

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration
21 CFR Parts 101 and 104
[Docket No. 90N-0134]**

RIN 0905-AD08

Food Labeling; Reference Daily Intakes and Daily Reference Values

AGENCY: Food and Drug Administration, HHS.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish two sets of label reference values, Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's), for use in declaring the nutrient content of a food on its label or labeling. FDA intends to use these two sets of values as a single set of label reference values known as the Daily Value, which will assist consumers in understanding the relative significance of the information about the amount of certain nutrients in a food in the context of a total daily diet. It will also assist consumers in comparing the nutritional values of food products.

EFFECTIVE DATE: May 8, 1994.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29476), FDA published a proposed rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (the July 1990 proposal) to amend its food labeling regulations by revising and expanding label reference values for nutrients in foods. In the **Federal Register** of November 27, 1991 (56 FR 60366, and corrected at 57 FR 8178, March 6, 1992), FDA issued a document entitled: "Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter referred to as the "supplementary proposal") to supplement and to republish, in modified form, the July 1990 proposal. The agency proposed to: (1) Replace the current label reference values known as "U.S. Recommended Daily Allowances" (U.S. RDA's) with RDI's; (2) provide RDI's for five groups adults and children 4 or more years of age, children less than 4 years of age,

infants, pregnant women, and lactating women; (3) establish RDI's for protein and 26 vitamins and minerals for all five groups; and (4) establish DRV's for adults and children 4 or more years of age for eight nutrients and food components considered important to the maintenance of good health. FDA requested comments on the proposed regulation. Interested persons were given until February 25, 1992, to comment.

FDA received approximately 800 responses to the July 1990 proposal and approximately 700 responses to the supplementary proposal, each of which contained one or more comments, from trade and retail associations, government organizations, retailers, consumer groups, State groups, private organizations, professional societies, and universities. Many comments suggested modification and revision of various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (hereinafter referred to as the "DS Act") that, in section 203, instructed FDA to not promulgate regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993, (other than regulations establishing the United States recommended daily allowances specified in 21 CFR 101.9(c)(7)(iv) as in effect on October 6, 1992).

II. Authority for New Label Reference Values .

A. RDI's: Revision of U.S. RDA's

1. Several comments suggested that the change from the current label reference values, the U.S. RDA's, to the proposed new label reference values, the RDI's, was not mandated by the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments), and that retaining the U.S. RDA's is not inconsistent with the amendments.

FDA agrees that the 1990 amendments do not require that the U.S. RDA's be changed. The agency points out, however, that section (2)(b)(1)(A) of the 1990 amendments (21 U.S.C. 343 note) does require that the required nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. Such information should be consistent with current scientific knowledge about nutrients and health.

Over the last 20 years, there have been significant advances in scientific knowledge with respect to essential nutrient requirements. In 1989, the National Academy of Sciences (NAS) updated the Recommended Dietary Allowances (RDA's)—the basis for label reference values derived by the agency—to include for the first time RDA values for vitamin K and selenium and to make significant revisions in the allowances for several nutrients, including vitamin B6, folate (folic acid), vitamin B12, magnesium, iron, and zinc. In addition, scientific advances permitted NAS to substantively revise values for the listing known as "Estimated Safe and Adequate Daily Dietary Intakes" (ESADDI's). The ESADDI's published in 1989 include revised values for three nutrients (biotin, pantothenic acid, and copper) for which FDA established U.S. RDA's in 1973 as well as new values for manganese, fluoride, chromium, and molybdenum.

Based on these considerable changes in scientific knowledge, FDA tentatively determined that it was appropriate to revise the current U.S. RDA's to be more consistent with newer data on nutrient allowances. FDA attempted in this food labeling initiative to base its actions on the most current scientific and public health knowledge. Continuing to base label reference values on a 1968 standard would be inconsistent with such an approach and would not appropriately assist consumers in understanding the nutrition label information relative to a total daily diet. However, based on the provisions of the DS Act, the agency is, in this rulemaking, retaining the current label reference values, the U.S. RDA's as established in 21 CFR 101.9(c)(7)(iv). As discussed in section III below, the terminology used to designate label reference values for vitamins and minerals is being changed however.

The label reference values in current § 101.9(c)(7)(iv) will be referred to, in this document and in companion documents published elsewhere in this issue of the **Federal Register**, as "Reference Daily Intakes" (RDI's). As specified by the DS Act, the agency will promulgate final regulations on label reference values for vitamins and minerals after November 8, 1993. The agency will consider any further information submitted or obtained in the interim in reaching a decision on the form and substance of such final regulations.

B. DRV's: New Label Reference Values for Nutrients of Public Health Concern

2. A few comments suggested that establishing DRV's was beyond the authority granted by the 1990 amendments.

The majority of comments supported the concept of establishing a DRV. These comments were provided by consumers, health professionals, and trade representatives. Several comments specifically highlighted the DRV's as an invaluable addition to nutrition labeling, as a labeling component that is important to the idea of the relative contribution of a food to the total day's recommended amount of a nutrient, and as a way to decrease confusion among consumers.

FDA disagrees that the establishment of DRV's is inconsistent with the 1990 amendments. The agency proposed this new set of label reference values in 1990 in an attempt to address current concerns about information on food components that have an important bearing on diet and health. With the passage of the 1990 amendments, the agency also recognized that these values respond to the directive in the legislation that the information required in the nutrition label be conveyed to the public 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 (section 2(b)(1)(A) of the 1990 amendments).

FDA does not believe that merely listing the quantitative amount of nutrients such as fat and fiber on the nutrition label will adequately allow consumers to understand, the significance of the amount of the nutrient in the food in the context of the total daily diet or to understand the nutrition information pertaining to that food in relation to recommended daily intakes of the food component. FDA found in focus group discussions that it conducted as part of its research on label format that many persons could not specify the recommended intakes for nutrients such as sodium, even when they indicated that the nutrient was important to their health and were concerned about their intake of the nutrient (Ref. 29).

Moreover, contrary to the assertion in some of the comments, the use of DRV's was clearly contemplated by Congress. In discussing section 2(b)(1)(A) of the 1990 amendments, the House report states:

In order to present nutrition information in a manner that facilitates the public's understanding, the Secretary may choose among a variety of options. For example, one

way that this could be accomplished would be to include information about the recommended daily intake on the label. (Ref. 19,p.18)

Therefore, for the foregoing reasons and consistent with the majority of the comments, FDA concludes that DRV's provide an appropriate approach to accomplishing the statutory mandate and are fully consistent with the authority extended to the agency by the 1990 amendments. Significantly, consumers are becoming more aware of diet/health interrelationships and have expressed growing interest in the inclusion of information about food components on labels to help them determine how individual foods fit within general recommendations for a total daily diet. Additionally, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" (Ref. 30) proposes that there be an increase in nutrition labeling that provides information to facilitate choosing foods consistent with the Dietary Guidelines for Americans published jointly by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health, and Human Services (DHHS). The DRV's will be an important tool for this purpose.

III. RDI'S: Label Reference Values for Vitamins and Minerals

A. Terminology

3. Several comments expressed concerns about consumer confusion if the more familiar U.S. RDA term was replaced with a new term. These comments generally suggested that the term "U.S. RDA" be retained and used on the label in order to reduce consumer confusion. One comment argued that while the agency asserts that the term "U.S. RDA" is too confusing, FDA cited no evidence of this confusion.

A number of other comments supported eliminating the term "U.S. RDA." One health professional stated that even professionals fail to make the distinction between the RDA established by NAS and the U.S. RDA. A food company stated that it frequently encountered expressions of confusion from consumers and professionals alike over the difference between the U.S. RDA and the NAS RDA. An association of nutrition educators agreed that a change in terminology is needed in order to reduce consumer confusion surrounding the distinction between RDA's and U.S. RDA's. Several comments specifically supported the term "RDI" One comment stated that the use of terminology that differentiates between reference standards used for

nutrition labeling and the RDA established by NAS should be beneficial to the consumer.

In 1973, FDA created label reference values known as "U.S. RDA's" and based them on the "Recommended Dietary Allowances," 7th ed., 1968 (the NAS RDA publication) (Ref. 27). As stated in the proposal for this final rule, FDA believes that the term "U.S. RDA" can easily be confused with "RDA" and that this confusion presents difficulties both in consumer education and professional communication (55 FR 29476 at 29478). The comments received have supported the need for a change in terminology and FDA agrees that because of the potential for confusion a change in terminology is appropriate. FDA notes that in the comments submitted in response to this proposal, the agency found numerous examples of confusion and inappropriate interchange concerning the two terms.

Additionally, the agency advises that consumers will not be confused by the change from U.S. RDA to RDI because the term will not appear on the food label. The RDI's, which refer to label reference values for vitamins and minerals only, will not be used on the food label because a new more comprehensive term will be used, a term that includes label reference values for DRV'S as well as RDI's. The provision for a single term ("Daily Value") is discussed in more detail in a companion document entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter referred to as "Mandatory Nutrition Labeling final Rule"), published elsewhere in this issue of the **Federal Register**.

As discussed in this companion document, the decision to use a single term is based on the fact that the nutrition label will contain label reference values for nutrients other than those with NAS RDA's (e.g., total fat). Clearly the term "RDI" cannot be used to generally refer to all the new label reference values because it implies that all values are based on the NAS RDA. In fact, less than half of the mandatory components of the nutrition label will be nutrients with a NAS RDA. The agency also believes that it would be needlessly confusing to consumers if the two terms were used on the food label. Consumers are expected to perceive the label reference values as a single overall set of values. Therefore, to reduce consumer confusion, FDA has decided to choose a new term to denote the combined set of label reference values, a term that refers to both RDI's and DRV's.

The distinction between RDI and DRV nutrients remains necessary for regulatory purposes because the values were derived from separate sources and because these nutrients play different roles under the imitation and substitute food regulations. However, there is no need to make consumers aware of the regulatory distinction between RDI and DRV. Rather, educational efforts will focus on the overall set of label reference values.

4. Several comments suggested that FDA delay selecting terminology for the food label until consumer research can be completed.

While FDA supports and recognizes the value of consumer research, the time constraints placed on the agency by the 1990 amendments and the clear need to provide for the label terminology at the time of final rules, preclude the possibility of extensive consumer research. The terminology specified in these final rules derives from available information.

During the Fall of 1990, FDA conducted focus group research that included some discussions of terminology (Ref. 29). The sessions suggested that the term for the overall label reference value (proposed as "Daily Value") could be problematic, yet better terms for this or any other label reference values did not emerge during these sessions. The agency requested in the supplementary proposal (56 FR 60366) that persons submit available research, information, or suggestions concerning terminology. FDA has reviewed the relevant comments and they are discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. Based on these comments, as explained in the Mandatory Nutrition Labeling document, FDA has decided to use the term "Daily Value" to refer to the combined set of label reference values.

5. Two comments suggested that the proposed term "RDI" created consumer confusion by continuing to use the letters R and D in some combination, and that "RDI" was too similar to "U.S. RDA" and "RDA." Another comment suggested that to avoid confusion with the previous U.S. RDA terminology, the term "recommended" be retained and used instead of the term "reference."

FDA acknowledges that the inclusion of the letters R and D in RDI may have the potential to cause consumer confusion relative to U.S. RDA. However, because the term will not be used either on the food label or in roost consumer education programs, the agency rejects this argument as a basis to abandon a term that accurately

reflects the fact that the value it denotes represents a point of reference rather than a specific recommended intake level for individuals. Therefore, FDA has retained the term "RDI" to denote those nutrients whose label reference values have been derived from the NAS RDA's and ESADDI's.

6. One comment requested that FDA work with the European Economic Community and Codex Alimentarius to establish compatible nomenclature whenever possible.

FDA agrees with this suggestion and will, in its ongoing labeling activities, attempt to harmonize with international terminology as much as possible. However, within the time constraints of the 1990 amendments, the agency finds that it must make a unilateral decision concerning terminology.

B. Use of the 1989 NAS RDA's as the Basis for Label Reference Values

In 1973, FDA created label reference values known as U.S. RDA's and based them on the 7th edition of the NAS RDA publication (Ref. 27). At that time, comments supported the use of a single set of values derived from the NAS RDA's. In the July 1990 proposal (55 FR 29476) and again in the supplementary proposal (56 FR 60366), FDA proposed to revise the U.S. RDA's using the 1989 NAS RDA's (Ref. 26). This section responds to the comments that addressed the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals, as well as the appropriateness of using the most current NAS RDA's (i.e., the 10th edition of the NAS RDA publication (1989)), for this purpose.

7. The majority of comments on this topic, primarily from health professionals and the food industry, supported the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals. These comments also supported the desirability of updating the current label reference values (U.S. RDA's) to be consistent with the most recent edition (i.e., 1989) of the NAS RDA's. Numerous comments stated that revisions to the values were long overdue given the fact that changes had not been made by FDA since it developed the label reference values in 1973 based on the 1968 NAS RDA's. Comments urged FDA to continue to review and update label reference values as advances in scientific data lead to significant changes in the NAS RDA's. One comment requested that FDA establish an official mechanism in the final rule to provide for regular updates of label reference values.

FDA tentatively agrees with the appropriateness of continuing to rely on the NAS RDA's as the basis for label reference values. Strong and uniform support was provided for the use of NAS RDA's during the initial development of label reference values in 1972. As evidenced by the comments to the current proposal, this support remains. The agency believes that these established nutrient allowances remain the most widely accepted and respected source of information on human nutrient requirements and recommended intakes. FDA also notes that the preface to the 1989 edition of the NAS RDA's (Ref. 26) states that the RDA's reflect a concurrence of scientific opinion and will be appropriate for use by governmental and private agencies as a basis for developing nutrition programs and policies pertaining to public health. In general, the comments submitted in this rulemaking agreed with this statement. FDA therefore, has tentatively concluded that the label reference values (formerly known as U.S. RDA's, now RDI's) should be based on the 1989 NAS RDA's. However, based on the provisions of the DS Act and as discussed above, the agency is, for the time being retaining the current label reference values as established in § 101.9(c)(7)(iv) and will reach a final decision on the issue of the appropriate reference values for vitamins and minerals following the provisions of the DS Act.

