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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2023-1992; Project Identifier MCAI-2023-00414-T; Amendment 39-22568; AD 2023-20-09]

RIN 2120-AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all MHI RJ Aviation ULC Model CL-600-2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by a determination that a new airworthiness limitation is necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to establish a new life limit for a certain main landing gear (MLG) retract actuator piston rod. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 30, 2023.

The FAA must receive comments on this AD by November 27, 2023.

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 *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:* Deliver to Mail address above between 9 a.m. and 5

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA-2023-1992; 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 final rule, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Gabriel D. Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7343; email *9-avs-nyaco-cos@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA-2023-1992; Project Identifier MCAI-2023-00414-T” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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 received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received 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 Gabriel D. Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7343; email *9-avs-nyaco-cos@faa.gov*. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF-2022-56, dated September 26, 2022 (referred to after this as “the MCAI”), to correct an unsafe condition on all MHI RJ Aviation ULC (formerly Bombardier Inc.) Model CL-600-2E25 (Regional Jet Series 1000) airplanes. The MCAI states MLG fatigue testing that was accomplished at the time of aircraft certification was not performed in accordance with the Qualification Test Plan. According to the MCAI, the pressure impulse testing was repeated on the CL600-2E25 MLG retract actuator using the required load spectrum, and as a result, a “safe life limitation” of 9,300 flight cycles was established for piston rod part number (P/N) 55615-1.

The FAA is issuing this AD to establish a life limit for MLG retract actuator piston rod part number 55615-1. Exceeding this life limit could result in failure of the MLG retract actuator piston in flight, causing an undamped MLG free fall extension, which may result in MLG collapse on landing.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA-2023-1992.

FAA’s Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this AD after determining that the unsafe condition described previously is

likely to exist or develop on other products of the same type design.

Requirements of the Final Rule

This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate a new life limit of 9,300 flight cycles for MLG retract actuator piston rod P/N 55615-1.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because there are no airplanes currently on the U.S. registry and thus, it is unlikely that the FAA will receive any adverse comments or useful information about this AD from U.S. operator. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, for the foregoing reasons, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

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

Costs of Compliance

Currently, there are no airplanes with this type certificate on the U.S. registry. If an affected airplane is imported and placed on the U.S. Registry in the future, the FAA provides the following cost estimates to comply with this AD:

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes

that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the total cost per operator to be \$7,650 (90 work-hours × \$85 per work-hour).

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 Findings

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.

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:

2023–20–09 MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–22568; Docket No. FAA–2023–1992; Project Identifier MCAI–2023–00414–T.

(a) Effective Date

This airworthiness directive (AD) is effective October 30, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all MHI RJ Aviation ULC (type certificate previously held by Bombardier Inc.) Model CL–600–2E25 (Regional Jet Series 1000) airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Reason

This AD was prompted by a determination that a new airworthiness limitation is necessary. The FAA is issuing this AD to establish a life limit for main landing gear (MLG) retract actuator piston rod part number 55615-1. Exceeding this life limit could result in failure of the MLG retract actuator piston in flight, causing an undamped MLG free fall extension. The unsafe condition, if not addressed, could result in MLG collapse on landing.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 60 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to establish a life limit of 9,300 flight cycles for the MLG retract actuator piston rod (part of MLG retract actuator 55600), part number 55615-1. The initial compliance time for removing the part from service is at the applicable time specified in paragraphs (g)(1) through (3) of this AD.

Note 1 to paragraph (g): The life limit in paragraph (g) of this AD can be found in Airworthiness Limitation (ALI) Task Number 32–32–05–709 for Configuration B, “Piston Rod, MLG Retractable Actuator (part of MLG Retractable Actuator 55600)” of MHI RJ CRJ700/900/1000 Temporary Revision ALI–0763, dated April 14, 2022 (TR ALI–0763), which specifies an effective date of April 14, 2022.

(1) For a MLG retract actuator piston rod that has accumulated fewer than 4,300 total flight cycles as of April 14, 2022 (phase-in Effective Date of TR ALI–0763): Before accumulating 9,300 total flight cycles.

(2) For a MLG retract actuator piston rod that has accumulated 4,300 total flight cycles

or more and 18,000 total flight cycles or fewer as of April 14, 2022 (phase-in Effective Date of TR ALI-0763): Within 5,000 flight cycles from April 14, 2022, or before exceeding 20,000 total flight cycles, whichever occurs first.

(3) For a MLG retract actuator piston rod that has accumulated more than 18,000 total flight cycles as of April 14, 2022 (phase-in Effective Date of TR ALI-0763): Within 2,000 flight cycles from April 14, 2022.

(h) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless they are approved as an alternative method of compliance in accordance with paragraph (i)(1) of this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Validation 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 manager of the International Validation Branch, mail it to the address identified in paragraph (j)(3) of this AD or email to: 9-AVS-AIR-730-AMOC@faa.gov. If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to Transport Canada AD CF-2022-56, dated September 26, 2022, for related information. This Transport Canada AD may be found in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-1992.

(2) For more information about this AD, contact Gabriel D. Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7343; email 9-avs-nyaco-cos@faa.gov.

(3) For MHI RJ service information identified in this AD that is not incorporated by reference, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833-990-7272 or direct-dial telephone 450-990-7272; fax 514-855-8501; email thd.crj@mhirj.com; website mhirj.com.

(k) Material Incorporated by Reference

None.

Issued on October 4, 2023.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023-22486 Filed 10-12-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-N-0179]

Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled “Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry.” The guidance document updates the current version of the guidance by including three additional questions. One question relates to any effect systems recognition or equivalency determinations have on prior notice requirements. The other two questions relate to FDA’s notice to a submitter or transmitter of prior notice of an FDA refusal for inadequate prior notice or hold, if the food article is from a foreign facility that is not registered and addresses the timeframe for making requests for FDA review of such refusal or hold. FDA is also making other technical editorial changes. The guidance announced in this notice finalizes the draft guidance of the same title dated September 13, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on October 13, 2023.

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>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2011-N-0179 for “Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit