

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

[Docket No. FAA–2011–0918; Directorate Identifier 2011–NM–090–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200 and –300 Series Airplanes; Model A340–200 and –300 Series Airplanes; Model A340–500 and –600 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During a pre-flight test before delivery of an aeroplane from the Airbus production line, a fault message was triggered on FDU1 [fire detection unit].

Investigations by the supplier on the faulty FDU have identified a soldering quality issue on one of the internal cards. This quality issue resulted from a specific repair process that was applied to some FDU * * * during manufacturing.

The FDU monitors the engine, Auxiliary Power Unit (APU) and Main Landing Gear (MLG) bay fire detection systems.

This condition, if not corrected, may adversely affect the fire detection system performance in case of a fire in the area that is monitored by the faulty FDU, potentially resulting in an unsafe condition.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by October 31, 2011.

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—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; e-mail airworthiness.A330-A340@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, Washington. 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:

Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1138; 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–2011–0918; Directorate Identifier 2011–NM–090–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 Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2011–0073, dated April 20, 2011 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

During a pre-flight test before delivery of an aeroplane from the Airbus production line, a fault message was triggered on FDU1.

Investigations by the supplier on the faulty FDU have identified a soldering quality issue on one of the internal cards. This quality issue resulted from a specific repair process that was applied to some FDU Part Number (P/N) 3711–00 during manufacturing.

The FDU monitors the engine, Auxiliary Power Unit (APU) and Main Landing Gear (MLG) bay fire detection systems.

This condition, if not corrected, may adversely affect the fire detection system performance in case of a fire in the area that is monitored by the faulty FDU, potentially resulting in an unsafe condition.

For the reasons described above, this [EASA] AD requires the identification and replacement of the affected FDU.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued the all operators telexes (AOT) listed in the following table.

TABLE—ALL OPERATORS TELEXES

Model	Airbus all operators telex	Date
Model A330	AOT A330–26A3052	April 19, 2011.
Model A340–200, –300	AOT A340–200/300–26A4044	April 19, 2011.
Model A340–500, –600	AOT A340–500/600–26A5024	April 19, 2011.

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.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 58 products of U.S. registry. We also estimate that it would take about 1 work-hour 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 \$0 per product. Replacement parts may be provided free of charge by the manufacturer. 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 \$4,930, or \$85 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); 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.

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–2011–0918;

Directorate Identifier 2011–NM–090–AD.

Comments Due Date

- (a) We must receive comments by October 31, 2011.

Affected ADs

- (b) None.

Applicability

- (c) This AD applies to Airbus Model A330–201, –202, –203, –223, –223F, –243, and –243F airplanes; Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; Model A340–211, –212, and –213 airplanes; Model A340–311, –312, and –313 airplanes; Model A340–541 airplanes; and Model A340–642 airplanes; certificated in any category; all serial numbers.

Subject

- (d) Air Transport Association (ATA) of America Code 26: Fire Protection.

Reason

- (e) The mandatory continuing airworthiness information (MCAI) states:

During a pre-flight test before delivery of an aeroplane from the Airbus production line, a fault message was triggered on FDU1 [fire detection unit].

Investigations by the supplier on the faulty FDU have identified a soldering quality issue on one of the internal cards. This quality issue resulted from a specific repair process that was applied to some FDU * * * during manufacturing.

The FDU monitors the engine, Auxiliary Power Unit (APU) and Main Landing Gear (MLG) bay fire detection systems.

This condition, if not corrected, may adversely affect the fire detection system performance in case of a fire in the area that is monitored by the faulty FDU, potentially resulting in an unsafe condition.

* * * * *

Compliance

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

Actions

- (g) Within 1,000 flight hours after the effective date of this AD: Do an inspection to identify the Fire Detection Unit (FDU) part number (P/N) and serial number (S/N) of each engine, auxiliary power unit (APU), and MLG bay (for Model A340–500 and –600 series airplanes only), as applicable, in accordance with the instructions of Airbus All Operators Telex (AOT) A330–26A3052, dated April 19, 2011 (for Model A330–200 and –300 series airplanes); Airbus AOT A340–200/300–26A4044, dated April 19, 2011 (for Model A340–200 and –300 series airplanes); or Airbus AOT A340–500/600–26A5024, dated April 19, 2011 (for Model A340–500 and –600 series airplanes). A review of maintenance records is acceptable in lieu of this inspection if the P/N and S/N of the installed FDU can be conclusively determined from that review.

