

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2015-0673; Directorate Identifier 2014-SW-034-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters (Previously Eurocopter France)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters. This proposed AD would require inspecting the swashplate assembly rotating star to determine whether a ferrule was installed. If a ferrule exists, this proposed AD would require inspecting the rotating star for a crack and removing any cracked rotating star. This proposed AD is prompted by a report that reconditioning the rotating swashplate per a certain repair procedure could result in the rotating star cracking. The proposed actions are intended to detect a crack in the rotating star and prevent failure of the rotating star and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by May 26, 2015.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.
- *Fax:* 202-493-2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.
- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD

docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Airbus Helicopters, Inc., 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at <http://www.airbushelicopters.com/techpub>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-0673.

FOR FURTHER INFORMATION CONTACT:

Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222-5110; email robert.grant@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, issued EASA AD No. 2014-0132R1, dated June 2, 2014, to correct an unsafe condition for Airbus Helicopters (previously Eurocopter France) Model AS 350 B, BA, BB, B1, B2, B3, D, AS 355 E, F, F1, F2, N, NP, EC 130 B4, and T2 helicopters if equipped with a swashplate assembly with a rotating star, part number (P/N) 350A371003-04, P/N 350A371003-05, P/N 350A371003-06, P/N 350A371003-07, or P/N 350A371003-08. EASA advises that during a repair of a helicopter, it was discovered that rotating swashplates reconditioned in accordance with a certain repair procedure could experience a high stress level. This condition, if not corrected, could affect the service life of the part. To address this unsafe condition, EASA AD No. 2014-0132R1 requires repetitive inspections and replacement of the rotating star.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 14 CFR Part 51

We reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. EC130 62A010 for Model EC130B4 and EC130T2 helicopters; ASB No. AS355 62.00.33 for Model AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters; and ASB No. AS350 62.00.34 for Model AS350B, AS350BA, AS350BB, AS350B1, AS350B2, AS350B3, AS350D, and military version AS350L1 helicopters; all Revision 0 and all dated April 28, 2014.

The ASBs report that a certain repair sheet instruction, which requires reconditioning the rotating swashplate by machining and adding a steel ferrule to accommodate a swashplate bearing, potentially affects the service life limit specified in the airworthiness limitations section. The ASBs provide procedures for inspecting the swashplate assembly's rotating star for a ferrule and if a ferrule exists, inspecting

for a crack. The ASBs call for replacing the rotating star before further flight if a crack exists, and before December 31, 2014, if a ferrule is present and there are no cracks. If there is no ferrule, the ASBs require no additional action. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

Proposed AD Requirements

This proposed AD would require, within 165 hours time-in-service (TIS), visually inspecting the swashplate assembly to determine whether a ferrule is installed with the rotating star. If no ferrule exists, no further action would be needed. If a ferrule is installed, the proposed AD would require, before further flight, dye-penetrant inspecting the rotating star for a crack. The proposed AD would also require removing the rotating star and all attachment hardware before further flight if the rotating star has a crack, or within 160 hours TIS if the rotating star has a ferrule installed but does not have a crack.

This proposed AD would also prohibit installing a rotating star with a ferrule.

Differences Between This Proposed AD and the EASA AD

The EASA AD requires reporting inspection findings to Airbus Helicopters. This proposed AD would make no such requirement. The EASA AD does not apply to Airbus Model AS350C and AS350D1 helicopters, whereas this proposed AD would apply to those models. The EASA AD applies to Model AS350BB helicopters, and this proposed AD would not because that model is not type certificated in the United States. The EASA AD would require replacing the rotating star, unless already accomplished, by December 31, 2014, while we would require replacing the rotating star within 160 hours TIS, unless already accomplished.

Costs of Compliance

We estimate that this proposed AD would affect 1,132 helicopters of U.S. Registry and that labor costs would average \$85 a work hour. Based on these estimates, we would expect the following costs:

- Visually inspecting the swashplate assembly would require 0.25 work-hour for a labor cost of about \$21 per inspection. No parts would be needed for a total cost of about \$21 per

inspection per helicopter, or about \$23,772 for the U.S. fleet.

- Dye-penetrant inspecting the rotating star would require 1 work-hour for a labor cost of about \$85 per helicopter. No parts would be needed for a total cost of \$85 per inspection helicopter and \$96,220 for the U.S. fleet.

- Replacing the rotating star, ferrule, and associated parts would require 16 work hours and parts would cost \$8,354, for a total cost of \$9,714 per helicopter.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD 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.

