

coating applied to either the spacer or the hub) and were manufactured after June 1, 1988. These engines are installed on, but not limited to McDonnell Douglas MD-80 series airplanes.

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 a rupture of the HPC front hub, that could result in an uncontained engine failure and damage to the airplane, do the following:

Inspect hubs

(a) Strip the protective coating, visually inspect for fretting wear, fluorescent magnetic particle inspect (FMPI), reidentify and replate HPC front hubs and the stage 8–9 spacers, and replace if necessary in accordance with the accomplishment instructions of Pratt & Whitney Alert Service Bulletin (ASB) JT8D A6430, dated September 5, 2002, as follows:

(1) For HPC front hubs with fewer than 17,000 total cycles-in-service (CIS) on the effective date of this AD, inspect as follows:

(i) For HPC front hubs not inspected in accordance with ASB JT8D A6430, dated September 5, 2002, before accumulating 9,000 total CIS, inspect at the first shop visit after accumulating 9,000 total CIS not to exceed 18,000 total CIS.

(ii) For HPC front hubs inspected in accordance with ASB JT8D A6430, dated September 5, 2002, before accumulating 9,000 total CIS, inspect at the next accessibility of the HPC front hub after accumulating 9,000 total CIS not to exceed 15,500 total CIS.

(2) For HPC front hubs with greater than or equal to 17,000 total CIS but less than 19,000 total CIS on the effective date of this AD, inspect at the next shop visit, not to exceed 1,000 CIS from the effective date of this AD or 19,500 total CIS, whichever occurs first.

(3) For HPC front hubs with greater than or equal to 19,000 total CIS on the effective date of this AD, inspect within 500 CIS from the effective date of this AD.

Repetitive-Inspections

(b) Thereafter, strip the protective coating, visually inspect for fretting wear, FMPI and replate HPC front hubs, and replace if necessary in accordance with the accomplishment instructions of Pratt & Whitney Alert Service Bulletin (ASB) JT8D A6430, dated September 5, 2002, at intervals not to exceed 6,500 CIS since the last inspection.

Optional Terminating Action

(c) Installation of a Nickel-Cadmium plated HPC front hub that has never operated with PWA-110 coating in the interface between the HPC front hub and the stage 8–9 spacer and a Nickel-Cadmium or Electroless Nickel plated spacer is an optional terminating action for the inspections of paragraphs (a) and (b) of this AD.

Definitions

(d) For the purposes of this AD, a shop visit is defined as an engine removal, where engine maintenance entails separation of pairs of major engine flanges or the removal of a disk, hub, or spool at a maintenance facility, regardless of other planned maintenance, except as follows:

(1) Engine removal for the purpose of performing field maintenance type activities at a maintenance facility in lieu of performing them on-wing is not a "shop visit".

(2) Separation of flanges of the Combustion Chamber and Turbine Fan Duct Assembly (split flanges) for the purpose of accessing non-rotating accessory hardware is not a "shop visit".

(3) Separation of flanges for the purpose of shipment without subsequent internal maintenance is not a "shop visit".

(e) For the purposes of this AD accessibility of the HPC front hub is removal of the hub from the engine and deblading of that hub.

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 requests 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 airplane to a location where the requirements of this AD can be done.

Documents That Have Been Incorporated By Reference

(h) The inspections must be done in accordance with Pratt & Whitney Alert Service Bulletin (ASB) JT8D A6430, dated September 5, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108, telephone (860) 565–6600; fax (860) 565–4503. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(i) This amendment becomes effective on December 31, 2002.

Issued in Burlington, Massachusetts, on November 15, 2002.

Mark C. Fulmer,

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

[FR Doc. 02–29670 Filed 11–25–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NE–44–AD; Amendment 39–12957; AD 2002–23–13]

RIN 2120-AA64

Airworthiness Directives; Pratt & Whitney Canada PT6A Series Turboprop Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), that is applicable to Pratt & Whitney Canada PT6A series turboprop engines that have certain turbine exhaust ducts that were modified by a number of different companies. This amendment requires inspections for low-quality welds and cracks of a large population of turbine exhaust ducts. This amendment is prompted by reports of cracks along the weld seams of certain turbine exhaust ducts. The actions specified by this AD are intended to prevent failure of the turbine exhaust duct due to cracking that could result in possible separation of the reduction gearbox and propeller from the engine, and possible loss of control of the airplane.

DATES: Effective December 31, 2002. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 31, 2002.

