

under this subpart may not be used to satisfy more than 50 percent of the alternative fueled vehicle requirements of a fleet or covered person under sections 490.201, 490.302 and 490.307, and Title III of the Energy Policy Act of 1992.

(c) A fleet or covered person that is a biodiesel alternative fuel provider described in section 490.303 of this part may use its credits allocated under this subpart to satisfy all of its alternative fueled vehicle requirements under section 490.302.

§ 490.706 Procedure for modifying the biodiesel component percentage.

(a) DOE may, by rule, lower the 20 percent biodiesel volume requirement of this subpart for reasons related to cold start, safety, or vehicle function considerations.

(b) Any person may use the procedures in section 490.6 of this part to petition DOE for a rulemaking to lower the biodiesel volume percentage. A petitioner should include any data or information that it wants DOE to consider in deciding whether or not to begin a rulemaking.

§ 490.707 Increasing the qualifying volume of the biodiesel component.

DOE may increase the qualifying volume of the biodiesel component of fuel for purposes of allocation of credits under this subpart only after it:

(a) Collects data establishing that the average annual alternative fuel use in light duty vehicles by fleets and covered persons exceeds 450 gallons or gallon equivalents; and

(b) Conducts a rulemaking to amend the provisions of this subpart to change the qualifying volume to the average annual alternative fuel use.

§ 490.708 Violations.

Violations of this subpart are subject to investigation and enforcement under subpart G of this part.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM152; Special Conditions No. 25-144-SC]

Special Conditions: Boeing Model 717-200 Airplane; Operation Without Normal Electrical Power

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Boeing Model 717-200 airplane. This airplane will have novel or unusual design features associated with its electronic flight and engine control systems. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

EFFECTIVE DATE: June 18, 1999.

FOR FURTHER INFORMATION CONTACT: Gerry Lakin, FAA, Standardization Branch, ANM-113, Transport Standards Staff, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055-4056; telephone (425) 227-1187, facsimile (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Background

On August 8, 1994, the Los Angeles Aircraft Certification Office received an application from the McDonnell Douglas Corporation, now a wholly owned subsidiary of The Boeing Company, informing the FAA of their intention to seek an amendment to FAA Type Certificate No. A6WE to add the new Model MD-95-30, which was later renamed the Boeing Model 717-200.

The Boeing Model 717-200 is a derivative of the DC-9/MD-80/MD-90 series of airplanes, Type Certificate No. A6WE, and is scheduled to be certificated in September 1999. The Boeing Model 717-200 is a low-wing, pressurized airplane with twin, body-mounted, jet engines that is configured for approximately 100 passengers. The airplane has a maximum takeoff weight of 121,000 pounds, a maximum landing weight of 104,000 pounds, a maximum operating altitude of 37,000 feet, and a range of 1500 nautical miles at a cruise speed of Mach 0.76. The overall length of the Boeing Model 717-200 is 124 feet, the height is 29 feet, 1 inch, and the wing span is 93 feet, 4 inches. Features have been added to the Boeing Model 717-200 to provide cost-efficient performance and decreased crew workload. These features include an advanced flight compartment, BMW/Rolls-Royce BR715 engines, an advanced auxiliary power unit (APU), advanced environmental systems, and an updated interior.

The advanced flight compartment includes an electronic instrument system, with six liquid crystal displays,

to show navigation, engine, and system data. For decreased crew workload, the Boeing Model 717-200 has a flight management system and an autoflight system, with Category IIIa autoland capability. A central fault display system allows maintenance personnel access to fault data to perform return-to-service tests.

The Boeing Model 717-200 is equipped with two electronically controlled BMW/Rolls-Royce BR715 high-bypass ratio engines capable of supplying up to 21,000 pounds of thrust. For reverse thrust, the engine has fixed pivot door type thrust reversers.

The advanced APU is a simple design with a single-stage compressor and turbine. The APU uses modular components for increased reliability and decreased maintenance and is controlled by an electronic control unit.

