[Billing Code 4710-25]

DEPARTMENT OF STATE

22 CFR Part 121

RIN 1400-AD03

[Public Notice: 9166]

Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII

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 Categories XIV (toxicological agents, including chemical agents, biological agents, and associated equipment) and XVIII (directed energy weapons) of the U.S. Munitions List (USML) to describe more precisely the articles warranting control on the USML. The revisions contained in this rule are part of the Department of State's retrospective plan under E.O. 13563 completed on August 17, 2011. The Department of State's full plan can be accessed at http://www.state.gov/documents/organization/181028.pdf.

DATES: The Department of State will accept comments on this proposed rule until [insert date 60 days from date of publication in the *Federal Register*].

ADDRESSES: Interested parties may submit comments within 60 days of the date of publication by one of the following methods:

- E-mail: *DDTCPublicComments@state.gov* with the subject line, "ITAR Amendment – Categories XIV and XVIII."
- Internet: At *www.regulations.gov*, search for this proposed rule by using this rule's RIN (1400-AD03).

Comments received after that date will be considered if feasible, but consideration cannot be assured. Those submitting comments should not include any personally identifying information they do not wish to be made public or information for which a claim of confidentiality is asserted because those comments and/or transmittal e-mails will be made available for public inspection and copying after the close of the comment period via the Directorate of Defense Trade Controls website 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: Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663-2792; e-mail *DDTCPublicComments@state.gov*. ATTN: ITAR Amendment – USML Categories XIV and XVIII.

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 (CCL) in Supplement No. 1 to 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.

Revision of Category XIV

This proposed rule revises USML Category XIV, covering toxicological agents, including chemical agents, biological agents, and associated equipment. The revisions are proposed in order to advance the national security objectives of greater interoperability with U.S. allies, enhancing the defense industrial base, and permitting the U.S. government to focus its resources on transactions of greater concern. Additionally, the revisions are intended to more accurately describe the articles within the subject categories, in order to establish a "bright line" between the USML and the CCL for the control of these articles.

This proposed rule implements changes consistent with the requirements of Executive Order 13546 on Optimizing the Security of Biological Select Agents and Toxins in the United States, which includes direction to address variations in, and limited coordination of, individual executive departments' and agencies' oversight that add to the cost and complexity of compliance. It also directs a risk-based tiering of the biological select agent list. As a result, the proposed control language in paragraph (b) adopts the "Tier 1" pathogens and toxins established in the Department of Health and Human Services and the United States Department of Agriculture select agent regulations (42 CFR Part 73 and 9 CFR 121) for those pathogens and toxins that meet specific capabilities

listed in paragraph (b). The Tier 1 pathogens and toxins that do not meet these capabilities remain controlled in Export Control Classification Number (ECCN) 1C351 or 1C352 on the CCL.

Additionally, this rule, in concert with the analogous proposed rule published by the Department of Commerce, proposes the movement of riot control agents to the export jurisdiction of the Department of Commerce, as well as the articles covered currently in paragraphs (j), (k), and (l), which include test facilities, equipment for the destruction of chemical and biological agents, and tooling for production of articles in paragraph (f), respectively.

Other changes include the addition of paragraph (a)(5) to control chemical warfare agents **"**adapted for use in war" and not elsewhere enumerated, as well as the removal of paragraphs (f)(3) and (f)(6) and movement to the CCL of equipment for the sample collection and decontamination or remediation of chemical agents and biological agents. Paragraph (f)(5) for collective protection was removed and partially combined in (f)(4) or the CCL. Proposed paragraph (g) enumerates antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts exclusively funded by a Department of Defense contract for detection of the biological agents listed in paragraph (b)(1)(ii).

The Department notes that the controls in paragraph (f)(2) that include the phrase "developed under a Department of Defense contract or other funding authorization" do not apply when the Department of Defense acts solely as a servicing agency for a contract on behalf of another agency of the U.S. government.

The Department notes that the controls in paragraphs (g)(1) and (h) that include the phrase "exclusively funded by a Department of Defense

contract" do not apply when the Department of Defense acts solely as a servicing agency for a contract on behalf of another agency of the U.S. government, or, for example, in cases where the Department of Defense provides initial funding for the development of an item but another agency of the U.S. government provides funding to further develop or adapt the item.

Proposed paragraph (h) enumerates certain vaccines funded exclusively by the Department of Defense, as well as certain vaccines controlled in (h)(2) that are specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in (b). Thus, the scope of vaccines controlled in (h)(2) is circumscribed by the nature of funding, the satisfaction of the term "specially designed" as that term is defined in ITAR §120.41, and the limitations in (b) that control only those biological agents and biologically derived substances meeting specific criteria. In evaluating the scope of this control, please note that the Department offers a decision tool to aid exporters in determining whether a defense article meets the definition of "specially designed." This tool is available at http://www.pmddtc.state.gov/licensing/dt_SpeciallyDesigned.htm.

