

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

Issued on November 16, 2022.

Christina Underwood,

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

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2022-1165; Project Identifier MCAI-2022-00700-T; Amendment 39-22254; AD 2022-24-14]

RIN 2120-AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020-12-11, which applied to all Airbus SAS Model A319-111, -112, -113, -114, -115, -151N, and -153N airplanes; Model A320-251N, -252N, -253N, -271N, -272N, and -273N airplanes; and Model A321-251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes. AD 2020-12-11 required revising the existing airplane flight manual (AFM) to limit the use of speed brakes in certain airplane configurations, as specified in a European Union Aviation Safety Agency (EASA) AD. This AD was prompted by a non-stabilized approach followed by an automatic go-around that led to an airplane pitch-up attitude and resulted in an auto-pilot disconnection. This AD continues to require the actions in AD 2020-12-11 and also requires, for certain airplanes, installing updated FG 3G standard software for the FMGC, and prohibits the installation of affected FG standards, as specified in an EASA AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 18, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 18, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2022-1165; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference 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 material 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. It is also available in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2022-1165.
- FOR FURTHER INFORMATION CONTACT:** Hye Yoon Jang, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 817-222-5584; email Hye.Yoon.Jang@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2020-12-11, Amendment 39-19920 (85 FR 41177, July 9, 2020) (AD 2020-12-11). AD 2020-12-11 applied to all Airbus SAS Model A319-111, -112, -113, -114, -115, -151N, and -153N airplanes; Model A320-251N, -252N, -253N, -271N, -272N, and -273N airplanes; and Model A321-251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes. AD 2020-12-11 required revising the existing airplane flight manual (AFM) and applicable corresponding operational procedures to limit the use of speed brakes in certain

airplane configurations. The FAA issued AD 2020-12-11 to address certain airplane configurations, which could result in auto-pilot disconnection and high angle of attack, and consequent increased workload for the flightcrew during a critical phase of flight, and possible loss of control of the airplane.

The NPRM published in the **Federal Register** on September 19, 2022 (87 FR 57150). The NPRM was prompted by AD 2022-0096, dated May 31, 2022, issued by EASA (EASA AD 2022-0096) (referred to after this as the MCAI). The MCAI states that a non-stabilized approach followed by an automatic go-around led to an airplane pitch-up attitude and resulted in an auto-pilot disconnection. The development of updated FG 3G standard software for the flight management and guidance computer (FMGC) will address certain airplane configurations that could result in autopilot disconnection and high angle of attack, and consequent increased workload for the flightcrew during a critical phase of flight, and possible loss of control of the airplane.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2022-1165.

In the NPRM, the FAA proposed to continue to require revising the existing airplane flight manual (AFM) and applicable corresponding operational procedures to limit the use of speed brakes in certain airplane configurations. The NPRM also proposed to require installing updated FG 3G standard software for certain airplanes, and to prohibit the installation of affected FG standards, as specified in EASA AD 2022-0096. The FAA is issuing this AD to address certain airplane configurations that could result in auto-pilot disconnection and high angle of attack, and consequent increased workload for the flightcrew during a critical phase of flight, and possible loss of control of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Air Line Pilots Association, International, who supported the NPRM without change.

Conclusion

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 referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2022-0096 specifies procedures for revising the existing AFM to limit the use of speed brakes in certain landing conditions, and updating the FG 3G standard software for the FMGC for certain airplanes. EASA AD 2022-0096 also prohibits the installation of affected FG standards. 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.

Interim Action

The FAA considers that this AD is an interim action. If final action is later identified, the FAA might consider further rulemaking then.

Costs of Compliance

The FAA estimates that this AD affects 693 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2020-12-11.	1 work-hour × \$85 per hour = \$85.	\$0	\$85	\$58,905
Software update	Up to 5 work-hours × \$85 per hour = \$425.	Up to \$570	Up to \$995	Up to \$689,535

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,
- (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:
 - a. Removing Airworthiness Directive 2020-12-11, Amendment 39-19920 (85 FR 41177, July 9, 2020); and
 - b. Adding the following new airworthiness directive:

2022-24-14 Airbus SAS: Amendment 39-22254; Docket No. FAA-2022-1165; Project Identifier MCAI-2022-00700-T.

(a) Effective Date

This airworthiness directive (AD) is effective January 18, 2023.

(b) Affected ADs

This AD replaces AD 2020-12-11, Amendment 39-19920 (85 FR 41177, July 9, 2020) (AD 2020-12-11).

(c) Applicability

This AD applies to all Airbus SAS Model airplanes identified in paragraphs (c)(1) through (3) of this AD, certificated in any category.

(1) Model A319-111, -112, -113, -114, -115, -151N, and -153N airplanes.

(2) Model A320-251N, -252N, -253N, -271N, -272N, and -273N airplanes.

(3) Model A321-251N, -251NX, -252N, -252NX, -253N, -253NX, -271N, -271NX, -272N, and -272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 22, Auto Flight.

(e) Unsafe Condition

This AD was prompted by a report of a non-stabilized approach followed by an automatic go-around, which led to an airplane pitch-up attitude and resulted in an auto-pilot disconnection. This AD was further prompted by the need for updated flight guidance (FG) 3G standard software for the flight management and guidance computer (FMGC) on certain airplanes. The FAA is issuing this AD to address certain airplane configurations that could result in auto-pilot disconnection and high angle of attack, and consequent increased workload for the flightcrew during a critical phase of flight, and possible loss of control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022-0096, dated May 31, 2022 (EASA AD 2022-0096).

(h) Exceptions to EASA AD 2022-0096

(1) Where EASA AD 2022-0096 refers to "the effective date of EASA AD 2020-0118," this AD requires using July 24, 2020 (the effective date of AD 2020-12-11).

(2) Where EASA AD 2022–0096 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraph (1) of EASA AD 2022–0096 specifies to “inform all flight crews, and, thereafter, operate the aeroplane accordingly,” this AD does not require those actions as those actions are already required by existing FAA operating regulations (see 14 CFR 91.9, 14 CFR 91.505, and 14 CFR 121.137).

(4) The “Remarks” section of EASA AD 2022–0096 does not apply to this AD.

(i) Additional FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Large Aircraft Section, 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 Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j) 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, Large Aircraft Section, 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 (i)(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.

(j) Additional Information

For more information about this AD, contact Hye Yoon Jang, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des

Moines, WA 98198; telephone 817–222–5584; email Hye.Yoon.Jang@faa.gov.

(k) 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 2022–0096, dated May 31, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0096, 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 material 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 material 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 November 16, 2022.

Christina Underwood,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 528, and 558

[Docket No. FDA–2022–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for

new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during April, May, and June 2022. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective December 14, 2022.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and cNADAs during April, May, and June 2022, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>.

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.