BUREAU OF INDUSTRY AND SECURITY

UPDATE CONFERENCE ON EXPORT CONTROLS AND POLICY

MARCH 18-20, 2025







Tara Gonzalez, PhD Director, Emerging Technology Division Kate Koren Director, Foreign Technology Analysis Division



Agenda

- Organization
- Emerging Technology Mission
 - Section 1758 Technologies
 - Identification and Analysis of Section 1758 Technologies
 - Case Studies
- Foreign Technology Analysis Mission
 - Foreign Availability
 - Case Studies

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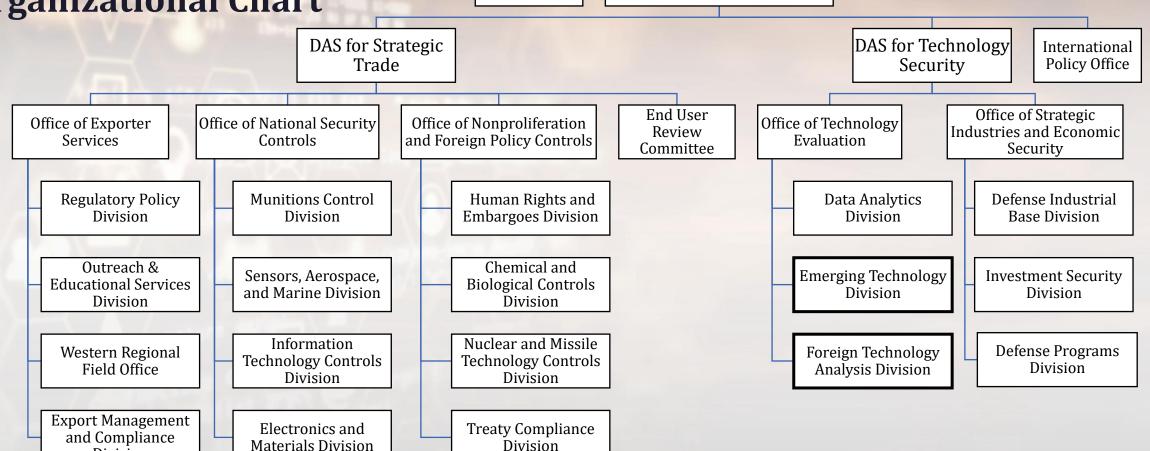


Export Administration Organizational Chart

Division

Operating Committee

PDAS for Strategic Trade and Technology Security



Last revised: Oct 2024



Office of Technology Evaluation

OTE is responsible for analyzing the economic impact of export controls on key sectors in the U.S. industrial base. OTE identifies key technologies, analyzes the foreign availability and mass market status of those technologies, and reviews the practices of the relevant multilateral export control regimes in controlling these technologies. OTE also analyzes critical sectors of the defense industrial base to assess those sectors' ability to support U.S. security requirements. In addition, OTE oversees the operation of BIS's Technical Advisory Committees (TACs) to ensure industry input on the impact of export controls on key sectors of the U.S. industrial base.

Office of Technology Evaluation (OTE) Kevin Coyne, Director

Data Analytics Division (DAD)

Anna Bruse, Director

Emerging Technology
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Emerging Technology

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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.

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Emerging and Foundational Technologies

- Emerging Technology ANPRM | November 2018 (83 FR 58201)
 - Sought public comment on criteria for defining and identifying emerging technologies in 14 technology categories identified by BIS
- Foundational Technology ANPRM | August 2020 (85 FR 52934)
 - Sought public comment to inform the interagency process to identify and describe foundational technologies
- Controls on Certain Marine Toxins NPRM | May 2022 (87 FR 31195)
 - ECRA does not define the terms "emerging technology" or "foundational technology."
 - "Section 1758 Technologies" was developed to help streamline process of identifying and controlling technologies vital to U.S. national security

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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



Identification & Engagement Strategies

- Industry
 - TAC membership and participation in open sessions
 - Comments on Federal Register Notices
 - Targeted outreach
- Technical Advisory Committee (TAC)
 - Advise the Department on the technical parameters for export controls applicable to dual-use commodities and technology and on the administration of those controls.
 - The TACs are composed of representatives from industry and Government representing diverse points of view on the concerns of the exporting community.
 - BIS currently has 6 TACs Emerging Technology TAC, Information Systems TAC, Materials and Equipment TAC, Regulation and Procedures TAC, Sensors and Instrumentation TAC, and Transportation and Related Equipment TAC
- Interagency partners Emerging Technology Steering Committee (ETSC)



Emerging Technology Technical Advisory Committee

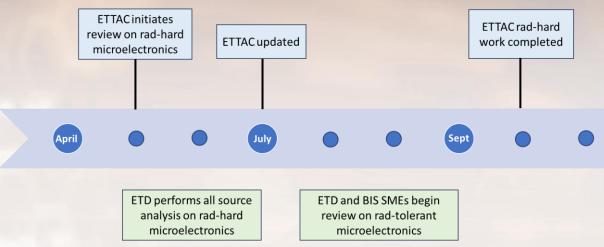
- The ETTAC focuses both on the current state of such technologies and projecting their potential future impact on U.S. national security, the U.S. defense industrial base, and the overall health and competitiveness of the U.S. economy.
- Provides assessments and information on emerging technologies and foundational technologies, potential so-called "chokepoint technologies," and trends in technologies in the United States and abroad of particular interest to BIS.

