

(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, EASA AD 2018–0289.

(h) Exceptions to EASA AD 2018–0289

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2018–0289 refers to its effective date, this AD requires using the effective date of this AD.

(2) The “Remarks” section of EASA AD 2018–0289 does not apply to this AD.

(3) Where Table 1 of EASA AD 2018–0289 refers to a compliance time “after 31 May 2017,” this AD requires using a compliance time after May 31, 2018 (the effective date of task 531103–01–1 in “ALS Part 2 rev. 6”).

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. 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.

(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 Section, Transport Standards 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)*: For any service information referenced in EASA AD 2018–0289 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC 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) Related Information

(1) For information about EASA AD 2018–0289, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email ADs@easa.europa.eu;

Internet

www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>. You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2018–0289 may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0254.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

Issued in Des Moines, Washington, on May 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–09440 Filed 5–7–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA–2019–0320; Product Identifier 2019–NM–017–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus SAS Model A330–200 Freighter, –200 and –300 series airplanes; and certain Airbus SAS Model A340–200, –300, –500, and –600 series airplanes. This proposed AD was prompted by a determination that certain wing slat tracks that were inadvertently indicated as eligible for installation on all Model A330 and A340 series airplanes are unable to sustain the ultimate loads relative to the weight variant of certain airplane configurations. This proposed AD would require inspecting any affected part for cracking, and replacing with a serviceable part, as specified in an European Aviation Safety Agency (EASA) AD, which will be incorporated by reference. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 24, 2019.

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 <http://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*: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For the incorporation by reference (IBR) material described in the “Related IBR material under 1 CFR part 51”

section in **SUPPLEMENTARY INFORMATION**, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email ADs@easa.europa.eu;

internet www.easa.europa.eu. You may find this IBR material on the EASA website at <https://ad.easa.europa.eu>. You may view this IBR material at the FAA, Transport Standards 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 on the internet at <http://www.regulations.gov>.

Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0320; 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 regulatory evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St, Des Moines, WA 98198; telephone and fax: 206–231–3229.

SUPPLEMENTARY INFORMATION:**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA–2019–0320; Product Identifier 2019–NM–017–AD” at the beginning of your comments. We specifically invite

comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019-0026, dated February 4, 2019 (“EASA AD 2019-0026”) (also referred to as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus SAS Model A330-200 Freighter, -200 and -300 series airplanes; and certain Airbus SAS Model A340-200, -300, -500, and -600 series airplanes. The MCAI states:

It was recently determined that, since June 2010, the affected parts were inadvertently indicated as eligible for installation on all A330 and A340 aeroplanes in the applicable Illustrated Part Catalogue (IPC), although in fact, those parts are not valid for some aeroplane configurations (weight variants), because they are unable to sustain ultimate load. Investigation demonstrated that affected parts were never delivered as spare part. However, it cannot be excluded that an affected part was removed in-service from an aeroplane and installed on another.

This condition, if not detected and corrected, could lead to slat detachment in flight, possibly resulting in reduced control of the aeroplane.

To address this potential unsafe condition, Airbus published the applicable SB [service bulletin] to provide instructions to identify affected parts, and instructions to inspect [for cracking of] those affected parts found installed.

For the reasons described above, this [EASA] AD requires a one-time detailed (DET) and special detailed inspection (SDI) of the aft lug of each affected part and replacement of each affected part. This [EASA] AD also prohibits installation of affected parts.

Related IBR Material Under 1 CFR Part 51

EASA AD 2019-0026 describes procedures for one-time detailed and special detailed (high frequency eddy current) inspections for cracking of the aft lug of each affected wing slat track (including an inspection to first determine if an affected part is installed), and replacing any affected part with a serviceable part. 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, and it is publicly available through the EASA website.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists

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

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2019-0026 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. As a result, EASA AD 2019-0026 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with the provisions specified in EASA AD 2019-0026, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in EASA AD 2019-0026 that is required for compliance with EASA AD 2019-0026 will be available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0320 after the FAA final rule is published.

Costs of Compliance

We estimate that this proposed AD affects 104 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
7 work-hours × \$85 per hour = \$595	\$0	\$595	\$61,880

We estimate the following costs to do any necessary on-condition action that would be required based on the results

of any required actions. We have no way of determining the number of aircraft

that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTION

Labor cost	Parts cost	Cost per product
8 work-hours × \$85 per hour = \$680	\$0	\$680

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. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our 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.

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

We 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. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. 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 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 adding the following new airworthiness directive (AD):

Airbus SAS: Docket No. FAA-2019-0320; Product Identifier 2019-NM-017-AD.

(a) Comments Due Date

We must receive comments by June 24, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1), (c)(2), (c)(3), (c)(4), (c)(5), and (c)(6) of this AD, certificated in any category, as identified in European Aviation Safety Agency (EASA) AD 2019-0026, dated February 4, 2019 ("EASA AD 2019-0026").