Proposed revised paragraph (i) is updated to provide better clarity on the scope of the control by including examples of Department of Defense tools that are used to determine or estimate potential effects of chemical or biological weapons strikes and incidents in order to plan to mitigate their impacts.

A new paragraph (x) has been added to USML Category XIV, allowing ITAR licensing on behalf of the Department of Commerce for commodities, software, and technology subject to the EAR provided those

commodities, software, and technology are to be used in or with defense articles controlled in USML Category XIV and are described in the purchase documentation submitted with the application. The intent of paragraph (x) is not to impose ITAR jurisdiction on commodities, software, and technology subject to EAR controls.

Finally, the rule proposes to only control on the USML chemical or biological agent detectors when they contain Department of Defense reagents, spectra, algorithms, databases, etc.

Revision of Category XVIII

This proposed rule revises USML Category XVIII, covering directed energy weapons. As with USML Category XIV, the revisions are proposed in order to advance the national security objectives set forth above and to more accurately describe the articles within the subject categories, in order to establish a "bright line" between the USML and the CCL for the control of these articles. A change proposed in this rule would revise paragraph (a) to control only those items that satisfy the paragraph's definition of "directed energy weapon," which focuses on the sole or primary purpose of the article in order to exclude those items that might achieve the same effect in an incidental, accidental, or collateral manner.

The articles controlled currently in paragraphs (c) and (d) would move to the export control jurisdiction of the Department of Commerce.

The remaining paragraphs in this category would undergo conforming changes to bring their structures into alignment with the analogous provisions found in other revised USML categories.

Request for Comments

The proposed revisions to the USML will control items in normal commercial use and on the Wassenaar Arrangement's Dual Use List. 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 Munitions List Categories 7 (WA-ML7) and 19 (WA-ML19). The public is therefore asked to identify any potential lack of coverage brought about by the proposed rules for Categories XIV and XVIII contained in this proposed rule and the new Category 1 and Category 6 ECCNs published separately by the Department of Commerce when reviewed together.

2) Another key goal of this rulemaking is to identify items proposed for control on the USML or the CCL that are not controlled on the Wassenaar Arrangement's Munitions or Dual Use List. The public is therefore asked to identify any potential expansion of coverage brought about by the proposed rules for Categories XIV and XVIII contained in this proposed rule and the new Category 1 and Category 6 ECCNs published separately by the Department of Commerce when reviewed together.

3) A third key goal of this rulemaking is to establish a "bright line" between the USML and the CCL for the control of these materials. The public is asked to provide specific examples of toxicological agents, including chemical agents, biological agents, and associated equipment, as well as directed energy weapons, whose jurisdiction would be in doubt based on this revision. The public is also asked to comment on whether there is a sufficiently clear line drawn between the biological items proposed for control by USML Category XIV(b) and those proposed for control under the CCL.

4) Although the proposed revisions to the USML do not preclude the possibility that items in normal commercial use would or should be ITAR-controlled because, *e.g.*, they provide the United States with a critical military or intelligence advantage, the U.S. government does not want to inadvertently control items on the ITAR that are in normal commercial use. Items that would be controlled on the USML in this proposed rule have been identified as possessing parameters or characteristics that provide a critical military or intelligence advantage. The public is thus asked to provide specific examples of items, or associated technical data, if any, that would be controlled in the revised USML Categories XIV or XVIII that are now in normal commercial use, or that are commonly used or produced in civilian scientific laboratories. The examples should demonstrate actual commercial or civilian scientific use, not just potential or theoretical use, with supporting documents, as well as foreign availability of such items. Additionally, for any criteria the public believes control items in normal commercial or civilian scientific use, the public is asked to identify parameters or characteristics that cover items exclusively or primarily in military use. Finally, for any criteria the public believes control items in normal commercial use, the public is asked to identify the multilateral controls (such as the Wassenaar Arrangement's Dual Use List), if any, for such items, and the consequences of such items being controlled on the USML.

5) The public is asked to provide comment on the proposed definition of "non-naturally occurring" in Note 2 to Category XIV(b), if the proposed definition does not appear to be comprehensive. The public is also asked to comment on "non-naturally occurring" in the context of genetic modification and consider whether the definition is sufficient to distinguish military or intelligence purposes from commercial or civilian purposes.

6) The public is asked to provide specific examples of reagents that may be inadvertently controlled by Category XIV(b), XIV(f), XIV(g), or XIV(m), that are commonly used for scientific research and development, or medical countermeasures that may similarly be inadvertently controlled and the dissemination of which would be in the interest of public health or medical preparedness.

