purchase products that have a significant reduction in fat and calories. Water is an ingredient that could effectively accomplish this purpose when used to replace fat and calories in modified products. Therefore, the agency is adding new § 130.10(d)(5) to provide for the addition of water as an ingredient to replace fat and calories in modified products. FDA believes that such addition of water will assist consumers in maintaining healthy dietary practices by providing for an ingredient that will allow manufacturers to produce a greater variety of modified versions of traditional standardized foods. Moreover, the consumer is protected against the possibility of excess water being added by new § 130.10(c), which states that deviations from the ingredient and noningredient provisions of the traditional standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be adulterated under section 402(b) of the act.

FDA also agrees that the use of high moisture ingredients is necessary to reduce calories and fat in some foods. Comments did not mention any specific high moisture ingredients that the regulation should include. Therefore, all high moisture ingredients used in a § 130.10 food must either be ingredients that are provided for by the respective standard of identity or provided for by the safe and suitable ingredient provision of new §130.10(d)(1).

The agency notes that some foods subject to new .§ 130.10 may need to exceed the moisture requirements of the respective standards of identity to make a nutrient, content claim. For example, the standard of identity for cheddar cheese (§ 133.113) stipulates a maximum moisture content of 39 percent by weight and a minimum rnilkfat content of 50 percent by weight of the solids. Under new § 130.10(c),a reduced fat cheddar cheese may exceed the maximum moisture level stipulated by § 133.113 concurrent with the 50-percent reduction in the fat content, but it still must not be nutritionally inferior. The increase in moisture content occurs because less whey is drained from the product during processing. The high moisture ingredients would, therefore, be the same dairy ingredients (i.e., milk, nonfat milk, or cream) provided for by the traditional standard.

The addition of water and high moisture ingredients must be declared in the ingredient statement as required in new § 130.10(f). Because new § 130.10(b) requires that the modified food must not be nutritionally inferior to the standardized food, a modified food that contains significantly less calcium or any other nutrient than the standardized food because of the use of water or a high moisture ingredient must be labeled as an imitation. FDA believes that moisture differentials will be adequately reflected on the label through order of predominance ingredient labeling and labeling of any differences in performance characteristics (e.g., shorter shelf life because of increased moisture content).

4. Flavors

30. Two comments urged FDA to exempt from the labeling requirement of § 101.22(i) those flavors added solely at the level necessary to replace flavors lost by reformulation of the food. The comments also said that there was no reason to exempt any flavor added in amounts greater than necessary to maintain the flavor of the traditional food.

FDA disagrees that there is a need to exempt flavors added to replace flavors lost by reformulation of the food from the requirements of § 101.22(i). Section 101.22(i) only refers to the labeling of characterizing flavors. Natural and artificial flavors that do not characterize a food need only be declared in the ingredient statement. However, FDA believes that consumers should be informed from information on the principal display panel when artificial characterizing flavors have been added to a food.

In the **Federal Register** of January 19, 173 (38 FR 2139), FDA proposed a uniform labeling policy for flavor designation that was patterned, with appropriate modification, after the ice cream standard of identity in §20.1 (21 CFR 20.1) (current § 135.110 (21 CFR 135.110)). According to the standard, ice cream may or may not be characterized by the addition of flavoring ingredients, The existing standard in 1973 listed the optional characterizing ingredients (§ 20.1(b)) that could be used in ice cream. These characterizing ingredients, not the individual flavors contributed by the milk, cream, and other optional ingredients, were the flavors subject to the labeling provisions.

Therefore, the flavors that are lost by reformulation are likely not to be those that characterize the food but those that are an inherent part of the basic required ingredients that are no longer present in the reformulated food. Thus, they need only be declared in the ingredient, statement as natural or artificial flavors, as appropriate. For example, natural and artificial eggnog flavor components may be added to light eggnog to add flavor. These flavor components must be included in the declaration of ingredients but need not appear anywhere else on the label. However, if a natural and artificial eggnog flavor that comprises the total eggnog flavor profile is added to a light eggnog, it is a characterizing flavor and must be labeled according to § 101.22(i). If any portion of the characterizing flavor is artificial, it must be labeled as artificial flavor under § 101.22(i).

31. A comment objected to FDA's choice of "light margarine" as an example of a § 130.10 food using a standardized name. According to the comment, this example implied that the label of a food with the name "light margarine" would have to comply with the flavor labeling regulations of § 101.22 if artificial butter flavor were used in the food for flavoring purposes.

