

Impacts: Policies and Procedures,” paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Correction to the Final Rule

Accordingly, pursuant to the authority delegated to me, the amendment of Class D airspace for Greenbrier Valley Airport, Lewisburg, WV, in Docket No. FAA–2023–2275, as published in the **Federal Register** of April 8, 2024 (89 FR 24367), FR Doc. 2024–07245, in 14 CFR part 71, is corrected as follows:

§ 71.1 [Corrected]

■ 1. On page 24368, in the third column, correct the description for AEA WV D Lewisburg, WV [Amended] to read:

* * * * *

AEA WV D Lewisburg, WV [Amended]

Greenbrier Valley Airport, WV
(Lat. 37°51′30″ N, long. 80°23′58″ W)

That airspace extending upward from the surface to and including 4,800 feet MSL within a 4-mile radius of Greenbrier Valley Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be published continuously in the Chart Supplement.

Issued in College Park, Georgia, on May 15, 2024.

Patrick Young,

Manager, Airspace & Procedures Team North,
Eastern Service Center, Air Traffic
Organization.

[FR Doc. 2024–10967 Filed 5–17–24; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 705

[Docket No. 240306–0071]

RIN 0694–AJ27

Revisions of the Section 232 Steel and Aluminum Tariff Exclusions Process

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule revises aspects of the process for requesting exclusions from the duties and quantitative

limitations on imports of aluminum and steel discussed in five previous Bureau of Industry and Security (“BIS”) interim final rules implementing the exclusion process authorized by the President under section 232 of the Trade Expansion Act of 1962, as amended (“Section 232”). The changes in this final rule are also informed by public comments on a proposed rule on the Section 232 exclusions process that was published by BIS on August 28, 2023 (August 2023 Proposed Rule), detailed below. This final rule thus removes 12 General Approved Exclusions (GAEs) that were added in the December 2020 rule and maintained through the December 2021 rule, consisting of six GAEs for steel and six GAEs for aluminum.

DATES: This final rule is effective July 1, 2024.

FOR FURTHER INFORMATION CONTACT: For questions regarding this interim final rule, contact Kevin Coyne at 202–482–2313 or via email *Kevin.Coyne@bis.doc.gov*, or email *Steel232@bis.doc.gov* regarding provisions in this rule specific to steel exclusion requests and *Aluminum232@bis.doc.gov* regarding provisions in this rule specific to aluminum exclusion requests.

SUPPLEMENTARY INFORMATION:

Background

On March 8, 2018, Proclamations 9704 and 9705 were issued imposing duties on imports of aluminum and steel, respectively. The Proclamations also authorized the Secretary of Commerce (“the Secretary”) to grant exclusions from the duties if the Secretary determines the steel or aluminum article for which the exclusion is requested is not “produced in the United States in a sufficient and reasonably available amount or of a satisfactory quality” or should be excluded “based upon specific national security considerations,” and provided authority for the Secretary to issue procedures for exclusion requests. On April 30, 2018, Proclamations 9739 and 9740, and on May 31, 2018, Proclamations 9758 and 9759, set quantitative limitations on the import of steel and aluminum from certain countries in lieu of the duties. On August 29, 2018, in Proclamations 9776 and 9777, the Secretary was authorized to grant exclusions from quantitative limitations based on the same standards applicable to exclusions from the tariffs.

Implementing and Improving the 232 Exclusions Process

Since March 19, 2018, Commerce has published five interim final rules (IFRs)

that established and made various improvements to the Section 232 exclusions process, as well as a Notice of Inquiry and a Proposed Rule seeking public comment on certain aspects of the Section 232 exclusions process.

On March 19, 2018, BIS issued an IFR, *Requirements for Submissions Requesting Exclusions from the Remedies Instituted in Presidential Proclamations Adjusting Imports of Steel into the United States and Adjusting Imports of Aluminum into the United States; and the Filing of Objections to Submitted Exclusion Requests for Steel and Aluminum* (83 FR 12106), establishing the Section 232 exclusions process in supplements no. 1 and 2 to 15 CFR part 705.

