

(2) 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.

(l) Related Information

(1) For more information about this AD, contact Jim Rutherford, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; phone: (816) 329-4165; fax: (816) 329-4090; email: jim.rutherford@faa.gov.

(2) Refer to European Union Aviation Safety Agency (EASA) AD No. 2020-0068-E, dated March 23, 2020, for more information. You may examine the EASA AD in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating it in Docket No. FAA-2020-0714.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Blanik Mandatory Bulletin Document No. L23/060a, Revision 2, dated March 17, 2020.

(ii) Blanik Information Bulletin Document No. L23/061b, Revision 1, dated March 17, 2020.

(3) For Blanik service information identified in this AD, contact Blanik Aircraft CZ s.r.o., Beranovych 65, Letnany, Praha, 199 00, Czech Republic; phone: +420 731 425 699; internet: <https://www.blanik.aero/customer-support>; email: info@blanik.aero.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the internet at <https://www.regulations.gov> by searching for locating Docket No. FAA-2020-0714.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on July 28, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020-17650 Filed 8-12-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2020-0711; Project Identifier MCAI-2020-00719-A; Amendment 39-21188; AD 2020-16-04]

RIN 2120-AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Pacific Aerospace Limited Model 750XL airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as an incorrect illustration of the screw jack assembly in the airplane maintenance manual, which may cause potential errors with installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 2, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of September 2, 2020.

The FAA must receive comments on this AD by September 28, 2020.

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

- *Federal eRulemaking Portal:* Go to <https://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 AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: <https://www.aerospace.co.nz/>. You may view

this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the internet at <https://www.regulations.gov> by searching for locating Docket No. FAA-2020-0711.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2020-0711; or in person at Docket Operations 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 Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Mike Kiesov, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: mike.kiesov@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

The Civil Aviation Authority (CAA), which is the aviation authority for New Zealand, has issued AD DCA/750XL/38A, dated September 5, 2019 (referred to after this as “the MCAI”), to correct an unsafe condition for Pacific Aerospace Limited Model 750XL airplanes. The MCAI states:

DCA/750XL/38A with effective date 5 September 2019 and a 5 hour TIS compliance is prompted by two reports of finding incorrectly assembled flap screw jacks on affected aircraft. This AD is revised to introduce Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/117 issue 2, dated 21 August 2019 and expand the AD applicability to include additional aircraft S/N and parts held as spares.

There are no additional AD requirements for aircraft and affected parts in compliance with DCA/750XL/38.

A Pacific Aerospace Ltd (PAL) review of the 750XL Maintenance Manual (MM) and the 750XL Illustrated Parts Manual (IPM) has determined that the orientation shown in these two manuals for the flap screw jack bearing stop is incorrect. PAL has subsequently issued temporary revisions dated 5 June 2019, for both the 750XL MM and the 750XL IPM to correct the orientation shown for the flap screw jack bearing stop. These temporary revisions can be obtained from Pacific Aerospace Ltd, Hamilton, New Zealand.

Due to the possibility that there may be incorrectly assembled flap screw jack assemblies in service, this [CAA] AD is issued to introduce the corrective actions in Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/117 issue 2, dated 21 August 2019. The aircraft may be recovered back to a maintenance base for the inspection, provided the flight is a non-hire or reward flight with no passengers carried.

You may examine the MCAI on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2020-0711.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Pacific Aerospace Mandatory Service Bulletin PACSB/XL/117, Issue 2, dated August 21, 2019. The service information contains procedures for inspecting the flap screw jack assembly to verify proper configuration of the assembly. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

Pacific Aerospace Limited has also issued temporary revisions for the P-750 XSTOL Maintenance Manual for the 750XL Aircraft, Revision 16, dated October 2018; and the P-750 XSTOL III Maintenance Manual P/N 11-08002-1 for the 750XL (EFIS) Aircraft, Revision 2, dated August 2018. These temporary revisions contain corrections for the orientation of the flap screw jack bearing stop.

