

of the local flight standards district office/
certificate holding district office.

(k) Additional Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238-7146; email: barbara.caufield@faa.gov.

(l) 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) Transport Canada AD CF-2022-22, dated April 22, 2022.

(ii) [Reserved]

(3) For Transport Canada AD CF-2022-22, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: (888) 663-3639; email: AD-CN@tc.gc.ca; website: tc.canada.ca/en/aviation.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222-5110.

(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: www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued on January 17, 2023.

Christina Underwood,

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

[FR Doc. 2023-01148 Filed 1-23-23; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2023-0023; Project Identifier MCAI-2022-01030-T]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2021-08-08, which applies to all Airbus SAS Model A350-941 and -1041 airplanes. AD 2021-08-08 requires

replacing affected bleed duct assemblies and bleed gimbals at the wing-to-pylon interface, and prohibits the installation of affected parts. This AD was prompted by a report of a welding quality issue in the gimbal joint of the air bleed duct at each wing-to-pylon interface and the consequent deformation of the gimbal inner ring, and by new findings that affected bleed gimbals were found on certain airplanes that did not have any maintenance record of affected part replacement. This proposed AD would continue to require the actions in AD 2021-08-08 and, for certain airplanes, would require inspection of the bleed gimbals to determine the part number and replacement if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 10, 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-2023-0023; 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 NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

- 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.

FOR FURTHER INFORMATION CONTACT: Dat Le, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 516-228-7317; email dat.v.le@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA-2023-0023; Project Identifier MCAI-2022-01030-T” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, 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 proposal 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 NPRM.

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 NPRM 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 NPRM, 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 NPRM. Submissions containing CBI should be sent to Dat Le, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 516-228-7317; email dat.v.le@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

The FAA issued AD 2021–08–08, Amendment 39–21502 (86 FR 20453, April 20, 2021) (AD 2021–08–08), for all Airbus SAS Model A350–941 and –1041 airplanes. AD 2021–08–08 was prompted by MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2020–0169R1, dated August 19, 2020 (EASA AD 2020–0169R1), to correct an unsafe condition.

AD 2021–08–08 requires replacing affected bleed duct assemblies and bleed gimbals at the wing-to-pylon interface with serviceable parts. The FAA issued AD 2021–08–08 to address a welding quality issue in the gimbal joint of the air bleed duct located at each wing-to-pylon interface; the inner ring of a gimbal had deformed to an oval shape, which could cause cracking by direct contact between metal parts, and could lead to hot bleed air leakage in the pylon area, and possibly result in loss of the pneumatic system and exposure of the wing structure to high temperatures, and lead to reduced structural integrity of the airplane.

Actions Since AD 2021–08–08 Was Issued

Since the FAA issued AD 2021–08–08, EASA superseded EASA AD 2020–0169R1 and issued EASA AD 2022–0156, dated August 2, 2022 (EASA AD 2022–0156) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes. Since EASA AD 2020–0169R1 was issued, affected bleed gimbals at the wing-to-pylon interface have been found installed on certain airplanes without having any maintenance record of affected part replacement.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2023–0023.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2021–08–08, this proposed AD would retain all of the requirements of AD 2021–08–08. Those requirements are referenced in EASA AD 2022–0156, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0156 specifies procedures, for certain airplanes, for replacing affected bleed duct assemblies and bleed gimbals at the wing-to-pylon interface with serviceable parts, and, for certain other airplanes, inspecting each bleed gimbal at the wing-to-pylon interface to determine if it is an affected part and replacing affected parts. EASA AD 2022–0156 also prohibits the installation of an affected part on any airplane. This material 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.

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 the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in

EASA AD 2022–0156 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0156 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0156 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0156 does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in EASA AD 2022–0156. Service information required by EASA AD 2022–0156 for compliance will be available at regulations.gov under Docket No. FAA–2023–0023 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 31 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions (Group 1 airplanes in the MCAI).	Up to 25 work-hours × \$85 per hour = \$2,125.	Up to \$48,800	Up to \$50,925	* \$0
New proposed actions (Group 2 airplanes in the MCAI).	2 work-hours × \$85 per hour = \$170	0	170	5,270

* The retained replacement from AD 2021–08–08 applies to Group 1 airplanes specified in the MCAI. There are no affected U.S.-registered airplanes in Group 1.

