

(k) Additional Information

For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329-4165; email: jim.rutherford@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Agência Nacional de Aviação Civil (ANAC) AD 2023-05-03R02, effective May 17, 2024.

(ii) [Reserved]

(3) For ANAC material identified in this AD, contact ANAC, Continuing Airworthiness Technical Branch (GTAC), Rua Doutor Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246-190—São José dos Campos—SP, Brazil; phone: 55 (12) 3203-6600; email: pac@anac.gov.br; website: anac.gov.br/en/. You may find this material on the ANAC website at sistemas.anac.gov.br/certificacao/DA/DAE.asp.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222-5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on August 8, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 129****International Aviation Safety Assessment (IASA) Program**

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Request for comments on proposed changes to the IASA Program.

SUMMARY: On September 28, 2022, the FAA published a Policy Statement in the **Federal Register** that described policy changes to the FAA's International Aviation Safety Assessment (IASA) program as well as clarification or restatement of prior

policy to “enhance engagement with civil aviation authorities (CAAs) through pre- and post-*IASA* assessment and to promote greater transparency.” After receiving inquiries and questions about the changes described in that policy statement, the FAA is, elsewhere in this issue of the **Federal Register**, suspending implementation of the September 28, 2022, Policy Statement while the agency reassesses the policy, and invites public comments on proposed changes to the FAA *IASA* program policy contained herein. The policy statement of March 8, 2013, remains active.

DATES: The FAA must receive comments by September 16, 2024.

ADDRESSES: You may send comments identified by docket number FAA-2024-2058 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at (202) 493-2251.

FOR FURTHER INFORMATION CONTACT:

Rolandos Lazaris, Division Manager, International Program Division (AFS-50), Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; (202) 267-3719.

SUPPLEMENTARY INFORMATION:**Background**

The *IASA* program is the means by which the FAA determines whether another country's oversight of its air carriers that (1) operate, or seek to operate, services to/from the United States using their own aircraft and crews, or (2) seek to display the code of a U.S. air carrier on any services, complies with safety standards established by the International Civil Aviation Organization (ICAO). The published *IASA* results of a country's placement in Category 1 or Category 2 is the notification to the U.S. traveling public as to whether a foreign air carrier's homeland civil aviation

authority meets ICAO safety standards. A Category 1 rating indicates that the civil aviation authority meets ICAO safety standards for these operations, and a Category 2 rating indicates that the civil aviation authority does not meet ICAO safety standards. The *IASA* program was established by a document published in the **Federal Register** in 1992. Subsequent published documents in the **Federal Register** notified of the program's evolution. These **Federal Register** documents are as follows:

- August 24, 1992—Established the FAA Procedures for Examining and Monitoring Foreign Air Carriers (57 FR 38342).

- September 8, 1994—Established the Public Disclosure of the Results of Foreign Civil Aviation Authority Assessments, through a three-category numbered rating system (59 FR 46332).

- October 31, 1995—DOT Notice Clarification Concerning Examination of Foreign Carriers' Request for Expanded Economic Authority, clarified the Department's licensing policy regarding requests for expanded economic authority from foreign air carriers whose CAA's safety oversight capability has been assessed by the FAA as conditional (Category II) or unacceptable (Category III) (60 FR 55408).

- May 25, 2000—Changes to the International Aviation Safety Assessment program removed the Category 3 rating and combined it with Category 2 (65 FR 33751).

- March 8, 2013—Changes to the International Aviation Safety Assessment program removed inactive countries (countries with no air carrier operations to the United States or code-shares with U.S. air carrier for four years and no significant interaction between the country's CAA and the FAA) from the *IASA* Category list (78 FR 14912).

Through the *IASA* program, the FAA seeks continuous improvement to global aviation safety. As noted in the above-referenced policy statement of September 8, 1994, initial *IASA* assessments found that two-thirds of the assessed CAAs were deficient in meeting their safety oversight obligations under the Convention on International Civil Aviation.

The September 28, 2022, Policy Statement (87 FR 58725) (now suspended) announced certain changes to the *IASA* program and provided clarification to other aspects of the *IASA* policy. Since that publication, the FAA and DOT have received inquiries and questions that warrant reassessment of those changes and clarifications, and an opportunity for public comment before they are adopted permanently. As noted above, the FAA is suspending

implementation of the September 28, 2022, Policy Statement while the agency reassesses the policy and considers public comments. Public comment is invited on the matters and issues described below.

IASA Program Policy Changes, Clarification, or Restatement

The following paragraphs describe proposed policy changes, clarification, or restatement to the FAA's IASA program to enhance engagement with CAAs through pre- and post-*IASA* assessment and to promote greater transparency.

