

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that 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); and (3) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

Empresa Brasileira De Aeronautica S.A. (Embraer): Docket 2004–NM–48–AD.

Applicability: Model EMB–120 series airplanes, serial numbers 120004, and 120006 through 120359 inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent possible multiple avionics failures caused by a lightning strike, which could reduce the ability of the flightcrew to control the airplane, accomplish the following:

Installation

(a) Within 4,000 flight hours or 30 months after the effective date of this AD, whichever

comes first, install a lightning bonding jumper from the lower rotating beacon to the airframe in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 120–33–0037, dated November 5, 2003.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Note 1: The subject of this AD is addressed in Brazilian airworthiness directive 2004–01–06, dated February 5, 2004.

Issued in Renton, Washington, on April 19, 2004.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–325–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP Model Galaxy and Model Gulfstream 200 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Gulfstream Aerospace LP Model Galaxy and Model Gulfstream 200 airplanes. This proposal would require a one-time detailed inspection of the wing flap actuators for proper bonding of the flap actuator fairings to the lower skin of the wings, and related corrective or preventative actions. These actions are necessary to prevent possible damage to adjacent structural elements (such as the horizontal stabilizer) caused by separation of the flap actuator fairings from the wing lower skin, which could result in reduced controllability of the airplane. These actions are intended to address the identified unsafe condition.

DATES: Comments must be received by June 1, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–

325–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9–anm–nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2002–NM–325–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D25, Savannah, Georgia 31402. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer; International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by

interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2002-NM-325-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 2002-NM-325-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Civil Aviation Administration of Israel (CAAI), which is the airworthiness authority for Israel, notified the FAA that an unsafe condition may exist on certain Gulfstream Aerospace LP Model Galaxy and Model Gulfstream 200 airplanes. The CAAI advises that several cases of adhesive separation of the flap actuator fairings from the lower skin of the wings have been reported. This condition, if not corrected, could result in possible damage to adjacent structural elements (such as the horizontal stabilizer), which could result in reduced controllability of the airplane.

Explanation of Relevant Service Information

Gulfstream Aerospace LP has issued Alert Service Bulletin 200-57A-161, Revision 1, dated November 7, 2002, which describes procedures for a one-time detailed inspection of the wing flap actuators for proper bonding of the flap actuator fairings to the lower skin of the wings. Related corrective or preventative actions, as applicable, include initial reinforcement of the adhesive of the actuator fairings; and removal and reattachment of the fairings to the lower skin of the wings. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The CAAI classified this service bulletin as mandatory and issued Israeli airworthiness directive 57-02-10-15, dated October 31, 2002, to ensure the continued airworthiness of these airplanes in Israel.

FAA's Conclusions

These airplane models are manufactured in Israel and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAAI has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAAI, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Difference Between Proposed Rule and Referenced Service Bulletin

Operators should note that, although the referenced service bulletin describes procedures for reporting compliance with the service bulletin to the manufacturer, this proposed AD would not require that action. The FAA does not need this information from operators.

Cost Impact

The FAA estimates that 60 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 13 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$65 per work hour. Required parts would be supplied free of charge by the manufacturer. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$50,700, or \$845 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up,

planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that 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); and (3) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

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The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

Gulfstream Aerospace LP (Formerly Israel Aircraft Industries, Ltd.): Docket 2002-NM-325-AD.

Applicability: Model Galaxy and Model Gulfstream 200 airplanes, serial numbers 004 through 074 inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent possible separation of the flap actuator fairings from the wing lower skin from causing damage to adjacent structural elements (such as the horizontal stabilizer), which could result in reduced controllability of the airplane, accomplish the following:

Inspection

(a) Within 30 flight hours or 5 flight cycles after the effective date of this AD, whichever occurs earlier, perform a one-time detailed inspection of the wing flap actuators for proper bonding of the flap actuator fairings to the lower skin of the wings; in accordance with Part A of the Accomplishment Instructions of Gulfstream Aerospace LP Alert Service Bulletin 200-57A-161, Revision 1, dated November 7, 2002.

Note 1: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Reinforcement of Actuator Fairing Adhesive

(b) If the inspection required by paragraph (a) of this AD reveals either no separation or separation of the flap actuator fairings from the lower skin of the wings that is within the limits specified in Gulfstream Aerospace LP Alert Service Bulletin 200-57A-161, Revision 1, dated November 7, 2002, do paragraphs (b)(1) and (b)(2) of this AD.

(1) Prior to further flight, apply sealant around the edges of the fairings, in accordance with Part A of the Accomplishment Instructions of the service bulletin.

(2) Within 300 flight hours after performing paragraph (b)(1) of this AD, remove and reattach the flap actuator fairings in accordance with Part B of the Accomplishment Instructions of the service bulletin.

Removal and Reattachment of Actuator Fairings

(c) If the inspection required by paragraph (a) of this AD reveals separation of the flap actuator fairings from the lower skin of the wings that is outside the limits specified in Gulfstream Aerospace LP Alert Service Bulletin 200-57A-161, Revision 1, dated November 7, 2002: Prior to further flight, remove and reattach the flap actuator fairings in accordance with Part B of the Accomplishment Instructions of the service bulletin.

Actions Accomplished Per Previous Issue of Service Bulletin

(d) Actions accomplished before the effective date of this AD per Gulfstream Aerospace LP Alert Service Bulletin 200-57A-161, dated November 5, 2002, are considered acceptable for compliance with the corresponding actions specified in this AD.

Reporting Requirements

(e) Although the service bulletin referenced in this AD specifies to submit certain information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance

(f) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM-116, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 2: The subject of this AD is addressed in Israeli airworthiness directive AD 57-02-10-15, dated October 31, 2002.

Issued in Renton, Washington, on April 21, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 04-9764 Filed 4-28-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 59**

[Docket No. 2002N-0085]

RIN 0910-AB96

Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations for persons who use sampling services (services that collect samples for another party) and private laboratories used in connection with imported food. The proposal would require samples to be properly identified, collected, and maintained. Additionally, the proposal would require laboratories to use validated or recognized analytical methods, and to submit analytical results directly to FDA. The proposal is intended to help assure the integrity and scientific validity of data and results submitted to FDA.

DATES: Submit written or electronic comments by July 28, 2004. Submit written or electronic comments on the information collection provisions by June 1, 2004. See section VIII of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. 2002N-0085, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2002N-0085 and RIN number 0910-AB96 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

SUPPLEMENTARY INFORMATION:**I. Introduction**

Persons who import food products into the United States often use private laboratories to test their food imports and submit the results of such tests to FDA. For example, FDA may refuse admission of an imported food into the United States if the food appears to be adulterated or misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the act). Pending a decision to refuse admission, the owner or consignee of the imported article may wish to present evidence to show that