area, and repairs or replacement, if necessary.

Since this unsafe condition may exist or develop on other airplanes of the same type design equipped with a non-ventral aft pressure bulkhead, this AD requires repetitive high frequency eddy current inspection of the 5910163–91 and –92 attach tee, coupled with repetitive optically aided visual inspections of the attach tee from the aft side of the bulkhead, and repair or replacement, if necessary. Subsequent inspections are also required after any repair or replacement. Additionally, affected operators are required to remove sealant from the inspection area prior to inspection.

The requirements of this AD differ from and replace the requirements of AD 88–13–09 for airplanes equipped with non-ventral aft pressure bulkheads by: (1) Deleting the option for low frequency eddy current inspections from the forward side of the bulkhead; (2) lowering the initial inspection threshold called out in AD 88–13–09 to 25,000 landings; (3) eliminating the interim repair provided by that AD; and (4) eliminating the optional inspections from the forward side of the bulkhead.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The FAA is currently preparing a similar action to address revised inspection requirements for Model DC–9 series airplanes equipped with a ventral aft pressure bulkhead. However, the proposed compliance time would not preclude a period for public comment. (Therefore, that action will appear as a Notice of Proposed Rulemaking.)

The regulations adopted herein will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required).

**List of Subjects in 14 CFR Part 39**

Aviation safety, Aircraft.

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

**PART 39—[AMENDED]**

1. The authority citation for Part 39 continues to read as follows:

**Authority:** 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

**§ 39.13 [Amended]**

2. By adding the following new airworthiness directive:

**McDonnell Douglas:** Applies to Model DC–9–10 through –30 series and C–9 (Military) series airplanes, equipped with a non-ventral aft pressure bulkhead, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent cracks which could result in structural failure of the nonventral aft ventral pressure bulkhead, accomplish the following:

A. Prior to the accumulation of 25,000 landings or within 500 landings after the effective date of this AD, whichever occurs later, inspect the aft pressure bulkhead attach tee section, in accordance with the following procedures.

1. Remove any sealant from inspection area of the tee section that might hinder optically aided and high frequency eddy current inspections. Clean dirt, grease, and all foreign materials from inspection area using lint-free wipers and 1,1,1 trichloroethane solvent or equivalent;

2. Using an optically aided visual inspection technique, inspect the 5910163–89, –93, –94, and –95 attach tees from the aft side of the bulkhead, in accordance with McDonnell Douglas Alert Service Bulletin A53–231, dated February 24, 1989 (hereinafter referred to as ASB53–231). Repeat this inspection thereafter at interval not to exceed 1,500 landings; and

3. Using a high frequency eddy current inspection technique, in accordance with ASB53–231, inspect the 5910163–91 and –92 attach tees from the aft side of the bulkhead. Repeat this inspection thereafter at intervals not to exceed 500 landings.

B. If cracks are found, prior to further flight, replace the cracked tee cap or repair by splicing in a section of tee cap with a new like or improved part, in accordance with McDonnell Douglas Service Rework Drawings SR09530001, Revision C, dated August 18, 1987, and SR09530001, Revision "Advance D", dated October 29, 1987. Prior to the accumulation of 25,000 landings after the repair or replacement, resume the repetitive inspections in accordance with paragraph A., above.

C. Compliance with the requirements of this AD constitutes terminating action for the requirements of AD 88–13–09, Amendment 39–5954, relating to airplanes equipped with non-ventral aft pressure bulkheads.

**Note.**—The requirements of AD 88–13–09 relating to airplanes with ventral aft pressure bulkheads are not affected by this AD.

D. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

**Note.**—The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who may add any comments then send it to the Manager, Los Angeles Aircraft Certification Office.

E. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes unpressurized to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director of Publications, C1–L00 (54–60). These documents may be examined at FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or 3229 East Spring Street, Long Beach, California.

This amendment becomes effective March 24, 198.

Issued in Seattle, Washington, on February 24, 1989.