The Boeing Model 717-200 has a simplified pneumatic system to supply bleed-air for the airplane systems. The dual cabin pressure control system has automatic control, with a manual backup.

The passenger compartment interior has overhead stowage compartments, forward and aft lavatories, and two forward service galleys. The interior also has a full-grip lighted handrail attached to the overhead stowage compartments, for safety and convenience. Class C cargo compartments are located in the lower forward and aft ends of the airplane.

Type Certification Basis

Under the provisions of § 21.101, The Boeing Company must show that the Model 717-200 meets the applicable provisions of the regulations incorporated by reference in Type Certificate No. A6WE or the applicable regulations in effect on the date of application for the change to the Model 717-200. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The regulations incorporated by reference in Type Certificate No. A6WE are as follows:

The type certification basis for the Boeing Model 717-200 airplane is 14 CFR part 25, effective February 1, 1965, as amended by Amendments 25-1 through 25-82, except for certain reversion to earlier amendments for parts of the airplane not affected by these special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25 as amended) do not contain adequate or appropriate safety standards for the Boeing Model 717-200 because of a novel or unusual design feature,

special conditions are prescribed under the provisions of § 21.16.

In addition, to the applicable airworthiness regulations and special conditions, the Model 717-200 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

Special conditions, as appropriate, are issued in accordance with § 11.49 after public notice, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The Boeing Model 717-200 will incorporate the following novel or unusual design features:

The Boeing Model 717-200 airplane will utilize electronic flight and engine control systems that establish the criticality of the electrical power generation and distribution systems. Since the loss of all electrical power may be catastrophic to the airplane, a special condition is proposed to retain the level of safety envisioned by § 25.1351(d).

The Boeing Model 717-200 airplane will require a continuous source of electrical power in order for the electronic flight instrument system to remain operable. Section § 25.1351(d), "Operation without normal electrical power," requires safe operation in visual flight rule (VFR) conditions for a period of not less than five minutes with inoperative normal power. This rule was structured around a traditional design utilizing analog/mechanical flight instrumentation, which allows the crew to sort out the electrical failure, start engine(s) if necessary, and re-establish some of the electrical power generation capability. However, with today's aircraft, complex electronic/avionics systems are now performing critical functions that may require uninterrupted electrical power for continued safe flight (in instrument meteorological conditions (IMC)) and landing.

In addition, § 121.161 states that an operator may fly a twin-engine airplane

over a route that allows up to one-hour flying time from a suitable airport. If Boeing seeks operational approval for extended over water operations, with a possible diversion time of one hour, the emergency power system must be capable of providing at least one hour of operation to critical and essential systems. If, however, Boeing intends to exclude extended over water operations, then only 30 minutes of emergency power will be required.

In order to maintain the same level of safety associated with traditional designs, the Boeing Model 717-200 design must provide at least 30 minutes of emergency power without the normal source of engine or APU generated electrical power. It should be noted that service experience has shown that the loss of all electrical power generated by the airplane's engine generators or APU is not extremely improbable. Thus, it must be demonstrated that the airplane can continue through safe flight and landing with only the use of its emergency electrical power systems. These emergency electrical power systems must be able to power loads that are essential for continued safe flight and landing. The emergency electrical power system must be designed to:

1. Continue to operate the airplane for immediate safety without the need for crew action following the loss of the normal engine (which includes APU power) generator electrical power system,
2. Supply electrical power required for continued safe flight and landing, and
3. Supply electrical power required to restart the engines.

For compliance purposes a test demonstration of the loss of normal engine generator power is to be established such that:

1. The failure condition is assumed to occur during night IMC at the most critical phase of the flight relative to the electrical power system design and distribution of equipment loads on the system.
2. The airplane engine restart capability must be provided and operations continued in IMC after the unrestorable loss of normal engine generator power.
3. The airplane is demonstrated to be capable of continuous safe flight and landing. The length of time must be computed based on the maximum diversion time capability for which the airplane is being certified. Consideration for speed reductions resulting from the associated failure must be made.
4. The availability of APU operation should not be considered in

establishing emergency power system adequacy.

