BUREAU OF INDUSTRY AND SECURITY

UPDATE CONFERENCE ON EXPORT CONTROLS AND POLICY

MARCH 18-20, 2025

Biological Controls: New Regulations and Future Issues

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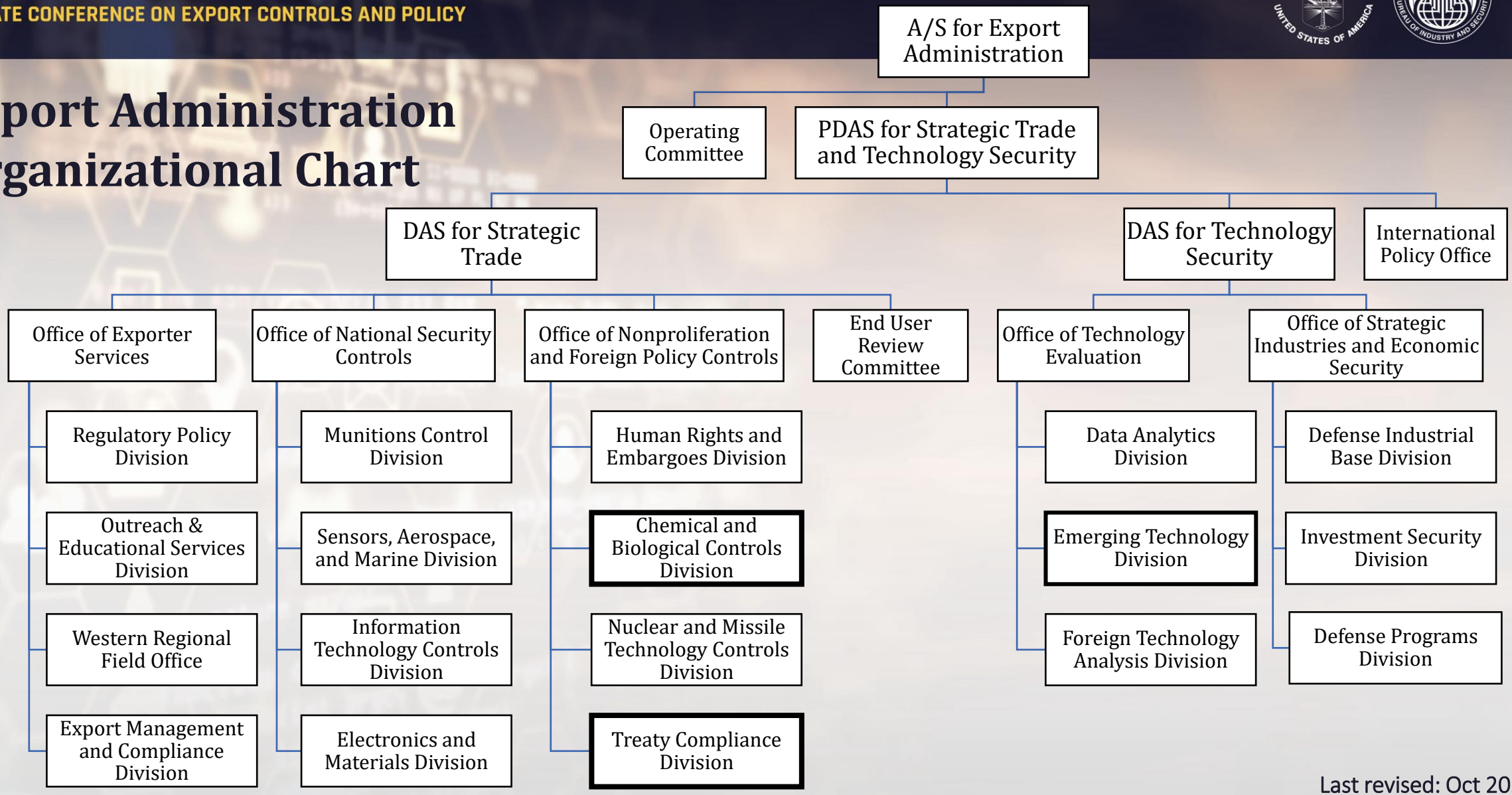
Export Administration Organizational Chart



