

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NE-33-AD]

RIN 2120-AA64

Airworthiness Directives; Turbomeca Artouste III Series Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Aviation Administration (FAA) proposes to supersede an existing airworthiness directive (AD), applicable to Turbomeca Artouste III series turboshaft engines with injection wheels part numbers (P/N's) 218.25.700.0, 218.25.704.0, 243.25.709.0, 243.25.713.0, 0.218.27.705.0, 0.218.27.709.0, and 0.218.27.713.0 installed. That AD currently requires smoke emission checks after every ground engine shutdown. If smoke is detected, that AD requires inspecting for fuel flow. If fuel flow is not detected, the engine may have injection wheel cracks, which requires removing the engine from service for repair. If fuel flow is detected, the engine may have a malfunctioning electric fuel cock, which requires removing the electric fuel cock from service and replacing with a serviceable part. That AD was prompted by reports of cracked injection wheels. This proposal would, in addition to the requirements in the existing AD, require the smoke emissions to be checked after the last flight of the day as opposed to after every flight as required by the original AD. This proposal would also require inspection of central labyrinths not previously inspected or not replaced after the engine logged 1,500 operating hours, and, replacement if necessary. This proposal would also require the removal of injection wheels at a new lower life limit. This proposal is prompted by reports and analyses of in-

flight shutdowns (IFSD's) occurring since the issuance of AD 2000-06-12. The actions specified by the proposed AD are intended to prevent injection wheel cracks and excessive central labyrinth wear, which could result in an IFSD.

DATES: Comments must be received by July 9, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-NE-33-AD, 12 New England Executive Park, Burlington, MA 01803-5299. Comments may be inspected at this location, by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: *9-ane-adcomment@faa.gov*. Comments sent via the Internet must contain the docket number in the subject line. The service information referenced in the proposed rule may be obtained from Turbomeca, 40220 Tarnos, France; telephone +33 05 59 64 40 00, fax +33 05 59 64 60 80. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Glorianne Niebuhr, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7132, fax (781) 238-7199.

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 should 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.

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 99-NE-33-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-NE-33-AD, 12 New England Executive Park, Burlington, MA 01803-5299.

Discussion

On March 21, 2000, the Federal Aviation Administration (FAA) issued airworthiness directive (AD) 2000-06-12, Amendment 39-11653 (65 FR 19300, April 11, 2000), to require smoke emission checks after every ground engine shutdown. If smoke is detected, that AD requires inspecting for fuel flow. If fuel flow is not detected, the engine may have injection wheel cracks, which requires removing the engine from service for repair. If fuel flow is detected, the engine may have a malfunctioning electric fuel cock, which requires removing the electric fuel cock from service and replacing with a serviceable part. The Direction Generale de L'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on Turbomeca Artouste III B-B1-D series turboshaft engines. The DGAC advises that cracks have been reported on the rear face of the injection wheels, which can lead to fuel leakage into the turbine shaft tube during operation. When the engine is shut down, fuel flows into the combustion chamber, which could result in a slight increase of rundown time and/or emission of smoke through the exhaust pipe, the air intake, or the turbine casing drain after the rotating assembly has stopped. This condition

may be caused by the thermal stresses to which the injection wheel is subjected or a malfunctioning electric fuel cock. These conditions, if not corrected, could result in injection wheel cracks, which could result in an IFSD.

Since AD 2000-06-12 was issued, further analyses of the IFSD that prompted that AD, and a subsequent IFSD have concluded that the root cause of those IFSD's was excessive wear of the central labyrinth. The injection wheel crack could still cause an IFSD but the labyrinth had caused the IFSD, that prompted this proposed AD. The wear or deterioration of the bronze lips of the central labyrinth may result in overheating and damage through creeping of the turbine shaft and lead to an uncommanded engine shutdown. Therefore, this proposal would require smoke emission checks, inspection of central labyrinth, and removal of injection wheel at a new lower life limit.

Manufacturer's Service Information

Turbomeca has issued Artouste III Service Bulletin (SB) No A218 72 0099, Update 1, dated June 6, 2001, that specifies procedures for smoke emission checks, and fuel flow inspections if smoke is detected. Turbomeca has also issued Artouste III SB No. A218 72 0100, Update 1, dated March 13, 2001, that specifies procedures for inspection of central labyrinths not previously inspected or not replaced after the engine logged 1,500 operating hours, and, replacement if necessary. The DGAC classified these SB's as mandatory and issued AD 2001-235(A) in order to assure the airworthiness of these Turbomeca Artouste III series engines in France.

Differences Between This AD and the Manufacturer's Service Information

Although the manufacturer calls for a check for smoke emission through the exhaust pipe, air intake, or turbine casing drain during rundown and after every engine shutdown, this proposal will require the same check, except after the last flight of the day. Also, although the manufacturer calls for inspection of the central labyrinth based on several cycle/hours ratios, within certain hours or months from the published date of the SB, this proposal will require inspection using the same criteria, except from the effective date of this AD.

Bilateral Agreement Information

This engine model is manufactured in France and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal

Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, 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.

Proposed Requirements of This AD

Since an unsafe condition has been identified that is likely to exist or develop on other Turbomeca Artouste III series turboshaft engines of the same type design that are used on helicopters registered in the United States, the proposed AD would require:

- Smoke emission checks after each last flight of the day.
- If smoke is detected, then inspection for fuel flow.
- If fuel flow is not detected, the engine may have injection wheel cracks, which would require removing the engine from service for repair.
- If fuel flow is detected, the engine may have a malfunctioning electric fuel cock, which would require removing the electric fuel cock from service and replacing with a serviceable part.
- Inspection of central labyrinths not previously inspected or not replaced after the engine logged 1,500 operating hours, and, replacement if necessary.
- Removal of injection wheel part number 0.218.27.713.0 at a new lower life limit.

