

Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001-NE-50-AD]

RIN 2120-AA64

Airworthiness Directives; Dowty Aerospace Propellers Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 Propeller Assemblies

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to supersede an existing airworthiness directive (AD), applicable to Dowty Aerospace Propellers Type R334/4-82-F/13 propeller assemblies. That AD currently requires a one-time ultrasonic inspection of propeller hubs part number (P/N) 660709201 for cracks. This proposal would require initial and repetitive ultrasonic inspections of propeller hubs P/N 660709201, that are installed on airplanes, and for hubs and propellers in storage, initial ultrasonic inspection of propeller hubs before placing in service. Propeller hubs P/N 660709201 are installed on Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 propeller assemblies. This proposal is prompted by the manufacturer's reevaluation of potential hub failure on Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 propeller assemblies. The actions specified by the proposed AD are intended to prevent propeller hub failure due to cracks in the hub, which could result in loss of control of the airplane.

DATES: Comments must be received by June 27, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel,

Attention: Rules Docket No. 2001-NE-50-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may be inspected at this location, by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: *9-ane-adcomment@faa.gov*. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in the proposed rule may be obtained from Dowty Propellers, Anson Business Park, Cheltenham Road East, Gloucester GL 29QN, UK; telephone 44 (0) 1452 716000; fax: 44 (0) 1452 716001. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Frank Walsh, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate, telephone (781) 238-7158, fax (781) 238-7170.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action

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must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2001-NE-50-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001-NE-50-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

Discussion

On January 18, 2002, the FAA issued AD 2002-01-28, Amendment 39-12623 (67 FR 4351, January 30, 2002), to require a one-time ultrasonic inspection for cracks of the rear wall of the rear half of propeller hubs P/N 660709201, installed in Type R334/4-82-F/13 propeller assemblies. The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom (UK), notified the FAA that an unsafe condition may exist on Dowty Aerospace Propellers Type R334/4-82-F/13 propeller assemblies. The CAA advises that two different events occurred where the complete R334/4-82-F/13 propeller separated from the engine flange, on Construcciones Aeronauticas, S.A. (CASA) 212 airplanes.

Since AD 2001-01-28 was issued, the manufacturer has reevaluated the potential for P/N 660709201 hub failure on Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 propeller assemblies.

Manufacturer's Service Information

Dowty Aerospace Propellers has issued Mandatory Service Bulletin (MSB) No. 61-1119, Revision 3, dated March 8, 2002, MSB No. 61-1124, Revision 1, dated October 8, 2002, MSB No. 61-1125, Revision 1, dated October 9, 2002, and MSB No. 61-1126, Revision 1, dated October 9, 2002, that specify initial and repetitive ultrasonic inspections of the rear wall of the rear half of the propeller hub for cracks on Types R334/4-82-F/13, R333/4-82-F/12, R321/4-82-F/8, and R324/4-82-F/9 propeller assemblies, respectively. The CAA classified these service bulletins as mandatory and issued CAA UK AD No. 003-11-2001, dated November 30, 2001, in order to assure the airworthiness of

these Dowty Aerospace Propellers in the UK.

Differences Between This AD and the Manufacturer's Service Information

Although Appendix A of MSB No. 61-1119, Revision 3, dated March 8, 2002, MSB No. 61-1124, Revision 1, dated October 8, 2002, MSB No. 61-1125, Revision 1, dated October 9, 2002, and MSB No. 61-1126, Revision 1, dated October 9, 2002, require reporting the inspection data to Dowty Aerospace Propellers, this AD requires that the data be reported to the Boston Aircraft Certification Office of the FAA.

Bilateral Agreement Information

These propeller models are manufactured in the UK and are Type certificated for operation in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this Type design that are certificated for operation in the United States.

Proposed Requirements of This AD

Since an unsafe condition has been identified that is likely to exist or develop on other Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 propeller assemblies of the same Type design that are used on airplanes registered in the United States, the proposed AD would require initial and repetitive ultrasonic inspections of propeller hubs P/N 660709201, that are installed on airplanes, and for hubs and propellers in storage, initial ultrasonic inspection of propeller hubs before placing in service. Propeller hubs P/N 660709201 are installed on Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 propeller assemblies. The actions would be required to be done in accordance with the mandatory service bulletins described previously.

Economic Analysis

There are approximately 116 airplanes with propellers of the affected design in the worldwide fleet. The FAA estimates that 10 airplanes with Type R334/4-82-F/13 propeller assemblies installed on airplanes of U.S. registry would be affected by this proposed AD. It is unknown how many Type R321/4-82-F/8, R324/4-82-F/9, and R333/4-

82-F/12 propeller assemblies are installed on airplanes of U.S. registry. The FAA also estimates that it would take approximately 11 work hours per propeller to perform one inspection and replacement, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$1,650 per propeller. Based on these figures, the total cost of the proposed AD to known U.S. operators is estimated to be \$46,200.

Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39-12623, (67 4351, January 30, 2002), and by adding a new airworthiness directive:

Dowty Aerospace Propellers: Docket No. 2001-NE-50-AD. Supersedes AD 2002-01-28, Amendment 39-12623.

Applicability: This airworthiness directive (AD) is applicable to Dowty Aerospace Propellers Type R321/4-82-F/8, R324/4-82-F/9, R333/4-82-F/12, and R334/4-82-F/13 propeller assemblies with propeller hubs part number (P/N) 660709201. These propeller assemblies are installed on, but not limited to, Construcciones Aeronauticas, S.A. (CASA) 212, British Aerospace Regional Aircraft Jetstream Models 3101 and 3201, Merlin IIIC, and Merlin IVC/Metro III airplanes.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Compliance with this AD is required as indicated, unless already done.

