DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 90N–0134]

RIN 0910–AA19

Food Labeling: Reference Daily Intakes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish Reference Daily Intakes (RDI's) for vitamin K, selenium, manganese, chromium, molybdenum, and chloride, but not for fluoride. The agency is also amending its regulations to modify the units of measure that are used to declare the amount of biotin, folate, calcium, and phosphorus in food. In addition, the agency is amending its regulations to make consideration of selenium, chromium, molybdenum, and chloride optional in making a determination as to whether a food is nutritionally inferior to a food for which it substitutes and that it resembles. These actions are intended to assist consumers in understanding the nutritional significance of foods in the context of a total daily diet and are in recognition of the fact that the National Academy of Sciences (NAS) established Recommended Dietary Allowances (RDA's) and Estimated Safe and Adequate Daily Dietary Intakes (ESADDI's) for vitamin K, selenium, manganese, chromium, molybdenum, and chloride either in 1980 or 1989.

EFFECTIVE DATE: January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION

I. Background

In the Federal Register of January 4, 1994 (59 FR 427), FDA published a proposed rule in a document entitled ''Food Labeling: Reference Daily Intakes'' (hereinafter referred to as ''the January 1994 proposal''). This document grew out of earlier proposals that, among other things, sought to amend FDA's label reference value regulations to replace the United States Recommended Daily Allowances (U.S. RDA's) with Reference Daily Intakes (RDI's) for protein and 26 vitamins and minerals.

In the Federal Register of July 19, 1990 (55 FR 29476), FDA published its initial proposal on RDI's in a document entitled ''Food Labeling Reference Daily Intakes and Daily Reference Values'' (hereinafter referred to as ''the July 1990 proposal''). Following the passage of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (hereinafter referred to as ''the 1990 amendments''), FDA republished this proposal in modified form on November 27, 1991 (56 FR 60366) (hereinafter referred to as ''the supplementary proposal''). FDA summarized and reviewed the comments to these proposals in a final rule entitled ''Food Labeling; Reference Daily Intakes and Daily Reference Values'' (58 FR 2206, January 6, 1993, and corrected at 58 FR 17104, April 1, 1993) (hereinafter referred to as ''the RDI/DRV final rule'').

However, on October 6, 1992, before FDA issued the final rule, Congress passed the Dietary Supplement Act of 1992 (Title II of Pub. L. 102–571) (hereinafter referred to as the ''DS act''). Section 202(a)(1) of the DS act imposed a moratorium on the implementation of the 1990 amendments as they applied to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances until December 15, 1993. Section 203 of the DS act prohibited FDA from promulgating regulations before November 8, 1993, that required the use of, or that were based on, recommended daily allowances of vitamins or minerals, other than regulations establishing the U.S. RDA's specified in § 101.9(c)(7)(iv)(21 CFR 101.9(c)(7)(iv)) (1992), as in effect on October 6, 1992.

The label reference values in § 101.9(c)(7)(iv) (1992) were based to a large extent on the 1968 RDA's (Ref. 1), and thus they are more than 25 years old. These label values do not reflect the significant advances in scientific knowledge about essential nutrient requirements that have occurred over the last 20 years. Based on these advances, in 1980, the NAS established, for the first time, ESADDI values for vitamin K, biotin, pantothenic acid, copper, manganese, fluoride, chromium, selenium, molybdenum, sodium, potassium, and chloride (Ref. 2). In 1989, the NAS updated the values for vitamin K and selenium, making them RDA's rather than ESADDI's (Ref. 3). At the same time, the NAS continued to provide ESADDI values for manganese, fluoride, chromium, and molybdenum, but NAS dropped the suggested values for sodium, potassium, and chloride, giving instead estimated minimum requirements for healthy persons at various ages (Ref. 3).

With its discretion constrained by section 203 of the DS act, and yet faced with a need to establish a labeling scheme that manufacturers could implement as quickly as possible, FDA simply adopted in its new regulations the values in § 101.9(c)(7)(iv) as in effect in 1992 (see RDI/DRV final rule). This solution created a new problem. Section 101.9(c)(7)(iv) (1992) did not contain label reference values for vitamin K, selenium, manganese, chromium, molybdenum, chloride, and fluoride, which were addressed in the 1989 RDA's (Ref. 3).

In its January 1994 proposal, FDA proposed to establish RDI's for vitamin K, selenium, manganese, chromium, molybdenum, chloride, and fluoride for the following reasons: Such values are necessary to permit the declaration of these nutrients in the nutrition labeling of all foods; they will assist consumers in understanding the significance of the amount of these nutrients present in foods in the context of a total daily diet; and these values will permit nutrient content claims to be made for these nutrients.

FDA received approximately 65 letters in response to the January 1994 proposal. Each letter contained one or more comments. Many comments supported the proposal generally or supported aspects of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., nutrition education, freedom of choice, premarket clearance, and fortification policies) and will not be discussed here. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of the comments, the agency's responses to the comments, and a discussion of the agency's conclusions with respect to the RDI's for the seven nutrients follows:

II. Authority for Additional Label Reference Values

Section 2(b)(1)(A) of the 1990 amendments provides that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue regulations that require that the required nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. FDA, in its food labeling initiative, has tried generally to assist consumers in understanding the nutrition label information relative to a total daily diet (see 55 FR 29476) and to do so based on the most current scientific and public health knowledge.

1. The majority of comments agreed with establishing RDI's for the

additional nutrients. These comments applauded FDA's intention to broaden the list of nutrients for which RDI's are established and stated that this action is in keeping with the intent of the 1990 amendments to provide additional useful information to consumers. On the other hand, one comment questioned the wisdom of establishing new RDI's before conducting surveys to gauge the extent to which the RDI's can be comprehended and expressed concern the new RDI's would only add to public confusion.

The agency does not agree with the latter comment. Before issuing final food labeling rules on January 6, 1993, FDA and the food industry conducted numerous focus groups and informal preference studies that analyzed consumer understanding of different formats for presenting nutrition information, including the question of whether consumers could understand RDI's, which are incorporated into the ''Nutrition Facts'' panel by means of the percent Daily Value (DV) declaration. This research demonstrated that the percent DV format improved consumers' abilities to make correct dietary judgments about a food in the context of the total daily diet (58 FR 2070 at 2127). Therefore, FDA finds that percent DV's, and the underlying RDI's can be, and are, understood by consumers and used by them successfully. Therefore, FDA finds that this comment provides no basis for not establishing RDI's for the seven nutrients. Consistent with the vast majority of comments, FDA is adopting these values except the value for fluoride, as explained below.

III. Nutrient Selection and Determination of Values for RDI's

A. Basis for RDI's

2. Most comments strongly supported the use of the NAS' RDA's as the basis for the establishment of RDI values. However, a couple of comments objected to providing RDI's only for nutrients with RDA's. One comment urged FDA to permit the inclusion of boron, nickel, silicon, tin, and vanadium as nutrients to be declared within the nutrition label. The comment stated that these nutrients have been recognized as essential by leading experts on trace minerals.