The actions would be required to be done in accordance with the service bulletins described previously.

Economic Analysis

There are approximately 2,279 engines of the affected design in the worldwide fleet. The FAA estimates that 184 engines installed on helicopters of U.S. registry would be affected by this AD, that it would take approximately one work hour per engine to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$3,500 per engine. Based on these figures, the total cost of the proposed AD on U.S. operators is estimated to be \$655,040.

Regulatory Analysis

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it 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. Accordingly, the FAA has not consulted with State authorities prior to publication of this proposed rule.

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 removing Amendment 39-11653, (65 FR 19300, April 11, 2000), and by adding a new airworthiness directive:

Turbomeca: Docket No. 99-NE-33-AD.
Supersedes AD 2000-06-12,
Amendment 39-11653.

Applicability

This airworthiness directive (AD) is applicable to Turbomeca Artouste III B-B1-D series turboshaft engines with injection wheels part numbers (P/N's) 218.25.700.0, 218.25.704.0, 243.25.709.0, 243.25.713.0, 0.218.27.705.0, 0.218.27.709.0, and 0.218.27.713.0. These engines are installed on, but not limited to Eurocopter SA 315 LAMA and SA 316 Alouette III helicopters.

Note 1: This AD applies to each engine 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 engines 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 (f) 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

Compliance with this AD is required as indicated, unless already done.

To prevent injection wheel cracks and excessive central labyrinth wear, which could result in an in-flight shutdown (IFSD), do the following:

Smoke Check

(a) Do the following in accordance with Turbomeca Artouste III Service Bulletin (SB)

No. 218 72 0099, Update 1, dated June 6, 2001:

(1) After the last flight of every day, check for smoke emission through the exhaust pipe, air intake, or turbine casing drain during rundown.

(2) If smoke is detected, inspect for fuel flow in accordance with paragraph 2.B.(1) and 2.B.(2) of the SB.

(i) If fuel flow is not detected, remove the engine from service and replace with a serviceable engine before further flight.

(ii) If fuel flow is detected, remove the electric fuel cock from service and replace with a serviceable part in accordance with section 2.B.(4) and 2.B.(5) of the referenced SB.

(iii) Before entry into service, perform an engine ground run and check the fuel system again for smoke emission through the

exhaust pipe, air intake, or turbine casing drain during engine rundown and after shutdown. If smoke emission still remains after replacement of the electric fuel cock, before further flight, remove the engine from service and replace with a serviceable engine.

Central Labyrinth Inspection

(b) If the central labyrinth has not been inspected or replaced since engine accumulation of 1,500 flight hours (FH) or more time-since-new (TSN) or time-since-last-overhaul (TSO), perform the checks and inspections, and replace if necessary the central labyrinth, in accordance with paragraph 2 of the Instructions of Turbomeca Artouste III SB No. 218 72 0100, Update 1, dated March 13, 2001 and the following Table 1:

TABLE 1.—INSPECTION SCHEDULE

For engine hours TSN, or TSO that are:	And cycles/FH ratio is:	Then inspect central labyrinth:
(1) More than 1,500 but fewer than 2,000	(i) Above 2 cycles	Within 250 FH time-in-service (TIS) after the effective date of this AD.
	(ii) Below or equal to 2 cycles	Within 500 FH TIS after the effective date of this AD.
(2) 2,000 or more	Not applicable	Within 50 FH TIS or 6 months after the effective date of this AD, whichever occurs first.

Injection Wheel New Life Limits

(c) Injection wheels are now life-limited to no more than 3,000 FH TSN or TSO, or 6,000 cycles-since-new (CSN) or cycles-since-overhaul (CSO), whichever occurs first. Replace injection wheels that are over the life limits, before further flight, and replace all other injection wheels before reaching the new life limits.

(d) Do not install any injection wheels that have accumulated 3,000 FH TIS or TSO, or 6,000 CSN or CSO onto any engine.

(e) For the purpose of this AD, a serviceable engine is defined as an engine that does not exhibit smoke emission.

Alternative Methods of Compliance

(f) 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, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Special Flight Permits

(g) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be done.

Note 3: The subject of this AD is addressed in Direction Generale de L'Aviation Civile airworthiness directive 2001-235(A).

Issued in Burlington, Massachusetts, on May 2, 2002.

Diane S. Romanosky,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 02-11667 Filed 5-9-02; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 02N-0058]

RIN 0910-AA01

Pediculicide Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) pediculicide drug products to revise labeling for the statement of identity, warnings, directions, and other required statements. Pediculicide drug products are used for the treatment of head, pubic (crab), and body lice. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by August 8, 2002; written comments on the agency's economic impact determination by August 8, 2002. See section VIII for the effective and compliance dates of any final rule that may publish based on this proposal.

ADDRESSES: Submit written 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/ecommments>.

FOR FURTHER INFORMATION CONTACT: Michael T. Benson, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 14, 1993 (58 FR 65452), the agency published a final rule in the form of a final monograph in part 358 (21 CFR part 358, subpart G) establishing conditions under which OTC pediculicide drug products are generally recognized as safe and effective. The effective date of the final rule was December 14, 1994. Since that time, the agency has determined that labeling in the statement of identity, warnings, directions, and certain other required statements in the pediculicide monograph should be amended to