



August 17, 2015

Mr. C. Edward Peartree
Director, Office of Defense Trade Controls Policy
Department of State

Attn: ITAR Amendment— Categories XIV and XVIII

The American Society for Microbiology (ASM) commends the ongoing efforts by the US Department of State and US Department of Commerce to update and further clarify federal control regulations for Category XIV materials (Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment) included on the United States Munitions List and the Commerce Control List. These regulations have a significant influence on the microbial sciences and on public health.

The departments' recent proposed rule changes for the Export Administration Regulations (EAR) and the International Traffic in Arms Regulations (ITAR) represent important steps in balancing national security against Category XIV threats with robust scientific research on such agents and relevant information exchange among researchers. The amended regulations, published in the Federal Register, include:

- Revisions to Definitions in the Export Administration Regulations [RIN 0694-AG32], Department of Commerce
- International Traffic in Arms: Revisions to Definitions of Defense Services, Technical Data, and Public Domain; Definition of Product of Fundamental Research; Electronic Transmission and Storage of Technical Data; and Related Definitions [RIN 1400-AD70], Department of State
- Commerce Control List: Addition of Items Determined to No Longer Warrant Control Under United States Munitions List Category XIV (Toxicological Agents) or Category XVIII (Directed Energy Weapons) [RIN 0694-AF52], Commerce
- Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII [RIN 1400-AD03], State

The ASM is concerned that the proposed definition of fundamental research, as stated in RIN 1400-AD70, fails to adequately encompass the full scope of activities and outcomes of such research. We agree with other stakeholders who have questioned specifics of the new definition, such as the omission of software as part of technical data derived from fundamental research, or certain restrictions tied to proprietary information review by research sponsors. The too narrow definition has significant impacts on both the research community and the export of US technology.

The ASM supports the proposed rule revisions that would allow the transfer of certain Category XIV materials from ITAR's export control jurisdiction to the Commerce Department's EAR jurisdiction [RIN 0694-AF52; RIN 1400-AD03]. Other changes include needed clarifications on materials developed under Department of Defense funding. The stated intent of the revisions also includes clarification of which agents are controlled by the respective jurisdictions. Category XIV contains multiple microorganisms and toxins utilized in basic and applied research, important to both ensuring national security and improving public health. The ASM has consistently argued that any guidelines relevant to this research must be clearly understood and regularly reviewed for possible revision. The ASM believes that due to the rapidly changing scientific advances and epidemiology of many of the microorganisms listed in Category XIV, a review of the list now seems warranted.

We appreciate this opportunity to comment on the proposed changes.



August 17, 2015

C. Edward Peartree
Director
Office of Defense Trade Controls Policy
U.S. Department of State
Washington, DC
By email to DDTCTPublicComments@state.gov

RE: ITAR Amendment – Amendment to the International Traffic in Arms Regulations:
Revision of U.S. Munitions List Categories XIV and XVIII (RIN 1400-AD03)

Dear Mr. Peartree:

I am writing on behalf of the Association of University Export Control Officers (AUECO), a group of 129 senior export practitioners with export control responsibilities from 100 accredited institutions of higher learning in the United States (U.S.). AUECO members monitor proposed changes in export control laws and regulations affecting academic activities and advocate for policies, procedures, and award terms and conditions that advance effective university compliance with applicable U.S. export controls and trade sanction regulations.

AUECO appreciates the opportunity to comment on the proposed amendment to the International Traffic in Arms Regulations (ITAR), Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII, federal register notice June 17, 2015.

The adoption of this new proposed rule will have a negative impact on the academic research enterprise, especially those research institutions that regularly include foreign national students in their academic and research activities, and those which, by academic policy do not accept restrictions on publication of or participation in research. There are currently many research awards made to our member institutions from multiple federal and non-federal sources to conduct research involving one or more items in sections (b) through (h). The majority of these awards made to research institutions permit open dissemination of the research results, and there are no contractual restrictions on participation based on national origin. The biological agents listed in section (b) are governed by the EAR which allow for inclusion of foreign national students in most cases without a license. Moreover, these biological agents are also governed by the federal select agent program overseen by the USDA and CDC and the new Dual Use Research of Concern (DURC) regulations. Thus, multiple sets of regulations are already in place

to controls these agents while providing adequate flexibility for publication and foreign national inclusion.

General Comment on ITAR XIV(b)

We understand why the government wants to put stricter controls on technologies and activities that could potentially lead to the weaponization of biological agents. However, the proposed rule will likely cause confusion for compliance officers regarding which agency has licensing jurisdiction. This will increase the number of commodity jurisdiction requests submitted, increasing administrative workload for the submitting entity as well as the Departments of State and Commerce.

Request for Note to be Added to ITAR XIV(b)

NIH funds a large amount of research at universities for the identification, characterization, prevention and treatment of microorganisms and their associated diseases. This research should not be controlled under the ITAR. Because of the way the proposed regulations are written, NIH funded microbial research could fall under ITAR, which would seem counter to the charter of NIH. We recommend that a specific carve out be added to exempt NIH, CDC, and USDA funded work from ITAR controls.

Request for Wording Change on ITAR XIV(b)

ECCN 1C352 has been combined with 1C351 and removed from the Commerce Control List. Therefore, any mention of 1C352 should be removed from the proposed regulation.

Request to Reinstate Current ITAR XIV(n)

Section XIV(n) from the current USML has been removed in the proposed regulations. XIV(n)(2) contained an exemption for modifications to biological agents made for civilian applications (i.e., medical use). We do not understand the reason for the removal of this exemption, which is particularly useful to universities performing research.

Comments on ITAR XIV(b)(1)(i)

This section states that genetically modified biological agents where the modifications result in an increase in persistence in the field environment or the ability to defeat detection methods, personal protection, etc. would be controlled under the ITAR. However, a majority of the “properties” of microorganisms mentioned in XIV(b)(1)(i) are not something that researchers would typically test for, unless those properties were the subject of the research.

1. The lack of testing in these areas somewhat invalidates the usefulness of this paragraph. It does not seem appropriate to define the regulatory control environment around “properties” for which testing may not be completed (see example in 4 below).
2. There is a concern that the mention of these “properties” within the regulations may lead to requirements for mandatory testing of these “properties” for genetically

modified versions of the microorganisms listed in XIV(b)(1)(ii). Mandatory testing could create a significant burden on research laboratories from workload, cost, schedule and documentation standpoints.

3. What standards do we use to make a determination that a genetic modification has increased a microorganism's environmental persistence, decreased its ability to be detected or overcome natural host immunity? Will there be a uniform set of standards to help guide researchers in making this determination or will individual research labs need to develop these standards themselves? Allowing labs to set their own standards could result in differences in determining which regulation (ITAR or EAR) may apply. For example:
 - a. Lab Differences – Labs may have difference standards regarding the “properties”. Two labs conducting research on the same virus may have separately determined that the virus can survive temperatures up to 170°F (lab 1) and 155°F (lab 2). They each make modifications to the virus and they both measure that the “modified’ virus can survive temperatures up to 170°F. Therefore, lab 1 would state that the modification did not increase the virus’s environmental persistence, whereas lab 2 would conclude that the change did increase its persistence.
 - b. Interpretation of Change – A lab genetically modifies a controlled virus and finds through testing that the “genetically-modified” organism now appears to be able to survive temperatures up to 170°F, whereas the unmodified virus appears to survive in temperatures up to 160°F. Although this appears to be a “real” increase in persistence, some researchers may state it is not a statistically significant increase, or is of no practical importance (i.e., for transmission or sterilization purposes). Therefore, some labs may consider this genetically modified organism as ITAR-controlled and others may consider it EAR-controlled.
4. Such testing can delay license application reviews. For example, we submit a license application to BIS to ship genetically modified *Bacillus anthracis* to France. After initial screening, the reviewer asks us if the modification makes the bacteria more resistant to extreme hot or cold temperatures, or can defeat normal detection methods. We state “we don’t know; we never tested for that”. What happens to our application at that point? Is it put on indefinite hold until we conduct the tests and provide the results? Is it assumed to be subject to ITAR, even though that was not the subject of the research, nor is there evidence to indicate an increase in these “properties”? Is the application RWA’d for lack of information?
5. Based upon the “e.g.” in XIV(b)(1)(i)(A), the list of “properties” is incomplete. If this is the criteria for determining whether the subject microorganisms are ITAR or EAR

controlled, this list should be complete in the regulations and not subject to change through administrative guidances or reviewer preference.

6. To eliminate the potential confusion and issues caused by these “property-based” regulations, we would recommend the control be based upon the nature of the research to be conducted with the subject microorganism.
 - a. Research regarding the identification, characterization, prevention or treatment of the subject microorganism or its associated disease would be controlled under the EAR.
 - b. Research used to (1) increase the microorganism’s persistence in the environment, or (2) defeat detection methods, personal protection, host immunity, etc. would be controlled under the ITAR.

Although this may seem like a subtle difference from what is currently written, the difference lies in the intent of the research. Research that is intended to characterize a disease (of one of the subject microorganisms) will likely not test for many, if any, of the stated properties. However, research intended to defeat detection methods will likely test for that property.

Comments on ITAR XIV(b)(2)(ii)

As evidenced by the “e.g.” in XIV(b)(2)(ii)(A) and (B), the list of “properties” is incomplete. If this is the criteria for determining whether the subject microorganisms are ITAR or EAR controlled, this list should be complete in the regulations and not subject to change through administrative guidance or reviewer preference.

Comments on ITAR XIV(f)(1)(ii), XIV(f)(2) and XIV(f)(2)(ii)

The phrase “...developed under a Department of Defense contract or other funding authorization” is unclear. If this phrase is attempting to capture multiple funding vehicles under DOD, it should be changed to “...developed under Department of Defense funding.”

Research toward the development of new vaccines and therapeutics is currently funded by DOD as well as other sponsors. This research is intended to benefit and the vaccines/therapeutics be used to protect public and veterinary health against any event resulting from exposure to naturally occurring or non-naturally occurring pathogens. The proposed rule may inadvertently prevent this basic research and hinder the ability to develop or utilize these vaccines using the proposed language in the following ways:

Preparation of agents with non-naturally occurring genetic mutations are a necessary step in the process to understanding how an organism replicates, persists and to ultimately developing a vaccine. For example, investigators often introduce specific mutations or deletions within the organism to better understand how that organism replicates, survives and is transmitted to

another organism. These are critical steps in the development of new vaccines and therapeutics. Thus, understanding how the organism survives under extreme temperatures or arid conditions, how these conditions affect transmission, etc. will impact vaccine development.

The current broad interpretation of the language, specifically “persistence in the field”, will preclude this research from its traditional fundamental research status to a restricted status. Since these pathogens largely fall under the jurisdiction of the Select Agent or DURC policies already (e.g., *F. tularensis*, *Y. pestis*, certain strains of influenza, *Burkholderia spp.*), other regulatory processes are already in place to monitor these studies. Thus, it will be necessary to clarify the language and not duplicate efforts that will hinder basic science research.

AUECO appreciates the opportunity to provide the Department of State with the above comments on ITAR Amendment-Category XIV to enable the government to understand how the technologies we are developing and using are impacted by export controls. The research enterprise in the United States is critical to the economic advancement of our country and having export regulations that are not overly broad ensure that innovation is not stifled in performing fundamental research.

Sincerely,

A handwritten signature in blue ink that reads "JJ Souface". The signature is stylized with large, flowing loops.

Chair

Association of University Export Control Officers

Email: auecogroup@gmail.com

Website: <http://aueco.org>

June 28, 2015

To: DDTCPublicComments@state.gov
publiccomments@bis.doc.gov

From: William A. Root, waroot23@gmail.com

Subject: ITAR Amendment - Categories XIV and XVIII
Toxicological Agents and Directed Energy Weapons RIN 0694-AF52

The June 17, 2015 Department of State proposed rule requests public comments on eight questions:

- (1) Would the State and Commerce proposed rules control all of Wassenaar Arrangement (WA) commitments embodied in Wassenaar Munitions List items ML 7 and ML 19?

State and Commerce proposed rules do not control the following from WA ML 7 and 19:

WA ML 7.a Biological agents or radio active materials “adapted for use in war” to produce casualties in humans or animals, degrade equipment, or damage crops or the environment.

WA ML 19.f “Laser” systems specially designed to cause permanent blindness to unenhanced vision, *i.e.*, to the naked eye or to the eye with corrective eyesight devices.

In addition, State and Commerce rules, both existing and proposed, do not control the following from related commitments embodied in Australia Group List items chemical manufacturing 6.b and biological equipment 8.b:

6.b Valves with closure element designed to be interchangeable
(This subset of AG 6.a is omitted from ECCN 2B350.g)

8.b Nose-only exposure apparatus utilizing directed aerosol flow and having capacity for exposure of 12 or more rodents, or 2 or more animals other than rodents; and closed animal restraint tubes designed for use with such apparatus

- (2) Would the State and Commerce proposed rules expand coverage beyond the Wassenaar Munitions and Dual-Use Lists?

State proposed rules expand coverage not only beyond the Wassenaar Munitions and Dual-Use Lists but also beyond the Australia Group (AG) and Chemical Weapons Convention (CWC) lists, as follows (no Commerce proposed items involve such expansion):

XIV.a.3.iii.D Other nitrogen mustards

XIV.a.5 Other CW agents

XIV.g Antibodies

XIV.h.1-3 Specific vaccines

XIV.n Developmental countermeasures

XVIII.f Developmental directed energy weapons

State and Commerce proposed rules continue the following existing unilateral controls beyond WA, AG, and CWC coverage:

- XIV.a.3.iv,v DA
- XIV.a.4.ii, iii DZ
- XIV.h.4 Vaccines against XIV(b) biological agents

AG Note (1) An agent/pathogen is covered by this list except when it is in the form of a vaccine. (This contrasts with proposed XIV.h.1-4 vaccines.)

- XIV.i Modeling or simulation
- 1A607.j Process samples
- 1A607.k Medical countermeasures
- 1B607.a Destruction of chemical agents
- 1C607.a.7-14 Riot control agents
- 1C351.a.50 Teschen disease
- 1C351.b.3 Tick-borne encephalitis
- 1C353.a.2, b.2... coding ...
- 1C354.a.6 Raythayibactor toxicus
- 1C354.b.12 Pharma glycinicola

The above are clear examples of unilateral U.S. controls. The attached cross-references from multilateral items to U.S. items and from U.S. items to multilateral items include the following other examples of similarities which are not identical, *i.e.*, partially unilateral:

<u>Multilateral WA ML</u>					<u>United States</u>		
<u>7</u>	<u>18</u>	<u>19</u>	<u>21</u>	<u>22</u>	<u>XIV</u>	<u>XVIII</u>	<u>ECCNs</u>
e					f.1		1A607.e, x; 1B607.x
f.1					f.4		1A607.f
f.3							1C607.d
g							1A607.x; 1B607.x
x		x					all
	18						1B607.b, c; 6B619.a, x
		heading				e	
		a,b,c				a	
			21		m	g	1D607; 6D619
				22	m	g	1E607; 6E619

EAA Section 5(c)(6) prohibits unilateral National Security controls absent a finding of no foreign availability or active negotiations to achieve multilateral export controls. Designation of “600 series” ECCNs as controlled for Regional Stability reasons is an evasion of EAA 5(c)(6) Congressional intent. “Regional” Stability Column 1 all countries except Canada is a contradiction in terms. AG, CWC, and USML controls are not technically EAA National Security controls. However, their purpose is national security. Putting aside such legal nuances, multilateral controls are more effective than unilateral controls.

(3) Is there a sufficiently “bright line” between the USML and the CCL? Are there examples of doubtful jurisdiction based on this revision? Is the line sufficiently clear between

biological items proposed under USML XIV(b) and those proposed under the CCL?

The State proposals for new biological items in XIV(b) increase jurisdictional doubts with respect to existing items on the CCL. There are no new Commerce proposals which would have that effect. However, there are existing CCL controls for which Commerce jurisdiction is made doubtful by State USML proposals.

The existing XIV(b) definition of biological agents controlled on the USML uses language (“adapted for use in war” to produce human casualties, degrade equipment, and damage crops) which is not found on the CCL. Even though this language is in Wassenaar ML 7.a, State proposes to delete it from the USML and to substitute the following language, which is substantially the same as the following language now in the CCL:

State proposed XIV(b)

- (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.*, ...); or
 - (B) The ability to defeat or overcome standard detection methods, ... or response to standard medical countermeasures; and
 - (ii) Being any microorganisms/toxins or their non-naturally occurring genetic elements as listed below: (A-L).
- (XIV(b)(1)(ii)(A-L) are identical to 1C351.a.13, 14, 30, 43, 52 and 1C351.c.1, 6, 7, 8, 14, 22.)
- (2) Biological agent or biologically derived substances as controlled in ECCNs 1C351, 1C353, or 1C354 (1C352 deleted because it was transferred to 1C351 on 06/16/2015):
 - (i) Physically modified, formulated, or produced as any of the following: (A-D); 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-C).
- vs.