Since the inception of the nutrition labeling program, FDA has relied on the judgment of the NAS' Food and Nutrition Board concerning the essentiality of particular nutrients in human nutrition and the required levels of those nutrients (37 FR 6493, March 30, 1972). The procedures followed by the NAS ensure that scientific consensus exists for the essentiality in human nutrition of nutrients for which RDA's and ESADDI's are established. In brief, these procedures include a review of the available scientific literature by experts in the field of human nutrition, requests for public input, consultation with other knowledgeable experts, a review by the Food and Nutrition Board, and a review by the National Research Council's Report Review Committee. The types of evidence on which the RDA's are based include: (1) Studies of subjects maintained on diets containing low or deficient levels of a nutrient, followed by correction of the deficit with measured amounts of the nutrient; (2) nutrient balance studies that measure nutrient status in relation to intake; (3) biochemical measurements of tissue saturation or adequacy of molecular function in relation to nutrient intake; (4) nutrient intakes of fully breast-fed infants and of apparently healthy people from their food supply; (5) epidemiological observations of nutrient status in populations in relation to intake; and (6) in some cases, extrapolation of data from animal experiments (Ref. 3, p. 1).

Strong and uniform support was provided for the use of NAS RDA's as the basis for nutrition label information during the initial development of nutrition labeling regulations in 1972 as well as in response to the July 1990 proposal and the supplementary proposal. FDA noted in the RDI/DRV final rule that ''The majority of comments on this topic * * * supported the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals'' (58 FR 2206 at 2208). Based on the continuing support shown in the comments submitted in the present rulemaking, the agency continues to believe that the NAS' ''Recommended Dietary Allowances'' (Ref. 3) remains the most widely accepted and respected source of information on human nutrient requirements.

The lack of an RDA or ESADDI does not mean that other substances should not be included in the diet. It does mean, however, that the level of scientific agreement does not exist that would justify highlighting these substances for special attention to ensure that they are included in the diet at appropriate levels.

There are two criteria for determining which nutrients should be considered for RDI's. The first and foremost is scientific consensus as to the essentiality of the nutrient. Nutrients that are essential in human nutrition warrant special consideration on the label to guarantee that consumers have the means, through nutrition labeling, to account for the nutrient in the total daily diet.

The second criterion is scientific agreement concerning the level at which the nutrient should be consumed. The RDA's are defined as ''the levels of intake of essential nutrients that, on the basis of scientific knowledge, are judged by the Food and Nutrition Board to be adequate to meet the known nutrient needs of practically all healthy persons'' (Ref. 3, p. 1). The ESADDI's are defined as ''a category of safe and adequate intakes for essential nutrients when data were sufficient to estimate a range of requirements, but insufficient for developing an RDA'' (Ref. 3, pp. 6 and 7).

The criteria of essentiality and of recommended intakes provides assurance that there is scientific agreement regarding the need for certain nutrients and guidance regarding appropriate levels.

While the comment supporting the inclusion of boron, nickel, silicon, tin, and vanadium submitted published reports of the requirements for these nutrients in animal nutrition, it submitted no data or other information that there is scientific consensus that these minerals are essential in human nutrition, or that there is agreement concerning recommended daily intake levels for these minerals. Because of the lack of such data and the NAS' position that deficiencies of these trace elements have not been established in humans, and, hence, that there are no data from which human requirements can be established (Ref. 3, p. 267), the agency is not establishing RDI's for boron, nickel, silicon, tin, or vanadium. Therefore, in accordance with § 101.9(c), these nutrients cannot be declared within the nutrition label on conventional foods. However, in a companion document in this issue of the Federal Register entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements,'' FDA is proposing regulations to implement the Dietary Supplement Health and Education Act of 1994 (the DSHEA) that will, in part, allow dietary ingredients for which RDI's have not been established (e.g., boron) to be listed in the nutrition label of dietary supplements.

3. One comment urged FDA to consider the promotion of optimal health, instead of nutrient adequacy, in the determination of label reference values.

As discussed in the response to the previous comment, the RDI's are based on the NAS RDA's, and the agency is

not persuaded that a change in that basis is warranted. NAS is in the process, however, of evaluating the basis on which it determines the RDA's. In 1994, the Food and Nutrition Board (FNB) of the Institute of Medicine of the NAS published a document entitled ''How Should the Recommended Dietary Allowances Be Revised'' (Ref. 4). In this document, NAS summarized its multi-step plan for reconceptualizing the RDA's and announced its intention to examine alternate bases for determining the RDA's. NAS stated:

> Nutrition science, similar to all scientific endeavors, is rapidly changing and evolving. Nutrition scientists and practitioners continue to learn more with each passing day about nutrition and its effect on health. The role of the RDAs at any time is to provide the best consensus of nutrition science interpreted to recommended values at that time. The FNB believes that the science of nutrition has advanced significantly, and the next edition of the RDAs will need to reflect this progress. One consideration is expanding the RDA concept to include reducing the risk of chronic disease. (Ref. 4, p. 14.)

To accomplish this task the FNB proposed to develop four reference points: Deficient, average requirement, recommended dietary allowances, and upper safe levels (Ref. 4, pp. 18–20). They also proposed to develop a publication describing how the new RDA's could be used for the variety of purposes to which they are put (e.g., for food labeling) (Ref. 4, pp. 20–21).

FDA is committed to working with the NAS in its development of new approaches for providing standards to serve as goals for good nutrition and in the implementation of those approaches. The agency believes that any action to change the basis for the RDI's should await completion of the NAS process to ensure that such an action reflects scientific consensus and to avoid the possible need for consecutive relabeling of foods that might occur if FDA were to proceed to revise the RDI's before NAS published new values.

B. Method for the Determination of RDI Values

4. Many comments supported the method that FDA used for determining the proposed RDI's for the seven nutrients. One comment, however, supported the proposal to establish RDI's for nutrients with RDA's (i.e., vitamin K, selenium) but not for nutrients with ESADDI's (i.e., chloride, manganese, chromium, molybdenum, and fluoride). The comment contended that FDA's proposed use of ESADDI's for establishing RDI's is not scientifically sound. The comment argued that because ESADDI's are merely estimates, established when scientific data are insufficient to develop an RDA, RDI's should not be based on them. The comment also stated that, because recommended levels are presented as a range of values, using the midpoint of such a range is of questionable scientific validity.

Another comment stated that using the midpoint of the ESADDI range results in RDI's that are too high for manganese, chromium, and molybdenum. The comment stated that the upper value of the ESADDI range is the upper limit of safety for the specified age group. This comment recommended that the lowest value of the ESADDI range be used for determining the RDI for these nutrients because this level is more than adequate to meet the needs of most individuals and is higher than usual intakes. The comment stated that the proposed values would be difficult to obtain by diet and would likely result in many people believing that they are ''deficient'' when they are not.