7) The public is asked to specifically evaluate and comment on the decision process outlined in the proposed rule that would be used to determine whether vaccines that are intended to be developed and used to protect public and veterinary health against any event resulting from exposure to naturally occurring or non-naturally occurring pathogens or toxins is sufficiently clear to allow research and commercial entities to determine whether a vaccine would unintentionally be captured under this rule. Please provide specific examples that demonstrate how the proposed rule would prevent or hinder the ability to develop or utilize vaccines for public health or veterinary benefit under this proposed language and decision process.

8) In the interest of ensuring the security of and control over certain types of chemical and biological detection equipment, Category XIV(f)(2) could incidentally impose ITAR controls on certain civilian and public health equipment containing the items listed in paragraph (f)(2). Accordingly, as proposed, paragraph (f)(2) may control detection equipment that may not warrant ITAR control, but contains items that are fully or partially Defense-funded. The Department requests comment from the public, including specific examples of equipment that the public believes may be unintentionally controlled by this text by virtue of Defense funding.

In addition, the Department acknowledges that some members of the public may not be able comment meaningfully on this matter because they lack full awareness of items that have previously been fully or partially developed under Defense funding. To the extent that commenters require specific additional information about the scope of Defense funding in certain contexts, the Department requests that commenters identify any relevant gaps in knowledge.

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 sections 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 60-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) on December 10, 2010 (75 FR 76935), and accepted comments for 60 days.

Regulatory Flexibility Act

Since the Department is of the opinion that this rule is exempt from the rulemaking provisions of 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 and 13563

Executive Orders 12866 and 13563 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, distributed 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 designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

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 preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

Following is a listing of approved collections that will be affected by revision of the U.S. Munitions List (USML) and the Commerce Control List pursuant to the President's Export Control Reform (ECR) initiative. This rule continues the implementation of ECR. The list of collections and the description of the manner in which they will be affected pertains to revision of the USML in its entirety, not only to the categories published in this rule. In accordance with the Paperwork Reduction Act, the Department of State will request comment on these collections from all interested persons. In particular, the Department will seek comment on changes to licensing burden based on implementation of regulatory changes pursuant to ECR, and

on projected changes based on continued implementation of regulatory changes pursuant to ECR. The affected information collections are as follows:

1) Statement of Registration, DS-2032, OMB No. 1405-0002. The Department estimates that between 3,000 and 5,000 of currently-registered persons will not need to maintain registration following full revision of the USML. This would result in a burden reduction of between 6,000 and 10,000 hours annually, based on a revised time burden of two hours to complete a Statement of Registration.

2) Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data, DSP-5, OMB No. 1405-0003. The Department estimates that there will be 35,000 fewer DSP-5 submissions annually following full revision of the USML. This would result in a burden reduction of 35,000 hours annually.

3) Application/License for Temporary Import of Unclassified Defense Articles, DSP-61, OMB No. 1405-0013. The Department estimates that there will be 200 fewer DSP-61 submissions annually following full revision of the USML. This would result in a burden reduction of 100 hours annually.

4) Application/License for Temporary Export of Unclassified Defense Articles, DSP-73, OMB No. 1405-0023. The Department estimates that there will be 800 fewer DSP-73 submissions annually following full revision of the USML. This would result in a burden reduction of 800 hours annually.

5) Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Technical Data, DSP-6, -62, -74, -119, OMB No. 1405-0092. The Department estimates that

there will be 2,000 fewer amendment submissions annually following full revision of the USML. This would result in a burden reduction of 1,000 hours annually.

6) Request for Approval of Manufacturing License Agreements, Technical Assistance Agreements, and Other Agreements, DSP-5, OMB No. 1405-0093. The Department estimates that there will be 1,000 fewer agreement submissions annually following full revision of the USML. This would result in a burden reduction of 2,000 hours annually.

7) Maintenance of Records by Registrants, OMB No. 1405-0111. The requirement to actively maintain records pursuant to provisions of the International Traffic in Arms Regulations (ITAR) will decline commensurate with the drop in the number of persons who will be required to register with the Department pursuant to the ITAR. As stated above, the Department estimates that up to 5,000 of the currently-registered persons will not need to maintain registration following full revision of the USML. This would result in a burden reduction of 100,000 hours annually. However, the ITAR does provide for the maintenance of records for a period of five years. Therefore, persons newly relieved of the requirement to register with the Department may still be required to maintain records.

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); 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat.

1920; Section 1261, Pub. L. 112-239; E.O. 13637, 78 FR 16129.

2. Section 121.1 is amended by revising U.S. Munitions List Categories XIV and XVIII to read as follows:

§121.1 The United States Munitions List.

