of the same type design registered in the United States, the proposed AD would require: inspecting the flaps control pulley bracket for alignment; correcting any mis-alignment; inspecting the flaps control pulley cable for wear; and, replacing the bracket and cable if worn. Accomplishment of the proposed action would be in accordance with SIAI Marchetti Service Bulletin No. 205B60, dated July 24, 1995.

Cost Impact

The FAA estimates that 70 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 4 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Parts cost approximately $150 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $27,300 or $390 per airplane.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this 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, 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 (AD) to read as follows:

Aermacchi, S.P.A.: Docket No. 97–CE–146–AD.

Applicability: Models S205–18/F, S205–18/R, S205–20/F, S205–20/R, S205–22/R, S208, and S208A airplanes (all serial numbers), 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 (d) 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 the next 100 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

To prevent flap control failure which, if not corrected, could result in loss of control of the airplane, accomplish the following:

(a) Inspect the flaps cable pulley bracket for mis-alignment, and if misaligned, prior to further flight, replace the pulley bracket in accordance with the Instructions section of SIAI Marchetti Service Bulletin No. 205B60, dated July 24, 1995.

(b) Inspect the flaps control cable for wear (cuts, nicks, frays, etc.), and if wear is found, prior to further flight, replace the control cable in accordance with the Instructions section of SIAI Marchetti Service Bulletin No. 205B60, dated July 24, 1995.

(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.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

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

(e) Questions or technical information related to SIAI Marchetti Mandatory Service Bulletin No. 205B60, dated July 24, 1995, should be directed to SIAI Marchetti, Product Support, Via Indipendenza 2, 21018 Sesto Calende (VA), Italy: telephone: +39–331–929117; facsimile: +39–331–922525. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in Italian AD 95–237, dated August 29, 1995.

Issued in Kansas City, Missouri, on March 5, 1998.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–6451 Filed 3–12–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–SW–49–AD]

Airworthiness Directives; Eurocopter France Model SA–365N1, AS–365N2, and SA–366G1 Helicopters

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 Eurocopter France (Eurocopter) Model SA–365N1, AS–365N2, and SA–366G1 helicopters. This proposal would require initial and repetitive inspections of the tail rotor blade Kevlar tie-bar (Kevlar tie-bar) for cracks or delaminations. This proposal is prompted by a report of delamination of a Kevlar tie-bar. The actions specified by the proposed AD are intended to detect cracks that could lead to delamination of the Kevlar tie-bar, loss of tail rotor control, and subsequent loss of control of the helicopter.

DATES: Comments must be received by April 13, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 97–SW–49–AD, 2601 Meacham Blvd, Room 663, Fort Worth, Texas 76197. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

This service information referenced in the proposed rule may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas

75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Mathias, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0111, telephone (817) 222–5123, fax (817) 222–5961.

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 notice 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 notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–SW–49–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, Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 97–SW–49–AD, 2601 Meacham Blvd, Fort Worth, Texas 76137.

Discussion

The Direction Generale De L'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on SA–365N1, AS–365N2, and SA–366G1 model helicopters. The DGAC advises that delamination outside certain tolerance limits may occur on Kevlar tie-bars.

Eurocopter France issued Telex Service Bulletin (SB) 05.33, dated August 19, 1992, that specifies visually checking the condition of the Kevlar tie-bar assembly for delamination around the blade-to-hub attachment point within 10 flying hours. If delamination exists that is outside certain tolerance limits, SB 05.33 specifies removing the rail rotor blade (blade) and replacing it with an airworthy blade. Eurocopter France also issued SB 05.00.34, Revision 3, dated November 14, 1996, that specifies repetitive visual inspections at intervals of 250 flying hours of the Kevlar tie-bar for delaminations. If certain cracks exist, SB 05.00.34, Revision 3, specifies removing the blade from service. The DGAC classified these service bulletins as mandatory and issued DGAC AD 92–185–033(B)R4, dated December 4, 1996, to ensure the continued airworthiness of these helicopters in France.

This helicopter model is manufactured in France 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 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.