Based on its consideration of the comments on the 1990 proposal and on the supplementary proposal, FDA determined in the RDI/DRV final rule that it is appropriate to establish label reference values for vitamins and minerals by selecting the highest NAS RDA value from among those for adults and persons 4 or more years of age (excluding pregnant and lactating females) (58 FR 2206 at 2211). The agency concluded that use of these values would ensure that the value set as the RDI would take into account the intakes of vulnerable and at-risk groups. At the same time, where several ESADDI ranges were established by the NAS for specific age groups, FDA said that it would select the highest range, and then use the midpoint of that range as the RDI (58 FR 2206 at 2212). In its July 1990 proposal, FDA based the proposed RDI's for nutrients with ESADDI's presented as a series of ranges of values on the midpoint of the highest ESADDI range (55 FR 29476 at 29481), and most of the comments supported that approach. Accordingly, in the current rulemaking, FDA used this method to derive the proposed values for chloride, manganese, fluoride, chromium, and molybdenum (59 FR 429).

As stated previously, the vast majority of comments to the January 1994 proposal supported this approach. FDA disagrees with the comment that it is not scientifically sound to base RDI's on ESADDI's. In the July 1990 proposal, FDA acknowledged that available data regarding nutrients with ESADDI's are not sufficient to allow NAS to set specific RDA values. However, in ''Recommended Dietary Allowances,'' the NAS does state that ESADDI's are established ''for essential nutrients when data were sufficient to estimate a range of requirements'' (Ref. 3, p. 7). From this statement, the agency concludes that, for those nutrients for which it has established ESADDI's, the NAS reviewed similar types of evidence as that used in arriving at RDA's and applied the same rigorous scientific approach, satisfying itself that the nutrients were essential for human nutrition, and that, while the data were not sufficient to set precise recommended levels, they were sufficient to arrive at a scientifically supported range.

Accordingly, these nutrients meet the two criteria (discussed in comment 2 of section III.B. of this document) used by FDA in determining which nutrients should be considered for RDI's, namely, that there is scientific consensus as to the essentiality of the nutrient and scientific agreement concerning the level at which the nutrient should be consumed. While for these nutrients that level is a range rather than an exact amount, it nonetheless reflects the amount of the nutrient known to be necessary to meet the nutrient needs of individuals according to age group. Based on these facts, FDA concludes that it is proper to establish RDI's for nutrients for which the NAS has established ESADDI's.

This action is consistent with the agency's action in 1973 when it established U.S. RDA values for biotin, pantothenic acid, copper, and zinc based on discussions of nutrient requirements in the text of the seventh edition of ''Recommended Dietary Allowances'' (Ref. 1) (38 FR 2125 and 2146, January 19, 1973). At that time, RDA's did not exist for these four nutrients, and ESADDI's had not been introduced. Both then and now, by providing a reference value, the agency allowed for the nutrients to be listed in nutrition labeling so that manufacturers could voluntarily provide consumers with information on the amount (in terms of percent of a reference value) of these essential nutrients that is present in a serving of food.

The agency is not persuaded that using the lowest value of the ESADDI range is a preferable method for determining RDI's for nutrients with ESADDI's. The vast majority of comments received on this subject in this rulemaking, as well as on the July 1990 proposal and on the supplementary proposal, argued strongly for label reference values that

targeted vulnerable or at-risk groups by selecting the highest recommended values. In the RDI/DRV final rule, FDA was persuaded by the comments to use a ''population coverage approach'' that did, in fact, rely on the highest NAS RDA values from among those persons 4 or more years of age (excluding pregnant or lactating women). For those nutrients with ESADDI values presented as ranges, the agency attempted to be consistent with this approach by selecting the highest range and then using the midpoint of that range.

Use of the lowest point in the ESADDI range would be inconsistent with the population coverage approach because it would set the RDI at a value considered by the NAS as the minimum adequate dietary intake level, not at a value that is targeted at vulnerable or at risk groups. The agency recognizes the need for some caution, however, because NAS has stated that the upper limits of the ESADDI ranges of intake should not be habitually exceeded because the toxic level for many trace elements may be only several times usual intake (Ref. 3, p. 7).

Therefore, in recognition of NAS' expressed concern and based on the comments, FDA is persuaded to modify its method for determining RDI's for nutrients with ESADDI's. While FDA will look first to the midpoint of the highest range, if that value exceeds the upper limit of the range for any ESADDI age group within the age range for which the RDI will apply (i.e., adults and children 4 or more years), FDA will select as the RDI the lowest upper level of the ESADDI ranges that are less than the midpoint of the highest ESADDI range. For example, a review of the 1989 ESADDI values for manganese shows a range from 1.5 to 2 milligrams (mg) for children 4 to 6 years of age, from 2 to 3 mg for children 7 to 10 years of age, and from 2 to 5 mg for children 11 years of age through adults (Ref. 3). The agency proposed an RDI for use on labels of foods intended for adults and children 4 or more years of age of 3.5 mg for manganese. This value was the midpoint in the highest ESADDI range (2 to 5 mg). Under this new method for determining RDI's for nutrients with ESADDI's, FDA is setting the RDI value at 2 mg since the midpoint of the highest ESADDI range (3.5 mg) exceeds the upper limit for 4 to 6 year old children (2 mg).

Other nutrients affected by this modified method are chromium and molybdenum. FDA proposed an RDI for chromium of 130 micrograms (µg). The upper limit of the ESADDI range for children 4 to 6 years of age is 120 µg. Therefore, the agency is adopting an RDI for chromium of 120 µg, rather than 130 µg. Likewise, FDA proposed an RDI for molybdenum of 160 mg. The upper limit of the ESADDI range for children 4 to 6 years of age is 75 mg. Therefore, the agency is adopting an RDI for molybdenum of 75 mg, rather than 160 mg. FDA has revised § 101.9(c)(8)(iv) to reflect these new values for manganese, chromium, and molybdenum.

FDA reiterates that the RDI's do not represent dietary goals for individuals. Their purpose is to provide an overall population reference value for use on the food label (55 FR 29476 at 29481). As such, they may underrepresent or exceed the needs of particular individuals, particularly for manganese and molybdenum. Nonetheless, on a population basis FDA concludes that these values are appropriate.

IV. Issues Concerning Specific Nutrients

A. Fluoride

5. A number of form letters opposed establishing an RDI for fluoride. Most of these comments did not provide any justification for their position. Some comments stated that fluoride has been shown to be a poison when ingested in very small quantities. These comments associated the ingestion of minute quantities of fluoride with several adverse health effects (e.g., dental fluorosis, gastrointestinal disorders, allergies) but provided no data or information to support this position. Another comment said that FDA should not establish an RDI for fluoride because fluoride has never been identified as an essential nutrient. This comment also expressed concern about difficulties that would be encountered with an RDI for fluoride, given the variability in dietary intake levels of this substance resulting from the use or nonuse of fluoridated water as well as the unintentional consumption of fluoride from mechanically deboned meat and fluoridated toothpastes, and about the harm that might occur if foods (including supplements) began fortifying with fluoride.

Another comment recommended that either fluoride be deleted from the list of nutrients for which RDI's are established, or that the agency establish an upper limit at 1.3 parts per million for added fluoride in foods and dietary supplements because this level would be consistent with the agency's proposal for the addition of fluoride to bottled water.

