

**(e) Reason**

This AD was prompted by a report of an engine multiple fan blade release event. We are issuing this AD to detect and correct an incorrect adjustment of the (emergency) maximum reverse thrust stop, which could result in engine fan blade release causing injury to occupants, damage to the airplane, and consequent uncontrollability of the airplane.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Required Action(s)**

Within 30 days after the effective date of this AD, request instructions from the Manager, International Section, Transport Standards Branch, FAA, to address the unsafe condition specified in paragraph (e) of this AD; and accomplish the actions at the times specified in, and in accordance with, those instructions. Guidance can be found in Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) AD 2013-0010, January 14, 2013.

**(h) Alternative Methods of Compliance (AMOCs)**

The Manager, International Section, Transport Standards Branch, 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 Section, send it to the attention of the person identified in paragraph (i)(2) of this AD. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto: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.

**(i) Related Information**

(1) Refer to MCAI EASA AD 2013-0010, January 14, 2013 for related information. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1183.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone: 425-227-1137; fax: 425-227-1149.

**(j) Material Incorporated by Reference**

None.

Issued in Renton, Washington, on December 26, 2017.

**John P. Piccola, Jr.,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2017-28486 Filed 1-4-18; 8:45 am]

**BILLING CODE 4910-13-P**

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

[Docket No. FAA-2017-1182; Product Identifier 2013-NM-093-AD; Amendment 39-19146; AD 2018-01-05]

**RIN 2120-AA64**

**Airworthiness Directives; Fokker Services B.V.**

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

**ACTION:** Final rule; request for comments.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. This AD requires contacting the FAA to obtain instructions for addressing the unsafe condition on these products, and doing the actions specified in those instructions. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage frames are subject to widespread fatigue damage (WFD). We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD becomes effective January 22, 2018.

We must receive comments on this AD by February 20, 2018.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, 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.

**Examining the AD Docket**

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1182; 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 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:** Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057-3356; telephone: 425-227-1137; fax: 425-227-1149.

**SUPPLEMENTARY INFORMATION:****Discussion**

Fatigue damage can occur locally, in small areas or structural design details, or globally, in widespread areas. Multiple-site damage is widespread damage that occurs in a large structural element such as a single rivet line of a lap splice joining two large skin panels. Widespread damage can also occur in multiple elements such as adjacent frames or stringers. Multiple-site damage and multiple-element damage cracks are typically too small initially to be reliably detected with normal inspection methods. Without intervention, these cracks will grow, and eventually compromise the structural integrity of the airplane. This condition is known as WFD. It is associated with general degradation of large areas of structure with similar structural details and stress levels. As an airplane ages, WFD will likely occur, and will certainly occur if the airplane is operated long enough without any intervention.

The FAA's WFD final rule (75 FR 69746, November 15, 2010) became effective on January 14, 2011. The WFD rule requires certain actions to prevent structural failure due to WFD throughout the operational life of certain existing transport category airplanes and all of these airplanes that will be certificated in the future. For existing and future airplanes subject to the WFD rule, the rule requires that DAHs establish a limit of validity (LOV) of the engineering data that support the structural maintenance program. Operators affected by the WFD rule may not fly an airplane beyond its LOV, unless an extended LOV is approved.

The WFD rule (75 FR 69746, November 15, 2010) does not require identifying and developing maintenance actions if the DAHs can show that such actions are not necessary to prevent WFD before the airplane reaches the LOV. Many LOVs, however, do depend on accomplishment of future maintenance actions. As stated in the WFD rule, any maintenance actions

necessary to reach the LOV will be mandated by airworthiness directives through separate rulemaking actions.

In the context of WFD, this action is necessary to enable DAHs to propose LOVs that allow operators the longest operational lives for their airplanes, and still ensure that WFD will not occur. This approach allows for an implementation strategy that provides flexibility to DAHs in determining the timing of service information development (with FAA approval), while providing operators with certainty regarding the LOV applicable to their airplanes.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2013-0102, dated May 2, 2013 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. The MCAI states:

From service experience, it was concluded that the fuselage frames, which act as back-up structure for the hook latch fitting brackets of the large cargo doors, are sensitive to fatigue cracking. To ensure the continued structural integrity with respect to fatigue, a repetitive inspection was included in the Airworthiness Limitations Section (ALS) of the Instructions for Continued Airworthiness under tasks 533026-00-03 and 533026-01-03.

