Deemed exports and fundamental research involving chemical and biological items

Many people have questions on what triggers a requirement for a deemed export license under the Export Administration Regulations (EAR) for releases to foreign nationals in the U.S. of technology or source code controlled for biological and chemical reasons in the context of research activities.

Additional questions arise in the context of research activities, including activities that constitute fundamental research under the EAR. See Section 734.8 (a) and (c).

The guidance below builds upon website guidance that addresses questions regarding deemed exports and fundamental research that BIS issued in September 2016 following publication of the "Definitions" Rule.

What is a deemed export?

Any release of technology or source code subject to the EAR to a foreign person (national) in the United States is deemed to be an export to the individual's most recent country of citizenship or permanent residence(see Section 734.13(b) for which a deemed export license may be required. This "deemed export rule" does not apply to lawful permanent residents or protected individuals. See

What technology is subject to the EAR?

All technology in the United States is subject to the EAR *except* for the following:

Technology under the jurisdiction of another agency, printed books, publicly available technology, technology that has been or will be published, technology that arises during or results from fundamental research, educational technology, and technology in certain patent applications (Part 734.3).

Is biological or chemical research subject to the EAR?

Research in the United States would be subject to the EAR unless it met one of the exclusions noted above. Many of the research activities in university or commercial laboratories located in the United States or funded by USG or US persons are not subject to the EAR if they are undertaken as a part of fundamental research.

What is fundamental research (Section 734.8)?

Fundamental research means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons. See Section 734.8(c).

As a general matter, technology (link to EAR definition) or software (link to EAR definition) that arises during or results from fundamental research and is intended to be published is not subject to the EAR. See Section 734.8(a).

- **Example:** University based research on vectors for salmonella typhi, with results that are published and shared broadly.

What is NOT fundamental research?

It is NOT considered fundamental research when there are restrictions placed on the outcome of the research or restrictions on methods used during the research. Proprietary research, industrial development, design, production, and product utilization, the results of which are restricted, and government funded research that specifically restricts the outcome for national security reasons are *not* considered fundamental research. For additional guidance regarding the scope of fundamental research under the EAR, see 2016 FAQs, specifically [...].

- **Example:** University based research on bacillus anthracis that has restrictions on publications of scientific and technical information resulting from the research.
- **Example:** A university in the United States has a collaborative research agreement with a private company. The company transmits proprietary technology to the university to conduct the research with the condition that it not be published or otherwise made public. The company proprietary information, if subject to the Export Administration Regulations (i.e., not subject to the jurisdiction of another Agency, e.g., the Department of State and the International Trade in Arms Regulation), may require deemed export licensing authorization if released to a foreign national.

Deemed exports (releases of biological/chemical technology)

If your research is not fundamental research, then the technology (or software) arising out of the research or resulting from the research may be subject to the EAR.

Is a deemed export license required to release the technology to a foreign national? Does your biological research involve a controlled pathogen (1C351, 1C353, 1C354, 1C991) or controlled equipment (2B352)? Please review the Commerce Control List or use the interactive Commerce Control List.

If you are working with controlled pathogens or equipment, then the technology being shared with/released to the foreign national needs to be classified. There are 5 main technology ECCNs that need to be reviewed in the area of biological research:

- **1E001** which is technology for the “development” or “production” of controlled biological agents
- **1E351** which is technology for the disposal of controlled biological agents
- **2E001** which is technology for the “development” of controlled equipment
- **2E002** which is technology for the “production” of controlled equipment
- **2E301** which is technology for the “use” of controlled items

Let’s go through each type of technology and give examples

1E001: “development” or “production” technology – If technology being shared with/released to the foreign national on how to grow, maintain, quality check a pathogen is in the public domain and the research is going to be published, then this research is not subject to the EAR and no deemed export license is required. Alternatively, if the researcher was working on a sensitive project involving biodefense or some other type of research for which there is required prepublication review and

involved proprietary or non-standards technology regarding the pathogen (not in the scientific literature), then 1E001 might apply.

1E351: disposal technology – Most biological agents are destroyed through autoclave, chemicals, and other publicly available techniques and therefore it is not subject to the EAR.

2E001 and 2E002 technology controls – These would only apply if the researcher was developing or producing 2B352 controlled biological equipment. An example of controlled technology would be technological data for constructing cross flow filters controlled under 2B352d. The same exclusion applies, that if the research is intended to be published or broadly shared, then it would be considered fundamental research. Information arising during or resulting from such fundamental research would not be subject to the EAR.

