

# Proposed Rules

Federal Register

Vol. 77, No. 223

Monday, November 19, 2012

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-2012-1164; Directorate Identifier 2012-NM-075-AD]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A310-204, -222, -304, -322, and -324 airplanes. This proposed AD was prompted by the manufacturer re-classifying slat extension eccentric bolts as principle structural elements (PSE) with replacement due at or before newly calculated fatigue life limits. This proposed AD would require replacing slat extension eccentric bolts, and associated washers with new slat extension eccentric bolts and washers. We are proposing this AD to prevent fatigue cracking, which could result in the loss of structural integrity of the airplane.

**DATES:** We must receive comments on this proposed AD by January 3, 2013.

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

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

For service information identified in this proposed AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

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

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2012-1164; Directorate Identifier 2012-NM-075-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

#### Discussion

The European Aviation Safety Agency (EASA), which is the aviation authority for the Member States of the European Community, has issued EASA Airworthiness Directive 2012-0042, dated April 10, 2012 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

Slat extension eccentric bolts have been reclassified as Principal Structural Elements (PSE). As a result, associated fatigue lives will be published in the Airbus A310 Airworthiness Limitation Section (ALS) Part 1 and bolts must be replaced at or before their calculated fatigue lives.

Failure to replace the bolts within the new fatigue life limits constitutes an unsafe condition.

For the reasons explained above, this [EASA] AD requires:

- For A310-300 aeroplanes, the replacement of slat extension eccentric bolts, Part Number (P/N) A57844015200, with slat extension eccentric bolts P/N A57844015204 at the slat 2 tracks 4 and 7 and slat 3 track 8 positions on both Left Hand (LH) and Right Hand (RH) wings, and
- For A310-300 and A310-200 aeroplanes that incorporate Airbus modification 04809, the replacement of slat extension eccentric bolts, P/N A57843624200 and associated washers P/N A57844016200, with slat extension eccentric bolts P/N A57843624202 and washers P/N A57844391200 at the slat 2 track 5 position, on both LH and RH wings.

The unsafe condition is fatigue cracking, which could result in the loss of structural integrity of the airplane. You may obtain further information by examining the MCAI in the AD docket.

#### Relevant Service Information

Airbus has issued Mandatory Service Bulletin A310-57-2100, Revision 01, dated February 3, 2012. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

#### FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent

information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

### Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 1 product of U.S. registry. We also estimate that it would take about 9 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$25,250 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be \$26,015, or \$26,015 per product.

### 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 above, 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; 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 a regulatory 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 AD:

**Airbus:** Docket No. FAA-2012-1164; Directorate Identifier 2012-NM-075-AD.

#### (a) Comments Due Date

We must receive comments by January 3, 2013.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Airbus Model A310-204, -222, -304, -322, and -324 airplanes, certificated in any category, having received in production Airbus modification 04809 without Airbus modification 06243 or 13596.

#### (d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

#### (e) Reason

This AD was prompted by the manufacturer re-classifying slat extension eccentric bolts as principle structural elements (PSE) with replacement due at or before newly calculated fatigue life limits. We are issuing this AD to prevent fatigue cracking, which could result in the loss of structural integrity of the airplane.

#### (f) Compliance

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

### (g) Compliance Times

At the applicable time specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD: Do the replacements specified in paragraphs (h)(1) and (h)(2) of this AD, as applicable. For the purposes of this AD, to establish the average flight time (AFT), take the accumulated flight time (counted from the take-off up to the landing) and divide it by the number of accumulated flight cycles. This gives the AFT per flight cycle.

(1) For Model A310-304, -322, and -324 airplanes operated with an AFT of less than 4 hours: Before the accumulation of 66,000 total flight hours or 40,000 total flight cycles, whichever occurs first.

(2) For Model A310-304, -322, and -324 airplanes operated with an AFT of 4 hours or more: Before the accumulation of 66,000 total flight hours or 31,400 total flight cycles, whichever occurs first.

(3) For Model A310-204 and -222 airplanes with Airbus modification 04809: Before the accumulation of 71,800 total flight hours or 35,900 total flight cycles, whichever occurs first.

