Hogan Lovells

Export Control Considerations for Sponsored Research, Technology Transfer and Licensing

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Export Considerations - Overview

Key Export Considerations Under the EAR

- When engaging in sponsored research and technology transfers, a license may be required based on:
  - WHAT: Export classification
    - Is the information/service being provided “technology”?
    - Check the Commerce Control List (“CCL”)
  - WHERE: Destination
    - Where is this going? China? Sanctioned country?
  - WHO: End-user
    - Who is using it? Restricted Parties? Military or Military-Intelligence end-user?
  - HOW: End-use
    - How is it being used? Military end-use?

- Level of vetting depends on the above factors, whether any Restricted Parties are involved, and the type of Restricted Party involved
  - Activities involving Burma, China, Russia, and Venezuela require increased diligence and vetting under military and military-intelligence end-use/end-user rules

Restricted Parties - Overview

- U.S. Government maintains restricted party lists, such as:
  - OFAC: Specially Designated Nationals (“SDN”) List, Sectoral Sanctions Identification (“SSI”) List, Foreign Sanctions Evaders List
  - BIS: Entity List, Denied Persons List, Unverified List, Military End User List, Military-Intelligence End User List
  - DDTC: Debarred Parties List
- Restrictions vary depending on the applicable Restricted Party List
- U.S. companies and organizations are expected to screen for Restricted Parties and conduct appropriate due diligence


Understanding
Restricted Party
Lists

Entity List requirements - licensing

- License required for export, reexport, or transfer of any item subject to the EAR to an Entity List entity
- License requirement applies if Entity List entity is any party to the transaction, not just consignee or end user of goods
  - This includes purchaser, intermediate consignee, ultimate consignee, and end user
- Example: Entity List party purchases item subject to the EAR and seeks delivery to another party
  - Even though Entity List party never takes physical possession of the item subject to the EAR, it acts as a party to the transaction as a purchaser
- Example: MGB employee provides technology subject to the EAR to a visiting professor in Boston employed by a Chinese research institute on the Entity List
  - Licensing requirement applies to employees of listed entities wherever located
  - Hiring ex-employee of an Entity List party is a “red flag”

Entity List reach - “legally distinct” analysis

- Generally Entity List license requirements **do not** *per se* apply to “legally distinct” entities
  - Separate legal entities such as subsidiaries, parent companies, sister companies
  - But this is a “red flag” that requires due diligence
  - Different than SDN List and other OFAC lists
- Branches and operating divisions are, by definition, part of a listed entity, and are not legally distinct
- Acting as an agent, a front, or a shell company for the listed entity would be subject to Entity List restrictions or could result in a violation

Entity List v. Other Lists

- **SDN List**
  - All activities that directly or indirectly involve an SDN are prohibited under primary U.S. sanctions (where there is a US nexus) absent an exemption or OFAC authorization
  - Secondary sanctions apply to certain SDN programs even where there is no US nexus
  - Restrictions extend to any non-listed entity that is owned (at 50% or greater level) or controlled directly or indirectly by a listed party
- **BIS Denied Persons List**
  - Listed individuals and entities have been denied export privileges
  - Any dealings with a party on this list that violate the terms of its denial order are prohibited
- **BIS Unverified List ("UVL List")**
  - Listed parties raise a red flag requiring additional diligence
  - Listed parties are ineligible to receive items subject to EAR by means of a license or license exception
- **OFAC Sectoral Sanctions Identifications List ("SSI List")**
  - Targeted restrictions based on the OFAC Directive under which they were designated
  - No broad prohibitions on dealings – targeted financial or other restrictions
  - No blocking requirement
- **OFAC Foreign Sanctions Evaders ("FSE List")**
  - All transactions prohibited
  - No blocking requirement

Military End Use / End User ("MEU") List

- MEU Rule prohibits export, reexport or transfer of certain items to military end users or for military end uses in China, Russia, and Venezuela without a license
  - Army, navy, marine, air force, or coast guard, as well as national guard/ police, government intelligence or reconnaissance organizations (except those subject to the MIEU rule), or any person or entity whose actions or functions are intended to support military end uses
- Restrictions only apply to the specific items listed in Supplement No. 2 to Part 744 of the EAR
  - Includes certain items subject to low levels of export controls (e.g., 5D992 "mass market" software and 3A991 electronic items)
  - Does not apply to EAR99 items (i.e., most items used by hospitals)
- BIS provided a list of MEU entities but it is not exhaustive
  - U.S. entities must conduct due diligence to confirm counterparty is not an MEU