Existing Commerce 1C353

- a Genetic elements that contain nucleic acid sequences
 - a.1 associated with the pathogenicity of microorganisms controlled by 1C351.a to .c or 1C354;
 - a.2 coding for any of the “toxins” controlled by 1C351.d or “sub-units of toxins” thereof.
 - b. Genetically modified organisms that contain nucleic acid sequences:
 - b.1 associated with the pathogenicity of microorganisms controlled by 1C351.a to .c or 1C354;
 - a.2 coding for any of the “toxins” controlled by 1C351.d or “sub-units of toxins” thereof.
- Technical Note 1. “Genetic elements” include ...
- 3. “Nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c or 1C354” means ...
 - a. ... hazard to human, animal or plant health; or

- b. ... cause serious harm to human, animal or plant health.
4. “Genetically modified organisms” include organisms in which the genetic material (nucleic acid sequences) has been altered in a way that does not occur naturally ...

Some of the broad State and Commerce language is the same, *e.g.*, “genetic elements” and “genetically modified organisms.” Commerce defines these terms. In the absence of State definitions, State will logically use the Commerce definitions. The biological agents in proposed USML XIV of concern to State are all listed on the CCL. Even where the language used by the two agencies differs, the substance seems to be the same. It is difficult to imagine a more doubtful agency jurisdiction.

Proposed new XIV.a.5 chemical warfare agents not enumerated in XIV.a.1-4 refers to Commerce-controlled agents which become State-controlled if “adapted for use in war.” The Note which defines “adapted for use in war” is not a “bright line,” because it omits numerical specifications for the stated purity, shelf life, and resistance to ultraviolet radiation parameters.

Proposed XIV.m controls technical data and defense services “directly related” to the other portions of XIV. The lack of a “bright line” for other portions is exacerbated for technical data and defense services because of the lack of a definition for “directly related.”

- (4) What items or associated technical data in revised USML Categories XIV and XVIII are in normal commercial use?

All the proposed XIV,b biological agents and associated technical data have been on the Commerce dual civil and military use list for decades. Moreover, the only identified chemical warfare agents and associated technical data in proposed new XIV.a.5 have also been on the CCL dual-use list for decades.

- (5) Is “non-naturally occurring” sufficient to distinguish military or intelligence purposes from commercial or civilian purposes?

No. Technical Note 4 to 1C353 uses “does not occur naturally” in the definition of “genetically modified organisms” as used in that ECCN.

- (6) Does Category XIV.b, f, g, or m inadvertently control medical countermeasures which would be in the interest of public health or medical preparedness?

XIV does control medical countermeasures which would be in the interest of public health or medical preparedness. This is not inadvertent. The following indicates that this is intentional: XIV.b.1.i.B controls “the ability to defeat or overcome ... response to standard medical countermeasures.” XIV.f, g, and m control related equipment, antibodies, and technical data.

A medical countermeasure against harmful biological agents controlled by XIV.b “would be in the interest of public health or medical preparedness.” A “response” to prevent the effectiveness

of such a countermeasure would NOT “be in the interest of public health or medical preparedness.” The “ability to defeat or overcome” such a “response” “would be in the interest of public health or medical preparedness.” Therefore, controlling the export of such an ability would NOT “be in the interest of public health or medical preparedness.”

The purpose of XIV.b.1.i.B appears to be to further the effectiveness of biological warfare rather than to “be in the interest of public health or medical preparedness.” A double negative is positive; but a triple negative is still negative, unless the first negative (*i.e.*, the “response”) is a warfare positive rather than a public health negative.

- (7) Would the proposed rule prevent or hinder the ability to develop or utilize vaccines for public health or veterinary benefit?

Yes. The process described in Supplementary Information on page 34573, bottom of left column and top of right column, is apparently intended to justify a negative response to this question. It does not accomplish that objective. The scope of XIV.h controls of vaccines is limited by funded exclusively by DOD and specially designed for protecting against controlled biological agents which must meet specified criteria. Even so, there must be vaccines which meet those conditions. If not, the control would be meaningless. Therefore, the proposed rule may not prevent, but it would at least hinder, the ability to develop or utilize vaccines for public health or veterinary benefit.

The purpose of XIV.h appears to be to further the effectiveness of biological warfare rather than to further development or utilization of vaccines for public health or veterinary benefit.

The United States is out of step with its allies in controlling vaccine exports. The AG explicitly exempts vaccines from control.

- (8) Does XIV.f.2 (for detection, identification, warning, or monitoring) unintentionally control civilian and public health equipment by virtue of Defense funding?

The XIV.f.2 wording relevant to funding is “developed under a Department of Defense contract or other funding authorization” in f.2 and “specified by a Department of Defense contract or other funding authorization” in f.2.ii. Such wording literally covers another funding authorization from any source, not just from the Department of Defense. However, question (8) assumes that the intent is that the other funding authorization is from DOD. Unlike XIV.h, XIV.f.2 omits “exclusively” funded by DOD. This was apparently intentional. Question (8) refers to “detection equipment that may not warrant ITAR control, but contains items that are fully or partially Defense funded.”

The purpose of question (8) seems to be to seek technical parameters and limits as a substitute for control based on DOD funding. Existing XIV.f.2 has neither a reference to DOD funding nor technical parameters and limits. It is limited only by “specifically designed or modified for military operations and compatibility with military equipment.” This is very close to WA 7.g

“specially designed or modified for military use” and to proposed 1A607.h:

Equipment not controlled by USML Category XIV(f) and specially designed for military use and for the detection or identification of materials specified by USML Category XIV(a) or (b)

A party to a DOD contract or other DOD funding authorization must comply with the terms of that contract or authorization, whether or not it is included in the USML. If question (8) does not elicit technical parameters and limits from the public or from USG reconsideration, then equipment for detection and identification of XIV.a and .b would be controlled only under 1A607.h.

It is unclear why question (8) is limited to XIV.f.2. The following controls are also based on DOD funding: f.1, g.1, h, i, and n. There is no need for export controls on items separately controlled by a DOD contract or other DOD funding authorization.

Cross-references from WA ML 7 and 19 to proposed USML XIV and XVIII and ECCNs

7.a Biological agents or radioactive materials, “adapted for use in war” ...

(Neither State nor Commerce controls WA 7.a.)

7.b.1.a,b,c = XIV.a.1.i,ii,iii

7.b.2.a.1-9, b.1-3, c.1-3 = XIV.a.3.i, ii, and iii.A_C; but XIV.a.3.iii.D is new and not WA

7.b.3.a BZ = XIV.a.4.i; but a.4.ii,iii are not WA, although they are now on USML

7.b.4.a LNF = XIV.e.2

7.b.4.b agent orange = XIV.e.1

7.c.1-4 = XIV.c.1-4

7.d.1-6 = 1C607.a.1-6; but a.7-14 are not WA; although they are now USML XIV.d.6-13

7.e.1 for .a or .b and 7.e.2 for .c = XIV.f.1.i

7.e.1 for .d = 1A607.e for 1C607.a.1-6; but for a.7-14 not WA; although now USML XIV.f.1

7.f.1 = XIV.f.4 + 1A607.f

7.f.2 = 1A607.g

7.g = XIV.f.2 + 1A607.h

7.h = XIV.g + 1C607.b

7.i = 1C607.c

19.a,b,c = XVIII.a

19.d = XVIII.b

19.e = 6B619.a

19.f Laser equipment causing blindness
(Neither State nor Commerce controls WA 19.f.)

Cross-references from Australia Group and CWC to USML XIV and ECCNs

Chemical precursors

1C350.d lists all 24 Australia Group-controlled precursors which are not CWC-controlled. CWC-controlled items on Schedules 1, 2, and 3 are on U.S. control lists (and WA ML 7) as follows:

<u>CWC</u>	<u>U. S.</u>	<u>WML</u>
1: 1-3	XIV.a.1	7.b.1
1: 4-6	XIV.a.3	7.b.2
1: 7,8	1C351.d.11, 12	
1: 9-12	XIV.c.1-4	7.c
2: 1	XIV.a.2	
2: 2	1C355.a.1.a	
2: 3	XIV.a.4.i	7.b.3
2: 4	XIV.c.5; 1C355.a.2.a*	
2: 5	1C355.a.2.b	
2: 6	1C355.a.2.c; 1C350.b.5	
2: 7	1C350.b.1	
2: 8	1C350.b.2	
2: 9	1C350.b.19	
2: 10	1C355.a.2.d; 1C350b.8, 10, 12	
2: 11	1C355.a.2.e; 1C350.b.6, 9	
2: 12	1C355.a.2.f; 1C350.b.7	
2: 13	1C350.b.20	
2: 14	1C350.b.18	
3: 1	1C355.b.1.a	7 Note 1.d**
3: 2	1C355.b.1.b	7 Note 1.a**
3: 3	1C355.b.1.c	7 Note 1.b**
3: 4	1C355.b.1.d	7 Note 1.p**
3: 5	1C350.c.3	
3: 6	1C350.c.5	
3: 7	1C350.c.4	
3: 8	1C350.c.11	
3: 9	1C350.c.10	
3.10	1C350.c.2	
3.11	1C350.c.1	
3.12	1C350.c.5	
3.13	1C350.c.6	
3.14	1C350.c.8	

3.15	1C355.b.2.a; 1C350.c.12
3.16	1C355.b.2.b
3.17	1C350.c.9

* The following 10 sub-items of 1C350.b are portions of CWC Schedule 2 item 4: 1C350.b.1, 3, 4, 11, 13, 14, 21, 22, 23, and 24. Even this is not a complete list of the CWC 2: 4 family of chemicals. Dow Chemical prepared a much longer, but inherently still incomplete, list.

** Wassenaar ML 7 Note 1 lists 15 chemicals to which WA ML 7.b and 7.d do not apply. But these four are, nevertheless, controlled by CWC Schedule 3. Existing USML XIV Note 3 lists 9 of the 15 (including these 4) plus 3 not on the WA ML 7 Note 1 list as not included in XIV(a) and (d). The State proposed XIV omits existing Note 3.

Human and Animal Pathogens and Toxins

Viruses

<u>AG</u>	<u>1C351.a</u>	<u>1C351.b</u>	<u>XIV.b.1.ii</u>
1-8	1-8		
9-16	typo error, repeats 1-8		
17	20		
18-21	9-12		
22, 23	13, 14		E, F
24-27	15-18		
28-37	21-30		
38	31		H
39-48	32-41		
49		1	
50	42		
51	43		L
52-54	44-46		
55		2	
56-58	47-49		
59	19		
	50		Teschen disease
60	20		
61	51		
		3	Tick-borne encephalitis (Siberian subtype)
62	52		I, J
63-66	53-56		

Bacteria

<u>AG</u>	<u>1C351.c</u>	<u>XIV.b.1.ii</u>
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1	1	A
2-5	2-5	
6-8	6-8	C, D, B
9-13	9-13	
14	14	G
15-21	15-21	
22	22	K

Toxins

<u>AG</u>	<u>1C351.d</u>	<u>CWC</u>
1-10	1-10	
11, 12	11, 12	1: 8, 1: 7
13-19	13-19	

Fungi

<u>AG</u>	<u>1C351.e</u>
1, 2	1, 2

Plant Pathogens

Bacteria

<u>AG</u>	<u>1C354</u>
1-5	a.1-5
	a.6 Raythayibactor toxicus

Fungi

1-11	b.1-11
	b.12 Pharma glycinicola

Viruses

1-2	c.1,2
-----	-------

Genetic elements and genetically-modified organisms

<u>AG</u>	<u>1C353</u>
1	a.1
	a.2 ... coding ...
2.	b.1
	b.2 ... coding

Chemical manufacturing

<u>AG I</u>	<u>US</u>
1	2B350.a, b
2-5	2B350.c-f
6.a	2B350.g

- 6.b Valves subset of 6.a with closure element designed to be interchangeable
(omitted from 2B350.g)
7-9 2B350.h-j

Toxic gas monitoring

AG

II.a, b; IV 2B351.a, b; 2D351

Technology “directly associated” with CW agents, precursors, or equipment

AG III 1E001, 1E350, 1E351, 1E355, 2E001, 2E002, 2E301

Biological equipment

AG I 2B352

1-7 a-g

8.a h

8.b Nose-only exposure apparatus utilizing directed aerosol flow and having capacity for exposure of 12 or more rodents, or 2 or more animals other than rodents; and closed animal restraint tubes designed for use with such apparatus

9 i

Technology “directly associated” with biological agents or equipment

AG II 1E001, 1E351, 2E001, 2E002, 2E301

Cross-references from USML XIV and XVIII and ECCNs to Multilateral and Unilateral Controls

<u>XIV</u>	<u>Multilateral</u>			<u>Unilateral</u>	
	<u>WA 7</u>	<u>CWC</u>	<u>AG</u>	<u>Now</u>	<u>Proposed</u>
a.1	b.1	1:1-3			
a.2		2:1			
a.3.i,ii,iii.A-C	b.2	1:4-6			
a.3.iii.D					Other nitrogen mustards
a.3.iv,v			x DA		
a.4.i		2:3			
a.4.ii, iii				x DZ	
a.5					Other CW agents
b.1.i			x		
b.1.ii			x		
b.2			x		
c.1-4	c.1-4	1:9-12			
c.5		2:4			
e.1, 2	b.4				
f	e				
g	h, i				x except part of WA 7.h, i
h.1-3					x special vaccines

h.4					x other vaccines
i					x modeling or simulation
m		x	x	x	x x
n					x developmental countermeasures
x		x	x	x	x x
XVIII	<u>WA 19</u>				
a	a, b, c				
b	d				
e	heading				
f					x developmental
CCL	<u>WA 7</u>				
1A607.e	e				
1A607.f	f.1				
1A607.g	f.2				
1A607.h	g				
1A607.j					x process samples
1A607.k					x medical countermeasures
1A607.x	e, g				x
1B607.a					x destruction of chemical agents
1B607.b	18				
1B607.c	18				
1B607.x	e, g				x
1C607.a.1-6	d				
1C607.a.7-14					x riot control agents
1C607.b	h				
1C607.c	i				
1C607.d	f.3				
1D607.a	21				x
1E607.a	22				x
1C350		x	x		
1C351.a.1-49				x	
1C351.a.50					x Teschen disease
1C351.a.51-56		x			
1C351.b.1, 2				x	
1C351.b.3					x Tick-borne encephalitis
1C351.c, d, e				x	
1C353.a.1, b.1		x			

1C353.a.2, b.2		x ... coding ...
1C354.a.1-5		x
1C354.a.6		x Raythayibactor toxicus
1C354.b.1-11		x
1C354.b.12		x Pharma glycinicola
1C354. c.1, 2		x
1C355		x
6B619.a, x	18	
6D619	21	
6E619	22	

VIA EMAIL: DDTCPublicComments@state.gov

August 17, 2015

U.S Department of State
Bureau of Political-Military Affairs
Directorate of Defense Trade Controls
2401 E. St., NW
12th Floor, SA-1
Washington, DC 25002

Attention: Mr. C. Edward Peartree
Director, Office of Defense Trade Controls Policy

Re: **ITAR AMENDMENT CATEGORY XIV
COMMENTS ON PROPOSED REVISION OF USML CATEGORY XIV
80 FEDERAL REGISTER 34572 (JUNE 17, 2015) (RIN 1400-AD03)**

Dear Mr. Peartree,

BioFire Defense, LLC (“BioFire”) appreciates the opportunity to comment on the proposed revisions to USML Category XIV and respectfully submits the following comments, recommendations, and examples.

BioFire is based in Salt Lake City, Utah, and is a subsidiary of bioMerieux Inc. BioFire develops, manufactures, and sells instruments, assay kits, and reagents for real-time detection of pathogens and emerging infectious diseases. Its technology includes DNA amplification, real-time thermocycling, and high resolution melting. Its products include the FilmArray Ebola Test and RAZOR EX biodetection instruments, along with Hi-Res Melting dyes and kits and an expanding line of freeze-dried reagents and DNA/RNA purification kits. BioFire has developed and provided products for pathogen identification and detection for military and civilian use and for life science research since 1990.

I. General Comments on Nature of Funding Under Category XIV Paragraphs (g)(1) and (f)(2)

BioFire supports the administration’s Export Control Reform Initiative and the substantial on-going effort by the Directorate of Defense Trade Controls (“DDTC”) and the Bureau of Industry and Security to more precisely describe the articles warranting control on the USML. BioFire, however, has identified several instances where the proposed USML Category XIV could inadvertently control detection systems in normal commercial use, or could inadvertently



detrimentally impact the interests of public health and medical preparedness for the civilian population.