Proposed Changes to the Definition of the IASA Categories

The FAA is proposing to modify the scope of the IASA Category definitions to align them with the types of operations that require an IASA Category rating. The March 8, 2013, IASA policy statement describes two possible IASA Categories in which the FAA places countries:

- *Category 1, Meets ICAO Standards:* The FAA has found that the country meets ICAO standards for safety oversight of civil aviation. When a country is in Category 1, its foreign air carriers may provide service to the United States with their own aircraft/crews under 14 CFR part 129 and 14 CFR 375.42 and 375.70 or may, with the DOT's Office of the Secretary (OST) and FAA approval, engage in code-sharing partnerships with U.S. air carriers where a U.S. air carrier places its code on flights operated by a foreign air carrier(s).

- *Category 2, Does Not Meet ICAO Standards:* The FAA has found that the country does not meet ICAO standards for safety oversight of civil aviation.

In addition, the May 25, 2000, policy statement introduced the Category 2* designation for those countries not serving the U.S. at the time of their IASA assessment.

The 2013 policy statement further states that "the IASA category rating applies only to services to and from the United States and to codeshare operations when the code of a U.S. air carrier is placed on a foreign carrier flight. . . . The [FAA] assessment team looks at [a foreign carrier's domestic flights or flights by that carrier between its homeland and a third country] only to the extent that they reflect on the country's oversight of operations to and from the United States and to codeshare operations where a U.S. air carrier code is placed on a flight conducted by a foreign air operator." The FAA highlights this explanation in this document to address any mistaken

perception that the IASA program evaluates the oversight of all operations of foreign air carriers of a particular country. The FAA exercises oversight authority of foreign air carriers with service to the United States through issuance and oversight of operations specifications (OpSpecs) issued under 14 CFR part 129 to foreign air carriers that operate services to/from the United States with their own aircraft and crews. This requires the FAA to engage in regular contact with the relevant foreign CAA as to various aspects of these operations. When a U.S. air carrier places its code on a foreign air carrier's flight that is conducted by the foreign carrier entirely outside the United States, part 129 OpSpecs are not required, but those code-share arrangements are subject to regular audits conducted by the FAA under the U.S. Department of Transportation Office of the Secretary (OST)/FAA Code-Share Safety Program Guidelines.

In addition, as part of its standard foreign carrier licensing process, the DOT requests that the FAA determine if foreign charters requesting service to the U.S. under 14 CFR 375.42 and 375.70 are receiving ICAO-compliant safety oversight from their CAA. In some instances, these part 375 applications have resulted in the FAA extending the IASA program to countries with only part 375 operators and no part 129 operators. Foreign civil aircraft operators authorized by OST to conduct charters to/from the United States under part 375 do not hold operations specifications from the FAA, nor are they allowed to carry the code of a U.S. operator.

Remove Category 2 *

The FAA proposes to remove the 2* designation. The FAA has used the 2* category for those countries not serving the U.S. at the time of their IASA assessment. This distinction is no longer relevant, and the FAA will simply categorize any country that does not meet ICAO standards with a Category 2 rating.

New Category 1 *

In order to better address the safety awareness and expectations of the U.S. traveling public, and to advise the U.S. traveling public, once a Category 1 country has been notified through official channels for a reassessment based on identified risks of possible noncompliance with ICAO standards pursuant to the FAA's risk assessment process, the FAA proposes that it would adjust the Category 1 rating of the country to a rating of Category 1*.

- *Category 1*:* The FAA will add an asterisk "*" to a country's Category 1 rating once that country has been notified through official channels for a reassessment based on identified risks of possible noncompliance with ICAO standards. The 1* category designation does not indicate that the FAA has determined that safety risks have been conclusively found or that a country's air operations are being modified at this time, but rather only serves as notice that the FAA initiated the IASA reassessment. The asterisk "*" will be removed once a reassessment is complete and the country either retains its Category 1, or the country is assessed as not meeting ICAO standards and is subsequently assigned a Category 2 rating.

Change in the Timeframe for Country Removal From the IASA Category List Due to Inactivity, and Clarification on "Significant Activity"

Under the March 8, 2013, policy statement, a country can be removed from the IASA category list after four years of inactivity. The three criteria that must be met for the FAA to remove the country from the IASA category list are: the country has no air carrier providing air transport service to the United States; the country has no air carrier that participates in a code-share arrangement with U.S. air carriers; and the CAA does not "interact significantly with the FAA."

The FAA's experience and analysis indicates that IASA information is not reliable after an initial assessment or reassessment without significant safety oversight interaction between the FAA and foreign CAA. Such interaction includes when a foreign air carrier is conducting services to/from the United States with its own aircraft/crews and holds FAA OpSpecs under part 129, operating under §§ 375.42 and 375.70, and/or when a U.S. air carrier places its code on any of a foreign air carrier's flight as authorized under the OST/FAA Code-Share Safety Program Guidelines.