A couple of comments suggested that an RDI of 3 mg for fluoride will become a formulation target level for manufacturers. One comment stated that manufacturers of vitamin-mineral supplements may incorporate an amount of fluoride corresponding to 100 percent of the RDI and reflect this fact on the nutrition label. The comment argued that if such formulations are produced, the intake of 3 mg fluoride from the vitamin-mineral supplement in addition to the intake of fluoride from the diet, drinking water, and fluoridated dentifrices would pose a risk of dental fluorosis for young children and might lead to excess skeletal fluoride accumulation.

A professional association of pediatric dentists supported establishing an RDI for fluoride for nutrition labeling purposes. However, the comment stated that establishing the RDI at 3 mg would place millions of children from infancy through 16 years at risk for dental fluorosis. The comment urged FDA to establish the RDI for fluoride at 1 mg because this level is scientifically proven to provide significant anti-caries protection without increasing the risk of dental fluorosis. The comment stated that levels above 1 mg have shown no greater anti-caries protection, while greatly increasing the risk of dental fluorosis in children. Another comment suggested that the lowest fluoride ESADDI of 1.5 mg be adopted as the RDI because this level would be compatible with the available food supply, and because fluoride has about 70 percent availability for absorption resulting in an absorbed level of 1 mg.

The agency rejects the argument that an RDI should not be established because low levels of ingested fluoride (i.e., levels at or below the proposed RDI) represent significant health risks and are associated with a variety of toxicities. The U.S. Department of Health and Human Services, in a report titled ''Review of Fluoride, Benefits and Risks'' (Ref. 5), examined the literature on the adverse effects of ingested fluoride. The report could not substantiate that there are adverse health effects or toxicities associated with low level fluoride exposure in normal individuals. In 1993, the Subcommittee on the Health Effects of Ingested Fluoride of the NAS Committee on Toxicology (the Subcommittee) examined possible adverse health effects associated with fluoride intake including dental fluorosis; bone fracture; reproductive, renal, gastrointestinal, and immunological toxicities; genotoxicity; and carcinogenicity. The Subcommittee found that it could not conclude that adverse health effects were associated with current levels of fluoride intake resulting from ingestion of drinking water with a maximum contaminant

level for fluoride at 4 mg/liter (as set by the U.S. Environmental Protection Agency) and of other sources of fluoride, such as toothpaste, mouth rinses, dietary fluoride supplements, and foods prepared with fluoridated water (Ref. 6). Therefore, FDA rejects the argument that the ingestion of low levels of fluoride is associated with adverse health effects and toxicities.

FDA wishes to clarify that the proposed RDI for fluoride was not intended to be a target level for supplementation. The agency stated in the July 1990 proposal that the proposed RDI for fluoride was to be used only in conjunction with a declaration of the level of fluoride that is naturally present in a food or that results from the use of a fluoridated water supply in the processing operation (55 FR 29476 at 29482). This issue was addressed again in the RDI/DRV final rule (58 FR 2206 at 2215).

FDA is persuaded, however, that an RDI should not be established for fluoride because fluoride does not meet the first criterion discussed previously for determining which nutrients should be considered for RDI's, namely, that there is scientific consensus as to the essentiality of the nutrient. Fluoride is a unique nutrient in that an ESADDI for it was included in the 10th edition of ''Recommended Dietary Allowances,'' yet in the text of that publication, the NAS states that the contradictory results of published studies ''do not justify a classification of fluorine as an essential element, according to accepted standards'' despite the fact that it is considered a beneficial element for humans because of its valuable effects on dental health (Ref. 3, p. 235). In proposing an RDI for fluoride, the agency mistakenly proposed an RDI for each nutrient listed in the NAS' RDA and ESADDI tables. The agency failed to focus on the fact that, unlike the other nutrients listed, the supporting text did not conclude that fluoride is an essential nutrient.

In addition, FDA is persuaded by the comments that establishing an RDI for fluoride would have limited usefulness in assisting consumers to understand the nutritional significance of the amount of fluoride in a serving of food in comparison to the total amount consumed per day because the primary sources of fluoride (i.e., community fluoridated water supplies, toothpastes, mouth rinses, and fluoride supplements) will not bear nutrition labeling. Approximately 132 million Americans receive drinking water that contains either naturally occurring or added fluoride (Refs. 5 and 6). This water supply contributes significantly to the total daily dietary intake of fluoride. Additionally, fluoride supplements that may contribute significantly to the total daily dietary intake of fluoride of persons consuming them are regulated as drugs because of their intended use (to prevent disease) and, therefore are not subject to the food labeling regulations. Consequently, because the primary sources of dietary fluoride are beyond the purview of nutrition labeling regulations, the agency concludes that the declaration of percent DV of fluoride within nutrition labeling on a limited number of foods that are relatively minor sources of the nutrient will be of little use in assisting consumers in maintaining healthy dietary practices.

Accordingly, because there is no consensus on the essentiality of fluoride, and because declaration of a percent DV for this nutrient would be of little value to consumers, the agency is removing fluoride from the RDI list in § 101.9(c)(8)(iv). Consistent with this action, FDA is not including a reference to fluoride in § 101.3(e)(4)(ii) (21 CFR 101.3(e)(4)(ii)) and is removing a reference to it in § 101.36 (b)(3), (b)(3)(i), (b)(3)(ii), (b)(4), and (b)(4)(vi) (21 CFR 101.36(b)(3),(b)(3)(i), (b)(3)(ii), (b)(4), and (b)(4)(vi)).

B. Selenium and Chromium

6. Several form letters from consumers encouraged FDA to establish RDI's for selenium and chromium that are higher than the proposed levels because the proposed levels did not take prevention into account. A few comments cited therapeutic benefits of high doses of selenium and chromium.

The agency is not persuaded to establish higher RDI's for selenium and chromium. As discussed in comment 3 of section III.B. of this document, the NAS is considering expanding the RDA concept to include reducing the risk of disease. If that occurs, the recommended levels of some nutrients can be expected to rise. As stated previously, FDA intends to work cooperatively with the NAS in its deliberations and to propose to implement recommendations resulting from that process.

7. One comment recommended that consumers be cautioned against ingesting levels of selenium in excess of the RDI to prevent potential toxicity because the toxic level may only be a few times greater than the average daily intake.

FDA does not agree with this comment. The 10th edition of the RDA states that national food composition data in the United States indicate that the adult mean dietary intake of selenium was 108 µg per day between 1974 and 1982 (Ref. 3). Toxicities have not been seen in persons who ingested less than 1 mg per day and generally much more (Ref. 3). Such levels are many times the RDI being established for selenium at 70 µg. However, even if the agency were persuaded of the need to consider a label warning statement about selenium, it would be outside the scope of this rulemaking.

C. Chloride

8. One comment noted that the RDI for every nutrient should be based on the most current scientific information available and should rely on the 10th edition of ''Recommended Dietary Allowances.'' The comment stated that the ESADDI for chloride (as well as for sodium and potassium) was eliminated from the 10th edition because it was difficult to justify. The comment contended that if FDA were to use the ESADDI for chloride as the basis for an RDI, it would be disregarding the best judgment of the scientific experts who establish the RDA's. Furthermore, the comment stated that it would be unscientific to establish an RDI for chloride in the absence of either an RDA or an ESADDI. All other comments addressing this issue supported the proposed RDI for chloride.

