and salt products can be measured volumetrically.

Second, there must be a significant difference in the densities (i.e., 25 percent or more) of the different forms of the product such that a range of densities are represented within the product category (see discussions on aerated products in § 101.12(e) and peanut butter (58 FR 2229 at 2263)). FDA considers the 33-percent density difference reported for low-density salt relative to conventional table salt to be significant and to justify a finding that the densities of different products within the category vary widely.

Third, the amount customarily consumed must be more uniform when expressed volumetrically than when expressed gravimetrically (56 FR 60394 at 60406 and 58 FR 2229 at 2238). There must be some indication or likelihood that similar volumes, rather than similar weights, of both low- and high-density products within the same product category are customarily consumed. The evidence must show that the amount that people consume is more consistent when expressed in volumetric terms than when expressed in terms of weight.

In the final serving sizes regulation (58 FR 2229 at 2260), FDA rejected a request for a volume-based reference amount for salt products, even though salt products are measured volumetrically. The agency observed that ''[t]he comment did not submit any data to support that regular salt and the low-density salt are consumed equally on a volume basis.'' FDA noted that like sugar, salt is used as a flavoring agent to attain a given level of saltiness. Thus, the agency stated, the reference amount for a salt substitute, such as a low-density salt product, should be the amount necessary to provide a salty taste equivalent to one reference amount of salt.

In reconsidering whether the amounts consumed of the various products within the salt category are more similar when expressed in terms of volume than in terms of weight, FDA looked at the quality of the supporting evidence submitted, including the study design, the results, and the conclusions. The agency evaluated the data provided in the supplementary submission and determined: (1) That the consumer research conducted on behalf of the petitioner is a reasonably well controlled experiment that meets scientific standards for testing household salt consumption differences due to two types of salt; and (2) that the result supports, but does not prove, the hypothesis that salt is used on a volumetric rather than on a weight basis (Ref. 2). Thus, FDA has tentatively concluded that the data provide evidence that similar volumes, rather than similar weights, of low- and high-density products are customarily consumed.

Section 101.12(e), which applies to discrete products like waffles, requires that the aerated version bear a descriptive term indicating that air has been incorporated (e.g., whipped, aerated). Some product categories that have volumetric reference amounts contain products whose common or usual names clearly indicate that air has been incorporated into the product (e.g., whipped peanut butter, whipped dessert topping). Some products in other product categories with volumetric reference amounts do not bear such descriptive terms (e.g., pudding, ice cream). Given these differences, FDA is requesting comments on whether low-density salt products should be required to clearly identify that they contain more air than conventional salt products. It is the agency's opinion that terms such as ''whipped salt'' or ''aerated salt'' are apt to be confusing to consumers. Therefore, FDA is also requesting comments on what kind of descriptive terms would be clear and nonmisleading for consumers.

IV. Conclusion

FDA has determined that volumetric reference amounts are appropriate when: (1) Products are bulk products that can be measured volumetrically; (2) there are significant differences in densities among the products within a product category such that a range of densities are represented within the particular product category; and (3) the amount customarily consumed is more uniform when expressed volumetrically, that is, there is some indication or likelihood that similar volumes, rather than similar weights, of both low- and high-density products within the same product category are customarily consumed.

The petition and supplemental submission contain information that evidences that similar volumes rather than similar weights of low- and high-density salt products are customarily consumed. Because the products within the category can be measured volumetrically, and the density difference among products within the same product category appear to be significant, FDA has concluded that the petitioner has made a prima facie showing that it is appropriate for the reference amount for salt and salt products to be expressed on a volumetric rather than a gravimetric (i.e., weight) basis.

FDA is proposing to change the reference amount for salt andsalt products from 1 g to 1/4 tsp and to solicit public comment on the proposed change. The agency selected 1/4 tsp because it is the volumetric amount that most closely reflects the amount customarily consumed. It is the smallest volumetric amount permitted in the regulations (21 CFR 101.9(b)(5)(i)). In addition, the 1/4 tsp reference amount will permit comparison with herbs and spices which also have a reference amount of 1/4 tsp.

V. Comments

Interested persons may, on or before October 4, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because there is no cost to industry, the agency certifies that the proposed rule will not have a significant