The FAA seeks to amend the criteria for removal as follows: the country has no foreign operators holding OpSpecs under part 129, or operating under §§ 375.42 and 375.70 with service to the United States nor foreign operators carrying the code of a U.S. operator as authorized under the OST/FAA Code-Share Safety Program Guidelines, and the country has not received technical assistance from the FAA for identified ICAO safety oversight deficiencies within the prior two-year period. The FAA seeks comment on these proposed additional or clarifying criteria for

removal of a country from the IASA category list.

In addition, the FAA proposes to reduce the time for removal from the IASA list from four years to two years. The removal criteria published in 2013 no longer meet the need for timeliness and accuracy of information on the IASA Category Rating list. The 2013 criteria leave Category 1 countries on the list for an extended period of time and may give the U.S. traveling public a false sense of safety. Also, leaving Category 2 countries on the list for an extended period of time can be perceived as unfairly penalizing those countries when there has been no activity since the Category 2 rating was issued. As a result, the FAA proposes to reduce the removal benchmark from four years to two years absent the interaction described above. The FAA seeks comment on the proposed change from four years to two years, or whether any other timeframe would be appropriate.

Clarification as to When an IASA Will Be Performed in a Country With No IASA Category Rating

The FAA will perform an IASA of a country with no IASA Category rating after an operator from that country files an application with OST for economic authority to conduct (1) services to/from the United States with its own aircraft/crews, and/or (2) code-share operations that involve the foreign air carrier displaying the code of a U.S. air carrier on any services operated by the foreign air carrier. This would ensure that an initial IASA is used to assess whether the CAA and its operator(s) have each taken the necessary measures to manage and oversee operations in accordance with ICAO standards.

Clarification of FAA and CAA Development of a Corrective Action Plan Upon Notification of an IASA Category 2 Rating

If the FAA finds, as a result of an assessment, that a foreign CAA is not overseeing aviation safety in accordance with ICAO standards, the FAA will, prior to the conclusion of an assessment, state its findings in an oral briefing to that foreign CAA. The FAA will also deliver to the foreign CAA a written record of FAA findings and will schedule a follow-up final discussion with the foreign CAA. The final discussion shall take place no earlier than 15 calendar days following the delivery of the written record of findings. In any case in which the assessment finds an instance of non-compliance, the FAA will notify the foreign CAA that is the subject of such

finding. Within 90 days after the transmission of such notification, the FAA will request and initiate final discussions with the foreign country to recommend actions by which the foreign country can mitigate the noncompliance. If the FAA determines that the foreign CAA has not corrected its oversight deficiencies after the conclusion of the final discussion, the country will, upon formal communication from the United States Government, receive an official determination of Category 2 status, and be subject to restrictions on the operations of its air carriers to the United States and on the placement of U.S. carrier codes on flights operated by its carriers.

For additional communication and support for a country assigned an IASA Category 2 rating, the FAA may conduct a virtual meeting with the CAA to discuss the IASA findings. The FAA proposes to provide the CAA with a Corrective Action Plan outline for the CAA to use to document the actions needed to resolve safety deficiencies and the timelines for resolution. This would allow the CAA to begin work to address its safety oversight findings from the IASA in a timely manner.

Upon CAA request, the FAA may, under a technical assistance agreement, assist the CAA in developing a Corrective Action Plan to address its safety oversight deficiencies and timelines for completion.

FAA Actions To Address Safety Concerns Outside of the IASA Process

The FAA retains its authority to take action to address a known safety concern to prevent further non-compliance or unsafe operation of an aircraft by an air carrier, including limiting operations to/from the United States by foreign air carriers with their own aircraft/crews; placing limits on code share arrangements involving the display of a U.S. air carrier code by foreign air carriers from countries for which the FAA has identified safety oversight concerns and initiating immediate IASA category changes when justified based on available safety information. The FAA may also communicate with a CAA about safety concerns the FAA may be aware of so that the CAA can immediately take its own mitigating action. The FAA believes that immediate action that results in the resolution of a safety concern or provides the avenue for clarifying information from the CAA is in the best interest of public safety.

Comments Invited

The FAA invites public comments on the proposed IASA policy modifications and clarifications. The FAA will consider the public comments submitted during this comment period in finalizing the IASA policy.

Issued in Washington, DC.

Jodi L. Baker,

Deputy Administrator for Aviation Safety.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2024–N–1111]

RIN 0910–AI64

Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration, with the Department of the Treasury's concurrence, proposes amending its regulations to require that the Submission Tracking Number for Electronic Nicotine Delivery System tobacco products that are being imported or offered for import be submitted in the Automated Commercial Environment or any other electronic data interchange system authorized by U.S. Customs and Border Protection, at the time of entry.

DATES: Either electronic or written comments on the proposed rule must be submitted by October 15, 2024. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by October 15, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 15, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.