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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 91

[Docket No.: FAA-2008-1097; Amendment No. 91-312]

RIN 2120-AJ31

#### Aircraft Noise Certification Documents for International Operations

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends the operating rules to require U.S. operators flying outside the United States to carry aircraft noise certification information on board the aircraft. This rule is intended to ensure that affected U.S. operators have the appropriate noise certification information on board when they fly outside the United States as required by the International Civil Aviation Organization (ICAO), and to ensure compliance between domestic U.S. regulations and ICAO Annex 16, Amendment 8.

**DATES:** This amendment becomes effective May 3, 2010.

**FOR FURTHER INFORMATION CONTACT:** For technical questions concerning this final rule contact Laurette Fisher, Office of Environment and Energy, AEE-100, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3561; facsimile (202) 267-5594, e-mail [Laurette.fisher@faa.gov](mailto:Laurette.fisher@faa.gov). For legal questions concerning this final rule contact Karen Petronis, Senior Attorney for Regulations, Office of the Chief Counsel, AGC-200, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone 202-267-3073, e-mail [Karen.petronis@faa.gov](mailto:Karen.petronis@faa.gov).

#### SUPPLEMENTARY INFORMATION:

#### Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44715, Controlling aircraft noise and sonic boom. Under that section, the FAA is charged with prescribing regulations to measure and abate aircraft noise. This proposed regulation is within the scope of that authority since it would require certain operators to carry on board documentation listing the noise characteristics of the aircraft. These characteristics are already contained in the aircraft flight manual and approved as part of the aircraft's airworthiness certification, and compliance with 14 CFR part 36.

#### Background

On October 23, 2008, the FAA published a notice of proposed rulemaking (NPRM) proposing to amend 14 CFR part 91 to add a new paragraph in § 91.703 to require the carriage of noise certification documents on board aircraft that leave the United States (73 FR 63098). A brief history of the FAA's regulation of aircraft noise certification requirements (14 CFR part 36) was presented in the preamble of the NPRM.

The FAA proposed requiring affected operators that fly outside the United States using aircraft subject to the International Civil Aviation Organization (ICAO) Annex 16<sup>1</sup> to carry aircraft noise certification information on board the aircraft. As stated in the NPRM, the ICAO adopted this requirement in Amendment 8 of Annex 16, Volume 1 on February 23, 2005, and it became effective on November 24, 2005. Paragraph 1.4 of Annex 16 now requires that "documents attesting noise certification shall be approved by the State of Registry and required by that State to be carried on the aircraft."

The current U.S. regulations in part 36 (§§ 36.1581 and 36.1583) describe the

<sup>1</sup> ICAO Annex 16, Volume I, Part II, Chapter 1, Paragraph 1.1 states that: *The provisions of 1.2 to 1.6 shall apply to all aircraft included in the classifications defined for noise certification purposes in Chapters 2, 3, 4, 5, 6, 8, 10, 11 and 12 of this part where such aircraft are engaged in international air navigation.*

specific noise certification data requirements that need to be included in an FAA-approved Airplane Flight Manual (AFM) or Rotorcraft Flight Manual (RFM) as part of an aircraft's certification. However, there is no specific operating requirement for the entire FAA-approved AFM/RFM to be carried on board an aircraft, including the noise certification data. In the United States, we have relied on the fact that no airworthiness certificate will be issued unless an aircraft complies with the applicable noise requirements in part 36. Accordingly, we have never implemented a separate operating rule that requires the data be on board the aircraft. The addition of this requirement is meant to satisfy the ICAO standard since other countries may not recognize the underlying U.S. system.

For U.S. air carriers operating under part 121, a carrier is allowed to create an Aircraft Operations Manual (AOM) or a Flight Crew Operating Manual (FCOM) as an alternative to the AFM to be carried on board the aircraft. That manual typically contains only the aircraft limitations and performance information from the FAA-approved AFM. The AOM or FCOM may or may not contain the noise characteristics pages from the FAA-approved AFM, depending on the operator's needs and the manual's organization. This rule requires all U.S. operators to carry the appropriate noise certification information on board when they fly outside the United States.

