

described previously except compliance with the caution and reporting requirements are not mandatory. In addition, the FAA considers shimming by the addition of washers as a permanent repair.

The FAA estimates that 2 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per helicopter to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$480.

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 a new airworthiness directive to read as follows:

Eurocopter France: Docket No. 2002–SW–26–AD.

Applicability: Model EC 155B helicopters, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters 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 within 25 hours time-in-service, unless accomplished previously, and each time a pilot, co-pilot, or passenger hinged or sliding (door) is replaced.

To prevent loss of a door in flight and subsequent loss of helicopter control, accomplish the following:

(a) Inspect and adjust, if necessary, the position of each door's locking pins in accordance with the Accomplishment Instructions, paragraph 2., of Eurocopter France Alert Telex No. 52-A008, dated March 11, 2002 (Telex), except you are not required to comply with the caution and with the reporting requirements of the Telex, and you may consider shimming by washers a permanent repair.

(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, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

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

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 2002–186–005(A), dated April 3, 2002.

Issued in Fort Worth, Texas, on August 5, 2002.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 02–20517 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–71–AD]

RIN 2120–AA64

Airworthiness Directives; MORAVAN a.s. Models Z–143L and Z–242L Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain MORAVAN a.s. (Moravan) Models Z–143L and Z–242L airplanes. This proposed AD would require you to modify the engine secondary vent line. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the Czech Republic. The actions specified by this proposed AD are intended to prevent the engine crankcase ventilation lines from freezing during flight in cold weather (winter) conditions, which could result in oil leaking from the engine. Such a condition could lead to engine failure.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before September 20, 2002.

ADDRESSES: Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–71–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. You may also send comments electronically to the following address: 9-ACE–7-Docket@faa.gov. Comments sent electronically must contain "Docket No. 99–CE–71–AD" in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII text.

You may get service information that applies to this proposed AD from Moravan, Inc., 765 81 Otrokovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may also view this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901

Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; facsimile: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How Do I Comment on This Proposed AD?

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES**. We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

Are There Any Specific Portions of This Proposed AD I Should Pay Attention to?

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

How Can I Be Sure FAA Receives My Comment?

If you want FAA to acknowledge the receipt of your mailed comments, you must include a self-addressed, stamped postcard. On the postcard, write "Comments to Docket No. 99-CE-71-AD." We will date stamp and mail the postcard back to you.

Discussion

What Events Have Caused This Proposed AD?

The Civil Aviation Authority (CAA), which is the airworthiness authority for the Czech Republic, notified FAA that an unsafe condition may exist on certain Moravan Models Z-143L and Z-242L airplanes. The CAA reports that during a production delivery flight of a Model Z-242L airplane, smoke accumulated in the cockpit of the airplane, and engine oil pressure dropped significantly. As a result of this situation, the pilot was forced to make an emergency landing.

Investigation analysis revealed that the engine crankcase ventilation lines became frozen while flying in low ambient air temperature (winter) conditions. When the engine crankcase ventilation lines freeze, the front crankcase seal ring slips out, which allows oil to leak from the engine.

What Are the Consequences if the Condition Is Not Corrected?

This condition, if not corrected, could result in the engine crankcase ventilation lines freezing during flight in cold weather (winter) conditions. Such a condition could lead to engine failure.

Is There Service Information That Applies to This Subject?

Moravan has issued Mandatory Service Bulletin Z 242L/19a—Rev. 3, Z 143L/20a, dated April 30, 1999.

What Are the Provisions of This Service Information?

The service bulletin includes procedures for modifying the engine vent lines.

What Action Did the CAA Take?

The CAA classified this service bulletin as mandatory and issued Czech Republic AD Number CAA-AD-042/1999, dated August 18, 1999, in order to ensure the continued airworthiness of these airplanes in the Czech Republic.

Was This in Accordance With the Bilateral Airworthiness Agreement?

These airplane models are manufactured in the Czech Republic 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 CAA has kept FAA informed of the situation described above.

The FAA's Determination and an Explanation of the Provisions of This Proposed AD

What Has FAA Decided?

The FAA has examined the findings of the CAA; reviewed all available information, including the service information referenced above; and determined that:

- The unsafe condition referenced in this document exists or could develop on other Moravan Models Z-143L and Z-242L airplanes of the same type design that are on the U.S. registry;
- The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and
- AD action should be taken in order to correct this unsafe condition.

What Would This Proposed AD Require?

This proposed AD would require you to incorporate the actions in the previously-referenced service bulletin.

Cost Impact

How Many Airplanes Would This Proposed AD Impact?

We estimate that this proposed AD affects 39 airplanes in the U.S. registry.

What Would Be the Cost Impact of This Proposed AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the proposed modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
1 workhour × \$60 per hour = \$60	No parts required	\$60	\$60 × 39 = \$2,340.

Regulatory Impact

Would This Proposed AD Impact Various Entities?

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 proposed rule would not have federalism implications under Executive Order 13132.

Would This Proposed AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this proposed action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under 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 has been placed 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, under 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. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Moravan A.S.: Docket No. 99–CE–71–AD

(a) *What airplanes are affected by this AD?* This AD affects the following airplane models and serial numbers that are certificated in any category:

Model	Serial Nos.
Z–143L	All serial numbers up to and including 0029, except 0025 and 0027.
Z–242L	All serial numbers up to and including 0733.

(b) *Who must comply with this AD?*

Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?*

The actions specified by this AD are intended to prevent the engine crankcase ventilation lines from freezing during flight in cold weather (winter) conditions, which could result in oil leaking from the engine. Such a condition could lead to engine failure.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
Modify the engine vent lines	Within the next 100 hours time-in-service after the effective date of this AD.	In accordance with Moravan Mandatory Service Bulletin Z 242L/19a—Rev. 3, Z vent service after the 143L/20a, dated April 30, 1999.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

- (1) Your alternative method of compliance provides an equivalent level of safety; and
- (2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, 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 (e) 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of

the documents referenced in this AD from Moravan, Inc., 765 81 Otrokovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in Czech Republic AD Number CAA–AD–042/1999, August 18, 1999.

Issued in Kansas City, Missouri, on August 7, 2002.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–20516 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N–0305]

Dental Devices; Classification of the Dental Sonography Device and the Jaw Tracking Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the dental sonography device into class I, when it is used to monitor temporomandibular joint sounds, and

into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is also proposing to classify the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is publishing the recommendations of the Dental Products Advisory Panel (the panel) regarding the classification of these devices in this document. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control for the class II devices if this proposal becomes final. **DATES:** Submit written or electronic comments by November 12, 2002.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.