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,

(2) Will not affect intrastate aviation in Alaska, 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.

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:

2022–18–10 Bombardier, Inc.: Amendment 39–22161; Docket No. FAA–2022–0687; Project Identifier MCAI–2021–01405–T.

(a) Effective Date

This airworthiness directive (AD) is effective October 20, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–2A12 airplanes, certificated in any category, serial numbers (S/Ns) 70006 through 70044 inclusive, S/Ns 70046 through 70052 inclusive, and S/Ns 70055, 70056, and 70062.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Unsafe Condition

This AD was prompted by a determination that the baggage bay line fire extinguishing tube assembly might not have been installed with the correct torque. The FAA is issuing this AD to address improper torqueing, which may lead to loss of the fire extinguishing system, which could prevent extinguishing a fire and possibly result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Re-Torque Fire Extinguishing Tube Assembly

Within 28 months after the effective date of this AD: Re-torque the baggage bay line fire extinguishing tube assembly to the correct torque values, and apply corrosion inhibiting compound on the discharge tubes, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 700–26–7503, dated April 22, 2021.

(h) No Reporting Requirement

Although Bombardier Service Bulletin 700–26–7503, dated April 22, 2021, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(i) Other AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO 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 responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300. 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, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to TCCA AD CF–2021–48, dated December 15, 2021, for related information. This TCCA AD may be found in the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–0687.

(2) For more information about this AD, contact Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(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 this AD specifies otherwise.

(i) Bombardier Service Bulletin 700–26–7503, dated April 22, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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 *fr.inspection@nara.gov,* or go to: *archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 19, 2022.

Christina Underwood,

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

[FR Doc. 2022–19807 Filed 9–14–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1162; Project Identifier MCAI–2022–01087–A; Amendment 39–22180; AD 2022–19–11]

RIN 2120–AA64

Airworthiness Directives; Costruzioni Aeronautiche Tecnam S.P.A. 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 Costruzioni Aeronautiche Tecnam S.P.A. (Tecnam) Model P2006T airplanes. This 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. This AD

requires performing a detailed visual inspection (DVI) of the aileron control assembly, repairing the aileron control assembly if any crack or damage (including missing paint, nicks, or scrapes) is found, measuring the length of the screws installed on the ceiling cover panel, and replacing the screws if found to be of excessive length. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 30, 2022.

The FAA must receive comments on this AD by October 31, 2022.

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–2022–1162; 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, the MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–1162; Project Identifier MCAI–2022–01087–A'' 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 Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0167, dated August 11, 2022 (referred to after this as ''the MCAI''), to correct an unsafe condition on certain Tecnam Model P2006T airplanes. The MCAI states that screws attaching the ceiling panel covering the aileron control assembly could be of excessive length and cause the aileron control rod to become blocked, cracked, or damaged. This condition, if not detected and corrected, could result in unintended jamming of the aileron control rod assembly, the inability to use the aileron control surfaces, and loss of control of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1162.

Other Related Service Information

The FAA reviewed Tecnam Service Bulletin 574–CS-Edition 1, Revision 3, dated August 1, 2022. The service information specifies performing a DVI of the aileron control assembly, measuring the length of the screws installed on the ceiling cover panel, and replacing the screws if found to be of excessive length. The service information also specifies contacting Tecnam for repair instructions if any crack or damage is found on the aileron control rod.

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 described 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.

AD Requirements

This AD requires accomplishing the actions specified in the service information already described, except as discussed under ''Differences Between this AD, the MCAI, and the Service Information.''

Differences Between This AD, the MCAI, and the Service Information

The MCAI specifies that the DVI of the aileron control assembly and measurement of screws installed on the ceiling cover panel be performed within 10 flight hours after the effective date of EASA AD 2022–0132, dated July 4, 2022, or the effective date of the MCAI, depending on the airplane's serial number. This AD requires the inspection and measurement be performed before further flight after the effective date of this AD.

The service bulletin specifies contacting Tecnam for approved corrective action instructions, and this AD requires using a repair method approved by the FAA, EASA, or Tecnam's Design Organization Approval.

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.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because the pilot could lose control of the airplane due to the jamming of the aileron control rod caused by screws of excessive length installed on the ceiling cover panel. Since this condition happens rapidly and without warning, the inspections and any necessary repair or replacement must be accomplished before further flight. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, 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, for the same reasons the FAA found good cause to forego notice and comment.