Specifically, BioFire notes that under proposed Category XIV paragraphs (f) and (g) control of its pathogen detection and identification products is not based on specific parameters that are uniquely military, or a clear intent to control an item on the USML, but rather on the nature of the funding for the development of the pathogen detection and identification systems. BioFire submits the following comments and examples that show where the proposed rule (1) is ambiguous or (2) could encompass civilian specific detection and identification systems for pathogens, and BioFire provides recommendations to clarify the proposed rules.

A. Comments on Phrase “Exclusively Funded by a Department of Defense Contract” Under XIV(g)(1)

In particular, BioFire notes that control under paragraph (g)(1) hinges on whether an item is “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.”

BioFire notes that DDTC provided only one example of when the phrase “exclusively funded by a Department of Defense contract” would not apply. (See, 80 FR at 34573, Col. 1.) To provide clarity to the exporting community and to assist exporters in understanding the scope of the proposed controls, we recommend providing additional examples that reflect other funding situations typical in the industry.

In the only example provided, an item would not be controlled under (g)(1) where “the Department of Defense provides initial funding for the development of an item, but another agency ... provides funding to further develop or adapt the item.” Please provide clarity on the converse funding situation. To provide a specific example, a detection test kit that contains multiple assays for civilian use is developed using National Institute of Health and private company funds. Then additional funding is received from the Department of Defense (“DOD”) to further modify the civilian use detection test kit.

In this situation, (g)(1) may inadvertently encompass a test kit that contains several assays, which were initially developed with funds from a non-DOD source, and where DOD funds were exclusively provided to further adapt or add a reagent listed in (g). In such a situation, does the “see through rule” apply and control the entire test kit under (g)(1) simply because a reagent exclusively funded by DOD was adapted or added to the civilian kit? If the entire civilian kit is controlled, then (g)(1) could control detection systems in normal commercial civilian use and detrimentally impact medical preparedness for the civilian population.

To resolve ambiguity and provide needed guidance to the exporting community, we recommend adding the following note to paragraph (g):



Note 1 to paragraph (g): This paragraph does not control items that (a) are part of a multiple component product, and (b) are identified in the relevant Department of Defense contract or other Defense funding authorization as being developed for both civil and military applications.

The Department specifically stated that 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. (See, 80 FR at 34573, Col. 2.) The proposed note is recommended to ensure consistency with this goal by allowing identification in the relevant contract of any reagents (e.g., polynucleotides) in a multiple component product that are for both civilian and military applications to prevent inadvertent control of those reagents under (g)(1).

Additionally, the explanation and example at 80 FR at 34573, Col. 1, para (3) only discusses funding from “another agency of the U.S. government”. We recommend that this example be changed to read in the last three lines of the paragraph “but another agency of the U.S. government, a state or local governmental agency, or a private entity provides funding to further develop or adapt the item”.

B. Proposed Revised Paragraph XIV(f)(2) May also Control Civilian and Public Health Equipment

The proposed language related to Department of Defense funding in paragraph (f)(2) may inadvertently control certain types of biological detection systems in normal commercial civilian use and essential for civilian public health. (See, 80 FR at 34574, Col. 1 & 2, para (8)). An example of a type of commercial product that could be controlled on the USML under the language as proposed under (f)(2) is an infectious disease platform intended for civilian medical use, including PCR or immunotechnology, which typically receives funding from private sources, NIH, and DOD.

In this example, it is ambiguous under proposed (f)(2) whether the phrase “developed under a Department of Defense contract” applies to a product (e.g., a detection test kit for civilian use) that contains multiple assays, where the product is developed from different funding sources (e.g., funding from private sources, NIH, and DOD).

Additionally, similar to the discussion regarding (g)(1), it is just as ambiguous whether the phrase “developed under a Department of Defense contract” applies to a detection test kit for civilian use that contains multiple assays, where the product is further developed under a DOD contract to adapt an existing reagent or assay or to add a reagent or an assay, where the initial development of the multiple assay product was funded by non-DOD sources. In such a situation, is the entire test kit for civilian use controlled under (f)(2) simply because some DOD funding was used to develop or modify the detection kit? If the entire kit is controlled, (f)(2) could control detection systems in normal commercial civilian use and (f)(2) could detrimentally impact medical preparedness for the civilian population.

We also recommend inserting the term “Defense” before the term “funding” in the clauses “or other funding authorization” in note 1 to paragraph (f)(2), (f)(2), and (f)(2)(ii) to clarify that they mean other Defense funding authorization only. As written, the language could be interpreted to mean funding authorization by any other agency of the U.S government.

Moreover, use of the term “equipment” as defined in Section 120.45(h) of the ITAR refers to an end-item, parts, components, accessories, attachments, firmware or software. As the term is used in (f)(2) it contributes to the ambiguity and may result in control of a detection system or any part of a detection system if the system itself is partially funded by the Department of Defense. For example, a complete detection system that is designed to detect a number of agents of public health concern and would be useful in a hospital laboratory setting may fall within Category XIV if the system contains an algorithm used in the detection of an agent merely because the agent is mentioned in a DOD funding authorization

Additionally, (f)(2)(ii) is ambiguous regarding whether this section applies to any chemical or biological agent mentioned in a DOD contract or whether it applies to chemical or biological agents intended for control under Category XIV. We note that this section could be interpreted to cover testing for any of a number of routine infectious agents, and we do not believe that the intent is to cover such testing under Category XIV and restrict such testing from civilian medical use. To resolve this ambiguity, we recommend revising (f)(2)(ii) to “Chemical or biological agents specified by a Department of Defense contract or other Defense funding authorization as intended for control under Category XIV of the USML.”

The addition of the language “as intended for control under Category XIV of the USML” directly in paragraph (f)(2)(ii), as opposed to a “note”, eliminates the risk that certain items may be inadvertently captured under (f)(2)(ii) simply because they are mentioned in a Defense contract, but it was never the intent to control those item. For example, a routine test that distinguishes between two strains of flu may use an algorithm that may be inadvertently captured by this section. Such an affirmative statement of intent to control an agent on the USML minimizes the inadvertent control of routine tests for infectious agents necessary to protect the health of the civilian population.

II. The Proposed Rule Inadvertently Controls Items in Normal Commercial Use or Commonly Used or Produced in Civilian Laboratories

The Department specifically noted that the U.S. government does not want to inadvertently control items on the USML that are in normal commercial use, and has requested specific examples of items that are in normal commercial use now, or that are commonly used or produced in civilian scientific laboratories that could be controlled under the revised Category XIV. (See, 80 FR at 34573, Col. 3, para (4)). One such example is the FilmArray BioThreat-E Test for Ebola Kit Part No: RFIT-ASY-0122. (<http://biofiredefense.com/biosurveillance-systems/biothreat-e/>). This is a commercial test developed with non-DOD funds and is used extensively by hospitals for the diagnosis of infection by naturally-occurring Ebola. It is



unclear whether this type of item could be controlled under the proposed language in paragraph (g)(1) or (f)(2) in the event of further development using some DoD funds in order to accelerate development of a detection test kit for emerging strains intended for use in a civilian outbreak.

III. CONCLUSION

In conclusion, for the reasons stated above the source of funding alone should not be the determining factor on whether a product is controlled on the USML under Category XIV. Rather, the determining factor should be the clear intent by the Department of Defense to control an item on the USML as specified in the applicable Defense contract or other Defense funding authorization.

We appreciate the Department's consideration of these comments.

Respectfully submitted,



Jill Powlick
VP of Legal Affairs
BioFire Defense, LLC



August 17, 2015

Mr. C. Edward Peartree, Director
Office of Defense Trade Controls Policy
Directorate of Defense Trade Controls
Department of State
SA-1, 12th Floor
Washington, DC 20522-0112

Ms. Hillary Hess, Director
Regulatory Policy Division
Office of Exporter Services
Bureau of Industry and Security
Department of Commerce
14th Street and Pennsylvania Avenue NW
Washington, DC 20230

Subject: ITAR Amendment—Categories XIV and XVIII; RIN 1400-AD03 & 0694-AF52

Reference: Federal Register/ Vol. 80, No. 116/ Wednesday, June 17, 2015/ Proposed Rule: International Traffic in Arms (“ITAR”) (Revisions of U.S. Munitions List Categories XIV and XVIII)

Commerce Control List: Addition of Items Determined to No Longer Warrant Control Under United States Munitions List Category XIV (Toxicological Agents) or Category XVIII (Directed Energy Weapons)

Dear Mr. Peartree, Ms. Hess,

The Boeing Company (“Boeing”) appreciates the opportunity to provide comments on the proposed *ITAR: Revisions of U.S. Munitions List Categories XIV and XVIII* and *CCL: Addition of Items Determined to No Longer Warrant Control Under USML Category XIV or Category XVIII*, published June 3rd 2015.

We have reviewed the proposed changes to U. S. Munitions List (“USML”) Category XVIII – Directed Energy Weapons and the related items for movement from the USML to the export control jurisdiction of the Commerce Control List (“CCL”). Overall, these changes appear appropriate and clear. Movement of tooling, production equipment, test & evaluation equipment, test models and related articles of commodities related to USML Category XVIII reflects the objectives of Export Control Reform and we appreciate the interagency effort to affect this change.

Thank you for the opportunity to provide comments. Please do not hesitate to contact me if you have any questions or need additional information. I can be reached at 703-465-3505 or via email at christopher.e.haave@boeing.com.



Mr. Edward Peartree
Page 2

Sincerely,

A handwritten signature in cursive script, appearing to read "Christopher Haave".

Christopher Haave
Director, Global Trade Controls



Richard D. Rose
Senior Vice President,
General Counsel and Secretary
3000 GSK Drive
Moon Township, PA 15108
412.787.6786
RRose@calgoncarbon.com

August 13, 2015

VIA EMAIL (DDTCTPublicComments@state.gov)

U.S. Department of State
PM/DDTC, SA-1, 12th Floor
2401 E Street, NW
Washington, DC 20037

RE: ITAR Amendment – Categories XIV and XVIII

Dear Sir or Madam:

Calgon Carbon Corporation (“CCC”) provides the following comments on the U.S. Department of State’s June 17, 2015 proposed revisions to U.S. Munitions List Categories XIV and XVIII in the International Traffic in Arms Regulations (“ITAR”).¹ As detailed below, CCC respectfully submits that ASZM-TEDA™ should not be ITAR-controlled Significant Military Equipment. However, should the State Department continue to control ASZM-TEDA™, proposed Category XIV(f)(4)(iii) should be revised to control equivalent products under different trade names.

CCC notes that proposed Category XIV(f)(4)(iii) specifically controls “ASZM-TEDA carbon,”² an activated carbon with military application produced by CCC. By way of background, during the 1990s, the U.S. military began using ASZM-TEDA™ activated carbon, which was designed to be a chrome-free replacement for a predecessor activated carbon product used by the U.S. military. Although originally developed under a U.S. Government contract, ASZM-TEDA™ is a name trademarked by CCC.

ASZM-TEDA™ should not be ITAR-controlled Significant Military Equipment. The U.S. military’s gas performance requirements drive the formulation for ASZM-TEDA™. During the development process for ASZM-TEDA™, it was critical that the carbon provided adequate protection against reactive gases that are not included in the current or proposed version of Category XIV(a) or (b). The original specification for ASZM-TEDA™ (EC-C-1704, 24 January 1992) illustrates this, as does the most current version, MIL-DTL-32101A Rev 3. Thus, CCC believes there is some incongruity in retaining control over ASZM-TEDA™ in the ITAR, especially given that this carbon was specifically designed to protect against certain agents exempted from the ITAR’s

¹ *Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII*, 80 Fed. Reg. 34,572 (Dep’t State June 17, 2015) (proposed rule).

² *Id.* at 80 Fed. Reg. 34,577.

control. Further, while ASZM-TEDA™ was developed for the military, it also has civil applications, including for civil defense and manufacturing processes. In this connection, police, first responders, embassies, and semiconductor chip manufacturers, among others, use ASZM-TEDA™.

Nonetheless, should the State Department continue to maintain control over ASZM-TEDA™, CCC respectfully submits that the carbon should not be considered Significant Military Equipment, as it is designated in the proposed rule.³ Activated carbon is incorporated into other products, such as filters for gas masks, and is low on the distribution chain. CCC does not believe that special export controls, including a DSP-83 requirement, are warranted for ASZM-TEDA™.⁴ Although ASZM-TEDA™ has military utility, it also can be used for civil applications and is for defensive, protective purposes, as opposed to, for example, the chemical and biological warfare agents listed in Category XIV. Moreover, as the State Department is aware, there are many practical difficulties inherent in obtaining DSP-83 forms for a product so low in the chain of distribution.

If ASZM-TEDA™ is to remain ITAR-controlled, proposed Category XIV(f)(4)(iii) should be revised to control equivalent products under different trade names. As noted above, ASZM-TEDA™ is a name trademarked by CCC. As currently drafted, proposed Category XIV(f)(4)(iii) would not explicitly control an equivalent activated carbon product manufactured by a competitor of CCC under a different name. In other words, proposed Category XIV(f)(4)(iii) creates ambiguity as to whether future activated carbons manufactured by other companies to the same specifications as ASZM-TEDA™ would be controlled by the ITAR. This generates a potential loophole in the regulations, as an identical product marketed under a different name may not be ITAR-controlled. It also results in a competitive disadvantage to CCC, as its competitors' carbons may be subject to lower-level export controls even if the carbons meet the same specifications as and perform functions equivalent to ASZM-TEDA™. Therefore, if ASZM-TEDA™ will remain ITAR-controlled, the State Department should revise Category XIV(f)(4)(iii) to remove the reference to "ASZM-TEDA carbon" and instead include a general description of the U.S. Government specifications for ITAR-controlled carbon and/or a reference to the applicable U.S. military specification.

If you have any questions about this submission, please do not hesitate to contact the undersigned.

Respectfully submitted,



Richard D. Rose
Senior Empowered Official and
Senior Vice President, General Counsel and Secretary

³ *Id.* at 80 Fed. Reg. 34,576 (designating subparagraph (f) as Significant Military Equipment).

⁴ *See* 22 C.F.R. § 120.7.



August 17, 2015

Office of Defense Trade Controls Policy
U.S. Department of State
2401 E. Street NW
Washington, D.C. 20037

Subject: ITAR Amendment – Categories XIV and XVIII

Dear Sir/Madame:

Communications & Power Industries LLC (CPI) appreciates this opportunity to submit comments and recommendations to the proposed changes to USML XVIII.

The stated objective of Export Control Reform (ECR) is to create a “*positive* list that controls only items that provide the United States with a *significant* military or intelligence advantage.” CPI believes that the proposed changes to XVIII fails to provide performance based parameters for determining when a commodity is or isn’t ITAR controlled and continues to maintain the existing broad catch-all controls.

Moreover, the proposed USML XVIII rules do not provide a bright line for determining jurisdiction and/or classification when a commodity is described in XVIII but enumerated¹ in USML XI. For example Vacuum Electron Devices (VEDs) and antennas, based on their design and/or usage, may be captured under XVIII(e), a catch-all category, but yet released from the ITAR as a result of failing to meet the performance parameters *enumerated* under XI(c)(9) and XI(c)(10). CPI believes this lack of bright line rules or performance parameters will result in insistent application of the ITAR.

As such CPI offers the following recommendations.

1) Add the following language to the end of 121.1(b)(1) Order of Review. “If the article does not meet or exceed the control parameters for the specific entry within the appropriate category you must review the remaining USML categories to determine if is captured under one or more categories before it is released from the ITAR.”

While it is commonly understood by compliance professionals that a commodity is released from the ITAR when it is not enumerated in *any* USML category, CPI believes it is important to include the language in the Order of Review to ensure a more consistent review by industry.

2) XVIII(e) controls “components, parts, accessories, attachments, and associated systems or equipment specially designed for any of the articles in paragraphs (a) and (b)

¹ Note to §120.41(b) The term “enumerated” refers to any article on the U.S. Munitions List or the Commerce Control List and not in a “catch-all” control



of this category.”

It is unclear what is meant by *associated* systems and equipment and how associated systems and equipment differs from systems and equipment controlled under paragraphs (a) and (b). CPI asks that DDTC clarify how ‘associated’ should be applied.

3) Add a note to XVIII(e) stating that “Components, parts, accessories, attachments and associated systems or equipment specially designed *for USML XVIII (e)* are controlled under the EAR”.

CPI believes that this note creates a bright line between commodities (i.e. components, parts, accessories, attachments and associated systems or equipment) specially designed for paragraph (e) and commodities specially designed for paragraph (a) or (b) resulting in a more consistent application of the ITAR. CPI is concerned without this note items such as connectors, cables, RF components, or microwave windows specially designed for a commodity controlled under paragraph (e) may be controlled as XVIII(e) rather than a 600-series ECCN such as 3A611.x.

4) CPI believes it is not clear as to the class of commodities (i.e. only systems and equipment or systems, equipment, parts, components, and accessories) that XVIII(f) seeks to control.

