and relabel some products. However, the number of such products will likely be very small because available databases reveal that many foods do not contain measurable amounts of vitamin K (Refs. 11, 12, and 13).

A ''measurable amount'' of an essential nutrient is defined as 2 percent or more of the RDI for that nutrient per reference amount customarily consumed (see § 101.3(e)(4)(ii) as revised in this final rule). FDA has stated that analysis is not needed for nutrients where reliable databases or scientific knowledge establish that a nutrient is not present in the product (58 FR 2079 at 2109). For example, current databases (Refs. 11, 12, and 13) show that foods that consist primarily of sugar and water (e.g., soft drinks, hard candies, honey), as well as many oils, beverages, fruits, and fish, do not contain measurable amounts of vitamin K, so there is no need to analyze such foods for it. Conversely, green leafy vegetables, legumes, and certain oil products (e.g., soybean oil), which are important sources of vitamin K, are not generally reformulated as substitute foods. The primary categories of substitute foods that may need to be reformulated or relabeled appear to be those that substitute for foods containing eggs, milk, grains, or those oils that contain vitamin K.

The agency is not persuaded by the comments that there is a lack of analytical methods for vitamin K, or that technological barriers to analyzing foods for vitamin K, or to adding vitamin K to foods, are insurmountable. The Association of Official Analytical Chemists (AOAC) International has authorized methods for analyzing vitamin K for infant formula (Refs. 14 and 15). In addition, there are High Performance Liquid Chromatographic methods available that are being used in university and government laboratories in the United States for the analysis of vitamin K in a wide, diverse portion of the food supply (Refs. 16, 17, and 18). These methods could be utilized by commercial laboratories if there was a demand for information on the vitamin K content of food products other than infant formula. The agency believes that such methods can be readily adapted for use by industry. However, the agency considers it inadvisable to explicitly recommend a specific analytical method for vitamin K. The applicability of a specific method to products of different matrices varies. If FDA were to require the use of a specific method, it could give the erroneous impression that other methods that are more appropriate to a matrix, or that utilize newer techniques, could not, or would not, be acceptable. In accordance with § 101.9(g)(2), FDA advises that manufacturers should select the most appropriate method for the matrix involved.

The agency also is not persuaded by the comments that there is a scarcity of ingredient sources of vitamin K. Vitamin K is required for addition to infant formula as specified in part 107 (21 CFR part 107) and is found in many dietary supplement products. These facts evidence that ingredient sources are available to supply this nutrient.

In summary, the consideration of vitamin K in determinations of nutritional inferiority is consistent with the original intention of the imitation food provisions (i.e., § 101.3(e)(4)) that consumers be protected from the uninformed purchase of nutritionally inferior substitute products. Because the lack of vitamin K would make a food inferior to the one for which it substitutes, the agency concludes that its addition should be required according to the criteria established in § 101.3(e)(4).

FDA appreciates that there are presently some gaps in knowledge about the vitamin K content of foods and technological issues related to its addition to foods. However, as noted previously, considerable recent scientific activity has occurred and knowledge is evolving rapidly (Refs. 10 through 17). Therefore, based on its review of current data, FDA concludes that there are adequate analytical methods, food composition data, and technological expertise available to support consideration of vitamin K when determining nutritional inferiority of substitute foods. FDA will continue to monitor the evolving scientific knowledge regarding vitamin K content of food and will work with industry on specific foods or issues, should problems arise.

10. Several comments noted that chloride and manganese are not of public health concern and encouraged FDA to modify § 101.3(e)(4)(ii) to state that these minerals need not be considered when determining nutritional inferiority. A few comments specifically noted that no chloride deficiencies have been found except among infants fed chloride deficient formulas as the sole source of the diet. These comments also argued that requiring the inclusion of chloride in nutritional inferiority determinations would jeopardize the development and continued availability of certain reduced sodium foods. The comments said that if this provision was not changed, manufacturers would be required to add chloride to the modified products to compensate for the amount originally contributed by salt, and that the addition of chloride-containing salts would seriously affect the flavor and acceptability of many such products.

As explained in the preceding comment, the requirement for a determination of nutritional inferiority that is set forth in § 101.3(e)(4) is intended to ensure that alternative products are nutritionally comparable to the foods for which they substitute. In promulgating these regulations, FDA tentatively concluded that the term ''imitation'' should only be applied to substitute foods that are nutritionally inferior to the foods for which they substitute (38 FR 2138). In response to comments received, FDA confirmed this view and defined nutritional inferiority as any reduction in the content of an essential vitamin or mineral or of protein that is present in a ''measurable amount,'' with ''measurable amount'' defined as 2 percent or more of the U.S. RDA of that nutrient per serving (38 FR 20703, August 2, 1973). Adequacy of intake of a particular nutrient or concern over whether the nutrient was of public health concern (e.g., due to widespread deficiencies) was not considered to be an issue in determining whether a substitute food was nutritionally inferior to the food for which it is a substitute.

Consistent with the agency's longstanding definition of nutritional inferiority in § 101.3(e)(4), FDA finds that the adequacy of current dietary intakes of a nutrient is not determinative of the issue. Therefore, the agency is not persuaded by this argument to drop chloride and manganese from consideration in determining nutritional inferiority. The agency concludes that the lack of manganese would make a food inferior to the one which it replaces.

However, FDA is persuaded that a change in its position on inclusion of chloride in determinations of nutritional inferiority is warranted given its commitment to lower sodium intake, consistent with the ''Dietary Guidelines for Americans'' (Refs. 19 and 20) and ''The Surgeon General's Report on Nutrition and Health'' (Ref. 21). The Surgeon General's report pointed to the need for moderation in sodium consumption, not only because there is a benefit to persons whose blood pressure rises with increased sodium intake, but also because there is no biological marker for individual sodium sensitivity. The report notes that there is no apparent harm to the general population from moderate sodium restriction (Ref. 21, p. 13). Because salt (i.e., sodium chloride) is the major source of dietary chloride, the agency is