

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-2012-1346; Directorate Identifier 2012-CE-047-AD]

RIN 2120-AA64

Airworthiness Directives; REIMS Aviation S.A. Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for REIMS AVIATION S.A. Model F406 airplanes. 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 fretting (wear and/or chafing) found between the elevator pushrod assembly and horizontal tail structure, which could cause the elevator pushrod to jam and could result in loss of control. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 19, 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 20590, between 9 a.m.

and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact REIMS Aviation Industries, A  rodrome de Reims Prunay, 51360 Prunay, France; telephone: 03.26.48.46.65; fax: 03.26.49.18.57; Internet: <http://www.geciaviation.com/en/>. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility 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 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:

Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4119; fax: (816) 329-4090; email: albert.mercado@faa.gov.

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-2012-1346; Directorate Identifier 2012-CE-047-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 because of 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 AD No. 2012-0164, dated August 28, 2012 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

During maintenance, fretting has been found between the elevator pushrod assembly and horizontal tail structure on Reims F406 aeroplanes. In addition, bending was found on a pushrod assembly Part Number (P/N) 6015034-1. The investigation has not yet established the exact cause(s) of these occurrences.

This condition, if not detected and corrected, could lead to failure of a pushrod and consequent jamming of the elevator controls, possibly resulting in loss of control of the aeroplane.

For the reasons described above, this AD requires inspection of the pushrods and horizontal tail structure to detect fretting, bending or eccentricity and, depending on findings, replacement with a serviceable pushrod, or repair. This AD also requires the return on replaced pushrods to RAI for investigation.

This AD is considered to be an interim action and further AD action may follow.

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

Relevant Service Information

REIMS Aviation Industries has issued Service Bulletin No. F406-70, dated July 16, 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 the 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 this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD would affect 7 products of U.S. registry. We also estimate that it would take about 4 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$2,380, or \$340 per product.

In addition, we estimate that any necessary follow-on actions would take about 2.5 work-hours and require parts costing \$1,900, for a cost of \$2,112.50 per product. We have no way of determining the number of products that may need these actions.

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.

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:

REIMS Aviation S.A.: Docket No. FAA–2012–1346; Directorate Identifier 2012–CE–047–AD.

(a) Comments Due Date

We must receive comments by February 19, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Reims Aviation S.A. Model F406 airplanes, serial numbers F406–0001 through F406–0096, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by reports of fretting (wear and/or chafing) found between the elevator pushrod assembly and horizontal tail structure. We are issuing this AD to detect and correct any discrepancies with the elevator pushrod assembly and the horizontal tail structure, which could cause the elevator pushrod to fail. Failure of the elevator pushrod could cause the flight control to jam, which could result in loss of control.

(f) Actions and Compliance

Unless already done, do the following actions:

- (1) Within the next 4 months after the effective date of this AD, inspect the elevator pushrod assemblies, part number (P/N) 6015034–1, and the horizontal tail structure following the Accomplishment Instructions in REIMS Aviation Industries Service Bulletin No. F406–70, dated July 16, 2012.
- (2) Before further flight after the inspection required in paragraph (f)(1) of this AD, if fretting is found on the horizontal tail structure, or the clearance between the elevator pushrod assemblies and the horizontal tail structure is found to be

insufficient, or looseness at riveted end fittings is found on the elevator pushrods, contact REIMS Aviation Industries at the address specified in paragraph (h) of this AD for a repair scheme and incorporate the repair scheme.

(3) Before further flight after the inspection required in paragraph (f)(1) of this AD, if bending or eccentricity of an elevator pushrod is found that exceeds the allowable limits, replace each affected elevator pushrod with a serviceable part following REIMS Aviation Industries Service Bulletin No. F406–70, dated July 16, 2012.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090; email: albert.mercado@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(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.

(3) *Reporting Requirements:* For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2012–0164, dated August 28, 2012, and REIMS Aviation Industries Service Bulletin No. F406–70, dated July 16, 2012, for related information. For service information related to this AD, contact REIMS Aviation Industries, Aérodrome de Reims Prunay, 51360 Prunay,

France; telephone: 03.26.48.46.65; fax: 03.26.49.18.57; Internet: <http://www.geciaviation.com/en/>. You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on December 27, 2012.

John Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012-31602 Filed 1-2-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2012-N-1148]

Food and Drug Administration Actions Related to Nicotine Replacement Therapies and Smoking-Cessation Products; Report to Congress on Innovative Products and Treatments for Tobacco Dependence; Public Hearing; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; Extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of public hearing that appeared in the **Federal Register** of November 28, 2012 (77 FR 70955). In the public hearing notice, FDA requested comments on FDA consideration of applicable approval mechanisms and additional indications for nicotine replacement therapies (NRTs), and input on a report to Congress examining the regulation and development of innovative products and treatments for tobacco dependence. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by January 16, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ayanna Augustus, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 3219, Silver Spring, MD 20993, 301-796-3980, FAX: 301-796-2310, email: Section918PublicMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 28, 2012, FDA published a document announcing a public meeting on December 17, 2012, and the opening of a public docket to receive comments related to the implementation of section 918 of the FD&C Act (21 U.S.C. 387r), as amended by the Tobacco Control Act (Pub. L. 111-31). Under Section 918(a), the Secretary of the Department of Health and Human Services (the Secretary of HHS) is required to consider certain new approval mechanisms and additional indications for NRTs. Several NRTs, including nicotine-containing gums, patches, and lozenges, are already marketed for smoking cessation. Section 918(b) requires that the Secretary of HHS, after consultation with recognized scientific, medical, and public health experts, submit a report to Congress examining how best to regulate, promote, and encourage the development of “innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments)” to better achieve the following three goals: (1) Total abstinence from tobacco use, (2) reductions in consumption of tobacco, and (3) reductions in the harm associated with continued tobacco use. FDA will consider the information it obtains from the public hearing and related docket submissions in its implementation of the requirements of section 918, including in drafting the report to Congress required by section 918(b).

II. Submission of Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify 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>.

Dated: December 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-31578 Filed 1-2-13; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 63, 80, 85, 122, 123, and 412

[EPA-HQ-OW-2012-0813, FRL-9764-8]

Section 610 Review of NPDES Permit Regulation and Effluent Limitations Guidelines Standards for Concentrated Animal Feeding Operations (CAFOs); Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of public comment period.

SUMMARY: On October 31, 2012 the EPA published a request for comments on a Regulatory Flexibility Act section 610 review titled, Section 610 Review of NPDES Permit Regulation and Effluent Limitations Guidelines Standards for Concentrated Animal Feeding Operations (CAFOs). As initially published in the **Federal Register**, written comments were to be submitted to the EPA on or before December 31, 2012 (a 60-day public comment period). Since publication, the EPA has received a request for additional time to submit comments. Therefore, the EPA is extending the public comment period for 60 days until March 1, 2013.

DATES: The public comment period for the review published October 31, 2012 (77 FR 65840) is being extended for 60 days to March 1, 2013 in order to provide the public additional time to submit comments and supporting information.

ADDRESSES:

Comments: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2012-0813, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- **Email:** rfa-sbrefa@epa.gov, Attention Docket ID No. EPA-HQ-OW-2012-0813.
- **Fax:** (202) 566-9744.
- **Mail:** Water Docket, Environmental Protection Agency, Mailcode: 28221T, Attention Docket ID No. EPA-HQ-OW-2012-0813, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- **Hand Delivery:** EPA Docket Center, EPA West, Room 3334, 1301