The issue of noise documentation was undertaken by the Certificate Task Group (CTG) of the ICAO's Committee on Aviation Environmental Protection Noise Technical Working Group. As a member State of ICAO, the United States participates in this task group. A more in-depth discussion of the task group's activities may be found in the preamble to the NPRM for this rule.

The CTG considered various options for standardization of documents to be carried by aircraft operators. The ICAO member States use a variety of administrative systems, with differing requirements for noise documentation at certification and for designating documents that must be carried on board. The CTG proposed three options designed to accommodate the varying certification practices and existing regulatory systems of its member States.

The three options were incorporated into a new Attachment G to Annex 16, Volume 1, Amendment 8. Attachment G describes the three options to satisfy the certification documentation requirements of Sections 1.4 and 1.5 as follows:

1. A stand-alone State-issued noise certificate in which the mandatory information requirements of Annex 16, Volume 1, are contained in a single document.

2. Two complementary documents, one of which may be the Airplane Flight Manual (AFM) or the Airline Operations Manual (AOM).

3. Three complementary documents.

As explained in the NPRM, Option 1 is not available to U.S. operators. The FAA does not have the statutory authority required to issue stand-alone noise certificates.

Option 2, which requires the carriage of two complementary documents, accommodates those ICAO member States, including the United States, that do not include all noise certification data on a single certificate.

Option 3, which requires three documents, was designed for other member States and would be more burdensome than option 2.

#### ICAO Option 2 Compliance

For U.S. operators, the first document is the aircraft airworthiness certificate issued by the FAA. An aircraft must meet the noise certification requirements of part 36 in order to be issued an airworthiness certificate, and it is already required to be carried on board.

The second document is one that contains the noise certification data that is already contained in the AFM/RFM, but not required under current U.S. regulation to be carried on board. Operators that currently carry the noise data on board in the AFM, RFM, AOM, or FCOM may already satisfy ICAO option 2 and this regulation.

Operators that do not carry the noise certification data as part of one of those documents have several choices. One is to incorporate the approved data as part of on-board manuals. One of the limits of this option is that noise certification data is often contained in different parts of the original flight manuals, and could be burdensome to locate, incorporate, and access.

Operators may choose to create and carry a separate document containing the noise certification data required by ICAO. Annex 16 does not specify the format for that information, and neither does this regulation.

Before ICAO changed Annex 16 to make the carriage of noise data

mandatory, the FAA had published a draft Advisory Circular (AC) (70 FR 60127, October 14, 2005) that recommended that U.S. operators be prepared to produce noise certification data when operating outside of the United States. That draft AC also included a suggested format for the data. Before that AC was made final, ICAO made data carriage mandatory. In response, the FAA realized that a regulatory change was needed and that advisory material was no longer appropriate. The AC was never finalized.

When we proposed this rule change in 2008, we included an almost-identical version of the form from the draft AC as an optional means of gathering the AFM/RFM noise data that would satisfy the ICAO requirements as the second document for Option 2. That suggested form is also included here as one method of ensuring that the already approved data is easily accessed. Operators are free to adopt other ways to carry the data as fits their operations.

#### Comments to the NPRM

The FAA received 8 comments in response to the NPRM. Comments were submitted by four operators, two individuals, one industry association and one aircraft manufacturer. All the commenters except one supported the proposed rule.

The NPRM sought input on the form in which the information is to be carried and included the draft optional form that included the information already in the possession of operators and required by Annex 16. Five of the commenters suggested that operators be allowed to determine the format in which noise certification data is to be carried, and where on the aircraft it will be kept. Ameristar Air Cargo suggested it be made part of an operator's operations specifications because an additional document would be burdensome. FedEx Express indicated it had developed its own form and has been using it successfully in several ICAO countries since the FAA issued the draft AC in 2005. Continental Airlines indicated that it has chosen to maintain the information in graph form as it appears in its airplane flight manuals from the manufacturers. Gulfstream Aerospace also stated that it had developed its own certificate for its customer that it believes meets the intent of the proposed regulation.