* * * * *

Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment

*(a) Chemical agents, to include:

(1) Nerve agents, as follows:

(i) O-Alkyl (equal to or less than C_{10}, including cycloalkyl) alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonofluoridates, such as: Sarin (GB): O-Isopropyl methylphosphonofluoridate (CAS 107–44–8) (CWC Schedule 1A); and Soman (GD): O-Pinacolyl methylphosphonofluoridate (CAS 96–64–0) (CWC Schedule 1A);

(ii) O-Alkyl (equal to or less than C_{10}, including cycloalkyl) N,N-dialkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphoramidocyanidates, such as: Tabun (GA): O-Ethyl N, N-dimethylphosphoramidocyanidate (CAS 77–81–6) (CWC Schedule 1A); or

(iii) O-Alkyl (H or equal to or less than C_{10}, including cycloalkyl) S–2-dialkyl (Methyl, Ethyl, n-Propyl or Isopropyl) aminoethyl alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonothiolates and corresponding alkylated and protonated salts, such as VX: O-Ethyl S-2-diisopropylaminoethyl methyl phosphonothiolate (CAS 50782–69–9) (CWC Schedule 1A);

(2) Amiton: O,O-Diethyl S-[2(diethylamino)ethyl] phosphorothiolate and corresponding alkylated or protonated salts (CAS 78–53–5) (CWC Schedule 2A);

(3) Vesicant agents, as follows:

(i) Sulfur mustards, such as: 2-Chloroethylchloromethylsulfide (CAS 2625–76–5) (CWC Schedule 1A); Bis(2-chloroethyl)sulfide (HD) (CAS 505–60–2) (CWC Schedule 1A); Bis(2-chloroethylthio)methane (CAS 63839–13–6) (CWC Schedule 1A); 1,2-bis (2-chloroethylthio)ethane (CAS 3563–36–8) (CWC Schedule 1A); 1,3-bis (2-chloroethylthio)-n-propane (CAS 63905–10–2) (CWC Schedule 1A); 1,4-bis (2-chloroethylthio)-n-butane (CWC Schedule 1A); 1,5-bis (2-chloroethylthio)-n-pentane (CWC Schedule 1A); Bis (2-chloroethylthiomethyl)ether (CWC Schedule 1A); Bis (2-chloroethylthioethyl)ether (CAS 63918–89–8) (CWC Schedule 1A);

(ii) Lewisites, such as: 2-chlorovinyldichloroarsine (CAS 541–25–3) (CWC Schedule 1A); Tris (2-chlorovinyl) arsine (CAS 40334–70–1) (CWC Schedule 1A); Bis (2-chlorovinyl) chloroarsine (CAS 40334–69–8) (CWC Schedule 1A);

(iii) Nitrogen mustards, or their protonated salts, as follows:

(A) HN1: bis (2-chloroethyl) ethylamine (CAS 538–07–8) (CWC Schedule 1A);

(B) HN2: bis (2-chloroethyl) methylamine (CAS 51–75–2) (CWC Schedule 1A);

(C) HN3: tris (2-chloroethyl) amine (CAS 555–77–1) (CWC Schedule 1A); or

(D) Other nitrogen mustards, or their salts, having a propyl, isopropyl, butyl, isobutyl, or tertiary butyl group on the bis(2-chloroethyl) amine base;

Note 1 to paragraph (a)(3)(iii): Pharmaceutical formulations containing nitrogen mustards or certain reference standards for these formulations are not considered to be chemical agents and are subject to the EAR when: 1) the pharmaceutical is in the form of a final medical product, or 2) the

reference standard contains salts of HN2 [bis(2-chloroethyl) methylamine], the quantity to be shipped is 150 milligrams or less, and individual shipments do not exceed twelve per calendar year per end user.

Note 2 to paragraph (a)(3)(iii): A "final medical product," as used in this paragraph, is a pharmaceutical formulation that is (1) designed for testing and administration in the treatment of human medical conditions, (2) prepackaged for distribution as a clinical or medical product, and (3) approved by the Food and Drug Administration to be marketed as a clinical or medical product or for use as an "Investigational New Drug" (IND) (see 21 CFR part 312)

(iv) Ethyldichloroarsine (ED) (CAS 598-14-1); or

(v) Methyldichloroarsine (MD) (CAS 593-89-5);

(4) Incapacitating agents, such as:

(i) 3-Quinuclindinyl benzilate (BZ) (CAS 6581–06–2) (CWC Schedule 2A);

(ii) Diphenylchloroarsine (DA) (CAS 712–48–1); or

(iii) Diphenylcyanoarsine (DC) (CAS 23525-22-6);

(5) Chemical warfare agents not enumerated above adapted for use in war to produce casualties in humans or animals, degrade equipment, or damage crops or the environment. (*See* the CCL at ECCNs 1C350, 1C355, and 1C395 for control of certain chemicals not adapted for use in war.)

Note to paragraph (a)(5): "Adapted for use in war" means any modification or selection (such as altering purity, shelf life, dissemination characteristics, or resistance to ultraviolet radiation) designed to increase the effectiveness in producing casualties in humans or animals, degrading equipment, or damaging crops or the environment.

