Demystifying Department of Commerce Export Controls for the Biosafety Professional

Kimberly Orr and Betty Lee

Bureau of Industry and Security, Washington, DC

The Department of Commerce, Bureau of Industry and Security (BIS) has the jurisdiction to oversee dual use exports that have an impact on the national security of the nation. BIS is responsible for implementing and enforcing the Export Administration Regulations (EAR) that regulate the export and re-export of most dual use items to advance the national security, foreign policy, and economic interests of the United States of America. The term *dual use* is used to describe items that have both commercial and military or proliferation applications. Certainly not all, or even a large proportion, of biological agents and processing equipment are considered dual use and listed on the Commerce Control List (CCL). However, the majority of these items **is subject to the EAR** and thus controlled by the Department of Commerce and may indeed, depending upon the destination, require a license for export. However, some general medical equipment, devices, and pharmaceuticals are classified as EAR99 and may not require a license to most countries except the sanctioned countries such as Iran, Syria, Sudan, North Korea, and Cuba.

This article presents an overview of Department of Commerce regulations and commodities that relate to biological science research. Under almost all circumstances, license applications and commodity classification requests must be completed electronically through the Simplified Network Application Process Redesign (SNAP-R) using an assigned PIN. SNAP-R is available as a link on the homepage of the BIS web site, www.bis.doc.gov.

The first area of export controls that relate to life sciences are the biological items listed in Category 1 of the CCL under Export Control Classification Numbers (ECCN) 1C351, 1C352, 1C354, and 1C360. Items controlled include the Select Agents (any form, even attenuated) as well as other agents that the Australia Group (AG-multilateral regime of 41 countries including the European Commission) has agreed jointly to control. These additional agents include Rabies (Lyssa virus) and Chlamydia psittaci, so it is important to consult the CCL to confirm that the agent to be exported does not require a license. If the item happens to be a licensed vaccine for an agent listed in one of the above ECCN, you should review ECCN 1C991 since an export license may be required for anti-terrorism reasons to some sanctioned or embargoed countries.

If the item to be exported is a genetic modification of a CCL-listed microorganism, then ECCN 1C353 is the reference to check to determine if a license is necessary. The language and application differ from the Select Agent regulations; they focus on nucleic acid sequences associated with the pathogenicity of *any* CCL-listed organisms or coding for listed toxins or sub-units of toxins. This includes pathogenicity-associated genetic elements taken from a CCL-listed organism or inserted into another organism which may result in increased pathogenicity as indicated by representing a significant hazard to human, animal, or plant health. Questions as to whether a genetic element requires a license or not can be addressed through a Commodity Classification request (supplement to part 748.3 of the EAR) submitted online through the SNAP-R.

Other items related to biosafety/security fall under Category 2 (e.g., ECCN 2B352). This ECCN controls the export of various bioprocessing equipment including fermenters, cross-flow filtration devices, Class III biological safety cabinets, and others. This control is unlikely to impact on international collaborations of research, unless the equipment is being provided.

Technology (according to the General Technology Note – Supplement 2 to part 774 of the EAR) related to "development" or "production" of all the above-listed ECCNs as well as "use" technology for 2B352 may be controlled as well (the terms "development," "production," and "use" are defined in Part 772 of the EAR). Key ECCNs include 1E001, 1E351, 2E001, 2E002, and 2E301. These controls apply when technology is being exported via overseas training, sharing of laboratory protocols, etc. If the controlled technology is shared with a foreign worker in the United States, it is considered a deemed export to the country of the foreign national.

Deemed export is a term that causes a lot of consternation when laboratories have foreign-national students or workers. People exempt from a deemed export license are green card holders or permanent residents, those granted U.S. citizenship, or "protected persons" under 8 USC 1324b(a)(3). Likewise, fundamental research for CCL-listed items does not require a deemed export license. The definition of fundamental research is found in the EAR Part 734.8 as well as a discussion of its

interpretation at a university, federal agency, corporation, or other setting. So, a person most likely requiring a deemed export license is a foreign national (who is not a green card holder, nor a citizen, nor a protected person) who is doing non-fundamental research involving growth or manipulation of a listed microbial agent. In addition, foreign nationals of some countries may need deemed export licenses for technology associated with the use of biological processing equipment listed under ECCN 2B352 (corresponding to technology controls 2E301).

This has been a short review of the key ECCNs associated with life science research. Information on export to specific countries of concern, help with filing licenses, frequently asked questions, etc., are all posted on the BIS web site (www.bis.doc.gov). Changes to the Commerce Control List are driven by Australia Group deliberations and Select Agent list updates. All changes are posted in the *Federal Register* and the online version of the EAR. Listed below are some direct links to helpful information:

- Bureau of Industry and Security web site, www.bis.doc.gov
- Commerce Control List, Supplement No. 1 to Part 774, EAR, www.access.gpo.gov/bis/ear/ear_data.htm l#ccl
- Deemed Export FAQ from the Bureau of Industry and Security web site, www.bis.doc.gov/deemedexports/
- SNAP-R information from the Bureau of Industry and Security web site, www.bis.doc.gov/snap/index.htm
- Australia Group web site, www.australiagroup.net
- Select Agents web site, www.selectagents.gov

Guidance for Evaluating Efficacy of *Clostridium difficile* Spores

Clostridium difficile (*C. difficile*) is a microorganism that has been implicated as a cause of potentially dangerous diarrheal illness. In 2008 the EPA reversed its decision to allow disinfectant product label claims for the vegetative form of the organism, *C. difficile*. This decision was made in light of current research demonstrating that the spore form is persistent on environmental surfaces and is implicated in the spread of diarrhea associated with *C. difficile*. In addition, products effective against only the vegetative form could spread the spores and increase the possibility of infection. Given this information, the Agency believes products with claims of efficacy against only the vegetative form of the organism pose unreasonable risks of harm to health and the environment. Registrants were contacted and required to eliminate label claims for this organism until sporicidal data against *C. difficile* is generated.

The Agency has posted interim guidance for efficacy testing to obtain the *C. difficile* sporicidal claim for hard non-porous surfaces. The guidance presents four standard test methods for evaluation of dilutable and ready-to-use liquids; as well as procedural details, product performance standards, and special label language. The guidance also outlines the procedure if registrants wish to test spray, towelette or foam products; or if another test method is desired. Agency scientists and regulators are continually working to improve knowledge in this area and are confident that this interim approach will serve to educate registrants on testing against *C. difficile* that reflects real-world challenges, and will allow effective products to enter the market and address rising numbers of *C. difficile*-associated infections. For a copy of the guidance, see www.epa.gov/oppad001/cdif-guidance.html