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Treaty Compliance

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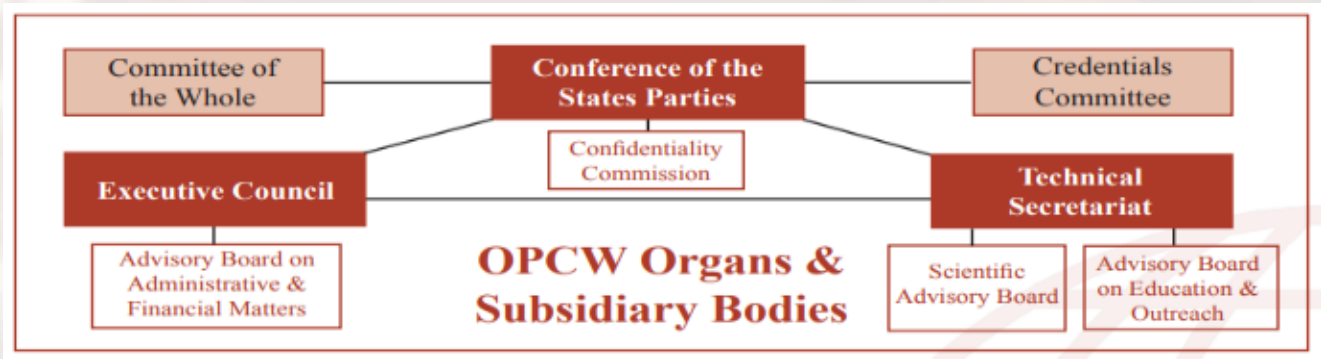
Treaty Compliance Mission

- **Commerce/BIS Mission for Arms Control Treaties**
  - ***Protect and support National Security*** (e.g., deter state WMD capabilities, prevent terrorist acquisition and use, reduce proliferation, reinforce international norms, etc.)
  - Ensure the ***health of the U.S. Economy*** and ***competitiveness of U.S. industry***
  - Ensure private sector ***compliance*** with nonproliferation treaties (i.e., not making WMD) and ***represent industry equities*** in these treaty fora
- **Treaty Compliance Mission at BIS**
  - ***Demonstrate U.S. compliance*** with international arms control & nonproliferation agreements including the Chemical Weapons Convention (CWC), the Biological and Toxin Weapons Convention (BWC), and the Additional Protocol (AP)
  - ***Assist domestic industry*** and other non-government sector' compliance with U.S. regulations
- **Treaty Compliance Objectives**
  - ***Protect*** Confidential business information, physical site security information, ITAR-controlled information, national security information
  - ***Minimize burden*** and costs to U.S. industry
  - Ensure ***equitable international implementation***
  - ***Represent industry equities*** in interagency deliberations

The CWC - OPCW

Only Egypt, North Korea, and South Sudan have neither signed nor acceded to the CWC

The Organization for the Prohibition of Chemical Weapons (OPCW) is the implementing body of the CWC



In 2013, The OPCW was awarded The Nobel Peace Prize "for its extensive efforts to eliminate chemical weapons"

	Schedule 1	Schedule 2	Schedule 3	Unscheduled Discrete Organic Chemicals (UDOCs)
Chemicals	CW agents; key final-stage CW precursors.	Potential CW agents; other CW precursors; and certain dual-use chemicals.	Old CW agents; other CW precursors; and certain dual-use chemicals.	UDOCs (including UDOCs containing phosphorus, sulfur, or fluorine (aka PSF chemicals).
Examples	1) **Sarin**: O-Isopropyl methylphosphonofluoridate 2) **Mustard gas**: Bis(2-chloroethyl)sulfide 3) **VX**: O-Ethyl S-2-diisopropylaminoethyl methyl phosphonothiolate	1) **Amiton**: O,O-Diethyl S-[2-(diethylamino)ethyl] phosphorothiolate and corresponding alkylated or protonated salts 2) **PFIB**: 1,1,3,3,3-Pentafluoro-2-(trifluoromethyl)-1-propene 3) **Thiodiglycol**	1) Phosgene: Carbonyl dichloride 2) Hydrogen cyanide 3) Phosphorus oxychloride 4) Thionyl Chloride 5) Triethanolamine	1) Acetophenone 2) 6-Chloro-2-methyl aniline 3) Acetone
Commercial Uses	Low or none	Low or moderate	High	High
Annual Threshold for Declarations & Reports	**>100 g aggregate** production of all Schedule 1 chemicals	Production, consumption, or processing > 1kg for BZ; 100kg for other Part A chemicals; **> 1 metric ton** for Part B chemicals	Production **> 30 metric tons**	Production **> 200 metric tons aggregate** for UDOCs Production **> 30 metric tons for each PSF chemical**
Threshold for Inspection	**>100 g aggregate** production of all Schedule 1 chemicals	**Production, consumption, or processing** > 10kg BZ; 1 metric ton other Part A chemicals; **> 10 metric tons** Part B chemicals	Production **> 200 metric tons** aggregate	Production **> 200 MT** aggregate UDOCs

