Biotechnology and Export Controls

Because the proliferation of chemical and biological weapons is viewed as a major threat to U.S. national security, export controls may be new to many in the biotech field.

Outsourcing of biological testing, engineering and manufacturing is quickly expanding, and involves critically important Export Control requirements.

Biological material includes:

- Toxins
- Pathogens (including human, animal and plant)
- Genetically modified organisms

Bureau of Industry & Security (BIS) - EAR

Categories 1 and 2 of the CCL are the particular controls for the biotechnology sector.

- ECCN 1C351 (human pathogens)
- ECCN 1C352 (animal pathogens)
- ECCN 1C354 (plant pathogens)
- ECCN 1C360 (select agents)
- ECCN 1C991 (vaccines)
- ECCN 2B352 (equipment for use in biological material handling)

These ECCN numbers, as with all ECCNs, contain specific information in regards to what material is controlled, the reason for control, and whether license for exceptions apply.

Directorate of Defense Trade Center (DDTC) - ITAR

The DDTC controls certain biological agents and chemicals that have been or have the potential of being weaponized, and/or equipment specifically designed or modified to dispose of biologics within Category XIV**.**

- Category XIV(b) - biological agents
- Category XI(h) - medical countermeasures

The export of controlled technology/technical data is governed by both EAR and ITAR.

- Technology (as defined by EAR) - information that is required for the development, production or use of a controlled item on the CCL. *it is possible for technologies to be controlled even when the product associated with it is not controlled (e.g. some coatings)*

- Technical data (as defined by ITAR) - any information, classified or not, required for the design, development, production, operation, repair, testing, maintenance or modification of defense articles.

Please contact the Export Control Office for guidance on your particular biologic to determine if export controls apply.