To prevent propeller hub failure due to cracks in the hub, which could result in loss of control of the airplane, do the following:

Initial Ultrasonic Inspection

(a) Within 50 flight hours time-in-service (TIS) after the effective date of this AD, or within 60 days after the effective date of this AD, whichever occurs earlier, perform an initial ultrasonic inspection of the rear wall of the rear half of the propeller hub for cracks in accordance with Appendix A of the applicable Dowty Aerospace Propellers Mandatory Service Bulletin (MSB) listed in the following Table 1:

TABLE 1.—APPLICABLE MSB FOR PROPELLER TYPE

Propeller assembly type	Applicable MSB
(1) R334/4-82-F/13.	MSB No. 61-1119, Revision 3, dated March 8, 2002.
(2) R333/4-82-F/12.	MSB No. 61-1124, Revision 1, dated October 8, 2002.
(3) R321/4-82-F/8.	MSB No. 61-1125, Revision 1, dated October 9, 2002.
(4) R324/4-82-F/9.	MSB No. 61-1126, Revision 1, dated October 9, 2002.

(b) For hubs and propellers in storage, perform an initial ultrasonic inspection of the rear wall of the rear half of the propeller hub for cracks, before placing in service, in accordance with Appendix A of the applicable Dowty Aerospace Propellers Mandatory Service Bulletin (MSB) listed in Table 1 of this AD.

(c) Propeller hubs P/N 660709201 used on Type R334/4-82-F/13 propeller assemblies

that have been previously inspected using Dowty Aerospace Propellers MSB No. 61-1119, Revision 3, dated March 8, 2002, or earlier issue, are considered to be in compliance with paragraph (a) of this AD.

Repetitive Ultrasonic Inspections

(d) Thereafter, within 1,000 flight hours TIS after each ultrasonic inspection, perform an ultrasonic inspection of the rear wall of the rear half of the propeller hub for cracks in accordance with Appendix A of the applicable Dowty Aerospace Propellers MSB listed in Table 1 of this AD.

Inspection Reporting Requirements

(e) For each inspection, record the inspection data on a copy of Appendix B of the applicable MSB listed in Table 1 of this AD, and report the findings to the Manager, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299 within 10 days after the inspection. Reporting requirements have been approved by the Office of Management and Budget (OMB) and assigned OMB control number 2120-0056.

Alternative Methods of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Boston Aircraft Certification Office. Operators must submit their request through an appropriate FAA principal Maintenance Inspector, who may add comments and then send it to the Manager, Boston Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Boston Aircraft Certification Office.

Special Flight Permits

(g) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

Note 3: The subject of this AD is addressed in CAA UK AD 003-11-2001, dated November 30, 2001.

Issued in Burlington, Massachusetts, on April 22, 2003.

Robert Guyotte,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03-10334 Filed 4-25-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 107

[Docket No. 95N-0309]

RIN 0910-AA04

Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 27, 2003, the comment period for the proposed rule, published in the **Federal Register** of July 9, 1996 (61 FR 36154), revising its infant formula regulations in 21 CFR parts 106 and 107. The proposed rule would establish requirements for current good manufacturing practice (CGMP) and audits, establish requirements for quality factors, and amend its quality control procedures, notification, and records and reports requirements for infant formula. FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit written or electronic comments by June 27, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-435-1491, or e-mail: Shellee.Anderson@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Reopening of Comment Period

In the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed regulations (the 1996 proposal) to revise its infant formula regulations to establish requirements for quality factors and CGMP; to amend its quality control procedure, notification, and records and report requirements for infant formulas; to require that infant formulas contain, and be tested for,

required nutrients and for any nutrient added by the manufacturer throughout their shelf life, and that they be produced under strict microbiological controls; and to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design. The agency proposed these requirements to implement provisions of the Drug Enforcement, Education and Control Act of 1986 (Public Law 99-570) that amended section 412 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a).

Interested persons were originally given until October 7, 1996, to comment on the 1996 proposal. However, at the request of a trade organization, the comment period was extended to December 6, 1996 (61 FR 49714, September 23, 1996).

FDA's Food Advisory Committee (FAC) met on April 4 and 5, 2002, to discuss general scientific principles related to quality factors for infant formula. The committee was also asked to discuss the scientific issues related to the generalization of findings from a clinical study using preterm infant formula consumed by preterm infants to a term infant formula intended for use by term infants. On November 18 and 19, 2002, the Infant Formula Subcommittee (IFS) of the FAC met to discuss the scientific issues and principles involved in assessing and evaluating whether a "new" infant formula supports normal physical growth in infants when consumed as a sole source of nutrition. The Contaminants and Natural Toxicants Subcommittee (CNTS) of the FAC met on March 18 and 19, 2003, to discuss the scientific issues and principles involved in assessing and evaluating *Enterobacter sakazakii* contamination in powdered infant formula, risk reduction strategies based on available data, and research questions and priorities. Information on these three meetings, including the agenda, questions asked, guest speakers, committee roster, briefing information, and transcripts of the meetings can be found at <http://www.fda.gov/ohrms/dockets/ac/cfsan02.htm>.

II. Request for Comments

Because of the length of time that has elapsed since publication of the 1996 proposal and the occurrence of the FAC, IFS, and CNTS meetings, FDA is interested in updating comments and receiving any new information before issuing a final rule. Accordingly, the agency is requesting comments on all