**Darrell M. Pederson,**

*Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 89–5910 Filed 3–14–89; 8:45 am]

BILLING CODE 4910–13–M

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**14 CFR Part 39**

**[Docket No. 89–NM–04–AD; Amdt. 39–6151]**

## Airworthiness Directives; Avions Marcel Dassault-Breguet Aviation (AMD–BA) Model Mystere Falcon 50 and 900 Series Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to certain Avions Marcel Dassault-Breguet Aviation (AMD–BA) Model Mystere Falcon 50 and 900 series airplanes, which requires repetitive inspections of the main landing gear (MLG) door emergency release mechanism to detect broken or damaged unlocking pins, and replacement of the pins, if necessary. This amendment is prompted by reports of the MLG door emergency unlocking pin breaking due to fatigue failure. This condition, if not corrected, could prevent emergency extension of the MLG.

**EFFECTIVE DATE:** March 24, 1989.

**ADDRESSES:** The applicable service information may be obtained from Falcon Jet Corporation, 777 Terrace Avenue, Hasbrouck Heights, New Jersey 07604. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

**FOR FURTHER INFORMATION CONTACT:** Mr. Adriano Pasion, Standardization Branch, ANM–113; telephone (206) 431–1977. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C–68966, Seattle, Washington 98168.

**SUPPLEMENTARY INFORMATION:** The Direction Générale de L'Aviation Civile (DGAC), which is the airworthiness authority of France, has notified the FAA of an unsafe condition which may exist on certain Avions Marcel Dassault Breguet Aviation (AMD–BA) Model Mystere Falcon 50 and 900 series airplanes. There have been two reports of the MLG door emergency unlocking pin breaking due to fatigue failure. This condition, if not corrected, could prevent emergency extension of the MLG.

The DGAC has issued French Airworthiness Directive 88–140–006(B)R1, dated December 28, 1988, which contains procedures for repetitive inspection of the main landing gear door emergency release mechanism for a broken or damaged unlocking pin, and replacement of the pins, if necessary.

This airplane model is manufactured in France and type certificated in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD requires repetitive inspections of the MLG door emergency release mechanism for a broken or damaged unlocking pin, and replacement, if necessary.

Since a condition exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required).

**List of Subjects in 14 CFR Part 39**

Aviation safety, Aircraft.

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

1. The authority citation for Part 39 continues to read as follows:

**Authority:** 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

**Avions Marcel Dassault Breguet Aviation (AMD–BA):** Applies to Model Mystere Falcon 50 and 900 series airplanes, certificated in any category, equipped with emergency unlocking levers part numbers:

—for Mystere Falcon 50:
F50B793600160 or 160A1 or 161 or 161A1—LH side
F50B793700160 or 160A1 or 161 or 161A1—RH side

—for Mystere Falcon 900:
FGFB793600160 or 160A2 or 161 or 161A2 or F50B793600160A1 or 161 or 161A1—LH side
FGFB793700160 or 160A2 or 161 or 161A2 or F50B793700160A1 or 161 or 161A1—RH side.

Compliance is required as indicated, unless previously accomplished.

To prevent inability to open the main landing gear (MLG) door for MLG emergency extension, accomplish the following:

A. Prior to the accumulation of 1,000 landings on the MLG door emergency unlocking pin, or within 7 days after the effective date of this AD, whichever occurs later, verify the integrity of the MLG door emergency unlocking system by operating the manual opening system, in accordance with the instructions in the AMD–BA Falcon 50 or 900 series (as applicable) Maintenance Manual, Work Card 480.0, paragraph 3.

1. If the unlocking pin is broken or damaged, replace the pin with a serviceable pin of the same part number prior to further flight.

2. If the unlocking pin is not damaged, repeat the inspection prior to accumulation of 2,000 landings. Replace broken or damaged pins in accordance with paragraph A.1., above.

B. Upon the accumulation of 2,000 or more landings on the MLG door emergency unlocking pin, repeat the inspection described in paragraph A., above, at intervals not to exceed 50 landings from last inspection. Replace broken or damaged pins in accordance with paragraph A.1., above.