The agency is not persuaded that it is unscientific to establish an RDI for chloride. There is a clear consensus that chloride meets the first criterion discussed previously for determining which nutrients should be considered for RDI's, that is, that it be essential. As stated by the NAS, ''the principal electrolytes (sodium, potassium, and chloride) * * * are essential dietary components, in that they must be acquired from the diet * * *'' (Ref. 3, p. 247).

In regard to the second criterion (i.e., that there is scientific agreement concerning the level at which the nutrient should be consumed), in the case of chloride and the other electrolytes, there is scientific agreement concerning the estimated minimum required level for consumption (Ref. 3, table 11–1). While these levels are given in a separate table from the RDA and ESADDI levels in the 10th edition of the ''Recommended Dietary Allowances,'' there is nonetheless scientific consensus in support of them.

Since the estimated minimum required levels for these nutrients were based on estimates of only what is needed for growth and replacement of obligatory losses (Ref. 3), and other RDI values represent higher levels that are ''adequate to meet known nutrient

needs of practically all healthy persons,'' FDA looked to the 9th edition of ''Recommended Dietary Allowances'' (Ref. 2), which provided ESADDI values for chloride, in arriving at the value that the agency first proposed as the RDI for chloride for adults and children 4 or more years of age (i.e., 3,150 mg) (55 FR 29476 at 29482). In the RDI/DRV final rule, FDA stated that, using the ''population coverage approach,'' this value would raise to 3,400 mg. This value, which the agency is adopting as the RDI for chloride, is 4.5 times the highest estimated minimum required level of 750 mg specified in the 10th edition of ''Recommended Dietary Allowances'' (Ref. 3, table 11–1). This value is proportional to the DRV for sodium, 2,400 mg, which is 4.8 times its highest estimated minimum required level of 500 mg (Ref. 3, table 11–1). Because dietary chloride comes almost entirely from sodium chloride, and because chloride loss tends to parallel losses of sodium (Ref. 3, p. 258), it is logical that the RDI's for both of these nutrients be in roughly the same proportion to their respective estimated minimum required levels.

Potassium has a Daily Reference Value (DRV) of 3,500 mg which is 1.75 times its highest estimated minimum value. The agency points out that it is not necessary that the label reference value for potassium be in the same proportion to the estimated minimum required levels for sodium or chloride because neither the intake nor obligatory losses for potassium are in direct proportion to those of sodium and chloride (Ref. 3, p. 256).

V. Determination of Nutritional Inferiority of Substitute Foods

The RDI/DRV final rule discussed the effect of the label reference values on alternative products (e.g., reduced fat foods, reduced sodium foods) formulated to achieve nutritional equivalency with their traditional counterparts in accordance with § 101.3(e)(4). The agency acknowledged that an increase in the number of nutrients for which RDI's are established would mean that efforts to obtain nutritional equivalency may require the addition of additional nutrients to some substitute foods (58 FR 2206 at 2225).

In recognition of this fact and because there are no listed sources for selenium, fluoride, chromium, and molybdenum that can be used to add these nutrients to foods (i.e., FDA has not authorized the use of any food additives or listed any substances as generally recognized as safe (GRAS) that are sources of supplementation of these four nutrients), the agency proposed in § 101.3(e)(4)(ii) in the January 1994 proposal that these nutrients need not be considered in determining nutritional inferiority (59 FR 427).

9. One comment agreed with the agency's position on determinations of nutritional inferiority. A few comments from the food industry supported the proposal that selenium, fluoride, chromium, and molybdenum not be considered in determining nutritional inferiority of an substitute product. These comments expressed concern, however, that the proposed inclusion of vitamin K in determinations of nutritional inferiority will lead to the unnecessary fortification of existing substitute foods and be a serious disincentive for manufacturers to continue to develop and market ''healthier'' products. The comments suggested that FDA include vitamin K among the nutrients that need not be considered in determining nutritional inferiority.

The comments cited several factors in support of their suggestion, including the lack of practical analytical methodology for determining levels of vitamin K in food, the need to analyze current substitute food products for vitamin K, the lack of a data base on vitamin K content of foods, and the fact that there are a variety of technical issues (e.g., compatibility with the product, ability to achieve uniform distribution, stability during processing and storage, and flavor maintenance) that would need to be resolved with respect to this nutrient. The comments also stated that food manufacturers would be required to seek appropriate ingredient sources for vitamin K, determine product formulations and performance characteristics with the new ingredients, and change product labels if the nutrient is added to the modified products. A couple of comments requested guidance regarding analytical methods for vitamin K. One comment stated that current intakes of vitamin K appear to be adequate based on estimated intakes and that vitamin K is synthesized by intestinal microflora.

FDA has carefully reviewed the comments but has concluded that vitamin K should be considered in determining whether substitute foods are nutritionally inferior to the foods for which they substitute. The authority for the provisions of § 101.3 on substitute foods is section 403(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(c)). When this section of the act was adopted in 1938, Congress was seeking to protect the consumer from the uninformed purchase of an inferior substitute product that could be mistaken for a traditional food product (38 FR 2138, January 19, 1973). In 1973, in proposed regulations pertaining to ''imitation foods,'' the agency noted that vast strides in food technology had taken place since section 403(c) of the act was enacted, and that since 1938 many new wholesome and nutritious food products had entered the marketplace, some of which resembled and substituted for traditional foods (38 FR 2138). The agency stated that it was no longer the case that such products were necessarily substandard compared to the traditional foods for which they were substituted. However, FDA still believed that the consumer must be protected from unwittingly purchasing a product that is different from what he or she may reasonably expect (38 FR 2138). FDA continues to believe that, as substitute products proliferate, it is important to ensure that these products contain essential nutrients in amounts consistent with the reference food, so that consumers can continue to have confidence that a varied diet will supply adequate nutrition. For this reason the agency disagrees that the consideration of vitamin K in determining the status of substitute foods is unnecessary.

Moreover, the agency disagrees that adequacy of intake is a sufficient reason to make the addition of vitamin K optional in substitute foods. Contrary to the comments, a recent analysis of data from FDA's Total Diet Study indicates that 25 to 30 year old women and men are consuming less than the current RDA for vitamin K (Ref. 10). Although it is widely assumed that the daily vitamin K requirement is met by bacterial synthesis of vitamin K in the form of menaquinones, the relative contribution of this form of vitamin K remains uncertain (Ref. 9), and recent studies underscore the importance of the dietary intake of vitamin K (Refs. 7, 8, and 9). However, adequacy of intake of a nutrient is not the issue in deciding whether the nutrient should be considered in determining nutritional inferiority. The agency's consistent view has been that, as stated previously, if a nutrient is essential, it should be considered in such determinations unless there are factors that demonstrate that it is inappropriate to do so.