According to § 166.110(b)(7) (21 CFR 166.110(b)(7)) on flavoring substances in margarine, "if the flavoring ingredients impart to the food a flavor *other* than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with § 101.22 of this chapter" (emphasis added). Flavoring ingredients that impart the flavor of butter to margarine thus may be added to the food without declaring such flavor as part of the name of the food.

Because the intent in producing "light margarine" is to modify the fat and calorie content and not the flavor, the agency believes that it is reasonable to treat the declaration of flavoring ingredients on the label of "light margarine" in a like manner to their declaration on the label of margarine that complies with the standard of identity in § 166.110. The use of an artificial butter flavor in the formulation of a "light margarine" would not, therefore, necessitate the naming of this food as "light margarine, artificially flavored" as the preamble to the November 27, 1991, proposal (56 FR 60512 at 60519) stated. The agency reiterates, however, that natural and artificial flavors other than those in semblance of butter in "light margarine" must be declared in the ingredient statement in accordance with the applicable sections of part 101.

5. Fat Analogs

In the proposal FDA stated that it is aware of the recent development of fat analogs and requested comments from Interested persons concerning the appropriateness of the use of approved fat analogs to replace the fat in foods subject to proposed § 130.10 (56 FR 60512 at 60520).

32. A number of comments stated that it would be appropriate to allow for the

addition of fat analogs in modified versions of standardized foods that are subject to proposed § 130.10. One comment recommended that FDA not impose any unique requirements on the use of fat analogs as replacements for fat and calories. Several comments stated that the addition of fat analogs would be appropriate as long as the food is properly labeled. One comment urged the use of a prominent disclosure statement of ingredients such as fat analogs on the principal display panel.

One comment stated that the use of approved fat analogs should be permitted in proposed § 130.10 foods only; (1) Where a particular analog is appropriate for the type of food in view of the composition of the standardized food (e.g., dairy fat analogs for dairy products), and (2) use of an analog is necessary to achieve a substantial reduction in fat. The comment stated that limiting the uses of analogs to those appropriate for a particular product category would serve the consumer interest in limiting deviations from standardized products to those really necessary to achieve reductions of fat.

Another comment stated that without the ability to use fat analogs, food manufacturers may find it difficult or impossible to accomplish the desired reductions, in fat while maintaining product performance. It urged FDA to provide for the use of these ingredients in proposed § 130.10, rather than requiring a much more cumbersome regulatory process in the future. It stated that a statement should be added to proposed § 130.10(d) to the effect that fat substitutes that are approved for use in the food may replace the milkfat or other fat required by the standard.

Several comments stated that no addition of fat analogs should be allowed for a food subject to proposed § 130.10. One comment was concerned that the use of fat analogs would significantly alter the identity of the food and, therefore, the food would no longer resemble the traditional food. Other comments stated that fat analogs should not replace ingredients that would provide more healthful nutrients in modified foods.

FDA believes that there may be some instances where the use of fat analogs is appropriate and may be necessary to reduce the fat and calories while maintaining the performance characteristics of a food. The use offal analogs will allow manufacturers to produce a variety of modified foods with greater reductions in fat and with the same performance characteristics as the traditional food. Thus, consumers will benefit by having a greater variety of modified foods available.

However, under § 130.10(d)(1), the fat analog used in § 130.10 foods must be safe and suitable as defined in new § 130.3(d). Moreover, under § 130.10(c), the amount used must he the minimum necessary to achieve similar performance characteristics as with the fat they replace, and under § 130.10(c). In addition, FDA agrees with the comment that stated that the fat analog must be appropriate for use in the particular type of food. New § 130.10(d)(2) states that an ingredient or component of an ingredient that is specifically required by the standard must not be replaced or exchanged with a similar ingredient from another source unless the traditional standard provides for the addition of such ingredient. The § 130.10 food must resemble the traditional standardized food. Thus, the major ingredients of a category of products should be from that variety of food (e.g., the major ingredients in dairy products should be dairy ingredients), and some ingredients are not appropriate to add to some modified foods that use the traditional standardized name. For example, under new § 130.10(d)(2), vegetable oil is not an appropriate ingredient to replace the milkfat in dairy products, or the fat in egg products, if the food is to use the standardized name as provided for in new § 130.10. Similarly, a fat analog from a vegetable or egg source Is not an appropriate ingredient to replace the milkfat in dairy products using the standardized terms unless the dairy product provides for the use of egg or vegetable ingredients.