- (1) Airbus SAS Model A330-223F and -243F airplanes.
- (2) Airbus SAS Model A330-201, -202, -203, -223, and -243 airplanes.
- (3) Airbus SAS Model A330-301, -302, -303, -321, -322, -323, -341, -342, and -343 airplanes.
- (4) Airbus SAS Model A340-211, -212, and -213 airplanes.
- (5) Airbus SAS Model A340-311, -312, and -313 airplanes.
- (6) Airbus SAS Model A340-541 and -642 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by a determination that certain wing slat tracks that had been inadvertently indicated as eligible for installation on all Model A330 and A340 series airplanes are unable to sustain the ultimate loads relative to the weight variant of certain airplane configurations. We are issuing this AD to address installation of affected parts, which could result in slat detachment in flight and consequent reduced 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, EASA AD 2019-0026.

(h) Exceptions to EASA AD 2019-0026

- (1) For purposes of determining compliance with the requirements of this AD:

Where EASA AD 2019-0026 refers to its effective date, this AD requires using the effective date of this AD.

- (2) The "Remarks" section of EASA AD 2019-0026 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. 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.

(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 Section, Transport Standards 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):* For any service information referenced in EASA AD 2019-0026 that contains RC procedures and tests: Except as required by paragraph (i)(2) of this AD, RC 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) Related Information

(1) For information about EASA AD 2019-0026, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this EASA AD on the EASA website at <https://ad.easa.europa.eu>. You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. EASA AD 2019-0026 may be found in the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0320.

- (2) For more information about this AD, contact Vladimir Ulyanov, Aerospace

Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206-231-3229.

Issued in Des Moines, Washington, on May 1, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019-09442 Filed 5-7-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2019-C-1782]

CooperVision, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by CooperVision, Inc., proposing that the color additive regulations be amended to provide for the safe use of disperse orange 3 methacrylamide to color contact lenses. The color additive is intended to be copolymerized with various monomers to produce colored contact lens materials.

DATES: The color additive petition was filed on March 28, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 9C0315), submitted by CooperVision, Inc., 5870 Stoneridge Dr., Suite 1, Pleasanton, CA 94588. The petition proposes to amend the color additive regulations in 21 CFR part 73, *Listing of*

Color Additives Exempt from Certification, to provide for the safe use of disperse orange 3 methacrylamide (CAS Reg. No. 58142-15-7; CAS name 2-propenamamide, 2-methyl-N-[4-[2-(4-nitrophenyl)diazenyl]phenyl]-) to color contact lenses. The color additive is intended to be copolymerized with various monomers to produce colored contact lens materials.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(l) because disperse orange 3 methacrylamide is intended for use in contact lenses. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-09411 Filed 5-7-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2019-0300]

RIN 1625-AA08

Special Local Regulations; Festival of Sail Duluth 2019 Parade of Sail, Lake Superior, Duluth, MN

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary special local regulation for a designated area of the Duluth Harbor entrance to Superior Bay on Lake Superior during the Festival of Sail 2019 event in Duluth, MN. This action is necessary to provide for the safety of life on these navigable waters around the port of Duluth, MN during a parade of sail event on August 11, 2019. This proposed rulemaking would prohibit persons and vessels from being in the designated region unless authorized by the Captain of the Port Duluth or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 7, 2019.

ADDRESSES: You may submit comments identified by docket number USCG-2019-0300 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Abbie Lyons, Waterways Management, MSU Duluth, U.S. Coast Guard; telephone 218-725-3818, email Abbie.E.Lyons@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On December 11, 2018, Draw Events LLC notified the Coast Guard that it will be conducting a Parade of Sail from 7 a.m. through 1 p.m. on August 11, 2019, as part of the 2019 Festival of Sail event in Duluth, MN from August 11 through August 13, 2019. Hazards from spectator vessels and the limited maneuverability of the sailing vessels exist. The Captain of the Port Duluth (COTP) has determined that potential hazards associated with the parade of sail would be a safety concern for anyone within the route of the parade.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the parade route before, during, and immediately after the scheduled event. The legal basis for this proposed rule is the Coast Guard's authority under 46 U.S.C. 70041; 33 CFR 1.05-1.

III. Discussion of Proposed Rule

The COTP is proposing to establish a special local regulation from 7 a.m. through 1 p.m. on August 11, 2019. The special local regulation would cover all navigable waters encompassed within the following boundaries: Beginning at position 46°46'48.36" N, 092°05'16.44" W, across Duluth Harbor to 46°47'02.76" N, 092°05'17.88" W, turning north toward the Duluth Lift Bridge at to 46°47'19.32" N, 092°04'04.80" W, to 46°46'50.88" N, 092°05'17.88" W, out