The FAA agrees that operators are free to use whatever format works best for them as long as the information required by Annex 16 is available to the flight crew. It can be a form developed by a manufacturer, or by the operator for its

own use. Operators may choose to incorporate the applicable pages from an FAA-approved flight manual, or they may transfer that data to an optional form such as the one provided as an example in the rule. As long as the information required by Annex 16 Sections 1.4 and 1.5 is included for individual aircraft and accessible to the flight crew, an operator will be in compliance with this regulation.

We disagree that the operations specifications are an appropriate place for such information. Operations specifications are not designed to be aircraft specific. As illustrated by the optional form and indicated in the NPRM, discrete information for each airplane must be carried. Airplanes may not be grouped on a form, such as a list of serial numbers for all of the aircraft of one model.

Note that we do not and will not refer to this information carried in any form as a "noise certificate" since it is not issued by the FAA and does not have the legal standing of a certificate issued by the FAA. As discussed previously, the FAA has no authority to issue such a certificate. Calling such items "noise certificates" could be confusing since there are countries that issue noise certificates.

FedEx Express suggested several changes to the information as shown on the optional form, including changing the name to "Noise Certification Document," removing certain information identifying the operator, deleting the references to the source of the noise data (such as the dated airplane flight manual with the revision number), and deleting the information at the end of the form indicating that the data were included in an FAA-approved document and that responsibility for its correct transfer is that of the operator. None of these changes is acceptable. The suggested change to reference part 36 compliance in lieu of a reference to an approved manual is unacceptable since a statement of part 36 compliance, by itself, does not provide any information specific to the aircraft. While FedEx Express states that it could be burdensome to have to change the reference when an AFM is revised, the AFM remains the document that contains the FAA approval for the aircraft noise data, and is thus the source of the data regardless of the format in which an operator chooses to carry it. Further, allowing the operator the choice of format is a reason to clearly indicate that the data were formatted by the operator, not the FAA, and that the only FAA-approved source is the airplane flight manual. That

information is considered essential to Annex 16 compliance.

One operator, Florida Air Transport, indicated that it operates several older airplanes between the United States and places in the Caribbean. None of its airplanes have ever been noise certificated since all pre-date the requirements for such testing and certification. Florida Air Transport asked if ICAO has an exemption for such aircraft.

Annex 16 does not account for the existence of older airplanes that were never subject to noise certification requirements. The concept is well understood in other ICAO member States, however, and certain "grandfathering" clauses have been adopted, some informally.

The FAA will be publishing guidance in the form of an AC on what airplanes it has determined pre-date the noise certification requirements of part 36. In order to comply with this regulation, we suggest that some form be carried containing as much information as is available regarding the aircraft, but we will provide a recommended statement for inclusion that replaces certain noise levels that are not entered on the form. The FAA anticipates that the AC will be available at the time the final rule is published.

The Regional Airline Association requested that the proposed rule be withdrawn since the FAA did not indicate in the NPRM how we concluded that a regulation was necessary. The RAA indicated that the "only rationale" for the proposed regulation is that "it might 'help' U.S. air carriers who might possibly be cited by inspectors in other countries." The RAA said that since ICAO standards "are directed at 'States of Registry' not the individual airlines," it is within the prerogative of a member State not to enforce, and suggests the FAA request a waiver, which the RAA characterizes as "routine."

The RAA is mistaken in its characterization of Annex 16 and the

actions required by ICAO member States. While it is possible to file a difference with ICAO standards, it is not a routine occurrence and carries more than moderate risk. It is not simply a matter of a member State choosing not to enforce one of the ICAO regulations. Aircraft operators that do not comply with ICAO standards may be denied entry to other ICAO countries. Filing a difference merely serves notice that the operators from a member State are not in compliance, it is not a free pass to ignore particular ICAO regulations.

