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Deemed Exports and Fundamental Research for Biological Items

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Many people have questions on what triggers a requirement for a deemed export license in the Export Administration Regulations (EAR) for biological research.

What is a Deemed Export ?

Any release of technology or source code subject to the EAR to a foreign national (Part 734.2(b)(2)(ii)). This does not apply to permanent residents or protected individuals.

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 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. Much of the research in University laboratories is not subject to the EAR if it is fundamental research.

What is Fundamental Research (Part 734.8) ?

Fundamental research is basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community. The techniques used during the research are normally publically available or are part of the published information.

- Example: University based research on vectors for salmonella typhi which is published 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

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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.

- Example: University based research on bacillus anthracis that has restrictions on publications of scientific and technical information resulting from the research

- Example: A university has a collaborative research agreement with a private company. The company releases its proprietary technology to the university to conduct the research with the condition that it not be released to the public. The university agrees to a non-disclosure statement as part of the collaborative agreement. 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.

If your research is NOT fundamental Research, then your technology may be subject to the EAR, but does it require a license ? Does your biological research involve a controlled pathogen (1C351, 1C352, 1C353, 1C354, 1C360, 1C991) or controlled equipment (2B352) ? Please review the Commerce Control List which can be found at www.bis.doc.gov.

If you are working with controlled pathogens or equipment, then the technology being shared with the foreign national needs to be determined. There are 5 main technology ECCNs that need to be reviewed for 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 most of the technology being shared with 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 that would not be allowed to be published without strict 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 publically 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 2B352 controlled biological equipment. They would be producing or developing controlled equipment. The same exclusion applies, that if the research will be broadly published, then it would be considered fundamental research and not 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 fermentor. 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

Definitions (Part 772)

Required. (General Technology Note) – As applied to “technology” and “software”, refers to only that portion of “technology” or “software” which 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, therefore 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. If a foreign national is working with a controlled pathogen does that require a deemed export license ? (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.) **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. If a foreign national is using controlled equipment in a laboratory does that require a deemed export license ? **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. If a foreign national works in a BSL3 or BSL4 lab does that require a deemed export license ? **Answer:** No – working in a 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. If a foreign national is coming to accept the purchase of a piece of equipment and get trained on how to use the equipment does that require a deemed export license ? **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? **Answer:** No, fundamental research only applies to technology. 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 are controlled in ECCNs 1C351 and 1C352) would require authorization for export and may require a license depending on the recipient university’s country.