8. One comment suggested that the agency's reliance on the NAS RDA values raises questions under the Administrative Procedure Act. According to this comment, the NAS RDA report has been developed under closed processes and thus the use of such reports may not be appropriate for rulemaking. Another comment submitted by a health professional on behalf of 40 other health professionals suggested that any future replacement of the labeling standard should be developed by the nutrition and public health community, through an open and scientifically sound process conducted by FDA, USDA, and other relevant Federal agencies.

FDA does not agree with the comment that use of the NAS RDA's as the basis for the RDI's is inconsistent with the requirements of the Administrative Procedure Act. The NAS RDA's were developed under a National Institutes of Health (NIH) contract and are based on nutrient intake measurements, nutrient balance studies, experimental intake studies, biochemical measurements, epidemiological observations of nutrient status, and extrapolation of data from animal experiments. Furthermore, as

part of the contract, public meetings were held which afforded opportunity for public input into the development of the NAS RDA's. Additionally, the NAS subjected the draft of the RDA publication to outside review by qualified experts.

More importantly, while the NAS RDA's served as the starting point for the RDI's, FDA developed its proposal based on its review of the NAS RDA's, its views on the relevant science, and its tentative conclusions about how to turn the NAS RDA's into RDI's. Moreover, the agency subjected its proposed approach to public comment (55 FR 29476 and 56 FR 60366). In reviewing the comments that it received, FDA was open to any evidence that values other than those derived from the NAS RDA's would provide a more appropriate starting point in developing values that will place the information required to appear on the nutrition label into the context of a total daily diet. No such evidence was submitted. Thus, FDA tentatively finds that the NAS RDA's provide a scientifically valid starting point from which to develop the RDI's. As stated above, FDA will reach a final decision on the appropriate reference values for vitamins and minerals in accordance with the DS Act.

9. One comment suggested that the NAS RDA's are of questionable value for developing RDI's because NAS RDA's are reflective of diets that people actually eat without showing signs of deficiency, rather than being based on the recommended diets that people should eat according to government authorities. Several comments suggested that the NAS RDA's are designed to avoid deficiency diseases and are not the optimal levels to prevent chronic diseases. A few comments suggested that the NAS RDA's (and resulting label reference values) are inconsistent with current dietary guidance.

As stated in the "Summary" section of the 10th edition of the NAS RDA publication (Ref. 26), the NAS RDA's are based not only on data from nutrient intake measurements but also on information from nutrient balance studies, experimental intake studies, biochemical measurements, epidemiological observations of nutrient status, and extrapolation of data from animal experiments. The NAS RDA's reflect scientific judgment on nutrient allowances for the maintenance of good health. Their purpose is not just to prevent nutrient deficiency but also to meet nutrient needs for good health (Ref. 26).

Available government reports have stressed the importance of healthy dietary patterns and increased

consumption of certain food categories and food components rather than quantitative recommendations for intake, especially for vitamins and minerals (Refs. 2, 3, and 5). FDA is not aware of any Federal government-issued quantitative recommendations for the general public for a vitamin or mineral that surpasses the levels specified by the NAS RDA's with the exception of 1,500 milligrams (mg) calcium for postmenopausal women suggested as a result of a 1984 consensus conference sponsored by NIH (Ref. 31) and, very recently, a PHS recommendation that women of childbearing age consume 400 mg/day of folate (Ref. 40). NIH republished the report of this conference in 1986 with the following caveat: "It has not yet been proven by convincing scientific evidence that a high calcium intake will prevent osteoporosis" (Ref. 31). This qualification reflected the results of studies that failed to show that calcium intakes above the NAS RDA slowed bone loss in postmenopausal women (Refs. 31 through 34).

Furthermore, the major consensus report Diet and Health (Ref. 3), which is an important summary of the current science on the relationship between diet and chronic disease, does not offer quantitative intakes for vitamins and minerals for the purpose of reducing the risk of chronic disease. Instead, it states that it is advisable to use the NAS RDA's in combination with the dietary recommendations in planning optimal diets to attain maximal benefit. This view is echoed in the 10th edition of the NAS RDA publication (Ref. 26), which states that the RDA's and the recommendations specified in Diet and Health should be considered together in planning appropriate diets.

Therefore, FDA concludes that the NAS RDA's are consistent with, as well as necessary for, implementation of current dietary recommendations. As such, NAS RDA's can be considered to be an appropriate basis for developing label reference values (i.e., RDI's) for nutrition labeling of foods.

10. Two comments stated that while it is reasonable for FDA to begin to develop new label reference values based on the most current NAS RDA's, FDA should not necessarily limit label reference values to only those values derived from the NAS RDA's because the most current NAS RDA's are derived from data available 3 or more years ago. Therefore, these comments suggested that rather than adopting the 1989 NAS RDA's as the sole basis for setting label reference values for vitamins and minerals, FDA should consider the totality of evidence for each nutrient.

Another comment suggested that FDA, as a well-qualified, scientifically-based agency, should conduct its own reviews, if for no other reason than to be sure that the latest data are encompassed in its rulemaking.

FDA is aware that it is desirable to base label reference values on the most current scientific data. However, the existence of data from recently completed or ongoing studies does not necessarily mean that there is scientific agreement or consensus that these data require changes in the NAS RDA, or that these data render the NAS RDA invalid. FDA believes that, should scientific consensus shift or compelling evidence of a need for change in the RDI's be presented to the agency, its rulemaking procedures are sufficiently flexible to allow for timely and appropriate changes to label reference values.

In this rulemaking, FDA tentatively concludes that the NAS RDA's provide an appropriate starting point for the values that it is adopting. FDA will reach a final decision in this matter in accordance with the provisions of the DS Act.

11. One comment from a consumer organization suggested that 1989 NAS RDA values for certain nutrients (vitamin D, vitamin B12, and vitamin B6.) are too low for older persons, and that this, in turn, results in label reference values that are too low. The comment urged FDA to consider basing the reference values for certain nutrients on the NAS RDA's in the 1980 edition which are higher than the 1989 NAS RDA's, and thus, according to the comment, provide greater protection to older citizens. Furthermore, two comments specifically expressed concern for the nutrition of the elderly relative to the 1989 NAS RDA's for vitamin B12 because these values are lower than the 1980 NAS RDA's. The comments suggested that FDA retain the current U.S. RDA value of 6 micrograms (μg) rather than adopting the 1989 NAS RDA's as the basis for the RDI's.

FDA does not agree that it is necessary to use the 1980 rather than the 1989 NAS RDA's for certain nutrients because of nutritional risk relative to older persons. The comment provided no specific evidence to support the statement that the 1989 values are too low for this segment of the population. FDA notes that the discussion provided in the 1989 NAS RDA publication clearly reveals that the development of the NAS RDA's took into consideration available evidence on nutrient levels needed by the elderly.

FDA further notes that the 1980 NAS RDA for vitamin D for persons 51 or more years of age is the same as the

1989 NAS RDA for vitamin D. While the 1989 NAS RDA's for vitamins B1 and B6 are lower, they are the result of a systematic lowering for all persons, not just those over 51 years of age. The 1989 NAS RDA publication cites decisions on the desirability of maintaining a substantial body pool of the vitamin as the reason for the change for vitamin B12 relative to 1980 levels, and the need to correct the figure for mg per gram (g) of protein as the basis for the change in vitamin B6. Thus, FDA finds that this comment does not provide any basis for changing the agency's approach in calculating the RDI's.

Finally, FDA does not agree that concerns for vitamin B12 nutriture among the elderly require that the agency retain the U.S. RDA value for vitamin B12 (which is based on the 1968 NAS RDA's). FDA notes that the discussion in the 1989 NAS RDA publication (Ref. 26) clearly states that the NAS RDA's are based on consideration of the available evidence on the nutrient needs of older persons. In fact, an allowance is specified for persons 51 or more years of age.

Furthermore, the discussion on vitamin B12 in the NAS RDA publication (Ref. 26) specifically addresses the issue of vitamin B12 nutriture and the elderly. The text states that the results of various surveys have shown that although serum vitamin B12 levels decline in the elderly, they tend to remain in the normal range. The evidence suggests that the decline in the serum level is the result of the gradual appearance among the elderly of vitamin B12 malabsorption. As stated in the NAS RDA report (Ref. 26), such malabsorption would require injection of vitamin B12, rather than an increase in the allowance or, by implication, the label reference value. Therefore, the agency's tentative view is that the need for an increased RDI relative to the issues of malabsorption cannot be supported.

However, based on the provisions of the DS Act, the agency is, for the time being, retaining the current label reference values as established in current § 101.9(c)(7)(iv) and will reach a final decision on this issue following the provisions of the DS Act.

C. Use of a Population-Adjusted Mean of the NAS RDA's to Derive RDI's for Vitamins and Minerals

The NAS RDA for a vitamin or mineral is established for each of approximately 18 age and sex categories. When FDA created the label reference values known as U.S. RDA's in 1973, it concluded that it was most practical to develop a single label

reference value for each nutrient for the purposes of food labeling. Generally, the agency selected the highest NAS RDA value (for persons 4 or more years of age excluding pregnant and lactating women) to serve as the U.S. RDA. In July of 1990 and again in November of 1991, FDA proposed to replace the . approach of generally selecting the highest NAS RDA value with an approach, that averages the NAS RDA values for the various age/sex categories and adjusts the average for differences in population size of the age/sex groups. This section deals with the comments that addressed the proposed change in approach used to calculate label reference values for those vitamins and minerals based on NAS RDA's.

The use of a population-adjusted average (or mean) of NAS RDA's was the major issue addressed by many commenting on the proposal. Several health-professional groups and food industry representatives supported the use of an averaged value as the label reference values for vitamins and minerals. However, the majority of comments urged FDA to abandon the averaging approach and to continue to use the approach of selecting the highest NAS RDA value as the label reference value. A wide range of persons submitted comments supporting this view, including health professionals, industry representatives, and consumers. Many of the comments from consumers were variations of a form letter that opposed the change but did not provide a substantive rationale for the position expressed.

12. A few comments opposing use of averaged values raised the concern that lower label reference values would downgrade the nutritional quality of fortified and substitute foods. Some comments asserted that a change in label reference values would affect FDA food fortification practices or the nutrient content of food assistance programs. Other comments expressed concern that the approach changed the label reference values by as much as 80 percent.

The agency notes that many comments concluded that the difference (i.e., lower values) between the current label reference values (U.S. RDA's) and the proposed, label reference values (RDI's) could be attributed solely to the change in the approach used to calculate the values. The comments were incorrect. The proposed approach lowered the label reference values for vitamins and minerals by an average of about 1.4 percent compared to values that would have been derived if the agency had used the approach of selecting the highest 1989 NAS RDA

value, i.e., the traditional approach with the most recent NAS RDA values. The remaining differences are the result of changes in the NAS RDA values from 1968 to 1989. In the 10th edition of the NAS RDA publication, NAS lowered several of its RDA values compared to the 1980 or earlier NAS RDA values to reflect new evidence in nutrition science and advances in analytical methodology. Thus, regardless of which approach had been used with the 1989 NAS RDA's—either the population adjusted mean approach or the .approach of selecting the highest NAS RDA value—the resulting revised label reference values would be lower when compared to the existing U.S. RDA's.

FDA further advises that label reference values are not used in the agency's policies on nutrient fortification. Some foods must be fortified to meet standards of identity, nutrition quality guidelines, substitute food regulations, or infant formula regulations. Moreover, FDA's guidelines on food fortification (§ 104.20 (21 CFR 104.20)) recommend that nutrients be added on the basis of specific quantities for a given amount of food. The levels are based on the needs of those segments of the population that are at risk of deficiency of those nutrients and not on the U.S. RDA's.

FDA's fortification policy states that traditional foods will be fortified if there is a public health need, or if nutrients need to be restored to a particular food, for example, if they are depleted during processing. Fortification of foods not covered by this policy is at the discretion of the manufacturer. The agency acknowledges that it is common practice for some manufacturers to fortify to a specific percentage of the label reference value (e.g., 25 percent). To the extent that this practice is continued, nutrient levels in some foods could be affected by changes in label reference values. However, this practice does not derive in any way from FDA regulations.

FDA also advises that the current label reference values (U.S. RDA's) have never served as standards for food packages or meal patterns for government feeding programs such as the Food Stamp Program, the Special Supplemental Food Program for Women, Infants and Children (WIC), or the National School Lunch Program and other child-feeding programs. There is one reference to U.S. RDA's in the regulations governing the National School Lunch Program, but it is merely used to determine whether certain foods—such as some snack food items that do not contain meaningful levels of nutrients—can be sold near or in school

cafeterias in competition with the school lunch program (7 CFR 210.11). The food packages and meal patterns used by these programs are based on the specific NAS RDA for each program's targeted group or include foods that contain required amounts of nutrients per unit. Thus, much of the comment that opposed the use of the averaging approach was significantly misinformed in several important respects.

13. The most frequent concern expressed in the comments that opposed the averaging approach was that the approach resulted in a value that was too low for at least half of the population, and that these lower values will result in suboptimal nutrient intakes. Many commented that consumers should be assured that if they meet 100 percent of the label reference value, they are meeting or exceeding their own individual allowances. Some were concerned that for certain nutrients, such as calcium, for which health authorities are emphasizing maximum intakes within a target population group, a label reference value based on an average undermines these dietary guidance efforts. Several comments argued that health educators have invested years in teaching consumers about the use and interpretation of the current label reference value (U.S. RDA), and that the proposed change would consequently cause consumer confusion as well as erase educational inroads. One professional commented that the label reference value should not provide guidance about what amount a person should consume; rather, its purpose is to provide values that allow comparative shopping. However, according to the comment, if a single value is to be used as a guide for nutritional adequacy, the first principle of public health should be followed, which is to aim at the most vulnerable group. Several comments provided data or reviews of studies linking nutritional deficiencies or suboptimal intakes with a range of adverse effects from learning disabilities to cataracts.

FDA is persuaded by the comments that the proposed averaging approach should be modified. To understand the modified approach some background discussion is necessary.

The agency has always viewed the food label as an important tool for informing consumers about the

nutritional content of the foods that they buy—one that shoppers can use to compare the vitamins, minerals, and protein in one food with another. This view is reinforced by the 1990 amendments. Additionally, the agency has been concerned that label reference values be set at levels consistent with levels of nutrients found naturally in foods so that regular, unfortified foods do not appear to be less than nutritious. If regular, unfortified foods were to appear less than nutritious, this could encourage needless fortification of foods.