Before the carriage of noise documentation was a requirement in Annex 16, it was a note, which was advisory in nature and suggested that noise certification data be carried on an aircraft that left its member State. In 2005, however, ICAO adopted it as a requirement in Annex 16 and the advisory nature of compliance disappeared. As stated in the NPRM, when a review of our regulations revealed that there was no requirement in U.S. regulations to carry noise data, we began the process of this rulemaking to comply with the Annex requirement.

The FAA is not requiring any particular format for carriage of the information, but cautions operators that all of the information required by the Annex must be carried to comply with both Annex 16 and the new § 91.703(a)(5). Annex 16 contains Attachment G, which is the ICAO's suggested format for the document. The FAA developed the optional form included in this document from Attachment G, modifying it to indicate that the form is the responsibility of the operator and not an FAA-approved document. For an operator that does not have the resources to research and develop its own form, we strongly suggest that the optional FAA form be used to eliminate inconsistencies in the data carried. The FAA has received approval from the Office of Management and Budget (OMB #2120-0737) to maintain this as an official form.

One commenter recommended that the FAA also issue an Advisory Circular (AC) or other guidance regarding means of compliance for this proposal.

The FAA will be issuing guidance material at the time this final rule is published. We anticipate that the AC will contain the optional form, the instructions for completing the form that appear in this document, and guidance for aircraft that are not required to be noise certificated because of their age.

#### Summary of Changes to the Final Rule

No substantive changes are being made from the rule proposed in the NPRM. This final rule adds a new paragraph (a)(5) to § 91.703 that requires aircraft subject to ICAO Annex 16 to carry noise certification data on board when those aircraft leave the United States.

Format of the data is at the operator's discretion. Operators developing their own formats are advised to ensure that all of the information required by ICAO Annex 16 Sections 1.4 and 1.5 is included. Data carried on board must be specific to each aircraft. Lists of aircraft noise levels that apply to more than one serial number aircraft are not acceptable for compliance. The FAA encourages operators to use the optional form included in this publication as a means of ensuring that all of the required data are included. The data, in whatever chosen format, must be available to the flight crew. To the extent that operators have the approval to carry documents electronically, this information may be included. The FAA will not be signing or otherwise approving the forms carried by the operator. The FAA does not issue noise certificates and information carried to comply with this regulation may not be referred to as an official or approved noise certificate. Accurate data transfer from an FAA-approved data source is the responsibility of the operator.

BILLING CODE 4910-13-P

<b>1.</b> <b>United States of America</b>				
<b>2.</b> <b><u>Aircraft Noise Certification Information</u></b> <b>Name of Operator</b> (Address, Telephone, and Fax Number)				
<b>3. Document Number: (Optional)</b>	<b>4. Nationality and Registration Marks:</b>	<b>5. Manufacturer; Manufacturer's Designation Of Aircraft (Model/Series):</b>	<b>6. Aircraft Serial Number:</b>	
<b>7. Engine:</b>		<b>8. Propeller: (If applicable)</b>		
<b>9. Maximum Takeoff Weight/ Mass:</b>  _____ pounds ( _____ kg)	<b>10. Maximum Landing Weight/ Mass:</b>  _____ pounds ( _____ kg)	<b>11. Noise Standard: (If applicable)</b>  Stage _____		
<b>12. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards:</b>				
<b>13. Lateral/Full-Power Level (if applicable)</b>	<b>14. Approach Noise Level (if applicable)</b>	<b>15. Flyover Noise Level (if applicable)</b>	<b>16. Overflight Noise Level (if applicable)</b>	<b>17. Takeoff Noise Level (if applicable)</b>
<b>18. Subject Aircraft Noise Levels:</b>  The aircraft listed on this form meets the requirements of 14 CFR part 36. The noise information on this document has been copied from FAA-approved AFM/RFM/AOM/FCOM, number XXX-XXX-XXX, Revision X, dated MM-DD-YYYY.				
<b>19. Date</b> _____ <b>20. Signature</b> _____ (Official of Operator)				

This document supports compliance with ICAO Annex 16, Volume 1 for noise certification documentation carried on board U.S. aircraft. Information on this form has been transferred from an FAA-approved Aircraft Flight Manual by the named operator; that operator is solely responsible for the content.

