may take the food industry to implement these new rules. The proposed 30-day effective date was intended to permit the inclusion of the subject nutrients in nutrition labeling as quickly as possible. The agency believes that many companies want, and will be able, to implement these rules quickly, while others will need more time to make the necessary changes.

Accordingly, while companies who wish to add vitamin K, selenium, manganese, chromium, molybdenum, and chloride to the nutrition labeling on their products may do so immediately, FDA is changing the effective date to January 1, 1997, in recognition of the analytical work and formulation changes that may be needed with some food products to come into compliance with revised §§ 101.3(e)(4)(ii) and 101.9(c)(8)(iv). This effective date provides approximately 12 months for industry to implement the subject changes, sufficient time to accomplish an orderly and economical adjustment to the subject rules. It is also consistent with the effective date established in the DSHEA and proposed in the document addressing nutrition labeling of dietary supplements published elsewhere in this issue of the Federal Register. The agency encourages industry to comply with these new rules earlier than the effective date wherever it is feasible to do so.

X. Economic Impact

FDA has examined the economic implications of the final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires that agencies analyze options for regulatory relief for small businesses. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant impact on a substantial number of small businesses.

A. Costs

14. FDA received several comments rejecting the agency's analysis of the costs of this regulation as proposed. One comment stated that the cost of evaluating the manganese, vitamin K, and chloride content of substitute foods and relabeling affected products would exceed the agency's estimates. Another comment explained that a lack of a practical analytical method for vitamin K in food systems and other technical issues would lead to major costs.

FDA agrees that including manganese and vitamin K in the consideration of nutritional equivalency will lead to increased costs of analyzing and relabeling substitute products. Because FDA has reevaluated its decision regarding chloride, there will be no increased costs attributable to that substance.

As stated previously in this document, analysis is not needed for nutrients where reliable data bases establish, or scientific knowledge establishes, that a nutrient is not present in the product. Current data bases show that foods that consist primarily of sugar and water, as well as many oils, beverages, fruits, and fish, do not contain measurable amounts of vitamin K, so there is no need to analyze for it in products substituting for such foods. Conversely, green leafy vegetables, legumes, and certain oil products, which are major sources of vitamin K, are not generally reformulated as substitute foods. Therefore, FDA expects that only a limited number of products will require analysis for vitamin K. Likewise, manganese is prevalent in cereal grains, green leafy vegetables, and tea. Therefore, FDA predicts that only a limited number of products will require analysis for manganese. However, when there is a reasonable expectation that either nutrient occurs in the food, an analysis for the nutrient will be necessary, and the manufacturers of those products will bear the cost of testing for the nutrient.

FDA does not have an estimate of the cost of testing for vitamin K in foods other than infant formulas or dietary supplements, although such testing has been performed in university settings. The cost of testing for vitamin K in infant formulas or dietary supplements is approximately $187 per product (Ref. 22). The cost of testing for manganese is approximately $34 per product (Ref. 23). While FDA cannot determine the exact cost of testing for these nutrients because the total number of products that must be tested is unknown, the cost per test and the fact that vitamin K and manganese levels will be significant in only a small number of foods lead the agency to conclude that the costs that will be engendered by this final rule will not approach the levels that represent a significant rule.

15. Several comments objected to the economic analysis on the basis that the short lead time of the proposed effective date would lead to increased costs. One comment objected to the proposed effective date given due to the impossibility of evaluating foods for nutritional equivalency and relabeling of affected products within the 30-day effective date proposed. Another comment stated that extending the effective date would reduce the impact of making two label changes.

FDA agrees that the proposed effective date would lead to increased costs. However, because FDA is extending the effective date to give firms approximately 12 months, the analysis need not be changed in response to these comments.

B. Benefits

This regulation allows manufacturers to declare certain nutrients within the nutrition panel and to make content claims about those nutrients. This regulation will create benefits to the extent that the additional information allowed on labels will help consumers make healthy dietary choices.

This regulation also establishes requirements for determining nutritional inferiority such that substitute products must contain equivalent amounts of vitamin K and manganese as the products for which they substitute.

There are currently no widespread deficiencies of either vitamin K or manganese in the United States. Although it is theoretically possible that additional deficiencies could occur if enough consumers switch to substitute products containing inferior amounts of the nutrient, the likelihood of widespread deficiencies is small because the number of foods containing significant amounts of the nutrients that could be substituted is small. Also, it is unlikely that the deficiencies that might occur would result in anything other than minor effects. Therefore, the health benefits of including vitamin K and manganese in tests for nutritional equivalency are small and unmeasurable.

C. Summary

The agency has examined the economic impact of this final rule and has determined that it is not significant as defined by Executive Order 12866.

XI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (59 FR 427). At that time, the agency determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human