Discussion of Comments

Notice of Proposed Special Conditions No. 25-99-01-SC for the Boeing Model 717-200 series airplanes was published in the **Federal Register** on March 25, 1999 (64 FR 14408). One commenter responded and had no objection to the special conditions. The special conditions are adopted as proposed.

Applicability

As discussed above, these special conditions are applicable to Boeing Model 717-200 airplanes. Should the McDonnell Douglas Corporation, now a wholly owned subsidiary of The Boeing Company apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain novel or unusual design features on Boeing Model 717-200 airplanes. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 717-200 airplanes.

1. *Operation Without Normal Electrical Power.* In lieu of compliance with § 25.1351(d), "It must be demonstrated by test, or combination of test and analysis, that the airplane can continue safe flight and landing with inoperative normal engine and APU generator electrical power (electrical power sources excluding the battery and any other standby electrical sources). The airplane operation must be considered at the critical phase of flight and include the ability to restart the engines and maintain flight for the maximum diversion time capability being certified."

Issued in Renton, Washington on May 11, 1999.

Donald E. Gonder,

*Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service,
ANM-100.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 95F-0191]

Indirect Food Additives: Polymers

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 polyestercarbonate resins produced by the condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride. The finished resins are composed of 45 to 85 mole percent ester, of which up to 55 mole percent is the terephthaloyl isomer, as articles or components of articles in contact with food. This action responds to a petition filed by the General Electric Co.

DATES: This regulation is effective May 19, 1999; written objections and requests for a hearing by June 18, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 31, 1995 (60 FR 39000), FDA announced that a food additive petition (FAP 5B4470) had been filed by the General Electric Co., 1 Lexan Lane, Mt. Vernon, IN 47620-9364. The petition proposed to amend the food additive regulations in § 177.1585

Polyestercarbonate resins (21 CFR 177.1585) to provide for the safe use of polyestercarbonate resins produced by the condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride. The finished

resins are composed of 45 to 85 percent ester, of which up to 55 percent is the terephthaloyl isomer, as articles or components of articles in contact with food. (The agency will subsequently use mole-percent to describe these resins because this term better describes the resin composition.)

In its evaluation of the safety of this food additive, FDA has reviewed the safety of the additive itself, the starting materials used, and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain residual amounts of methylene chloride, which has been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as methylene chloride, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The food additives anticancer, or Delaney, clause of the act (409(c)(3)(A)) 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 the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, polyestercarbonate resins, as food packaging, will not significantly increase the overall exposure to polyestercarbonate oligomers, monomers, *p*-cumylphenol, and methylene chloride above the exposure from the currently regulated

uses of these polyestercarbonate resins (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive use of which will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure resulting from the petitioned use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by methylene chloride, the carcinogenic chemical that may be present as an impurity in the additive. This risk evaluation of methylene chloride has two aspects: (1) Assessment of exposure to the impurity from the petitioned use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Methylene Chloride

FDA has estimated the exposure to methylene chloride from the petitioned and regulated uses of polyestercarbonate resins as articles intended to contact food to be no more than 4.9 parts per billion in the daily diet (3 kilogram), or 15 micrograms per person per day (Ref. 1). The agency used data in the National Toxicology Program Report No. 306 (January 1986), on inhalation studies in F344/N rats and B6C3F₁ mice to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned and regulated uses of the additive (Ref. 3). The authors reported that the test material caused an increased incidence of liver cell neoplasms and lung neoplasms in both male and female B6C3F₁ mice.

Based on the agency's estimate that exposure to methylene chloride will not exceed 15 micrograms/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the regulated and petitioned uses of the polyestercarbonate resins is 1×10^{-7} or 1 in 10 million (Ref. 4). Because of numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to methylene chloride is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the