Therefore, FDA is adding a provision to new § 130.10(d)(5) to permit the use of safe and suitable fat analogs in accordance with new § 130.10(c), (d)(1), and (d)(2) in modified versions of the standardized food. The addition of fat analogs must be declared in the ingredient statement as required in new § 130.10(f). Because new § 130.10(b) requires that the modified food must not be nutritionally inferior to the standardized food, a modified food that contains significantly less of any nutrient than the standardized food because of the use of fat analogs must be labeled as an imitation. FDA believes that any use of fat analogs would be adequately reflected on the label through order of predominance ingredient labeling.

6. Use of Similar Ingredients

33. One comment suggested that the requirement that ingredients "specifically required" in new § 130.10(d)(2) either needs to be defined or its relationship to "mandatory" and "characterizing" ingredients needs to be explained by FDA. The comment said it assumed that it was FDA's intent in the proposed rule to not allow substitution for ingredients with similar ingredients that are deemed to be mandatory by the standard. FDA agrees with this comment. Ingredients that are specifically required by the standard are mandatory ingredients in standardized foods. Characterizing ingredients may be as optional ingredients under some standards (e.g., ice cream (§ 135.110)) and in those cases are not mandatory. The provision in new § 130.10(d)(2) prohibits the replacement or exchange of ingredients specifically required or mandated by the traditional standard with functionally similar ingredients from other sources that are not provided for by the traditional standard.

34. One comment stated that only dairy products should be used to replace milkfat in dairy products.

FDA agrees that dairy ingredients should be used to replace milkfat in dairy products. However, FDA acknowledges that other ingredients may be needed in small amounts to replace all of the functions of the milkfat that has been removed. A safe and suitable ingredient may be added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness under new § 130.10(d)(1), so long as it meets the requirements of the other parts of new § 130.10(d) and the label of the food complies with new § 130.10(f)(2). FDA adds that as stated previously, any fat analog used in dairy products must be from a dairy source.

35. One comment stated that proposed § 130.10(d)(2) is unnecessary and has the potential to be misinterpreted as, for example, prohibiting the use of a synthetic fat replacer to replace milkfat.

FDA disagrees that proposed § 130.10(d)(2) is unnecessary. Some ingredients are not appropriate to add to some modified foods that use the standardized name. In new § 130.10(d)(5), FDA is specifically providing for the use of safe and suitable fat analogs in new § 130.10 foods to replace fat and calories. However, some fat analogs are not appropriate for a particular type of food and are prohibited from use in a modified food by new § 130.10(d)(2). For example, the standard for sour cream (§ 131.160) states that sour cream contains not less than 18 percent milkfat. FDA believes that replacing the milkfat in sour cream with vegetable oil would be misleading because consumers expect sour cream to be a dairy product. Similarly, consumers would be misled of a fat analog from a

vegetable source replaced the milkfat in sour cream.

7. Ingredients Prohibited By the Reference Standard

36. Several comments opposed proposed § 130.10(d)(3), which states that an ingredient or component of an ingredient that is specifically prohibited by the standard cannot be added to a substitute food under this section.

Two comments requested that proposed § 130.10(d)(3) be made more flexible. One comment stated that the use of nutritionally insignificant amounts of ingredients, such as colorings and flavorings, could be permitted in § 130.10 foods, even if they are specifically forbidden by a standard of identity, to enhance the consumer acceptance of the substitute food. Another comment requested that FDA permit the use of flavorings simulating the flavor of a cheese of any age or variety in reduced fat versions of pasteurized process cheese to achieve a similar product to the traditional full fat counterpart.

FDA disagrees that safe and suitable ingredients specifically prohibited by a standard should be provided for in a substitute food under new § 130.10. There are valid reasons why these ingredients were specifically excluded in the traditional-standard (e.g., economic deception or inappropriateness for the type of food). However, in some cases there are other quality ingredients that may be added for the same purposes,

For example, the agency finds that simulated cheese flavors are unsuitable for use in cheese and related cheese products. Although new § 130.10(d)(1) would permit ingredients to add flavor in substitute foods, flavoring ingredients that are specifically prohibited by standards of identity from inclusion in such foods are specifically prohibited in the modified form of such food (new § 130.10(d)(3)). The standard of identity for pasteurized process cheese in § 133.163(d)(6) specifically excludes any flavorings that, singly or in combination with other ingredients, simulate the flavor of a cheese of any age or variety from use in such food. However, "safe and suitable enzyme modified cheese" may provide a source of flavor in pasteurized process cheese, and this source of flavor is one of the optional ingredients that the agency now permits in this food, as specified in §133.169(d)(9).

