Proposed Rules

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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. FAA-2006-25658; Directorate Identifier 2006-NM-054-AD]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) that applies to certain Airbus Model A318, A319, A320, and A321 airplanes. The existing AD currently requires repetitive detailed inspections of the inboard flap trunnions for any wear marks and of the sliding panels for any cracking at the long edges; and corrective actions if necessary. This proposed AD would add airplanes to the applicability in the existing AD and change the inspection type. This proposed AD results from a determination that certain airplanes must be included in the applicability of the AD, and that the inspection type must be revised. We are proposing this AD to detect and correct wear of the inboard flap trunnions, which could lead to loss of flap surface control and consequently result in the flap detaching from the airplane. A detached flap could result in damage to the tail of the airplane.

DATES: We must receive comments on this proposed AD by September 21, 2006.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

• DOT Docket Web site: Go to http://dms.dot.gov and follow the instructions for sending your comments electronically.

- Government-wide rulemaking Web site: Go to http://www.regulations.gov and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.
 - Fax: (202) 493-2251.
- Hand Delivery: Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2125; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the ADDRESSES section. Include the docket number "Docket No. FAA—2006—25658; Directorate Identifier 2006—NM—054—AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to http:// dms.dot.gov, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit http:// dms.dot.gov.

Examining the Docket

You may examine the AD docket on the Internet at http://dms.dot.gov, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the ADDRESSES section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Discussion

On February 6, 2006, we issued AD 2006-04-06, amendment 39-14487 (71 FR 8439, February 17, 2006), for certain Airbus Model A318-100 series airplanes, Model A319-100 series airplanes, Model A320-111 airplanes, Model A320-200 series airplanes, and Model A321–100 series airplanes. That AD requires repetitive detailed inspections of the inboard flap trunnions for any wear marks and of the sliding panels for any cracking at the long edges; and corrective actions if necessary. That AD resulted from reports of wear damage to the inboard flap trunnions after incorporation of a terminating modification required by an earlier AD, which was superseded by AD 2006-04-06. We issued that AD to detect and correct wear of the inboard flap trunnions, which could lead to loss of flap surface control and consequently result in the flap detaching from the airplane. A detached flap could result in damage to the tail of the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 2006–04–06, we determined that we inadvertently excluded Airbus Model A321–200 airplanes from the applicability of the existing AD. This proposed AD emulates the French airworthiness directive by listing Airbus Model A318, A319, A320, and A321 airplanes in lieu of including the dash numbers, as done in the existing AD.

In addition, in the existing AD we identified the inspection in paragraph (g) of the AD as a "detailed" inspection. Upon further review of the service bulletin, we have determined that the appropriate inspection type is "general visual." We have revised paragraph (i) and the inspection definition in Note 4 of this proposed AD accordingly.

We have changed paragraph (i) of the existing AD, paragraph (j) of this proposed AD, by adding the words "if damaged" to clarify that replacing the sliding panel is required at the specified time if that condition is found.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in France 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. As described in this bilateral airworthiness agreement, the Direction Générale de l'Aviation Civile (DGAC) has kept the FAA informed of the situation described above. We have examined the DGAC's findings, evaluated all pertinent information, and determined that AD action is necessary for airplanes of this type design that are certificated for operation in the United States.

This proposed AD would supersede AD 2006–04–06 and would continue to

require repetitive inspections of the inboard flap trunnions for any wear marks and of the sliding panels for any cracking at the long edges; and corrective actions if necessary. This proposed AD would also add airplanes to the applicability of the existing AD, and would change the inspection type from detailed to general visual.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S registered airplanes	Fleet cost
Modification in AD 2006–04–06.	14	\$80	The manufacturer states that it will supply required parts to operators at no cost.	\$1,120	755	\$845,600
Detailed inspection in AD 2006–04–06.	2	80	None	\$160, per inspection cycle	755	120,800
General visual inspection (new action).	1	80	None	\$80, per inspection cycle	741	59,280

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 have 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 above, I certify that the 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. 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 a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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 Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–14487 (71 FR 8439, February 17, 2006) and adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA-2006-25658; Directorate Identifier 2006-NM-054-AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by September 21, 2006.

Affected ADs

(b) This AD supersedes AD 2006–04–06.

Applicability

(c) This AD applies to Airbus Model A318, A319, A320, and A321 airplanes; certificated in any category; on which Airbus Modification 26495 has been incorporated in production.

Unsafe Condition

(d) This AD results from a determination that certain airplanes must be included in the applicability of the AD, and that the inspection type must be revised. We are issuing this AD to detect and correct wear of the inboard flap trunnions, which could lead to loss of flap surface control and consequently result in the flap detaching from the airplane. A detached flap could result in damage to the tail of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Restatement of Requirements of AD 2006–04–06

Modification

(f) For Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model

A320–111 airplanes; Model A320–211, –212, –214, –231, 232, and –233 airplanes; and Model A321–111, –112, and –131 airplanes; except those on which Airbus Modification 26495 has been accomplished in production: Within 18 months after January 8, 2001 (the effective date of AD 2000–24–02, amendment 39–12009), modify the sliding panel driving mechanism of the flap drive trunnions, in accordance with Airbus Service Bulletin A320–27–1117, Revision 02, dated January 18, 2000.