C. Following the replacement of any unlocking pin with a new pin, repeat the inspection required by paragraphs A. and B., above, at the intervals specified. Replace broken or damage pins in accordance with paragraph A.1., above.

D. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM–113, FAA, Northwest Mountain Region.

**Note.**—The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who may add any comments and then send it to the Manager, Standardization Branch, ANM–113.

E. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of the inspections required by this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to Falcon Jet Corporation, 777 Terrace Avenue, Hasbrouck Height, New Jersey 07604. This information may be examined at FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East

Marginal Way South, Seattle, Washington.

This amendment becomes effective March 24, 1989.

Issued in Seattle, Washington, on February 24, 1989.

**Darrell M. Pederson,**

*Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 89-5908 Filed 3-14-89; 8:45 am]

BILLING CODE 4910-13-M

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

### 14 CFR Part 1215

### Tracking and Data Relay Satellite System (TDRSS)

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Final rule.

**SUMMARY:** NASA is amending 14 CFR Part 1215, "Tracking and Data Relay Satellite System (TDRSS)," by revising Appendix A to reflect the estimated service rates in 1990 dollars for TDRSS standard services, based on NASA escalation estimates. 14 CFR Part 1215 sets forth the policy governing the Tracking and Data Relay Satellite System (TDRSS) services provided to non-U.S. Government users and the reimbursement for rendering such services. The TDRSS represents a major investment by the U.S. Government with the primary goal of providing improved tracking and data acquisition services to spacecraft in low earth orbit or to terrestrial users.

**EFFECTIVE DATE:** March 15, 1989.

**ADDRESS:** Office of Space Operations, Code T, NASA Headquarters, Washington, DC 20546.

**FOR FURTHER INFORMATION CONTACT:** Eugene Ferrick, 202-453-2030.

**SUPPLEMENTARY INFORMATION:** The existing regulation was published in the **Federal Register** on March 9, 1983 (48 FR 9845). Each year since that time, 14 CFR Part 1215 has been amended by revising Appendix A to reflect the rate changes for the appropriate calendar years (CY). Since this revision of Appendix A to 14 CFR Part 1215 reflects the rate changes for CY 1990 and involves NASA management procedures and decisions, no public comment is required.

The National Aeronautics and Space Administration has determined that this rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612, since it will not exert a significant economic impact on a substantial number of small entities, and it is not a major rule as defined in Executive Order 12291.

**List of Subjects in 14 CFR Part 1215**

Satellites, Tracking and Data Relay Satellite System, Communications equipment, Government contract.

### PART 1215—TRACKING AND DATA RELAY SATELLITE SYSTEM (TDRSS)

For reasons set out in the Preamble, 14 CFR Part 1215 is amended as follows:

1. The authority citation for 14 CFR Part 1215 continues to read as follows:

**Authority:** Sec. 203, Pub. L. 85-568, 72 Stat. 429, as amended; 42 U.S.C. 2473.

2. Appendix A is revised to read as follows:

**Appendix A—Estimated Service Rates in 1990 Dollars for TDRSS Standard Services (Based on NASA Escalation Estimate)**

TDRSS user service rates for services rendered in CY-90 based on current projections in 1990 dollars are as follows:

*Single Access Service*—Forward command, return telemetry, or tracking, or any combination of these, the base rate is $164.00 per minute for non-U.S. Government users.

*Multiple Access Forward Service*—Base rate is $36.00 per minute for non-U.S. Government users.

*Multiple Access Return Service*—Base rate is $11.00 per minute for non-U.S. Government users.

**Robert O. Aller,**

*Associate Administrator for Space Operations.*

[FR Doc. 89-5970 Filed 3-14-89; 8:45 am]

BILLING CODE 7510-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 176

**[Docket No. 85F-0400]**

### Indirect Food Additives: Paper and Paperboard Components

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of $C_{15}$-$C_{21}$ groups. This action responds to a petition by Chevron Chemical Co.