2E301 which is 'use' of controlled biological equipment. In order for technology to be considered "use' it must have all six elements of the definition of 'use': operating, installing, maintaining, repairing, overhauling, and refurbishing. This is not the normal activity of researchers. They are typically operating, maintaining and maybe repairing a controlled item such as a fermenter. The operation of a piece of equipment is not 'use' technology as defined in the EAR.

General Technology Note (Supplement Number 2 to Part 774)

"The export of "technology" that is "required" for the "development," "production," or "use" of items on the Commerce Control List is controlled according to the provisions of each Category.

Deemed exports for chemical items

Deemed exports may also apply to the production, development and use of chemicals and chemical equipment that are, in particular, classified under ECCN 1C350 and 2B350, respectively. Controlled technology can take many forms, including technical data, technical assistance and software source code. Such information may be transferred through visual inspection of equipment or facilities, oral exchanges with others, the application of personal knowledge or technical expertise to a particular situation, transfers of electronic or physical documents, review of technical drawings/blueprints or other similar methods. Such documents may include blueprints, drawings, photographs, plans, diagrams, models, formulae, tables, and engineering specifications

However, if a person is only given information concerning how to operate certain controlled equipment, this is usually not enough to trigger a deemed export license requirement under the EAR. This may include a general operating manual or a basic Piping and Instrumentation Diagram (PID) which are usually publicly available documents. Basic marketing materials on function, purpose or general descriptions of these items are generally not included as well.

Specific examples

2E001 and 2E002 which is technology for the "development" and "production" of controlled equipment:

Research and development into proprietary Inconel cladding application methods for the development and production of valves classified under ECCN 2B350.

1E001 which is technology for the "development" or "production" of controlled chemical agents:

Research and development of novel synthetic pathways for the synthesis of thiodiglycol, a chemical controlled under ECCN 1C350.

Definitions (Part 772)

Required. (General Technology Note) – As applied to "technology" and "software", refers to only that portion of "technology" or "software" that is peculiarly responsible for achieving or exceeding controlled performance levels, characteristics or functions.

Development. (General Technology Note) – "Development" is related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, layouts.

Production. (General Technology Note) (All Categories) – Means all production stages, such as: product engineering, manufacture, integration, assembly (mounting), inspection, testing, quality assurance.

Use. (All Categories and General Technology Note – Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.

Thumb Rule on "use" technology: if the technology does not enable improvement of equipment design (i.e., "development" technology) or replication of the item (i.e., "production" technology) then the information, if subject to the EAR (i.e., not in the public domain) is likely EAR99.

Note on "required" technology: if the information is not in the public domain, is subject to the EAR, and does not enable achieving or exceeding the controlled parameters of the end item, then the technology is likely EAR99.

Quiz

1. Does a foreign national require a deemed export license if he/she is working with a controlled pathogen, toxin or genetic element of a controlled pathogen? (Remember: Access to a controlled pathogen or to controlled equipment associated with the work on a pathogen is not a deemed export. A deemed export is the release to a foreign national in the United States of "technology" or "source code" "required" for the "development," "production," or "use" of the controlled pathogen or controlled equipment.)
    a. **Answer**: No, if technology arises during or results from fundamental research, or if the technology to be shared does not meet the definition of development or production as noted above even if the research is not fundamental. Yes, if the technology being shared meets the definitions and it is during fundamental research.
2. Does a foreign national require a deemed export license if he/she is using controlled equipment in a laboratory?
    a. **Answer:** No, the information provided did not indicate that the individual was overhauling or refurbishing equipment – they were only operating the equipment, and it does not meet the definition of 'use'.

3. Does a foreign national require a deemed export license if he/she works in a BSL3 or BSL4 lab?

    a. **Answer:** No, working in a BSL3 or BSL4 facility is indicative of the types of dangerous pathogens but just stepping foot into a facility does not trigger a deemed export license requirement.

4. Does a foreign national require a deemed export license if he/she is purchasing controlled equipment and getting trained on how to use the equipment in the U.S.?

    a. **Answer:** No, being taught how to operate a purchased piece of equipment is not considered use technology. A deemed export license is not needed.

5. I have determined the research being conducted at my university is fundamental research and foreign nationals are involved in the research. My university is collaborating with a foreign university on this effort and as part of this collaboration we need to export the controlled pathogen involved. Does the fundamental research exclusion authorize this export without a license?

    a. **Answer:** No, fundamental research only applies to technology or software. Deemed exports only applies to release to a foreign national of technology and source code in Products Group D and E on the Commerce Control List. Material commodities including systems, equipment, and components (Product Group A), test inspection and production equipment (Product Group B) and raw materials (Product Group C – pathogens, toxins and genetic elements) would require authorization for export and may require a license depending on the recipient university's country.