Furthermore, FDA has also been concerned that the label reference values that appear on food labels not be interpreted as recommended intakes for individuals. Given the limited nutrition information that can be presented within the small space of most food labels, the agency sought in the proposal to establish values that represented a population-based average that consumers could use as a reference, adjusting it upward or downward based on how they compared to the average.

Most comments agreed that nutrition information on food labels must by necessity be limited and generalized, but suggested that public health concerns as well as consumer confidence and educational goals are best served by selecting label reference values that target "vulnerable groups" or at least that provide coverage for most of the population (i.e., the highest level recommended). Comments urged FDA to select protective levels of intake for vitamins and minerals that would be compatible with health promotion and disease prevention.

One comment suggested that consumers will not necessarily distinguish between a reference intake and a recommended intake, and that FDA should assume that consumers will see label reference values as recommended intakes. This comment offered a modification of the general approach of selecting the highest NAS RDA values. According to the comment, for each nutrient FDA should choose the most vulnerable segments of the population as the basis for the RDI. This segment should be established, the comment said, by identifying the group that has the highest NAS RDA and assessing its risk of a health problem caused by inadequate intakes of the nutrient. If the group with the highest

NAS RDA is not at risk, FDA should move to the group with the second highest NAS RDA and assess its risk, and so on until the agency identifies a group that is at risk, or until it reaches a group that constitutes a major portion of the population.

FDA has considered all of these comments in determining the most appropriate alternative approach. FDA finds that there is considerable and uniform support for continuing to establish a label reference value for vitamins and minerals with NAS RDA's by selecting the highest NAS RDA value from among those persons 4 or more years of age (excluding pregnant and lactating females). The comments clearly demonstrated that vulnerable or at-risk groups would be sufficiently covered by selecting the highest value. While FDA understands the intent of the comment suggesting that the agency conduct an iterative process to determine at-risk groups or vulnerable segments of the population, the broad support in the comments for the view that the highest value is sufficient to protect vulnerable groups must be taken into account. Moreover, the iterative approach could complicate the selection of label reference values, especially in situations where data are limited or subject to varying interpretations. Thus, FDA has concluded that the iterative process offers no public health advantages as compared to the approach of selecting the highest NAS RDA.

Furthermore, it is likely that the overall concern of the comment that suggested the iterative process is reasonably met by selecting the highest NAS RDA, in that the comment suggested an approach that was intended to provide coverage for a larger proportion of the population than did the proposed averaging approach. Therefore, FDA has tentatively determined that label reference values (i.e., RDI's) should be based on an approach that selects the highest NAS RDA values from among those for adults and children 4 or more years of age but excludes values for pregnant females and lactating females. FDA refers to this approach as the "population coverage approach." The label reference values that result from application of this approach to the 1989 NAS RDA's are set out in the following table:

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Children less than 4 years of age ¹	Infants ²	Pregnant women	Lactating Women
Vitamin A.....	retinol equivalents ³ ...	1,000.....	400.....	375.....	800.....	1,300.....
Vitamin C.....	mg.....	60.....	40.....	35.....	70.....	95.....
Calcium.....	do.....	1,200.....	800.....	600.....	1,200.....	1,200.....

Nutrient	Unit of measurement	Adults and children 4 years or more years of age	Children less than 4 years of age ¹	Infants ²	Pregnant Women	Lactating Women
Iron.....	do.....	15.....	10.....	10.....	30.....	15
Vitamin D.....	µg ⁴	10.....	10.....	10.....	10.....	10
Vitamin E.....	Alpha tocopherol equivs. ³	10.....	6.0.....	4.....	10.....	12
Vitamin K.....	µg.....	80.....	15.....	10.....	65.....	65
Thiamin.....	mg.....	1.5.....	0.7.....	0.4.....	1.5.....	1.6
Riboflavin.....	do.....	1.8.....	0.8.....	0.5.....	1.6.....	1.8
Niacin.....	niacin equivalents ³	20.....	9.0.....	6.....	17.....	20
Vitamin B6.....	mg.....	2.0.....	1.0.....	0.6.....	2.2.....	F2.1
Folate ⁵	µg.....	400.....	50.....	35.....	400.....	400
Vitamin B12.....	do.....	2.....	0.7.....	0.5.....	2.2.....	2.6
Phosphorous.....	mg.....	1,200.....	800.....	500.....	1,200.....	1,200
Magnesium.....	do.....	400.....	80.....	60.....	320.....	355
Zinc.....	do.....	15.....	10.....	5.....	15.....	19
Iodine.....	µg.....	150.....	70.....	50.....	175.....	200
Selenium.....	do.....	70.....	20.....	15.....	65.....	75
Chloride.....	mg.....	3,400.....	1,000.....	800.....	3,400.....	3,400 ¹

¹ The term "children less than 4 years of age" means persons 13 through 47 months of age.

² The term "infants" means persons not more than 12 months of age.

³ 1 retinol equivalent = 1 µg beta-carotene; 1 alpha-tocopherol equivalent=1mg d-alpha-tocopherol (RRR-alpha-tocopherol); 1 niacin or 60mg of dietary tryptophan.

⁴ As cholecalciferol.

⁵ Discussion of folate RDI in section III. G. (comment 21) of this document.

However, based on the provisions of the DS Act, the agency is retaining the current label reference values established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv) and redesignated as "Reference Daily Intakes"). It should be noted, however, that there are, in current § 101.9(c)(7)(iv), no label reference values for vitamin K, selenium, or chloride. Therefore, for the time being, the agency is not establishing label reference values for these three nutrients. FDA will reach a final decision on these issues, following the provisions of the DS Act.

D. Use of the NAS ESADDI as a Basis for Establishing an RDI

14. One comment was received that suggested that the RDI's based on ESADDI's may be a risk to health because in establishing the ESADDI's, NAS has stated that the upper limits of the ranges of intake should not be habitually exceeded. The comment asserted that some of the proposed RDI's based on ESADDI's exceed the upper limits of intake for children, specifically biotin, pantothenic acid, copper, manganese, and molybdenum.

FDA disagrees that the proposed label reference values based on the ESADDI's represent a risk to children. The agency is unaware of any evidence that would suggest that consumption at the proposed levels constitutes a health risk for children. The 10th edition of the NAS RDA publication (Ref. 26) states that:

(1) There have been no reports of toxicity associated with biotin intakes as high as 10 mg/day;

(2) Evidence suggests that pantothenic acid is relatively nontoxic;

(3) Usual intakes of copper in the U.S. are between 2 and 5 mg/day which is considered safe, and occasional intakes of up to 10 mg/day are probably safe for human adults;

(4) Manganese toxicity is rare, and nearly all cases are associated with environmental exposure. While there have been reports that learning disabilities in children might be associated with increased manganese levels in hair, more evidence is required before this association can be substantiated; and

(5) While the level of dietary intake of molybdenum that is known to be associated with increased loss of copper in the urine is approximately 2-fold that of the highest ESADDI, relatively large doses are necessary to overcome homeostatic mechanisms (Ref. 35).

Chloride tolerance is very high and likely many times the proposed RDI. The 9th edition of the NAS RDA publication (Ref. 36), which provides the basis for the RDI for chloride, does not even discuss the possibility of chloride toxicity.

As for chromium, although the agency is unaware of any safety issues at levels of current consumption, FDA recognizes that the safe range of intake of this mineral is fairly narrow. Thus, until sources of chromium have been affirmed, FDA advises that the RDI for chromium should not be interpreted as

a recommendation for use for either direct supplementation or adding nutrients to foods.

Finally, a label reference value for fluoride does not present issues of risk for children because it is to be used only in conjunction with a declaration of the level of this nutrient that is naturally present in a food.

Thus, the agency concludes that children eating from the general food supply are extremely unlikely to be at risk for toxic intakes of these micronutrients. To be consistent with the population coverage approach being used for other vitamins and minerals with NAS RDA's, FDA has selected the highest ESADDI within the specified age group to serve as the label reference value. If an ESADDI value is presented as a range, FDA has used the midpoint of the range as the RDI. No comments were received that objected to this approach.

FDA's approach would, provide RDI's for three age groups for nutrients with ESADDI's: adults and children 4 or more years of age, children less than 4 years of age, and infants. The NAS does not provide ESADDI's for pregnant or lactating females, but, as proposed, FDA used the midpoint of the ESADDI range for adults as the basis for the RDI for pregnant and lactating women in order to provide a reasonably appropriate reference value for this population. No comments objected to this approach. The RDI's determined by the agency based on the ESADDI's are set out in the following table:

Nutrient	Unit of Measurement	Adults and children 4 or more years of age	Less than 4 years of Age ¹	Infants ²	Pregnant women	Lactating women
Biotin.....	µg.....	65.....	20.....	15.....	65.....	65.....

Nutrient	Unit of measurement	Adults and child 4 or more yrs of age	Less than 4 years of age ¹	Infants ²	Pregnant women	Lactating women
Pantothenic acid	mg.....	5.5.....	3.0.....	3.0.....	5.5.....	5.5
Copper	do.....	2.5.....	0.9.....	0.7.....	2.5.....	2.5
Manganese	do.....	3.5.....	1.3.....	0.8.....	3.5.....	3.5
Fluoride	do.....	3.0.....	1.0.....	0.6.....	3.0.....	3.0
Chromium	µg.....	130.....	50.....	40.....	130.....	130
Molybdenum	do.....	160.....	38.....	30.....	160.....	160

(1) The term "children less than 4 years of age" means persons 13 through 47 months of age.
 (2) The term "infants" means persons not more than 12 months of age.

However, based on the provisions of the DS Act, the agency is retaining the current label reference values as established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv) and redesignated as "Reference Daily Intakes"). FDA notes that, in current § 101.9(c)(7)(iv) there are no label reference values for manganese, fluoride, chromium, and molybdenum. Therefore, for the interim, the agency is not establishing label reference values for these four nutrients. FDA will reach a final decision on these issues following the provisions of the DS Act.

E. Five Sets RDI's for Different Developmental Groups

15. One comment supported the development of RDI's for different age groups and recognition of the special needs of pregnant or lactating women. However, the comment suggested that the grouping of adults and children more than 4 years of age into a single group is not appropriate and is contrary to well established evidence that nutritional requirements vary throughout the lifecycle. On the other hand, many comments supported the agency's proposed approach.

FDA faced considerable difficulties in developing the RDI's for use on foods given that nutritional needs vary considerably among persons who will consume the foods. This issue was also

a consideration in the early 1970's when FDA was promulgating its first set of label reference values known as U.S. RDA's:

Because of space constraints on the food label—a problem that is becoming ever more compelling given the mandatory requirement for nutrition labeling on most foods—FDA does not believe that a viable option exists other than to develop a single set of label reference values for most consumers of the general food supply. Clearly, children over the age of 4 years consume the same foods that the rest of the population consumes.

Further, label reference values are intended to help persons to understand the nutrient levels in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate. Therefore, FDA believes that no harm can be done by using a single set of label reference values for nutrition labeling, especially if appropriate nutrition education is conducted.

The agency notes that, in following the provisions of the DS Act and retaining the label reference values in current § 101.9(c)(7)(iv) there will be no label reference values codified specifically for use on foods purported to be or represented for use by infants,

children under 4 years of age, or pregnant or lactating women. FDA had proposed such label reference values and had intended to include RDI's for different developmental groups in these final regulations.

The agency further notes that label reference values for these groups had been established in 1976, based on the 1968 NAS RDA's (41 FR 46156, October 19, 1976). These values were codified in § 125.1(b) (21 CFR 125.1(b)), later redesignated as § 105.3(b) (21 CFR 105.3(b)). In 1979, FDA in response to a decision by the Court of Appeals of the Second Circuit, revised § 105.3 by, among other things, deleting paragraph (b) (44 FR 16005, March 16, 1979). Therefore, since 1979 there have been no codified label reference values for these specific groups. However, some manufacturers have continued to use the values that were contained in § 105.3(b) for labeling products, without objections from FDA.

Thus, following the spirit of the DS Act that implies that 1968 NAS RDA's should be used for labeling purposes and to provide guidance to manufacturers, the agency is republishing, in this document, the values formerly contained in § 105.3(b). The label reference values are as follows:

Vitamins and Minerals	Units of Measurement	Infants	Children under 4 years of age	Pregnant or lactating women
Vitamin A.....	International Units.....	1,500.....	2,500.....	8,000
Vitamin D.....	do.....	400.....	400.....	400
Vitamin E.....	do.....	5.....	10.....	30
Vitamin C.....	Milligrams.....	35.....	40.....	60
Folic acid.....	do.....	1.....	.2.....	.8
Thiamine.....	do.....	.5.....	.7.....	2.5
Riboflavin.....	do.....	.6.....	.8.....	2.0
Niacin.....	do.....	8.....	9.....	20
Vitamin B6.....	do.....	.4.....	.7.....	2.5
Vitamin B12.....	Micrograms.....	2.....	3.....	8
Biotin.....	Milligrams.....	.05.....	15.....	.30
Pantothenic acid.....	do.....	3.....	5.....	10
Calcium.....	Grams.....	.6.....	.8.....	1.3
Phosphorus.....	do.....	.5.....	.8.....	1.3
Iodine.....	Micrograms.....	45.....	70.....	150
Iron.....	Milligrams.....	15.....	10.....	18
Magnesium.....	do.....	70.....	200.....	450
Copper.....	do.....	.6.....	1.0.....	2.0
Zinc.....	do.....	5.....	8.....	15

These values are to be used as guidance in the interim for labeling products purported to be or represented for use by infants, children under 4 years of age, or pregnant or lactating women. FDA will make a final decision on these issues, following the provisions of the DS act.

F. Units of Measurement

16. A dietary supplement trade association requested that the agency continue to use the International Units nomenclature for vitamins A, D, and E. The comment stated that the new equivalents nomenclature (e.g., retinol equivalents) would be confusing and is not well understood by either professionals or consumers.

