Biosafety/Export Control Collaborations

UNIVERSITY
OF
CALIFORNIA

A common issue?

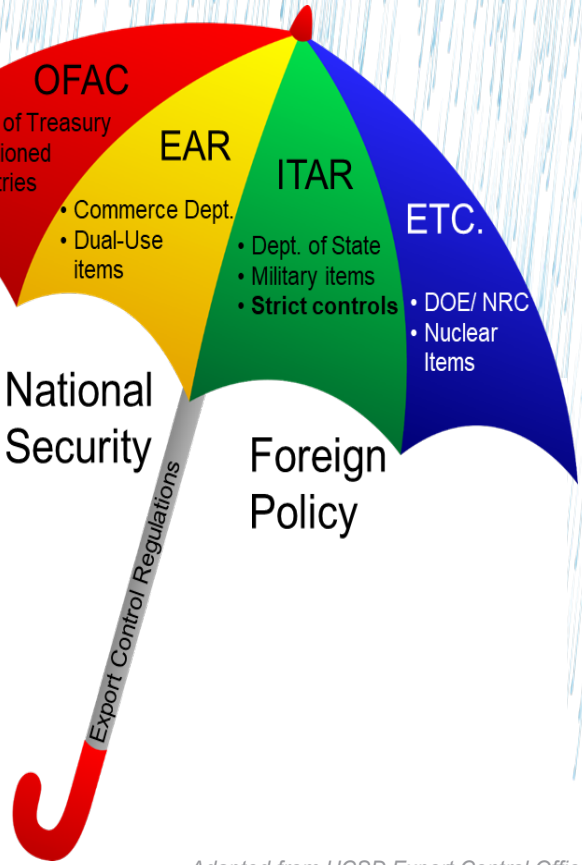
- February 2021 - U.S. Department of Commerce **$54,000 administrative settlement with Princeton University**.
- **37 occasions** between November of 2013 and March of 2018, Princeton University **exported various strains and recombinants of animal pathogens** from the United States to various overseas research institutions without the required export licenses.
- The items were valued in total about $27,000.
- Princeton University voluntarily self-disclosed potential violations of the Export Administration Regulations (EAR) to BIS, and cooperated with the investigation.
- **Princeton University also agreed to complete one external audit and one internal audit of its export compliance program.**

What are Export Controls?

Federal laws and regulations that control:

- The export of sensitive equipment, software, and technology
- Trade and financial transactions

Promote **national security interests** and **foreign policy objectives**.



Adapted from UCSD Export Control Office.

What might require an export license?

- Listed biological agents and genetic elements
- Vaccines, immunotoxins, medical products, diagnostic and food testing kits

More than the Select Agents

Agents/Toxins with

1. History of attempted use in biowarfare
2. Serious economic/public health potential
3. Australia Group (multilateral agreement) Member consensus

Some non-Select Agents controlled on the Commerce Control List

Yellow Fever virus

Lyssaviruses

Aflatoxin

Genetically Modified Organisms

U.S. DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY

Chimeric viruses

Vesicular Stomatitis Virus (1C351)

+

Ebolavirus (1C351)

Genetically modified Vesicular Stomatitis Virus Expressing Ebolavirus G-protein (1C353 until formulated as deliverable vaccine, then 1C991)

Genetically Modified Organisms

U.S. DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY

Chimeric viruses

Vesicular Stomatitis Virus (1C351)