BIS CWC Activities

- Prepare the chemical industry's portion of U.S. declaration
  - Process ~600 declarations, reports, and End Use Certificates annually
- Host industry inspections
  - Nearly 400 inspections since May 2000
- Conduct outreach to the private sector
  - >100 Site Assistance Visits conducted since April 2000
- Represent U.S. economic and industry issues at the OPCW

Commerce's Role

- Responsible for all facilities not owned by or leased to DOD, DOE, or other U.S. Government agencies
- Manages both the declaration process and the on-site inspection process to ensure U.S. compliance with the CWC
- Performs facility outreach and site assistance visits
- Issues Chemical Determinations – by company request; determines whether a chemical or activity is subject to the CWCR

Declarations

- Commercial facilities submit declarations on production, processing, consumption, and import/export activities for certain chemicals.
- Commerce collects approximately 600 declarations and reports from roughly 530 companies annually.
- Commerce reviews the declarations, and forwards them to the State Department for transmittal to the OPCW.
- Plant sites that produce, consume, or process certain chemicals above specific thresholds are subject to inspection by the OPCW.

Declaration and Report Requirements

Activities that trigger a declaration and/or report:

- **Schedule 1:** production, export or import above treaty threshold
- **Schedule 2:** production, processing, consumption, export or import above treaty threshold
- **Schedule 3:** production, export or import above treaty threshold

Chemical Regime	Quantity Threshold
Schedule 1	Production – 100 grams Transfers - Any quantity
Schedule 2A/2A*	100 kg/1 kg
Schedule 2B	1 metric ton
Schedule 3	30 metric tons

- **Unscheduled Discrete Organic Chemicals** (UDOCs; also known as 'other chemical production facilities' or OCPFs): production by synthesis (i.e., isolated for use or sale as a specific end-product) above 200 metric tons

Declarations cont'd.

Submission Deadlines

Inspections

- Each year the OPCW selects the plant sites for inspection
  - CWC inspections are performed in the U.S. and around the world
- The OPCW is targeting 200 inspections globally this year
  - Commerce plans to receive 16 - 22 inspections
- 361 commercial inspections since 2000
  - Occur on property owned and operated by chemical companies
  - Performed by foreign nationals (EAR License Exception GOV)
- Short notice arrival of Inspection Team (IT)