On September 11, 2018, BIS issued a second IFR, *Submissions of Exclusion Requests and Objections to Submitted Requests for Steel and Aluminum* (83 FR 46026), which revised the exclusions process to increase transparency, fairness, and efficiency.

On June 10, 2019, BIS issued a third IFR, *Implementation of New Commerce Section 232 Exclusions Portal* (84 FR 26751), that revised the two supplements to part 705 to grant the public the ability to submit new exclusion requests through the Section 232 Exclusions Portal while still allowing the opportunity for public comment on the portal.

On May 26, 2020, BIS issued a notice of inquiry with request for comment, *Notice of Inquiry Regarding the Exclusions Process for Section 232 Steel and Aluminum Import Tariffs and Quotas* (85 FR 31441), that sought public comment on the appropriateness of the information requested and considered in applying the exclusion criteria and the efficiency and transparency of the process employed.

On December 14, 2020, BIS issued a fourth IFR, *Section 232 Steel and Aluminum Tariff Exclusions Process* (85 FR 81060) (4th IFR), which established General Approved Exclusions (GAEs) to reduce the number of exclusion requests for products consistently found not to be produced in the United States, reducing the submission burden on both industry and the Section 232 exclusions process. The 4th IFR identified 123 GAEs that had generally never received an objection or very few objections via the Section 232 exclusions process. GAEs are available to all would-be requesters for steel and aluminum products imported under 10-Digit Harmonized Tariff Schedule of the United States (HTSUS) classifications without quantity limit or expiration date. For information regarding the

adoption of the GAE policy, please review the 4th IFR.

On December 9, 2021, BIS subsequently suspended 30 GAEs in its fifth IFR, *Removal of Certain General Approved Exclusions Under the Section 232 Steel and Aluminum Tariff Exclusion Process* (86 FR 70003), on the Section 232 Exclusions process because they were determined by BIS to no longer fit the criteria of a GAE.

On January 3, 2022, Presidential Proclamations 10327 (87 FR 1) and 10328 (87 FR 11) were published. These Proclamations implemented an understanding reached between the United States and the European Union including the establishment of tariff rate quotas for steel and aluminum articles imported from the European Union member countries. Proclamation 10328 also directed the Secretary of Commerce to seek public comment on the Section 232 exclusions process, including the responsiveness of the exclusions process to market demand and enhanced consultation with U.S. firms and labor organizations.

On February 10, 2022, BIS published *Request for Public Comments on the Section 232 Exclusions Process* (87 FR 7777) (February 2022 Notice), as directed by Presidential Proclamation 10328. The notice sought public comment on a variety of topics regarding the responsiveness of the exclusions process to market demand and enhanced consultation with U.S. firms and labor organizations. The notice comment period closed in March 2022, having received nearly 100 comments.

On August 28, 2023, BIS published its proposed rule entitled *Revisions of the Section 232 Steel and Aluminum Exclusions Process* (88 FR 58525) (August 2023 Proposed Rule). The rule proposed several revisions to the Section 232 exclusions process, including adjustments to the current criteria for identifying GAEs, the introduction of new General Denied Exclusions (GDEs), and the introduction of new certification requirements for both Requestors and Objectors.

Public Comments and BIS Responses

The public comment period on the August 2023 Proposed Rule closed on October 12, 2023. BIS received roughly 100 public comments on the proposed rule. This is the first of at least two final actions stemming from the August 2023 Proposed Rule. While BIS will further analyze the comments received on the August 2023 Proposed Rule, the public comments described below provide a sufficient basis for the action taken in this final rule. This rule is a response to

that issue alone. BIS will respond to comments received on the August 2023 Proposed Rule in a forthcoming final rule that details broader changes to the Section 232 exclusions process.

