

FDA has received a request to extend the comment period. The request stated that additional time is needed to coordinate factual information and policy positions with a large number of States on several of the questions in the ANPRM. The request noted that their comments will be more thorough and of more assistance to FDA if more time is available to develop them.

FDA has considered the request and is extending the comment period an additional 6 weeks, until January 19, 2012. We believe that the additional time will provide interested parties sufficient time to submit comments on the ANPRM.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this ANPRM. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-31225 Filed 12-5-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF STATE

22 CFR Part 121

RIN 1400-AC98

[Public Notice 7703]

Amendment to the International Traffic in Arms Regulations: Establishment of U.S. Munitions List Category XIX for Gas Turbine Engines

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: As part of the President's Export Control Reform effort, the Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to establish Category XIX of the U.S. Munitions List (USML) to describe gas turbine engines and associated equipment warranting control on the USML.

DATES: The Department of State will accept comments on this proposed rule until January 20, 2012.

ADDRESSES: Interested parties may submit comments within 45 days of the

date of publication by one of the following methods:

- **Email:**

DDTCResponseTeam@state.gov with the subject line, "ITAR Amendments—Category XIX, Gas Turbine Engines."

- **Internet:** At *www.regulations.gov*, search for this notice by using this rule's RIN (1400-AC98).

Comments received after that date will be considered if feasible, but consideration cannot be assured. We will make all comments (including any personally identifying information or information for which a claim of confidentiality is asserted in those comments or their transmittal emails) available for public inspection and copying after the close of the comment period via the Directorate of Defense Trade Controls Web site at *www.pmddtc.state.gov*. Parties who wish to comment anonymously may do so by submitting their comments via *www.regulations.gov*, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself. Comments submitted via *www.regulations.gov* are immediately available for public inspection.

FOR FURTHER INFORMATION CONTACT:

Director Charles B. Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663-2792 or Fax (202) 261-8199; Email *DDTCResponseTeam@state.gov*. **Attn:** Regulatory Change, USML Category XIX.

SUPPLEMENTARY INFORMATION: The Directorate of Defense Trade Controls (DDTC), U.S. Department of State, administers the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130). The items subject to the jurisdiction of the ITAR, *i.e.*, "defense articles," are identified on the ITAR's U.S. Munitions List (USML) (22 CFR 121.1). With few exceptions, items not subject to the export control jurisdiction of the ITAR are subject to the jurisdiction of the Export Administration Regulations ("EAR," 15 CFR parts 730-774, which includes the Commerce Control List in part 774), administered by the Bureau of Industry and Security (BIS), U.S. Department of Commerce. Both the ITAR and the EAR impose license requirements on exports and reexports. Items not subject to the ITAR or to the exclusive licensing jurisdiction of any other set of regulations are subject to the EAR.

Export Control Reform Update

The Departments of State and Commerce described in their respective Advance Notices of Proposed

Rulemaking (ANPRM) in December 2010 the Administration's plan to make the USML and the CCL positive, tiered, and aligned so that eventually they can be combined into a single control list (see "Commerce Control List: Revising Descriptions of Items and Foreign Availability," 75 FR 76664 (December 9, 2010) and "Revision to the United States Munitions List," 75 FR 76935 (December 10, 2010)). The notices also called for the establishment of a "bright line" between the USML and the CCL to reduce government and industry uncertainty regarding export jurisdiction by clarifying whether particular items are subject to the jurisdiction of the ITAR or the EAR. While these remain the Administration's ultimate Export Control Reform objectives, their concurrent implementation would be problematic in the near term. In order to more quickly reach the national security objectives of greater interoperability with our allies, enhancing our defense industrial base, and permitting the U.S. Government to focus its resources on controlling and monitoring the export and reexport of more significant items to destinations, end uses, and end users of greater concern than our NATO and other multi-regime partners, the Administration has decided, as an interim step, to propose and implement revisions to both the USML and the CCL that are more positive, but not yet tiered.

Specifically, based in part on a review of the comments received in response to the December 2010 notices, the Administration has determined that fundamentally altering the structure of the USML by tiering and aligning them on a category-by-category basis would significantly disrupt the export control compliance systems and procedures of exporters and reexporters. For example, until the entire USML was revised and became final, some USML categories would follow the legacy numbering and control structures while the newly revised categories would follow a completely different numbering structure. In order to allow for the national security benefits to flow from re-aligning the jurisdictional status of defense articles that no longer warrant control on the USML on a category-by-category basis while minimizing the impact on exporters' internal control and jurisdictional and classification marking systems, the Administration plans to proceed with building positive lists now and afterward return to structural changes.