**DATES:** Effective March 15, 1989; written objections and requests for a hearing by April 14, 1989.

**ADDRESS:** Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of September 19, 1985 (50 FR 38035) FDA announced that a food additive petition (FAP 5B3878) had been filed by Chevron Chemical Co., 575 Market St., P.O. Box 3744, San Francisco, CA 94119, proposing that § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) be amended to provide for the safe use of a mixture of substituted polyethylene glycol succinates in the manufacture of paper and paperboard used in contact with dry food.

FDA, in its evaluation of the safety of this additive, has reviewed the proposed nomenclature for the additive and the safety of both the additive and the starting materials used to manufacture the additive. The agency concludes that a more appropriate name for this additive is mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in Which the alkenyl groups are derived from olefins that contain not less than 95 percent of $C_{15}$-$C_{21}$ groups. The agency also finds that although the additive has not been found to cause cancer, it may contain minute amounts of ethylene oxide and 1,4-dioxane as impurities carried through the production process. Ethylene oxide and 1,4-dioxane have been shown to cause cancer in test animals. Residual amounts of reactants and impurities in reactants, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

**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" of the statute, 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. 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 an 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 definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the Federal Register of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

## II. Safety of Petitioned Use

FDA estimates that the petitioned use in paper and paperboard products that contact dry food of the additive mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of $C_{15}$–$C_{21}$ groups will result in levels of exposure to this additive that are quite small. FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing here. However, the agency has reviewed available acute and subchronic studies in the rat and a mutagenicity test with the additive. No adverse effects were reported in these studies.

As stated above, the additive may Contain 1,4-dioxane and ethylene oxide, substances that have been shown to cause cancer in test animals. These impurities may be present as a result of impurities in reactants used to produce the additive. Because the additive itself has not been shown to cause cancer, however, the anticancer clause does not apply.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemicals, 1,4-dioxane and ethylene oxide, that may be present as impurities in the additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that the agency has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (49 FR 13018; April 2, 1984). This risk evaluation of the carcinogenic impurities has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

### *A. 1,4-Dioxane*

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of $C_{15}$ $C_{21}$ groups, and assuming 100 percent migration of the 1,4-dioxane that could be present in the paper containing the additive, FDA estimated the hypothetical worst-case exposure to 1,4-dioxane to be 4.5 nanograms per person per day (Ref. 5). The agency used data from a carcinogenesis bioassay on 1,4-dioxane conducted for the National Cancer Institute (Ref. 4) to estimate the upper bound level of lifetime human risk from the exposure to this impurity that might result from the proposed use of the additive. The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee (the Committee) reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The Committee further concluded that the 1,4-dioxane bioassay provided the appropriate basis on which to calculate an estimate of the upper bound level of lifetime risk from potential exposure to 1,4-dioxane stemming from the proposed use of the additive.

The agency used a quantitative risk assessment procedure ( linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine, to a reasonable certainty, whether any harm will result from the proposed conditions and levels of use of the food additives.

Based on a worst-case exposure of 4.5 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from the potential exposure to 1,4-dioxane from use of the subject additive is $1.6 \times 10^{-10}$, or less than 2 in 10 billion (Ref. 6). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and, therefore, the calculated upper bound limit of risk would be less. Thus the agency concludes that there is a reasonable certainty of no harm from the exposure to 1,4-dioxane that might

result from the proposed use of the additive.

*B. Ethylene Oxide*

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of $C_{15}$–$C_{21}$ groups (Ref. 5), FDA estimated the hypothetical worst-case exposure to ethylene oxide from the use of the additive to be 4.5 nanograms per person per day. The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Federal Republic of Germany (Ref. 3), to estimate the upper bound level of lifetime human risk from the exposure to this impurity that might result from the proposed use of the additive. The results of the bioassay on ethylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinoma of the forestomach and carcinoma in situ of the glandular stomach.

The Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on ethylene oxide. The Committee further concluded that the ethylene oxide bioassay provided the appropriate basis on which to calculate an estimate of the upper bound level of lifetime risk from potential exposure to ethylene oxide stemming from the proposed use of the additive.