Comment 1: BIS received multiple comments regarding the efficacy of specific GAEs. The majority of commenters opposed the continuing use of certain GAEs as thwarting the objective of the Section 232 action, including the ability to submit objections to exclusion requests. One commenter specifically said:

As a result of these GAEs, the vast volume of aluminum extrusion imports exempt from Section 232 tariffs . . . are once again able to directly and unfairly compete with U.S.-produced extrusions. This includes imports . . . covered by the GAEs (HTSUS 7609.00.0000; 7604.21.0010; 7604.29.1010; and 7604.29.5090) . . . By offering blanket duty-free treatment to importers of these products, the GAEs have effectively gutted any relief the Section 232 could provide for the extrusions industry.

BIS Response: GAEs addressed a long-standing request from exclusion requesters to create a more efficient process to approve certain exclusions where Commerce has determined that: (1) No objections will be received; and (2) it is warranted to approve an exclusion for all importers to use. As always, BIS evaluates all changes to the Section 232 exclusions process to determine if they improve the efficiency and effectiveness of the process, and thus U.S. national security. It was clear to BIS that an evaluation of the GAEs was warranted. The initial review has highlighted the need to remove additional GAEs. Removing these GAEs supports the effectiveness of the Section 232 tariffs and therefore U.S. national security.

Regulatory Changes

With this final rule, BIS is removing 12 of the 93 GAEs from supplements no. 2 and no. 3 to part 705 (six from each supplement). These GAEs were introduced in the December 2020 rule and maintained through the December 2021 rule. This final rule removes the following 12 GAEs:

- 6 GAEs for steel: GAE.24.S: 7211296080; GAE.43.S: 7209900000; GAE.46.S: 7216330090; GAE.84.S: 7209270000; GAE.90.S: 7216100010; and GAE.93.S: 7208380015 and

- 6 GAEs for aluminum: GAE.1.A: 7609000000; GAE.4.A: 7604210010; GAE.5.A: 7604291010; GAE.9.A: 7601209080; GAE.10.A: 7607116010; and GAE.13.A: 7604295090.

The steel and aluminum articles specified by these 12 GAEs will revert to the duties and treatment previously

established under Presidential Proclamations 9704 and 9705 as well as subsequent Proclamations.

BIS does not anticipate that suspension of these 12 GAEs will substantially increase the total volume of submitted exclusion requests in the Section 232 Exclusions Portal. BIS has received 1,645 exclusion requests from 31 requestors for articles covered by these 12 GAEs in the Section 232 Exclusions Portal over an approximate eighteen-month period prior to the December 2020 rule. BIS estimates that the removal of these 12 GAEs will affect roughly 30 requestors who submit exclusion requests and will lead to the submission of an additional 1,000 exclusion requests per year in the Section 232 Exclusions Portal.

This final rule makes no additional changes to the other 81 GAEs that will continue to remain in supplements no. 2 and no. 3. As noted above, BIS made the determination to remove these 12 GAEs based on public comments received to the August 2023 Proposed Rule that was bolstered by internal analysis of exclusions data. It must be noted that should analysis of these GAEs change in the future, BIS may reissue these GAEs in whole or in part in subsequent rules.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be a “significant regulatory action,” under Executive Order 12866. Pursuant to Proclamations 9704 and 9705 of March 8, 2018, and Proclamations 9776 and 9777 of August 29, 2018, the establishment of procedures for an exclusions process under each Proclamation shall be published in the **Federal Register**.

2. The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, unless that collection has obtained Office of Management and Budget (OMB)

approval and displays a currently valid OMB Control Number.

This final regulation involves three collections currently approved by OMB with the following control numbers:

- Exclusions from the Section 232 National Security Adjustments of Imports of Steel and Aluminum (control number 0694–0139).
- Objections from the Section 232 National Security Adjustments of Imports of Steel and Aluminum (control number 0694–0138).
- Procedures for Submitting Rebuttals and Surrebuttals Requests for Exclusions from and Objections to the Section 232 Adjustments for Steel and Aluminum (OMB control number 0694–0141).

This rule is expected to increase the burden hours for one of the collections associated with this rule, OMB control number 0694–0139. This increase is expected because of the removal of 6 GAEs for steel and 6 GAEs for aluminum, which is expected to result in an increase of 1,000 exclusion request submissions per year. These GAE removals are expected to increase the burden hours for this collection by 4000, for a total cost increase of \$148,000 to the public. BIS submitted, and OMB approved a non-substantive change for an increase in 4000 burden hours to the current 237,846. As BIS asserted in the 4th IFR that the steel and aluminum articles identified as being eligible for GAEs, including those being removed in today's rule, had not received any objections, the addition of those new GAEs was not estimated to result in a decrease in the number of objections, rebuttals, or surrebuttals received by BIS.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) (APA) requiring notice of proposed rulemaking, the opportunity for public comment, and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (See 5 U.S.C. 553(a)(1)). As explained in the reports submitted by the Secretary to the President, steel and aluminum are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States, and therefore the President is implementing these remedial actions (as described Proclamations 9704 and 9705 of March 8, 2018) to protect U.S. national security interests. That implementation includes the creation of an effective process by

which affected domestic parties can obtain exclusion requests “based upon specific national security considerations.” BIS started this process with the publication of the March 19 rule and refined the process with the publication of the September 11, June 10, December 2020, and December 2021 rules and is continuing the process with the publication of this final rule. Commenters on the past rules (March 19, September 11, and June 10 rule, December 2020, and December 2021) were generally supportive and welcomed the idea of creating an exclusion process, but most of the commenters believe the exclusion process, although improving over time, still could be significantly improved for it to achieve the intended purpose. The commenters identified several areas where transparency, effectiveness, and fairness of the process could be improved. BIS understands the importance of having a transparent, fair, and efficient product exclusion request process, consistent with the directive provided by the President to create this type of process to mitigate any unintended consequences of imposing the tariffs on steel and aluminum to protect critical U.S. national security interests. The revisions to the 232 exclusions process are informed by the comments received in response to the August 2023 Proposed Rule and BIS's experience with managing the 232 exclusions process.

Additionally, BIS finds that there is good cause under 5 U.S.C. 553(d)(3) to waive the delay in effective date; given the delays would be either impracticable or contrary to the public interest because the actions are tied to the effectiveness of the Section 232 tariffs and therefore U.S. national security. The public comments on this matter indicated that there was an urgency to ensuring the changes are implemented for the effectiveness of the Section 232 process. Therefore, this final rule will be effective upon publication in the **Federal Register**.

Consistent with the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), BIS has prepared the following final regulatory flexibility analysis (FRFA) of the impact that this final rule will have on small businesses.

Description of the Reasons Why Action Is Being Considered

The policy reasons for issuing this final rule are discussed in the background section of the preamble of this document and, consequently, are not repeated here.

Statement of the Objectives of, and Legal Basis for, the Proposed Rule; Identification of All Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule

The objective of this final rule, and all other Section 232-related rules published by BIS, is discussed in the background section of the preamble of this document and, consequently, are not repeated here. The legal basis for this final rule is as follows: Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979).

No other Federal rules duplicate, overlap, or conflict with this final rule.

Number and Description of Small Entities Regulated by the Proposed Action

This final rule would apply to all persons engaged in the Section 232 exclusions process. BIS does not collect or maintain the data necessary to determine exactly how many of the affected persons are small entities as that term is used by the Small Business Administration. However, BIS does ask requestors of the Section 232 exclusions process to self-identify if they are a small business as defined by the Small Business Administration. From this data, BIS has estimated the total number of requestors and objectors who are likely to be small businesses that would be impacted by changes identified in this rule.

Roughly 380 requestors self-identified as small businesses, filing roughly 27,000 exclusion requests in the Section 232 exclusions portal since March 2022, when BIS began including the option for requestors to self-identify as a small business. BIS does not have the same self-identification option for objectors. However, over the same period of time, roughly 100 objectors filed objections in the Section 232 exclusions portal; many of these are easily identifiable as being large corporations, not small businesses. Therefore, somewhere between 380 and 500 small businesses could be impacted by these changes. Specific burden estimates for OMB under control numbers 0694–0139 (Exclusions from the Section 232 National Security Adjustments of Imports of Steel and Aluminum), 0694–0138 (Objections from the Section 232 National Security Adjustments of Imports of Steel and Aluminum), and 0694–0141 (Procedures for Submitting Rebuttals and Surrebuttals Requests for Exclusions from and Objections to the Section 232 Adjustments for Steel and Aluminum) are detailed in paragraph 2 of the

Rulemaking Requirements section above.

