

02, dated May 28, 1998; or McDonnell Douglas Alert Service Bulletin MD90-25A019, dated February 11, 1997; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1-L51 (2-60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on June 13, 2000.

Issued in Renton, Washington, on April 19, 2000.

Donald L. Riggan,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-10288 Filed 5-8-00; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 30029; Amdt. No. 422]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace

System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

EFFECTIVE DATE: 0901 UTC, June 10, 2000.

FOR FURTHER INFORMATION CONTACT:

Donald P. Pate, Flight Procedure Standards Branch (AMCAFS-420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and

safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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. It, therefore—(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. For the same reason, the FAA certifies that this amendment 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 95

Airspace Navigation (air).

Issued in Washington, D.C. on May 3, 2000.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC.

PART 95—[AMENDED]

1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS

[Amendment 422 Effective Date: June 15, 2000]

Table with 3 columns: From, To, MEA. It lists two sets of color routes: Amber Federal Airway 7 and Blue Federal Airway 2, with specific route examples and their Minimum En Route Altitudes (MEA).

REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS—Continued

[Amendment 422 Effective Date: June 15, 2000]

From	To	MEA
*4,100—MOCA Hotham, AK NDB	Tin City, AK NDB/DME	*5,000
*4,300—MOCA Tin City, AK NDB/DME	Fort Davis, AK NDB	*7,000
*5,900—MOCA		
Color Routes		
§ 95.60 Blue Federal Airway 4 Is Added To Read		
Bishop, AK NDB	Utopia Creek, AK NDB	*7,000
*5,900—MOCA Utopia Creek, AK NDB	Evansville, AK NDB	*8,000
Evansville, AK NDB	Yukon River, AK NDB	*8,000
*6,600—MOCA		
Color Routes		
§ 95.60 Blue Federal Airway 5 Is Added To Read		
Cape Lisburne, AK NDB/DME	Point Hope, AK NDB	4,000
Color Routes		
§ 95.60 Blue Federal Airway 8 Is Added To Read		
Tin City, AK NDB/DME	Shishmaref, AK NDB	4,000
Color Routes		
§ 95.4 Green Federal Airway 1 Is Added To Read		
Mount Moffett, AK NDB/DME	Horth, AK FIX	8,000
*2,500—MOCA Horth, AK FIX	Mordi, AK FIX	*8,000
Mordi, AK FIX	Elfee, AK NDB	*8,000
Color Routes		
§ 95.4 Green Federal Airway 4 Is Added To Read		
Borland, AK NDB/DME	Woody Island, AK NDB	*10,000
Color Routes		
§ 95.4 Green Federal Airway 4 Is Added To Read		
Wood River, AK NDB	Iliamna, AK NDB/DME	*4,500
*3,000—MOCA		
Color Routes		
§ 95.56 Green Federal Airway 16 Is Added To Read		
Point Lay, AK NDB	Wainwright Village, AK NDB	*1,700
*1,200—MOCA Wainwright Village, AK NDB	Browerville, AK NDB	*1,600
*1,100—MOCA Browerville, AK NDB	Nuiqsut Village, AK NDB	1,600
Nuiqsut Village, AK NDB	Put River, AK NDB	*1,700
*1,200—MOCA		
Color Routes		
§ 95.57 Green Federal Airway 17 Is Added To Read		
Wainwright Village, AK NDB	Atqasuk, AK NDB	*1,600
*1,100—MOCA		
Color Routes		
§ 95.58 Green Federal Airway 18 Is Added To Read		
Hotham, AK NDB	Point Lay, AK NDB	*10,000
*6,000—MOCA 0 Point Lay, AK NDB	Atqasuk, AK NDB	2,300
Color Routes		
§ 95.20 Red Federal Airway 1 Is Added To Read		
St Paul Island, AK NDB/DME	Garrs, AK FIX	*4,600

REVISIONS TO IFR ALTITUDES AND CHANGEOVER POINTS—Continued

[Amendment 422 Effective Date: June 15, 2000]

From	To	MEA
*2,700—MOCA Garrs, AK FIX	Saldo, AK NDB	4,600
Color Routes		
§ 95.20 Red Federal Airway 2 Is Added To Read		
Elfee, AK NDB	Port Heiden, AK NDB/DME	6,000
§ 95.6001 Victor Routes—U.S.		
§ 95.6004 VOR Federal Airway 4 Is Amended To Read in Part		
Saden, MO FIX	St Louis, MO VORTAC	*2,400
*1,700—MOCA		
§ 95.6013 VOR Federal Airway 13 Is Amended To Read in Part		
Farmington, MN VORTAC	*Wagnr, MN FIX	5,500
*5,500—MRA		
Wagner, MN FIX	Cinci, MN FIX	5,500
§ 95.6077 VOR Federal Airway 77 Is Amended To Read in Part		
Topeka, KS VORTAC	St Joseph, MO VORTAC	3,000
§ 95.6159 VOR Federal Airway 159 Is Amended To Read in Part		
Vero Beach, FL VORTAC	*Presk, FL FIX	2,900
*2,500—MRA		
Presk, FL FIX	Orlando, FL VORTAC	*2,100
*1,500—MOCA		
§ 95.6189 VOR Federal Airway 189 Is Amended To Read in Part		
Wright Brothers, NC VOR/DME	Darez, NC FIX	*6,000
*1,300—MOCA		
Darez, NC FIX	Tar River, NC VORTAC	*4,000
*2,600—MOCA		
§ 95.6222 VOR Federal Airway 222 Is Amended To Read in Part		
Lake Charles, LA VORTAC	Maxon, LA FIX	*2,000
*1,500—MOCA		
Maxon, LA FIX	*Wrack, LA FIX	**6,000
*3,000—MRA		
**1,600—MOCA		
Wrack, LA FIX	Mc Comb, MS VORTAC	*3,000
*2,000—MOCA		
§ 95.6469 VOR Federal Airway 469 Is Amended To Read in Part		
Relee, VA FIX	Exras, VA FIX	*8,000
*5,200—MOCA		
Exras, VA FIX	Brucy, VA FIX	*10,000
*6,100—MOCA		
§ 95.6552 VOR Federal Airway 552 Is Amended To Read in Part		
Lake Charles, LA VORTAC	Hatha, LA FIX	*2,000
*1,500—MOCA		
Hatha, LA FIX	Lafayette, LA VORTAC	2,800
§ 95.6412 Hawaii VOR Federal Airway 12 Is Amended To Read in Part		
Maggi, HI FIX	*Shark, HI FIX	NE BND
*16,000—MRA	
**1,200—MOCA	

From	To	MEA	MAA
§ 95.7001 Jet Routes			
§ 95.7056 Jet Route No. 56 Is Amended To Read in Part			
Salt Lake City, UT VORTAC # MEA is established with a Gap in navigation signal coverage.	HAYDEN, CO VOR/DME	25000	45000
§ 95.7600 Jet Route No. 600 Is Added To Read			
Mount Moffett, AK NDB/DME	EL/FEE, AK NDB	18000	45000
§ 95.7601 Jet Route No. 601 Is Added To Read			
Port Heiden, AK NDB/DME	Cold Bay, AK VORTAC	18000	45000
Cold Bay, AK VORTAC	St Paul Island, AK NDB/DME	18000	45000
§ 95.7603 Jet Route No. 603 Is Added To Read			
Elfee, AK NDB	Dillingham, AK VOR/DME	18000	45000
§ 95.7604 Jet Route No. 604 Is Added To Read			
Borland, AK NDB/DME	Woody Island, AK NDB	18000	45000
§ 95.7605 Jet Route No. 605 Is Added To Read			
Biorka Island, AK VORTAC	Middleton Island, AK VOR/DME	23000	45000
§ 95.7606 Jet Route No. 606 Is Added To Read			
St Paul Island, AK NDB/DME	Saldo, AK NDB	180000	45000
§ 95.7617 Jet Route No. 617 Is Added To Read			
Homer, AK VORTAC	Johnstone Point, AK VORTAC	18000	45000
§ 95.7619 Jet Route No. 619 Is Added To Read			
Cape Newenham, AK NDB	St Paul Island, AK NDB/DME	18000	45000
§ 95.7711 Jet Route No. 711 Is Added To Read			
Sitka, AK NDB	Laire, AK FIX	18000	45000
Laire, AK FIX	Hinchinbrook, AK NDB	18000	45000
From	To	Changeover Points	
		Distance	From
§ 95.8005 Jet Routes Changeover Points Airway Segment Is Added to Read			
Homer, AK VORTAC	J627 Johnstone Pointe AK VORTAC	63	Homer
95.1001 Direct Routes—U.S. Changover Points Color Routes Airway Segment is Added to Read			
Campbell Lake, AK NDB	A7 Mineral Creek, AK NDB	69	Campbell Lake
Cape Lisburne, AK NDB	B2 Hotham, AK NDB	57	Cape Lisburne
Browerville, AK NDB	G16 Nuiqsut, AK NDB	82	Browerville, AK NDB
Hotham, AK NDB	G18 Point Lay, AK NDB	96	Hotham, AK, NDB
Point Lay, AK NDB	Atqasuk, AK NDB	50	Point Lay, AK NDB

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F-1019]

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 polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid as a component of cap liners used on bottles in contact with food. This action responds to a petition filed by BF Goodrich Specialty Chemicals.

DATES: This rule is effective May 9, 2000. Submit written objections and requests for a hearing by June 8, 2000.

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: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of November 30, 1998 (63 FR 65793), FDA announced that a food additive petition (FAP 8B4631) had been filed by BF Goodrich Specialty Chemicals, 9911 Brecksville Rd., Cleveland, OH 44141. The petition proposed to amend the food additive regulations in § 177.1210 *Closures with sealing gaskets for food containers* (21 CFR 177.1210) to provide for the safe use of polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid as a component of cap liners used on bottles in contact with food.

In its evaluation of the safety of these resins, 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 dianiline (MDA), which has been shown to cause cancer in test animals. MDA is produced when diphenylmethane diisocyanate (MDI), a starting material used in the manufacture of polyurethane resins, reacts with water. Residual amounts of reactants and manufacturing aids, such as MDA, 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 (section 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

The petitioner determined the levels of three migrants extracted from the additive, polyurethane resins manufactured from MDI, 1,4-butanediol, and adipic acid. These three migrants were 1,4-butanediol, oligomers of the additive, and MDA (the hydrolysis product of MDI). FDA agrees that the determination of the levels of these three types of migrants are appropriate to evaluate the safe use of the additive. FDA estimates that the petitioned use of the additive will result in exposure to 1,4-butanediol of not more than 90 micrograms per person per day ($\mu\text{g}/\text{p}/\text{d}$) while exposure to the other two migrants will be even lower (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use 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 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 MDA, the carcinogenic chemical that may be present as an impurity in the additive. This risk evaluation of MDA 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 Dianiline

FDA has estimated the exposure to MDA from the petitioned use of the additive in the manufacture of cap liners intended to contact food to be no more than 4.1 parts per trillion in the daily diet, or 0.012 $\mu\text{g}/\text{p}/\text{d}$ (Refs. 1 and 5). The agency used data from a bioassay of MDA, sponsored by the National Toxicology Program, to estimate the upper-bound limit of lifetime human risk from exposure to MDA that may result from the proposed use of the additive (Ref. 3). The bioassay report showed that MDA ingestion produced tumors at multiple sites in both sexes of rats and mice.

Based on the agency's estimate that exposure to MDA will not exceed 0.012 $\mu\text{g}/\text{p}/\text{d}$, FDA estimates that the upper-bound limit of lifetime human risk for MDA from the petitioned use of the subject additive is 1×10^{-8} or 1 in 100 million (Ref. 4). Because of numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to MDA 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 agency concludes that there is reasonable certainty that no harm from exposure to MDA would result from the petitioned use of the additive.

B. Need for Specifications

The agency also has considered whether specifications are necessary to control the amount of MDA present as an impurity in the additive. The agency finds that the specifications are not necessary for the following reasons: (1)