Since those tasks were implemented, it was determined, as part of a re-evaluation for Widespread Fatigue Damage, that the current repetitive fatigue inspections in the ALS do

not provide a sufficient level of protection against fatigue-induced cracks.

This condition, if not corrected, would affect the structural integrity of the centre fuselage.

For the reasons described above, this [EASA] AD requires modification of the affected fuselage frames.

Post-modification inspections will be included in a revision to the ALS, which will likely be the subject of further [EASA] AD action.

You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1182.

#### FAA’s Determination and Requirements of This 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. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

#### FAA’s Determination of the Effective Date

Since there are currently no domestic operators of this product, we find good cause that notice and opportunity for prior public comment are unnecessary. In addition, for the reason(s) stated above, we find that good cause exists for

making this amendment effective in less than 30 days.

#### Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2017-1182; Product Identifier 2013-NM-093-AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this 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 AD.

#### Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. This AD requires contacting the FAA to obtain instructions for addressing the unsafe condition, and doing the actions specified in those instructions. Based on the actions specified in the MCAI AD, we are providing the following cost estimates for an affected airplane that is placed on the U.S. Register in the future:

#### ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product
Modification .....	102 work-hours × \$85 per hour = \$8,670 .....	\$18,600	\$27,270

#### 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

#### Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 this AD:

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.

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

#### 2018–01–05 Fokker Services B.V.:

Amendment 39–19146; Docket No. FAA–2017–1182; Product Identifier 2013–NM–093–AD.

#### (a) Effective Date

This AD becomes effective January 22, 2018.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes, certificated in any category, having serial numbers 11268 through 11283 inclusive, 11286, 11289, 11291, 11293, 11295, 11300, 11303, 11306, 11308, 11310, 11312 through 11314 inclusive, 11316, 11318, 11321, 11323 through 11335 inclusive, 11337, 11338, 11340, 11345, 11349, 11352 through 11361 inclusive, 11365 through 11367 inclusive, 11369, 11370, 11372, 11373, 11376 through 11380 inclusive, 11387, 11388, 11391, 11395, 11397, 11399, 11404, 11405, 11407, 11411 through 11419 inclusive, 11425 through 11428 inclusive, 11432, 11435 through 11439 inclusive, 11444 through 11450 inclusive, 11456 through 11460 inclusive, 11464 through 11469 inclusive, and 11475 through 11585 inclusive.

#### (d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

#### (e) Reason

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage frames are subject to widespread fatigue damage (WFD). We are issuing this AD to prevent cracking of the

center fuselage, which could result in reduced structural integrity of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Required Action(s)

Within 30 days after the effective date of this AD, request instructions from the Manager, International Section, Transport Standards Branch, FAA, to address the unsafe condition specified in paragraph (e) of this AD; and accomplish the actions at the times specified in, and in accordance with, those instructions. Guidance can be found in Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) AD 2013–0102, dated May 2, 2013.

#### (h) Alternative Methods of Compliance (AMOCs)

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#### (i) Related Information

(1) Refer to MCAI EASA AD 2013–0102, dated May 2, 2013, for related information. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–1182.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057–3356; telephone: 425–227–1137; fax: 425–227–1149.

#### (j) Material Incorporated by Reference

None.

Issued in Renton, Washington, on December 26, 2017.

**John P. Piccola, Jr.,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2017–28487 Filed 1–4–18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 1, 11, 16, 106, 110, 111, 112, 114, 117, 120, 123, 129, 179, 211, and 507**

[Docket No. FDA–2017–N–6908]

### Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs; Guidance for Industry; Availability

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

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.” This guidance states agency compliance policy regarding certain entities and/or activities related to the “farm” definition, written assurances, food contact substances, and human food by-products for use as animal food.

**DATES:** The announcement of the guidance is published in the **Federal Register** on January 5, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.