Based on the analysis provided above, the revisions in this rule would not impose a significant economic impact on a substantial number of small businesses.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The changes in this rule and the corresponding reporting, recordkeeping, and other compliance requirements are discussed in the background section of the preamble of this document and, consequently, are not repeated here. To the extent that compliance with the changes in this rule would impose a burden on persons, including small businesses, BIS believes the burden will be minimal.

Significant Alternatives and Underlying Analysis

As noted above, BIS does not believe that the revisions in this rule will have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these revisions to assess whether the alternatives would: (1) accomplish the stated objectives of this final rule (consistent with the objectives of the Section 232 exclusions process); and (2) minimize any significant economic impact of this final rule on small entities. BIS has determined that revisions detailed above are the least disruptive alternative for implementing changes to the Section 232 exclusions process.

Lastly, consistent with 5 U.S.C. 603(c), BIS assessed the use of performance standards rather than design standards and also considered whether an exemption for small businesses was practical under the circumstances (*i.e.*, within the context of the changes in this rule).

This final rule does not contain an exemption for small businesses from the Section 232 exclusions process changes because these controls are essential to U.S. national security and BIS' regulations apply to all parties. An exemption for small businesses would undermine the effectiveness of these revisions.

Conclusion

BIS has identified changes to the Section 232 exclusions process. Consequently, consistent with the Regulatory Flexibility Act, BIS has prepared this FRFA addressing the impact that this final rule will have on small entities. BIS's assessment

indicates that the amendments in this rule will not have a significant economic impact on a substantial number of small entities.

Please submit any comments concerning this FRFA in accordance with the instructions provided in the **ADDRESSES** section of this final rule.

List of Subjects in 15 CFR Part 705

Administrative practice and procedure, Business and industry, Classified information, Confidential business information, Imports, Investigations, National defense.

For the reasons set forth in the preamble, part 705 of subchapter A of 15 CFR chapter VII is amended as follows:

PART 705—EFFECT OF IMPORTED ARTICLES ON THE NATIONAL SECURITY

■ 1. The authority citation for part 705 continues to read as follows:

Authority: Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979).

■ 2. Supplement no. 2 to part 705 is amended by removing the entries for “GAE.24.S: 7211296080;” “GAE.43.S: 7209900000;” “GAE.46.S: 7216330090;” “GAE.84.S: 7209270000;” “GAE.90.S: 7216100010;” and “GAE.93.S: 7208380015”.

■ 3. Supplement no. 3 to part 705 is amended by removing the entries for “GAE.1.A: 7609000000;” “GAE.4.A: 7604210010;” “GAE.5.A: 7604291010;” “GAE.9.A: 7601209080;” “GAE.10.A: 7607116010;” and “GAE.13.A: 7604295090”.

Matthew S. Borman,

Principal Deputy Assistant Secretary for Export Administration.

[FR Doc. 2024–10725 Filed 5–17–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2018–N–3074]

Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or

we) is issuing a final order reclassifying the ultrasound cyclodestructive device, a postamendments class III device (product code LZR), into class II (special controls), subject to premarket notification. FDA is also establishing special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on valid scientific evidence. For this class II device, instead of a premarket approval application, manufacturers may submit a premarket notification, *i.e.*, a 510(k) submission, and obtain FDA clearance of the device before marketing it.

DATES: This order is effective June 20, 2024.

FOR FURTHER INFORMATION CONTACT:

Claudine Krawczyk, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1238, Silver Spring, MD 20993, 301–796–6860, claudine.krawczyk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls and general controls), and class III (premarket approval and general controls).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until (1) FDA reclassifies the device into class I or class II; or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of the procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and our implementing regulations (part 807, subpart E (21 CFR part 807, subpart E)).