FDA advises that units of measurement based on units of equivalents have been in wide use for over 15 years, and, in fact, the NAS RDA has been listed in such units since the 1980 edition. The comment cites no evidence to support the contention that professionals are confused by the nomenclature, or that consumers will necessarily be misled. FDA believes that it is more likely that consumers will use label information to compare products, and that the agency's provision for uniform units of measurement that are consistent with current measurement practices will be most beneficial. Additionally, for many foods, specific units of measurements will not be expressed. Rather, the levels of the nutrient present will appear as a percentage of the label reference value.

However, based on the provisions of the DS Act, the agency is, for the time being, retaining the current label reference values as established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv)), including the units of measurement contained therein. Therefore, in the interim the agency will continue to use the International Units nomenclature for vitamins A, D, and E. FDA will reach a final decision on these issues, following the provisions of the dietary supplement act.

G. RDI's for Specific Nutrients

17. Several comments stated that the proposed RDI's for particular nutrients were too low. Several of the comments recommended higher levels for these nutrients. Specifically, the comments said that vitamin A should be 1,000 retinol equivalents; calcium, 1,200 mg; iron, 15 mg; vitamin D, 400 IU; vitamin E, 10 alpha-tocopherol equivalents; Thiamin, 1.5 mg; riboflavin, 1.7 mg; niacin, 19 niacin equivalents; vitamin B6, 2 mg; and zinc, 15 mg.

If FDA decided to use the population coverage approach in establishing the RDI for vitamins and minerals, the RDI values for the nutrients listed above would be consistent with the comments. However, based on the provisions of the DS Act, the agency is retaining the label reference values as established in current § 101.9(c)(7)(iv). Therefore, FDA notes that the RDI for vitamin A is 5000

International Units; for calcium, 1.0 g; iron, 18 mg; vitamin E, 30 International Units; and niacin 20 mg. FDA will reach a final decision on these issues, following the provisions of the DS Act.

18. Several comments asserted that there is a need to distinguish between retinol and beta-carotene as a source of vitamin A activity, and one requested that FDA establish a label reference value for beta-carotene. The general rationale provided was that beta-carotene is more strongly associated with reducing the risk of chronic disease than is retinol.

The issue of providing for separate beta-carotene declarations in the nutrition label is discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. FDA does not agree that it is appropriate to establish a label reference value for beta-carotene separate from the value for overall vitamin A activity. As set forth in the preamble to the proposal for this final rule (55 FR 29476 at 29479). FDA intended to establish label reference values for those nutrients for which quantitative values were provided by the widely recognized and accepted consensus reports, specifically the 10th edition of the NAS RDA publication (Ref. 26), Diet and Health (Ref. 3), and the Surgeon General's Report on Nutrition and Health (Ref. 2). While these reports have discussed evidence to link lower beta-carotene consumption with increased risk for certain cancers, notably lung cancer, the reports noted the evolving nature of the issue and failed to make specific dietary recommendations concerning this food component. The reports, therefore, did not specify quantitative recommendations for intake, and the comments received relative to this proposal have not suggested or justified an appropriate intake level.

Without guidance from established scientific bodies and in the absence of scientific consensus both on the role of beta-carotene in the risk of onset of certain chronic diseases and on the quantitative level that could be appropriate for a population-based recommended intake of beta-carotene, FDA concludes that establishing such a label reference value cannot be supported. However, FDA will continue to monitor scientific advances as well as ongoing recommendations relative to beta-carotene nutriture. The agency will consider modifying or expanding label reference values as evidence warrants.

19. A few comments specifically expressed concern that the RDI for vitamin C was too low for persons in the U.S. population who smoke. This

concern stems from evidence that persons who smoke cigarettes may require more vitamin C than persons who do not.

FDA is aware that the 10th edition of the NAS RDA publication includes a statement in the text that recommends that regular cigarette smokers ingest at least 100 mg of vitamin C daily. However, FDA advises that the NAS RDA for vitamin C for the general population is set no higher than 60 mg. FDA has established label reference values that, of necessity, must be targeted to the entire population, rather than special population subgroups. In the absence of information to suggest that the 1989 NAS RDA's are an inappropriate basis for label reference values, FDA does not agree that the RDI for vitamin C should be a value other than the highest value set for persons 4 or more years of age. FDA supports nutrition education efforts that will inform those individuals whose requirements may be altered by lifestyle choices about their special nutrient needs.

20. One comment from a research foundation expressed concern about the high levels of iron available in the diet and thus supported the proposed RDI for iron of 12 mg as compared to the current U.S. RDA of 18 mg. The comment was made within the context of a discussion of hemochromatosis, a genetic disorder resulting in iron overload. A number of comments from consumers also expressed concern about excess levels of iron in the diet and supported lower label reference values for iron.

FDA advises that with the advent of mandatory nutrition labeling, virtually all foods will bear information on iron content. Thus, those persons diagnosed with, or at risk for, hemochromatosis will be able to select or reject a food based on their special dietary needs. Additionally, the agency will continue to make use of the active nutrition monitoring system to evaluate clinical measures and dietary intakes concerning the incidence of hemochromatosis. The agency notes that data from the Third National Health and Nutrition Examination Survey conducted by the National Center for Health Statistics can be used as a basis for reconsidering of the values for iron if concerns regarding hemochromatosis are demonstrated.

21. A number of comments addressed the issue of the RDI for folate. The majority opposed the proposed RDI value of 180 µg, which is lower than the current U.S. RDA of 400 µg. Several of the comments suggested that the 1989 NAS RDA for folate was an

inappropriate basis for establishing a RDI for folate, and a number of comments requested that the agency retain the U.S. RDA level of 400 µg (800 µg for pregnant women). One comment, in referring to the conclusion in the 1989 NAS RDA publication (Ref. 26) that diets containing about half as much folate as the previous NAS RDA maintain adequate folate status, asserts that the folate content of foods in nutrient data bases is recognized as inaccurate and incomplete. According to the comment, basing recommended intakes on intake data derived from these data bases is unsound. Several comments stated that there is evidence that folic acid supplements play a role in reduction in neural tube defects.

To a certain extent, some of these comments would be addressed by use of the population coverage approach to deriving RDI's. As a result of this approach, the RDI for folate would be 200 µg, i.e., based on the highest RDA value for persons 4 or more years of age (excluding pregnant or lactating women). However, FDA is aware of concerns regarding the adequacy of the data base for folate content of foods, which in part served as the basis for establishing the RDA for folate. Recent analytical work (Ref. 37) has shown that folate content of some foods may be underestimated because of methodological problems in current food folate assay procedures. FDA therefore agrees that additional work is needed to evaluate the adequacy of current intakes of folate.

Moreover, several studies have become publicly available since the publication of the 1989 RDA's, and these studies have shown that periconceptional intake of folate may reduce the risk of some neural tube defects. A randomized clinical intervention trial conducted in Great Britain by the Medical Research Council (Ref. 38) showed significant protective effects against recurrence of neural tube defects when women at high risk of recurrence were treated periconceptionally with daily doses of 4,000 µg of folic acid. Additionally, data available from a recently terminated Hungarian trial showed reductions in occurrence of neural tube defects with periconceptional use of a multivitamin/multimineral supplements containing 800 µg/day of folic acid (Ref. 39).

The results of these trials have led to reassessment of several earlier observational studies. Protective effects of the vitamin at levels of 100 to 1,000 µg/day (obtained from foods and supplements) against occurrence of neural tube defects have been found in

several but not all such observational studies.

FDA concludes that the available data demonstrate that there is a folate-related subset of neural tube defects in populations with high prevalence rates for these defects, and that folate intakes of about 400 µg/day may reduce the risk of some, but not all, neural tube defects in such populations. Furthermore, the agency notes that the United States Public Health Service (U.S. PHS) recently recommended that women of childbearing age in the United States who are capable of becoming pregnant should consume 400 µg of folate/day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 40).

FDA has seriously considered these findings relative to the appropriateness of retaining the approach of selecting the highest 1989 NAS RDA value (excluding pregnant or lactating women) when determining the RDI for folate. The agency has weighed the established and well-recognized scientific consensus inherent in the NAS RDA along with newer evidence of a possible at-risk population that constitutes a considerable segment of the U.S. population. Taken together, the agency concludes that these findings—specifically, the evidence of problematic data on folate intakes, the possibility that intakes of 400 µg/day may reduce the risk of some neural tube defects, and the recommendation of the U.S. PHS that women of childbearing age consume 400 µg/day of folate—are sufficiently compelling to justify at this time a RDI value of 400 µg for persons 4 or more years of age and, for consistency, a RDI of 400 µg for lactating women. Given that the current U.S. RDA is 400 µg, and that the DS Act compels retaining the U.S. RDA's at this time, no action is necessary. However, the issue of folate allowances for women is a significant one. Specifically, as discussed in a companion document entitled "Final Rule; Health Claims: Folic Acid and Neural Tube Defects" published elsewhere in this issue of the **Federal Register**, FDA is concerned about the uncertainties regarding the folate requirement of women of childbearing age and is planning to implement a peer review of several scientific issues relating to folate and its benefits for U.S. women. In this review, the agency will include an evaluation of the appropriate intake level for folate for women of childbearing age.

22. Two comments suggested that an intake based on a range of 6 to 10 mg/kilogram (kg) body weight would be appropriate for maintenance of healthy

magnesium status. Another comment suggested that the RDI be increased to at least 350 mg as compared to the proposed value of 300 mg.

The 10th edition of the NAS RDA publication (Ref. 26) states that 4.5 mg/kg is the upper range of requirements determined in modern balance studies for adults of both sexes. Therefore, FDA cannot agree that a range of 6 to 10 mg/kg is supported. The level of 4.5 mg/kg provides the basis for the NAS RDA's for magnesium which range from 120 to 400 mg for persons 4 or more years of age. Given that dietary magnesium deficiency has not been reported in people consuming foods commonly available and has been induced experimentally only once (Ref. 26), the agency believes that this level is more than adequate to cover the needs of virtually all population groups.

Moreover, FDA use of the population coverage approach in establishing the RDI for vitamins and minerals, would result in an RDI for magnesium of 400 mg, and thus would respond to concerns that the proposed RDI of 300 mg was too low. However, in accordance with the DS Act, FDA is not acting on this issue at this time.

23. FDA received several comments expressing concern about the generally recognized as safe (GRAS) status of selenium, fluoride, and chromium. These comments centered primarily around issues of their use in supplements.

The use of selenium, fluoride, and chromium compounds in dietary supplements discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. In that final rule, the agency states that FDA is deferring resolution of the status of selenium and chromium. However, FDA would like to reiterate (as stated in the July 1990 proposal, 55 FR 29476) that until the GRAS status of sources of these nutrients is resolved, the RDI's for selenium, fluoride, and chromium, if established, would be intended to be used only in conjunction with a declaration of the levels of these nutrients that are naturally present in the food or, in the case of fluoride, that are present as a result of the use of a fluoridated water supply in the processing operation (in accordance with 21 CFR 250.203). Any direct addition of these trace minerals to a food is based solely on the manufacturer's judgment that the nutrient sources are GRAS and is not sanctioned by the agency.

However, because FDA is, for the time being, retaining the label reference values in current § 101.9(c)(7)(iv), there

are no label reference values for selenium, fluoride, or chromium. FDA will reach a final decision on these issues based on the provisions of the DS Act.

IV. Label Reference Value for Protein

24. Two comments were received concerning the inconsistency between the label reference value for protein (RDI) and the label reference values for fat and carbohydrate (DRV's) in that the total caloric contribution of the three nutrients does not sum to 100 percent. One comment stated that the proposed value of 50 g for protein is too low because, based on a 2,350 calorie diet (i.e., the level proposed to serve as the basis for certain label reference values), the proposed 50-g level of protein would provide only 8.5 percent of the calories in a daily diet. The comment suggested that a level of protein that is consistent with 10 to 11 percent of calories from protein is appropriate, along with levels of 35 percent of calories from fat and 55 percent of calories from carbohydrate. The second comment suggested that FDA should resolve the discrepancy between the proposed protein RDI (50 g) and the value for protein that would be established if the value were based on the percentage of calories derived from protein. The comment stated that 10 percent of calories from protein is appropriate, and that the remaining 5 percent of calories that results after 30 percent of calories is attributed to fat, 10 percent to protein, and 55 percent to carbohydrate should be added to the carbohydrate caloric contribution (specifically, to the contribution from complex carbohydrates).

FDA has not traditionally specified label reference values for calorie-providing nutrients other than protein (i.e., no label reference values existed for fat or carbohydrate). Thus, the agency has not needed to consider issues related to the sum of caloric contributions from protein, carbohydrate, and fat, specifically that these values sum to 100 percent. Furthermore, recognized authorities on protein allowances provide for the allowance based on the amount of protein needed per kg of body weight rather than on the basis of percent of calories (Refs. 2, 3, and 26).

However, the agency agrees that with the advent of label reference values for fat and carbohydrate, it is appropriate to reconsider the approach used to derive the label reference value for protein. In addition to providing for a consistent and interrelated set of label reference values for calorie-providing nutrients,

the change in approach will facilitate consumer education efforts.

Furthermore, the decision to use the population coverage approach (i.e., selecting the highest NAS RDA value for persons 4 or more years of age excluding pregnant or lactating females) for establishing label reference values for essential vitamins and minerals (i.e., nutrients with NAS RDA's) must also be evaluated relative to its appropriateness for protein, a nutrient for which an NAS RDA is also established. This is especially important given the caution expressed in Diet and Health (Ref. 3) concerning excessive protein intake, particularly from animal sources.

While FDA received many comments that suggested that FDA return to the approach of selecting the highest NAS RDA value to serve as the label reference value, no specific comments were received suggesting that the proposed label reference value for protein (50 g, based on an adjusted average of the RDA's for protein) was too low because of public health concerns, or that the label reference value placed certain population groups at-risk for low protein intakes. Therefore, the appropriateness of using the population coverage approach for protein was not specifically supported by the comments.

FDA therefore concludes that there is sufficient support to establish a DRV for protein rather than a RDI. This change to a DRV is necessary because the agency is no longer basing the label reference value for protein on the RDA's for protein. RDI's are based on RDA's. Rather, like the label reference values (i.e., DRV's) for fat and carbohydrate, the label reference value for protein is based on percent of calories.