FAA's Determination and Requirements of the 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, it has notified us of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD because it evaluated all information provided by the State of Design Authority 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

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because of the possibility there may be incorrectly assembled flap screw jack

assemblies in service, which could cause failure of the flap screw jack and result in a failure of the flap actuator to fully extend the flaps during the completion of a final approach. This condition, if not detected and corrected, could result in a longer landing distance and a possible runway overrun condition. The risk assessment received by the FAA, and reconfirmed in July of 2020, indicates that urgent action is required. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reason stated above, the FAA finds 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 was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the Docket Number FAA-2020-0711 and Product Identifier MCAI-2020-00719-A at the beginning of your comments. We will post all comments we receive, without change, to <https://www.regulations.gov>, including any personal information you provide.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments we receive, without change, to <https://www.regulations.gov>, including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact we receive about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Mike Kiesov,

Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Costs of Compliance

The FAA estimates that this AD will affect 22 products of U.S. registry. The FAA also estimates that it will take 1 work-hour per product to comply with the inspection requirement of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, the FAA estimates the cost of the inspection for U.S. operators to be \$1,870, or \$85 per product.

In addition, the FAA estimates that any necessary follow-on actions will take 4 work-hours and require parts costing \$50, for a cost of \$390 per product. The FAA has no way of determining the number of products that may need these actions.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all costs in our cost estimate.

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.

The FAA is 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 Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA

has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Regulatory Findings

The FAA has 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, and
- (2) Will not affect intrastate aviation in Alaska.

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:

2020-16-04 Pacific Aerospace Limited:

Amendment 39-21188; Docket No. FAA-2020-0711; Project Identifier MCAI-2020-00719-A.

(a) Effective Date

This airworthiness directive (AD) becomes effective September 2, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, serial numbers 101 through to 215, 220, 8001, and 8002, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by an incorrect illustration of the screw jack assembly in the airplane maintenance manual, thus causing potential errors with installation. The FAA is issuing this AD to require an inspection of

the flap screw jack assembly to verify proper configuration of the assembly and make the correction if found improperly installed. This unsafe condition, if not addressed, could cause fatigue failure of a flap screw jack, which could result in a failure of the flap actuator to fully extend the flaps during the completion of a final approach, a longer landing distance, and consequent runway overrun condition.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD.

(1) Within 20 hours time-in-service after September 2, 2020 (the effective date of this AD), inspect the left hand (LH) and right hand (RH) flap screw jack assemblies for proper installation by following the Accomplishment Instructions, paragraphs A.1) through A.3), of Pacific Aerospace Mandatory Service Bulletin (MSB) PACSB/XL/117, Issue 2, dated August 21, 2019 (PACSB/XL/117, Issue 2). If flap screw jack assembly is not properly installed as shown in figures 1 and 2 of PACSB/XL/117, Issue 2, before further flight, comply with the Accomplishment Instructions, Part B, of PACSB/XL/117, Issue 2.

(2) As of September 2, 2020 (the effective date of this AD), do not install a LH flap screw jack assembly P/N 11-45621-1 or RH flap screw jack assembly P/N 11-45622-1 on any airplane, unless it is installed in accordance with the Accomplishment Instructions, Part B, of PACSB/XL/117, Issue 2.

(g) Credit for Previous Actions

You may take credit for the actions required by paragraph (f)(1) of this AD if you performed those actions before the effective date of this AD using Pacific Aerospace MSB PACSB/XL/117, Issue 1, dated June 7, 2019.

(h) Special Flight Permit

Special flight permits may be issued may be issued for the purpose of operating the airplane to a location where the requirements of this AD can be performed with the following limitations: Flights must not carry passengers.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Small Airplane Standards Branch, 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: Mike Kiesov, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: mike.kiesov@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.

(j) Related Information

Refer to mandatory continuing airworthiness information (MCAI) New Zealand Civil Aviation Authority AD No.

DCA/750XL/38A, dated September 5, 2019, for related information. You may examine the MCAI on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2020-0711.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Pacific Aerospace Mandatory Service Bulletin PACSB/XL/117, Issue 2, dated August 21, 2019.

(ii) [Reserved]

(3) For Pacific Aerospace Limited service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 7843 6134; email: pacific@aerospace.co.nz; internet: <https://www.aerospace.co.nz/>.

(4) You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the internet at <https://www.regulations.gov> by searching for Docket No. FAA-2020-0711.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued on July 29, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020-17607 Filed 8-12-20; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2014-N-1021]

RIN 0910-AH00

Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to establish requirements