Moreover it appears paragraphs (a) and (b) control commodities in *production or in development and funded by someone other than the US DOD* while (f) controls commodities that are both in development *and* funded by the US DoD.

CPI recommends that DDTC explicitly state the class of commodities to be controlled under this category.

Thank you for this opportunity to comment on the proposed changes to XVIII.

Regards,
Creighton Chin
Export Compliance Manager
Communications & Power Industries LLC
Tel: 650-846-3021

RE: RIN 1400-AD03

August 14, 2015

PUBLIC COMMENT

This is a public comment to RIN 1400–AD03, as published by the Department of State Directorate of Defense Trade Controls (“DDTC”) at 80 Fed. Reg. 34,572 (June 17, 2015) (the “Proposed Rule”), titled, “Amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Categories XIV and XVIII.”

DDTC published the Proposed Rule as part of the President’s Export Control Reform (“ECR”) Initiative. This reform promised a single export control list, single export control agency, and single information technology (“IT”) system. However, following half a decade of complex regulatory amendments, and despite over a thousand pages in Federal Register notices, ECR has not achieved any of these goals. Instead, ECR has vastly increased the complexity of already overly complex regulations. This has significantly increased the compliance burden and cost on industry without the benefits of a single list, single agency, or single IT system.

The Proposed Rule seeks to transfer jurisdiction over certain specific biological agents, vaccines, and associated technology and services from the export control jurisdiction of the Department of Commerce Export Administration Regulations (“EAR”), 15 C.F.R. Parts 730-780, to the State Department International Traffic in Arms Regulations (“ITAR”), 15 C.F.R. Parts 120-130. As specifically noted at page 34,573 of the Proposed Rule:

The proposed revisions to the USML will control items in normal commercial use and the Wassenaar Arrangement’s Dual Use List.

Imposing control over dual-use biomedical research will prevent timely dissemination of critical public health information, create confusion at U.S. biomedical facilities, bar certain foreign students from participating in various biomedical research activities, reduce university participation in vaccine development and various other biomedical research activities, and impede U.S. interoperability with allies and involvement in global response to biological threats. This will, in turn, substantially impact public health research and the consequent ability of civilian government agencies, public health organizations, and private industry to respond to threats posed by the listed agents.

The Proposed Rule will also create apparent conflicts with United States multilateral regime obligations. A separate letter, contemporaneously submitted herewith outside of the public comment process to the Department of Commerce Bureau of Industry and Security Office of Nonproliferation and Treaty Compliance, addresses this issue.

These issues and other concerns with the Proposed Rule are discussed in detail below. Suggested revisions are provided where appropriate.

I. THE PROPOSED RULE TRANSFERS EAR ITEMS AND TECHNOLOGY TO ITAR CONTROL.

The ITAR presently controls “Biological agents and biologically derived substances specifically developed, configured, adapted, or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment or damage crops.” However, subparagraph (n)(2) of U.S. Munitions List (“USML”) Category XIV(b) excludes biological agents subjected to “modifications made only for civil applications (e.g., medical or environmental use)” from ITAR control.

As a result of subparagraph (n)(2), USML Category XIV(b) has largely served as an empty box for over twenty years because, as defined, Category XIV(b) biological agents constitute munitions,¹ the export licensing of which would violate U.S. multilateral regime obligations under the Biological Weapons Convention and violate U.S. law.²

It is only in recent years that the Defense Department and DDTC officials began attempts to subject certain biological agents and associated technology to ITAR control under USML Category XIV(b).

Under the subparagraph (n)(2) exclusion, the EAR and the Federal Select Agent Program have historically served the public interest by imposing intelligent restrictions on biomedical research that balances national security concerns with the need to foster university and private industry research vital to our nation’s ability to combat infectious diseases.

In the Proposed Rule, DDTC now seeks to remove the subparagraph (n)(2) exclusion and, at the same time, subject certain genetically modified biological agents, vaccines, and related technical information to ITAR control. The proposed text is as follows (emphasis added):

¹ A “Munitions List” is intended to regulate munitions and not dual-use items.

² See Article I of the Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction; 18 U.S. Code § 175(b) (“Whoever knowingly possesses any biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both.”).

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

* * *

*(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.

* * *

(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.

In addition to subjecting a variety of listed biological agents to ITAR control at USML Category XIV(b), proposed Category XIV(h)(4) seeks to impose ITAR control over “Vaccines specially designed for the sole purpose of protecting against biological agents and biologically derived substances identified in paragraph (b) of this category.” While page 34,573 of the Proposed Rule states that proposed Category XIV(h)(2) only controls vaccines when funded by the Defense Department when certain other criteria are present, it is noticeably silent on whether XIV(h)(4) applies regardless of whether the vaccines are funded by the Defense Department. This is likely a scrivener’s error. Still, to resolve this possible lack of clarity, DDTC should clearly state whether USML Category XIV(h)(4) applies regardless of Defense Department funding.

Proposed USML Category XIV(m) will impose ITAR control over technical information and research and development activities directly related to the biological agents and vaccines transferred to the ITAR under the Proposed Rule.

II. DDTC MUST ADEQUATELY DEFINE WHAT IT MEANS BY THE TERM “PERSISTENCE IN A FIELD ENVIRONMENT.”

The Proposed Rule imposes ITAR control over a list of genetically modified biological agents where the agents are subjected to non-naturally occurring genetic modifications which result in an increase in “[p]ersistence in a field environment (e.g., resistance to oxygen, UV damage, temperature extremes, or arid conditions).”

Although these types of modifications may sound scary, they are often necessary steps to the preparation of test samples used in laboratories for the development of vaccines and new drugs. As noted by Kathryn Nixdorff and Welcome Bender, distinguished professors in the fields of microbiology and genetics:

Some of the most intensive research concerns the elucidation of the mechanisms of pathogenesis. This work is essential for combating infectious diseases. It is hoped that the production of more effective vaccines with [fewer] side effects, better diagnostics and new therapeutic drugs will result from this research.³

A key question is how the State Department will interpret the term “persistence in a field environment” under the new rule. A broad interpretation of the term will subject the specified genetically modified biological agents to ITAR control even when modifications are made by a civilian agency or public health organization for the development of vaccines and new drugs.

³ Nixdorff, K., and W. Bender. 2002. “Biotechnology, Ethics of Research, and Potential Spin-off,” INESAP Information Bulletin, 19 (March): p. 19-22.

III. THE PROPOSED RULE WILL HAMPER DUAL-USE BIOMEDICAL RESEARCH BY CIVILIAN GOVERNMENT AGENCIES, PUBLIC HEALTH ORGANIZATIONS, AND PRIVATE INDUSTRY.

The expected impact of the Proposed Rule's transfer of export jurisdiction over the dual-use biomedical research at issue includes the following:

A. Prevent Timely Dissemination of Critical Public Health Information

Public dissemination of information critical to public health is not subject to a prepublication approval requirement under the EAR. However, following transfer of the specific agents and vaccines from EAR to ITAR control, technical information regarding these articles will be subject to DDTC's recently proposed "Harmonization" Rule, which seeks to explicitly require U.S. Government approval of public speech concerning technical data controlled by the ITAR.⁴

B. Create Confusion at U.S. Biomedical Research Facilities

ITAR control over technical information arising from research involving the listed agents and vaccines will create confusion over when information on the use of common laboratory equipment, such as vaporizers, fermenters, centrifugal separators, filtration, and other equipment, becomes ITAR-controlled by virtue of their use in the production of ITAR-controlled agents and vaccines.

C. Increase Burdens in Obtaining Agency Authorization

It currently takes DDTC several months or more to issue licenses and other forms of authorization, depending on the article, technical data, or services at issue. DDTC also requires complicated Technical Assistance agreements to authorize collaborative research between U.S. and foreign partners on controlled articles and technical data. Neither of these authorization burdens presently exists under the EAR.

⁴ 80 Fed. Reg. 31525, 31528 (June 3, 2015) ("Paragraph (b) of the revised definition explicitly sets forth the Department's requirement of authorization to release information into the "public domain." Prior to making available "technical data" or software subject to the ITAR, the U.S. government must approve the release through one of the following: (1) The Department; (2) the Department of Defense's Office of Security Review; (3) a relevant U.S. government contracting authority with authority to allow the "technical data" or software to be made available to the public, if one exists; or (4) another U.S. government official with authority to allow the "technical data" or software to be made available to the public.").

D. Reduces Availability of Fundamental Research Exclusion

The ITAR fundamental research exclusion is extremely narrow compared to the EAR version of the exclusion. One reason for this is that DDTC officials take the position that the exclusion does not cover exchanges of technical information arising from fundamental research to foreign nationals during the performance of research involving articles subject to the ITAR. Under this application of the exclusion, DDTC officials instruct that the disclosure of the results of fundamental research and any other information, regardless of if in the public domain, to foreign persons for use in research involving a defense article constitutes a defense services requiring DDTC authorization. DDTC also does not presently recognize the fundamental research exclusion for work performed at Federally Funded Research Facilities or at private research institutions. As a result of this narrow DDTC application of the fundamental research exclusion, DDTC authorization will be required for the inclusion of foreign nationals in research involving the agents and vaccines transferred to ITAR control by the Proposed Rule.

E. Bar Certain Foreign Students in the U.S. from Participating in Various Biomedical Research Activities

Once transferred to the ITAR, the biological agents, vaccines, and related technical data will be subject to the United States arms embargo described at ITAR Section 126.1, which generally prohibits exports of articles, technical data, and defense services listed on the USML to China, Vietnam, and many other countries. Many graduate students from these countries are presently involved in biomedical research at U.S. universities and research institutions. Therefore, applying this new control alongside DDTC's narrow interpretation of the Fundamental Research and other university-based exclusions will require universities to exclude many valued foreign national students from biomedical research concerning the transferred agents and vaccines.

F. Reduce University Participation in Vaccine Development and Various Other Biomedical Research Activities

Many of the best U.S. universities follow an "Open Research" policy. These universities are committed to maintaining non-discrimination, academic freedom in publications, and the free exchange of ideas. These universities therefore maintain a policy not to undertake ITAR-controlled research that requires exclusion of students based on their nationality and/or restrictions on the publication and dissemination of research results. As a result, imposition of ITAR control over the biological agents at issue will result in a substantial reduction in university participation in biomedical research on how to combat these threats. This impact is contrary to our national security interests.

G. Impede U.S. Interoperability with Allies and Involvement in Global Response to Biological Threats

The majority of biological threats to U.S. persons come from abroad. Foreign partners, to include major U.S. allies, generally refrain from research involving ITAR-controlled technologies because the ITAR restricts retransfers and reexports of any foreign technology that incorporates ITAR-controlled technology. As a result, imposition of ITAR control over biomedical research will discourage foreign governments, public health organizations, and private companies from collaborating with their U.S. counterparts. This will hamper the interoperability of U.S. and allied civilian government agencies as well as international partnerships in the private sector necessary to our nation's pandemic preparedness.

H. Outright Prohibits Working with Over Twenty Countries and Their Nationals on Biomedical Research

As noted above, once transferred to the ITAR, the biological agents, vaccines, and related technical data will be subject to the United States arms embargo described at ITAR Section 126.1. This creates an absolute prohibition on the sharing of any agents, vaccines, technical data, and related services transferred to the ITAR, regardless of whether the sharing is necessary to the transfers with embargoed countries in the prevention of disease, or for other peaceful purposes. The transfer of biomedical research under the Proposed Rule is therefore contrary to U.S. multilateral regime obligations, an issue further discussed in the letter sent to the BIS NTC. It is also contrary to the recently promulgated U.S. Policy on Oversight of Dual Use Research of Concern ("DURC"), which provides, "The United States Government will facilitate the sharing of the results and products of life sciences research conducted or funded by United States Government agencies, and honor United States Government obligations within relevant international frameworks and agreements, while taking into account United States' national security interests."⁵

IV. NO LEGITIMATE RATIONAL IS PROVIDED FOR THE CHANGES.

As explained above, the Proposed Rule will prevent timely dissemination of critical public health information, create confusion at U.S. biomedical facilities, bar certain foreign students from participating in various biomedical research activities, reduce university participation in vaccine development and various other biomedical research

⁵ United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern, U.S. Department of Health and Human Services at Section (3)(d) (March 29, 2012). This policy has since been updated on [September 2014](http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern), available at <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>

activities, impede U.S. interoperability with allies and involvement in global response to biological threats, and conflict with U.S. multilateral obligations and policy on DURC.

The Proposed Rule provides little in the way of any actual justification for the proposed transfers in jurisdiction. Instead, page 34,572 of the Proposed Rule summarily claims that the imposition of ITAR control over biomedical research will “advance 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.” This boilerplate claim defies logic.

The Proposed Rule also fails to explain how the adverse impacts of the Proposed Rule outweigh any perceived benefits or whether the agency has considered any less drastic alternatives.

V. RECOMMENDED REVISIONS

Based on the above and for the reasons stated in the letter to the Department of Commerce Bureau of Industry and Security Office of Nonproliferation and Treaty Compliance, DDTC should not impose ITAR-control over dual-use biomedical research.

To the extent the Defense Department is concerned with exports of any agents or technical information developed by its own programs, it can simply classify the agents and information. Relevant here, page 34,572 of the Proposed Rule states that “[i]tems 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.” If this is true, classification is the proper mechanism of control rather than the confusion caused by the proposed changes.

Alternatively, if DDTC is committed to subjecting the dual-use biomedical items and technology to ITAR control, developmental countermeasures would already be caught under proposed USML Category XIV(n), which would impose ITAR control over developmental countermeasures funded by the Defense Department via contract or other funding authorization.

To the extent that classification and Category XIV(n) are not considered adequate to cover agents and vaccines in production, DDTC should at least narrow the scope of ITAR control to catch only those agents and vaccines produced with Defense Department funding. Such a bright line will allow universities, public health organizations, and private research institutions to avoid ITAR control over the transferred items and technology by refusing to accept Defense Department funding.

* * *

Thank you for your consideration.

Yours truly,

ON BEHALF OF THE FIRM



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August 17, 2015

Department of State
Bureau of Political-Military Affairs
Department of Defense Trade Controls
2401 E Street, N.W.
12th Floor, SA-1
Washington, D.C. 20522

ATTN: Mr. C. Edward Peartree, Director, Defense Trade Controls Policy

SUBJECT: Honeywell Response to Proposed USML Category XIV Changes

Reference: Federal Register Vol. 80, No. 116, amendment to the International Traffic in Arms Regulations: Revision of U.S. Munitions List Category XIV and XVIII, published June 17, 2015.

Dear Mr. Peartree:

Honeywell International Inc. provides the following comments with regard to the proposed changes to ITAR Category XIV.

Specific concerns and requests for clarification are outlined below:

1. The proposed language in USML Category XIV(a) and USML Category XIV(b) includes terms that appear to have two distinctly different reasons for control.
 - a. Category XIV(a) states "Chemical agents, **to include;**" and
 - b. Category XIV(b) states Biological agents and biologically derived substances and genetic elements **thereof as follows....."**

Honeywell is requesting whether the term "**to include**" and the list of chemical agents under Category XIV(a) is all inclusive or only a representation or examples of chemical agents controlled under the ITAR?

Honeywell is requesting whether the term "**thereof as follows**" and the list of Biological agents and biologically derived substances and genetic elements under Category XIV(b) is all inclusive or only a representation or examples of Biological agents and biologically derived substances and genetic elements controlled under the ITAR?

2. The condition regarding defense contract under Cat. XIV (f)(2) appears to be rather vague and subjective. The language as written states:

***(f)** Equipment or items, as follows:

“(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.”

Honeywell is seeking clarification regarding whether or not the business cases described below are considered outside the scope of Cat. XIV (f)(2) and not subject to export control under the ITAR:

- a. A company receives a contract from a U.S. military end user (e.g., DoD, Air Force, etc.) in which there is no USG funding but the contract stipulates that the detector’s alarms activate at specific values directed by the customer; however, the values are within the already advertised alarm settings range for the detector. The company creates unique part numbers for the gas detector units sold to the military end user with the alarm settings specified in the military contract. These gas detectors have the same form, fit, function and performance capability as the detectors sold in commercial applications with the exception of the alarm settings.
- b. A company receives a contract from a U.S. military end user in which there is no funding but the contract specifies the detector’s alarm set point for detecting a substance not identified as a USML Category XIV item or otherwise “classified.” The detector’s alarm set points are within the published/advertised alarm range and are available to both commercial and military customers. The detector also provides the customer the ability to adjust the alarm set point by themselves without manufacturer’s assistance as long as the alarm range conforms to a manufacturer’s specification.
- c. A company sells a vapor and gas detector that detects a variety of organic compounds and is not specially designed for any one chemical. The detector is an ideal instrument for applications such as industrial hygiene, indoor air quality, hazmat response, homeland security and military applications. The detector has the ability to detect a wide variety of volatile organic compounds including some items specified in USML XIV but it cannot identify any specific chemical gas. In fact, it takes the measurement of all VOC compounds being detected and simply provides the user with a total VOC detected reading. For the

purpose of the term "detection" specified in USML XIV(f)(2), is it the intent to treat the term "detection" independent of "identification? Or is it the intent to subject a detector to USML XIV(f)(2) when it is developed under a Department of Defense contract or other funding authorization for the "detection **AND** identification" of items controlled in USML XIV(a) or (b)?