Note 1 to paragraph (a): Paragraph (a) of this category does not include the following: Cyanogen chloride, Hydrocyanic acid, Chlorine, Carbonyl

chloride (Phosgene), Ethyl bromoacetate, Xylyl bromide, Benzyl bromide, Benzyl iodide, Chloro acetone, Chloropicrin (trichloronitromethane), Fluorine, and Liquid pepper.

Note 2 to paragraph (a): Regarding U.S. obligations under the Chemical Weapons Convention (CWC), refer to Chemical Weapons Convention Regulations (CWCR) (15 CFR Parts 710 through 722). As appropriate, the CWC schedule is provided to assist the exporter.

*(b) Biological agents and biologically derived substances and genetic elements thereof as follows:

(1) Genetically modified biological agents:

(i) Having non-naturally occurring genetic modifications which result in an increase in any of the following:

(A) Persistence in a field environment (*e.g.*, resistance to oxygen, UV damage, temperature extremes, or arid conditions); or

(B) The ability to defeat or overcome standard detection methods, personnel protection, natural or acquired host immunity, host immune response, or response to standard medical countermeasures; and

(ii) Being any micro-organisms/toxins or their non-naturally occurring genetic elements as listed below:

(A) Bacillus anthracis;

(B) Botulinum neurotoxin producing species of Clostridium;

(C) Burkholderia mallei;

(D) Burkholderia pseudomallei;

(E) Ebola virus;

(F) Foot-and-mouth disease virus;

(G) Francisella tularensis;

(H) Marburg virus;

(I) Variola major virus (Smallpox virus);

(J) Variola minor virus (Alastrim);

(K) Yersinia pestis; or

(L) Rinderpest virus.

(2) Biological agent or biologically derived substances controlled in ECCNs 1C351, 1C352, 1C353, or 1C354:

(i) Physically modified, formulated, or produced as any of the following:

(A) 1 – 10 micron particle size;

(B) Particle-absorbed or combined with nano-particles;

(C) Having coatings/surfactants, or

(D) By microencapsulation; and

(ii) Meeting the criteria of paragraph (b)(2)(i) of this category in a manner that results in an increase in any of the following:

(A) Persistence in a field environment (*e.g.*, resistant to oxygen, UV damage, temperature extremes, or arid conditions);

(B) Dispersal characteristics (*e.g.*, reduce the susceptibility to shear forces, optimize electrostatic charges); or

(C) The ability to defeat or overcome: standard detection methods, personnel protection, natural or acquired host immunity, or response to standard medical countermeasures.

Note 1 to paragraph (b): Non-naturally occurring means that the modification has not already been observed in nature, was not discovered from samples obtained from nature, and was developed with human intervention.

Note 2 to paragraph (b): This paragraph does not control biological agents or biologically derived substances, when these agents or substances have been demonstrated to be attenuated relative to natural

pathogenic isolates, and are incapable of causing disease or intoxication of ordinarily affected and relevant species (*e.g.*, humans, livestock, crop plants) due to the attenuation of virulence or pathogenic factors. This paragraph also does not control genetic elements, nucleic acids, or nucleic acid sequences (whether recombinant or synthetic) that are unable to produce or direct the biosynthesis of infectious or functional forms of the biological agents or biologically derived substances that are capable of causing disease or intoxication of ordinarily affected and relevant species.

Note 3 to paragraph (b): Biological agents or biologically derived substances that meet both paragraphs (b)(1) and (b)(2) of this category are controlled in paragraph (b)(1).

*(c) Chemical agent binary precursors and key precursors, as follows:

(1) Alkyl (Methyl, Ethyl, n-Propyl or Isopropyl) phosphonyl difluorides, such as: DF: Methyl Phosphonyldifluoride (CAS 676–99–3) (CWC Schedule 1B); Methylphosphinyldifluoride (CAS 753–59–3) (CWC Schedule 2B);

(2) O-Alkyl (H or equal to or less than C_{10}, including cycloalkyl) O–2-dialkyl (methyl, ethyl, n-Propyl or isopropyl) aminoethyl alkyl (methyl, ethyl, N-propyl or isopropyl) phosphonite and corresponding alkylated and protonated salts, such as QL: O-Ethyl-2-di-isopropylaminoethyl methylphosphonite (CAS 57856–11–8) (CWC Schedule 1B);

(3) Chlorosarin: O-Isopropyl methylphosphonochloridate (CAS 1445–76–7) (CWC Schedule 1B);

(4) Chlorosoman: O-Pinakolyl methylphosphonochloridate (CAS 7040–57–5) (CWC Schedule 1B); or

(5) Methlyphosphonyl dichloride (CAS 676–97–1) (CWC Schedule 2B); Methylphosphinyldichloride (CAS 676–83–5) (CWC Schedule 2B).

(d) [Reserved]

(e) Defoliants, as follows:

(1) 2,4,5-trichlorophenoxyacetic acid (CAS 93-76-5) mixed with 2,4-dichlorophenoxyacetic acid (CAS 94-75-7) (Agent Orange (CAS 39277-47-9));or

(2) Butyl 2-chloro-4-fluorophenoxyacetate (LNF).