ADDRESSES: The service information referenced in this AD may be obtained from Pratt & Whitney Canada, 1000 Marie-Victorin, Longueuil, Quebec, Canada J4G1A1. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT:
James Lawrence, Aerospace Engineer,

Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7176; fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: A supplemental proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to Pratt & Whitney Canada PT6A series turboprop engines was published in the **Federal Register** on June 10, 2002 (67 FR 39640). That action proposed to require inspections for low-quality welds and cracks of a large population of turbine exhaust ducts that were modified by a number of companies, all using a similar unapproved gas tungsten arc welding (GTAW) process instead of the resistance (seam or stitch) weld process. Since the issuance of that supplemental proposal, Pratt & Whitney Canada issued a revised SB P&WC SB No. PT6A-72-1610, Revision 2, dated October 1, 2002, which deletes models PT6A-114 and PT6A-114A from the applicability.

Bilateral Agreement Information

This engine model is manufactured in Canada 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, Transport Canada (TC) has kept the FAA informed of the situation described above. The FAA has examined the findings of TC, 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.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Remove SAL Reference

One commenter requests removal of any reference to Standard Aero Limited (SAL) of Winnipeg, Canada, from the AD. Since the first issue of the NPRM, the FAA has found that several other companies have incorrectly used the GTAW weld process. Therefore, any references to SAL can and will cause confusion for the operators.

The FAA agrees. All references to SAL are removed from the final rule.

Misinterpretation of Unsafe Condition

The same commenter points out that the SNPRM incorrectly notes that TC AD CF-98-14 says "that condition if not corrected could result in possible separation of the reduction gearbox and propeller from the engine and possible loss of control of the airplane," and that the TC AD actually states that compliance is required "to minimize the possibility of an in-flight shutdown due to a cracked exhaust duct."

The FAA does not agree. The FAA feels that the commenter has misinterpreted the unsafe condition statement in the proposal's preamble, incorrectly attributing it to the TC AD. Based on the structure of the preamble, the FAA understands how the statement could be attributed to the TC AD. However, the FAA has determined "that condition if not corrected could result in possible separation of the reduction gearbox and propeller from the engine and possible loss of control of the airplane," is the correct unsafe condition. Since the questionable section does not appear in the preamble of the final rule, no change needs to be made to the final rule.

Incorrect Total of Cracked Ducts

The same commenter remarks that the SNPRM incorrectly states that a total of 116 exhaust ducts have been discovered with cracks along the affected weld seam, when in fact, to date the actual number of cracked ducts found with cracks is 18.

The FAA agrees. However, since the questionable statement does not appear in the preamble of a final rule, no change needs to be made to the final rule.

Request to Exclude Single Port Exhaust Duct

One commenter requests that the single port exhaust duct, P/N 3112171-01 and subsequently any reference to the PT6A-114 and PT61-114A engine models be excluded from the AD. For conversion of single port exhaust ducts, part number (P/N) 3112171-01, welding is done in a much different fashion. The original inner cone remains in place and the majority of it is untouched. Only a small portion of its free end is removed for the attachment of a cover. No welding is performed anywhere on or near the load bearing outer skin. The original junction between the outer skin and the inner cone is entirely undisturbed so adhesion between the propeller reduction gearbox flange and the outer skin is entirely unaffected and the load path is uncompromised.

The FAA agrees. The FAA has consulted with P&WC and has

confirmed that the commenter is correct. The inner skin replacement is performed differently on a single port duct than on the dual duct. No welding is done in the "A" flange area for the -114 series. It was the welding at the "A" flange that triggered the original TC AD. There have been no reports of cracks or poor welds on the -114 models. P&WC has revised the -114 manuals to clearly state that the "A" flange is to be examined in detail at aircraft minor (150 hours) inspections and at hot section inspection. The PT6A-114 and PT6A-114A engines have been incorrectly included in the proposal. Therefore, models -114 and -114A, and exhaust duct P/N 3112171-01 are removed from the final rule.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Economic Analysis

There are approximately 22,000 Pratt & Whitney Canada PT6A series turboprop engines of the affected design in the worldwide fleet. The FAA estimates that 7,000 engines installed on airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 work hours per engine to perform the required actions, and that the average labor rate is \$60 per work hour. Based on these figures, the total cost of the AD to U.S. operators is estimated to be \$840,000.

Regulatory Analysis

This final 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 final rule.

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 the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 final evaluation has been prepared for this action and it 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, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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:

2002-23-13 Pratt & Whitney Canada:

Amendment 39-12957. Docket No. 99-NE-44-AD.