If you have any questions or would like to discuss any of the comments provided above, feel free to contact the undersigned at 202-662-2641 or via e-mail at dale.rill@honeywell.com.

Sincerely,

A handwritten signature in black ink that reads "Dale Rill". The signature is written in a cursive, flowing style.

Dale Rill

Director, Export Control and Compliance
Honeywell International Inc.



August 17, 2015

Office of Defense Trade Controls Policy
Department of State
2401 E Street NW, SA-1, Room H1200
Washington, DC 20037

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

To Whom It May Concern:

IPG Photonics Corporation appreciates the opportunity to comment on the proposed changes to the Category XVIII of the U.S. Munitions List ("USML").

1. IPG Photonics Background

IPG Photonics Corporation ("IPG") is the leading developer and manufacturer of a broad line of high-performance fiber lasers, fiber amplifiers and diode lasers used for diverse applications, primarily in materials processing. Key materials processing includes cutting, welding drilling, marking, engraving, brazing, annealing and 3D additive manufacturing. Fiber lasers are a relatively new generation of lasers that combine the advantages of semiconductor diodes, such as long life and high efficiency, with the high amplification and precise beam qualities of specialty optical fibers to deliver superior performance, reliability and usability.

A substantial majority of our products are used in materials processing applications (95.0% of sales in 2014), but our products are also used in advanced/research (3.3%), communications (1.1%) and medical applications (0.6%). We sell our products globally to original equipment manufacturers ("OEMs"), system integrators and end users. IPG markets its products internationally primarily through our direct sales force in the U.S.A. Europe and Asia.

Headquartered in Oxford, Massachusetts, IPG (NASDAQ listed: IPGP) had net sales of \$770 million in 2014, and employs over 3,000. In Oxford, Massachusetts, we employ approximately 1,000 in manufacturing, research and development, assembly and administrative capacities. In addition, IPG has research and development facilities in

Birmingham, Alabama, Mountain View, California, Santa Clara, California, and Holmdel, New Jersey. IPG exports its products internationally from the United States. For more information, visit www.ipgphotonics.com.

2. IPG Products and Customers

Our laser products include low (1 to 99 watts), medium (100 to 999 watts) and high (1,000 to 100,000 watts) output power lasers from 300 to 4,500 nm in output wavelengths. These lasers may be continuous wave (CW), quasi-CW (QCW) or pulsed. We offer several different types of lasers, which are defined by the type of gain medium they use: ytterbium, erbium and thulium, as well as Raman and hybrid fiber-crystal lasers.

Our amplifier products range from milliwatts to up to 1,500 watts of output power from 1,000 to 2,000 nm in output wavelengths. We offer erbium-doped fiber amplifiers, Raman amplifiers and integrated communications systems that incorporate our amplifiers. These products are predominantly deployed in broadband networks such as fiber to the home, fiber to the curb, and passive optical networks, and dense wavelength division multiplexing, networks.

IPG also develops and sells specialized fiber laser systems for unique material processing applications, including remote welding, micro-welding and cutting, and annealing, which are also commercial manufacturing applications.

Well over 95% of IPG sales are for non-military applications. Our largest customer in 2014 was Han's Laser, a PRC-based maker of laser cutting, welding, marking and engraving systems for the Chinese metal processing market. Other IPG customers include BMW, GM, Ford, Chrysler, a large Japanese auto maker, GE, Gillette, Foxconn, Bystronic, MAZAK, Philips, Mitsubishi Heavy Industries, Boeing and Pratt & Whitney.

3. Comments on Proposed Category XVIII

IPG's principal concern is that the proposed changes to USML Category XVIII would inadvertently control items that are currently in normal commercial use, that the proposal does not have thresholds that clearly delineate military and non-military products and that the proposal lacks sufficient clarity. Our comments are set forth below in further detail.

i. Paragraph (a) controls "directed energy weapons (DEW) as follows: systems or equipment that, as their sole or primary purpose (i.e., not as a result of incidental, accidental or collateral effect)...."

The phrase "or primary purpose" is not clear and does not satisfy the goal of the ECR in "establishing a bright line" between the USML and the Commerce Control List (CCL) for the control of systems or equipment that may be DEW. Although the proposal

attempts to qualify “primary purpose” with the parenthetical “i.e., not as a result of incidental, accidental or collateral effect”, it is not clear if the meaning of “primary purpose” is all purposes other than “incidental, accidental or collateral effect”, or if “primary purpose” is any purpose(s) totaling greater than 50%. Also, the proposal does not specify the metrics to measure “primary purpose” and is lacking in this regard. We note also that the parenthetical (“i.e., not as a result of incidental, accidental or collateral effect”) refers to “effects” rather than the “purpose” or goal of the DEW systems and equipment. The use of these different terms (effects and purpose) adds to the uncertainty of the new proposal.

Further, the phrase “primary purpose” does not appear elsewhere in the USML as determined by a search of the USML. Nor does the phrase “primary purpose” have a separate definition in the USML or descriptive criteria. The introduction of new terms detracts from the potential benefits of re-writing this rule.

Each year, thousands of high power laser sources (including CO₂, Nd:YAG, fiber, disc or diode) are sold to manufacturers of commercial laser systems. These laser systems are used to remotely cut, weld or drill commercial materials from a distance of several meters or more commonly using industrial robots. In some cases, lasers are now used to safely demolish or decommission structures or materials at a distance, called remote cutting, welding or processing. These laser systems are not in research or development, but are in actual use.

See, e.g., <http://www.twi-global.com/capabilities/joining-technologies/lasers/decommissioning-using-lasers/>

<http://www.industrial-lasers.com/articles/print/volume-30/issue-4/features/progress-in-the-use-of-laser-cutting-for-decommissioning.html>

http://www.ipgphotonics.com/apps_mat_lab_welding.htm

Some remote cutting systems are in the nuclear and offshore oil and gas sectors. One feature these applications have in common is that the resulting cut quality is not a particular issue. The main criterion in decommissioning is that the parts being cut must separate. These are clearly commercial applications and do not involve the high powers, precision control, packaging, size or reliability required for DEW systems and equipment. It is a special concern to us that the remote use of laser systems and equipment for common industrial purposes may be covered by proposed paragraph (a) of Category XVIII. The proposed rule does not have any thresholds that clearly delineate military and non-military products. A substantial majority of DEW systems remain in development, rather than production. Government requirements continue to evolve. As a result, objective or numerical criterion is difficult to specify currently because government requirements are not firmly established.

We suggest that the words “or primary” be omitted from the final rule for the foregoing reasons. In lieu of “sole or primary purpose”, we propose using the term

“specially designed” in paragraph (a). Paragraphs (b) and (e) of proposed Category XVIII employ “specially designed” and the inconsistency in proposed paragraph (a) leads to confusion in understanding the coverage of the new rule. In addition, a rewritten Category XVIII should fully implement the “specially designed” criteria to ensure that products with commercial applications are placed on the CCL, as opposed to the USML. The “specially designed” criteria as defined in §120.41 of the USML, should be applied fully to Category XVIII. The Department of Defense and the Department of Commerce agreed upon a definition and on October 15, 2013, the “specially designed” definition was finalized. Subsequently, this criteria was applied to USML categories as they were individually revised in the ECR process. However, in the Category XVIII proposal, the use of “specially designed” is not fully applied. There is, also, no similar criteria to interpret “primary purpose”.

Additionally, the munitions list should also align with the internationally agreed upon Wassenaar Munitions List. Commodities and components not specially designed for military purposes or on the Wassenaar Munitions List should be controlled under the CCL. Though still controlled under the CCL, the list controlled by the Department of Commerce allows for more flexibility on how controls are applied, and can adjust to conditions more quickly than items under the USML.

ii. Paragraph (a) also lacks clarity because it omits appropriate punctuation in the phrase “or cause permanent or flash blindness using any non-acoustic technique such as lasers...particle beams, particle accelerators...or high pulsed power or high average power radio frequency beam transmitters.” It is not clear if the list of non-acoustic techniques pertains only to permanent or flash blindness or if it also pertains to the other effects listed previously in the paragraph, *i.e.*, degrade, destroy or cause mission-abort of a target; disturb, disable, or damage electronic circuitry, sensors or explosive devices remotely; deny area access. We believe that the intent in paragraph (a) is for the non-acoustic techniques to modify all of the effects listed and, for this reason, we propose the following punctuation modifications to paragraph (a):

(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); (i) degrade, destroy or cause mission-abort of a target; (ii) disturb, disable, or damage electronic circuitry, sensors or explosive devices remotely; (iii) deny area access; cause lethal effects; or (iv) cause permanent or flash blindness, using for the effects in clause (i) to (iv) of this paragraph (a) 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 radiofrequency (RF), or high pulsed power or high average power radio frequency beam transmitters.

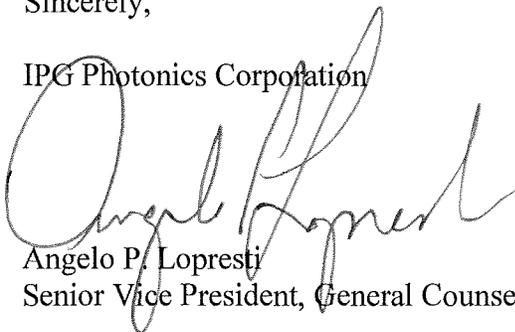
[Additions][deletions]

4. Conclusion

Thank you for this opportunity to comment on the proposed changes to the Category XVIII of the USML. If you would like to discuss this letter further or need other information, please contact me at 508-373-1123 or alopresti@ipgphotonics.com.

Sincerely,

IPG Photonics Corporation

A handwritten signature in black ink, appearing to read "Angelo P. Lopresti". The signature is written in a cursive style with a large initial "A".

Angelo P. Lopresti
Senior Vice President, General Counsel and Secretary

Various commercial products such as B. E. Myers GLARE or L E Systems CHP Laser Dazzler employ lasers to provide signaling and warning to persons approaching a restricted area such as a check point. The Marine Corp uses the term "Ocular Interruption", The Army, "Laser Interdiction" and commercial literature contains terms such as "laser hail and warning" and "visual disruption". The term "Flash Blindness" in the proposed definition of a Directed Energy Weapon has no scientific meaning. If referring to temporary blindness caused by laser emissions that are not eye safe at aperture it is suggested that parameters involving a unit's NOHD (Nominal Ocular Hazard Distance) under various circumstances and conditions be used to differentiate a device whose purpose is signaling from a true weapon designed to injure or destroy. If temporary ocular interruption or visual disruption is meant then parameters should be established for a typical subject to recover intelligible images similar to motor vehicle eye tests for recovery after being blinded by headlights. In both cases the objective is to differentiate a device designed to signal and capture a subject's attention under various lighting and environmental conditions for the purpose of warning them they are approaching a restricted or controlled area from a true energy weapon.

Noel D. Matchett

President

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August 17, 2015

Department of State
Bureau of Political-Military Affairs
Department of Defense Trade Controls
2401 E Street, N.W.
12th Floor, SA-1
Washington, D.C. 20522

ATTN: Mr. C. Edward Peartree
Director, Defense Trade Controls Policy

SUBJECT: ITAR Amendment—Categories XIV and XVIII

Dear Mr. Peartree:

Northrop Grumman Corporation (NGC) wishes to thank the Department for the opportunity to submit comments in review of the above proposed rules as we support the Department's objective of establishing a positive United States Munitions List (USML). In response, NGC provides the following recommendations:

Category XIV (f)(4): Recommend all of these protective items be moved to the CCL under 1A607. This proposed ECCN provides more than adequate levels of control and such classification would better enable exports to our allies as well as support individuals deploying in support of USG Operations.

If these protective items remain under Category XIV (f)(4), they should not be designated Significant Military Equipment (SME).

Further, if these protective items remain under Category XIV (f)(4), paragraph XIV(f)(4)(iv) should be revised (similar to paragraph (i)) to specify or enumerate whether the most common protective gear such as the Joint Service Lightweight Integrated Suit Technology (JSLIST) or Uniform Integrated Protection Ensemble (UIPE) is USML or CCL. This would greatly assist exporters since typically, brochures for the clothing/gear do not specify performance thresholds as described on the proposed rule but use more general language, such as "The gloves provide protection from battlefield concentrations of all known agents for up to 30 days." The current system performance specifications for the UIPE uses a completely different evaluation standard than that described in the Note to paragraph (f)(4)(iv).

Category XVIII: Recommend rewriting paragraph (a) as an enumerated list (i.e., add subparagraph listings) to be consistent with other categories. Also recommend adding a note to paragraph XVIII(a) to clarify this does not control items otherwise captured in USML Cat XI(a)(4)(iii) or Cat XII(b)(9).

Should clarification or subsequent technical discussions be necessary, please contact either Steve Headley at james.headley@ngc.com, (703 280-4806), or myself at thomas.p.donovan@ngc.com (703-280-4045).

Sincerely,

A handwritten signature in blue ink, appearing to read 'T. P. Donovan', with a long horizontal flourish extending to the right.

Thomas P. Donovan
Director, Export Management
Global Trade Management



PPG Industries, Inc.
One PPG Place
Pittsburgh, PA 15272

August 13, 2015

C Edward Peartree, Director
Office of Defense Trade Controls Policy
Department of State
SA-1, 12th Floor
Washington, D.C. 20522-0112

Subject: Regulatory Change: ITAR Amendment –Categories XIV and XVIII

Dear Mr. Peartree,

PPG Industries Inc. (PPG) appreciates the opportunity to comment on the proposed changes to the United States Munition List (USML) and the Commerce Control List (CCL) under Federal Register notices 80 FR 34572 and 80 FR 34562 as they relate to Chemical Agent Resistant Coatings (CARC). CARC provides protection against chemical and biological agents as well as high corrosion resistance. CARC is available globally and is being used extensively by the commercial airline industry in Europe. For example, CARC (without IR absorbing properties) is used on the landing gear due to its superior corrosion resistance property.

Presently, the United States controls CARC under Category XIV(f)(5) of the USML: *“Equipment and its components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment as follows: (5) Collective protection against the chemical agents and biological agents listed in paragraph (a) and (b) of this category.”*

Based on the Federal Register notices published in June 2015, PPG understands that, in the future, some CARC would be controlled under Category XIV(f)(7) of the USML and some under the newly created Export Control Classification Number (ECCN) 1A607.f of the CCL.

It further appears that only CARC qualified to three military specifications would be covered by the USML: **(f) Equipment or items, as follows: (7) Chemical Agent Resistant Coatings that have been qualified to military specifications (MIL-DTL-64159, MIL-C-46168, or MIL-C-53039), while all other CARC coatings would be controlled under ECCN 1A607: Military dissemination “equipment” for riot control agents, military detection and protection “equipment” for toxicological agents (including chemical, biological, and riot control agents), and related commodities (see List of Items Controlled). f. Protection “equipment” (including air conditioning units and protective clothing): f.1. Not controlled by USML Category XIV(f); and f.2. “Specially designed” for military use and for defense against: f.2.1. Materials specified by USML Category XIV (a) or (b); or f.2.2. Riot control agents controlled in 1C607.a.*



Based on this understanding, PPG submits that this proposed rule should be reconsidered altogether and, if not, at least clarified.

- **Reason for Reconsideration:**

PPG manufactures and sells coatings and sealants worldwide to various industries, including the aerospace industry. Currently, PPG does not manufacture any CARC in the United States, but does in some European countries. As PPG has a global export compliance program, PPG has become aware of the classification and treatment of CARC under the export laws in the other countries where PPG operates. More specifically, PPG has received ratings from the U.K. and the French governments regarding CARC and has been informed that, in these countries, CARC is not listed as subject to control (See Exhibit A).

This disparity in classification puts American companies at a competitive disadvantage as multi-national companies would rather purchase non-controlled materials for their projects. It has also been cause for some confusion particularly among these multinationals as the non-controlled product they buy in Europe becomes controlled when shipped to or through the United States. Consequently, this classification inconsistency heightens the risk for unintentional violations.

Therefore, PPG strongly recommends that the United States aligns its export control classification of CARC with that of its allies.

- **Reasons for Clarification:**

If CARC must remain export controlled in the United States, then it would be best if all CARC continued to be under the control of one agency as the current proposal of splitting the jurisdiction of CARC to both the ITAR and the EAR will only complicate the jurisdiction and classification process.