No evidence was submitted in the comments to support the argument that the addition of this nutrient to alternative products will be a disincentive for the development and marketing of substitute foods, nor were any examples presented that demonstrated that the fortification of an appropriate food with vitamin K would be impossible. FDA appreciates that manufacturers may need to reformulate

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

persuaded that it is contradictory to encourage a reduction in sodium intake and yet to require that chloride be considered in determining nutritional inferiority. When salt is removed from a product, chloride follows.

Therefore, FDA concludes that it is reasonable to delete the requirement for inclusion of chloride in the determination of nutritional inferiority. The agency points out, however, that chloride must be included in total replacement formulas, medical foods, and infant formula, as needed, to ensure that there are adequate levels of this essential nutrient in the diet of persons consuming a limited variety of foods.

Accordingly, the agency is retaining the requirement in § 101.3(e)(4)(ii) that manganese, but not chloride, be included in determinations of nutritional inferiority in substitute foods.

VI. Age/Sex Groupings

In the January 1994 proposal, FDA pointed out that in following the provisions of the DS act and retaining the label reference values in § 101.9(c)(7)(iv)(1992), the agency did not adopt label reference values for use on foods that are represented or purported to be for use by infants, children under 4 years of age, or pregnant or lactating women (59 FR 427 at 429). Given the continuing questions about how to arrive at such values, FDA deferred action on this issue. The agency stated that it intended to address the issue of RDI's for the various age groups in a future rulemaking (59 FR 427 at 430). It also stated that, until such rulemaking is completed, labels of dietary supplements of vitamins or minerals that are intended for these specific groups and that are regulated under § 101.36 may continue to specify the mg or µg amounts of vitamin K, selenium, manganese, chromium, molybdenum, and chloride with an asterisk in the percent DV column (59 FR 427 at 430). The asterisk would refer to a footnote stating ''Daily Value not established.'' However, because quantitative amounts are not listed for vitamins and minerals on labels of conventional foods, only the percent DV, FDA noted that the subject nutrients may not be declared on labels of foods in conventional food form that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women until such time as RDI's are established for such groups. The agency requested comment on how to list the subject nutrients on the labels of conventional foods that are represented or purport to be for use by infants, children under 4, and pregnant and lactating women (59 FR 427 at 430).

11. A couple of comments that supported establishing RDI's for the seven subject nutrients suggested that the agency establish RDI's for infants, children under 4 years of age, and pregnant or lactating women by using the same quantitative reasoning that it used to determine RDI's for children age 4 and above.

FDA advises that it intends to propose to establish RDI's for infants, children less than 4 years, and pregnant and lactating women in the near future. In that proposal, the agency intends to address all nutrients for which RDI's have been established for adults and children 4 or more years of age.

12. One manufacturer of dietary supplement products suggested that consumers of conventional foods represented for or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women would be best served by allowing quantitative information (i.e., mg or µg amounts) of vitamin K, selenium, manganese, chromium, molybdenum, and chloride to be listed in nutrition labeling of such products, with an accompanying asterisk and footnote that a DV has not been established, until such time as RDI's are established for those groups. The comment stated that while this information might not be all that meaningful to the average consumer, there are a significant number of sophisticated people who could put this information to good use in making intelligent food choices.

FDA has considered the suggested change and finds that while there may be merit to it, it would necessitate major changes in the nutrition label of such products that were not foreshadowed in the proposed rule. The agency had discussed simply the use of asterisks with the footnote stating that a DV had not been established (59 FR 427 at 430), but the agency received no support in the comments for that modification. In accordance with the Administrative Procedures Act, it would be necessary to propose a change in § 101.9 to allow quantitative amounts by weight of vitamin K, selenium, manganese, chromium, molybdenum, and chloride to be declared in nutrition labeling of conventional foods represented or purported for use by infants, children under 4, and pregnant or lactating women in advance of the establishment of RDI's for those groups. Given that the agency intends to propose to establish RDI's for the additional groups, that action can be accomplished as expeditiously as the one suggested by this comment, thereby negating the need for such additional rulemaking.

VII. Conforming Amendments

A. Section 101.3(e)(4)

As a result of questions that FDA received since the publication of the January 6, 1993 final rules, the agency has come to recognize that it inadvertently deleted the term ''per average or usual serving'' from § 101.3(e)(4)(ii) when it amended that paragraph as a part of the RDI/DRV final rule (58 FR 2206). Section 101.3(e)(4)(ii) defines a measurable amount of an essential nutrient in a food for the purposes of determining nutritional inferiority. FDA is correcting that error in this final rule.

However, to make this paragraph consistent with other regulations that FDA issued in implementing the 1990 amendments (e.g., serving size and nutrient content claim regulations in 21 CFR 101.12 and 101.13, respectively), the term ''per reference amount customarily consumed'' should be used instead of ''per average or usual serving'' to ensure that the comparison of products reflects the true characteristics of the product, not the container size. This concept underlies FDA's consideration of claims characterizing the levels of nutrients in foods (58 FR 2302 at 2314). FDA is not replacing the accompanying term ''per average or usual portion'' because FDA concluded in the final rule on serving size that the term ''portion'' is considered to be interchangeable with ''serving'' size and, therefore, deleted that term from the regulations (58 FR 2229 at 2232).

Accordingly, § 101.3(e)(4)(ii) is corrected to read as follows:

> For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under § 101.9(c)(7)(iii) per reference amount customarily consumed and of potassium listed under § 101.9(c)(9) per reference amount customarily consumed and 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv) per reference amount customarily consumed except that selenium, molybdenum, chromium, and chloride need not be considered.

B. Section 101.36

As noted in the proposed rule (59 FR 427 at 430), the amendments to the nutrition labeling regulations that FDA is making in this final rule necessitate that FDA revise §§ 101.36 (b)(3), (b)(4), and (b)(4)(vi).

Current § 101.36(b)(3) states that all nutrients in § 101.9(c) that are present in

a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in § 101.9(c) must be declared in nutrition labeling. This section goes on to state that those nutrients that are not present, or that are present in amounts that would be declared as zero, shall not be declared. The section states, in addition, that potassium, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, and selenium shall be declared, except when present in quantitative amounts by weight that allow a declaration of zero.

FDA is modifying § 101.36(b)(3) by removing all reference to vitamin K, chloride, chromium, manganese, molybdenum, and selenium. Because these nutrients are now included in § 101.9(c)(8)(iv), they can be listed in nutrition labeling without the need for a specific provision that authorizes such listing. As discussed under comment 5 of section IV.A of this document, the agency is also modifying this section to remove all references to fluoride to reflect the agency's decision not to establish an RDI for this nutrient.

Current § 101.36(b)(4) states that the nutrition label shall contain a listing of the percent of the DV (i.e., the percent of the RDI as established in § 101.9(c)(8)(iv) or DRV as established in § 101.9(c)(9)), where appropriate, of all nutrients listed in the nutrition label, except that the percent DV for protein may be omitted as provided in § 101.9(c)(7), and that no percent shall be given for sugars, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, selenium.