**BILLING CODE 4910-13-C**

The following describes the data to be entered on the form:

1. United States of America (ICAO-required name of member State).
2. Title (Aircraft Noise Certification Information), plus the name of the operator and contact information.

3. Document number (optional for operator's use).

4. The nationality or common mark and registration marks (in the United States, N-number).

5. The aircraft manufacturer and manufacturer's designation of the

aircraft (model and series, as appropriate).

6. The aircraft serial number.

7. The type and model of the subject aircraft's engine(s) (for identification and verification of the aircraft configuration).

8. For propeller-driven airplanes, the propeller type and model.

9. The maximum takeoff mass and unit. The primary U.S. unit differs from the international unit: the appropriate conversion factor can be found in ICAO Annex 5. To avoid confusion, a U.S. operator may choose to record weight/mass in both English and metric units. An example of a conversion change from pounds to kilograms is shown below:

*Aircraft weight (pounds) conversion to aircraft mass (kilograms) <sup>2</sup>:*

To convert aircraft weight from	to	Multiply by
pound (lb) .....	kilogram (kg)	4.53592 E-01.

*Example:* For a Boeing 747-400F that weighs 875,000 lb,  $875,000 \text{ (lb)} \times 4.53592 \text{ E-01 (kg/lb)} = 396,893 \text{ (kg)}$

10. The maximum landing mass and unit. To avoid confusion, a U.S. operator may choose to record weight/mass in both English and metric units. See conversion example above.

11. The Part 36 noise stage of the certificated aircraft. The terminology of aircraft certification classification in the United States is "Stage" rather than "Chapter" as used in Annex 16. The U.S. term is recognized by ICAO and is not considered a difference from Annex 16. Note that the term "Stage" is not applicable to airplanes certificated under 14 CFR part 36, Subpart F.

12. Any modifications to the aircraft incorporated for compliance with applicable noise certification standards. This item should include any modifications to the basic aircraft described in items 7 and 8.

13. The lateral/full-power noise level, as certificated. Operators of U.S.-registered aircraft must use the 14 CFR part 36 certificated noise levels, expressed as Effective Perceived Noise Level (EPNdB). Note: For 14 CFR part 36, appendix B, certifications that predate Amendment 36-24 use the term "sideline" instead of "lateral."

14. The approach noise level, as certificated. Operators of U.S.-registered aircraft must use the 14 CFR part 36, appendices B or H certificated noise levels, expressed as EPNdB.

15. The flyover noise level, as certificated. Operators of U.S.-registered

aircraft must use the 14 CFR part 36 certificated noise levels, expressed as EPNdB. For rotorcraft, certificated under appendices H or J, noise levels are expressed as either EPNdB or A-weighted Sound Exposure Level (dBA SEL), respectively. Note: For 14 CFR part 36, appendix B certifications that predate Amendment 36-24 use the term "takeoff" instead of "flyover."

16. The overflight noise level, as certificated. Operators of U.S.-registered aircraft must include the 14 CFR part 36 certificated noise levels. For small airplanes, certificated under appendix F, noise levels are expressed as maximum A-weighted sound level (dBA). For rotorcraft, certificated under appendices H or J, noise levels are expressed as either EPNdB or A-weighted SEL (dBA SEL), respectively.

**Note:** The terminology describing this noise level in 14 CFR part 36 is "flyover" rather than "overflight" as used in Annex 16.

17. The takeoff noise level, as certificated. Operators of U.S.-registered aircraft must use the 14 CFR part 36, appendices G and H certificated noise levels as described in item 16.

18. A statement that the individual aircraft complies with the applicable noise requirements of the U.S. regulations applicable to its type and size.

