

Issued in Fort Worth, Texas, on December 3, 1999.
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-SW-77-AD]

Airworthiness Directives; Eurocopter Deutschland GMBH Model MBB-BK 117 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Eurocopter Deutschland Model MBB-BK 117 helicopters. This proposal would change the retirement life for the tail rotor (output) drive bevel gear (bevel gear). This proposal is prompted by a fatigue analysis of the bevel gear conducted by the manufacturer due to installation of different tail rotor blades. The actions specified by the proposed AD are intended to prevent fatigue failure of the bevel gear, loss of tail rotor drive, and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before February 8, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 98-SW-77-AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Shep Blackman, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222-5296, fax (817) 222-5961.

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 notice 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 notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 98-SW-77-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 98-SW-77-AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for the Federal Republic of Germany, has notified the FAA that an unsafe condition may exist on Eurocopter Deutschland Model MBB-BK117 helicopters. The LBA advises that the working life of the tail rotor (output) drive unit of the main transmission has been recalculated, requiring the introduction of a life limitation of 18,500 hours time-in-service (TIS) on the bevel gear, part number 117-12215-01.

Eurocopter Deutschland GMBH has issued Eurocopter Deutschland GMBH Alert Service Bulletin MBB-BK 117 No. ASB-MBB-BK 117-10-113, dated September 30, 1997, which specifies entering a life limitation in the accessory replacement record and historical record "Main Transmission" section not later than December 31, 1997. The LBA classified this service bulletin as mandatory and issued AD No. 97-350, dated December 18, 1997, in order to assure the continued airworthiness of these helicopters in the Federal Republic of Germany.

This helicopter model is manufactured in the Federal Republic of Germany and is 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 LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, 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.

Since an unsafe condition has been identified that is likely to exist or develop on other Eurocopter Deutschland Model MBB-BK117 helicopters of the same type design registered in the United States, the proposed AD would require entering a recalculated life limitation for the bevel gear in the accessory replacement record and historical record "Main Transmission" section, determining the total operating time of the bevel gear, and replacing the bevel gear upon reaching the life limit of 18,500 hours TIS.

Cost Impact

The FAA estimates that 130 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 0.5 work hour per helicopter to change the retirement life in the records, and 36 work hours to replace the bevel gear. The average labor rate is \$60 per work hour. Required parts would cost approximately \$14,092 per helicopter. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$2,116,660 to change the retirement life entry and to replace the bevel gear upon reaching 18,500 hours TIS for the entire fleet.

Regulatory Impact

The regulations proposed herein would not impose substantial direct compliance costs on any states or local government or 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 13132, the FAA has not consulted with any states or local authorities prior to publication of the 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 adding a new airworthiness directive to read as follows:

Eurocopter Deutschland: Docket No. 98-SW-77-AD.

Applicability: Model MBB-BK 117 helicopters, serial numbers 7001 through 7250 and 7500 through 7509, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopter that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue failure of the tail rotor (output) drive bevel gear (bevel gear), loss of tail rotor drive, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 100 hours time-in-service (TIS):
 (1) Record in the accessory replacement record and historical record "Main Transmission" section the retirement life of 18,500 hours TIS for the bevel gear.

(2) Determine the total hours TIS of the bevel gear. If the total hours TIS cannot be determined, use the operating time of the main transmission.

(b) If the bevel gear's total hours TIS is equal to or greater than 18,400 hours TIS, remove the bevel gear within the next 100 hours TIS and replace it with an airworthy bevel gear. If the bevel gear's total hours TIS is less than 18,400 hours TIS, remove the bevel gear on or before 18,500 hours TIS and replace it with an airworthy bevel gear.

(c) This AD revises the helicopter Airworthiness Limitations section of the maintenance manual by establishing a new retirement life for the bevel gear of 18,500 hours TIS.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through a FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Luftfahrt-Bundesamt (Federal Republic of Germany) AD No. 97-350, dated December 18, 1997.

Issued in Fort Worth, Texas, on December 3, 1999.

Henry A. Armstrong,
Manager, Rotorcraft Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, and 510

[Docket No. 99N-4957]

Removal of Designated Journals; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to

remove its regulation that lists the veterinary and scientific journals available in FDA's library. The purpose of the list is to allow individuals to reference articles from listed journals in the new animal drug application (NADA) documents submitted to the Dockets Management Branch, and objections and requests for a hearing on a regulation or order instead of submitting a copy or reprint of the article. FDA is taking this action because this list of journals is outdated and because individuals rarely use the regulation. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. If FDA receives significant adverse comments about the direct final rule, it will be withdrawn, and the comments will be considered in the development of a final rule using usual notice-and-comment rulemaking based on this proposed rule.

DATES: Submit written comments on or before February 23, 2000. If FDA receives any significant adverse comment regarding this rule, FDA will publish in the **Federal Register** a document withdrawing the companion direct final rule within 30 days after the comment period ends. If FDA does not receive any significant adverse comment, the agency intends to publish in the **Federal Register** a document confirming the effective date of the final rule within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective April 24, 2000.

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

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0205.

SUPPLEMENTARY INFORMATION:

I. Background

FDA proposes to remove 21 CFR 510.95 *Designated journals*. This regulation lists veterinary and scientific journals available in FDA's library. It permits waiving submission of reprints and summaries of articles from listed journals. FDA is taking this action because the regulation has rarely been used, the list of journals is outdated, and FDA does not believe it to be a wise expenditure of its resources to update the list and to have reviewers retrieve copies of referenced journals from its library, given the minimal burden on individuals to submit copies. Because