

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:

SAAB Aircraft AB: Docket 2000–NM–213–AD.

Applicability: Model SAAB SF340A series airplanes, serial numbers –004 through –159 inclusive; and Model SAAB 340B series airplanes, serial numbers –160 through –459 inclusive; certificated in any category; on which a refuel/defuel panel having part number 7239160–505 is installed.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the

owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent electrical shorts or arcing at the illuminated panel connector at the refuel/defuel panel, which could result in a potential ignition source for fuel vapors during fueling procedures, accomplish the following:

Inspection and Corrective Actions

(a) Within 6 months after the effective date of this AD, inspect the electrical connector on the refuel/defuel panel and the electrical connector on the illuminated placard to detect signs of fluid ingress or corrosion; and accomplish applicable corrective actions (including a sealing procedure, a cleaning/sealing procedure, and repair of corrosion on the refuel/defuel panel mounting plate); in accordance with Saab Service Bulletin 340–28–022, dated February 25, 2000.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Swedish airworthiness directive 1–156, dated February 28, 2000.

Issued in Renton, Washington, on September 13, 2000.

Donald L. Riggins,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–24001 Filed 9–18–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–293–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 Series 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 all Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes. This proposal would require a one-time general visual inspection for proper rigging of the lift-dumper micro switches installed in the left- and right-hand sides of the pedestal; a functional check of the micro switches; and re-rigging the cam, if necessary. This action is necessary to detect and correct improper rigging of the lift-dumper micro switches, which could result in inadvertent extension of the lift-dumpers during takeoff roll. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by October 19, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–293–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 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. 2000–NM–293–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 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw-Vennep, the Netherlands. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT:

Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; 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 notice 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 notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000-NM-293-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. 2000-NM-293-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for

the Netherlands, notified the FAA that an unsafe condition may exist on all Fokker Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes. The RLD advises that it received two reports of inadvertent liftdumper deployments during takeoff roll. In each case, the flight crew did not notice anything abnormal; however, the liftdumper deployment was noticed and reported by outside observers. Subsequent investigation revealed some minor irregularities, but failed to establish the exact cause.

Results of a special test program performed by Fokker Services B.V. revealed that, with the throttle levers in full forward position and the liftdumper system armed, the rollers of both 75 percent liftdumper micro switches ran off the end of the cam. This caused the liftdumpers to deploy when the (simulated) wheel speed exceeded 50 knots and to remain extended until liftoff. Under normal circumstances, when the throttle levers are moved beyond approximately 75 percent high pressure (HP) revolutions per minute (rpm), these cams activate the micro switches to prevent liftdumper extension.

Improper rigging of the liftdumper micro switches could result in inadvertent extension of the liftdumpers during takeoff roll.

Explanation of Relevant Service Information

Fokker Services B.V. has issued Fokker Service Bulletin F28/27-186, including Manual Change Notification MCNM F28-020, dated May 8, 2000. The service bulletin describes procedures for a one-time general visual inspection for proper rigging of the liftdumper micro switches installed in the left- and right-hand sides of the pedestal; a functional check of the micro switches; and re-rigging the cam, if necessary. The RLD classified this service bulletin as mandatory and issued Dutch airworthiness directive 2000-073, dated May 31, 2000, in order to assure the continued airworthiness of these airplanes in the Netherlands.

FAA's Conclusions

This airplane model is manufactured in the Netherlands and is 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 RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD,

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.

Cost Impact

The FAA estimates that 23 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$5,520, or \$240 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:

Fokker Services B.V.: Docket 2000–NM–293–AD.

Applicability: All Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct improper rigging of the lift-dumper micro switches, which could result in inadvertent extension of the lift-dumpers during takeoff roll, accomplish the following:

Inspection and Functional Check

(a) Within 2 months after the effective date of this AD: Perform a one-time general visual inspection for proper rigging of the lift-dumper micro switches installed in the left- and right-hand sides of the pedestal; and a functional check of the micro switches; as specified in Fokker Service Bulletin F28/27–186, including Manual Change Notification MCNM F28–020, dated May 8, 2000. Perform the inspection and the check in accordance with the Accomplishment Instructions of the service bulletin. If the micro switches are not rigged within the specifications provided in

the service bulletin, prior to further flight, re-rig the cam in accordance with the service bulletin.

Note 2: For the purposes of this AD, a general visual inspection is defined as: “A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.”

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in Dutch airworthiness directive 2000–073, dated May 31, 2000.

Issued in Renton, Washington, on September 13, 2000.

Donald L. Riggan,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–24000 Filed 9–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 00N–1463]

RIN 0910–AB78

Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to

require that all systemic antibacterial drug products (i.e., antibiotics and their synthetic counterparts) intended for human use contain additional labeling information about the emergence of drug-resistant bacterial strains. The proposal reflects a growing concern in FDA and the medical community that overprescription and inappropriate use of systemic antibacterials has contributed to a dramatic increase in recent years in the prevalence of drug-resistant bacterial infections. The proposal is intended to encourage physicians to prescribe systemic antibacterials more judiciously and only when clinically necessary. The proposal is also intended to encourage physicians to counsel their patients about the proper use of such drugs and the importance of taking them exactly as directed.

DATES: Submit written comments by December 4, 2000. See section III of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gary K. Chikami, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20852, 301–827–2120.

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial resistance among disease-causing bacteria represents a serious and growing public health problem in the United States and worldwide. Many bacterial species, including the species that cause pneumonia and other respiratory tract infections, meningitis, and sexually transmitted diseases, are becoming increasingly resistant to the antimicrobial drugs used to treat them. Several bacterial species have developed strains that are resistant to every approved antimicrobial drug, thus severely limiting the therapeutic options available for adequate treatment.

Antimicrobial resistance in bacteria is not a new problem. For as long as antimicrobial drugs have been widely available—over 50 years now—bacteria have demonstrated an ability to develop resistance by a number of mechanisms, such as antibiotic-degrading enzymes. Over the past several years, however, the incidence of resistance in both hospital- and community-acquired