19. The date on which the noise certification document was created by the operator.

20. The signature of the official of the operator attesting to the accuracy of the information in the FAA Form.

Listing multiple aircraft with similar characteristics on the same document will not be allowed. Only the data for the single aircraft listed in the serial number and registration sections is to be listed on this form. Failure to carry the correct information, regardless of form, is considered a violation of the regulation.

#### Paperwork Reduction Act

Information collection requirements associated with this final rule have been previously approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), and have been assigned OMB Control Number 2120-0737.

#### International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, the FAA policy is to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA

has reviewed the corresponding ICAO Standards and Recommended Practices and has determined this regulation is a means of compliance with Annex 16 regarding noise documentation carried on board aircraft that leave the United States.

#### Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995).

The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that the proposal or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

This final rule will require operators of U.S. registered civil aircraft flying outside the United States subject to ICAO Annex 16, Volume 1, Amendment 8, to carry aircraft noise certification data on board the aircraft. Operators may comply with the rule by transferring the data from the Airplane Flight Manual or Airline Operations Manual to a suggested form included in this rulemaking. Operators may also choose to carry the required information in a different format. The rule will require that this information be easily accessible to the flight crew and

<sup>2</sup> In 1959, the directors of the national standards laboratories of the United States, Canada, the United Kingdom, Australia, New Zealand, and the Union of South Africa agreed on common definitions of the customary length and mass units. They define the pound avoirdupois as 4.53592 E-01 kg. The engineering practice of using lbm for pound mass is obsolete.

presentable upon request to the appropriate officials.

The FAA was unable to determine the exact number of U.S. registered aircraft that will be subject to this final rule. Also, the FAA received no comments about its methodology used to estimate the cost of this rule. Therefore, the FAA will continue to use (as an overestimate) the total number of passenger jet and cargo jet aircraft registered to U.S. mainline carriers in its cost computations. Based on the FAA Aerospace Forecast, there are a total of 5,066 aircraft currently registered to U.S. mainline air carriers.<sup>3</sup>

For the purposes of this analysis, we assume that operators would choose to comply with the final rule by using the provided recommended form. This form would be completed one time for each aircraft. We estimate that completion of the form would require 15 minutes of a technical writer's time and 10 minutes of a chief pilot's or chief engineer's time. The average wage rate for a technical writer is \$29.95 per hour<sup>4</sup> after accounting for fringe benefits. The average wage rate for a chief pilot or chief engineer is estimated at \$79.48 per hour<sup>5</sup> after accounting for fringe benefits.

The cost of the final rule per affected airplane was derived by multiplying the technical writer's wage rate of \$29.95 per hour by 0.25 hours required to complete the form, and adding to that the chief pilot's wage rate of \$79.48 per hour multiplied by 0.17 hours required to review and sign the form. Thus, compliance with this regulation will result in a per-airplane cost of \$21. As a result, the initial cost of the final rule will be \$21 per aircraft times 5,066 aircraft, for a total of \$106,386. Operators may subsequently decide to purchase or modify aircraft affected by the final rule. If they do so, operators will incur an extra cost of \$21 per additional airplane to bring it into compliance with ICAO Annex 16, Volume 1, Amendment 8.

This final rule will ensure that U.S. aircraft that fly outside the United States are in compliance with ICAO Annex 16, Amendment 8. Operators will benefit from the rule by having the proper documentation readily available for

foreign authorities, avoiding delays and detainment when noise certification status is questioned. The FAA believes that the negligible cost of compliance with this rule is outweighed by the benefit of compliance with the international standard.

#### Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration." The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rule will ensure that U.S. operators have consistent noise certification information on board when they fly outside the United States. This rule is needed to ensure compliance with the ICAO Annex 16 that requires certain noise information be carried on board. Under the final rule, each small entity will incur a one-time cost of \$21 per aircraft currently in its fleet. Operators may subsequently decide to purchase or modify aircraft affected by the final rule; if they do so, they will incur an extra cost of \$21 per airplane to comply. The FAA does not consider this a significant cost. The FAA received no comments from the public regarding this finding. Therefore, as the Administrator of the FAA, I certify that this final rule will not have a significant impact on a substantial number of small entities.