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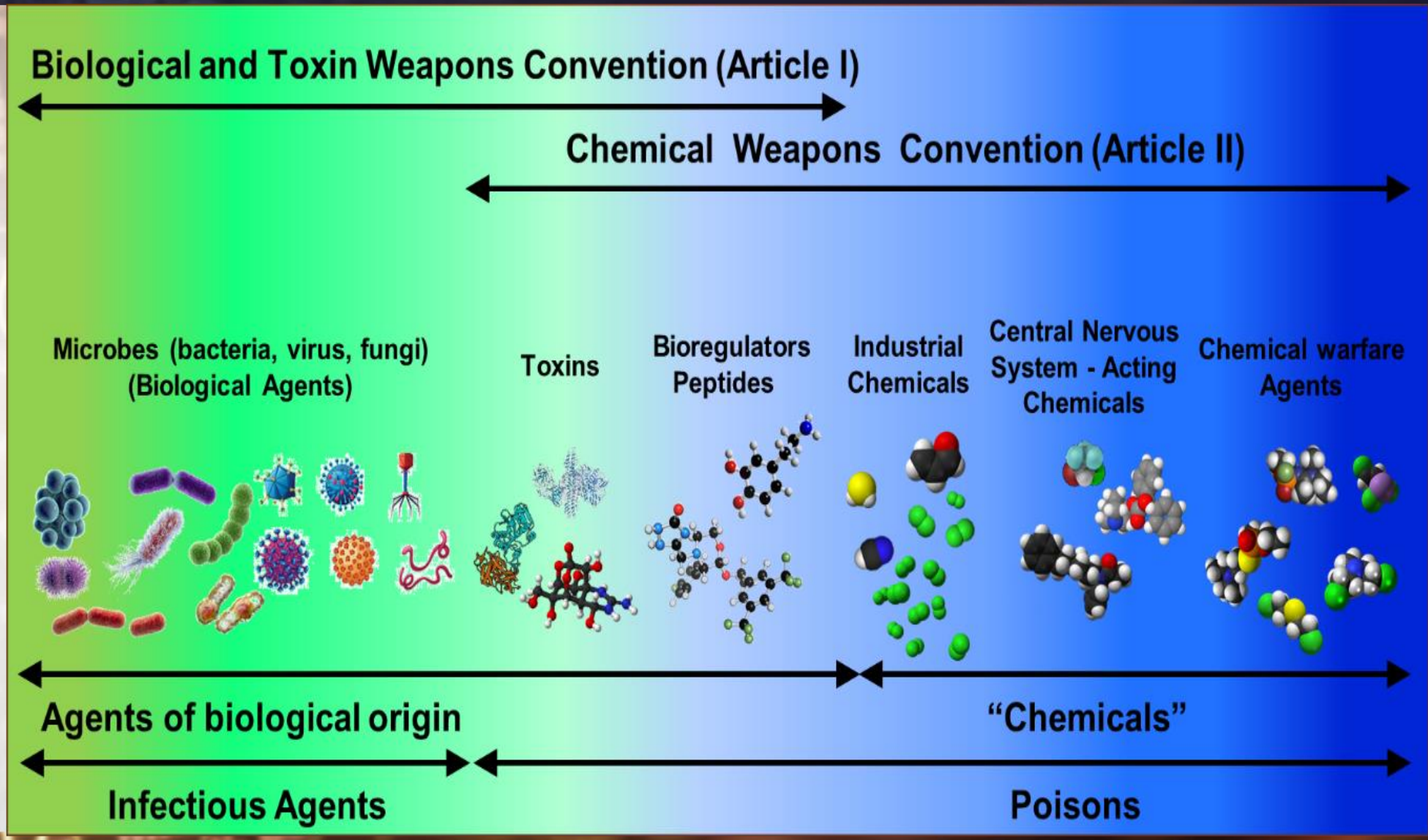
Biological Weapons Convention

BWC

- 163 States Parties
- U.S. Ratified in 1975
- Meetings at the United Nations in Geneva
- No legally-binding declaration or verification provisions



Confidence Building Measures

- **CBM A:** Exchange of information on (i) research centers and laboratories, and (ii) national biological defense research and development programs
- **CBM B:** Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins
- **CBM C:** Encouragement of publication of results and promotion of use of knowledge
- **CBM E:** Declaration of legislation, regulations and other measures
- **CBM F:** Declaration of past activities in offensive and/or defensive biological research and development programs
- **CBM G:** Declaration of vaccine production facilities

Contact Us

- Commerce requests industry input and advice on Treaty matters
  - METAC
  - Update Conference
  - Regular Bilateral Meetings

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Implementing Biological Controls in the Export Administration Regulations

Ted Curtin
Director, Chemical and Biological Controls Division

Australia Group Rules

- December 23, 2024 - 89 FR 104408 “Implementation of Certain Australia Group Decisions”
  - Implemented consensus decisions from 2023 and 2024 Plenary Meetings and 2023 and 2024 Intersessional Meetings
  - Changed text in 2B351.a from “at concentrations of less than” to “’minimum detection limit' of” and added a note defining the new term.
  - Added Dipropylamine to ECCN 1C350.d
  - Updated “Botulinum toxins” to “Botulinum neurotoxins”
  - Added Neosaxitoxin to ECCN 1C351.d
  - Added Single-use centrifugal separators to 2B352.c
  - Added Automated peptide synthesizers in a new paragraph, 2B352.k

Facilitating Exports to Partners

- December 8, 2023 - 88 FR 85479 "Allied Governments Favorable Treatment: Revisions to Certain Australia Group Controls"
  - Moved ECCNs 1C351, 1C353, 1C354 and related 1E001 and 1E351 technology from CB1 to CB2 (except saxitoxin and ricin)
  - Harmonized global license requirements for all AG-controlled items (No license required for AG members)

Controls on Certain Laboratory Equipment and Related Technology

- Purpose of the control
  - Prevent certain countries from "exploit[ing] the combination of biotechnology with other enabling technologies for asymmetric military advantage" -- NS and RS reason for control.
- Narrowly tailored
  - Items that can ". . . generate high-quality, high-content biological data including that which is suitable for use to facilitate the development of AI and biological design tools."

