

properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive (*Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Evaluation of Safety of the Petitioned Use of the Additive

In its original evaluation of acesulfame potassium, FDA concluded that a review of animal feeding studies showed that there is no association between neoplastic disease (cancer) and consumption of this additive (53 FR 28379 at 28380 and 28381, July 28, 1988). No new information has been received that would change that conclusion. Therefore, FDA has evaluated the safety of the petitioned use of acesulfame potassium under the general safety clause, considering all available data.

In determining whether the proposed use of an additive is safe, FDA considers, among other things, whether an individual's estimated daily intake of the additive will be less than the acceptable daily intake established from toxicological information. The agency has established an acceptable daily intake for acesulfame potassium of 15 milligrams per kilogram (mg/kg) of body weight per day (equivalent to 900 mg per person per day (mg/p/d)). The agency described its analysis of the data that led to the establishment of the acceptable daily intake in its original decision on the use of acesulfame potassium (53 FR 28379). The agency has considered consumer exposure to acesulfame potassium resulting from its use in alcoholic beverages, as well as all currently listed uses and other uses in a pending petition. FDA has calculated the 90th percentile estimated daily intake from these combined uses to be 180 mg/p/d, which is well below the acceptable daily intake.

A. Special Conditions Relevant to Use in Alcoholic Beverages

The use of acesulfame potassium as a nonnutritive sweetener in alcoholic beverages (e.g. malt beverages, wine coolers, presweetened cordials and cocktails) may subject the sweetener to conditions other than those considered in the petitions that supported the currently listed uses of this additive. FDA has evaluated data in the subject petition and other information regarding the stability of acesulfame potassium under a variety of conditions that characterize the proposed uses in alcoholic beverages. Based on these data and information, the agency concludes

that acesulfame potassium is stable under the proposed conditions of use.

B. Methylene Chloride

Residual amounts of reactants and manufacturing aids are commonly found as contaminants in chemical products, including food additives. FDA, in its evaluation of the safety of acesulfame potassium, reviewed both the safety of the additive and the chemical impurities that may be present in the additive from the manufacturing process.

In the current manufacturing process for acesulfame potassium, methylene chloride, a carcinogenic chemical, is used as a solvent in the initial step. Subsequently, the product is neutralized, stripped of methylene chloride, and recrystallized from water. Data submitted by the petitioner show that methylene chloride could not be detected in the final product at a limit of detection of 40 parts per billion (ppb).

FDA has recently discussed the significance of the use of methylene chloride in the production of acesulfame potassium. That discussion, published in the **Federal Register** of December 1, 1994 (59 FR 61538, 61540, and 61543), is incorporated into the agency's determination on the subject petition.

Specifically, in evaluating the safety of certain uses of the additive that are currently listed, FDA concluded, using risk assessment procedures, that the estimated upper-bound limit of individual lifetime risk from the potential exposure to methylene chloride resulting from the uses of acesulfame potassium, including the use of acesulfame potassium in alcoholic beverages, is 2.6×10^{-11} , or less than 3 in 100 billion. The agency also concluded that, because of the numerous conservative assumptions used in calculating this estimated upper-bound limit of risk, this upper-bound limit would be expected to be substantially higher than any actual risk (59 FR 61538 at 61539, 61540 at 61542, and 61543 at 61544, December 1, 1994). No new information has been received that would change the agency's previous conclusion (Ref. 1). Therefore, the agency concludes that there is a reasonable certainty of no harm from the exposure to methylene chloride that might result from the proposed use of acesulfame potassium.

In the evaluation described above, the agency also considered whether a specification is necessary to control the amount of potential methylene chloride impurity in acesulfame potassium. FDA concluded that there is no reasonable possibility that methylene chloride will

be present in amounts that present a health concern, and that there would thus be no justification for requiring manufacturers to monitor compliance with a specification (59 FR 61538 at 61539, 61540 at 61542, and 61543 at 61544, December 1, 1994). No new information has been received that would change the agency's previous conclusion. Therefore, the agency affirms its prior determination that a specification for methylene chloride impurity in acesulfame potassium is unnecessary.

III. Conclusion of Safety

FDA has evaluated the data in the petition and other relevant material and concludes that the use of acesulfame potassium in alcoholic beverages is safe. Therefore, the agency concludes that § 172.800 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 2, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a