### (h) Replacement of Slat Extension Eccentric Bolt and Hardware on Both Wings

(1) For Model A310-304, -322, and -324 airplanes: Replace the slat extension eccentric bolts, part number (P/N) A57844015200, at the slat 2 tracks 4 and 7 and slat 3 track 8 positions with new slat extension bolts, P/N A57844015204, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A310-57-2100, Revision 01, dated February 3, 2012.

(2) For Model A310-304, -322, and -324 airplanes, and Model A310-204 and -222 airplanes that have incorporated Airbus modification 04809: Replace the slat extension eccentric bolts, P/N A57843624200, at the slat 2 track 5 position with new slat extension bolts, P/N A57843624202; and replace the associated washers of eccentric bolts, P/N A57844016200, at slat 2 track 5 position with washers, P/N A57844391200; in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A310-57-2100, Revision 01, dated February 3, 2012.

### (i) Parts Installation Prohibition

After the modification of the airplane with the replacement of slat extension eccentric bolts and associated hardware required by paragraphs (g) and (h) of this AD, no person may install any slat extension eccentric bolt, P/N A57844015200 or P/N A57843624200, with associated washer P/N A57844016200, on that airplane.

### (j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as

appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone (425) 227-2125; fax (425) 227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product*: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

#### (k) Related Information

(1) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2012-0042, dated April 10, 2012; and Airbus Mandatory Service Bulletin A310-57-2100, Revision 01, dated February 3, 2012; for related information.

(2) For service information identified in this AD, contact Airbus SAS-EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on November 9, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012-27999 Filed 11-16-12; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 801

[Docket No. FDA-2011-N-0090]

RIN 0910-AG31

#### Unique Device Identification System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its

July 10, 2012, proposed rule (77 FR 40736) to establish a unique device identification system as required by recent amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act). On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law; section 614 of FDASIA amends the FD&C Act in ways that require modification of the timeframe for implementation of the proposed rule's requirements as they apply to devices that are implantable, life-saving (life-supporting), or life-sustaining.

**DATES:** Submit either electronic or written comments on the amendment to the Proposed Rule by December 19, 2012. See section VII for the proposed effective dates of a final rule based on the amended proposed rule.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2011-N-0090 and/or RIN Number 0910-AG31, by any of the following methods.

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Fax: 301-827-6870.
- Mail/Hand delivery/Courier (For paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the Agency name, Docket Number, and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jay Crowley, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-5995, email: [cdhrudi@fda.hhs.gov](mailto:cdhrudi@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 9, 2012, FDASIA was signed into law (Pub. L. 112-144). On July 10, 2012, FDA published a proposed rule to establish a unique device identification system, as required by section 519(f) of the FD&C Act (21 U.S.C. 360i(f)). Section 614 of FDASIA amends section 519(f) of the FD&C Act in ways that require modification of the timeframe for implementation of the proposed rule's requirements as they apply to devices that are implantable, life-saving (life-supporting), or life-sustaining. This document explains how FDA is amending the July 10, 2012, proposed rule to meet the requirements of amended section 519(f) of the FD&C Act.

##### II. Description of the Proposed Rule

###### A. FDA's July 10, 2012, Proposed Rule

Our July 10, 2012, document provides a detailed description of the proposed rule. The proposed rule includes unique device identifier (UDI) labeling requirements (proposed for inclusion in 21 CFR part 801), requirements relating to issuing Agencies and submission of data to the Global Unique Device Identification Database (GUDID) (proposed new part 830), and conforming amendments to several existing FDA regulations. FDA proposed a phased implementation of the rule's requirements, with some requirements going into effect immediately after publication of a final rule, and other requirements going into effect 1 year, 3 years, 5 years, and 7 years after publication of a final rule. This phased implementation is summarized in the July 10, 2012, proposed rule by Table 7—Effective Dates of UDI Regulatory Requirements (77 FR 40736 at 40764).

###### B. Changes Required by the Enactment of FDASIA

Section 614 of FDASIA amends section 519(f) of the FD&C Act, the provision that requires FDA to establish a unique device identification system. Prior to the enactment of FDASIA, section 519(f) of the FD&C Act did not specify the date by which a proposed rule is required, did not identify any particular devices as requiring expedited implementation of UDI requirements, and did not specify timeframes for publication of a final rule. The FDASIA amendments to section 519(f) address each of those points. As amended by FDASIA, section