37. One comment asked that the use of "skim milk cheese for manufacturing" in § 133.189 be permitted in the formulation of fat-modified pasteurized process cheese. even though the standard of identity in § 133.169 does not now provide for this lower fat, "traditional" dairy ingredient.

FDA disagrees with this comment. Although skim milk cheese for manufacturing is an ingredient in the same class as other cheese ingredients used in the manufacture of the pasteurized process cheese products, because the standard for pasteurized process cheese (§ 133.169) specifically prohibits the use of this ingredient, this lower fat cheese ingredient may not be used in modified versions of this food. Manufacturers wanting to utilize this ingredient in pasteurized process cheese products must label the product as a nonstandardized food or, if appropriate, as pasteurized process cheese food (§ 133.173) or a modified version of pasteurized process cheese food.

Persons interested in providing for the use of skim milk cheese for manufacturing in modified versions of pasteurized process cheese (§ 133.169) may petition the agency to amend the standard.

H. Nomenclature

38. Several comments stated that they believed that allowing the use of the name of a standardized food on foods to which additional safe and suitable ingredients are added is deceiving to consumers, in direct conflict with the standards of identity concept/ procedure, and should not be permitted. Comments stated that if FDA is going to permit optional ingredients to be added to standardized foods to accomplish the performance criteria cited in proposed § 130.10(d)(1), it should require that terms such as "substitute" or "modified" be used in the name of the food.

FDA disagrees with these comments. The major ingredients in a substitute food under new § 130.10 must be ingredients mandated by the relevant standard of identity. The only deviations from the standard that are authorized are those that are necessary to make the nutrient content claim, to ensure that the food meets the performance characteristics of the traditional standardized food, and to ensure the food is not nutritionally inferior to the traditional standardized food. FDA believes that the use of the nutrient content claim in the name of the food and the use of asterisks in the ingredient statement will alert consumers to the fact that the food contains ingredients that differ from those found in the standardized food. Therefore, FDA concludes that consumers will be adequately informed of differences between the § 130.10 food and the traditional standardized food. Because the § 130.10 food is itself a standardized food, it does not need to be labeled as a substitute.

39. One comment requested that the agency clarify that use of "substitute," "alternates" and a distinctive common or usual name remain viable for naming nonstandardized foods. Another comment stated that FDA should require the use of the term "substitute" in conjunction with a standardized name of a food when one or more of the basic characterizing ingredients of a standardized dairy food has been replaced with nondairy ingredients (e.g., vegetable oil in place of milkfat).

FDA notes that § 101.3(e)(4) requires that a food that resembles a standardized food but does not comply with the standard of identity must be labeled as imitation if it is nutritionally inferior to the food, or as a substitute or alternative if it is not nutritionally inferior. As stated above, foods that comply with new § 130.10 comply with a standard of identity.

New § 130.30(d)(2) prohibits the use of functionally similar ingredients to replace an ingredient that is specifically required by the standard. Therefore, a low-fat substitute for mozzarella cheese that is made with vegetable oil would have to be labeled as "imitation" mozzarella cheese if it is nutritionally inferior to mozzarella cheese, or "mozzarella cheese substitute" or "mozzarella cheese alternative" if it is not nutritionally inferior to mozzarella cheese because it does not comply with the standard of identity for mozzarella cheese (§133.155) or with new § 130.10.

40. One comment stated that FDA should clearly indicate that any applicable modifier may be used if more than one is applicable.

FDA agrees that any applicable nutrient content claim, if defined by FDA, may be used if more than one is applicable.

41. Two comments stated that if the name of a standardized food, coupled with the nutrient content claim, presents a contradiction in terms (e.g., nonfat ice cream), then the use of such nutrient content claim should be restricted. One comment added that standardized dairy products (e.g., ice cream) should not be reformulated to the extent that they lose their "dairy product" identity (e.g., nonfat ice cream). They would become "nondairy" products and should be named accordingly.

FDA disagrees with these comments. In the January 22, 1991, ANPRM (56 FR 2149) concerning the filing of several petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, low fat, and

nonfat ice creams. FDA received comments in response to the ANPRM concerning whether the use of the terms "reduced fat ice cream," "low fat ice cream," and "nonfat ice cream" is misleading to consumers.

