

(j) Exceptions to EASA AD 2020–0117

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0117 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2020–0117 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, to incorporate the “limitations, tasks and associated thresholds and intervals” specified in paragraph (3) of EASA AD 2020–0117 within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0117 is at the applicable “associated thresholds” specified in paragraph (3) of EASA AD 2020–0117, or within 90 days after the effective date of this AD, whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2020–0117 do not apply to this AD.

(5) The “Remarks” section of EASA AD 2020–0117 does not apply to this AD.

(k) New Provisions for Alternative Actions and Intervals

After the 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 2020–0117.

(l) Terminating Actions for Certain Actions in AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (i) of this AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, for Dassault Aviation Model FALCON 900EX airplanes, 900EX airplanes, S/N 97 and S/Ns 120 and higher.

(m) Other 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 local Flight Standards District 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 (n)(2) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov.

(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 Dassault Aviation’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) For information about EASA AD 2020–0117, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; 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 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. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–0677.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206–231–3226; email: tom.rodriguez@faa.gov.

Issued on July 27, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–16629 Filed 7–31–20; 8:45 am]

BILLING CODE 4910–13–P

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

[Docket No. FAA–2020–0678; Product Identifier 2020–NM–098–AD]

RIN 2120–AA64**Airworthiness Directives; Dassault Aviation Airplanes**

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2019–24–11, which applies to certain Dassault Aviation Model FALCON 900EX airplanes. AD 2019–24–11 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2019–24–11, the FAA determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require those maintenance or inspection program revisions, and would also 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 will be incorporated 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 September 17, 2020.

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 identified in this proposed AD that will be incorporated by reference (IBR), contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; 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>.

For Dassault service information identified in the proposed AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet <https://www.dassaultfalcon.com>.

You may view this IBR 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 on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–0678.

Examining the AD Docket

You may examine the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–0678; 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, any comments received, and other information. The street address for

Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax: 206-231-3226; email: tom.rodriguez@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2020-0678; Product Identifier 2020-NM-098-AD" at the beginning of your 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, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

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 the person identified in the **FOR FURTHER INFORMATION CONTACT** section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2019-24-11, Amendment 39-19814 (84 FR 69997, December 20, 2019) ("AD 2019-24-11"), which applies to certain Dassault Aviation Model FALCON 900EX airplanes. AD 2019-24-11 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2019-24-11 to address reduced structural integrity of the airplane.

AD 2019-24-11 specifies that accomplishing the actions required by paragraph (g) or (i) of that AD terminates the requirements of paragraph (g)(1) of AD 2010-26-05, Amendment 39-16544 (75 FR 79952, December 21, 2010) for Dassault Aviation Model FALCON 900EX airplanes, serial numbers 1 through 96 inclusive, and serial numbers 98 through 119 inclusive.

Actions Since AD 2019-24-11 Was Issued

Since the FAA issued AD 2019-24-11, the FAA determined that new or more restrictive airworthiness limitations are necessary.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020-0116, dated May 20, 2020 ("EASA AD 2020-0116") (also referred to as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Dassault Aviation Model FALCON 900EX airplanes. EASA AD 2020-0116 superseded EASA AD 2019-0133 (which corresponds to FAA AD 2019-24-11).

This proposed AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is proposing this AD to address reduced structural integrity of the airplane. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2020-0116 describes new or more restrictive maintenance tasks and airworthiness limitations.

This proposed AD would also require Chapter 5-40, Airworthiness

Limitations, Revision 16, dated September 2018, of the Dassault FALCON 900EX Maintenance Manual, which the Director of the Federal Register approved for incorporation by reference as of January 24, 2020 (84 FR 69997, December 20, 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 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 the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA 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 AD Requirements

This proposed AD would retain the requirements of AD 2019-24-11. 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 2020-0116 described previously, as incorporated by reference. Any differences with EASA AD 2020-0116 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 according to paragraph (m)(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 initially 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. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0116 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0116 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 the EASA AD 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 the EASA AD.

Service information specified in EASA AD 2020–0116 that is required for compliance with EASA AD 2020–0116 will be available on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–0678 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).