#### International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96-39), as amended by the Uruguay Round Agreement Act (Pub. L. 103-465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and has determined that it will affect only those U.S. operators that conduct international operations. The expected outcome of this final rule will be a minimal impact on affected operators with the net benefits of ICAO compliance.

#### Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of \$136.1 million in lieu of \$100 million.

This final rule does not contain such a mandate.

#### Executive Order 13132, Federalism

The FAA has analyzed this NPRM under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

#### Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the

<sup>3</sup> Tables 20 and 21, U.S. Mainline Air Carriers, Cargo Jet Aircraft, FAA Aerospace Forecast, FY 2008-2025.

<sup>4</sup> FAA, APO-310, N & O Rule Regulatory Evaluation.

<sup>5</sup> Hourly wage derived by taking median salary of \$133,916 for a chief pilot, dividing by 2,080 hours per year, and multiplying by the fringe benefit factor of 1.2345. Salary source: [http://swz.salary.com/salarywizard/layouthtmls/swz\\_compresult\\_national\\_TR20000019.html](http://swz.salary.com/salarywizard/layouthtmls/swz_compresult_national_TR20000019.html), last accessed June 30, 2008.

absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

### Regulations That Significantly Affect Energy, Supply, Distribution, or Use

The FAA has analyzed this NPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a "significant energy action" under the executive order because it is not a "significant regulatory action" under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

### Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents using the Internet by—

1. Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visiting the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies/](http://www.faa.gov/regulations_policies/) or
3. Accessing the Government Printing Office's Web page at <http://www.gpoaccess.gov/fr/index.html>.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-9680. Make sure to identify the amendment number or docket number of this rulemaking.

You may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://DocketsInfo.dot.gov>.

### Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the

beginning of the preamble. You can find out more about SBREFA on the Internet at [http://www.faa.gov/regulations\\_policies/rulemaking/sbre\\_act/](http://www.faa.gov/regulations_policies/rulemaking/sbre_act/).

### List of Subjects in 14 CFR part 91

Aircraft, Noise control, Reporting and recordkeeping requirements.

### The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter 1 of Title 14, Code of Federal Regulations, as follows:

### PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506, 46507, 47122, 47508, 47528-47531, articles 12 and 29 of the Convention on International Civil Aviation (61 stat 1180).

■ 2. Amend § 91.703 by adding paragraph (a)(5) to read as follows:

#### § 91.703 Operations of civil aircraft of U.S. registry outside of the United States.

(a) \* \* \*

(5) For aircraft subject to ICAO Annex 16, carry on board the aircraft documents that summarize the noise operating characteristics and certifications of the aircraft that demonstrate compliance with this part and part 36 of this chapter.

\* \* \* \* \*

Issued in Washington, DC, on February 18, 2010.

**J. Randolph Babbitt,**  
*Administrator.*

[FR Doc. 2010-4316 Filed 3-1-10; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

[Docket No. FDA-2010-N-0002]

#### Implantation or Injectable Dosage Form New Animal Drugs; Tilmicosin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal

drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides a dose range for use of an injectable solution of tilmicosin phosphate for treatment of respiratory disease in cattle and additional pathogens for which this therapy is effective.

**DATES:** This rule is effective March 2, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: [cindy.burnsteel@fda.hhs.gov](mailto:cindy.burnsteel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 140-929 for MICOTIL 300 (tilmicosin injection, USP) Injection, available by veterinary prescription for use in the treatment and control of respiratory disease in cattle and the treatment of respiratory disease in sheep. The supplemental NADA establishes a dose range and adds pathogens for which this therapy is effective in the management of bovine respiratory disease. As a consequence of revising the dosage, the preslaughter withdrawal period has been recalculated. The supplemental NADA is approved as of December 30, 2009, and the regulations in 21 CFR 522.2471 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because