Several comments received in response to the ANPRM maintained that consumers will recognize "reduced fat ice cream," "low fat ice cream," and "nonfat ice cream" as products that, while containing less fat than ice cream, will deliver what they have come to expect from that food, i.e., similar taste, appearance, mouthfeel, and nutrition as ice cream products. The comments also noted that the nutrition labeling on the reduced fat products will provide additional information on the fat content of the products for comparison purposes.

As noted in these comments on the ANFRM, consumers have had experience for many years with the term "nonfat" on ether dairy products (e.g., nonfat milk and nonfat yogurt). In addition, FDA has issued a number of temporary marketing permits and an extension of a temporary marketing permit for "nonfat cottage cheese," a mixture of dry curd cottage cheese with a dressing that contains less than 0.5 percent of milkfat, and has granted temporary marketing permits for "no fat sour cream." FDA believes that these products are dairy products even though milkfat has been reduced or removed because the milkfat is replaced with skim milk or other dairy ingredients. Nutrition labeling will also assist consumers in making value comparisons relative to the fat reduction as well as calorie reductions in these foods. Therefore, FDA concludes that consumers will not be confused or misled by the use of the nutrient content claim "nonfat" in conjunction with a standardized term such as "ice cream."

42. One comment disagreed with the prohibition on the use of a name permitted on a food under the new generic standard of identity if that food complies with another standard. It stated that this prohibition is a barrier to directing consumers to lower fat versions of products with which they are familiar. It stated that if a modified product meets a traditional standard and the general standard, food producers should be given the option of naming the food using any of the terms allowed under those standards.

FDA disagrees that the name of a modified food that meets the requirements of another standard in parts 131 through 169 should be either name. The common or usual name of a food that has been defined by a standard of identity under section 401 of the act is the name prescribed by the standard. Foods that comply with any standard in parts 131 through 169 must use that standardized name, and this rulemaking is not intended to amend existing standards nor create duplicative standards.

As FDA stated in the proposal (56 FR 60512 at 60520), comparative labeling in accordance with regulations in part 101 may be used to provide consumers with useful information in the selection of a variety of foods.

I. Ingredient Labeling

In the proposal, FDA requested comments on the proposed approach to ingredient labeling in proposed § 130.10(f) and on other methods of identifying ingredients not provided for by the tradition a I standard of identity (56 FR 60512 at 60520).

43. A number of comments objected to the proposed labeling requirements that ingredients not in the standardized food be highlighted with an asterisk, with a statement following the ingredient statement. One comment urged FDA not to establish the specific words that processors must use to convey information about the amount of ingredients not in the standardized food. Several comments stated that consumers generally are not concerned about, or even interested in, how these formulations are achieved, and that the use of asterisks and label statements may be potentially confusing. Several comments stated that the proposed ingredient disclosures would be burdensome to manufacturers and would result in label clutter.

The agency also received comments strongly supporting the use of the disclosures as meaningful steps in the goal of consumer information and understanding. One comment stated that food companies need to inform the consumer as to whether adjustments have been made to their products, and that the item is no longer the same as the standardized food. It stated that the simple labeling of a product as "low fat" is not sufficient because this claim may give the consumer the impression that the product is the same as always, but contains less fat, which may or may not be true.

FDA disagrees with the comments that opposed the use of asterisks. Standards of Identity regulations are established when such action will promote honesty and fair dealing in the interest of consumers. The highlighting of ingredients that are not part of the traditional standard of identity, or that are added m excess of what is permitted by that standard, is appropriate to ensure continued consumer confidence in standardized foods. FDA believes that under sections 201(n) and 403(d) of the act, consumers are entitled to know how the new standardized food differs from the traditional standardized food. In some cases, consumers may have allergies to certain ingredients that may not be normally encountered in the standardized food. Therefore, FDA finds that these ingredients must be highlighted.

44. Many comments stated that it is important for persons with hemochromatosis to know when iron is added to a food. They stated that added iron is often more biologically available than other forms of iron. Several of the comments opposed the language of proposed § 130.10(0(2) that exempts added iron from being identified with an asterisk 121 the ingredient statement.

Any added iron must be listed as an ingredient in the ingredient statement As stated in the proposal (56 FR 60512 at 60520), the consumer may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. Iron is added to a number of foods, not just standardized foods in including foods under new § 130.10. Most § 130.10 foods to which iron will need to be added to ensure that the product is not nutritionally inferior are foods that must contain added iron under the traditional standard of identity (e.g., enriched bread, roils, and buns (§ 136.115)). The agency notes that nutrition labeling will inform consumers of any iron present m significant amounts in the food. Thus, FDA concludes that persons with hemochromatosis will be adequately informed of added iron in any food, and that the use of an asterisk in the ingredient statement is not necessary for ingredients added to a § 130.10 food.