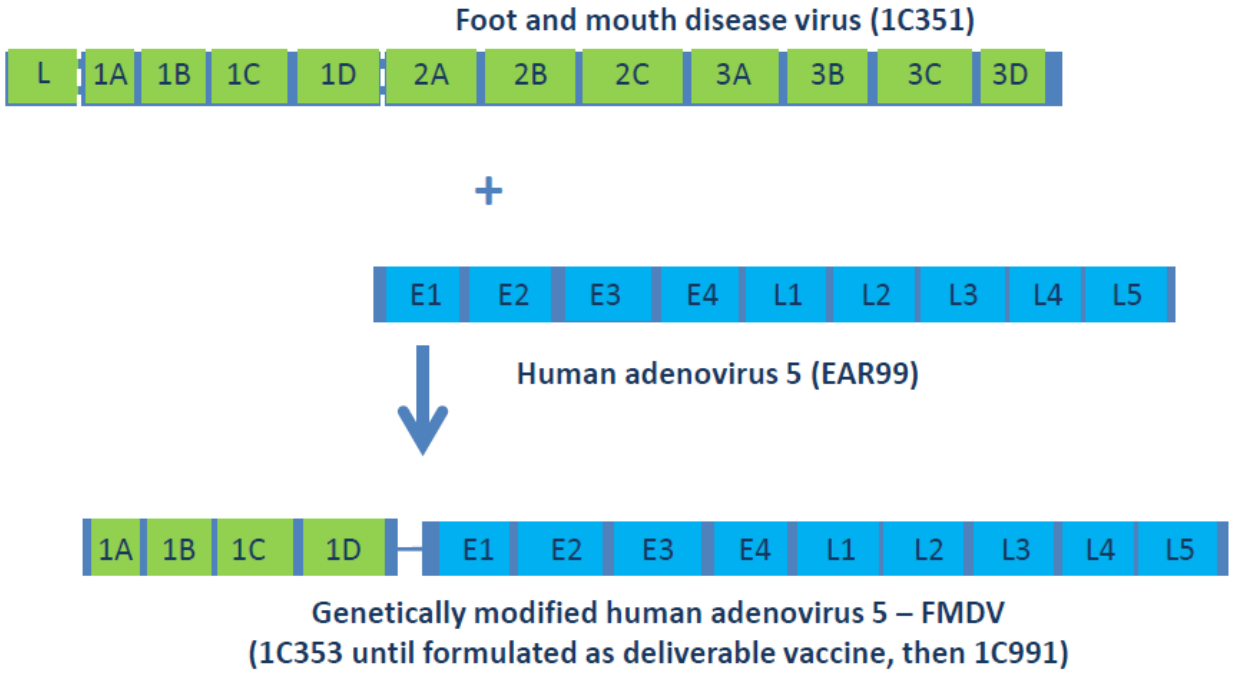
+

SARS-CoV-2 (EAR99)

Genetically modified Vesicular Stomatitis Virus expressing SARS-CoV-2 spike protein (1C353)

Genetically Modified Organisms

U.S. DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY



Genetically modified human adenovirus 5 – FMDV
(1C353 until formulated as deliverable vaccine, then 1C991)

License statistics 2014-2018 U.S. Universities

Table 7: Top Five CCL Categories Included on Export License Applications U.S. Universities Submitted to the Department of Commerce, Calendar Years 2014 through 2018

Commerce Control List (CCL) category	Category title	License applications	Percentage of total
1	Special Materials, Chemicals, Microorganisms and Toxins	253	37
9	Aerospace and Propulsion	133	20
EAR99[a]		91	13
6	Sensors and Lasers	56	8
3	Electronics	42	6
Other categories[b]		105	15
Total applications		**680**	**100**

Source: GAO analysis of Department of Commerce data. | GAO-20-394

Other factors reviewed by Export Control

Restricted Parties - federally sanctioned, debarred or restricted persons and organizations. Examples

- Huawei technologies
- BEIJING UNIVERSITY OF AERONAUTICS AND ASTRONAUTICS (BUAA) AKA BEIHANG UNIVERSITY- China
- NORTHWEST POLYTECHNICAL UNIVERSITY-Xian, China
- SICHUAN UNIVERSITY- Chengdu, China
- UNIVERSITY OF ELECTRONIC SCIENCE AND TECHNOLOGY OF CHINA - Chengdu, China
- National University of Defense Technology- China
- MALEK ASHTAR UNIVERSITY OF TECHNOLOGY- Tehran, Iran
- BAQIYATTALLAH UNIVERSITY OF MEDICAL SCIENCES – Tehran, Iran
- IMAM HOSSEIN UNIVERSITY- Tehran, Iran

Comprehensive Sanctions Programs (OFAC)

- Cuba, Iran, Syria, North Korea, Crimea region of Ukraine

Bio agent classification tool – under development

This Questionnaire is only for shipping biological, biologically-derived, and genetic materials including (but not limited to) seeds, cell lines, plasmids, algae, lignin, and human/animal tissue. This form must be completed and signed by the individual researcher, or PI (the "Shipper") from which the request for shipment originates. By completing this Self-Certification Questionnaire, the Shipper certifies that he/she has carefully reviewed the control lists provided below, and honestly answered all questions. For non-biological items or questions on this form, contact

- **Section A covers basic shipment information**
- **Section B covers basic biological questions**
- **Section C covers dependent questions that may or may not be required, based upon your responses in Section B or C**
- **Section D provides instructions after form completion, and resource links for the USML, EAR, AG, and APHIS/CDC lists**

As you complete questions in Section B and C, related questions in Section C will appear based on these responses. **Please review each section in its entirety to ensure all open questions have been addressed**. Note that most responses must be selected from a dropdown list, while a few allow freeform text entry. **Also note that any bold text in quotation marks " " indicates a regulatory definition - hover your cursor over this cell to view the definition.**

All Sections (A, B, C) and all 'visible' questions in those sections must be completed. While completing the questionnaire, you may see ECCNs appear as part of your responses, however this is not an indicator to stop and utilize that classification. The final classification can **only** be assessed / completed once all visible questions are answered (for example, you may respond with a virus that indicates a 1C351.a.x classification, however additional questions below are still required to review against USML criteria). Once all questions are complete, refer to Section D for further instructions.

Questionnaire Administrator Notes:

To view all of the questions in the event of a regulatory change, highlight all of Section C and update the font color to make these visible. Note that to the right of Section C (starting in Column H), there is a section titled 'Internal Only - Hidden Formatting and Question Tagging'. Each of these fields line up by row with the relevant Section C question and describes 1) the classification and regulatory provision where the question comes from and 2) the conditional formatting criteria that must occur to make that question appear while filling out the questionnaire. As with Section C, the font in this section is 'hidden', and can be made visible by applying a new font color different from the background. Please also note that all dropdown lists are housed on a separate tab (Data Validation (Internal)).

SECTION / QUESTION	RESPONSE	RESPONSE GUIDELINES
Section A: Shipment Information	**Responses**	**Response Guidelines**
Destination Country of Shipment		
Name and Institution of Recipient(s)		
Describe the intended application / end-use		The application / end-use question is focused on how the end-user is utilizing it, and not on the scientific aspect. For example - this biological may be for sequencing, but are they utilizing it for general research, vaccine production, etc.?

Contact for questions

Location Export Control Officers
https://www.ucop.edu/ethics-compliance-audit-services/compliance/export-control/campus-contacts.html