Note 1: Accomplishment of the modification required by paragraph (f) of this AD before January 8, 2001, in accordance with Airbus Service Bulletin A320–27–1117, dated July 31, 1997; or Revision 01, dated June 25, 1999, is acceptable for compliance with that paragraph.

Detailed Inspections

(g) For Model A318-111 and -112 airplanes; Model A319-111, -112, -113. -114, -115, -131, -132, and -133 airplanes; Model A320-211, -212, -214, -231, -232, and -233 airplanes; and Model A321-111, –112, and –131 airplanes; on which Airbus Modification 26495 has been incorporated in production: At the latest of the times specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, do a detailed inspection of the inboard flap trunnions for any wear marks and of the sliding panels for any cracking at the long edges, and do any corrective actions, as applicable, by accomplishing all of the applicable actions specified in the Accomplishment Instructions of Airbus Service Bulletin A320-57-1133, dated July 28, 2005; except as provided by paragraph (m) of this AD. Any corrective actions must be done at the compliance times specified in Figures 5 and 6, as applicable, of the service bulletin; except as provided by paragraphs (j), (k), and (l) of this AD. Repeat the inspection thereafter at intervals not to exceed 4,000 flight hours until the inspection required by paragraph (i) of this AD is done.

Note 2: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

- (1) Before accumulating 4,000 total flight hours on the inboard flap trunnion since new.
- (2) Within 4,000 flight hours after accomplishing paragraph (f) of this AD.
- (3) Within 600 flight hours after March 24, 2006 (the effective date of AD 2006–04–06).

New Requirements of This AD

Modification

(h) For Model A321–211 and –231 airplanes, except those on which Airbus Modification 26495 has been accomplished in production: Within 18 months after the effective date of this AD, modify the sliding panel driving mechanism of the flap drive trunnions, in accordance with Airbus Service Bulletin A320–27–1117, Revision 02, dated January 18, 2000.

Note 3: Accomplishment of the modification required by paragraph (h) of this AD before the effective date of this AD, in accordance with Airbus Service Bulletin A320–27–1117, dated July 31, 1997; or Revision 01, dated June 25, 1999, is acceptable for compliance with that paragraph.

General Visual Inspections

(i) For all airplanes: At the time specified in paragraph (i)(1) or (i)(2) of this AD, as applicable, do a general visual inspection of the inboard flap trunnions for any wear marks and of the sliding panels for any cracking at the long edges, and do all applicable corrective actions, by accomplishing all of the applicable actions specified in the Accomplishment Instructions of Airbus Service Bulletin A320-57-1133, dated July 28, 2005; except as provided by paragraph (m) of this AD. All corrective actions must be done at the compliance times specified in Figures 5 and 6, as applicable, of the service bulletin; except as provided by paragraphs (j), (k), and (l) of this AD. Repeat the inspection thereafter at intervals not to exceed 4,000 flight hours. Accomplishment of the general visual inspection required by this paragraph terminates the detailed inspection requirement of paragraph (g) of this AD.

Note 4: For the purposes of this AD, a general visual inspection is: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

- (1) For airplanes on which the detailed inspection required by paragraph (g) of this AD has been done before the effective date of this AD: Inspect before accumulating 4,000 total flight hours on the inboard flap trunnion since new, or within 4,000 flight hours after accomplishing the most recent inspection required by paragraph (g) of this AD, whichever occurs later.
- (2) For airplanes other than those identified in paragraph (i)(1) of this AD: Inspect at the latest of the times specified in paragraphs (i)(2)(i), (i)(2)(ii), and (i)(2)(iii) of this AD.
- (i) Before accumulating 4,000 total flight hours on the inboard flap trunnion since new
- (ii) Within 4,000 flight hours after accomplishing paragraph (f) of this AD.
- (iii) Within 600 flight hours after the effective date of this AD.

Compliance Times

(j) Where Airbus Service Bulletin A320–57–1133, dated July 28, 2005, specifies

replacing the sliding panel at the next opportunity if damaged, replace it within 600 flight hours after the inspection required by paragraph (g) or (i) of this AD, as applicable.

(k) If any damage to the trunnion is found during any inspection required by paragraph (g) or (i) of this AD, do the corrective actions specified in the service bulletin before further flight.

Grace Period Assessment

(l) Where the service bulletin specifies contacting the manufacturer for a grace period assessment after replacing the trunnion or flap, contact the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA) (or its delegated agent) for the grace period assessment.

No Reporting Requirement

(m) Although Airbus Service Bulletin A320–57–1133, dated July 28, 2005, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(n)(1) The Manager, International Branch, ANM–116, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(o) French airworthiness directive F–2005–139, dated August 3, 2005, also addresses the subject of this AD.

Issued in Renton, Washington, on August 14, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–13826 Filed 8–21–06; 8:45 am] **BILLING CODE 4910–13–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 25, 201, 202, 207, 225, 226, 500, 510, 511, 515, 516, 558, and 589

[Docket No. 2006N-0067]

RIN 0910-AF67

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration,

HHS.

ACTION: Proposed rule.