

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2022-0586; Project Identifier MCAI-2021-01262-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) 2016-26-05 and AD 2019-21-02, which apply to certain Airbus SAS Model A330-200, A330-200 Freighter, and A330-300 series airplanes. AD 2016-26-05 and AD 2019-21-02 require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2016-26-05 and AD 2019-21-02, the FAA has determined that new or more restrictive airworthiness limitations are necessary, and new airplanes have been added to the applicability. This proposed AD would continue to require the actions in AD 2019-21-02 and require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, 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 July 5, 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 <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 EASA 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](mailto:ADs@easa.europa.eu); internet [www.easa.europa.eu](http://www.easa.europa.eu). You may find this material on the EASA website at <https://ad.easa.europa.eu>. For Airbus service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office-EAL, Rond-Point Emile Dewoitine No. 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email [airworthiness.A330-A340@airbus.com](mailto:airworthiness.A330-A340@airbus.com); internet <https://www.airbus.com>. 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 <https://www.regulations.gov> by searching for and locating Docket No. FAA-2022-0586.

#### Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA-2022-0586; 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.

#### FOR FURTHER INFORMATION CONTACT:

Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206-231-3229; email [vladimir.ulyanov@faa.gov](mailto:vladimir.ulyanov@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-2022-0586; Project Identifier MCAI-2021-01262-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 <https://www.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 Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206-231-3229; email [vladimir.ulyanov@faa.gov](mailto:vladimir.ulyanov@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 2019–21–02, Amendment 39–19768 (84 FR 57313, October 25, 2019) (AD 2019–21–02), which applies to certain Airbus SAS Model A330–200, A330–200 Freighter, and A330–300 series airplanes. AD 2019–21–02 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2019–21–02 to address a safety-significant latent failure (that is not annunciated) that, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition. AD 2019–21–02 specifies that accomplishing the revision required by that AD terminates all requirements of 2016–26–05, Amendment 39–18763 (82 FR 1170, January 5, 2017) (AD 2016–26–05).

## Actions Since AD 2019–21–02 Was Issued

Since the FAA issued AD 2019–21–02, the FAA has determined that new or more restrictive airworthiness limitations are necessary.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0248, dated November 15, 2021 (EASA AD 2021–0248) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model Airbus A330–201, A330–202, A330–203, A330–223, A330–223F, A330–243, A330–243F, A330–301, A330–302, A330–303, A330–321, A330–322, A330–323, A330–341, A330–342, A330–343, A330–841, and A330–941 airplanes.

Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after July 1, 2021, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability.

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary, and that EASA AD 2021–0248 has added Airbus SAS Model A330–841 and A330–941 airplanes to the applicability. The FAA is proposing this AD to address a safety-significant latent failure (that is not annunciated) that, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition. See the MCAI for additional background information.

## Related Service Information Under 1 CFR Part 51

EASA AD 2021–0248 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits, and adds new models to the applicability.

This proposed AD would also require Airbus A330 Airworthiness Limitations Section (ALS) Part 3–Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018; and Airbus A330 ALS Part 3–Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019; which the Director of the Federal Register approved for incorporation by reference as of November 29, 2019 (84 FR 57313, October 25, 2019).

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

These products have been approved by the aviation authority of another country and are 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 these same type designs.

## Proposed AD Requirements in This NPRM

This proposed AD would retain the requirements of AD 2019–21–02. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2021–0248 described previously, as proposed for incorporation by reference. Any differences with EASA AD 2021–0248 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative

method of compliance (AMOC) according to paragraph (l)(1) 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 2021–0248 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0248 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 2021–0248 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 2021–0248. Service information required by EASA AD 2021–0248 for compliance will be available at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2022–0586 after the FAA final rule is published.

## Airworthiness Limitation ADs Using the New Process

The FAA’s process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.*, inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under “Additional FAA AD Provisions.” This new format includes a “New Provisions for Alternative Actions and Intervals” paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

### Costs of Compliance

The FAA estimates that this proposed AD affects 138 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2019–21–02 to be \$7,650 (90 work-hours × \$85 per work-hour).