90 Fed. Reg. 4612 (Jan. 16, 2025)

Controls on Certain Laboratory Equipment and Related Technology

- Equipment controlled (new ECCN 3A069)
  - High parameter flow cytometers
  - Liquid chromatography mass spectrometers specially designed for top-down proteomics

- "Technology" controlled (new ECCN 3E069)
  - Technology according to the General Technology Note for the "development" or "production" of items controlled by 3A069.

Controls on Certain Laboratory Equipment and Related Technology

- National Security License Requirement and Review Policy
  - License to all destinations, except Country Group A:1 (§ 742.4(a)(2))
  - Presumption of denial for destinations in both Country Group D:1 and D:5, Macau, or destinations in Country Group E
  - Case-by-case for all other destinations
- Regional Stability License Requirement and Review Policy
  - License required to D:5 or Macau (§ 742.6(a)(13))
  - Presumption of denial for destinations in both Country Group D:1 and D:5, Macau, or destinations in Country Group E
  - Case-by-Case all others including destinations in D:5 but not in D:1.

Controls on Certain Laboratory Equipment and Related Technology

- License Exception GBS
  - Country Group B countries
  - Not available for destinations subject to the RS control described in ECCN 3A999.
- License Exception TSR
  - Except to destinations in Country Group D:5, destinations subject to the RS control described in ECCN 3A999, or Macau
  - Written assurances required – including assurance of no reexport to D:5, destinations subject to the RS control described in ECCN 3A999, or Macau

Contact Information

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Emerging Biological Technologies

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U.S. National Security Commission on Emerging Biotechnology Interim Report

January 2024:

- Emerging biotechnologies could enable the world to improve human and planetary health, secure food and energy production, ensure supply chain resiliency, and grow the economy at a massive scale.
- Congress has rightly recognized the growing potential of emerging biotechnology, including its applications for defense and national security. We can imagine a future in which our warfighters are fed, fueled, equipped, protected, and healed on the battlefield, all thanks in part to biotechnology.
- Our failure to seize this moment and act decisively could empower China and others to deploy biotechnologies for the surveillance of vulnerable populations, to develop strangleholds on key supply chains, or to create weapons that could harm Americans.

BIS's Emerging Technology Mission

- BIS advances U.S. national security and foreign policy by maintaining effective and adaptable export control mechanisms, ensuring treaty compliance, and promoting continued U.S. leadership in strategic technologies and defense industries.
- Section 1758 (a)(1)(A) of the National Defense Authorization Act for Fiscal Year 2019 (PL 115-232) obligates the U.S. Departments of Commerce, Defense, State, and Energy (and others, as appropriate) to work jointly to identify the emerging technologies and the foundational technologies essential to the national security of the United States.
- The U.S. Department of Commerce must establish new export controls for dual-use technologies identified through those discussions.
- As of May 2022, BIS refers to controls imposed under Section 1758 as controls on "Section 1758 technologies" (a term that covers both emerging and foundational technologies).

Emerging Technology Division

- BIS reorganization established the Emerging Technology Division, which aims to formalize BIS's efforts in the identification, review, and implementation of export controls on emerging and foundational technologies (Section 1758 technologies).
- Strategies for the identification of potential Section 1758 technologies:
  - Interagency partners
  - Technical advisory committees
  - Industry engagement

Section 1758 Technologies

- Consistent with ECRA, Section 1758 technologies will be determined by an interagency process that will consider both public and classified information as well as information from the Emerging Technology Technical Advisory Committee (ETTAC) and the Committee on Foreign Investment in the United States (CFIUS).

- The U.S. interagency must consider the following when evaluating candidate emerging technologies and foundational technologies:

1. The development of emerging technologies and foundational technologies in other countries;
2. The effect imposing export controls may have on the development of such technologies in the United States; and
3. The effectiveness of export controls on limiting the proliferation of such technologies.