Neither the NAS RDA publication (Ref. 26), the Surgeon General's Report (Ret 2), nor Diet and Health (Ref. 3) suggests a specific level of total daily calories from protein. However, current intake of total dietary protein among Americans is estimated to be about 11 percent of calories (Ref. 3) and generally exceeds the NAS RDA for all age groups. Furthermore, some international guidelines for nutrient intake recommend that protein constitute 10 to 12 percent of calories (Ref. 3).

Based on the comments that suggested that approximately 10 percent of calories from protein should provide the basis for establishing a label reference value for this nutrient, FDA concludes that basing the DRV for protein on 10 percent of calories is reasonable. The level of 10 percent of calories is consistent with the NAS RDA in that the percent of calories from protein that results when the NAS RDA for each age/

sex group is compared with the caloric allowance established for that group ranges from 5 to 11 percent and could be rounded to 10 percent.

Thus, FDA advises that the label reference value for protein for adults and children 4 or more years of age (excluding pregnant or lactating females) will be a DRV rather than a RDI (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)), and will be the value that constitutes 10 percent of the calorie level to be used as the caloric basis for the DRV's. As discussed below, this calorie level is 2,000 calories. Therefore, the label reference value (DRV) for protein will be 50 g (i.e., 10 percent of 2,000 calories = 203 calories from protein; because 1 g of protein furnishes 4 calories (Ref. 26), the result is 50 g of protein).

FDA did not propose DRV's for infants, children less than 4 years of age, pregnant women, and lactating women. Therefore, for these groups the protein label references remain as RDI's (proposed as § 101.9(c)(11)(iv) and redesignated below as § 101.9(c)(8)(iv)). To be consistent with the population coverage approach, FDA has selected the highest NAS RDA for protein for infants and the highest NAS RDA for protein for lactating females. Only one NAS RDA value is provided for pregnant women and for children less than 4 years of age, thus no selection need be made. However, despite the change in approach, the RDI's for protein are the same as those proposed for these four groups. Therefore, the label reference value for protein will be: (1) A DRV of 50 g for adults and children 4 or more years of age and (2) RDI's of 14 g for infants, 16 g for children less than 4 years of age, 60 g for pregnant women, and 65 g for lactating women.

The decision to establish a DRV for protein based on 10 percent of caloric intake (so that DRV's for calorie-providing nutrients sum to 100 percent of calories) requires an adjustment in the proposed label reference value for total carbohydrate, i.e., 55 percent calories from carbohydrate. The necessary adjustment is discussed below.

Also, consistent with these changes, additional changes are necessary in proposed conforming amendments. FDA is amending § 101.3(e)(4)(ii) (21 CFR 101.3(e)(4)(ii)) by not only removing the term "U.S. RDA" and adding in its place the term "RDI," but also by adding the term "DRV of protein." FDA is also amending § 104.20(c)(1) and (d)(3) to list the DRV for protein.

V. DRV'S: Label Reference Values for Eight Nutrients without NAS RDA'S

A. Terminology

25. Two comments were received that expressed concern about the use of the word "value" in the term DRV. These comments stated that the word "value" may imply a goal rather than a reference level, and that the word generally connotes desirability.

No data were submitted to support the suggestion that word "value" may mislead consumers. Furthermore, FDA research has indicated that the term is generally understood by consumers as a point of reference. No other comments objected to the term on these grounds. FDA finds there is no compelling reason to abandon the proposed DRV terminology.

B. Scientific Basis for DRV's

26. Several comments expressed concern that the DRV's were based on insufficient or conflicting data, or that they lack sufficient scientific justification.

FDA acknowledges that the role of nutrients and food components in reducing the risk of disease is in an evolving state. However, numerous dietary reports and reviews relating to diet and health—particularly on the effect of diet on the risk of developing certain chronic diseases—have been published within the last decade. These reports, including *Diet and Health* (Ref. 3), the Surgeon General's Report on Nutrition and Health (Ref. 2), and *Dietary Guidelines for Americans* (Ref. 5), represent a sufficient scientific consensus that justifies the agency's proceeding with the establishment of DRV's. This conclusion is supported by the Institute of Medicine report entitled "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1), which states that health professionals have achieved a consensus on the characteristics of foods Americans should choose to have both a healthier diet and to reduce the risk factors for chronic diseases and conditions.

Concerns pertaining to the possibility that scientific consensus may change are not unique to the DRV's. The NAS RDA's, and thus the RDI's, are also subject to change and can be affected by shifts in scientific consensus. While it can be argued that the NAS RDA's are less likely to change because they have evolved over a longer period of time than the DRV's, any force from this argument is not sufficient to preclude using widely recognized and accepted recommendations to establish DRV's. This action is important given current public health goals and the clear role

that the food label can play in achieving these goals. FDA acknowledges that the scientific knowledge that underlies the DRV's may change over time, and so the agency intends to monitor and evaluate scientific consensus relative to existing DRV's as well as other nutrients known to bear on to the diet/health relationship. Furthermore, the petition process provided by agency regulations enhances and encourages this review. Accordingly, FDA is adopting the DRV's as proposed, with some modifications.

C. Caloric Basis for DRV's

27. While several comments supported FDA's proposal to use 2,350 calories as the basis for establishing certain DRV's that are based on daily caloric intake, most comments were opposed to the proposed value because they believed that it is too high. Many expressed concern that the resulting DRV's for total fat and saturated fat would overstate acceptable intakes for population groups that habitually consume less than 2,350 calories. Others were concerned that the calorie level would appear too high and, thus, would be irrelevant to many consumers. A few comments suggested that the level of 2,350 may encourage overconsumption of calories, especially among women.

Many comments suggested that FDA use 2,000 calories as the basis for the DRV's. The rationale for selecting 2,000 calories as opposed to other lower values varied, but reasons given included the fact that it is consistent with widely used food plans, it approximates the caloric requirements for postmenopausal women who are at-risk for excessive intake of calories and fat, and it is a "rounded down" value for 2,350 calories. These comments also pointed out that 2,000 calories is easier to use in quick, mental calculations compared to other calorie levels such as 1,900 or 2,350. Therefore, it is an easier tool for education purposes and is "consumer friendly." A few comments suggested 1,900 calories be used as the basis because it reflects the caloric allowance set by the NAS for women 51 or more years of age, a group believed to be at-risk for excessive calorie and fat intake.

FDA agrees with the comments that there is a need to select a lower caloric level for the DRV's. First, FDA agrees that a rounded value will be easier for consumers to use and is less likely to suggest such a level of precision that consumers lose sight of the concept of tailoring recommendations and reference values to their own diets. Secondly, the use of a lower caloric value is consistent with the population coverage approach to be used for

vitamins and minerals. The group "at risk," in this case the group most often targeted for weight control (i.e., older women), is covered by selecting a lower caloric basis for the DRV's, one that approximates the caloric requirements of such women. Given the support expressed for the 2,000 calorie level and how well it fits the reasons that support making this change, FDA will use 2,000 calories as the basis for DRV's (proposed as § 101.9(c)(12)(i), redesignated below as § 101.9(c)(9)).

Based on a 2,000 calorie level, the resulting DRV's being incorporated into § 101.9(c)(9) are listed in the following table:

Food component	Unit of measurement	DRV
Total fat.....	g.....	65
Saturated fat.....	do.....	20
Cholesterol...	mg.....	300
Total carbohydrates	g.....	300
Dietary fiber...	do.....	25
Sodium.....	mg.....	2,400
Potassium	do.....	3,500
Protein.....	g.....	50

As stated in the July 1990 proposal (55 FR 29476 at 29484), revisions of the nutrition labeling regulations in § 101.9 to update the U.S. RDA values necessitate that, for consistency, FDA revise several other regulations. FDA proposed to revise § 104.20(d)(3) to include the statement "The food contains all of the following nutrients per 100 calories based on 2,350-calorie total intake as a daily standard" and by providing a proposed table that listed the amounts of nutrients (per 100 calories) based on a 2,350 calorie diet and based on the proposed RDI levels. FDA has recalculated the nutrient levels in § 104.20(d)(3) to reflect the RDI values presented in this final rule based on a 2,000 calorie diet and included a statement indicating that the amounts of nutrients per 100 calories are based on a 2,000 calorie total intake.

28. Several comments stated that DRV's should be established in a fashion that provides for a different set of DRV's for different caloric intakes or, alternatively, that provides for a range of values such as a minimum/maximum range. These comments argued that the proposed DRV's are too simplistic and would encourage overconsumption of calories and fat, especially among women. One of these comments provided an extensive rationale for developing three sets of DRV's based on three levels ("benchmarks") of calorie intake.

FDA is aware of the problems associated with providing a single label reference value when in fact

recommended intakes or nutrient allowances for individuals vary considerably. The concern expressed is somewhat analogous to the difficulties in deriving a single set of RDI's based on the NAS RDA's, which are established for different sex/age groups.

In the case of DRV's, FDA believes that the purposes of nutrition labeling are better served by implementing a single value to serve as the DRV for each nutrient because the percent DRV (expressed as Daily Value) will be a component of mandatory nutrition labeling. This labeling will be required on virtually all foods, and, therefore, space considerations are significant. At the same time, if consumers are to use the important and necessary information provided by DRV's (expressed as Daily Value), the information must be presented in a readable format and in a manner that does not overburden or overwhelm consumers. The agency finds that a single value DRV will best accommodate these considerations of space and readability. In the companion document that specifies the final rule for Mandatory Nutrition Labeling, FDA is providing for a statement that is to be added to the label advising that the particular amount of certain nutrients a person may consume will vary depending upon calorie requirements. This information, coupled, with education, should adequately address the concerns raised by the comments by ensuring that consumers will understand that diets of individuals will not necessarily match label reference values.

The concerns that the proposed DRV's will encourage overconsumption among women is addressed by FDA's decision to base the DRV's on a caloric consumption of 2,000 calories rather than 2,350 calories. The 2,000 calorie level is very close to the 1,900 calories recommended for women 51 or more years of age.

However, the requirement that a single DRV be used in the nutrition label does not preclude the option of manufacturers voluntarily adding a listing of DRV's for other calorie intakes if label space allows. The comments have persuaded FDA that this voluntary declaration could be useful to consumers. Therefore, while the DRV's based on a 2,000 calorie diet constitute the mandatory component of the listing (space permitting), producers and retailers may voluntarily add a listing of DRV's for a different specified calorie level or levels than those provided by § 101.9(c)(9). Manufacturers who wish to take advantage of this option should calculate, with appropriate rounding, (1)

fat based on 30 percent of calories, (2) saturated fat based on 10 percent of calories, (3) carbohydrate based on 60 percent of calories, (4) protein based on 10 percent of calories, and (5) fiber based on 11.5 g of fiber per 1,000 calories. These calculations reflect those used to derive the DRV's based on a 2,000 calorie diet. As an example, a manufacturer could voluntarily list DRV's for a 1,500 calorie diet as follows: 50 g fat, 15 g saturated fat, 225 g carbohydrate, 40 g protein and 20 g fiber; or for a 2,500 calorie diet: 80 g fat, 25 g saturated fat, 375 g carbohydrate, 60 g protein, and 30 g fiber.

D. Units of Measurement and Rounding Procedures for DRV's

29. One comment disagreed with FDA's rounding procedure for the DRV's for fat, unsaturated fat, polyunsaturated fat, and carbohydrate. The comment suggested that the whole numbers derived before rounding should be used as the DRV. For instance, 30 percent of calories from fat (based on a 2,350 calorie diet) results in 78.3 g of fat. The comment argued that the DRV should be a value rounded to 78 g instead of the proposed 75 g.

FDA's rounding procedures for DRV's were intended to provide values that are consumer friendly numbers easily incorporated into educational programs as well as values that are generally consistent with the dietary recommendations. The possibility that DRV's could be listed on food labels as quantitative amounts instead of as percentage values led the agency to conclude that rounding to numbers such as 25 or 325 facilitated consumer education and did not imply more scientific precision than is justified given the evolving state of dietary recommendations. Furthermore, several comments urged FDA to select values that are easy for consumers to use and that do not suggest precision in determining the values. Therefore, the agency believes that there is support for the rounding approach that it used and agrees that consumers will find numbers such as 75 and 25 as more "friendly" and easily remembered than numbers such as 78 and 26. No other comments were received concerning this issue, and therefore FDA finds no compelling reason to provide alternative rounding procedures.

E. DRV for Total Fat

30. Several comments suggested that the use of 30 percent of calories from fat is inappropriate as the basis for developing a DRV for total fat. Some comments suggested that the level used should be 25 percent of calories from

fat; one stated that 20 percent of calories from fat should be used. These comments argued that the established recommendation is a maximum level because it is stated as 30 percent or less of calories from fat. Therefore, some level below this maximum should be used. On the other hand, one comment recommended that FDA use 35 percent of calories from fat. The concern expressed in this comment was that levels below 35 percent of calories from fat will bias diets toward vegetarianism.

FDA rejects the arguments that the DRV should be based on a criterion other than 30 percent of calories from fat. As described in the preamble to the proposal, the major available consensus documents, which were used by FDA in developing the DRV, consistently recommend 30 percent of calories or less from fat as an appropriate intake, given that current intake approaches 40 percent of calories from fat. Thus, a level higher than 30 percent of calories cannot be supported because the widely supported recommended intake is no more than 30 percent of calories from fat. The comment stating that intake levels below 35 percent of calories from fat will bias diets toward vegetarianism did not provide evidence to support this statement. FDA is not aware of any data that suggests that diets at or below 30 percent of calories from fat preclude the inclusion of animal products.

On the other hand, while current consensus reports suggest that less than 30 percent of calories from fat is achievable and may be desirable, they fail to provide specific quantitative recommendations as to how far below 30 percent is advisable. In fact, no consensus exists on the appropriateness of specific intakes of less than 30 percent of calories from fat.

However, the agency is aware of the desirability of alerting consumers to the direction of the DRV for total fat in that it is helpful for consumers to know that intakes of 30 percent of calories or less is the goal. Thus, FDA is providing that the listing of the DRV for total fat on the nutrition label include the words "less than" as described in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**.