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

The FAA estimates the total cost per operator for the new proposed actions 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

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 2016–26–05, Amendment 39–18763 (82 FR 1170, January 5, 2017); and Airworthiness Directive 2019–21–02, Amendment 39–19768 (84 FR 57313, October 25, 2019); and
  - b. Adding the following new airworthiness directive:

**Airbus SAS:** Docket No. FAA–2022–0586; Project Identifier MCAI–2021–01262–T.

#### (a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by July 5, 2022.

#### (b) Affected ADs

This AD replaces AD 2016–26–05, Amendment 39–18763 (82 FR 1170, January 5, 2017) (AD 2016–26–05); and AD 2019–21–02, Amendment 39–19768 (84 FR 57313, October 25, 2019) (AD 2019–21–02).

#### (c) Applicability

This AD applies to Airbus SAS Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, –343, –841, and –941 airplanes, certificated in any category, with an original

airworthiness certificate or original export certificate of airworthiness issued on or before July 1, 2021.

#### (d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

#### (e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary, and that new airplanes have been added to the applicability. The FAA is issuing this AD to address a safety-significant latent failure (that is not annunciated) that, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition.

#### (f) Compliance

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

#### (g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2019–21–02, with no changes. For Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 15, 2018: Within 90 days after November 29, 2019 (the effective date of AD 2019–21–02), revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Airbus A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018, as supplemented by Airbus A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019. The initial compliance times for doing the tasks is at the time specified in Airbus A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018, as supplemented by Airbus A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019, or within 90 days after November 29, 2019, whichever occurs later. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

#### (h) Retained No Alternative Actions or Intervals, With a New Exception

This paragraph restates the requirements of paragraph (h) of AD 2019–21–02, with a new exception. Except as required by paragraph (i) of this AD, after the 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 the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

**(i) New Revision of the Existing Maintenance or Inspection Program**

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0248, dated November 15, 2021 (EASA AD 2021–0248). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

**(j) Exceptions to EASA AD 2021–0248**

(1) Where EASA AD 2021–0248 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0248 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2021–0248 specifies revising “the approved AMP” within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA 2021–0248 is at the applicable “associated thresholds,” as incorporated by the requirements of paragraph (3) of EASA AD 2021–0248, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraphs (4) and (5) of EASA AD 2021–0248 do not apply to this AD.

(6) The “Remarks” section of EASA AD 2021–0248 does not apply to this AD.

**(k) New Provisions for Alternative Actions and Intervals**

After the existing maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (e.g., inspections) and intervals are allowed unless they are approved as specified in the provisions of the “Ref. Publications” section of EASA AD 2021–0248.

**(l) 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 (m)(2) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov.

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved previously for AD 2019–21–02 are approved as AMOCs for the

corresponding provisions of EASA AD 2021–0248 that are required by paragraph (g) of this AD.

(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.

**(m) Related Information**

(1) For EASA AD 2021–0248, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email [ADS@easa.europa.eu](mailto:ADS@easa.europa.eu); internet [www.easa.europa.eu](http://www.easa.europa.eu). You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3229; email [vladimir.ulyanov@faa.gov](mailto:vladimir.ulyanov@faa.gov).

(3) For Airbus service information identified in this AD, contact Airbus SAS, Airworthiness Office-EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email [airworthiness.A330-A340@airbus.com](mailto:airworthiness.A330-A340@airbus.com); internet <https://www.airbus.com>. 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.

Issued on May 16, 2022.

**Gaetano A. Sciortino,**

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

[FR Doc. 2022–10775 Filed 5–19–22; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 190**

[Docket No. FDA–2022–D–0281]

**Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-Market Notification; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notification.” The draft guidance, when finalized, will advise the dietary supplement industry of our intent to exercise enforcement discretion, for a limited time and in limited circumstances, regarding the requirement to submit a new dietary ingredient (NDI) notification prior to marketing. The purpose of the policy is to encourage manufacturers and distributors of certain NDI-containing dietary supplements to correct any past failures to submit a required NDI notification.

**DATES:** Submit either electronic or written comments on the draft guidance by July 19, 2022 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by July 19, 2022.

**ADDRESSES:** You may submit comments on any guidance 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”).