*(f) Equipment or items, as follows:

(1) Any equipment for the dissemination, dispersion, or testing of items controlled in paragraphs (a), (b), (c), or (e) of this category, as follows:

(i) Any equipment "specially designed" for the dissemination and dispersion of items controlled in paragraphs (a), (b), (c), or (e) of this category; or

(ii) Any equipment "specially designed" for testing the items controlled in paragraphs (a), (b), (c), (e), or (f)(4) of this category developed under a Department of Defense contract or other funding authorization.

(2) Any equipment containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense contract or other funding authorization for the detection, identification, warning, or monitoring of:

(i) Items controlled in paragraphs (a) or (b) of this category; or

(ii) Chemical or biological agents specified by a Department of Defense contract or other funding authorization.

Note 1 to paragraph (f)(2): This paragraph does not control items that are (a) determined to be subject to the EAR via a commodity jurisdiction determination (see §120.4 of this subchapter), or (b) identified in the

relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

Note 2 to paragraph (f)(2): Note 1 does not apply to defense articles enumerated on the USML.

Note 3 to paragraph (f)(2): This paragraph is applicable only to those contracts and funding authorizations that are dated [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], or later.

(3) [Reserved]

(4) For individual protection or collective protection against the items controlled in paragraphs (a) and (b) of this category, as follows:

(i) M53 Chemical Biological Protective Mask or M50 Joint Service General Purpose Mask (JSGPM);

(ii) Filter cartridges containing sorbents controlled in paragraph (f)(4)(iii) of this category;

(iii) ASZM-TEDA carbon; or

(iv) Ensembles, garments, suits, jackets, pants, boots, or socks for individual protection, and liners for collective protection that allow no more than 1% breakthrough of GD or no more than 2% of HD;

Note to paragraph (f)(4)(iv): Evaluation is made by applying 10 mg of GD or HD to a 1-inch swatch. Ambient air is directed through the swatch for 24 hours and sampled/tested from the opposite side of the swatch using a gas chromatograph with flame photometric detector (FPD) or pulsed FPD (PFPD) and using sorption/desorption tools to increase sensitivity.

(5) [Reserved]

(6) [Reserved]

(7) Chemical Agent Resistant Coatings that have been qualified to military specifications (MIL-DTL-64159, MIL-C-46168, or MIL-C-53039); or

(8) Any equipment, material, tooling, hardware or test equipment that:

(i) Is classified;

(ii) Is manufactured using classified production data; or

(iii) Is being developed using classified information.

Note to paragraph (f)(8): "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) Antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts (including their expression vectors, viruses, plasmids, or cultures of specific cells modified to produce them) as follows:

(1) When exclusively funded by a Department of Defense contract for detection of the biological agents at paragraph (b)(1)(ii) of this category even if naturally occurring;

(2) Joint Biological Agent Identification and Diagnostic System (JBAIDS) Freeze Dried reagents listed by JRPD-ASY-No and Description respectively as follows:

(i) JRPD-ASY-0016 Q-Fever IVD Kit;

(ii) JRPD-ASY-0100 Vaccinia (Orthopox) ;

(iii) JRPD-ASY-0106 Brucella melitensis (Brucellosis);

(iv) JRPD-ASY-0108 Rickettsia prowazekii (Rickettsia);

(v) JRPD-ASY-0109 Burkholderia ssp. (Burkholderia) ;

(vi) JRPD-ASY-0112 Eastern equine encephalitis (EEE);

(vii) JRPD-ASY-0113 Western equine encephalitis (WEE);

(viii) JRPD-ASY-0114 Venezuelan equine encephalitis (VEE);

(ix) JRPD-ASY-0122 Coxiella burnetii (Coxiella);

(x) JRPD-ASY-0136 Influenza A/H5 IVD Detection Kit;

(xi) JRPD-ASY-0137 Influenza A/B IVD Detection Kit; or

(xii) JRPD-ASY-0138 Influenza A Subtype IVD Detection Kit ;

(3) Critical Reagent Polymerase (CRP) Chain Reactions (PCR) assay kits with Catalog-ID and Catalog-ID Product respectively as follows:

(i) PCR-BRU-1FB-B-K Brucella Target 1 FastBlock Master Mix Biotinylated;

(ii) PCR-BRU-1FB-K Brucella Target 1 FastBlock Master Mix;

(iii) PCR-BRU-1R-K Brucella Target 1 LightCycler/RAPID Master Mix;

(iv) PCR-BURK-2FB-B-K Burkholderia Target 2 FastBlock Master Mix Biotinylated;

(v) PCR-BURK-2FB-K Burkholderia Target 2 FastBlock Master Mix;

(vi) PCR-BURK-2R-K Burkholderia Target 2 LightCycler/RAPID Master Mix;

