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

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

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

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

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

B. Selenium and Chromium

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

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

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

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

C. Chloride

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

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

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

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