Military-Intelligence End User ("MIEU") List

- MIEU Rule prohibits:
  - Export, reexport, and transfer of *any item subject to the EAR* to military-intelligence end users or military-intelligence end uses in China, Russia, Venezuela, Cuba, Iran, North Korea or Syria without a license
    - Applies to EAR99 items (e.g., common medicine and medical supplies such as cotton swabs)
  - Certain transactions by US persons in support of MIEUs or military-intelligence end uses *even if items are not subject to the EAR*.
    - Prohibited activities include performing any contract, service or employment to benefit or assist an MIEU
- MIEUs include any intelligence or reconnaissance organization of the armed services (army, navy, marine, air force or coast guard) or national guard
- BIS provided a list of MIEUs but it is not exhaustive
  - U.S. entities must conduct due diligence to confirm counterparty is not an MIEU

MEU and MIEU Lists – How do they impact MGB?

- MIEU is new as of March 2021 – scope of enforcement/interpretation unclear
- MEU List – restrictions apply only to certain items
  - Most common medical items unlikely to be subject to restriction
  - Restrictions do not apply if activities only involve EAR99 items or services only
  - Should also consider reputational and other risks related to engagements with MEUs
- MIEU List – restrictions apply for all items subject to EAR, and even to transactions where no items are being provided
  - Cannot provide any types of items to MIEUs
  - US organizations cannot provide support to MIEUs, including provision of services that benefit or assist an MIEU
    - This is the case even if your services are purely civil end-use
  - Given difficulty of confirming MIEU status some health sector participants are choosing not to engage with potential MIEU hospitals or research institutes as a risk mitigation policy

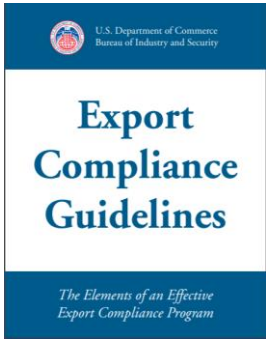
MEU/MIEU List Due Diligence

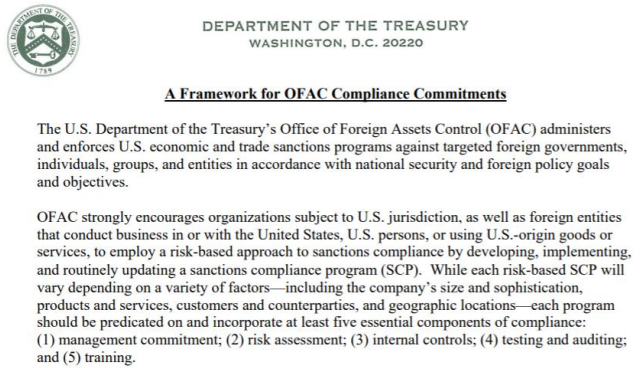
- Per BIS guidance, due diligence required to determine whether military hospitals would be considered MEUs or MIEUs. Factors to consider:
  - Actual relationship of hospital to the armed services
  - Patient population served
  - Whether the hospital develops, produces, maintains, or uses military items
- There is no one source for confirming this type of information; need to consider available information from public sources
  - General internet research
  - Databases/data services for reviewing ownership and affiliations (i.e. Kharon, Orbis)
  - Chinese language internet resources - review of entity websites and articles available in Chinese
  - Chinese corporate ownership information (may require assistance from Chinese service provider)
  - Information provided by potential customer (e.g., description of organization, certifications)

Best Practices for Screening/Vetting International Entities

Restricted Party Screening

- U.S. government expects organizations to have an effective screening program
  - BIS Export Compliance Guidelines
  - Framework for OFAC Compliance Commitments
  - OFAC settlements/press releases
- Compliance programs, including screening, should be "risk-based" – e.g., tailored to the company's particular risk profile





DEPARTMENT OF THE TREASURY
WASHINGTON, D.C. 20220

A Framework for OFAC Compliance Commitments

The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) administers and enforces U.S. economic and trade sanctions programs against targeted foreign governments, individuals, groups, and entities in accordance with national security and foreign policy goals and objectives.