Since an unsafe condition has been identified that is likely to exist or develop on other Eurocopter France Model SA–365N1, AS–365N2, and SA–366G1, helicopters of the same type design registered in the United States, the proposed AD would require within 10 hours time-in-service (TIS), and thereafter at intervals not to exceed 250 hours TIS, inspections of the Kevlar tie-bar for a crack of delamination and replacement of any balde in which a crack or delamination is found with an airworthy blade. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 47 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. Required parts would cost approximately $3,000 per blade. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $152,280 to replace one blade and perform one inspection on each helicopter.

The regulations proposed herein would not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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. 97–SW–49–AD.

Applicability: SA–365N1, AS–365N2, and SA–366G1 model helicopters, with tail rotor blade (blade), Part Number 365A12–010–all dash numbers, 365A12–0020–00, 365A33–2131–all dash numbers, or 365A12–0020–20, installed, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To detect cracks that could lead to delamination of the tail rotor blade Kevlar tie-bar (Kevlar tie-bar), loss of tail rotor control, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 10 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 250 hours TIS, inspect each Kevlar tie-bar for a crack or delamination in accordance with paragraph B, Operational Procedure, of Eurocopter France Service Bulletin 05.00.34, Revision 3, dated November 14, 1996.

(b) If any delamination or cracking is found during any of the inspections required by paragraph (a) of this AD, remove the blade and replace it with an airworthy blade before further flight.

(c) 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, Rotorcraft Standards Staff, 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, Rotorcraft Standards Staff.

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

(d) 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 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 92–185–33(B)R4 dated December 4, 1996.

Issued in Fort Worth, Texas, on February 28, 1998.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98–6496 Filed 3–12–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 89G–0393]

Direct Food Substances Affirmed as Generally Recognized as Safe; Egg White Lysozyme

AGENCY: Food and Drug Administration, HHS.

ACTION: Tentative final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a tentative final rule to amend its regulations to affirm that egg white lysozyme enzyme preparation, when labeled by the common or usual name ''egg white lysozyme'' to identify its source, is generally recognized as safe (GRAS) for use in preventing late blowing of cheese caused by the bacterium *Clostridium tyrobutyricum* during cheese production. This action is in response to a petition submitted by Fordras S.A. (formerly SPA-Società Prodotti Antibiotici S.p.A.). FDA has tentatively concluded that this use of the egg white lysozyme enzyme preparation is GRAS only when the ingredient statement for both bulk and packaged food that contains cheese manufactured using egg white lysozyme includes the common or usual name ''egg white lysozyme'' to identify the source of the protein. To give interested persons an opportunity to comment on this condition of use required for GRAS status, FDA is issuing this tentative final rule.

DATES: Submit written comments by May 27, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), SPA-Societa Prodotti Antibiotici S.p.A., now Fordras S.A., Milan, Italy, submitted a petition (GRASP 9G0355) requesting that egg white lysozyme used to inhibit the bacterium *C. tyrobutyricum* to prevent late blowing of cheese during production be affirmed as GRAS as a direct human food ingredient. FDA published the notice of filing for this petition in the **Federal Register** of October 27, 1989 (54 FR 43861), and gave interested persons until December 26, 1989, to submit written comments.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation, but ordinarily is based upon generally available data and information concerning the pre-1958 history of use of the substance.

FDA has evaluated Fordras S.A.'s petition on the basis of scientific procedures to whether the petitioned use of egg white lysozyme enzyme preparation to prevent the late blowing of cheese caused by the bacterium *C. tyrobutyricum* during cheese production is GRAS. In evaluating the petition, FDA considered published and unpublished data and information relating to the identity of, characteristic properties of, and estimated dietary exposure to the enzyme component (i.e., lysozyme) of the petitioned enzyme preparation (Refs. 1 through 7). FDA also considered that the source of the petitioned enzyme preparation, egg white, has been safely consumed by humans as a source of food protein throughout recorded history, and, therefore, is GRAS (§ 170.30(d)), and that the methods used for extracting lysozyme from the egg white source do not ordinarily alter the chemical identity and characteristic properties of enzymes (Ref. 8). FDA also considered published scientific review articles (Refs. 1 and 2) and a generally available trade association bulletin (Ref. 7) discussing the use of egg white lysozyme enzyme preparation for its