- (h) If during the inspection required by paragraph (g) of this AD, P/N 3711–00 FDU

is found installed and the S/N of the FDU is listed in table 1 of this AD: Before further flight, replace the FDU with a serviceable FDU, in accordance with the instructions of Airbus AOT A330–26A3052, dated April 19, 2011 (for Model A330–200 and –300 series airplanes); Airbus AOT A340–200/300–26A4044, dated April 19, 2011 (for Model A340–200 and –300 series airplanes); or Airbus AOT A340–500/600–26A5024, dated April 19, 2011 (for Model A340–500 and –600 series airplanes).

TABLE 1—AFFECTED P/N 3711–00
FIRE DETECTION UNITS

Serial Nos.
ZL0683.
ZL0718.
ZL0721 through ZL0725 inclusive.
ZL0727.
ZL0729 through ZL0731 inclusive.
ZL0736.
ZL0738.
ZL0740.
ZL0742.
ZL0743.
ZL0745.

TABLE 1—AFFECTED P/N 3711–00
FIRE DETECTION UNITS—Continued

Serial Nos.
ZL0747.
ZL0770.
ZL0772.
ZL0775.
ZL0788.
ZL0804.

Note 1: Some of the affected P/N 3711–00 FDUs have been installed in production on certain airplanes, as indicated in table 2 of this AD.

TABLE 2—FDU INSTALLED IN PRODUCTION

Model A330–200 and –300 airplanes manufacturer serial numbers	Position	S/N
1177	ENG2 FDU (1WD2)	ZL0683
1191	ENG2 FDU (1WD2)	ZL0723
1192	ENG1 FDU (1WD1)	ZL0721
	ENG2 FDU (1WD2)	ZL0722
1193	APU FDU (13WG)	ZL0718
1195	ENG1 FDU (1WD1)	ZL0740
1196	ENG1 FDU (1WD1)	ZL0742
	ENG2 FDU (1WD2)	ZL0736
	APU FDU (13WG)	ZL0743
1198	ENG2 FDU (1WD2)	ZL0738
1199	APU FDU (13WG)	ZL0731
1200	ENG1 FDU (1WD1)	ZL0747
1206	ENG2 FDU (1WD2)	ZL0770

Parts Installation

(i) As of the effective date of this AD, no person may install on any airplane, any P/N 3711–00 FDU with a serial number listed in table 1 of this AD, unless the FDU has been reworked and re-identified by L'Hotellier as specified in the instructions in Airbus AOT A330–26A3052, dated April 19, 2011 (for Model A330–200 and –300 series airplanes); Airbus AOT A340–200/300–26A4044, dated April 19, 2011 (for Model A340–200 and –300 series airplanes); or Airbus AOT A340–500/600–26A5024, dated April 19, 2011 (for Model A340–500 and –600 series airplanes).

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows:
No differences.

Other FAA AD Provisions

(j) 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:* Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–

3356; telephone (425) 227–1138; fax (425) 227–1149. Information may be e-mailed 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.

Related Information

(k) Refer to MCAI EASA Airworthiness Directive 2011–0073, dated April 20, 2011; Airbus AOT A330–26A3052, dated April 19, 2011; Airbus AOT A340–200/300–26A4044, dated April 19, 2011; and Airbus AOT A340–500/600–26A5024, dated April 19, 2011; for related information.

Issued in Renton, Washington, on September 7, 2011.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–23470 Filed 9–13–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. FDA–1978–N–0018] (formerly
Docket No. 1978N–0038)

RIN 0910–ZA40

Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; request for data and information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) that published on June 17, 2011. The ANPRM is requesting data and information on certain dosage forms of over-the-counter (OTC) sunscreen drug products marketed without approved applications. The comment period for that ANPRM will end on September 15, 2011. This document extends the comment period to October 17, 2011.