More specifically, the proposed language does not address under which agency a product being developed to meet the properties in CARC should be controlled until it is tested and qualified appropriately. Would the product be classified under ECCN 1A607 during the development phase and then move to Category XIV(f)(7) after qualification?

Additionally, PPG would like to suggest that the proposed rules be revised to add clarity to the control requirements.

- **DDTC Notice:**

- The word “qualifies” in the proposed USML definition [**(f) Equipment or items, as follows: (7) Chemical Agent Resistant Coatings that have been qualified to military specifications (MIL-DTL-64159, MIL-C-46168, or MIL-C-53039)*] should be clarified as this language would appear to exclude any CARC paint which would generally “meet the requirements” of one of these specifications but has not been “qualified” by testing and placed on the Qualified Product List (QPL).



Qualification testing for CARC can only be done by a limited amount of testing sites due to the sensitivity of the chemical and biological agents. Therefore, when manufacturers need to modify a previously qualified CARC paint for color or gloss, they do not always re-test the new paint. Based on the proposed definition, the manufacturer may not consider the new paint as “qualified” in the strict sense of the word and therefore might not think of controlling it under Category XIV(f)(7) of the USML.

- The current proposal seems to be limited to three specifications: MIL-DTL-64159, MIL-C-46168 and MIL-C-53039 (which, by the way, is not the correct reference for that specification, it should be “MIL-DTL-53039”). It would therefore appear that paints that would be qualified to other specifications, such as the relatively new military specification for Powder CARC (MIL-PRF-32348) or any non U.S.-specifications, would not be subject to the ITAR but fall under the EAR. If this was not DDTC’s intent, the rule should be clarified in order to better define which CARC paints fall under the USML.
- USML Category XIV(f)(5) is currently denoted as Significant Military Equipment (“SME”), however DDTC published guidance on September 14, 2009 which specifically states that CARC is not to be considered SME. It would be much clearer if DDTC would note this exception in its updated regulation. (See Exhibit B)
- On July 12, 2010, PPG was informed that the CARC properties of a coating having both CARC and Infra-Red properties determine the export controls applicable to the product. Therefore, such a product would be classified under USML XIV(f)(5) as opposed to XIII(j)(2). PPG suggests that this informal guidance be stated in the regulation for clarity and completeness.
- Finally, on May 13, 2014, DDTC also advised PPG, under case GC0887-14, that items controlled on the CCL do not become subject to the ITAR simply because they are painted with CARC. As this question is frequently asked of PPG by part manufacturers, it would be helpful if DDTC could add a statement into the USML re-affirming the above advice. (See Exhibit C)

➤ **BIS notice:**

PPG understands that all CARC that are not qualified to the three specifications identified in the USML would now be controlled for export under ECCN 1A607. This ECCN covers:

“Military dissemination “equipment” for riot control agents, military detection and protection “equipment” for toxicological agents (including chemical, biological, and riot control agents), and related commodities (see List of Items Controlled).



- f. Protection "equipment" (including air conditioning units and protective clothing):*
- f.1. Not controlled by USML Category XIV(f); and*
 - f.2. "Specially designed" for military use and for defense against:*
 - f.2.1. Materials specified by USML Category XIV (a) or (b); or*
 - f.2.2. Riot control agents controlled in 1C607.a.*
- As this definition only mentions the term "equipment" and does not specifically mention the term "Chemical Agent Resistant Coatings," it is not intuitive to industry that a paint would be included into this definition. It is even more confusing for the companies which are familiar with the EU military list as the definition under ML 7.f (see below) is similar to the definition of ECCN 1A607 but does not control CARC.
- f. Protective and decontamination equipment, specially designed or modified for military use, components and chemical mixtures, as follows:
- 1. Equipment designed or modified for defence against materials specified by ML7.a., ML7.b. or ML7.d., and specially designed components therefor;

Therefore, PPG suggests that the ECCN definition be updated to either include the term CARC or the word "material" which is more likely to be thought as encompassing coatings.

Again, PPG thanks both DDTC and BIS for this opportunity to comment on these proposed rules and welcomes any questions that may arise from these comments.

Please feel free to contact Mary Lynn Smith, Military Supervisor, at 412-434-2332 or at mlsmith@ppg.com if you have any questions or concerns.

Sincerely,

Patricia Doublet-Raymond
Manager, Export Compliance

EXHIBIT A

Our Ref: ERE2010/001348
Your Ref: ECRR001-150410
SPIRE Doc Ref:475400

Mr Carson
PPG INDUSTRIES (UK) LIMITED
PO BOX 162 NEEDHAM ROAD
STOWMARKET
SUFFOLK
IP14 2ZR

Date: 24th May 2010

Export Control Organisation

1 Victoria Street
London
SW1H 0ET

Tel +44 (0)20 7215 4594
Enquiries +44 (0)20 7215 5000
Mnicom +44 (0)20 7215 6740

www.bis.gov.uk
eco.spire@bis.gsi.gov.uk

Dear Mr Carson,

Thank you for your enquiry of 16th April 2010 for the export of goods, software and/or technology to France.

Goods, software and/or technology that we assess do not require an export licence from this Department are denoted by 'NLR' in the attached Schedule. This is because they are not listed as subject to control in any of the current legislation administered by the Export Control Organisation (ECO).

Other export controls may apply however. Please see website links found in the attached Supplementary Guidance.

Exporters are encouraged to consult the current export control legislation, to familiarise themselves with export controls and make their own evaluation of the need for export licences. These publications may be purchased from The Stationery Office (TSO) (0870 242 2345) or viewed online at The Office of Public Sector Information (OPSI) Internet site: <http://opsi.gov.uk/legislation>.

This assessment has been made taking into account the information given in your enquiry dated 16th April 2010 and attachments.

Yours sincerely

Validity unknown

Digitally signed by Licensing Casework Group
Date: 2010.05.24 09:09:08 +0100
Reason: On behalf of the Secretary of State
Location: Department for Business,
Innovation and Skills

Mr Peter Jessup
Export Control Organisation

Schedule of Goods Assessed

The following is our assessment of the goods enquired about.

#	Description	Control Entry	Relevant Legislation
1	8300 Series, High Solids Polyurethane Gloss Finish Part No: 8300*****E	NLR	
2	8311 Series, High Solids Polyurethane Matt Finish Part No: 8311*****E	NLR	

EXHIBIT B

9/14/09

DSP-83 Requirements for Licensing of Chemical Agent Resistant Coatings (CARC) Paint – Category XIV(f)(5)

Effective immediately, the Directorate of Defense Trade Controls no longer requires a DSP-83 to accompany licenses for the permanent export of CARC Paint under USML Category XIV(f)(5). Although USML Category XIV(f) is designated as Significant Military Equipment (SME) in its entirety, the Department has determined CARC paint does not possess “substantial military utility or capability” (see 22 CFR 120.7(a)). This determination **does not** apply to other items in USML Category XIV(f).

When submitting a DSP-5 via D-Trade, the selection of any SME category in block 11 automatically identifies the item as SME and makes the DSP-83 a mandatory document. Follow these procedures to submit your license without the DSP-83:

- Enter “XIV(f)” in Block 11.
- When asked if a DSP-83 is attached – answer “NO”
- When further asked “If SME, and a DSP-83 is not attached, state why.” – answer “DDTC Web Notice 9/14/09 ref: DSP-83 for CARC.”
- Please **do not** attach a copy of this web notice to each license submission

Any questions or concerns should be directed to Tony Dearth, Chief of Space and Missile Technology Division, deartham@state.gov.

EXHIBIT C



United States Department of State

*Bureau of Political-Military Affairs
Directorate of Defense Trade Controls*

Washington, D.C. 20520-0112

MAY 13 2014

In Reply Refer to
DTC Case GC 0887-14 (RE-ISSUE)

Ms. Mary Lynn Smith
ITAR Supervisor
PPG Industries Inc.
One PPG Place
Pittsburgh, PA 15272

YOUR LETTER DATED: March 24, 2014
**SUBJECT: Classification of "600 Series" Parts and Components Enhanced with
Chemical Agent Resistant Coatings (CARC)**

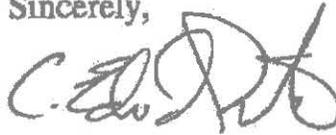
Dear Ms. Smith:

The Department of State has reviewed your request for a determination on the requirements, or lack thereof, for validated licenses involving "600" series parts and components that have been painted with CARC. The Directorate of Defense Trade Controls has determined that CARC coating on an item, in and of itself, does not provide a military capability warranting United States Munitions List control. Hence items that are controlled on the Commerce Control List, to include vehicles and equipment, do not become subject to the International Traffic in Arms Regulations simply due to the application of CARC paint. This finding is based on numerous Commodity Jurisdiction precedents spanning ten years.

In Reply Refer to
DTC Case GC 0887-14 (RE-ISSUE)

Should you require further assistance on this matter, please contact Rick Koelling,
(202) 663-2828 or KoellingRW@state.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Edward Peartree". The signature is stylized and cursive.

C. Edward Peartree
Director
Office of Defense Trade Controls Policy

smiths detection
bringing technology to life

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August 17, 2015

Sent via email to: DDTCPublicComments@state.gov

C. Edward Peartree
Director, Office of Defense Trade Controls Policy
Directorate of Defense Trade Controls
Bureau of Political Military Affairs
U.S. Department of State
Washington, DC 20522-0112

RE: Comments on Proposed ITAR Amendment – Categories XIV and XVIII

Dear Director Peartree:

Smiths Detection (“Detection”), a division of Smiths Group plc, appreciates the opportunity to comment on the proposed changes to the U.S. Munitions List (“USML”) of the International Traffic in Arms Regulations (“ITAR”), as described in the State Department’s proposed rule published in the *Federal Register* on June 17, 2015 (80 *Fed. Reg.* 34572 (June 17, 2015)) (the “Proposed Rule”), proposing changes to USML Category XIV and XVIII. The Proposed Rule requested public comment on various aspects of the rule, including the goal of establishing a “bright line” between the USML and the Commerce Control List (“CCL”) for the control of the items in question. Detection supports the goal of establishing a “bright line” between the two current control lists to determine on which list an item is controlled. The development of “positive lists” to describe controlled items, using objective criteria, and the elimination, to the extent possible, of broad, open-ended, subjective, generic, or design intent-based criteria from the USML and the CCL will support the overall goals of export reform.

Please accept our comments below on the Proposed Rule. Our comments address only the proposed Category XIV.

Category XIV in its current form controls toxicological agents, including chemical agents, biological agents, and associated equipment, including, in paragraph (f)(2), equipment and its components, parts, accessories, and attachments, specifically designed or modified for military operations, for the detection, identification, warning or monitoring of the chemical and biological agents listed in paragraphs (a) and (b). Examples of Detection items that are controlled under paragraph (f)(2) now are Joint Program Chemical Agent Detectors which are worn and / or hand-carried by military personnel; stationary Biological Agent Detectors which were developed for the U.S. Army and are still in use by several foreign governments military organizations.

We read the proposed revisions to Category XIV as relinquishing ITAR control over all detection equipment specially designed for military use and for the detection or identification of agents listed in the proposed paragraph (a) or (b), with two exceptions. We read the proposed revisions to Category XIV as maintaining ITAR controls:

- (i) in proposed paragraph (f)(8), on any detection equipment, material, tooling, hardware or test equipment that is classified, is manufactured using classified production data, or is being developed using classified information; and
- (ii) in proposed paragraph (f)(2), on detection equipment containing reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a Department of Defense (“DoD”) contract or other funding authorization for the detection, identification, warning, or monitoring of agents controlled in proposed paragraph (a) or (b), or other agents specified by a DoD contract or other funding authorization, PROVIDED, pursuant to proposed Note 3 to paragraph (f)(2), that the contract or funding authorization is dated one year after the date of publication of the final rule, or later.

Stated more simply, we read the proposed revisions to Category XIV as relinquishing ITAR control over all currently ITAR-controlled military detection equipment unless it is classified or relates to classified information. All currently existing, non-classified, military detection equipment appears to be covered under the proposed Export Control Classification Number (“ECCN”) 1A607.h, which will cover “‘equipment’ not controlled by USML Category XIV (f), and ‘specially designed’ for military use and for the detection or identification of materials specified by USML Category XIV(a) or (b). . . .” The only non-classified military detection equipment that will remain controlled on the USML should the Proposed Rule become final in its current form, would be detection equipment developed in the future for the DoD (i.e., one year or later after publication of the final rule).

We also read the proposed revisions to Category XIV as relinquishing ITAR control over all specially designed parts, components, accessories or attachments, of all military detection equipment (whether such equipment will be classified under the proposed USML Category XIV(f)(2) or (f)(8) in the future). This is because there is no paragraph in the proposed USML Category XIV that purports to enumerate or otherwise describe

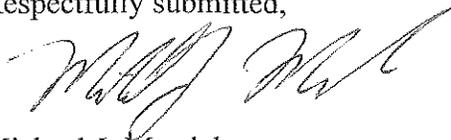
parts, components, accessories or attachments of military detection equipment (whether or not such equipment is classified).

We request the State Department's affirmative confirmation of our interpretations of the Proposed Rule.

Assuming that our reading of USML Category XIV (f)(2) is correct, and that (f)(2) will remain empty until at least one year after publication of the final rule, pursuant to Note 3, Detection requests that the State Department address a consequent question. This structure of control may present potential problems and confusion in the context of amendments to DoD contracts or funding authorizations. For example, if Detection is currently developing certain non-classified detection equipment under a DoD contract dated January 1, 2015, we read the proposed revisions of USML Category XIV as not covering any equipment so developed. However, what result if one year and one day after the publication of the final rule DoD requests an amendment to that contract, whereby Detection would make a minor change in development? Which date would control, January 1, 2015, or the date of the amendment, for the purpose of applying proposed Note 3 to USML Category XIV(f)(2) to the detection equipment developed under the amendment? We suggest that the State Department address this in the final rule, specifying either that the date of the original contract should govern, or the date of the amendment.

Once again, we appreciate the opportunity to comment on the Proposed Rule and we applaud the Administration for moving forward with this important initiative. If you have any questions or would like additional information, please do not hesitate to contact Paula Ireton, Trade Compliance Officer for Detection, at (410) 612-2501 or paula.ireton@smithsdetection.com.

Respectfully submitted,



Michael J. Mendelson
General Counsel, Americas
Smiths Detection Inc.



OFFICE OF THE VICE PRESIDENT - RESEARCH AND GRADUATE STUDIES

Research Policy Analysis and Coordination
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200
Web Site: www.ucop.edu/research/rpac/
Tel: (510) 587-6031
Fax: (510) 987-9456

August 17, 2015

Office of Defense Trade Controls Policy
Department of State
Washington, DC
email: DDTCPublicComments@state.gov

RE: ITAR Amendment— Categories XIV and XVIII
RIN (1400-AD03).

Dear Sirs/Madams,

The University of California (UC) system, consisting of ten research-intensive campuses and involved in the management of three DOE national laboratories, applauds the efforts undertaken by agencies committed to supporting the President's Export Control Reform initiative. UC appreciates the opportunity to provide comments which pertain to both the President's Export Control Reform (ECR) initiative in general and Category XIV in particular.

In addition to the specific comments provided below, UC strongly supports the remarks submitted the Association of University Export Control Officers (AUECO).

Category XIV(b): General Comment with regard to Select Agent, DURC, and Homeland Security Regulations

Category XIV(b) lists specific select agents and biological agents and toxins currently listed in the Export Administration Regulations (EAR), many of which are also covered by the Select Agent Program and the new Dual Use Research of Concern (DURC) Policy. The EAR regulates the physical export of select agents, but allows for inclusion of foreign national students in research at U.S. universities in most cases without an export license. Currently all individuals who wish to have access to select agents must pass a background check completed by the Department of Justice, through the Select Agent Program; such checks are not approved for nationals of terrorist supporting nations. The DURC Policy provides review and control of information and experiments for a particular set of select agents of most concern. These existing sets of regulations cover physical export, information and access controls. We feel the existing regulations adequately cover the need to control these items, while still allowing flexibility for university biological and health sciences fundamental research.

A potentially unintended consequence of elevating controls of items already covered under existing and appropriate regulations in the EAR to the proposed ITAR regulations would be to exclude participation for nationals of 126.1 countries, significantly limiting participation in this research and

requiring licensing for all foreign persons not meeting an available exemption. Participation by talented foreign scholars in fundamental biomedical research with these items is critical to the advancement of science and to the health of our nation. We question the benefit of moving these biological agents to the ITAR compared to the impact on science and the regulatory burden they will impose.

Request for clarification on ITAR XIV(b)

It seems that if literally interpreted, an expression vector that produces ebola virus envelope protein for use in pseudotyping minimal lentiviral vectors (for example to transduce cells of pulmonary origin), even though harmless in itself, might fall under these regulations, because the envelope is a pathogenicity factor to ebola virus, even in the absence of ebola virus. We recommend section (b) be clarified so this type of use of a gene of a pathogenicity factor, with the absence of the pathogen, is not caught under the proposed changes.