Section 1758 Controls

- A Section 1758 control can be:
  - A new standalone ECCN
  - A new subparagraph added to an existing ECCN
  - A modification of an existing ECCN
- Section 1758 controls can be adopted unilaterally or in a multilateral regime. Whenever practicable, BIS aims to seek public comment on proposed Section 1758 controls.
- To date, BIS has established 47 Section 1758 controls
  - 46 multilateral controls, agreed to with Wassenaar Agreement or Australia Group
  - 1 unilateral control that expired in January 2023

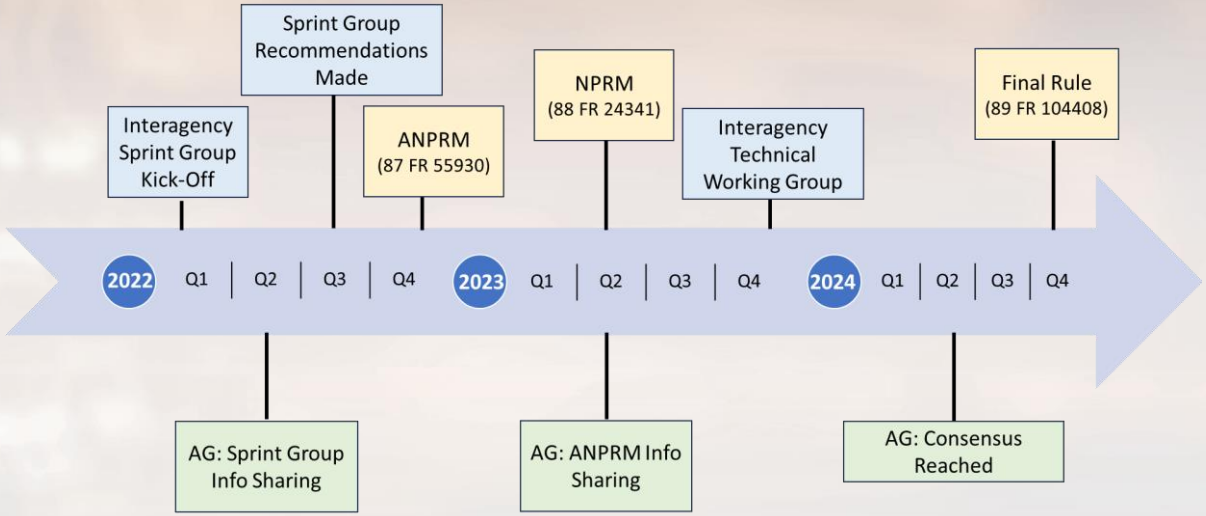
Section 1758 CB Controls

31 of the 47 Section 1758 controls are for chemical and biological weapons non-proliferation, all AG controlled

Date	Items
June 17, 2020	24 chemical weapons precursors are added under ECCN 1C350
June 17, 2020	Single-use biological cultivation chambers are added under ECCN 2B352.b
October 5, 2021	Nucleic acid assembler and synthesizer software that is capable of designing and building functional genetic elements from digital sequence data controlled under ECCN 2D352.
January 17, 2023	Four marine toxins (brevetoxins, gonyautoxins, nodularins and palytoxin) are added to ECCN 1C351.d
December 23, 2024	Certain automated peptide synthesis equipment are added to ECCN 2B352.k

1758 Case Study – Peptide Synthesizers

- Recent advances in peptide synthesis technology and instrumentation have increased both the speed of peptide synthesis and the length of peptide products, including peptides and proteins greater than 200 amino acids in length.
- Most protein toxins on the CCL are over 200 amino acids in length, with an average length of 300 amino acids.
- The notable exception in 1C351 being conotoxins, which range between 10-100 amino acids in length.



Final Rule December 23, 2024 (89 FR 104408)

2B352.k Peptide synthesizers that are both:
k.1 partly or entirely automated
k.2 and capable of generating peptides at a 'system synthesis scale' of 1 mmol or greater.

Biotechnology Export Controls

- Traditionally, biotechnology export controls have focused on chemical and biological weapons agents, their genetic elements, and the production equipment for these items.
- BIS has implemented controls on enabling technologies that can generate breakthroughs in biotechnologies.
    - This includes controls on certain advanced computing chips, semiconductor manufacturing equipment essential to producing advanced computing chips (and other advanced chips), and components and electronic design software that can be used to develop or produce critical inputs needed in the biotechnology ecosystem.
- BIS continues to assess rapidly changing and specific threats in this space, including the PRC's military-civil fusion strategy to use biotechnology to advance its military modernization.