31. Many comments suggested that the DRV for total fat should be lower than the proposed value of 75 g.

FDA agrees with these comments. With the change to a 2,000 calorie basis for DRV's, the DRV for total fat will be 65 g. The level was derived by calculating 30 percent of 2,000 calories and dividing by 9 which is the number of calories per g of fat. The calculated value is 66.7 g of fat. FDA rounded this

amount down to 65 g because, given that the current recommendation for total fat intake is 30 percent of calories or less, it is more appropriate to round down than to round up. Furthermore, as explained above, many comments have encouraged the agency to select label reference values that are easier for consumers to work with and recall, for instance 65 g of fat rather than 66 g.

F. DRV for Saturated Fat

32. Several comments suggested that because the proposed calorie basis (2,350 calories) is greater than the allowance for many persons, the proposed DRV for saturated fat (25 g) is too high.

FDA agrees with these comments. With the change in the basis for DRV's to 2,000 calories, and using the recommended intake of less than 10 percent of calories from saturated fat, the DRV for saturated fat is 20 g. The actual amount calculated using 10 percent of 2,000 calories is 22.2 g. However, because the current dietary recommendation specifies less than 10 percent of calories from saturated fat and for other reasons discussed above, FDA rounded this value down to 20 g.

33. One comment referenced Diet and Health (Ref. 3) which states that a saturated fat intake that is 7 to 8 percent of calories or lower would confer greater health benefits than the recommendation for less than 10 percent of calories. The comment suggested that FDA use 7 percent of calories from saturated fat as the basis for the DRV.

While the report cited does include an advisory statement as to the possibility of increased benefits with lower intakes, the committee responsible for Diet and Health specifically recommended that 10 percent of calories from saturated fat. This recommendation was based not only on issues of health benefits but also on considerations of realistic diet modifications among American consumers. FDA believes that this approach is both prudent and practical. No other comment suggested the level of 7 percent of calories from saturated fat as the basis for the DRV. The agency, therefore, used 10 percent of calories from saturated fat with a rounding down procedure as described above in deriving the DRV for saturated fat.

G. DRV for Unsaturated Fat

FDA's intent in developing a DRV for unsaturated fat was to complete the set of label reference values for fat. The DRV's for fat and saturated fat reflect current recommendations to limit total fat intake to 30 percent of calories and

saturated fat intake to less than 10 percent of calories. To account for the component of total fat that remains, FDA derived the DRV for unsaturated fat by calculating 20 percent of calories and dividing by 9. The agency arrived at the factor of 20 percent by subtracting the 10 percent of calories from saturated fats from the 30 percent of calories for total fat.

However, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, comments have convinced the agency that the listing of unsaturated fat on the food label is potentially confusing to consumers and could result in consumer deception. As discussed in that companion document, comments stated that the listing was not useful, that it offered no additional information that could not be obtained by subtracting the saturated fat content from total fat, and that it obscures the presence of essential fatty acids.

Moreover, other comments persuasively argued that the term "unsaturated fat" is misleading because it suggests that all unsaturated fats are synonymous by including both cis and trans isomers and poly- and monounsaturated fats together. Based on these comments, FDA decided not to include a listing of unsaturated fat in nutrition labeling. Therefore, FDA finds that there is no need for a label reference value for unsaturated fat and, accordingly, has deleted the proposed DRV for it in this final rule.

34. One comment requested that FDA eliminate the proposed DRV for unsaturated fat and replace it with a DRV for polyunsaturated fat with a value of 25 g. The comment argued that this approach was supported by evidence that: (1) Polyunsaturated fats lower serum cholesterol, (2) current dietary recommendations are to maintain or modestly increase polyunsaturated fat intake, (3) low polyunsaturated fat intake is linked to increased risk of coronary heart disease, (4) consumers are familiar with polyunsaturated fat declarations on labels, and (5) declarations of unsaturated fat will clutter a nutrition label and do not provide useful information.

While FDA has been persuaded to eliminate the DRV for unsaturated fat, FDA does not agree that the establishment of a DRV for polyunsaturated fat of 25 g is appropriate. As stated in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, FDA is not persuaded that there is a need to require the inclusion of polyunsaturated fats on the nutrition

label. As discussed, these fatty acids do not meet the agency's criteria set forth in the proposal to the final rule (55 FR 29487 at 29493) that the nutrient be of particular public health significance and that quantitative intake recommendations be given in major scientific consensus reports.

Nonetheless, given consumer interest in polyunsaturated fats, FDA is allowing manufacturers to voluntarily list the amounts of polyunsaturated fats on the nutrition label. This provision is discussed in detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. Also, the agency acknowledges that Diet and Health (Ref. 3) has recommended that total polyunsaturated fat intake be maintained at 7 percent of calories and not exceed 10 percent of calories. This guideline translates into a recommended level of intake of approximately 16 g of total polyunsaturated fat, which should not exceed 22 g, based on the criterion of a 2,000 calorie diet.

However, FDA's definition for polyunsaturated fat includes only the cis isomers of the polyunsaturated fatty acids as described in the Mandatory Nutrition Labeling final rule. Thus, voluntary label declarations for polyunsaturated fat exclude trans isomers. As discussed in the Mandatory Nutrition Labeling proposed rule (55 FR 29487 at 29496), FDA believes that the limited definition is appropriate because declarations concerning polyunsaturated fats are at a level of specificity associated with targeted diet and health relationships.

Therefore, while label declarations include only the cis isomers, the available recommendation for polyunsaturated fat intake is based on total polyunsaturated fat intake. There are no quantitative recommendations for polyunsaturated fat intake that distinguish between the recommended intake of cis isomers and trans isomers of polyunsaturated fat, FDA concludes that a DRV based on recommendations pertaining to total polyunsaturated fat would be inappropriate when label declarations are to be based on only a component of the total polyunsaturated fat. Declarations when compared to the DRV would be misleading. Thus, the agency has not established a DRV for polyunsaturated fat.

35. One comment stated that the proposed DRV for unsaturated fat (50 g) was too high because current guidelines suggest that saturated and polyunsaturated fat should be up to 10 percent of calories, and that the rest of

the caloric contribution should come from monounsaturated fats.

The comment does not reference the source for the guideline that it discusses, and FDA is unaware of such a guideline. FDA does not agree that the current consensus reports suggest that 20 percent of calories should come from monounsaturated fats, and that the remaining caloric contribution of 10 percent of calories should be attributed to all other fats. Rather, as discussed in Diet and Health (Ref. 3), the current general recommendations are that polyunsaturated fat not exceed 10 percent of total calories, and that saturated fat be less than 10 percent of total calories. No specific recommendations for monounsaturated fat are provided in the major consensus reports currently available to the agency.

36. One comment stated that it is not appropriate to recommend 20 percent of calories from unsaturated fat without also stating that linoleate is an essential fatty acid and as such should comprise at least 3 percent, and perhaps as much as 7 percent, of calories in line with the current average intake in the United States.

The agency's decision to eliminate the DRV for unsaturated fat responds to the essential concern of this comment, that declarations concerning levels of unsaturated fat could be misleading without further information. As stated earlier, no DRV for unsaturated fat will be established, and thus the issue concerning the linoleate component of the DRV need not be addressed.

H. DRV for Cholesterol

37. One comment suggested that many experts agree that a single number for recommended cholesterol intake cannot be supported and requested that FDA eliminate this DRV. The comment also suggested that if the DRV is to be retained, the DRV for cholesterol should be expressed as a range. However, the comment did not specify an appropriate range. One comment stated that the DRV for cholesterol was inappropriate because Canadian nutrition recommendations do not provide quantitative advice on cholesterol intake.

FDA cannot agree that a DRV for cholesterol is unnecessary, or that many experts do not support a single overall recommended intake for cholesterol. Major public health initiatives in the United States have cited the need to limit cholesterol intake, and quantitative recommendations for cholesterol intake have evolved over a long period of time. Recently the report on the Expert Panel on Population

Strategies for Blood Cholesterol Reduction, National Cholesterol Education Program (Ref. 41) stated that it is important for Americans to change their eating patterns to reduce the average intakes of dietary cholesterol.

As documented in Diet and Health- (Ref. 3), there are a number of sources of recommendations concerning cholesterol intake, and the most widely used recommendation is to limit intake to 300 mg or less/day. The American Heart Association has recently re-reviewed this issue and recommended that cholesterol intake should be less than 300 mg/day (Ref., 42). Furthermore, a review of a summary table in Diet and Health (Ref. 3) reveals only one U.S. recommendation that provides a range for cholesterol. The range is 250 to 300 mg/day prescribed for a high-risk population rather than for the general public. Therefore, FDA does not agree that the DRV for cholesterol is unnecessary or inappropriate, nor that it should be expressed as a range. The agency is retaining the DRV for cholesterol at 300 mg (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)).

38. One comment recommended that the DRV for cholesterol be eliminated because the 300 mg level may encourage women and children, whose mean intakes as indicated by national surveys are below 300 mg, to increase their intakes.

FDA cannot agree that the DRV of 300 mg for cholesterol will encourage women and children to increase consumption of cholesterol. The major consensus reports, upon which the DRV is based, have considered the intake of cholesterol relative to women and children and have found no evidence that establishing a recommendation at approximately 300 mg/day will cause risk for these groups, which constitute a large percentage of the target population (Refs. 2 and 3).

More importantly, the lower calorie intakes among these population groups will likely result in lower intakes of cholesterol by these persons. Given current widespread and highly visible education programs, it is very-unlikely that individuals will attempt to increase cholesterol intake to match a label reference value for a nutrient that is so generally known as one to be limited in the diet. Furthermore, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, the DRV for cholesterol will be stated as less than 300 mg, thus providing nutrition information in a way that will further discourage any increase intake.

39. One comment referenced a statement in Diet and Health (Ref.3) that reductions beyond 300 mg/day of cholesterol intake, for example to levels of 250 or 200 mg/day, may also confer health benefits. The comment suggested that the 300 mg level was based not only on issues of public health but on the feasibility of achieving lower intakes' given current consumption patterns, which, in turn, was based largely on anecdotal evidence and personal opinion.

While the report cited does include a statement as to the possibility of increased benefits with lower intakes of cholesterol, the committee responsible for the report specifically recommended a level of 300 mg/day. This recommendation was based not only on issues of health benefits but also on considerations of realistic diet modifications among American consumers. The comment does not cite specifically in what way this recommendation is based on anecdotal evidence or personal opinion and the agency is unaware of any evidence to support this claim. FDA believes that the DRV of 300 mg for cholesterol is both prudent and practical, and is consistent with current dietary recommendations. No other comment suggested a lower level of cholesterol for the DRV. The agency will therefore retain the DRV of 300 mg. However, as with other nutrients, FDA will continue to monitor consensus reports and scientific evidence concerning the appropriateness of this DRV.

I. DRV's for Total Carbohydrate, Complex Carbohydrates, and Sugars

In the July 1990 proposal (55 FR 29476) and again in the supplementary proposal (56 FR 60366). FDA proposed a level of 325 g to serve as the DRV for total carbohydrate. This quantity was based on recommendations provided by major consensus reports, and specifically on the quantitative recommendation from Diet and Health (Ref. 3) that carbohydrate intake be 55 percent or more of calories. The amount, 325 g, reflects 55 percent of 2,350 calories, the caloric level proposed to serve as the basis for the DRV's.

40. One comment expressed concern that the proposed DRV for carbohydrate exceeds levels that should be consumed by many in the population and is not based on a scientific consensus. The comment suggested that the DRV for carbohydrate be eliminated.

FDA disagrees with this comment. The vast majority of comments that FDA received support the appropriateness of establishing DRV's as well as the validity of the scientific documents

upon which they (including the DRV for carbohydrate) are based. A DRV for total carbohydrate is necessary to assist consumers in understanding the significance of the level of that nutrient in a food within the context of an overall total daily diet. Thus, establishing a DRV for total carbohydrate is consistent with section 2(b)(1)(A) of the 1990 amendments. Additionally several comments stated that it would be desirable to account for 100 percent of caloric intake in the DRV's for fat, protein, and carbohydrate (i.e., the energy-providing nutrients). Therefore, FDA concludes that a DRV for carbohydrates appropriate.

41. A few comments requested that FDA establish a DRV for complex carbohydrate. One comment suggested that FDA establish such a DRV because it could be used in nutrition education efforts to help consumers put the dietary recommendations regarding increased carbohydrate intake into perspective. This comment provided a rationale based on the assumption that the current dietary recommendation to increase consumption of complex carbohydrates is meant to provide a caloric source to replace the decrease in caloric intake that will result from following the recommendation to decrease fat in the diet. On this basis, a DRV for complex carbohydrate derived from 35 percent of calories was suggested. Another comment suggested that a DRV based on 40 percent of calories is appropriate (assuming that 10 percent of calories is attributed to naturally-occurring sugars and 10 percent to added sugars, for a total carbohydrate DRV of 60 percent of calories). The third comment suggested that a DRV for total carbohydrate in the absence of DRV's for complex Carbohydrates and simple sugars is inappropriate. One comment suggested eliminating the DRV for total carbohydrate and replacing it with a DRV for complex carbohydrate.

FDA agrees that recent dietary recommendations have included suggestions that persons increase their intake of complex carbohydrates. However, FDA does not agree that there is scientific agreement on a specific recommended intake of complex carbohydrates, particularly a level of agreement that will support establishing a DRV. To date, major consensus reports and dietary recommendations have provided only qualitative recommendations for intake of complex carbohydrates. No quantitative recommendations exist. While the calculations that accompany the suggestion of 35 percent of calories from complex carbohydrate are well thought

out, they are not at this time supported by other sources. The alternative suggestion of 40 percent of calories from complex carbohydrate is based on a calculation by difference that assumes that 20 percent of calories from naturally occurring and added sugars is justified. Again, FDA finds no basis in the consensus reports upon which to agree.

Moreover, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, the chemical definition for complex carbohydrate remains problematic. A DRV for complex carbohydrate would be inappropriate in the absence of an acceptable chemical definition for complex carbohydrate because the agency does know which chemical entities should be reflected in the complex carbohydrate DRV, and because the agency would be unable to measure complex carbohydrate to determine whether a level listed as present in a food is correct. FDA acknowledges that recommendations concerning complex carbohydrate intake as well as the analytical methodologies for this food component are in an evolving state. Therefore, the agency will continue to monitor scientific evidence relative to the appropriateness of establishing a DRV for this food component.