Request for Wording Change on ITAR XIV(b)

XIV(b)(2)

ECCN 1C352 no longer exists on the Commerce Control list as it has been combined with 1C351. Therefore, any reference of 1C352 should be removed from the proposed regulation.

XIV (b)(2)(i)(A)

The current wording is overly restrictive and in parts confusing. This is especially true for “1-10 micron particle size.” Bacteria fit in this range, so any work with pathogenic E. coli (1C351) would be unnecessarily restricted. We recommend that (b)(2)(i) be changed to eliminate (A) 1-10 micron particle size.

Note 2 to paragraph (b) suggests that the restriction would not hold for attenuated pathogenic E. coli, so only work with wild-type pathogenic E. coli would be restricted. However, we feel that this is still unnecessarily restrictive and would be an impediment to research aimed at combating infections caused by pathogenic E. coli.

We additionally request the term “persistence in a field environment” be defined so there is no regulatory ambiguity that may inadvertently capture modifications that are made for the development of vaccines and new drugs for public health.

The composition of the items listed in (b)(2) appears inconsistent, and doesn't seem to take into account the actual danger and exposure risk associated. For example, the conotoxins (1C351) are small peptides and would have to be injected to achieve toxicity. Hence, swallowing them is not likely to produce toxicity. In fact, the cone snail that makes conotoxin has to harpoon and inject the fish in order to paralyze it for food for the snail colony. The tetrodotoxins (1C351) are different and if ingested will produce toxicity. Neither of these compounds is volatile so they possess little danger with respect to inhalation. There are several marine toxins that are probably of greater risk, albeit still smaller, than the conotoxins. One also needs to consider the actual amounts of toxin used in the laboratory relative to their toxicity. We recommend the lists include exceptions depending on amount of material, actual toxicity, volatility and the potential mode of administration or portal of entry to the body.

Request for Spelling Change on ITAR XIV(c)

There are spelling errors that should be addressed for:

(4) Chlorosoman: O-Pinakolyl methylphosphonochloridate
Pinacolyl should be spelled with the “c” and not a “k”.

(5) Methlyphosponyl dichloride; Methylphosphinyldichloride .
Methyl is misspelled.

Comment on ITAR XIV(g) DOD funding

It appears these revised regulations are designed to not only control the "select agents", but also to actively restrict research on the agents from occurring even in the absence of the agents themselves (e.g. antibodies are restricted, PCR kits are restricted). Working with detection agents, like antibodies (even if naturally occurring), poses little risk of misuse since they are harmless in themselves and should not be restricted. It also seems odd that the concern is only for reagents that are funded exclusively by DOD.

Category XIV(g)(1) (also applies to XIV(h))

Restrictions should be based on the nature of the research, not the source of the funding. We are concerned that there appears to be an increasing tendency to equate Department of Defense research funding with ITAR status, regardless of the nature of research, which for universities such as UC consists of fundamental research, the results of which are shared broadly.

If however, the wording of this section is not revised, we request a note be added consistent with Note 1 to paragraph (n) and written as 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.”

Category XIV(h) Request for Clarification

Smallpox vaccine, vaccinia, is cited by the proposed regulation, but the restriction is not otherwise detailed. Does this restriction apply only to replicating vaccinia virus? To vaccinia vectored vaccines? Is having an expression vector that expresses a protein needed for vaccinia replication in the absence of the virus itself controlled? A number of candidate vaccines have used the vaccinia virus as a vector as a foreign gene for immunization. We request that this be clarified as these expression constructs are important for infectious disease research.

Request to Reinstate Current ITAR XIV(n)

It appears that Section XIV(n) from the current USML has been removed in the proposed regulations. This section contained an exemption for modifications to biological agents made for civilian applications (i.e., medical use), which includes the vast majority of research conducted at universities with the items listed in the proposed regulations. Universities use this paragraph to justify why an

ITAR license is not required for some biological research. We request that XIV(n) be reinstated into Category XIV.

Specific Impact Examples

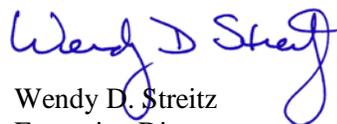
The new proposed ITAR regulations would constitute a serious impediment to many researchers' programs. For example, a neuroscientist at one of our campuses has indicated that his lab has numerous graduate students and postdoctoral fellows from around the world involved in his research program using Tetrodotoxin (TTX) (1C351) and several of the Conotoxins (1C351) to specifically block different classes of neuronal ion channels and thereby understand their function related to brain plasticity. UC is scrupulous in handling these toxins carefully according to the existing regulations including Select Agent regulations and the government policy on DURC. Our ability to make discoveries positively impacting human health would be inhibited if participation by talented students and scientists were restricted by the proposed ITAR XIV (b)(2)(i) parameters.

Having access to the TTX reagent is essential for our neurophysiological analysis of neural networks, funded primarily by NIH and other entities, not DOD. Some of the most experienced and capable people in an example lab include scientists and post-doctoral scholars from Italy, the UK, and China at the moment. If these foreign nationals, all of whom are here on legal visa status, were to be prevented from carrying out basic, publishable experiments in the lab, as the new regulations seem to imply, this would greatly hinder our ability to advance this research.

International collaborations involving the exchange of technical data could be severely hampered due to an increase in licensing, technical assistance agreements and proposed security review requirements for public domain release should these proposed regulations on biological agents and definitions (80 Fed. Reg. 31525, 31528 (June 3, 2015)) come into force as currently drafted. Interactions with our civilian and academic research partners overseas are increasingly critical, including to address health epidemics, and our inability to participate would leave the U.S. behind in related scientific advancements. We urge regulators to balance safety and security with facilitating scientific advancement and the ability to address global health crises. We understand the need to regulate physical exports, but research in university labs by foreign nationals legally admitted to the United States is already governed by the EAR, Select Agents Program and DURC policy, and beyond that should be unhindered for the performance of fundamental research. Furthermore, the proposed revisions could result in a chilling effect of research universities foregoing DOD-funded innovative research if it means that such work would automatically lose protections afforded by the fundamental research exclusion.

Thank you for this opportunity to comment. We greatly appreciate your efforts to seek input from stakeholders.

Sincerely yours,



Wendy D. Streit
Executive Director
Research Policy Analysis & Coordination
Office of Research & Graduate Studies



University of Pittsburgh

Office of Export Control Services

August 17, 2015

University Club B21
123 University Place
Pittsburgh, PA 15213
412-624-7400
Fax: 412-624-7409

C. Edward Peartree
Director
Office of Defense Trade Controls Policy
U.S. Department of State
2401 E Street, N.W.
Attn.: ITAR Amendment – USML Categories XIV and XVIII
Washington, DC 20522

RE: ITAR Amendment (RIN 1400-AD03)

Dear Mr. Peartree:

Founded in 1787, the University of Pittsburgh – Of the Commonwealth of Higher Education, is a state-related institution of higher learning located in Western Pennsylvania. With an enrollment of over 35,000 students, the University is one of the largest institutions of higher education in Pennsylvania. Supporting its commitment to the creation and dissemination of new knowledge are more than 13,200 faculty, research associates, and staff. The University's annual spending exceeds 1.74 billion dollars, of which approximately 700 million dollars are from externally sponsored research projects, making the University one of the top tier research institutions in the country. The University is a member of the Association for University Export Control Officers (AUECO), and joins that organization in their more detailed comments offered in this docket. These more specific comments are offered to emphasize the potentially significant, negative consequences of reclassifying some biological agents, including those currently classified as ECCN 1C351-1C354 in the Commerce Control List (CCL) under the Export Administration Regulations, into proposed ITAR Category XIV (b).

In general, the University recognizes and appreciates the efforts that the Department of State has placed into the proposed changes found in this ITAR Amendment. However, the adoption of this new proposed rule will have a negative impact on our campus for fundamental research projects that utilize biological agents currently classified as ECCN 1C351-1C354 on the CCL. The current EAR jurisdiction provides flexibility which allow for the inclusion of foreign national students and researchers in most cases without a specific license. Moreover, the biological agents proposed to be moved from the EAR to ITAR Category XIV (b) are already subject in most cases to the federal select agent program, and the new Dual Use Research of Concern regulations. Thus, multiple sets of regulations are already in place to control these biological agents while providing adequate flexibility for publication and foreign national inclusion.

C. Edward Peartree

August 17, 2015

Page 2

The proposed rule indicates that these new restrictions are necessary in order to advance national security objectives. However, it is unclear what additional benefits will be gained and how these proposed changes are necessary in light of the existing controls already in place for biological agents. Thus, the University of Pittsburgh strongly recommends that the biological agents and other items proposed to move into ITAR Category XIV (b) remain under Department of Commerce jurisdiction and governed by the Export Administration Regulations.

On the other topics proposed in this docket, the University fully supports the positions outlined in the AUECO comment letter. The University of Pittsburgh is appreciative of the opportunity to provide comments on these proposed changes.

Sincerely,



Allen A. DiPalma, MBA
Export Controls Official



UNIVERSITY of VIRGINIA
Office of Export Controls

August 17, 2015

via email: DDTCTPublicComments@state.gov

C. Edward Peartree, Director
Office of Defense Trade Controls Policy
U.S. Department of State
Washington, DC

RE: RIN 1400-AD03 - ITAR Amendment – USML Categories XIV and XVIII

Dear Mr. Peartree:

This letter is submitted on behalf of The Rector and Visitors of the University of Virginia (“University” or “University of Virginia”) to comment on the proposed changes to the International Traffic in Arms Regulations (“ITAR”), Proposed Revisions to United States Munitions List (“USML”) Categories XIV and XVIII (80 Federal Register 34572; June 17, 2015). The University supports the ongoing export control reform initiative and hopes that it will result in clear regulatory jurisdictions and positive lists of controlled items in order to better facilitate a clear understanding of regulatory requirements and compliance. At this time, the University does not intend to comment upon the proposed revisions to USML Category XVIII. Our analysis of the proposed revisions to USML Category XIV suggests that, if adopted as proposed, some of these revisions will have a significant and deleterious effect on the University’s ability to fulfill its core missions of conducting high quality research, teaching and service. These core missions importantly include the growth and broad, public dissemination of new discoveries in science, medicine and engineering.

Category XIV, paragraph (a):

In the current version of Category XIV, paragraph (a), the Chemical Agents that are controlled are limited, by virtue of paragraph (n), to those substances “having a military application, which by [their] ordinary and direct chemical action, produce a powerful physiological effect.” Thus, applications that are only civil applications would not be controlled under this paragraph. The proposed revisions to paragraph (a) no longer provide an exclusion for civil applications, with the narrow exception being “Pharmaceutical formulations containing nitrogen mustards or certain reference standards for these formulations... 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.” Imposing greater

controls on civil-only applications restricts the ability of university researchers to have open exploration and learning in labs that might be interested in beneficial, civil applications of these Chemical Agents.

Category XIV, paragraph (b):

The University appreciates the efforts made by the Department of State (“Department”) to propose revisions which are aimed at addressing variations in, and limited coordination of, individual executive departments’ and agencies’ oversight that add to the cost and complexity of compliance. The University recognizes that the Department has proposed language in paragraph (b) which adopts the “Tier 1” pathogens and toxins, established in the Federal Select Agent Program of the Department of Health and Human Services and the United States Department of Agriculture, which meet certain capabilities set forth in paragraph (b). However, the Department has failed to incorporate the exclusions found in the Federal Select Agent Program. In addition, the University has deep concern about how the capabilities or properties of these agents are characterized in the proposed revision.

Specifically, the characteristics set forth in paragraph (b)(1)(i)(A) “Persistence in a field environment...” and paragraph (b)(1)(i)(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;...” are both descriptions of features that a researcher may unknowingly, inadvertently or accidentally achieve when the purpose of their research or experiment had an entirely different or unrelated end result. The same concern is articulated for the criteria and characteristics set forth in paragraph (b)(2)(ii). Unless a researcher were specifically testing to insure against having these unintended or controlled results, the researcher may not be aware of these characteristics and would therefore be put in the position of unintentionally and unwittingly violating the ITAR. The cost, in time and resources, to universities and to industry to insure that these characteristics are not an unintended result of certain genetic modifications of biological agents would be significant and would negatively impact the search for new scientific and medical knowledge.

Research on biological agents, listed in paragraph (b), is already heavily regulated through the Federal Select Agent Program jointly comprised of the Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Services/Agriculture Select Agent Services. Furthermore, these agents will also be regulated by the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, which will become effective on September 24, 2015. It is the University’s position that these agents should not be

subject to further regulation by the Department and should, regarding export controls, remain controlled under the Export Administration Regulations (EAR). If research on biological agents rises to the level that it truly presents a significant risk to national security then the appropriate mechanism of control is classification rather than regulation under this proposed revision of ITAR Category XIV.

Furthermore, paragraph (b) of Category XIV currently does not include within its control, modifications which are made only for civil applications. This exclusion has been eliminated in the proposed revision to paragraph (b) and this change will negatively affect academic and industry research and development of beneficial, civil applications such as those for medical or environmental use. We urge the Department to retain this exclusion in the final rule.

Category XIV, paragraph (f):

In the proposed paragraph (f)(1)(ii), equipment “specially designed” for testing items in paragraphs (a), (b), (c), (e) or (f)(4) would now be ITAR controlled under the proposed revisions if it was “developed under” a Department of Defense (“DOD”) contract or other funding authorization.” If this is intended to mean that any amount of DOD funding is sufficient to trigger these controls then this language wherever it appears in the proposed revisions to Category XIV should be made more explicit so that this distinction is clear.

For paragraph (f)(2) regarding “equipment containing any reagents, algorithms, coefficients, software, libraries, spectral databases, or alarm set point levels developed under a DOD contract or other funding authorization for the “detection, identification, warning, or monitoring of: . . . chemical or biological agents controlled in paragraph (a) or (b) – is it the equipment that will end up being controlled or the reagents, algorithms, etc. . . that will be controlled? Assuming that the State Department intends that it is the equipment that is to be controlled, it is suggested that this provision be rewritten to make this intention clearer.

In paragraph (f)(2)(ii), the proposed revision indicates that, as long as the equipment contains “reagents, algorithms, coefficients, software, libraries. . . developed under a DOD contract or other funding. . . AND the chemical or biological agents being detected, identified, warned of or monitored are also “specified by” a DOD contract. . . then this equipment will be ITAR controlled under the proposed Category XIV. This control is based solely upon DOD funding of the equipment and DOD “specification of” the chemical or biological agent. Will this ITAR regulation then apply to any DOD funded equipment that pertains to ANY chemical or biological agent as long as it is “specified by” a DOD contract? Is it necessary that the DOD contract or other funding authorization

funding the equipment be the same DOD contract in which the chemical or biological agent is “specified”? Besides being unclear, it is the University’s position, again, that the source of funding for research should not serve as a basis for regulating these items under the ITAR.

The University does appreciate the exclusion provided for items “identified in the DOD contract or other funding authorization as being developed for both civil and military applications”, but suggests that the implementation of this exclusion, especially with respect to universities, which are frequently in the position of being subcontractors to industry contractors or industry prime recipients, may be difficult. The difficulty arises when the university subcontractor requests that the prime contractor go back to the DOD Contracting Officer and have the dual purpose language added to the contract via an amendment to the contract. Frequently, there is a reluctance on the part of the prime contractor to ask for this revision or amendment. As an alternative to the proposed language, the University suggests that it would be more effective to allow for the application of this exclusion if the proposal for such research contains the specification that the equipment would have dual-use applications.

Category XIV, paragraph (g):

With respect to paragraph (g)(1), the University has concerns that the proposed revisions will subject “antibodies, recombinant protective antigens, polynucleotides, biopolymers, or biocatalysts (including their expression vectors, viruses, plasmids, or cultures of specific cells modified to produce them)” to ITAR controls solely because they would be used in a project *funded exclusively by DOD* for the detection of biological agents listed in paragraph (b)(1)(ii) even if naturally occurring. This would result in having these items be ITAR controlled solely because of the source of funding. Should these items be used for any other research, even if that research is for the detection of biological agents listed in paragraph (b)(1)(ii), as long as that research is not exclusively funded by DOD, then these items would not be subject to control under the proposed revised version of Category XIV. This would lead to inconsistent compliance monitoring on the part of most organizations and, from a national security perspective, does not seem to provide the safety that may have been intended. We recommend against any proposed revisions that impose ITAR control merely based upon the source of funding.