- Membership in the ETTAC shall not exceed 40 members.
- Members must be highly ranked, accomplished and recognized leaders, engineers, and scientists working in their disciplines as researchers or program-level managers.
- In 2025, the ETTAC will focus on Advanced Manufacturing, Biotechnologies, Quantum, and Space Technologies.
- Reach out to apply to join the ETTAC!



1758 Case Study – Radiation-Hardened Microelectronics

- ETTAC initiates review on radiation-hardened (rad-hard) microelectronics
 - Testing limits on rad-hard chips should be reviewed
- ECCNs reviewed: 3A101.a, 9A515.d and 9A515.e
- Rad-hard controls are appropriate for items built to last, rad-tolerant controls should be considered for further review.



Proposed rule October 23, 2024 (89 FR 84784)

- Proposes the Addition of License Exception Commercial Space Activities (CSA)
- <u>Excludes rad-hard</u> and <u>rad-tolerant</u> items from use of this LE CSA.



Emerging Technology Steering Committee

- The Emerging Technology Steering Committee (ETSC) is an interagency group that regularly evaluates items for consideration as 1758 technologies, chaired by BIS's Emerging Technology Division.
- The ETSC members identify technical subject matter experts within their respective Departments/Agencies to participate in meetings that align with their field of expertise.
- All ETSC members are expected to submit items for consideration as 1758 technologies.
 - Core ETSC members include Defense, Energy, and State. Other agencies, particularly funding agencies, should participate in the ETSC.
 - Participation from the Intelligence Community is critical
- As items are identified, interagency small groups will form to fully evaluate the item with the aim of developing a Notice of Proposed Rulemaking (NPRM) for public comment, and, if appropriate, a proposal to the relevant multilateral regime.

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ETSC Review Considerations

Technology, Maturity and Adoption

Is this U.S.-origin technology?
What is the Technology
Readiness Level?
What is the adoption, or likelihood of adoption in the marketplace?

National Security Concerns

Identify the potential applications for use military, intelligence, or nefarious uses of concern directly relating to the technology.

Export Controls Review

Would new controls be administratively possible? Would controls substantially hinder U.S. competitiveness ? Would a new control help protect U.S. military advantage?

Applications and Enabling Technologies

Identify the existing applications of the technology. Identify any risks related to military use of the technology. Identify specialized equipment required for applying the technology.

U.S. Industrial Landscape

Provide an assessment of the size of the market, domestic and global. Identify U.S. companies or institutions that would likely export the technology. Is there foreign ownership?

Foreign Availability

What is the foreign availability? Identify the foreign companies or institutions that develop this technology. Identify the likelihood of partners adopting similar controls.



1758 Case Study - Peptide Synthesizers

Technology, Maturity and Adoption

Automated peptide synthesis technology; at least in part U.S.-origin technology.
Technology is commercialized (U.S. and foreign) and has been adopted in various industries.

National Security Concerns

Many peptides, including toxins, are currently only available via traditional biological production. Direct synthesis has the potential to be a simpler, more reliable route for peptide production.

Export Controls Review

There are export controls on toxins and their related technology, but there were not controls on peptide synthesis equipment. With clear technical parameters, controls on peptide synthesizers are likely be administrable and enforceable.



CSBio CS136M Automated Research Scale Peptide Synthesizer



1758 Case Study - Peptide Synthesizers

Applications and Enabling Technologies

Several dozen small peptides are on the market as therapeutics with more in the drug pipeline. Market for boutique peptide synthesis for academic research. Software, reagents and consumables, microelectronics, robotics are enabling.

U.S. Industrial Landscape

There are a number of U.S.-headquartered firms that produce this type of equipment. The global market for peptide synthesis was estimated to be around \$780 m in 2023; includes instruments and service providers.

Foreign Availability

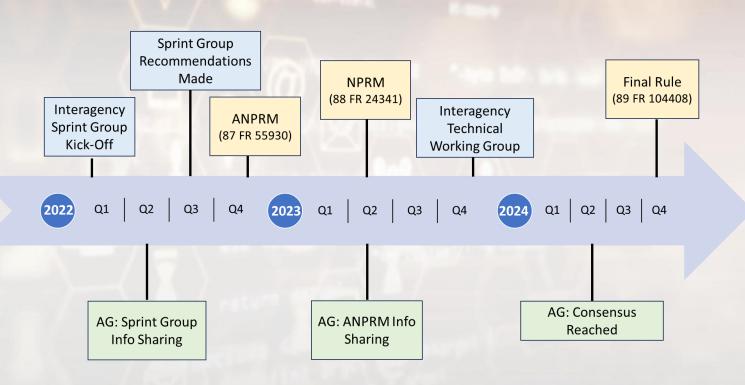
There is foreign availability on this equipment, including firms headquartered in the U.K. and Sweden. Foreign firms utilize these instruments as service providers globally. Working with partners critical to protect national security.