FDA is modifying § 101.36(b)(4) by limiting the exception that no percent DV shall be given for vitamin K, selenium, manganese, chromium, molybdenum, and chloride to only products represented or purported for use by infants, children less than 4 years of age, and pregnant or lactating women. Because RDI's are now established for these nutrients for adults and children 4 or more years of age, the percent DV of these nutrients can be calculated on products represented or purported for use by that group. Because FDA is not adopting an RDI for fluoride, revised § 101.36(b)(4) does not reference this nutrient.

Current § 101.36(b)(4)(vi) states that when no percent DV is given for sugars, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, or selenium, an asterisk shall be placed in the ''% Daily Value'' column that shall refer to another asterisk that is placed at the bottom of the nutrition label that is followed by the statement ''Daily Value not established.'' FDA is modifying this regulation to state that when no percent is given for sugars, or, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, when no percent is given for vitamin K, selenium, manganese, chromium, molybdenum, or chloride, an asterisk shall be placed in the ''Percent Daily Value'' column that shall refer to another asterisk that is placed at the bottom of the nutrition label and followed by the statement ''Daily Value not established.'' This action is needed until the rulemaking (discussed in comment 11 of section VI of this document) to establish RDI's for infants, children less than 4 years of age, and pregnant or lactating women is complete. While there are no RDI's codified for these groups for any nutrients, in its June 18, 1993, proposal pertaining to nutrition labeling of dietary supplements (58 FR 33715 at 33721), FDA encouraged manufacturers of products represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women to use label reference values for these groups given in the preamble of the RDI/DRV final rule on January 6, 1993 (58 FR 2206 at 2213). Since the table of label reference values at the bottom of page 2213 in that document addresses only the vitamins and minerals in current § 101.9(c)(8)(iv), there are no values for vitamin K, selenium, manganese, chromium, molybdenum, or chloride that can be used to calculate the percent DV of these nutrients on labels of products represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women at this time.

Again, because FDA is not adopting an RDI for fluoride, revised § 101.36(b)(4)(vi) does not reference that nutrient.

It should be noted that, while these conforming amendments to § 101.36 modify that current regulation, they will be superseded by any final regulations resulting from the proposed rule published in a companion document in this issue of the Federal Register entitled ''Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements.''

VIII. Other Provisions

FDA did not receive any comments that dealt with, or objected to, the other provisions of the proposal (e.g., units of measure for calcium, phosphorus, biotin, and folate and the conforming amendments). In the absence of any basis for doing otherwise, FDA is adopting those provisions as proposed.

IX. Effective Date

13. Several comments suggested that FDA reevaluate the effective date discussed in the proposed rule. These comments suggested a longer effective date because the proposed inclusion of vitamin K, chloride, and manganese in nutritional equivalency determinations would require that the composition of virtually all existing substitute foods be reevaluated. One comment suggested a 3-year extension of the effective date because food manufacturers are just completing a massive relabeling effort of all packaged foods in the marketplace. One comment from a printing company stated that it would have to change 2,600 labels very shortly if the effective date was adopted as proposed. The comment noted that new labels for dietary supplements will use an asterisk referring to the statement ''No Daily Value established'' for the subject nutrients. The comment stated that if the final rule did not issue by June 1994, the company would not be able to implement the new RDI values with the label changes it was making in response to the 1990 amendments. The comment requested that the final rule issue by June 1994 or establish an effective date after July 1996. Another comment suggested that establishing the effective date after July 1996 would reduce the impact of making two label changes to the same label. The comment noted that it is impossible for producers to undertake analysis, reformulation and relabeling of all the alternative products affected by this proposal within the 30 days allowed between publication of the final rule and the effective date.

One comment requested that the final rule on RDI's become effective 30 days after its publication with the clarification that the values may be used at that time but are not mandatory on the labels of food or dietary supplements until at least July 1, 1996, 1 year from the implementation deadline for the food labeling regulations for dietary supplements.

FDA points out that it published a notice on February 9, 1995 (60 FR 7711), indicating it will not enforce its regulations on nutrition labeling and nutrient content claims for dietary supplements until after December 31, 1996. Therefore, the July 1, 1995, date is not longer determinative. This delay allows FDA time to modify its regulations to respond to the DSHEA.

The agency is persuaded by the comments that it is necessary to reconsider the amount of time that it

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

environment. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

XII. Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Food and Nutrition Board, Division of Biology and Agriculture, National Research Council, ''Recommended Dietary Allowances,'' 7th ed., publication 1694, Printing and Publishing Office, NAS, Washington, DC, 1968.

2. Committee on Dietary Allowances, Food and Nutrition Board, Commission on Life Sciences, National Research Council, ''Recommended Dietary Allowances,'' 9th revised ed., Washington, DC, National Academy Press, 1980.

3. Subcommittee on the 10th Edition of the RDA's, Food and Nutrition Board, Commission on Life Sciences, National Research Council, ''Recommended Dietary Allowances,'' 10th revised ed., Washington, DC, National Academy Press, 1989.

4. Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, ''How Should the Recommended Dietary Allowances Be Revised,'' Washington, DC, National Academy Press, 1994.

5. Ad Hoc Subcommittee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs, Public Health Service, Department of Health and Human Services, ''Review of Fluoride Benefits and Risks,'' 1991.

6. Subcommittee on Health Effects of Ingested Fluoride, Committee on Toxicology, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, National Academy Press, ''Health Effects of Ingested Fluoride,'' Washington, DC, 1993.

7. Suttie, J. W., ''Vitamin K and Human Nutrition,'' *Journal of the American Dietetic Association*, 92585–92590, 1992.

8. Suttie, J. W., L. L. Mummah- Schendel, D. V. Shah, B. J. Lyle, J. L. Greger, ''Vitamin K Deficiency from Dietary Vitamin K Restriction in Humans,'' American *Journal of Clinical Nutrition*, 47475–47480, 1988.

9. Ferland, G., J. A. Sadowski, M. O'Brien, ''Dietary Induced Subclinical Vitamin K Deficiency in Normal Human Subjects,'' *Journal of Agricultural and Food Chemistry*, 911761–911768, 1993.

10. Booth, S. L., J. A. T. Pennington, J. A. Sadowski, ''Food Sources and Dietary Intakes of Phylloquinone,'' unpublished manuscript.

11. United States Department of Agriculture, Human Nutrition Information Service, Nutrient Data Research Branch, Nutrition Monitoring Division, ''Provisional Table on the Vitamin K Content of Foods,'' revised June 1990.

12. Booth, S. L., J. A. Sadowski, J. L. Weirauch, G. Ferland, ''Vitamin K_1 (Phylloquinone) Content of Foods A Provisional Table,'' *Journal of Food Composition and Analysis*, 6:109–120, 1993.

13. Pennington, J. A. T., ''Bowes & Church, Food Values of Portions Commonly Used, Sixteenth Edition.'' J. B. Lippincott Co., p. 421, 1994.

14. Tanner, J. T., S. A. Barnett, and M. K. Mountford, ''Analysis of Milk-Based Infant Formula. Phase IV. Iodide, Linoleic Acid, and Vitamins D and K: U.S. Food and Drug Administration-Infant Formula Council Collaborative Study,'' *Journal of the Association of Official Analytical Chemists International*, 76:1042–1056, 1993.