OFAC strongly encourages organizations subject to U.S. jurisdiction, as well as foreign entities that conduct business in or with the United States, U.S. persons, or using U.S.-origin goods or services, to employ a risk-based approach to sanctions compliance by developing, implementing, and routinely updating a sanctions compliance program (SCP). While each risk-based SCP will vary depending on a variety of factors—including the company's size and sophistication, products and services, customers and counterparties, and geographic locations—each program should be predicated on and incorporate at least five essential components of compliance: (1) management commitment; (2) risk assessment; (3) internal controls; (4) testing and auditing; and (5) training.

Risk-Based Compliance – key questions

- What is MGB's risk profile?
  - Look at risks associated with counterparties and location
- Factors to consider in screening:
  - Any parties involved in transaction should be screened (licensees, sponsors, contracting counterparties, banks used for payments, sponsors)
  - Restricted Party screening is conducted by MGB Export Control Officers in Research Compliance
  - Conduct screening at initial stages before a contract is signed
  - Consider rescreening on a regular basis or when terms of agreement are updated
  - Have an escalation and additional due diligence process for assessing any potential "hits"
    - Assess ownership and affiliations
    - Review of publicly available information (news reports, press releases)
  - Transactions with potential restricted party matches should be placed on hold until review is completed
- Have a process if existing counterparties are designated to restricted party list
  - Front-end: contractual clauses allowing termination, certifications
  - Immediate termination of activities with counterparty, stop payments or other financial activities, ensure relevant employees are alerted

Best practices for China

- "Holistic" screening process for China
  - Automated RPL screening is only one part of the compliance process for China
  - Also have procedures for the following:
    - Military and military-intelligence end use / end user rule
    - Human rights
    - Other red flags
- Front-end due diligence process for Chinese parties
  - Research corporate structure of business partners, including any potential affiliations with listed parties
  - As necessary, consult outside advisors to assist with diligence (e.g., Chinese language sources)
  - Understand differences between the lists ("legally distinct" analysis vs. OFAC 50% rule)
  - Ex: West China Hospital
    - Merged with Sichuan University, an Entity List entity, in 2000
    - Not considered "legally distinct" – subject to Entity List restrictions

Best practices for China

- Have a playbook for resolving any potential Entity List and Restricted Party affiliations
  - End-User/Customer Certifications
  - Contractual Provisions
  - Refresh analysis periodically (e.g., corporate structures in China can change frequently)
- Consider reputational issues and risk appetite prior to entering into engagements, even if transactions are not legally prohibited

Takeaways

- Restricted Party screening is conducted by MGB Export Control Officers in Research Compliance
  - MGB uses the Visual Compliance restricted party screening tool
- All parties to transactions should be screened
- Be alert for affiliations or ownership by restricted parties
- Be alert for potential military end use/military-intelligence end use activities of counterparties, even in purely commercial transactions
- Consider whether any services provided might involve controlled technology
- Support export compliance efforts of MGB
  - Screening
  - Due diligence
  - Contractual provisions
  - End use/end user certifications

Export Control Template Language for Agreements

Sample Contractual Provisions – Innovation Licensing Agreement

Export Controls Compliance (i) Company shall have the sole obligation for compliance with, and shall ensure that any Affiliates and Sublicensees comply with, all applicable laws and regulations of the United States and other applicable jurisdictions that relate to Products and Processes, including but not limited to, those of the Food and Drug Administration, U.S. Department of Agriculture, U.S. Centers for Disease Control and Prevention, the U.S. Department of Commerce's Export Administration Regulations ("EAR"), 15 C.F.R. 730-774, the U.S. Department of State's International Traffic in Arms Regulations ("ITAR"), 22 C.F.R. 120-130, and the economic sanctions programs administered by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), as set forth in 31 C.F.R. 500-598 and certain executive orders. Company will comply with all such laws and regulations in the performance of this agreement.