45. Two comments stated that FDA should require that the principal display panel of the label contain a referral statement directing consumers to the ingredient statement to be informed of any non standard ingredients. One comment recommended that this statement should be tailored to different types of foods, based on the ingredients that characterize the foods to consumers. For example, the comment noted, dairy products could be labeled with the term "made with nonstandard nondairy ingredients." In addition, the comment stated that products that meet the nutrient content claim requirements, but are made only from standard ingredients, could be permitted to use the term "pure" as part of the common

or usual name ("pure reduced fat sour cream").

The agency disagrees with these comments. FDA believes that this additional labeling is not necessary because the ingredients that are not in the traditional standardized food are already identified with an asterisk in the ingredient statement. FDA also disagrees with this use of the term "pure." The agency has not defined the term "pure" and believes that the use of the term in the requested manner could cause consumer confusion because of its ambiguity.

46. One comment stated that if these products contain saccharin, aspartame, or acesulfame potassium, they should clearly state this fact on the front label.

FDA notes that a product is misbranded under section 403(o)(1) of the act if it contains saccharin, unless, its label and labeling bear the following statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS." This statement must be located in a conspicuous place on the label and labeling, as proximate as possible to the name of such food, and must appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

FDA also notes that § 172.804 (21 CFR 172.804) requires that the label of any food containing aspartame bear, either un the principal display panel or on the information panel, the following statement: "PHENYLKETONURICS: CONTAINS PHENYLALANINE." The statement must appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The regulation in § 172.800 (21 CFR 172.800) concerning acesulfame potassium requires no special label statements. However, whenever acesulfame potassium, aspartame, or saccharin are ingredients in a food, the name of the ingredient must appear in the ingredient declaration according to part 101.

The comment did not provide any basis for requiring special label statements concerning the addition of these sweeteners for foods subject to new § 130.10. FDA believes that the above requirements provide adequate notice of the presence of these ingredients when they are used. Therefore, FDA concludes that no Additional statements need be required other than those that are required by the act and current FDA regulations, including the use of asterisks and label statements required in new § 130.10(f)(2).

J. Label Format

47. Two comments suggested that FDA should develop more simplified principal display panel labeling requirements and consider a mandatory format for comparative labeling of § 130.10 foods. The comment gave the following example: Reduced Fat "Modified" Cheddar Cheese; 25 percent Less Fat than Cheddar Cheese; Side panel provides nutrition information, per serving size comparisons, and nonstandardized (*) ingredients.

FDA disagrees with this comment. The principal display panel labeling requirements for use of nutrient content claims are mandated by the 1990 amendments and regulations in part 101 concerning the claim. New § 130.10 (c) requires additional labeling cm the principal display panel only when there are differences in performance characteristics. FDA concludes that the requirements that it is adopting are the minimum necessary to ensure that the labeling of § 130.10 foods is informative, adequate, and not misleading. In addition, FDA believes that except as provided in new § 13 0.10 (c), it is not necessary to mandate a particular format for the principal display panel.

K. Existing Standards Using Nutrient Content Claims

48. One comment expressed concern about FDA's tentative decision to exclude from this rule standards of identity that already incorporate nutrient content claims (e.g., lowfat milk). Another comment stated that FDA should give serious consideration to eliminating the existing standards of identity for those foods that have a nutrient content claim as part of their standardized names, in cases where the remainder of the name is also a standardized term.

The agency appreciates the concerns expressed in these comments. FDA did not include existing standards in the proposal to this final rule because Congress exempted nutrient content claims that are part of the name of a food defined by an existing standard of identity even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts (section 403(r)(5)(C)of the act). However, the legislative history makes clear that this exemption was included in the law because of the preexisting standards of identity and the possibility that these standards would conflict with the definitions adopted under the new law. The legislative history goes on to state that to the extent that those standards do provide definitions that are different from the definitions in the regulations issued by FDA under the 1990 amendments, one basic purpose of the 1990 amendments will be partially undermined. Therefore, the legislative history points out that the Secretary (and, by delegation, FDA) has the authority to correct this problem by amending the standards of identity to conform with the regulations issued under section 403(r) of the act (H. Rept 101-538, 101st Cong., 2d sess. 22 (June 13, 1990)).