42. One comment from a consumer advocacy group suggested that a DRV for added sugars and a DRV for naturally-occurring sugars be developed. The comment stated that DRV's in general do not describe ideal diets and do not reflect absolute scientific knowledge but are instead estimates based on the best knowledge available. The comment suggested that because sugars intake is a major public health concern, it is appropriate for FDA to establish a DRV for sugars despite the fact that neither the Surgeon General's Report (Ref. 2) nor Diet and Health (Ref. 3) present quantitative recommendations on sugars intake. The comment suggested that a DRV of approximately 50 g be established for added sugars. The comment said that this level was derived from a FDA report (Ref. 43) that estimated that, on average, 53 g. of added sugars are consumed per person per day. The comment asserted that FDA underestimated added sugars intake by one half (although it did not provide evidence to support his claim) and thus said that 50 g would be an appropriate level. The comment also suggested that the DRV for naturally-occurring sugars should be 50 g. also based on the FDA report concerning average consumption/

day. The comment again suggested that this estimate is too low by half.

Another comment concerning complex carbohydrates stated that a DRV for complex carbohydrate should be based on 35 percent of calories from carbohydrate, and implied that 20 percent of calories should be attributed to sugars.

In reviewing these comments, FDA considered the report from the World Health Organization (WHO) entitled "Diet, Nutrition and the Prevention of Chronic Diseases" (Ref. 44). The agency recognizes that the recommendation in the WHO report that consumption of refined sugars be limited to 10 percent of calories is not inconsistent with the comment that recommended that a DRV for added sugars be established at 50 g, because, with the agency's use of 2,000 calories as the basis for the DRV's, 50 g of sugars would constitute 10 percent of calories. Furthermore, the agency stated in its proposals (47 FR 53917, November 30, 1982 and 47 FR 53923, November 30, 1982) to affirm that sucrose, corn sugar, corn syrup, and invert sugar are GRAS, that it would monitor average dietary consumption of these ingredients and would reevaluate the safety of their use if total dietary consumption were to increase significantly. The agency concluded in those documents that there could be safety concerns if intake of these ingredients increased significantly over the current levels (approximately 50 g).

FDA acknowledges that there is some support for limiting the intake of added sugars to current intakes of about 50 g or 10 percent of calories. However, the agency has concluded that this support does not furnish a sufficient basis for establishing a DRV for added sugars. First, DRV's are established for nutrients of public health concern. As such, a rational basis for a DRV must in some way link particular, if not specific, levels of intake with adverse or positive health outcomes. Other than dental caries—the incidence of which has been declining considerably among the American population (Ref. 43)—no public health concerns are articulated by the comment or in the relevant reports. Further, in a special review conducted by the agency in the mid-1980's, FDA concluded that other than the contribution to dental caries, there is no conclusive evidence that demonstrates that sugars intake from any source is associated with chronic disease conditions (Ref. 43). The report also states that the development of dental caries occurs whether a sugar is added or naturally occurring, and that caries development is associated with the nature and texture of the food

Consumed, not just the total amount of sugars present in the food. Therefore, a specific level of intake that causes risk cannot be identified.

Secondly, as discussed in more detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, there is currently no analytical methodology that would allow the agency to distinguish between sugars that are added to a food and those that are naturally occurring. Therefore, FDA would be unable to evaluate the accuracy of claims about the levels of added sugars in foods. FDA discussed this consideration earlier in its final rule on the GRAS status of certain sugars (53 FR 44863, November 7, 1988). The agency concluded that it would be impractical to enforce limitations on the use of these ingredients in foods.

Moreover, in the absence of analytical capabilities to distinguish between added sugars and naturally-occurring sugars, FDA does not believe that it would be appropriate to establish a DRV for total sugars. There is no consensus concerning the specific proportions of total carbohydrate that should be attributed to total sugars and to complex carbohydrate. Moreover, a DRV for total sugars could be inconsistent with dietary guidelines that encourage the consumption of certain foods, such as fruits and dairy products, that contain naturally-occurring sugars, sometimes at high levels. FDA therefore, concludes that DRV's for added sugars, naturally-occurring sugars, and total sugars cannot be supported.

This conclusion, however, does not mean that FDA supports unlimited intake of sugars or sugar-rich foods that contain few nutrients except calories. Rather, FDA analyses of food consumption data (Ref. 45) suggest that certain groups in the population would benefit from educational efforts to help them assess the amount of Sugars present in foods in relation to the amounts of other nutrients contained in the food. Given this need, as well as consumer interest in levels of sugars in food, FDA has made provision in the Mandatory Nutrition Labeling final rule, published elsewhere in this issue of the **Federal Register**, for declarations in the nutrition label concerning the amount of total sugars present in the food. With educational efforts, consumers will be able to use the nutrition label to differentiate between sugars containing foods with high versus low nutrient values.

J. Adjustment in DRV for Carbohydrate Resulting from Change in Label Reference Value for Protein

As discussed earlier, the agency has decided to use a caloric basis for the DRV's of 2,000 calories instead of 2,350 calories and to establish a DRV for protein based on 10 percent of calories. These changes from the proposed approach have necessitated an adjustment in the DRV for total carbohydrate.

Based on comments, particularly as discussed above in comment 24, FDA is establishing a DRV for protein rather than an RDI. The DRV value reflects 10 percent of calories from protein, based on a 2,000 calorie diet. FDA proposed to base the DRV's for fat and carbohydrate on their percent contribution to total calories, 30 percent and 55 percent, respectively. If protein is to contribute 10 percent of calories, then it is necessary to account for the remaining 5 percent of calories using the contribution from fat or from carbohydrate. Given the current established recommendation that persons consume 30 percent or less of calories from fat (Refs. 2 and 3), FDA does not believe it would be appropriate to add the remaining 5 percent of calories to the contribution from fat.

Guided by a comment submitted to this docket, discussed above in comment 41, as well as by the fact that Diet and Health recommends that 55 percent or more of calories be derived from carbohydrate (Ref. 3), FDA believes that it is appropriate to increase the DRV for carbohydrate. While the comment suggested the change from 55 to 60 percent of calories from total carbohydrate within the context of providing a DRV for complex carbohydrates (which was not proposed by the agency), the approach can still be applied to total carbohydrate in the absence of a DRV for complex carbohydrate.

This change from 55 percent to 60 percent of calories from carbohydrate is consistent with the recommendation that persons consume 55 percent or more of their calories from carbohydrate, and it allows the energy-yielding nutrients to sum to 100 percent of calories as suggested by the comments to this docket. Therefore, FDA is adopting a DRV for carbohydrate of 300 g. which is 60 percent of 2,000 calories, (i.e., 60 percent of 2,000 calories = 1,200 calories; carbohydrate provides 4 calories per g (Ref. 26), thus 1,200 calories divided by 4 calories per g results in 300 g). This change is incorporated into § 101.9(c)(9)).

K. DRV for Dietary Fiber

43. Two comments suggested that the DRV for dietary fiber should, not be associated with a specific caloric intake, and that, as in the case of cholesterol, this DRV should be independent of the number of calories consumed. One comment stated that nutritionists recommend similar levels of fiber intake at different levels of caloric intake. However, the comment did not specify a level that would be appropriate for all persons.

As acknowledged in the proposal for this regulation, there is a relative lack of consensus concerning recommended quantitative values for fiber intake. However, several scientific bodies have recommended increased intake of fiber, and comments from consumers and health professionals have strongly suggested the desirability of providing quantitative fiber content labeling on foods. Available recommendations tend to be expressed as a range or as a level that should not be exceeded, rather than as a single number applicable to all persons.

FDA considers the current most authoritative source on recommended fiber intake to be the report issued by the Life Sciences Research Organization (LSRO) of the Federation of American Societies for Experimental Biology (Ref. 46). This report based recommended fiber intakes on an amount (10 to 13 g) per 1,000 calories which, when based on the 2,000 calorie level used for the DRV's, results in a level of intake (20 to 26 g) that is in general agreement with the recommendation of the National Cancer Institute, i.e., 20 to 30 g per day (Ref. 47).

FDA finds no reason to change the basis for deriving the DRV for dietary fiber that it used in the proposal which involved calculating 11.5 g, the midpoint of the 10 to 13 g range, of fiber per 1,000 calories. The change to a 2,000 calorie basis from a 2,350 calorie basis will not change the DRV for fiber (proposed as § 101.9(c)(12)(i) and redesignated below as 101.9(c)(9)) which FDA proposed as 25 g based on a 2,350 caloric intake. The 2,000 calorie calculation (i.e., 11.5 g times 2) results in a value of 23 g, which rounds up to 25 g to provide a number that is easily incorporated into educational programs and is generally consistent with the dietary recommendations.

44. One comment recommended that the DRV for fiber be established as 20 g rather than 25 g. The comment noted that the National Cancer Institute (Ref. 47) and the report from LSRO (Ref 46) both specify a range of about 20 to 35 g per day. The comment suggested that

the low end of the range is a more realistic goal for the U.S. population considering that current intakes are half of that amount.

FDA does not find the argument for dietary feasibility sufficiently compelling to abandon a level that is clearly within the range recommended by major scientific bodies. FDA is unaware of any evidence to suggest that 25 g per day cannot be met by consumers who select foods from the available food supply, or that it is not achievable through realistic diet modifications. FDA believes that the recommended intake is readily achievable with enhanced educational efforts. FDA is planning for and supporting such efforts.

45. One comment expressed concern that the proposed DRV for fiber exceeds levels consumed by many in the population and is not based on sufficient scientific data. The comment did not further specify the nature of the insufficient data.

As stated in the proposal to this document (55 FR 29476 at 29483), comments received by FDA show that many consumers and health professionals desire quantitative fiber content labeling. Yet, as the agency acknowledged, there is a lack of consensus concerning quantitative values for recommended fiber intake. However, several scientific bodies (Refs. 2, 3, 47, and 48) have recommended increased intake levels for fiber on the basis that fiber may have important health benefits, particularly relative to intestinal function. Furthermore, LSRO has issued a report that provides a quantitative recommended intake for dietary fiber (Ref. 46). Its recommendation of 10 to 13 g fiber per 1,000 calories in the diet is consistent with that of the National Cancer Institute (Ref. 47). The report developed for LSRO by a panel of qualified scientists contains numerous references to scientific research articles and reports in professional journals and publications. FDA is not aware of any concerns about the soundness of the LSRO review. Therefore, FDA is not persuaded that the scientific rationale for the fiber DRV is based on insufficient data.

Secondly, the fact that the DRV exceeds levels currently consumed by many in population is not significant in setting this DRV. As discussed in the preceding comment, FDA is unaware of any evidence to suggest that 25 g per day cannot be met by consumers who select foods from the available food supply. Therefore, FDA concludes that the 25 g level for the DRV for fiber is appropriate.

L. DRV for Sodium

46. A few comments specifically supported creating a DRV for sodium by pointing out that the scientific evidence demonstrates that sodium reduction is beneficial for hypertensive and normotensives alike, and that high salt intake coupled with low potassium and calcium intake is a major cause of high blood pressure and risk of stroke. A few were opposed and argued that the data are scientifically insufficient or questionable.

FDA disagrees that the data are insufficient or questionable. The basis for the agency's position is discussed in detail in the proposal pertaining to a sodium/hypertension health claim (56 FR 60825, November 27, 1991) and in the final rule for this health claim published elsewhere in this issue of the **Federal Register**. As discussed in these documents, it is the agency's opinion that based on the totality of publicly available scientific evidence, there is significant scientific agreement that there is a relationship between sodium and hypertension. There is also agreement that reductions in dietary sodium intake will provide a substantial public health benefit. Given the need to reduce sodium intake and the directive in the legislation that the information required in the nutrition label be conveyed to the public 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 (section 2(b)(1)(A) of the 1990 amendments), FDA believes that a DRV for sodium is supported.

47. Some comments argued that there is no consensus regarding sodium recommendations, and that a DRV is therefore inappropriate. One comment stated that Canada provides no quantitative advice regarding sodium, and another noted that public health agencies do not agree among themselves about an appropriate recommendation. It was pointed out that the Joint National Committee (Ref. 49) described "moderate sodium intake" as 1,500 to 2,500 mg, while the Surgeon General's Report (Ref. 2) discussed a desirable range of 1,100 to 3,300 mg in noting that dietary intakes exceed this range, which was established as "safe and adequate" in the 9th edition of the NAS RDA publication (Ref. 36). The Dietary Guidelines for Americans (Ref. 5) recommend "moderation" but provide no quantitative values, while the 10th edition of the NAS RDA publication (Ref. 26) specifies a minimum intake of 500 mg but no maximum bound. The comment pointed out that the

participants at the National Heart, Lung, and Blood Institute (NHLBI) Workshop held in 1989 (Ref. 50) expressed disparate views.

FDA is aware of these differences but believes that they are attributable to differences in the intended purposes of the recommendations and not necessarily to a lack of underlying agreement. In fact, these recommendations are usually expressed as a range that includes the 2,400 mg level proposed as the DRV.

The Surgeon General's Report (Ref. 2) cited the 9th edition of the NAS RDA publication (Ref. 36) that has been superseded by the more recent 10th edition (Ref. 26). The 10th edition of the NAS RDA publication identifies a minimum safe adult intake of 500 mg but also supports the level of 2,400 mg recommended in Diet and Health (Ref. 3). Diet and Health served as the basis for establishing the DRV for sodium.

The Joint National Committee (Ref. 49), in the context of hypertension detection and treatment, reported no serious adverse effects with moderate sodium restriction of 1,500 to 2,500 mg, which includes the 2,400 mg level used for the DRV. Finally, the NHLBI workshop (Ref. 50) was designed to explore current research topics and was not convened as a Federal government consensus panel, nor did it have the objective to identify a recommended intake.

Therefore, FDA believes that the level of 2,400 mg that is proposed as the DRV for sodium, and that is recommended in the major consensus report Diet and Health, is consistent with other recommendations and government reports and, thus, provides an appropriate basis for a DRV. The level of 2,400 mg is also well above the recommended minimum safe intake levels of 500 mg.

48. A few comments supported a DRV for sodium that is lower than the proposed 2,400 mg. One comment from a consumer stated that 2,400 mg seems too high. Two comments that preferred 1,800 mg argued that Diet and Health (Ref. 3) had recommended 2,400 mg as an "initial goal" and had stated that a level of 1,800 mg would probably confer greater health benefit. One of these comments supported the lower value as a way to better protect millions of Americans, especially older citizens, with hypertension.