Applicability: This airworthiness directive (AD) is applicable to Pratt & Whitney Canada (P&WC) PT6A series turboprop engines, with turbine exhaust ducts part number (P/N) 3012290, P/N 3031988, P/N 3032117, P/N 3035784, P/N 3035786, P/N 3105890-01, P/N 3112167-01, and P/N 3111780-01. These engines are installed on, but not limited to, Beechcraft King Air-90 and -100 series, Bombardier DHC-6 series, Empresa Brasileira de Aeronautica, S.A. (Embraer) EMB-110 series, Pilatus PC-6 series, and Piper PA-42 series airplanes.

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 (g) 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 failure of the turbine exhaust duct due to cracking that could result in possible separation of the reduction gearbox and propeller from the engine, and possible loss of control of the airplane, do the following:

Inspection of Turbine Exhaust Ducts for Low-Quality Welds

(a) If the engine has not yet been overhauled, and if the turbine exhaust duct has not yet been subject to a shop visit for repair, no further action is required.

(b) Otherwise, at the next shop visit or within 150 hours time-in-service (TIS) after the effective date of this AD, whichever occurs first, do the following:

(1) Inspect for low-quality welds created during repair, on the turbine exhaust duct near flange "A", in accordance with paragraphs 3B through 3E of P&WC service bulletin (SB) No. PT6A-72-1610, Revision 2, dated October 1, 2002, for models PT6A-6, -6A, -6B, -20, -20A, -20B, -21, -25, -25A, -25C, -27, -28, -34, -34AG, -34B, -36, -135, and -135A engines, and SB No. PT6A-72-12173, dated January 24, 2002, for models PT6A-11, -11AG, -15AG, -110, and -112 engines.

(2) If it is determined that the welds meet the acceptable criteria specified in SB No. PT6A-72-1610, Revision 2, dated October 1, 2002; or SB No. PT6A-72-12173, dated January 24, 2002, continue using the duct until the next scheduled overhaul. Inspect duct per the engine overhaul manual before reinstallation.

(3) If it is determined that the welds do not meet the acceptable criteria specified in SB No. PT6A-72-1610, Revision 2, dated October 1, 2002; or SB No. PT6A-72-12173, dated January 24, 2002, replace the duct with a serviceable part, or perform the initial and repetitive inspections in the following paragraphs.

Initial Visual Inspection of Welds That Do Not Meet SB Acceptable Criteria

(c) Use 5X magnification to visually inspect the circumference of the forward area of the exhaust duct from the propeller reduction gearbox mounting flange to 2 inches aft of the flange for any crack indications. Mark and record cracks and return the duct to service, or replace with a serviceable part as follows:

(1) If no cracks are found, the duct may be returned to service; or

(2) If three or less cracks are found, and the total cumulative length of the cracks exceeds 2.0 inches, replace the duct with a serviceable part; or

(3) If any one crack exceeds 1.0 inch in length, replace the duct with a serviceable part; or

(4) If any two cracks are separated by less than six times the length of the longest crack (6L) or 3.0 inches or less, whichever is the closest separation, replace the duct with a serviceable part; or

(5) If more than three cracks are found, replace the duct with a serviceable part; and

(6) Mark all allowable cracks, on the duct, with suitable metal marking material; and

Note 2: Marking materials that are suitable for use on the exhaust duct may be found in the P&WC Engine Manual.

(7) Record the length of the crack, location, number of duct hours, and time-since-overhaul (TSO).

Repetitive Visual Inspection of Welds That Do Not Meet SB Acceptable Criteria

(d) Repeat the inspection specified in paragraph (c) of this AD as follows:

(1) For ducts that did not exhibit any cracking at the last inspection, repeat the inspection within 150 hours TIS since the last inspection. Return the duct to service or replace with a serviceable part as specified in paragraph (c)(1) through paragraph (c)(5) of this AD.

(2) For ducts that exhibited cracking at the last inspection, repeat the inspection within 25 hours TIS since the last inspection. Return the duct to service or replace with a serviceable part as follows:

(i) Inspect for new cracks, and cracks that were recorded as specified in paragraph (c) of this AD. Return the duct to service or replace with a serviceable part as specified in paragraph (c)(1) through paragraph (c)(5) of this AD.

(ii) In addition, if the growth rate of an existing crack exceeds 0.015 inch per hour TIS since the last inspection, replace the duct with a serviceable part.