FDA will consider amending the existing standards of identity that use nutrient content claims in a food name to make them consistent with the definitions that the agency is adopting. The agency's options include amending standards of identity to comply with the nutrient content claim or deleting some standards and allowing the use of these claims with standardized terms in accordance with new § 130.10. Thus, FDA does intend to consider taking the actions suggested by these comments, although it is unable to do so at this time.

L. Legal and Policy Analysis

49. One comment stated that the same legal and policy analysis applies to foods that substitute for foods standardized by statute as to foods that substitute for foods standardized by regulation. It suggested that the preamble to the final rule adding new § 130.10 state that the same legal, and policy analysis applies to foods subject to new § 130.10 as to foods subject to §101.67.

FDA disagrees with this comment Butter, nonfat dry milk, milk, and oleomargarine or margarine are foods that have been defined by statute. Under section 401of the act, FDA has modified the definitions and has established standards of identity for nonfat dry milk, milks and oleomargarine or margarine. However, under section 401 of the act, FDA is prohibited from establishing standards for butter. Therefore, the legal, and policy analysis of butter is different from foods standardized by regulation. Proposed § 101.67 deals only with the use of nutrient content claims for butter. FDA can establish standards for other foods under section 401 of the act, and terms that are standardized by regulation are those that may be used under new §130.10.

III. Pending Petitions

As stated in the proposal (56 FR 60513 at 60516), FDA has received petitions from: (1) The Milk Industry Foundation (MIF) (Docket No. 88P-0329). H. P. Hood, Inc. (Docket No. 89P-0105), and Crowley Foods, Inc. (Docket No. 89P-0403) to establish a standard for "light sour cream;" (2) MIF (Docket No. 88P-0334) and H. P. Mood, Inc. (Docket No. 89P-0329) to establish a standard for "light eggnog;" and (3) the International Ice Cream Association (IICA), the Public Voice for Food and Health Policy, Kraft General Foods, and the Calorie Control Council to amend the standards for "ice cream" and "ice milk" and to establish standards for "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" (Docket No. 88P-0251).

FDA has received a number of applications from companies desiring to market test "nonfat cottage cheese." The agency has issued approximately 22 temporary marketing permits for the product. MIF filed a petition, dated November 2,1991 (Docket No. 91P-0448), to establish a standard of identity for "nonfat cottage cheese." MIF stated in its petition that establishing a standard of identity for "nonfat cottage cheese" would enhance public health, satisfy consumer demand, and promote honesty and fair dealing in the interest of consumers.

All of the petitions are requesting that the agency establish standards for modified versions of traditional standardized foods. Nutrient content claims for the fat content of foods are defined in § 101.62 and include "nonfat" (§ 101.62(b)(1)), "low fat" (§ 101.62(b)(2)), and "reduced fat" (§ 101.62(b)(4)). The term "light" or "lite" is defined in § 101.56. New § 130.10 establishes the requirements for use of these defined nutrient content claims with a standardized term. Therefore, the agency is responding to the above petitions by adopting this final role. However, new § 130.10 does not encompass some portions of the petitions to amend the standards for ice cream and ice milk. Therefore, FDA is responding to those portions of the petitions to amend the standards for ice cream and ice milk in a separate proposal published elsewhere in this issue of the **Federal Register**.

50. One comment requested that to ensure that there is consistency in nomenclature regarding nutrient modified ice creams, FDA should take final action on the petition from the IICA to establish specific standards for modified ice creams and defer the applicability of the provisions of the 1990 amendments to the products within the scope of the IICA petition until 12 months after: (1) The effective date of regulations that FDA adopts in response to the IICA petition, or (2) FDA takes final action to reject the petition, whichever is applicable.

The agency disagrees with the comment. The standard of identity for ice milk (§ 135.120) states that its milkfat content is more than 2 percent but not more than 7 percent. The agency realizes that some reduced fat ice cream products may comply with the standard of identity for ice milk and must be labeled as "ice milk." As stated above, elsewhere in this issue of the **Federal Register**, FDA is proposing changes in the standards of identity for ice cream and ice milk. The agency is proposing to repeal the standard of identity for ice milk. If FDA repeals the standard for ice milk, manufacturers would be able to label ice cream products containing more than 2 percent but not more than 7 percent milkfat according to new §130.10.

Because FDA is taking action on the IICA petition at this time, it does not believe that deferring the applicability of the provisions of new § 130.10 for ice cream products is necessary.

IV. Noncharacterizing Changes in Standardized Foods

51. One comment stated that because the use of nutrient content claims is voluntary, and because the standardized name alone is a proper statement of identity for a standardized food, the suggested use and placement of any nutrient content claim in conjunction with the name of a standardized food that meets the requirements of the standard of identity would, of course, be optional.