(ii) Company represents that it (i) is not identified on, or owned or controlled by or acting on behalf of any individuals or entities identified on, applicable government restricted party lists ("Restricted Parties"); (ii) is not located in, organized under the laws of or ordinarily resident in Cuba, Iran, North Korea, Syria or Crimea ("Restricted Territories"); or (iii) will not directly or indirectly export, re-export or otherwise transfer any goods, technology or services covered by the Agreement to or for use in, by or from Restricted Territories or Restricted Parties.

(iii) [Company acknowledges that the Agreement involves activities eligible for the fundamental research exclusion set forth in Section 734.8 of the EAR.][WOULD NEED TO CONFIRM ON A PROJECT BY PROJECT BASIS.]

Sample Contractual Provisions – Innovation Licensing Agreement

(iv) Company shall be responsible for obtaining all information regarding such regulations that is necessary for Company to comply with such regulations, and for implementing reasonable controls to confirm compliance.

(v) To the extent the fundamental research exclusion does not apply to its activities, Company shall be responsible for obtaining any export licenses or other authorizations required to export, reexport, transfer, or import any controlled technology, software, or any other item, including Products or Processes covered by Licensed Patent Rights and/or Confidential Information.

(vi) Company shall provide written notice to Hospital if Company intends to disclose any technology, software, or any other item to Hospital controlled under the ITAR or at a level higher than EAR99 or anti-terrorism controls only under the EAR. Such notice will include the proper export classification and reference the applicable export control laws and regulations. Hospital reserves the right, in its sole discretion and consistent with the fundamental research exclusion, to refuse to accept such controlled technology, software, or any other item or use it in the performance of the Agreement. Notice required under this section shall be sent to [Insert point of contact].

(vii) Company shall indemnify and hold harmless Hospital and [] for and against any claims, damages, losses or costs arising out of Company's breach of this Section.

Sample Contractual Provisions - SRA

Export Controls. (i) Hospital is committed to the principle of "Openness in Research" which precludes acceptance of any conditions that impose access, dissemination, publication, or participation restrictions on the conduct, products, or results of its research. Hospital performs only unclassified, non-secret research, openly conducted. Hospital conducts research that conforms with the meaning of "fundamental research" under the Commerce Department's Export Administration Regulations ("EAR") (15 C.F.R. § 734.8). Any information resulting from fundamental research would be excluded from the EAR pursuant to the Fundamental Research Exclusion ("FRE").

(ii) To the extent certain information is not eligible for the FRE, Company shall be responsible for obtaining any required export licenses or other authorizations. Company further acknowledges that the export, re-export, and/or retransfer of certain technology, software, and items may be subject to applicable laws and regulations of the United States and other applicable jurisdictions, including but not limited to, those of the Food and Drug Administration, U.S. Department of Agriculture, U.S. Centers for Disease Control and Prevention, U.S. Department of Commerce's Export Administration Regulations ("EAR"), 15 C.F.R. 730-774, the U.S. Department of State's International Traffic in Arms Regulations ("ITAR"), 22 C.F.R. 120-130, and the economic sanctions programs administered by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), as set forth in 31 C.F.R. 500-598 and certain executive orders. Each Party agrees to comply with all such laws and regulations and acknowledges and agrees that it shall be solely responsible for obtaining any necessary licenses or permits for it to export, re-export, or retransfer of any technology, software, or other items subject to these laws and regulations.

Sample Contractual Provisions - SRA

(iii) Company represents that it (i) is not identified on, or owned or controlled by or acting on behalf of any individuals or entities identified on, applicable government restricted party lists ("Restricted Parties"); (ii) is not located in, organized under the laws of or ordinarily resident in Cuba, Iran, North Korea, Syria or Crimea ("Restricted Territories"); or (iii) will not directly or indirectly export, re-export or otherwise transfer any goods, technology or services covered by the Agreement to or for use in, by or from Restricted Territories or Restricted Parties.

(iv) Company shall provide written notice to Hospital if Company intends to disclose any technology, software, or any other item to Hospital controlled under the ITAR or at a level higher than EAR99 or anti-terrorism controls only under the EAR. Such notice will include the proper export classification and reference the applicable export control laws and regulations. Hospital reserves the right, in its sole discretion and consistent with the fundamental research exclusion, to refuse to accept such controlled technology, software, or any other item or use it in the performance of the Agreement. Notice required under this section shall be sent to [Insert point of contact].

Questions?