Establishment of Category XIX for Gas Turbine Engines and Associated Equipment

This proposed rule establishes USML Category XIX to cover gas turbine engines and associated equipment currently covered in Categories VI, VII, and VIII. The USML identifies engine subcategories in all three of these categories, but there has been confusion concerning the controls in Category VI (which currently lists only “naval nuclear propulsion plants,” leading exporters to question whether other types of propulsion systems are controlled as “components” in Category VI(f)), Category VII (which controls both diesel and gas turbine engines under the same general term “engines” in Category VII(f)), and Category VIII (which controls “military aircraft engines” but not reciprocating engines). The intent of this change is to make clear that gas turbine engines for surface vessels, vehicles, and aircraft that meet certain objective parameters are controlled on the USML.

The most significant aspect of this more positive, but not yet tiered, proposed USML category is that it does not contain controls on all generic parts, components, accessories, and attachments that are in any way specifically designed or modified for a defense article, regardless of their significance to maintaining a military advantage for the United States. Rather, it contains a list of specific types of parts, components, accessories, and attachments that continue to warrant control on the USML. All other parts, components, accessories, and attachments will become subject to the new 600 series controls in the CCL to be published separately by the Department of Commerce. The Administration has also proposed revisions to the jurisdictional status of certain militarily less significant end items that do not warrant USML control, but the primary impact of this proposed rule will be with respect to current USML controls on parts, components, accessories, and attachments that no longer warrant USML control.

Definition for Specially Designed

Although one of the goals of the export control reform initiative is to describe USML controls without using design intent criteria, a few of the controls in the proposed revision nonetheless use the term “specially designed.” It is, therefore, necessary for the Department to define the term. Two proposed definitions have been published to date.

The Department first provided a draft definition for “specially designed” in the December 2010 ANPRM (75 FR 76935) and noted the term would be used minimally in the USML, and then only to remain consistent with the Wassenaar Arrangement or other multilateral regime obligation or when no other reasonable option exists to describe the control without using the term. The draft definition provided at that time is as follows: “For the purposes of this Subchapter, the term ‘specially designed’ means that the end-item, equipment, accessory, attachment, system, component, or part (see ITAR § 121.8) has properties that (i) Distinguish it for certain predetermined purposes, (ii) are directly related to the functioning of a defense article, and (iii) are used exclusively or predominantly in or with a defense article identified on the USML.”

The Department of Commerce subsequently published on July 15, 2011, for public comment the Administration’s proposed definition of “specially designed” that would be common to the CCL and the USML. The public provided more than 40 comments on that proposed definition on or before the September 13 deadline for comments. The Departments of State, Commerce, and Defense are now reviewing those comments and related issues, and the Departments of State and Commerce plan to publish for public comment another proposed rule on a definition of “specially designed” that would be common to the USML and the CCL. In the interim, and for the purpose of evaluation of this proposed rule, reviewers should use the definition provided in the December ANPRM.

Request for Comments

As the U.S. Government works through the proposed revisions to the USML, some solutions have been adopted that were determined to be the best of available options. With the thought that multiple perspectives would be beneficial to the USML revision process, the Department welcomes the assistance of users of the lists and requests input on the following:

(1) A key goal of this rulemaking is to ensure the USML and the CCL together control all the items that meet Wassenaar Arrangement commitments embodied in the Munitions List. To that end, the public is asked to identify any potential lack of coverage brought about by the proposed rules for engines for vessels of war, military vehicles, and military aircraft contained in this notice and the new ECCNs published

separately by the Department of Commerce when reviewed together.

(2) The assumption behind the creation of a single category for items that are part of systems controlled in several categories is that the consolidation of these items sharing essentially the same technology will clarify which engines and related items are controlled, will simplify the regulations as a whole, and will lead to more effective controls over engines with national security concerns. We ask the public to specifically address this assumption, and to provide its opinion on whether the creation of a new category, as opposed to retaining controls in various categories, would be easier for users of the list.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from § 553 (Rulemaking) and § 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department is publishing this rule with a 45-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function. As noted above, and also without prejudice to the Department position that this rulemaking is not subject to the APA, the Department previously published a related Advance Notice of Proposed Rulemaking (RIN 1400-AC78), and accepted comments for 60 days.

Regulatory Flexibility Act

Since this proposed amendment is not subject to 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This proposed amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This proposed amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This proposed amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this proposed amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this proposed amendment.