FDA proposed a DRV for sodium of 2,400 mg based on the recommendation in Diet and Health. While this report does note that a lower value of 1,800 mg may confer greater benefit, the committee specifically recommended 2,400 mg sodium. This recommendation

was based not only on issues of health benefits but also took into consideration realistic diet modifications among American consumers. FDA, therefore concludes that a DRV of 2,400 mg is consistent with the recommendation provided by Diet and Health. However, to guide consumers to the benefits of even lower levels, the agency is providing for the use of the phrase "less than" in the presentation of the DRV standard on the label. This label format provision is discussed in more detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**.

49. Several comments favored a higher DRV for sodium. One comment supported 2,900 to 3,000 mg, suggesting that a reasonable interpretation of the guideline provided in the 10th edition of the NAS RDA publication (Ref. 26) was to add the recommended intake to the 500 mg minimum naturally occurring (2,400 mg + 500 mg). This approach would produce a DRV of 2,900 mg (rounded to 3,000 mg). The comment stated that this level would be more realistic than 2,400 mg. Two other comments favored the 3,000 mg level. One expressed support for the American Heart Association position which is that sodium intake should not exceed 3 g per day (Ref. 42), and another stated that 3,000 mg has been recommended by most reputable health and nutrition organizations. One comment supported 3,300 mg, and another suggested a DRV of no less than 3,500 mg for a 2,350 calorie diet. According to the comment, the latter value represented a one-quarter decrease in what the comment identified as the usual American dietary intake of 4 to 6 g of salt. The one-quarter reduction was identified as the moderate intake recommended by Dietary Guidelines (Ref. 5). Another comment supported 4,000 mg, noting that the DRV is considered by dietitians to be in the range of "low sodium" diets (less than 2,000 mg) and that the general public should not use a "low sodium" diet as a reference because consumers would wrongly believe that sodium intakes in excess of safe and adequate levels would be harmful. One comment suggested that a range from 500 to 4,600 mg would be preferable to a single value.

First, FDA does not agree that the committee responsible for the 1989 NAS RDA's intended that 2,400 mg sodium should be consumed in addition to the 500 mg identified as safe and adequate in the 10th edition of the NAS RDA publication (Ref. 26). The publication specifically states that "there is no known advantage in consuming large amounts of sodium" and references the

recent NAS Diet and Health report (Ref. 3) which recommends that daily intakes of sodium chloride be limited to 2,400 mg of sodium or less. Further, FDA believes that a sodium DRV of 2,400 mg is not inconsistent with the current American Heart Association position that sodium intake should not exceed 3 g per day (Ref. 38). The agency notes that the written comments to this docket submitted by the American Heart Association did not object to the DRV of 2,400 mg for sodium (Ref 51).

FDA remains unconvinced that there is any reason to establish a value that is higher than the 2,400 mg specified in Diet and Health. The suggested higher values are not consistently supported, whereas 2,400 mg is consistent with other Federal agency recommendations and with current public health agency policies to moderate or reduce sodium intake. Furthermore, the 2,400 mg level is a feasible goal because sodium in food is primarily present as added salt, and current dietary recommendations specify a moderate reduction that is large enough to produce significant decreases in intake while remaining well in excess of the minimum safe intake level of 500 mg specified in the 10th edition of the NAS RDA publication (Ref. 26).

50. The feasibility of achieving an intake approximating the proposed DRV of 2,400 mg of sodium was questioned by a few comments. These comments stated that the proposed DRV is not reasonable or practical, will be difficult to achieve, and will cause unnecessary frustration to consumers trying to meet the goal. One comment suggested that the proposed DRV is too restrictive for restaurant nutrition programs, which must be concerned with taster affordability, and availability. To emphasize the difficulty of achieving daily sodium intakes of 2,400 mg, the comment referred to a recent review article on sodium intervention trials (Ref. 52) that found that daily intakes of 3,000 mg were only achievable with intensive, multifaceted interventions and highly motivated individuals. The article concluded that general population goals must be modest, or the food supply must change significantly.

FDA recognizes that the current sodium intake of many people exceeds the DRV level of 2,400 mg (56 FR 60825 at 60825), and that sodium is very prevalent in the food supply. However, the agency disagrees that intakes of 2,400 mg sodium are not feasible. Sodium is largely a discretionary addition to foods usually as sodium chloride or table salt. In fact, estimates suggest that 90 percent of the sodium in foods is from added salt (Refs. 53 and

54) and thus can more easily be controlled by food processors and consumers than can substances in food that are naturally-occurring. Additionally, because reduced sodium intake is a recognized public health priority (Refs. 2, 3, and 5), the agency believes that it is appropriate to set the DRV at a level that is consistent with that goal and that will stimulate changes in the marketplace that are technologically feasible. Therefore, FDA is retaining the DRV of 2,400 mg for sodium (proposed as § 101.9(e)(12)(i) and redesignated below as § 101.9(c)(9)).

51. One comment suggested that the statement in FDA's proposal that the "majority of the current dietary intake of sodium results from ingestion of sodium chloride" contradicts a previous FDA statement that a substantial amount of sodium comes from nonsalt sources. The comment did not identify the FDA statements to which it was referring.

This comment infers that "substantial" and "majority" are synonymous. FDA disagrees with this comment. A dictionary definition (Ref 55) for the word "substantial" characterizes the word as meaning of ample or considerable amount, quantity, size, etc., or of real worth, value, or effect. It does not define "substantial" as "majority." In its proposal on RDI's and DRV's, the agency referenced a statement from Diet and Health (Ref. 3) that the majority of sodium intake is from sodium chloride. This statement is not inconsistent with the agency's 1982 findings (47 PR 26590) that nonsalt sources can also provide meaningful, important, or "substantial" contributions to the diet.

M. *DRV for Potassium*

52. One comment suggested that the DRV's should be limited to those dietary components that are the subject of dietary guidelines. It highlighted the establishment of a DRV for potassium as scientifically unjustifiable.

As described in the proposal to this final rule, FDA has used major consensus reports in developing the DRV's. Among these is the well recognized and accepted Diet and Health (Ref. 3), published by NAS. This report specifically recommends a quantitative intake of potassium to assist in reducing the risk of stroke. FDA does not find compelling the comment's argument that, because potassium is not specifically listed in Dietary Guidelines for Americans (Ref. 5), a DRV is not justified. The Dietary Guidelines are intended to provide general food guidance and do not necessarily specify recommended intakes for individual nutrients. The agency notes that no

Other comments were received expressing concern about this DRV. The agency is, therefore, retaining the DRV for potassium (3, 500 mg).

Additionally, for completeness, FDA is including the listing of potassium based on its DRV value in §§ 101.3(e)(4)(ii) and 104.20(c)(1) and (d)(3).

VI. Conforming Amendments

53. One comment expressed concern that the proposed RDI's will have implications for all alternative products (e.g., reduced fat) formulated to achieve nutritional equivalency to their traditional counterparts. According to the comment, a traditional product containing nutrient levels at less than the 2 percent U.S. RDA criterion, and thus not requiring fortification of the analog, could now meet a 2 percent RDI criterion and thus fortification of the analog would be required. For example, a typical dressing contains 1.88 percent of the U.S. RDA for vitamin E. Because this amount is less than the 2 percent U.S. RDA criterion, fortification of an analog product is not required.

However, under the proposed RDI's, the traditional product would contain 4.58 percent of the RDI for vitamin E, requiring fortification in an analog product if the analog did not contain this level of the nutrient. The comment questioned whether the agency intended expanded fortification of analog products with introduction of new RDI's, because the agency had failed to address identity labeling of food in packaged form (§ 101.3(e)), particularly where the definition of "nutritional inferiority" is concerned.

The agency acknowledges that the levels of nutrients chosen as the RDI's will have an effect on achieving nutritional equivalency for all alternative products formulated to be substitutes for traditional products. However, FDA believes that the levels of the RDI should not be established or influenced by the effect that they will have on how nutritional equivalency is achieved in the formulation of alternative products. Rather, the levels should be based on sound public health principles. FDA established the 2 percent threshold for achieving nutritional equivalency (§ 101.3(e)) because that level is a measurable amount of most nutrients in a food. The adjustment of the RDI's upward, consistent with the population coverage approach, would however limit the number of situations in which nutrient levels in traditional products were below the threshold for some U.S. RDA's but are above that threshold with respect to the RDI's

54. One comment suggested that vitamin K, molybdenum, and chloride be removed from the list of nutrients required to meet nutritional equivalency (proposed § 101.9(c)(11)(iv) and redesignated as § 101.9(c)(8)(iv)), and that FDA should include a clear statement in § 101.3(e) that selenium, fluoride, and chromium are not to be considered for nutritional equivalency purposes. According to the comment, these nutrients are of little health significance for the general healthy population.

The agency acknowledges that an increase in the number of nutrients for which label reference values (RDI's) are established would mean that efforts to obtain nutritional equivalency may require the addition of additional nutrients to substitute foods. Furthermore, the agency agrees that some of these nutrients are not considered to be of public health interest. However, any change in what constitutes nutritional equivalency would require a reevaluation of § 101.3(e), which is beyond the scope of the 1990 amendments.

However, the agency recognizes that at this time there are no listed sources (i.e., GRAS or approved food additive) for selenium, molybdenum, fluoride, and chromium. In its proposal to this final rule, the agency failed to identify molybdenum as a nutrient without a listed source. However, despite no known issues of safety, the agency believes that it would be inappropriate to include molybdenum on a list of nutrients to be added to a food for nutritional equivalency when there are no listed sources for molybdenum. Therefore, FDA would have amended § 101.3(c)(4)(ii) to state that these elements are not required for nutritional equivalency.

However, based on the provisions of the OS Act, FDA is retaining, for the time being, the label reference values as established in current. § 101.9(c)(7)(iv). Because there are no label reference values for the nutrients mentioned in the comments (i.e., vitamin K, molybdenum, chloride, selenium, fluoride, and chromium), there is no need to revise § 101.3(e)(4)(ii) to specifically exclude these nutrients. Therefore, § 101.3(e)(4)(ii) is amended to be consistent with these final regulations referring to the Daily Reference Values (DRV's) of protein in § 101.9(c)(7)(iii) and of potassium in § 101.9(c)(9) and to the Reference Daily Intakes (RDI's) of vitamins and minerals in § 101.9(c)(8)(iv). FDA will reach a final decision on the other issues discussed in this comment following the provisions of the DS Act.

VII. Environmental Impact

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

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

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

environment is expected and that an environmental impact statement is not required.

VIII. Economic Impact

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

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

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

IX. 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.

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vitamin or mineral listed under §101.9(c)(8)(iv)

* * * * *

3. Section 101.9 is amended by adding paragraphs (c)(7)(iii), (c)(8)(iv), and (c)(9) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(7) * * *

(iii) For the purpose of labeling with a percent of the Daily Reference Value (DRV) or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

* * * * *

(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.
 Thiamin, 1.5 milligrams.
 Riboflavin, 1.7 milligrams.
 Niacin, 20 milligrams.
 Calcium, 1.0 gram.
 Iron, 18 milligrams.
 Vitamin D, 400 International Units.
 Vitamin E, 30 International Units.
 Vitamin B6, 2.0 milligrams.
 Folic acid, 0.4 milligrams.
 Vitamin B12, 6 micrograms.
 Phosphorus, 1.0 gram.
 Iodine, 150 micrograms.
 Magnesium, 400 milligrams.
 Zinc, 15 milligrams.
 Copper, 2 milligrams.
 Biotin, 0.3 milligram.
 Pantothenic acid, 10 milligrams.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat.....	gram (g).....	65
Saturated fatty acids.....	do.....	20
Cholesterol.....	Milligrams(mg).....	300
Total		
Carbohydrate....	grams(g)....	300
Fiber.....	do.....	25
Sodium.....	milligrams(mg)....	2,400
Potassium.....	do.....	3,500
Protein.....	grams(g).....	50

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

4. The authority citation for 21 CFR part 104 continues to read as follows:

List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 104

Food grades and standards, Frozen Foods, Nutrition.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101 and 104 are amended as follows;

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues 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)(n) to read as follows:

§101.3 Identify 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) and the Reference Daily Intake (RDI) of any

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

§ 104.20 Statement of purpose.

2 percent of the Reference Daily Intake (RDI) in a normal serving of the food.

* * * *

* * * *

(c) * * *

(1) The nutrient is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the Daily Reference Value (DRV) of protein and of potassium and

(d) * * *

(3) The food contains all of the following nutrients per 100 calories based on 2,000 calorie total intake as a daily standard:

5. Section 104.20 is amended in paragraph (a) by removing "U.S. RDA's" the two times it appears and replacing it with "Reference Daily Intakes (RDI's)" and "RDI's", respectively, and by revising paragraphs (c)(1) and (d)(3) to read as follows:

Nutrient	Unit of Measurement	DRV or RDI ¹	Amount per 100 calories
Protein.....	grams (g).....	50.....	2.5
Vitamin A.....	International Unit (IU).....	5,000.....	250
Vitamin C.....	milligrams (mg).....	60.....	3
Calcium.....	g.....	1.....	0.05
Iron.....	mg.....	18.....	0.9
Vitamin D.....	IU.....	400.....	20
Vitamin E.....	do.....	30.....	1.5
Thiamin.....	mg.....	1.5.....	0.08
Riboflavin.....	do.....	1.7.....	0.09
Niacin.....	do.....	20.....	1
Vitamin B ₆	do.....	2.0.....	0.1
Folate.....	micrograms (µg).....	400.....	20
Vitamin B ₁₂	do.....	6.0.....	0.3
Biotin.....	mg.....	0.3.....	0.015
Pantothenic acid.....	do.....	10.....	0.5
Phosphorus.....	g.....	1.0.....	0.05
Magnesium.....	mg.....	400.....	20
Zinc.....	do.....	15.....	0.8
Iodine.....	µg.....	150.....	7.5
Copper.....	mg.....	2.0.....	0.1
Potassium.....	do.....	3,500.....	175

¹RDI's for adults and children 4 or more years of age

Dated: October 29, 1992.

David A. Kessler,
Commissioner of Food and Drugs.

Louis W. Sullivan,
Secretary of Health and Human Services.

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