FDA agrees with this comment. The labeling for foods meeting a standard of identity and qualifying for the use of a nutrient content claim must comply with the respective standard of identity in parts 131 through 169 and the requirements of § 101.13 concerning nutrient content claims. Because these foods are not modified foods, they do not fall within the scope of new § 130.10. Therefore, FDA concludes that the use of a nutrient content claim in the name of a food complying with a standard of identity is not mandatory. For example, reduced cholesterol liquid eggs may still comply with the standard for liquid eggs (§ 160.115) although part or all of the cholesterol has been removed. The nutrient content claim "reduced cholesterol" may appear as part of the statement of identity in conjunction with the standardized name, or it may appear elsewhere on the label, according to applicable sections of part 101, with the statement of identity consisting of the standardized name.

V. Conclusion

In response to comments submitted regarding the proposal for requirements for foods named by use of a nutrient content claim and a standardized term (56 FR 60512), FDA has revised new § 130.10. The following summarizes the changes being made to new § 130.10 by this final rule:

FDA has revised the title of the regulation to delete the term "substitute" because new § 130.10 applies only to a certain category of substitute foods and not all types of substitute foods as defined under § 101.3(e)(4) and § 101.13(d).

FDA has revised new § 130.10(a) to more clearly establish the scope of the regulation by adding that § 130.10 foods use the name of the traditional standardized food in their statement of identity but do not comply with the traditional standard.

The agency has revised new § 130.10(a) to state that the deviation from the standard of identity "is described by an expressed nutrient content claim that has been defined by FDA regulation."

FDA has revised the last sentence of new § 130.10(a) to read: "The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section."

FDA has added a new sentence to new § 130.10(c) at the beginning of the paragraph to state: "Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food." In addition, FDA has included in new § 130.10(c) a requirement that deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to achieve this effect or the food will be deemed to be adulterated under section 402(b) of the act.

The agency has added a statement to new § 130.10(c) to require that the modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

The agency has also revised new § 130.10(c) by limiting the labeling requirement to changes that materially affect the use of the product.

Finally, FDA has revised new § 130.10(c) to require that the dated

label statement: concerning any differences in performance characteristics be in accordance with the requirements of § 101.13(d).

The agency has revised new § 130.10(d)(1) to include the use of safe and suitable ingredients to improve appearance and to add sweetness.

FDA has added new § 130.10(d)(4) to state that an ingredient specifically required by the standard as defined in parts 131 through 169 must be present in a significant amount. A significant amount of an ingredient is at least that amount that is required to achieve the technical effect provided by that ingredient in the modified food.

The agency has added new § 130.10(d)(5) to provide for the use of water and safe and suitable fat analogs in accordance with new § 130.10(c), (d)(1), and (d)(2) in modified foods to replace fat and calories.

FDA has revised new § l30.10(e) to state that the name of the substitute food "is the appropriate expressed nutrient content claim and the applicable standardized term."

VI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27,1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27,1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to allow additional time for companies to use up their old labels. Thus, the final rule will not be effective until May 8, 1994. FDA relieves there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact, on the human environment is expected and that an environmental impact statement is not required.

VII. Economic Impact

In its November 27, 1991, food labeling proposals (56 FR 60366). FDA stated that the food labeling reform initiatives taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in. this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

List of Subjects in 21 CFR Part 130

Food additives, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 130 is amended as follows:

PART 130— FOOD STANDANDS: GENERAL

1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321,336, 341, 343, 371).

2. Section 130.10 is added to subpart A to read as follows:

§ 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

(a) *Description*. The foods prescribed by this general definition and standard of identity are those foods that substitute (see § 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter and that use the name of that standardized food in their statement of identity but that do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of § 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section.

(b) *Nutrient addition*. Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in

§ 101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) *Performance characteristics.* Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food. Deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking"). Such statement shall comply with the requirements of § 101.13(d) of this chapter. The modified product shall perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis. extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169 of this chapter.

(2) An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(4) An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount. A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

(5) Water and fat analogs may be added to replace fat and calories in accordance with §130.10(c),(d)(1) and (d)(2).

(e) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate expressed nutrient content claim and the applicable standardized term.

(f) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter and part 130.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular _____"(fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular _____"(fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

Dated: October 27,1992.

David A. Kessler,

Commissioner of Food and Drugs,

Louis W. Sullivan,

Secretary of Health and Human Services,

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