Biotage Syro II Fully Automated Parallel Peptide Synthesizer



1758 Case Study - Peptide Synthesizers



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.

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Foreign Technology Analysis

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BIS's Foreign Technology Analysis Mission

- Assess foreign technology capabilities to inform decision-making:
 - Identify technology chokepoints
 - Enable multilateral controls
 - Assess timelines to parity
 - Evaluate impact of existing and proposed controls



Foreign Availability Criteria:

- Available-in-fact
- Non-U.S. source
- Sufficient quantity
- Comparable quality

A key to effective export controls is setting control levels above foreign availability



Available-In-Fact

Definition:

- Produced within a country
- Can be obtained by a country from a third country
- Does not apply if item requires a license from a country maintaining comparable export controls with the U.S. (§768.1(d))

Evidence:

- Marketing materials
- Sales receipts
- Shipping documents
- Information from foreign government or company officials

(§768(a)(1))



Sufficient Quantity

Definition:

- Meets the military needs of a controlled country
- U.S. exports would not make a significant contribution to military potential (§768.1(d))

Evidence:

- Serial production
- Use in civilian applications
- Excess capacity
- Lack of targeting or purchase requests

(§768(a)(3))



Comparable Quality

Definition:

- Matches characteristics specified in the Commerce Control List (CCL)
- Is alike in function, performance, and service life (§768.1(d))

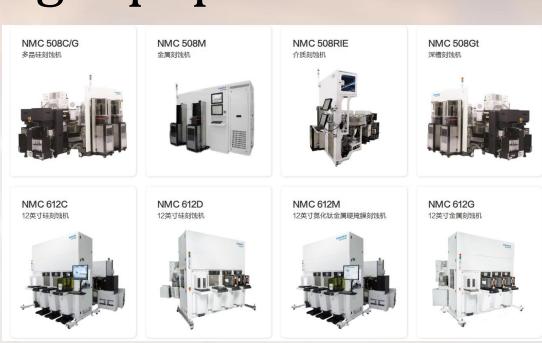
Evidence:

- Operation or maintenance manuals
- Patent descriptions
- Comparative evaluation
- Interchangeability (§768(a)(4))



Case Study - Dry Etching Equipment

- 2015: Determined foreign availability exists for anisotropic plasma dry etching equipment
 - Visited a Chinese producer of equipment meeting 3B001.c
 - Visited a foundry using Chineseproduced tool
- De-controlled for national security reasons

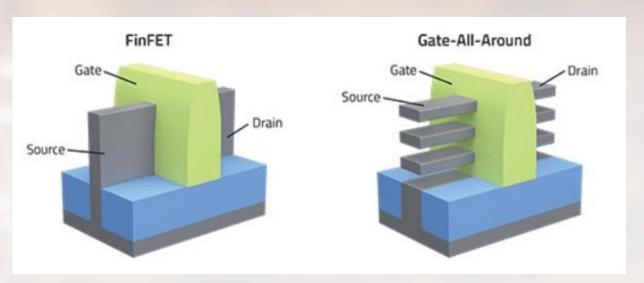


Plasma dry etching equipment advertised by Naura Technology



Case Study - Dry Etching Equipment

- Advances in technology have led to new types of dry etch equipment
- 2023: Added controls for isotropic and anisotropic dry etching equipment
 - Atomically precise equipment only available from Wassenaar Arrangement States

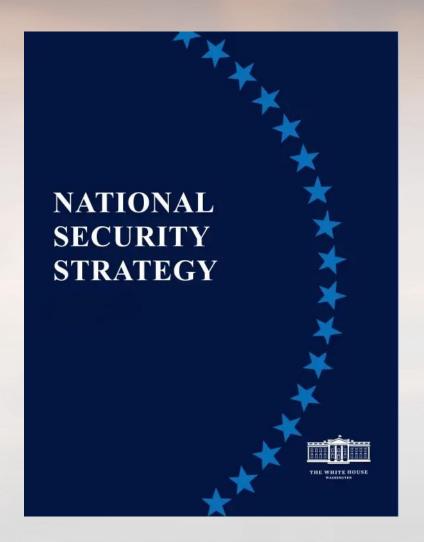


Gate-All-Around Field Effect Transistors (GAAFETs) require lateral etching with high selectivity.



Additional Considerations

- National Security Override (NSO)
 - The President may determine to maintain a control despite foreign availability if the absence of the control would be detrimental to national security (§768.7(i))





Questions?

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