For the reasons discussed, I certify 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);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. 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.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus Helicopters: Docket No. FAA-2015-0673; Directorate Identifier 2014-SW-034-AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters with a swashplate assembly with rotating star, part number (P/N) 350A371003-04, 350A371003-05, 350A371003-06, 350A371003-07, or 350A371003-08, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a rotating star in a main rotor blade (M/R) swashplate assembly. This condition could result in loss of the M/R pitch control and subsequent loss of helicopter control.

(c) Comments Due Date

We must receive comments by May 26, 2015.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 165 hours time-in-service (TIS), visually inspect the swashplate assembly to determine whether a ferrule is installed on the rotating star. If the ferrule is not visible, use a magnetic retriever positioned in Area (X) as shown in the pictures under paragraph 3.B.2.b., Accomplishment Instructions, of Airbus Helicopters Alert Service Bulletin (ASB) No. EC130 62A010, ASB No. AS350 62.00.34, or ASB No. AS355 62.00.33, all Revision 0, and all dated April 28, 2014, whichever is applicable to your helicopter, to determine whether the ferrule is installed. The magnetic retriever will be magnetized if a ferrule is installed.

(2) If a ferrule is not installed, no further action is needed.

(3) If a ferrule is installed on the rotating star, before further flight, dye-penetrant inspect the rotating star for a crack in areas "Z" depicted in Figure 1 of Airbus Helicopters ASB No. EC130 62A010, ASB No. AS350 62.00.34, or ASB No. AS355 62.00.33, all Revision 0, and all dated April 28, 2014, as applicable to your model helicopter.

(i) If the rotating star has a crack, before further flight, remove from service the rotating star; ferrule; and the screws, washers and nuts used to attach the pitch change rods, compass, and the rotating star deflector.

(ii) If the rotating star does not have a crack, within 160 hours TIS, remove from service the rotating star; ferrule; and the screws, washers and nuts used to attach the pitch change rods, compass, and the rotating star deflector.

(4) Do not install a rotating star P/N 350A371003-04, 350A371003-05, 350A371003-06, 350A371003-07, or 350A371003-08 with a ferrule.

(f) Special Flight Permit

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222-5110; email robert.grant@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

The subject of this AD is addressed in the European Aviation Safety Agency (EASA) AD No. 2014-0132R1, dated June 2, 2014. You may view the EASA AD on the Internet at <http://www.regulations.gov> in the AD Docket.

(i) Subject

Joint Aircraft Service Component (JASC)
Code: 6200, Main Rotor System.

Issued in Fort Worth, Texas, on March 18, 2015.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.
[FR Doc. 2015-06805 Filed 3-26-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2015-N-0540]

Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain information and comments from stakeholders about the current use of human drug and biological products labeled as homeopathic, as well as the Agency's regulatory framework for such products. These products include prescription drugs and biological products labeled as homeopathic and over-the-counter (OTC) drugs labeled as homeopathic. FDA is seeking participants for the public hearing and written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, health care professionals, patient groups, and industry. FDA is seeking input on a number of specific questions, but is interested in any other pertinent information participants would like to share.

DATES: The public hearing will be held on April 20 and 21, 2015, from 9 a.m. to 4 p.m. The meeting may be extended or may end early depending on the level of public participation. Register to attend or provide oral testimony at the hearing by April 13, 2015. See Registration and Request to Provide Oral Testimony for information on how to register or make an oral presentation at the hearing. Written or electronic comments will be accepted until June 22, 2015.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503A, Silver Spring, MD, 20993-0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Lesley DeRenzo, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 240-402-4612, FAX: 301-847-8747, Lesley.derenzo@fda.hhs.gov; or Cynthia Ng, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-7512, FAX: 301-847-8747, cynthia.ng@fda.hhs.gov.

Registration and Request to Provide Oral Testimony: The public hearing is free and seating will be on a first-come, first-served basis. If you wish to attend or make an oral presentation, see section III (Attendance and/or Participation in the Public Hearing) for information on how to register and the deadline for registration. If you cannot attend in person, information about how you can access a live Webcast will be located at <https://collaboration.fda.gov/hprapril2015/>.

Comments and Transcripts: You may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You should annotate and organize your comments to identify the specific questions or topic to which they refer. It is only necessary to send one set of comments. Please identify your comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts of the hearing will be available for review at the Division of Dockets Management and at <http://www.regulations.gov> approximately 45 days after the hearing. You may submit a request to obtain a hard copy or CD-ROM transcript. Send your request to the Division of Freedom of Information (ELEM-1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: FDA is evaluating its current enforcement policies for drug products labeled as homeopathic from scientific, risk, and process perspectives. The Agency is now soliciting opinions about whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace over the last approximately 25 years.