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By the National Credit Union Administration Board on April 27, 1995.

Becky Baker,
Secretary of the Board.

[FR Doc. 95-10851 Filed 5-2-95; 8:45 am]

BILLING CODE 7530-01-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95-ACE-6]

Proposed Removal of Class E Airspace; St. Louis, MO

AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Final rule.

SUMMARY: This document removes Class E airspace at St. Louis, MO. Weiss Airport at St. Louis, MO, has been abandoned making this necessary.

EFFECTIVE DATE: May 3, 1995.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, ACE-530c, Air Traffic Operations Branch, Federal Aviation Administration, Docket No. 95-ACE-6, 601 East 12th Street, Kansas City, MO 64106; telephone number: (816) 426-3408.

SUPPLEMENTARY INFORMATION:

History

The only SIAP for the airport was cancelled on July 21, 1994, after the airport was abandoned.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace area at St. Louis-Weiss Airport, MO, by removing the controlled airspace.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a

routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; E.O. 10854; 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace areas extending from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 St. Louis, MO [Removed]

Weiss Airport
(Lat. 38°32'13.5" N, long. 90°26'48.6" W)

* * * * *

Herman J. Lyons, Jr.,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 95-10772 Filed 5-2-95; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 93F-0286]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Acesulfame Potassium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acesulfame potassium as

a nonnutritive sweetener in alcoholic beverages. This action is in response to a petition filed by Hoechst Celanese Corp.

DATES: Effective May 3, 1995; written objections and requests for a hearing by June 2, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 10, 1993 (58 FR 47746), FDA announced that a food additive petition (FAP 3A4391) had been filed by Hoechst Celanese Corp., Rt. 202-206 North, Somerville, NJ 08876, proposing that § 172.800 *Acesulfame potassium* (21 CFR 172.800) be amended to provide for the safe use of acesulfame potassium as a nonnutritive sweetener in alcoholic beverages.

I. Determination of Safety

Under Section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause," a food additive cannot be listed for a particular use unless a fair evaluation of the evidence establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of the additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance" (H. Rept. 2284, 85th Cong., 2d sess. 4 (1958)). This concept of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)).

The food additives anticancer, or Delaney, clause (section 409(c)(3)(A) of the act) further provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to constituents of the additive. That is, where an additive has not been shown to cause cancer, even though it contains a carcinogenic impurity, the additive is not subject to the legal effect of the Delaney clause. Rather, the additive is

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

waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Reference

The following reference has 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.

1. Memorandum from M. DiNovi, Chemistry Review Branch, CFSAN, FDA, to P. Hansen, Biotechnology Policy Branch, CFSAN, FDA, dated April 28, 1994.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.800 is amended by adding new paragraph (c)(12) to read as follows:

§ 172.800 Acesulfame potassium.

* * * * *

(c) * * *

(12) Alcoholic beverages.

* * * * *

Dated: April 24, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-10897 Filed 5-2-95; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 95-5-6924; FRL-5190-8]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Mojave Desert Air Quality Management District and San Bernardino County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing the approval of revisions to the California State Implementation Plan (SIP) proposed in the **Federal Register** on January 19, 1995. The revisions concern rules from the Mojave Desert Air Quality Management District (MDAQMD) and the San Bernardino County Air Pollution Control District (SBCAPCD). This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The revised rules control VOC emissions from the loading, transfer, and storage of organic liquids, including gasoline. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

EFFECTIVE DATE: This action is effective on June 2, 1995.

ADDRESSES: Copies of the rules and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are available for inspection at the following locations:

Rulemaking Section (A-5-3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95814.

Mojave Desert Air Quality Management District (formerly San Bernardino County APCD), 15428 Civic Drive,

Suite 200, Victorville, CA 92392-2383.

FOR FURTHER INFORMATION CONTACT: Duane F. James, Rulemaking Section (A-5-3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901, Telephone: (415) 744-1191.

SUPPLEMENTARY INFORMATION:

Background

On January 19, 1995, in 60 FR 3794, EPA proposed to approve the following rules into the California SIP: MDAQMD's Rule 461, "Gasoline Transfer and Dispensing," and Rule 462, "Organic Liquid Loading," and SBCAPCD's Rule 463, "Storage of Organic Liquids" (the NPRM). Rules 461 and 462 were adopted by MDAQMD on May 25, 1994, and Rule 463 was adopted by SBCAPCD on November 2, 1992. These rules were submitted by the California Air Resources Board to EPA on January 11, 1993 (Rule 463) and July 13, 1994 (Rules 461 and 462). These rules were submitted in response to EPA's 1988 SIP-Call and the CAA section 182(a)(2)(A) requirement that nonattainment areas fix their reasonably available control technology (RACT) rules for ozone in accordance with EPA guidance that interpreted the requirements of the pre-amendment Act. A detailed discussion of the background for each of the above rules and nonattainment areas is provided in the NPRM cited above.

EPA has evaluated all of the above rules for consistency with the requirements of the CAA and EPA regulations and EPA interpretation of these requirements as expressed in the various EPA policy guidance documents referenced in the NPRM cited above. EPA has found that the rules meet the applicable EPA requirements. A detailed discussion of the rule provisions and evaluations has been provided in the NPRM and in technical support documents available at EPA's Region IX office, dated July 14, 1994 (Rule 463) and August 26, 1994 (Rules 461 and 462).

Response to Public Comments

A 30-day public comment period was provided in the NPRM. EPA received no comments on Rules 461, 462, and 463.

EPA Action

EPA is finalizing action to approve the above rules for inclusion into the California SIP. EPA is approving the submittal under section 110(k)(3) as meeting the requirements of section 110(a) and Part D of the CAA. This