15. Bueno, P. M., and M. C. Villabobos, Reverse Phase High Pressure Liquid Chromatographic Determination of Vitamin K_1 in Infant Formulas, *Journal of the Association of Official Analytical Chemists*, 66:1063–1066, 1983.

16. Booth S. L., K. W. Davidson, J. A. Sadowski, ''Evaluation of an HPLC Method for the Determination of Phylloquinone (Vitamin K_1) in Various Food Matrices,'' *Journal of Agricultural and Food Chemistry*, 42:295–300, 1994.

17. Haroon, Y., M. J. Shearer, S. Rahim, W. G. Gunn, G. McEnergy, P. Barkhan, ''The Content of Phylloquinone (Vitamin K_1) in Human Milk, Cow's Milk and Infant Formula Foods Determined by High-Performance Liquid Chromatography'', *Journal of Nutrition* 112:1105–1117, 1982.

18. Ferland, G., J. A. Sadowski, ''Vitamin K_1 (Phylloquinone) Content of Green Vegetables Effects of Plant Maturation and Geographical Growth Location,'' *Journal of Agricultural and Food Chemistry*, 40:1874–1877, 1992.

19. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Nutrition and Your Health, Dietary Guidelines for Americans,'' Washington, DC, *Home and Garden Bulletin*, No. 232, U.S. Government Printing Office, 1990.

20. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Nutrition and Your Health, Dietary Guidelines for Americans,'' Washington, DC, *Home and Garden Bulletin*, No. 232, Second Edition, U.S. Government Printing Office, 1985.

21. U.S. Department of Health and Human Services, Public Health Service, ''The Surgeon General's Report on Nutrition and Health,'' Washington, DC, DHHS (PHS) Publication No. 88–50210, U.S. Government Printing Office, p. 13, 1988.

22. Bush, Laina M., memorandum of telephone conversation with Wayne Ellefson, Hazelton Laboratories, April 23, 1995.

23. Bush, Laina M., memorandum of telephone conversation with John McKay, Lancaster Laboratories, January 11, 1995.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.3 is amended by revising paragraph (e)(4)(ii) to read as follows:

§ 101.3 Identity labeling of food in packaged form.

* * * * *

(e) * * *

(4) * * *

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under § 101.9(c)(7)(iii) and of potassium listed under § 101.9(c)(9) per reference amount customarily consumed and 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv) per reference amount customarily consumed, except that selenium, molybdenum, chromium, and chloride need not be considered.

* * * * *

3. Section 101.9 is amended by revising paragraph (c)(8)(iv) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(8) * * *

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units
Vitamin C, 60 milligrams
Calcium, 1,000 milligrams
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Vitamin K, 80 micrograms
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams
Vitamin B_6, 2.0 milligrams
Folate, 400 micrograms
Vitamin B_{12}, 6 micrograms
Biotin, 300 micrograms
Pantothenic acid, 10 milligrams
Phosphorus, 1,000 milligrams
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams

Selenium, 70 micrograms
Copper, 2.0 milligrams
Manganese, 2.0 milligrams
Chromium, 120 micrograms
Molybdenum, 75 micrograms
Chloride, 3,400 milligrams
* * * * *

4. Section 101.36 is amended by revising the introductory text of paragraph (b)(3), paragraphs (b)(3)(i), (b)(3)(ii), the introductory text of paragraph (b)(4), and paragraphs (b)(4)(vi) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements of vitamins or minerals.

* * * * *

(b) * * *

(3) A listing of all nutrients required in § 101.9(c) that are present in the dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in § 101.9(c). Those nutrients that are not present, or present in amounts that would be declared as zero, shall not be declared. In addition, potassium shall be declared except when present in quantitative amounts by weight that allow a declaration of zero. The name of each nutrient listed shall be immediately followed by the quantitative amount by weight of the nutrient. Nutrient names and quantitative amounts shall be presented in a column under the heading ''Amount Per Serving'' and aligned on the left side of the nutrition label. The heading ''Amount Per Serving'' shall be separated from other information on the label by a bar above and beneath it, except that when calories are listed, the bar shall be placed beneath the calorie declaration. When the serving size of the product is one unit (e.g., 1 tablet), a heading consistent with the declaration of serving size, such as ''Amount per Tablet'' or ''Each Tablet Contains,'' may be used in place of the heading ''Amount per Serving.'' Other appropriate terms, such as capsule, packet, or teaspoonful, may be used in place of the term ''Serving.''

(i) These amounts shall be expressed in the increments specified in § 101.9(c), except that the amounts of vitamins and minerals, excluding sodium and potassium, declared on the nutrition label shall be the actual amount of the vitamin or mineral included in the dietary supplement, using the units of measure and the levels of significance given in § 101.9(c). In declaring the amounts of vitamins and minerals, zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for copper is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram). Amounts for chloride and manganese shall be expressed in mg, and, amounts for chromium, molybdenum, selenium, and vitamin K shall be expressed in micrograms. These values shall be expressed in whole numbers.

(ii) Nutrients that are present shall be listed in the order specified in § 101.9(c); except that, when present, vitamin K shall follow vitamin E; calcium and iron shall follow pantothenic acid; selenium shall follow zinc; and manganese, chromium, molybdenum, chloride, sodium, and potassium shall follow copper. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium. A bar shall separate the last nutrient to be listed from the bottom of the nutrition label, as shown in the sample labels in paragraph (c)(9) of this section.

* * * * *

(4) A listing of the percent of the Daily Value (i.e., the percent of the RDI as established in § 101.9(c)(8)(iv) or DRV as established in § 101.9(c)(9)), where appropriate, of all nutrients listed in the nutrition label, except that the percent for protein may be omitted as provided in § 101.9(c)(7), no percent shall be given for sugars, and for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for vitamin K, selenium, manganese, chromium, molybdenum, or chloride. This information shall be presented in one column aligned under the heading of ''% Daily Value'' and to the right of the column of nutrient names and amounts. The headings ''% Daily Value (DV),'' ''% DV,'' ''Percent Daily Value,'' or ''Percent DV'' may be substituted for ''% Daily Value.'' The heading ''% Daily Value'' shall be placed on the same line as the heading ''Amount per Serving'' or placed beneath this heading and the bar underneath it, except that ''% Daily Value'' shall be placed beneath this bar when calorie information is required to be declared. Calorie information shall be placed beneath ''Amount Per Serving'' and above the bar.

* * * * *

(vi) When no percent is given for sugars, or for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, when no percent is given for vitamin K, selenium, manganese, chromium, molybdenum, or chloride, an asterisk shall be placed in the ''Percent Daily Value'' column that shall refer to another asterisk that is placed at the bottom of the nutrition label and followed by the statement ''Daily Value not established.''

* * * * *

Dated: September 26, 1995.

William B. Schultz

Deputy Commissioner for Policy.

[FR Doc. 95–31197 Filed 12–27–95; 8:45 am]

BILLING CODE 4160–01–P