Based on a worst-case exposure of 4.5 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from the potential exposure to ethylene oxide from the use of the subject additive is $8 \times 10^{-9}$, or less than 8 in 1 billion (Ref. 6). Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake, and, therefore, the calculated upper bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that might result from the proposed use of the additive.

## III. Need for Specifications

The agency has also considered whether specifications are necessary to control the amounts of 1,4-dioxane and ethylene oxide in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which 1,4-dioxane and ethylene oxide may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely low levels; and (2) the upper bound limit of lifetime risk from exposure to these impurities, even under worst-case assumptions, is very low, less than 2 in 10 billion for 1,4-dioxane and less than 8 in 1 billion for ethylene oxide.

## IV. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of the additive in paper and paperboard products in contact with dry food is safe, and that § 176.180 (21 CFR 176.180) 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.

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 April 14, 1989 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. References

The following references have 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. Carr, G.M., "Carcinogenicity Testing Programs," *in* "Food Safety: Where Are We?" Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, p. 59, July 1979.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology," *in* "Chemical Safety Regulation and Compliance," Edited by F. Homburger and J.K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

3. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide Upon Intragastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

4. "Bioassay of 1,4-Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI–CG–TR–80, 1978.

5. Memorandum dated November 3, 1987, from Food and Color Additives Review Section to Indirect Additives Branch, "FAP 5B3878—Chevron Chemical Co.—Alkenyl Polyethylene Glycol Succinate as an Emulsifier in Paper and Paperboard."

6. Memorandum dated June 21, 1988, from the Quantitative Risk Assessment Committee to the Office of Toxicological Sciences, Ethylene Oxide and 1,4-Dioxane Impurities (FAP 5B3878).

## List of Subjects in 21 CFR Part 176

Food additives, Food packaging, Paper and paperboard.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 176 is amended as follows:

## PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR Part 176 continues to read as follows:

**Authority:** Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 176.180 is amended in paragraph (b)(2) by alphabetically adding a new entry in the table under the headings "List of substances" and "Limitations" to read as follows:

**§ 176.180 Components of paper and paperboard in contact with dry food.**

* * * * *

(b) * * *
(2) * * *

| List of substances | Limitations |
|---|---|
| * * * * * | |
| Mono- and di(2-alkenyl)succinyl esters of polyethylene glycol containing not less than 90 percent of the diester product and in which the alkenyl groups are derived from olefins that contain not less than 95 percent of $C_{15}$–$C_{21}$ groups. | For use only as an emulsifier. |
| * * * * * | |

Dated: March 7, 1989.

**Richard J. Ronk,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 89–5994 Filed 3–14–89; 8:45 am]

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## 21 CFR Part 177

**[Docket No. 87F–0360]**

## Indirect Food Additives: Polymers

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polyoxyethylene-grafted polydimethylsiloxane as an extrusion aid in the production of olefin polymers for food contact. This action is in response to a petition filed by Union Carbide Corp.

**DATES:** Effective March 15, 1989; written objections and requests for a hearing by April 14, 1989.

**ADDRESS:** Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of December 15, 1987 (52 FR 47637), FDA announced that a food additive petition (FAP 7B4041) had been filed by Union Carbide Corp., Bound Brook, NJ 08805, proposing that § 177.1520 *Olefin polymers* (21 CFR 177.1520) be amended to provide for the safe use of polyoxyethylene-grafted polydimethylsiloxane as an extrusion aid in the production of olefin polymers for use in contact with food.

FDA, in its evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. Although polyoxyethylene-grafted polydimethylsiloxane has not been found to cause cancer, it may contain minute amounts of ethylene oxide and 1,4-dioxane as impurities from its production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and byproducts, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

### 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" of the statute, 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. 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 an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. No. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic chemicals but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

### II. Safety of Petitioned Use

FDA estimates that the petitioned use of polyethylene-grafted polydimethylsiloxane will result in extremely low levels of exposure to this additive. The agency calculated the estimated daily intake of the additive based on considerations such as the migration of the additive under the most severe intended use conditions and the types of food-contact articles that may contain this substance. The agency estimated the daily intake for the additive to be 428 micrograms per person per day.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive