

The Role of Export Controls in Regulating Dual Use Research of Concern

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Introduction

- **Purpose of the paper and agenda for discussion:**
 - Part I: Overview of key concepts in U.S. export controls, with a DURC orientation
 - The ITAR and the EAR, including their reach to technical data and exclusions for information in the public domain (ITAR) / published (EAR)
 - Part II: Discussion of the challenges of U.S. export controls in regulating the dissemination of DURC
 - Fundamental limitations on export controls
 - Constitutional constraints
 - Differences in objectives / methodologies between DURC policies and export controls
 - Risks of over relying on export controls to control DURC research

Part I - U.S. Export Controls

- **The U.S. export control system consists of two main bodies of regulations, administered by two different regulators, both of which could have a role in regulating DURC:**
 - The International Traffic in Arms Regulations (“ITAR”), administered by the U.S. Department of State, Directorate of Defense Trade Controls (“DDTC”)
 - The ITAR’s U.S. Munitions List (“USML”) controls at, Category XIV, “Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment,” as well as related technical data and defense services
 - The Export Administration Regulations (“EAR”), administered by the U.S. Department of Commerce, Bureau of Industry and Security (“BIS”)
 - The EAR’s Commerce Control List (“CCL”) controls, at Category 1, “Materials, Chemicals, Microorganisms and Toxins,” including related technology (technical data and technical assistance)

Part I - U.S. Export Controls

- **Both regimes control a range of activities with respect to regulated items:**
 - Exports from the U.S. to another country
 - Reexports/retransfers and in-country transfers abroad: movements of items subject to U.S. jurisdiction after their initial export from the U.S.
 - Deemed exports and deemed reexports: technology transfers to foreign persons
- **But note the focus on cross-border activity, or sharing controlled data or services with foreign persons**
- **Export controls are not intended to regulate purely domestic activity among U.S. persons – a key potential issue in seeking to use export controls to regulate DURC**

Part I - U.S. Export Controls

- **ITAR's USML (defense articles and defense services) controls:**
 - Prior to Export Control Reform (ECR): “[b]iological 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,” as well as related technical data and defense services
 - Post-ECR (effective Dec. 31, 2016): enumerated biological agents (and derived substances and related technical data/defense services), including the DURC agents when their harmfulness is increased through gain-of-function intervention, as well as certain vaccines and antibodies developed through DoD funding
- **EAR's CCL (dual-use and less sensitive military items) controls:**
 - Dozens of microbes, including all 15 DURC agents and those regulated by the Federal Select Agents Program, as well as certain related vaccines, immunotoxins, medical products, etc. and related technology

Part I - U.S. Export Controls

- **The ITAR do not control information released into the “public domain”**
 - This includes information made available to the public in eight enumerated ways (e.g., publication at libraries, newsstands, or conferences in the U.S. and through fundamental research at accredited U.S. academic institutions, provided there are no research restrictions)
- **The EAR do not control “published” information**
 - This includes information disseminated through subscriptions, at libraries, during conferences, and through Internet upload
 - This further includes pre-published work submitted, for publication, to co-authors/editors; researchers conducting fundamental research; or conference organizers
 - Information is still “published,” despite prepublication reviews (i) to protect patent rights, (ii) to ensure non-disclosure of sponsors’ proprietary information, or (iii) pursuant to federal agency review processes
 - Publication restrictions that are temporary only temporarily trigger export controls
 - Publication in compliance with research restrictions (self-imposed or government-mandated) is not subject to the EAR

Part II: Use of Export Controls to Regulate DURC

- **U.S. export controls may present a potentially appealing option for further controlling DURC:**
 - The 2012 and 2014 DURC Policies are limited in scope, formally applying only to government funded research, involving particular pathogens and particular experiments; U.S. export controls, by contrast, do not contain these constraints
 - Each of the 15 designated DURC pathogens, along with numerous others, are already listed in the EAR's CCL and pathogens with certain increased harmfulness due to gain-of-function modifications are already subject to the ITAR's USML
 - U.S. export controls are well established and the cognizant regulatory authorities seek to foster compliance through robust enforcement, outreach to the regulated community, and compliance support (e.g., publication of best practices and guidance, training, etc.)

Part II: Use of Export Controls to Regulate DURC

- **However, export controls have limits in their ability to regulate DURC**
- **Among the key issues: export controls are predominantly oriented toward activities that cross borders or involve foreign persons:**
 - Export controls do not apply to domestic activities of U.S. persons, which may be a focus of concern with respect to DURC
 - They also do not fully control imports:
 - The ITAR control temporary imports, but not permanent imports
 - The DoJ's Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) is responsible for regulating permanent imports; however, the U.S. Munitions Import List, which ATF administers, does not regulate biological agents or related technical data
 - The EAR do not control imports
- **Further, export controls do not apply to information in the public domain (ITAR) or that is published (EAR), further limiting their reach for DURC purposes**

Part II: Use of Export Controls to Regulate DURC

■ Constitutional constraints

Illustrative List of Tension Points between 1st Amendment and U.S. Export Controls



“[t]he First Amendment imposes significant constraints on the ability of the federal government to restrict publication of [WMD] information...anyone interested in manufacturing a...weapon of mass destruction can easily obtain detailed instructions for manufacturing and using such a device, both from legitimate publications and from so-called ‘underground’ publications [a]nd, presumably, most if not all of the writers and publishers of such publications do not obtain the information unlawfully, or from classified sources.”

(DoJ Report on the Availability of Bombmaking Information, the Extent to Which Its Dissemination Is Controlled by Federal Law, and the Extent to Which Such Dissemination May Be Subject to Regulation Consistent with the First Amendment to the U.S. Constitution (1997))

Part II: Use of Export Controls to Regulate DURC

■ **Distinct policy objectives**

- DURC Policies and export controls have different objectives
- DDTTC, July 2016: “[DURC policies and related government programs] are not munitions export control regimes and do not share the national security and foreign policy objectives of [U.S. defense export controls]” and these regimes “address largely unrelated regulatory concerns”

■ **Publication intent**

- Typically, export control classification is based on items’ technical specifications, with highly sensitive items subject to greater control, but for fundamental research content, intent to publish is the determining factor – not the nature or sensitivity of the research

BIS, September 2016 FAQs

- “Government-funded researchers studying *Bacillus anthracis* accept national security prepublication review of their research...[which is subject to the EAR]”
- “[A] joint U.K./U.S. university-based research project on vector identification for Marburg virus with no restrictions on publication...would be considered fundamental research...not subject to the EAR.”

Part II: Use of Export Controls to Regulate DURC

- **Using export controls to more extensively control DURC research risks eroding public-private collaboration and incentivizing scientists not to cooperate with biosecurity efforts**
 - Self-governance and public-private collaboration is critical in light of risks involved in DURC and the challenge of containing the spread of dangerous research information through traditional legal tools, such as export controls
 - Voluntarily submitting DURC for national security review can be prudent, but may risk triggering export controls, so the process must be managed wisely to avoid causing researchers to simply evade controls through unrestricted publication
 - Increased application of export controls to DURC could garner opposition from scientists and chill vital life sciences research

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