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

The FAA estimates that this AD affects 71 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect aileron control assembly	1 work-hour × $85 per hour = $85	Not Applicable	$85	$6,035
Measure ceiling cover panel attach screws	.50 work-hour × $85 per hour = $42.50	Not Applicable	42.50	3,017.50

The FAA estimates the following costs to do any necessary actions that would be required based on the results of the inspection and measurement. The agency has no way of determining the number of airplanes that might need this repair or replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair aileron control assembly	1 work-hour × $85 per hour = $85	$50	$135
Replace aileron control assembly	1 work-hour × $85 per hour = $85	500	585
Replace incorrect length ceiling cover panel screws	.50 work-hour × $85 per hour = $42.50	100	142.50

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:

2022–19–11 Costruzioni Aeronautiche Tecnam S.P.A.: Amendment 39–22180; Docket No. FAA–2022–1162; Project Identifier MCAI–2022–01087–A.

(a) Effective Date

This airworthiness directive (AD) is effective September 30, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Costruzioni Aeronautiche Tecnam S.P.A. Model P2006T airplanes, all serial numbers (S/N) up to 345 inclusive, and S/N 348, 352, 353, 355, and 357, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2710, Aileron Control System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information

originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The FAA is issuing this AD to detect and correct screws of excessive length installed on the ceiling panel covering the aileron control assembly, which could cause the aileron control rod to become jammed, cracked, or damaged. The unsafe condition, if not addressed, could result in unintended jamming of the aileron control assembly, the inability to use the aileron control surfaces, and loss of control of the airplane.

(f) Compliance

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

(g) Inspection/Measurement

Before further flight after the effective date of this AD, perform a detailed visual inspection of the aileron control assembly, part number 26–9–1502–000, for cracks and damage (including missing paint, nicks, or scrapes) and measure the length of the screws installed on the ceiling cover panel.

(1) If, during the inspection required by paragraph (g) of this AD, any crack or damage (including missing paint, nicks, or scrapes) is found on the aileron control rod assembly, before further flight, repair using a method approved by the FAA; the European Union Aviation Safety Agency (EASA); or Tecnam's Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(2) If, during the inspection required by paragraph (g) of this AD, any screws installed on the ceiling cover panel do not match the limits specified in paragraph (g)(2)(i) or (ii) of this AD, before further flight, replace that screw with the correct screw identified in paragraph (g)(2)(i) or (ii) of this AD, as applicable.

(i) If blind rivet nuts are installed on the ceiling panel covering the aileron control assembly, then the correct panel screw would be 12mm in length with part number UNI7689–3–12.

(ii) If blind rivet nuts are not installed on the ceiling panel covering the aileron control assembly, then the correct panel screw would be equal to or less than 10mm in length with part number UNI6594–2.9–9.5.

Note to paragraph (g): Tecnam Service Bulletin 574–CS-Edition 1, Revision 3, dated August 1, 2022, contains information related to this subject.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) 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 § 39.19. In accordance with § 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)(2) 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 local flight standards district office/certificate holding district office.

(j) Additional Information

(1) Refer to EASA AD 2022–0167, dated August 11, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1162.

(2) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at Costruzioni Aeronautiche Tecnam S.P.A., Airworthiness Office Via S. D'acquisto 62, 80042 Boscotrecase, Italy; phone: +39 0823 997538; email: *technical.support@tecnam.com;* website: tecnam.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(k) Material Incorporated by Reference

None.

Issued on September 8, 2022.

Christina Underwood,

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

[FR Doc. 2022–19934 Filed 9–14–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2022–N–1128]

RIN 0910–AI46

Defining Small Number of Animals for Minor Use Determination; Periodic Reassessment

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is revising the ''small number of animals'' definition for dogs and cats in our existing regulation for new animal drugs for minor use or minor species. The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) provides incentives to encourage animal drug sponsors to develop and seek FDA approval of drugs intended for use in minor animal species or for minor uses in major animal species. Congress provided a statutory definition of ''minor use'' that relies on the phrase ''small number of animals'' to characterize such use. We are revising the definition of ''small number of animals'' based on our most recent reassessment of the small numbers, which we conducted from 2018 to 2019.

DATES: This rule is effective December 14, 2022. Either electronic or written comments on this direct final rule or its companion proposed rule must be submitted by November 14, 2022. If FDA receives no significant adverse comments within the specified comment period, the Agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule within 30 days after the comment period on this direct final rule ends.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 14, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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.*