Category XIV, paragraph (h):

The proposed paragraph (h) to Category XIV for “vaccines exclusively funded by a Department of Defense contract”, again poses the same issue for consideration. Does this proposed language provide control of these items for national security purposes? Does



the government wish to only have its research considered ITAR controlled while industry might fund the same research and Category XIV would not be applicable? In paragraph (h)(4), is it truly in the best interest of the U.S. to have extra controls put upon the research that might provide protection against the dangers of the biological agents and biologically derived substances identified in the proposed revision to paragraph (b) of this Category? Furthermore, the qualifying term “specially designed”, used in paragraph (h)(2), by virtue of the release provisions provided in the definition of “specially designed”, arguably exempts these vaccines from control under this proposed revision to Category XIV if developed with knowledge that it could be used for both military and civil applications, and this would presumably apply even if the vaccines are exclusively funded by DOD by contract.

Category XIV, paragraph (n):

Finally, the proposed revision to paragraph (n) for “Developmental countermeasures or sorbents funded by the DOD via contract or other funding authorization” leave the same concern about imposing additional, more stringent controls upon these items solely due to the fact that they may be “funded by the Department of Defense”. Another issue is that, per Note 1 to paragraph (n) of the proposed revisions, items are controlled under this paragraph if any DOD funding went into the countermeasure or sorbent developed. This should be made explicit if the Department is going to keep this qualifying language. Further, as stated previously, the implementation of the exclusion for dual-use items IF identified in the DOD contract or other funding authorization may be especially difficult for universities which are frequently in the position of being subcontractors or subrecipients under the prime DOD contract or other DOD funding authorization. Thus, we suggest that it may be more effective to have the dual-use nature of the application identified at the proposal stage, thus eliminating the difficulties that universities face in having the prime contract or other funding authorization amended after it has already been negotiated with the prime contractor or recipient.

The University of Virginia appreciates having this opportunity to comment upon the proposed revisions to Category XIV of the USML.

Sincerely,

Kathryn Kim
Export Compliance Officer



Office of the Vice Chancellor
for Research and Graduate Education
UNIVERSITY OF WISCONSIN-MADISON

August 14, 2015

Office of Defense Trade Controls Policy
Department of State
Washington, DC
By email to DDTCPublicComments@state.gov

RE: RIN 1400-AD03
ITAR Amendment--Categories XIV and XVIII

Dear Sirs/Madams:

Please accept the following comments from the University of Wisconsin-Madison (UW-Madison) in response to the Department of State Proposed Rule for Revisions to *ITAR-Categories XIV and XVIII*. As one of the largest public research institutions in the United States, with approximately a billion dollars in annual research expenditures, a broad research portfolio, a strong international presence, and a large number of international students, staff and visitors, UW-Madison believes it is critical that export control laws strike an appropriate balance between the free interchange of scholarly information and the advancement of science, and the protection of national security and economic competitiveness. We appreciate and support the efforts of the Departments of State and Commerce to reform the export control rules, and there have been a number of positive outcomes from this process. However, it is important that this progress continue, and UW-Madison is greatly concerned that certain provisions in the above-referenced proposed rules represent a reversal of the overall positive trend of export control reform.

Please allow us to identify the items in the above-referenced proposed rules that are of most concern.

- **General Comment 1 on ITAR XIV(b)** – We understand the need to place stricter controls on technologies and activities that could potentially lead to the weaponization of biological agents as described in the proposed changes to Category XIV as posted to the Federal Register 80 FR 34572. However, the proposal lacks clarity and would raise questions for compliance officers regarding the agency to which they should submit license applications. This could increase the number of commodity jurisdiction requests submitted to determine the appropriate agency, thus increasing workload for the submitting organization as well as the Departments of State and Commerce. We suggest a way to address this issue without placing unnecessary burden on applicant institutions.

Suggestion: All export license applications for biological agents controlled under ECCNs 1C351, 1C353 and 1C354 should be processed through the Department of Commerce's Bureau of Industry and Security (BIS). The EAR already require a license for the export of any biological agent, toxin or material listed under 1C351,

University of Wisconsin – Madison
Comments to Proposed ITAR Category XIV and XVIII

1C353 and 1C354 with minimal allowance for the use of exceptions (only STA may be used for toxins). Therefore, the export licensing requirements for biological agents already approximate ITAR standards. Secondly, our experience has been that BIS refers export license applications for biological agents to the Departments of State and Defense. So, if initial screening or review determines the material described in the license application could be used as a weapon, in the creation of a weapon or in the distribution of a weapon, that application would be referred to the appropriate government agency for an advanced security screening. Sending all biological agent applications to BIS would prevent any confusion regarding the agency to which a license application should be submitted. This would effectively create the tiered, one-agency approach that was the ultimate goal of export control reform.

- **General Comment 2 on ITAR XIV(b)** – NIH funds a large amount of research at universities for the identification, characterization, prevention and treatment of microorganisms and their associated diseases. Because of the way the proposed regulations are written, NIH-funded microbial research could fall under ITAR. This is counter to the mission of NIH, which is to “seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability”. We recommend that a note be added to exempt NIH-funded work from ITAR controls or that paragraph (n) of the current ITAR XIV be retained to provide an exemption for civil applications (see General Comment 5).
- **General Comment 3 on ITAR XIV(b)** – Many universities use foreign staff and students to conduct research for the identification, characterization, prevention and treatment of microorganisms and their associated diseases that currently is considered fundamental research. There is the potential that the genetic modification of microorganisms controlled under the EAR could lead to an unintended outcome (such as increased persistence in the environment) that would make it subject to the ITAR. Therefore, any foreign persons that participated in the research (that was considered fundamental research when initiated) would be non-compliant with the regulations upon discovery that the environmental persistence had been increased (which was not the focus of the research). In order to manage the compliance concerns associated with select agent research, laboratories may need to choose among the following unsatisfactory options:
 1. Submit an ITAR license application for each foreign person in their lab working with agents controlled under the EAR, “just in case” the research increased the agent’s field persistence, made the agent less detectable, etc. This would increase agency and researcher workload, and could delay completion of research.
 2. Risk conducting the work without a license, which is not a good regulatory strategy.
 3. Not allow foreign persons to work on select agent research. This limits the pool of qualified researchers, reduces research opportunities for foreign students and is in direct opposition to the policies of most research universities.
 4. Not conduct select agent work. Therefore, methods for the identification, prevention or treatment of certain diseases may be delayed or not addressed at all.

Please see item 6 below in Comments on ITAR XIV(b)(1)(i) for a recommendation to address this concern.

- **General Comment 4 on ITAR XIV(b)** – ECCN 1C352 has been combined with 1C351 and removed from the Commerce Control List. Therefore, any mention of 1C352 should be removed from the proposed regulation.
- **General Comment 5 on ITAR XIV(b)** – Section XIV(n) from the current USML has been removed in the proposed regulations. XIV(n)(2) contained an exemption from ITAR-control for modifications to biological agents made for civilian applications (i.e., medical use). This paragraph has helped clarify to universities whether certain kinds of biological research are controlled under the ITAR or EAR. We request that XIV(n) be reinstated into Category XIV.
- **Comments on ITAR XIV(b)(1)(i)** – This section states that genetically modified biological agents where the modifications result in an increase in persistence in the field environment or the ability to defeat detection methods, personal protection, etc. would be controlled under the ITAR. However, a majority of the “properties” of microorganisms mentioned in XIV(b)(1)(i) are not something that researchers would typically test for, unless that was the subject of their research.
 1. The lack of testing in these areas somewhat invalidates the usefulness of this paragraph. It does not seem appropriate to define the regulatory control environment around “properties” for which testing may not be completed (see example in 4 below).
 2. There is a concern that the mention of these “properties” within the regulations may lead to requirements for mandatory testing of these “properties” for genetically modified versions of the microorganisms listed in XIV(b)(1)(ii). Mandatory testing could create a significant burden on research laboratories from workload, cost, schedule and documentation standpoints.
 3. What standards do we use to make a determination that a genetic modification has increased a microorganism’s environmental persistence, decreased its ability to be detected or overcome natural host immunity? Will there be a uniform set of standards to help guide researchers in making this determination or will individual research labs need to develop these standards themselves? Allowing labs to set their own standards could result in differences in determining which regulation (ITAR or EAR) may apply. For example:
 - a. Lab Differences – Labs may determine different starting values for standard “properties”. If lab 1 determined that a virus can survive temperatures up to 170°F and lab 2 separately determined survival to 155°F, their conclusions regarding change in environmental persistence would differ if a “modified” virus was found to survive temperatures up to 170°F.
 - b. Interpretation of Change – A lab genetically modifies a controlled virus and finds through testing that the “genetically-modified” organism now appears to be able to survive temperatures up to 170°F, whereas the unmodified virus appears to survive in temperatures up to 160°F. Although this appears to be a “real” increase in persistence, some researchers may state it is not a statistically significant increase, or is of no practical importance (i.e., for transmission or sterilization

- purposes). Therefore, some labs may consider this genetically modified organism as ITAR-controlled and others may consider it EAR-controlled.
4. Such testing can delay license application reviews. For example, we submit a license application to BIS to ship genetically modified *Bacillus anthracis* to France. After initial screening, the reviewer asks if the modification makes the bacteria more resistant to extreme hot or cold temperatures, or can defeat normal detection methods. What happens to the application if the laboratory has not tested for those properties? Is it put on indefinite hold until the tests are conducted? Is it assumed to be ITAR, even though that was not the subject of the research, nor is there evidence to indicate an increase in the “properties”? Is the application RWA’d for lack of information? This could place significant financial burden on the laboratory if the funded research project did not include testing for the properties.
 5. The “e.g.” in XIV(b)(1)(i)(A) indicates that the list of “properties” is incomplete. If the list serves as the criteria for determining whether the subject microorganisms are controlled by ITAR or EAR, it should be complete in the regulations and not subject to reviewer interpretation.
 6. To eliminate the potential confusion and issues caused by these “property-based” regulations, we recommend the agency/regulation of control be based upon the nature of the research to be conducted with the subject microorganism.
 - a. Research regarding the identification, characterization, prevention or treatment of the subject microorganism or its associated disease would be controlled under the EAR.
 - b. Research used to (1) increase the microorganism’s persistence in the environment, or (2) defeat detection methods, personal protection, host immunity, etc. would be controlled under the ITAR.
 - c. Although this may seem like a subtle difference from what is currently written, the difference lies in the intent of the research. Research that is intended to characterize a disease (or one of the subject microorganisms) will likely not test for many, if any, of the stated properties. However, research intended to defeat detection methods will likely test for that property.
- **Comments on ITAR XIV(b)(2)(ii)** –The “e.g.” in XIV(b)(2)(ii)(A) and (B) indicates that the list of “properties” is incomplete. If the list serves as the criteria for determining whether the subject microorganisms are controlled by ITAR or EAR, it should be complete in the regulations and not subject to reviewer interpretation.
 - **Comments on ITAR XIV(f)(1)(ii), XIV(f)(2) and XIV(f)(2)(ii)** – The phrase “...developed under a Department of Defense contract or other funding authorization” is unclear. Does the phrase “other funding authorization” refer to other funding vehicles under DOD, such as fee-for-service, cooperative agreements, grants and awards, or does it refer to other funding sources such NIH, NSF and private funding?
 1. If this phrase is attempting to capture multiple funding vehicles under DOD, it should be changed to “...developed under Department of Defense funding.”
 2. If this phrase is trying to capture funding from multiple agencies or sources, then the whole phrase could be deleted because the phrase itself includes all funding sources (as stated).

University of Wisconsin – Madison
Comments to Proposed ITAR Category XIV and XVIII

The University of Wisconsin-Madison appreciates the opportunity to provide the Department of State with the above comments on the revisions to *ITAR-Categories XIV and XVIII*. Please consider our comments in conjunction with the comments from other universities and university organizations.

Sincerely,



Thomas A. Demke
Export Control Officer



Dan Uhrich
Associate Vice Chancellor for Research Policy

My question or clarification relates to Category XIV in order to more accurately describe the articles in the subject category and establish the "bright line" between the USML and CCL.

Specifically, directly relating to XIV(f)(4)(iv), does this Entry control the military Pilot Flight Equipment (PFE) "CBW layer" which are worn as part of a PFE Ensemble by both military aircraft pilots and helicopter pilots.

OR is this specific CBW layer alternatively controlled in either VIII or 9A610? Please clarify?

Thank you very much.

Respectfully Submitted,

W. Brad Lewis

Principal & MD

TCA, LLC

San Diego, CA

Tel: 619-437-1080

Mbl: 949-423-4537

NAICS SIC = Division I.



7 August 2015

VIA E-MAIL: DDTCPublicComments@state.gov

Mr. C. Edward Peartree
Director, Office of Defense Trade Controls Policy
U.S. Department of State
PM/DDTC, SA-1, 12th Floor
2401 'E' Street, NW
Washington, DC 20037

ATTN: ITAR Amendment - USML Category XIV
REF: RIN 1400-AD03
RE: Proposed Revision to USML XIV(f)(4)(iv)

Dear Mr. Peartree:

W.L. Gore & Associates, Inc. ("Gore") respectfully offers the enclosed comments to the referenced Proposed Rule.

GORE® fabric laminates are used to produce recreational as well as military, first responder and industrial protective apparel. We welcome the shift of chemical-protective fabric to ECCN 1A607.x of the Commerce Control List, but have concerns regarding:

- 1) the chemical breakthrough test method for clothing that would remain in USML XIV(f)(4)(iv); and
- 2) civilian clothing sewn from 1A607.x fabric meeting the proposed chemical breakthrough criteria.

1) Chemical Breakthrough Test

Gore has no objection to the proposed bright line "breakthrough" challenge: 10 milligrams of two chemical agents, one percent (1%) for "GD" (soman) and two percent (2%) for HD (mustard gas). However, the test described in the Note to paragraph (f)(4)(iv) at 80 Fed. Reg. 34577 would apply only to air permeable materials ("ambient air is directed through the swatch") and not to protective materials that are semi-permeable or impermeable.

W. L. GORE & ASSOCIATES, INC.

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A publicly-available U.S. military test method is available to evaluate chemical breakthrough for all three material types: air permeable, semi-permeable and impermeable. This Test Operating Procedure (TOP) 08-2-501 (5 August 2013) is available at www.nist.gov/national-security/standards/upload/global_docs/TECMIPT_TTOP_08-2-501.pdf. Entitled “Permeation Testing of Materials with Chemical Agents or Simulants (Swatch Testing),” TOP 08-2-501 also provides uniform evaluation conditions such as temperature, relative humidity and test set-up using a “dual-flow” apparatus for semi-permeable and impermeable materials and a “convective flow” version for air permeable materials.

We therefore suggest the following simplification of the proposed Note to paragraph (f)(4)(iv) of USML XIV: “Evaluation is made by applying 10 mg of GD or HD in accord with methods described in the current version of Test Operating Protocol (TOP) 08-2-501 with a test duration of 24 hours 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.~~”

2) Clothing Not Specially Designed for Military Use (e.g., First Responder/Civil Defense)

The current scope of USML XIV(f) is limited to protective articles designed for “military operations and compatibility with military equipment.” Current USML XIV(f)(4)(i) further states that the Category includes “military protective clothing and masks, but not those items designed for domestic preparedness (e.g., civil defense).” As such, clothing with identifiably-civil features such as neck seals designed to integrate with civilian gas masks now falls under Commerce Control List ECCN 1A004 as “protective...equipment...not specially designed for military use.”

USML XIV(f) as proposed would not distinguish between military and non-military protective apparel, but would rely on a fabric-level “breakthrough” test to establish ITAR jurisdiction. If implemented as currently drafted, garments designed to National Fire Protection Association (NFPA) standards and/or designed to integrate with civil gas masks would move from ECCN 1A004 to USML Category XIV if they were made of fabrics that could withstand the proposed chemical breakthrough levels.

If shifting such civilian-design garments from 1A004 to the USML was not the intent of the Proposed Rule, we suggest adding the word “military” to proposed USML XIV(f)(4)(iv): “Military ensembles, garments, suits....” This is consistent with ECCN 1A607.f.1 in the companion BIS Proposed Rule, as that entry covers “Military...protection equipment...not controlled by USML XIV(f).” Civilian protective apparel would then cleanly fall into 1A004.b or 1A995 rather than being split between the USML and CCL depending on the chemical breakthrough performance of its component fabric.

We further suggest an addition to the proposed Note to Category XIV(f)(4)(iv): “Paragraph (f)(4)(iv) does not include items that are not specially designed for military operations, e.g., protective equipment for first responder (such as fire service, police, emergency personnel), civil defense, industrial, or other civilian purposes.” This addition would clarify the jurisdiction of civilian protective apparel for first responders and industrial applications, as these applications could be interpreted to be excluded from the current carve-out for “domestic preparedness/civil defense.”

We appreciate the opportunity to comment on the Proposed Rule and applaud the DDTC and interagency efforts to clarify the export control jurisdiction and classification of chemical-protective equipment and components.

Very truly yours,

A handwritten signature in blue ink, appearing to read "Lisa Gilmer".

Mary E. (“Lisa”) Gilmer
Counsel-International Trade