(vii) PCR-BURK-3FB-B-K Burkholderia Target 3 FastBlock Master Mix Biotinylated;

(viii) PCR-BURK-3FB-K Burkholderia Target 3 FastBlock Master Mix;

(ix) PCR-BURK-3R-K Burkholderia Target 3 LightCycler/RAPID Master Mix;

(x) PCR-COX-1FB-B-K Coxiella burnetii Target 1 FastBlock Master Mix Biotinylated;

(xi) PCR-COX-1R-K Coxiella burnetii Target 1 LightCycler/RAPID Master Mix;

(xii) PCR-COX-2R-K Coxiella burnetii Target 2 LightCycler/RAPID Master Mix;

(xiii) PCR-OP-1FB-B-K Orthopox Target 1 FastBlock Master Mix Biotinylated;

(xiv) PCR-OP-1FB-K Orthopox Target 1 FastBlock Master Mix;

(xv) PCR-OP-1R-K Orthopox Target 1 LightCycler/RAPID Master Mix;

(xvi) PCR-OP-2FB-B-K Orthopox Target 2 FastBlock Master Mix Biotinylated;

(xvii) PCR-OP-3R-K Orthopox Target 3 LightCycler/RAPID Master Mix;

(xviii) PCR-RAZOR-BT-X PCR-RAZOR-BT-X RAZOR CRP BioThreat-X Screening Pouch;

(xix) PCR-RIC-1FB-K Ricin Target 1 FastBlock Master Mix;

(xx) PCR-RIC-1R-K Ricin Target 1 LightCycler/RAPID Master Mix;

(xxi) PCR-RIC-2R-K Ricin Target 2 LightCycler/RAPID Master Mix; or

(xxii) PCR-VEE-1R-K Venezuelan equine encephalitis Target 1 LightCycler/RAPID Master Mix; or

(4) Critical Reagent Program Antibodies with Catalog ID and Product respectively as follows:

(i) AB-AG-RIC Aff. Goat anti-Ricin;

(ii) AB-ALVG-MAB Anti-Alphavirus Generic Mab;

(iii) AB-AR-SEB Aff. Rabbit anti-SEB;

(iv) AB-BRU-M-MAB1 Anti-Brucella melitensis Mab 1;

(v) AB-BRU-M-MAB2 Anti-Brucella melitensis Mab 2;

(vi) AB-BRU-M-MAB3 Anti-Brucella melitensis Mab 3;

(vii) AB-BRU-M-MAB4 Anti-Brucella melitensis Mab 4;

(viii) AB-CHOL-0139-MAB Anti-V.cholerae 0139 Mab;

(ix) AB-CHOL-01-MAB Anti-V. cholerae 01 Mab;

(x) AB-COX-MAB Anti-Coxiella Mab;

(xi) AB-EEE-MAB Anti-EEE Mab;

(xii) AB-G-BRU-A Goat anti-Brucella abortus;

(xiii) AB-G-BRU-M Goat anti-Brucella melitensis;

(xiv) AB-G-BRU-S Goat anti-Brucella suis;

(xv) AB-G-CHOL-01 Goat anti-V.cholerae 0:1;

(xvi) AB-G-COL-139 Goat anti-V.cholerae 0:139;

(xvii) AB-G-DENG Goat anti-Dengue;

(xviii) AB-G-RIC Goat anti-Ricin;

(xix) AB-G-SAL-T Goat anti-S. typhi;

(xx) AB-G-SEA Goat anti-SEA;

(xxi) AB-G-SEB Goat anti-SEB;

(xxii) AB-G-SEC Goat anti-SEC;

(xxiii) AB-G-SED Goat anti-SED;

(xxiv) AB-G-SEE Goat anti-SEE;

(xxv) AB-G-SHIG-D Goat anti-Shigella dysenteriae;

(xxvi) AB-R-BA-PA Rabbit anti-Protective Antigen;

(xxvii) AB-R-COX Rabbit anti-C. burnetii;

(xxviii) AB-RIC-MAB1 Anti-Ricin Mab 1;

(xxix) AB-RIC-MAB2 Anti-Ricin Mab 2;

(xxx) AB-RIC-MAB3 Anti-Ricin Mab3;

(xxxi) AB-R-SEB Rabbit anti-SEB;

(xxxii) AB-R-VACC Rabbit anti-Vaccinia;

(xxxiii) AB-SEB-MAB Anti-SEB Mab;

(xxxiv) AB-SLT2-MAB Anti-Shigella-like t x2 Mab;

(xxxv) AB-T2T-MAB1 Anti-T2 Mab 1;

(xxxvi) AB-T2T-MAB2 Anti-T2 Toxin 2;

(xxxvii) AB-VACC-MAB1 Anti-Vaccinia Mab 1;

(xxxviii) AB-VACC-MAB2 Anti-Vaccinia Mab 2;