Costs of Compliance

The FAA estimates that this proposed AD affects 72 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 2019–24–11 to be \$7,650 (90 work-hours × \$85 per work-hour).

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. 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. Therefore, 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) 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 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 removing Airworthiness Directive (AD) 2019–24–11, Amendment 39–19814 (84 FR 69997, December 20, 2019), and adding the following new AD:

Dassault Aviation: Docket No. FAA–2020–0678; Product Identifier 2020–NM–098–AD.

(a) Comments Due Date

The FAA must receive comments by September 17, 2020.

(b) Affected ADs

- (1) This AD replaces AD 2019–24–11, Amendment 39–19814 (84 FR 69997, December 20, 2019) (“AD 2019–24–11”).
- (2) This AD affects AD 2010–26–05, Amendment 39–16544 (75 FR 79952, December 21, 2010) (“AD 2010–26–05”).

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 900EX airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0116, dated May 20, 2020 (“EASA AD 2020–0116”).

(d) Subject

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

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Maintenance or Inspection Program Revision, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2019–24–11, with no changes. Within 90 days after January 24, 2020 (the effective date AD 2019–24–11), revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Chapter 5–40,

Airworthiness Limitations, Revision 16, dated September 2018, of the Dassault FALCON 900EX Maintenance Manual. The initial compliance times for accomplishing the actions are at the times specified in Chapter 5–40, Airworthiness Limitations, Revision 16, dated September 2018, or 90 days after the January 24, 2020, whichever occurs later, except as provided by paragraphs (g)(1) through (4) of this AD. Accomplishing the maintenance or inspection program revision required by paragraph (i) of this AD terminates the requirements of this paragraph.

(1) The term “LDG” in the “First Inspection” column of any table in the service information means total airplane landings.

(2) The term “FH” in the “First Inspection” column of any table in the service information means total flight hours.

(3) The term “FC” in the “First Inspection” column of any table in the service information means total flight cycles.

(4) The term “M” in the “First Inspection” column of any table in the service information means months since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness.

(h) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (j) of AD 2019–24–11, 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 (m)(1) of this AD.

(i) New Maintenance or Inspection Program Revision

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0116. Accomplishing the maintenance or inspection program revision required by this paragraph terminates the requirements of paragraph (g) of this AD.

(j) Exceptions to EASA AD 2020–0116

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0116 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2020–0116 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, to incorporate the “limitations, tasks and associated thresholds and intervals” specified in paragraph (3) of EASA AD 2020–0116 within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0116 is at the applicable “associated thresholds” specified in paragraph (3) of EASA AD 2020–0116, or

within 90 days after the effective date of this AD, whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2020–0116 do not apply to this AD.

(5) The “Remarks” section of EASA AD 2020–0116 does not apply to this AD.

(k) New Provisions for Alternative Actions and Intervals

After the 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 2020–0116.

(l) Terminating Actions for Certain Actions in AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (i) of this AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, for Dassault Aviation Model FALCON 900EX airplanes, serial numbers 1 through 96 inclusive, and serial numbers 98 through 119 inclusive.

(m) Other 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 local Flight Standards District 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 (n)(2) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov.

(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 Dassault Aviation’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) For information about EASA AD 2020–0116, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; 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 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. This material may be found in the AD docket on the internet at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2020–0678.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226; email tom.rodriguez@faa.gov.

Issued on July 27, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–16628 Filed 7–31–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2018–N–4268]

RIN 0910–AH66

Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Veterinary Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), with the Department of the Treasury’s concurrence, is proposing to amend its regulations to require that certain data elements be submitted for veterinary devices that are being imported or offered for import in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by U.S. Customs and Border Protection (CBP), in order for CBP to process the filing and to help FDA in determining the admissibility of that veterinary device. The proposed rule would make the submission of the general data elements currently required to be submitted in ACE for other FDA-regulated products at the time of entry also required in ACE for veterinary devices being imported or offered for import into the United States. This proposed rule would increase effective and efficient admissibility review by FDA of those entry lines containing a veterinary device, which will protect public health by allowing the Agency to focus its limited resources on FDA-regulated products that may be associated with a greater public health risk.

DATES: Submit either electronic or written comments on the proposed rule