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

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

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

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

B. Method for the Determination of RDI Values

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

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

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

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

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

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

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