The FAA estimates the following costs to do any necessary on-condition action that would be required based on

the results of any required actions. The FAA has no way of determining the

number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 25 work-hours × \$85 per hour = \$2,125	Up to \$48,800	Up to \$50,925.

According to the manufacturer, some or all of the costs of this proposed 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 known costs in the 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 Findings

The FAA 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) Would not affect intrastate aviation in Alaska, and
- (3) Would 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:
 - a. Removing Airworthiness Directive (AD) 2021–08–08, Amendment 39–21502 (86 FR 20453, April 20, 2021); and
 - b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2023–0023; Project Identifier MCAI–2022–01030–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 10, 2023.

(b) Affected ADs

This AD replaces AD 2021–08–08, Amendment 39–21502 (86 FR 20453, April 20, 2021) (AD 2021–08–08).

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 36, Pneumatic.

(e) Unsafe Condition

This AD was prompted by a report that a welding quality issue has been identified in the gimbal joint of the air bleed duct located at each wing-to-pylon interface; the inner ring of a gimbal had deformed to an oval shape, which could lead to cracking caused by direct contact between metal parts, and by new findings that affected bleed gimbals were found on certain airplanes that did not have any maintenance record of affected part replacement. The unsafe condition, if not addressed, could result in hot bleed air leakage in the pylon area, and possibly result in loss of the pneumatic system and exposure of the wing structure to high temperatures, and lead to reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0156, dated August 2, 2022 (EASA AD 2022–0156).

(h) Exceptions to EASA AD 2022–0156

(1) Where EASA AD 2022–0156 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (6) of EASA AD 2022–0156 refers to August 26, 2020 (the effective date of EASA AD 2020–0169R1), this AD requires using May 25, 2021 (the effective date of AD 2021–08–08).

(3) Where the definition of “Groups” in EASA AD 2022–0156 specifies Group 1 airplanes are those manufacturer serial numbers (MSN) listed in certain service information, replace the text “Airbus Service Bulletin (SB) A350–36–P021 and SB A350–36–P022” with “Airbus Service Bulletin A350–36–P021, dated January 17, 2020; and Airbus Service Bulletin A350–36–P022, dated January 17, 2020.”

(4) Where the definition of “Groups” in EASA AD 2022–0156 specifies Group 2 airplanes are those MSN listed in certain service information, replace the text “Airbus SB A350–36–P029” with “Airbus Service Bulletin A350–36–P029, Revision 01, dated February 3, 2022.”

(5) This AD does not adopt the Remarks paragraph of EASA AD 2022–0156.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0156 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional FAA 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 responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. 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 EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: Except as required by paragraph (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Dat Le, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 516-228-7317; email dat.v.le@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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) European Union Aviation Safety Agency (EASA) AD 2022-0156, dated August 2, 2022.

(ii) [Reserved]

(3) For EASA AD 2022-0256, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; website easa.europa.eu. You may find this EASA AD on the EASA website at ad.easa.europa.eu.

(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: www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued on January 18, 2023.

Christina Underwood,

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

[FR Doc. 2023-01166 Filed 1-23-23; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

[Docket No. FDA-2022-N-1635]

RIN 0910-AI69

Color Additive Certification; Increase in Fees for Certification Services; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule, "Color Additive Certification; Increase in Fees for Certification Services," which published in the **Federal Register** of November 2, 2022. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested parties to collect, analyze, and incorporate data to develop comments for this proposed rule.

DATES: FDA is reopening the comment period on the proposed rule "Color Additive Certification; Increase in Fees for Certification Services," which published in the **Federal Register** on November 2, 2022 (87 FR 66116). Either electronic or written comments must be submitted by March 10, 2023.

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 March 10, 2023. 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>.

- 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-2022-N-1635 for "Color Additive Certification; Increase in Fees for Certification Services; Reopening of the Comment Period." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." We will review this copy, including the claimed confidential information, in our 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 both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this