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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:

Multilateral WA ML					United States		
7	18	19	21	22	XIV	XVIII	ECCNs
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:

<u>State proposed XIV(b)</u>

(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.

<u>Existing Commerce 1C353</u>

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 XIVof 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.

<u>Cross-references from WA ML 7 and 19 to proposed USML XIV and XVIII and ECCNs</u>

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:

CWC	U. S.	WML
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

AG	1C351.a	1C351.b	XIV.b.1.ii
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

AG	1C351.c	XIV.b.1.ii

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

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

Fungi

AG	1C351.e
1, 2	1, 2

Plant Pathogens

Bacteria

AG	1C354
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

AG	1C353
1	a.1
	a.2 ... coding ...
2.	b.1
	b.2 ... coding

Chemical manufacturing

AG I	US
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

XIV	Multilateral			Unilateral	
	WA 7	CWC	AG	Now	Proposed
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		WA 19				
	a	a, b, c				
	b	d				
	e	heading				
	f					x developmental
CCL		WA 7				
	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			