(xxxix) AB-VACC-MAB3 Anti-Vaccinia Mab 3;

(xl) AB-VACC-MAB4 Anti-Vaccinia Mab 4;

(xli) AB-VACC-MAB5 Anti-Vaccinia Mab 5;

(xlii) AB-VACC-MAB6 Anti-Vaccinia Mab 6;

(xliii) AB-VEE-MAB1 Anti-VEE Mab 1;

(xliv) AB-VEE-MAB2 Anti-VEE Mab 2;

(xlv) AB-VEE-MAB3 Anti-VEE Mab 3;

(xlvi) AB-VEE-MAB4 Anti-VEE Mab 4;

(xlvii) AB-VEE-MAB5 Anti-VEE Mab 5

(xlviii) AB-VEE-MAB6 Anti-VEE Mab 6; or

(xlix) AB-WEE-MAB Anti-WEE Complex Mab.

(h) Vaccines exclusively funded by a Department of Defense contract, as follows:

(1) Recombinant Botulinum Toxin A/B Vaccine;

(2) Recombinant Plague Vaccine;

(3) Trivalent Filovirus Vaccine; or

(4) Vaccines specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in paragraph (b) of this category.

Note to paragraph (h): See ECCN 1A607.k for military medical countermeasures such as autoinjectors, combopens, and creams.

(i) Modeling or simulation tools, including software controlled in paragraph (m) of this category, for chemical or biological weapons design, development, or employment developed or produced under a Department of Defense contract or other funding authorization (*e.g.*, the Department of Defense's HPAC, SCIPUFF, and the Joint Effects Model (JEM)).

(j)—(l) [Reserved]

(m) Technical data (as defined in §120.10 of this subchapter) and defense services (as defined in §120.9 of this subchapter) directly related to the

defense articles enumerated in paragraphs (a) through (l) and (n) of this category; (*See* §125.4 of this subchapter for exemptions.)

(n) Developmental countermeasures or sorbents funded by the Department of Defense via contract or other funding authorization;

Note 1 to paragraph (n): This paragraph does not control countermeasures or sorbents that are (a) in production, (b) determined to be subject to the EAR via a commodity jurisdiction determination (see §120.4 of this subchapter), or (c) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

Note 2 to paragraph (n): Note 1 does not apply to defense articles enumerated on the USML, whether in production or development.

Note 3 to paragraph (n): This paragraph is applicable only to those contracts and funding authorizations that are dated [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], or later.

(o)-(w) [Reserved]

(x) Commodities, software, and technology subject to the EAR (see §120.42 of this subchapter) used in or with defense articles controlled in this category.

Note to paragraph (x): Use of this paragraph is limited to license applications for defense articles controlled in this category where the purchase documentation includes commodities, software, or technology subject to the EAR (see §123.1(b) of this subchapter).

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Category XVIII – Directed Energy Weapons

*(a) Directed energy weapons (DEW): systems or equipment that, as their sole or primary purpose (*i.e.*, not as a result of incidental, accidental or collateral effect), degrade, destroy or cause mission-abort of a target; disturb, disable, or damage electronic circuitry, sensors or explosive devices remotely; deny area access; cause lethal effects; or cause permanent or flash blindness using any non-acoustic technique such as lasers (including continuous wave or pulsed lasers), particle beams, particle accelerators that project a charged or neutral particle beam, high power radio-frequency (RF), or high pulsed power or high average power radio frequency beam transmitters.

*(b) Systems or equipment specially designed to detect, identify or provide defense against articles specified in paragraph (a) of this category.

(c)—(d) [Reserved]

(e) Components, parts, accessories, attachments, and associated systems or equipment specially designed for any of the articles in paragraphs (a) and (b) of this category.

(f) Developmental directed energy weapons funded by the Department of Defense via contract or other funding authorization;

Note 1 to paragraph (f): This paragraph does not control directed energy weapons (a) in production, (b) determined to be subject to the EAR via a commodity jurisdiction determination (see §120.4 of this subchapter), or (c) identified in the relevant Department of Defense contract or other funding authorization as being developed for both civil and military applications.

Note 2 to paragraph (f): Note 1 does not apply to defense articles enumerated on the USML, whether in production or development.

Note 3 to paragraph (f): This paragraph is applicable only to those contracts and funding authorizations that are dated [DATE ONE YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE], or later.

(g) Technical data (as defined in §120.10 of this subchapter) and defense services (as defined in §120.9 of this subchapter) directly related to the defense articles enumerated in paragraphs (a) through (e) of this category;

(h)—(w) [Reserved]

(x) Commodities, software, and technology subject to the EAR (see §120.42 of this subchapter) used in or with defense articles controlled in this category.

Note to paragraph (x): Use of this paragraph is limited to license applications for defense articles controlled in this category where the purchase documentation includes commodities, software, or technology subject to the EAR (see §123.1(b) of this subchapter).

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(Date)

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