Executive Order 12866

The Department is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules governing the conduct of this function are exempt from the requirements of Executive Order 12866. However, the Department has reviewed the proposed rule to ensure its consistency with the regulatory philosophy and principles set forth in the Executive Order.

Executive Order 12988

The Department of State has reviewed the proposed amendment in light of sections 3(a) and 3(b) (2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirement of Executive Order 13175 does not apply to this rulemaking.

Executive Order 13563

The Department of State has considered this rule in light of Executive Order 13563, dated January 18, 2011, and affirms that this regulation is consistent with the guidance therein.

Paperwork Reduction Act

This proposed amendment does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 121 is proposed to be amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

1. The authority citation for part 121 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat. 1920.

2. Section 121.1 is revised to read as follows:

§ 121.1 General. The United States Munitions List.

* * * * *

Category XIX—Gas Turbine Engines and Associated Equipment

*(a) Turbofan and Turbojet engines, whether in development, production, or inventory (including technology demonstrators), capable of 15,000 lbf (66.7 kN) of thrust or greater that have any of the following:

- (1) with or capable of thrust augmentation (afterburner);
- (2) thrust or exhaust nozzle vectoring;
- (3) contains parts or components controlled in paragraph (f)(4) of this category;

- (4) capable of inverted flight;
- (5) capable of high power extraction (greater than 50 percent of engine thrust) at altitudes greater than 40,000 feet; or

- (6) capable of directed flow thrust reversing using bypass/fan and core flow air and also capable for being deployed in flight.

*(b) Turboshift and Turboprop engines, whether in development, production, or inventory (including technology demonstrators), capable of 1500 shp (1119 kW) or greater that have any of the following:

- (1) Cooled low pressure turbine, cooled intermediate pressure turbine, or cooled power turbine;

- (2) contains parts or components controlled in paragraph (f)(4)(i) or (f)(4)(ii) of this category; or

- (3) capable of oil sump sealing when the engine is in the vertical position.

(c) Engines, whether in development, production, or inventory (including

technology demonstrators), “specially designed” for armed or military unmanned aerial vehicle systems, cruise missiles, or target drones.

*(d) AGT1500, CTS800, TF40B, T55, TF60, T700, and TF50 engines.

*(e) Digital engine controls (e.g., Full Authority Digital Engine Controls (FADEC) and Digital Electronic Engine Controls (DEEC)) “specially designed” for gas turbine engines controlled in this category.

(f) Components, parts, accessories, attachments, or associated equipment as follows:

(1) components, parts, accessories, attachments, and equipment “specially designed” for the following U.S.-origin engines (and military variants thereof): AE1107C, F101, F107, F112, F118, F119, F120, F124, F125, F135, F136, F414, F415, J402, GE38, TF40B, and TF60;

Note: Digital engine controls (e.g., Full Authority Digital Engine Controls (FADEC) and Digital Electronic Engine Controls (DEEC)) “specially designed” for the engines identified in (f)(1) of this category are controlled by (e) of this category.

*(2) hot section components (i.e., combustors, turbine blades, vanes, nozzles, disks and shrouds) “specially designed” for gas turbine engines controlled in this category and related cooled components (i.e., cooled low pressure turbine blades, vanes, disks; cooled augmenters; and cooled nozzles) “specially designed” for gas turbine engines controlled in this category. The cowl, diffuser, dome, chamber, shells, and liners for the combustors are also controlled by this paragraph;

(3) engine monitoring systems (i.e., prognostics, diagnostics, and health) “specially designed” for gas turbine engines and components controlled in this category; or

(4) any component, part, accessory, attachment, equipment, or system that:

- (i) is classified;
- (ii) contains classified software;
- (iii) is manufactured using classified production data; or
- (iv) is being developed using classified information.

“Classified” means classified pursuant to Executive Order 13526, or predecessor order, and a security classification guide developed pursuant thereto or equivalent, or to the corresponding classification rules of another government.

(g) Technical data and defense services directly related to the defense articles enumerated in paragraphs (a) through (f) of this category.

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Dated: November 28, 2011.

Ellen O. Tauscher,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2011-30977 Filed 12-5-11; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice 7702]

RIN 1400-AC77

Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Category VII

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: As part of the President's Export Control Reform effort, the Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to revise Category VII (ground vehicles) of the U.S. Munitions List (USML) to describe more precisely the military ground vehicles warranting control on the USML.

DATES: The Department of State will accept comments on this proposed rule until January 20, 2012.

ADDRESSES: Interested parties may submit comments within 45 days of the date of publication by one of the following methods:

- **Email:**

DDTCResponseTeam@state.gov with the subject line, "ITAR Amendments—Category VII."

- **Internet:** At *www.regulations.gov*, search for this notice by using this rule's RIN (1400-AC77).

Comments received after that date will be considered if feasible, but consideration cannot be assured. We will make all comments (including any personally identifying information or information for which a claim of confidentiality is asserted in those comments or their transmittal emails) available for public inspection and copying after the close of the comment period via the Directorate of Defense Trade Controls Web site at *www.pmdtc.state.gov*. Parties who wish to comment anonymously may do so by submitting their comments via *www.regulations.gov*, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself. Comments submitted via *www.regulations.gov* are immediately available for public inspection.

FOR ADDITIONAL INFORMATION CONTACT: Director Charles B. Shotwell, Office of

Defense Trade Controls Policy, Department of State, telephone (202) 663-2792, or email *DDTCResponseTeam@state.gov*. ATTN: Regulatory Change, USML Category VII.

SUPPLEMENTARY INFORMATION: On December 10, 2010, the Department published as a proposed rule a revised Category VII that included tiering (75 FR 76930). As discussed below, the tiering of the categories has been postponed. In this regard, this revision differs from the earlier one. Because the differences between the two proposed versions of Category VII are considerable, the Department will not provide an assessment of public comments received from the first proposed rule, but welcomes comments on this proposed rule from all parties. If you submitted comments in response to the December 2010 rulemaking, please re-submit your comments, if they are still appropriate.

Background

The Directorate of Defense Trade Controls (DDTC), U.S. Department of State, administers the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130). The items subject to the jurisdiction of the ITAR, i.e., "defense articles," are identified on the ITAR's U.S. Munitions List (USML) (22 CFR 121.1). With few exceptions, items not subject to the export control jurisdiction of the ITAR are subject to the jurisdiction of the Export Administration Regulations ("EAR," 15 CFR parts 730-774, which includes the Commerce Control List in part 774), administered by the Bureau of Industry and Security (BIS), U.S. Department of Commerce. Both the ITAR and the EAR impose license requirements on exports and reexports. Items not subject to the ITAR or to the exclusive licensing jurisdiction of any other set of regulations are subject to the EAR.

Export Control Reform Update

The Departments of State and Commerce described in their respective Advanced Notices of Proposed Rulemaking (ANPRM) in December 2010 the Administration's plan to make the USML and the CCL positive, tiered, and aligned so that eventually they can be combined into a single control list (see "Commerce Control List: Revising Descriptions of Items and Foreign Availability," 75 FR 76664 (Dec. 9, 2010) and "Revision to the United States Munitions List," 75 FR 76935 (Dec. 10, 2010)). The notices also called for the establishment of a "bright line" between the USML and the CCL to reduce government and industry uncertainty regarding export jurisdiction by clarifying whether

particular items are subject to the jurisdiction of the ITAR or the EAR. While these remain the Administration's ultimate Export Control Reform objectives, their concurrent implementation would be problematic in the near term. In order to more quickly reach the national security objectives of greater interoperability with our allies, enhancing our defense industrial base, and permitting the U.S. Government to focus its resources on controlling and monitoring the export and re-export of more significant items to destinations, end uses, and end users of greater concern than our NATO and other multi-regime partners, the Administration has decided, as an interim step, to propose and implement revisions to both the USML and the CCL that are more positive, but not yet tiered.

Specifically, based in part on a review of the comments received in response to the December 2010 notices, the Administration has determined that fundamentally altering the structure of the USML by tiering and aligning them on a category-by-category basis would significantly disrupt the export control compliance systems and procedures of exporters and reexporters. For example, until the entire USML was revised and became final, some USML categories would follow the legacy numbering and control structures while the newly revised categories would follow a completely different numbering structure. In order to allow for the national security benefits to flow from re-aligning the jurisdictional status of defense articles that no longer warrant control on the USML on a category-by-category basis while minimizing the impact on exporters' internal control and jurisdictional and classification marking systems, the Administration plans to proceed with building positive lists now and afterward return to structural changes.

Revision of Category VII

This proposed rule revises USML Category VII, Ground Vehicles, to establish a clear "bright line" between the USML and the CCL for the control of military ground vehicles. The proposed revision narrows the types of ground vehicle controlled on the USML to only those that warrant control under the stringent requirements of the Arms Export Control Act. Changes include the removal of most unarmored and unarmed military vehicles, trucks, trailers, and trains (unless "specially designed" as firing platforms for weapons above .50 caliber), and armored vehicles (either unarmed or with inoperable weapons) manufactured