Optional Terminating Action

(e) Replacing an affected exhaust duct with a serviceable exhaust duct constitutes terminating action for the repetitive inspection requirements of this AD.

Definition of a Serviceable Exhaust Duct

(f) For the purposes of this AD, a serviceable duct is defined as a duct that meets the acceptability limits of this AD.

Alternative Method of Compliance

(g) 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 requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the ECO.

Note 3: 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

(h) Special flight permits are not allowed.

Documents That Have Been Incorporated By Reference

(i) The inspections must be done in accordance with the following Pratt & Whitney Canada (P&WC) service bulletins:

Document No.	Pages	Revision	Date
PT6A-72-1610	All	2	October 1, 2002.

Document No.	Pages	Revision	Date
Total Pages: 10 PT6A-72-12173 Total pages: 9	All	Original	January 24, 2002.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney Canada, 1000 Marie-Victorin, Longueuil, Quebec, Canada J4G1A1. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in AD CF-98-41 in order to assure the airworthiness of these P&WC PT6A series turboprop engines in Canada.

Effective Date

(j) This amendment becomes effective on December 31, 2002.

Issued in Burlington, Massachusetts, on November 15, 2002.

Mark C. Fulmer,

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

[FR Doc. 02-29671 Filed 11-25-02; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N-0056]

RIN 0910-AA74

Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Amendment; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying until January 26, 2004, the effective date of a final rule published in the **Federal Register** of January 26, 2000 (65 FR 4103) (aluminum final rule), and originally scheduled to become effective on January 26, 2001. In the **Federal Register** of January 26, 2001 (66 FR 7864), the agency delayed the effective date of the aluminum final rule until January 26, 2003. The aluminum final rule imposes certain requirements for aluminum-containing large volume

parenterals (LVPs), small volume parenterals (SVPs), and pharmacy bulk packages (PBPs) used in total parenteral nutrition (TPN). FDA is delaying the effective date of the aluminum final rule to allow time for the agency to finalize an amendment to the aluminum final rule. The agency is also amending the aluminum final rule to change to January 26, 2004, the date that limits the use of historical levels to determine the maximum level of aluminum in SVPs and PBPs; this date corresponds to the effective date of the aluminum final rule, which is delayed until January 26, 2004, by this document.

DATES: This final rule is effective December 26, 2002. The effective date for § 201.323 (21 CFR 201.323), added at 65 FR 4103, January 26, 2000, is delayed until January 26, 2004.

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/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: On January 26, 2000, FDA published final regulations at § 201.323 imposing certain requirements for aluminum-containing LVPs, SVPs, and PBPs used in TPN (65 FR 4103). The aluminum final rule was originally scheduled to become effective on January 26, 2001. In the **Federal Register** of January 26, 2001 (66 FR 7864), the agency published a notice delaying the effective date until January 26, 2003.

In the **Federal Register** of August 12, 2002 (67 FR 52429), FDA published a proposed rule to amend § 201.323. The proposed rule would permit SVPs and PBPs containing 25 micrograms per liter ($\mu\text{g}/\text{L}$) or less of aluminum to be labeled with the statement "Contains no more than 25 $\mu\text{g}/\text{L}$ of aluminum", instead of stating the exact amount of aluminum they contain. Because there is insufficient time to finalize this proposed amendment before January 26,

2003, when § 201.323 is scheduled to become effective, the agency is delaying the effective date of § 201.323 until January 26, 2004.

The agency is also amending § 201.323(c)(3) of the aluminum final rule to reflect the fact that the effective date is now being extended to January 26, 2004. Section 201.323(c)(3) provides that a manufacturer may state the maximum level of aluminum in terms of historical levels, but only until completion of production of the first five batches after January 26, 2001, the date by which manufacturers were to have submitted supplements describing the validated assay method used to determine aluminum content. Because manufacturers now have until January 26, 2004, to submit supplements, this final rule is changing the date in § 201.323(c)(3) to reflect the fact that the effective date of the aluminum final rule has been extended to January 26, 2004.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. The agency is delaying the effective date of § 201.323 because the agency has proposed to amend § 201.323. Given the imminence of the effective date of current § 201.323, seeking prior public comment on this delay is impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations. Notice and comment procedures in this instance would create uncertainty, confusion, and undue financial hardship because, during the time that the agency would be proposing to extend the effective date for § 201.323, those companies affected would have to be preparing to relabel to comply with the January 26, 2003, effective date. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on which this delay should be modified or revoked.

FDA has examined the impacts of this delay of effective date under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory